

DRAFT FOR PUBLIC COMMENT

Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation

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Washington, DC 20460

EPA Document Number: EPA-822-P-23-001

MARCH 2023

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Acronyms and Abbreviations

ACS American Community Survey
AFFF Aqueous Film Forming Foam

AIX Anion Exchange
ALT Alanine Transaminase

ANSI American National Standards Institute

AOC Assimilable Organic Carbon

ARIC Atherosclerosis Risk in Communities

ATSDR Agency for Toxic Substances and Disease Registry

AWWA American Water Works Association

BAT Best Available Technology

BenMAP-CE EPA's Environmental Benefits Mapping and Analysis Program – Community Edition

BIL Bipartisan Infrastructure Law
BLS Bureau of Labor Statistics

BP Blood Pressure
BV Bed Volumes

CARDIA Coronary Artery Risk Development in Young Adults

CBX SafeWater Cost Benefit Model
CCL Contaminant Candidate List
CCR Consumer Confidence Report
CCRs Consumer Confidence Reports

CDC Centers For Disease Control And Prevention

CFR Code of Federal Regulations

CHMS Canadian Health Measures Survey
COBRA Co-Benefits Risk Assessment

COI Cost of Illness

CVD Cardiovascular Disease
CWSs Community Water Systems

CWSS Community Water System Survey

DBP Disinfection Byproduct

DHS Department of Homeland Security

DL Detection Limits

DWSRF Drinking Water State Revolving Fund

EBCT Empty Bed Contact Time

ECEC Employer Cost for Employee Compensation

ECI Employment Cost Index
ECTT Error Code Tracking Tool
EJ Environmental Justice

EP Entry Point

EPA U.S. Environmental Protection Agency

GAC Granular Activated Carbon
GDP Gross Domestic Product

gfd Gallons per Square Foot Per Day

gpm Gallons per Minute

GWUDI Ground Water Under the Direct Influence

HA Health Advisory

HDLC High-Density Lipoprotein Cholesterol
HECD Health and Ecological Criteria Division
HESDs Health Effects Support Documents

HFPO-DA Hexafluoropropylene Oxide Dimer Acid
HHS Department of Health and Human Services

HI Hazard Index

HRL Health Reference Level

HRRCA Health Risk Reduction and Cost Analysis

HTN Hypertension

HUC Hydraulic Unit Code

ICR Information Collection Request

ICR TSD Information Collection Rule Treatment Study Database

IS Ischemic Stroke
IX Ion Exchange
LBW Low Birth Weight

LDLC Low-Density Lipoprotein Cholesterol
LRAA Locational Running Annual Average
MCBC Multi-Contaminant Benefit-Cost Model
MCLGs Maximum Contaminant Level Goals
MCLs Maximum Contaminant Levels
MCMC Markov Chain Monte Carlo

MetS Metabolic Syndrome

MGD Million Gallons Per Day

MI Myocardial Infarction

MRL Minimum Reporting Level

NBW Normal Birth Weight

NCHS National Center for Health Statistics
NCWSs Non-Community Water Systems

NDWAC National Drinking Water Advisory Council

NF Nanofiltration

NHANES National Health and Nutrition Examination Survey

NOM Natural Organic Matter

NPDWR National Primary Drinking Water Regulation
NTNCWSs Non-Transient Non-Community Water Systems
NTTAA National Technology Transfer and Advancement Act

O&M Operation and Maintenance

OEHHA California Environmental Protection Agency's Office of Environmental Health Hazard

Assessment

OES Occupational Employment Survey
OMB Office of Management and Budget
ORD Office of Research and Development

OSHA Occupational Safety and Health Administration

PAF Population Attributable Fraction

PBPK Physiological-Based Pharmacokinetic

PFAA Perfluorinated Alkyl Acids

PFAS Per- And Polyfluoroalkyl Substances

PFBS Perfluorobutanesulfonic Acid
PFHpA Perfluoroheptanoic Acid
PFHxS Perfluorohexanesulfonic Acid

PFNA Perfluorononanoic Acid
PFOA Perfluorooctanoic Acid
PFOS Perfluorooctane Sulfonate

PK Pharmacokinetic

POU RO Point of Use Reverse Osmosis
PRA Paperwork Reduction Act
PWS Public Water System

PWSID Public Water System Identifier
PWSS Public Water System Supervision

Q Design Flow

QA/QC Quality Assurance/Quality Control

RCC Renal Cell Carcinoma
RFA Regulatory Flexibility Act
RfD Chronic Oral Reference Dose
RO Reverse Osmosis/ Nanofiltration

RO/NF Reverse Osmosis
ROB Risk of Bias

RSC Relative Source Contribution
RSSCT Rapid Small-Scale Column Test

SAB Science Advisory Board

SBAR Small Business Advocacy Review

SBREFA Small Business Regulatory Enforcement Fairness Act

SDWA Safe Drinking Water Act

SDWIS Safe Drinking Water Information System
SEER Surveillance, Epidemiology, And End Results

SER Small Entity Representatives SGA Small for Gestational Age

SMF Standardized Monitoring Framework

SOC Synthetic Organic Chemicals

SSCTs Small System Compliance Technologies

T&C Technologies and Costs

Triiodothyronine

T4 Thyroxine

TC Total Cholesterol

TDP Technology Design Panel

THM4 Four Regulated Trihalomethanes

TNCWSs Transient Non-Community Water Systems

TOC Total Organic Carbon

TRI Volatile Organic Compounds
TSH Thyroid Stimulating Hormone

UCMR Unregulated Contaminant Monitoring Rule

UCMR 3 Third Unregulated Contaminant Monitoring Rule
UCMR 4 Fourth Unregulated Contaminant Monitoring Rule

UMRA Unfunded Mandates Reform Act
VOCs Volatile Organic Compounds
VSL Value of a Statistical Life
WBS Work Breakdown Structure

WIFIA Water Infrastructure Finance and Innovation

WIIN Water Infrastructure Improvements for the Nation Act

1 Executive Summary

Under the Safe Drinking Water Act (SDWA), U.S. Environmental Protection Agency (EPA or "the Agency") has the authority to set enforceable National Primary Drinking Water Regulations (NPDWRs) for drinking water contaminants and require monitoring of public water supplies. EPA is proposing a NPDWR for per-and polyfluoroalkyl substances (PFAS) (EPA-HQ-OW-2022-0114). The Agency initiated the process for developing a NPDWR for PFAS compounds in March 2021, when EPA published the fourth regulatory determinations for contaminants on the fourth Contaminant Candidate List (CCL), which included a final determination to regulate perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in drinking water. Additionally, in EPA's final regulatory determination for PFOA and PFOS, as well as its PFAS Strategic Roadmap, the Agency committed to evaluating additional PFAS beyond PFOA and PFOS and considering actions to address groups of PFAS. The proposed NPDWR is one of several actions consistent with the Agency's commitment to address these long-lasting "forever chemicals" that occur in drinking water supplies and impact communities across the U.S.

The proposed PFAS NPDWR is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. An economic analysis (EA) is required for all significant rules under Executive Order (EO) 12866 (Regulatory Planning and Review). In addition, Section 1412(b)(3)(C) of the 1996 Amendments to the SDWA requires EPA to prepare a Health Risk Reduction and Cost Analysis (HRRCA) in support of any NPDWRs that include a maximum containment level (MCL). This EA addresses these and other regulatory reporting requirements, including those that direct EPA to conduct distributional and environmental justice analysis. With respect to the SDWA HRRCA requirements, this document provides the following:

- Quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur as the result of compliance with each level of treatment (Chapter 6);
- Quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the MCL, excluding benefits resulting from compliance with other proposed or promulgated regulations (Chapter 6);
- Quantifiable and nonquantifiable costs for which there is a factual basis in the rulemaking record to conclude that such costs are likely to occur solely as a result of compliance with the MCL, including monitoring, treatment, and other costs, and excluding costs resulting from compliance with other proposed or promulgated regulations (Chapter 5);
- Incremental costs and benefits associated with each alternative MCL considered (Chapter 7);
- Effects of the contaminant on the general population and on groups within the general population, such as sub-populations identified as likely to be at greater risk of adverse

health effects due to exposure to contaminants in drinking water than the general population (Chapters 6 and 8);

- Any increased health risk that may occur as the result of compliance, including risks associated with co-occurring contaminants (Chapter 6); and
- Other relevant factors, including the quality and extent of the information, the uncertainties in the analysis, and factors with respect to the degree and nature of the risk (Chapters 5–7).

Upon final rule promulgation and implementation, the proposed NPDWR would reduce PFAS concentrations in the drinking water distributed by public water systems (PWSs) from the current baseline to drinking water concentrations that are in compliance with MCLs of 4 parts per trillion (ppt; also expressed as ng/L) for PFOA, 4.0 ppt for PFOS, and a unitless hazard index (HI) of 1.0 for the group including perfluorononanoic acid (PFNA), HFPO-DA (hexafluoropropylene oxide dimer acid) and its ammonium salt (also known as GenX chemicals)¹, perfluorohexanesulfonic acid (PFHxS), and perfluorobutanesulfonic acid (PFBS). These impacts are assessed in comparison to the baseline scenario which is the PFAS occurrence and exposure conditions expected in the absence of finalizing a PFAS drinking water regulation. The proposed rule is referred to as the proposed option in presentation of EA results. This EA also presents the incremental costs and benefits associated with three regulatory alternative MCLs for PFOA and PFOS. The regulatory alternative MCLs are referred to as Option 1a (MCL of 4.0 ppt for PFOA and 4.0 ppt for PFOS), Option 1b (MCL of 5.0 ppt for PFOA and 5.0 ppt for PFOS), and Option 1c (MCL of 10.0 ppt for PFOA and 10.0 ppt for PFOS). The regulatory alternative MCLs for PFOA and PFOS (Options 1a, 1b, and 1c) do not directly regulate additional PFAS, thereby limiting public health protection and benefits relative to the proposed option.

In this EA, EPA presents the quantified and nonquantifiable health benefits expected from reductions in PFAS exposures resulting from the proposed rule. Quantified benefits are assessed as avoided cases of illness and deaths (or morbidity and mortality, respectively) associated with exposure to PFAS contaminants. Adverse human health outcomes associated with PFAS exposure but that cannot be quantified and valued are assessed as nonquantifiable benefits. Additionally, this EA presents the costs associated with the proposed NPDWR. Costs presented include those expenses incurred by PWSs to (1) monitor for PFAS, (2) inform consumers, (3) install and operate treatment technologies, and (4) perform record-keeping and reporting to comply with the PFAS NPDWR; and the costs incurred by states (or primacy agencies, i.e., states with authority to implement and enforce SDWA regulations) to implement the rule. EPA presents annualized quantified benefits and costs discounted at 3 percent and 7 percent, which are discount rates prescribed by the OMB (OMB Circular A-4, 2003).

Quantified economic benefits analyses consider the strength of evidence for each adverse health effect and the availability of data to quantify the morbidity and mortality impacts associated with that adverse health effect. To identify health effects that are associated with PFAS exposure and can be monetized, EPA used the assessment of adverse health effects associated with PFOA and

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¹ EPA notes that the chemical HFPO-DA is used in a processing aid technology developed by DuPont to make fluoropolymers without using PFOA. The chemicals associated with this process are commonly known as GenX Chemicals and the term is often used interchangeably for HFPO-DA along with its ammonium salt.

PFOS in the maximum contaminant level goal (MCLG) documents. EPA provides a quantitative estimate of cardiovascular disease (CVD), birth weight, and renal cell carcinoma (RCC)-avoided morbidity and mortality associated with reductions in PFOA and PFOS consistent with the proposed rule. EPA provides a qualitative assessment of potential benefits for adverse health effects that are associated with PFAS exposure but lack the economic or other information needed for a quantitative analysis. In this EA, a qualitative discussion is provided for other adverse health effects and potential avoided diseases associated with PFOA, PFOS, and the four PFAS compounds included in the HI group (PFHxS, PFNA, PFBS, and HFPO-DA). The Agency anticipates that the nonquantifiable human health benefits associated with reductions in drinking water PFAS exposure are substantial and may reasonably exceed the benefits the Agency was able to quantify for this regulatory proposal.

As part of its health risk reduction and cost analysis, EPA is directed by SDWA to evaluate quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the MCL (SDWA 1412(b)(3)(C)(II)). These co-occurring contaminants are expected to include additional PFAS contaminants not directly regulated by the proposed PFAS NPDWR, co-occurring chemical contaminants such as synthetic organic compounds (SOCs), volatile organic compounds (VOCs), and disinfection byproduct (DBP) precursors.

The Agency anticipates that because of the PFAS NPDWR, some community and non-transient non-community water systems will need to reduce their PFAS concentrations to comply with the rule. This EA describes the costs associated with activities PWSs are expected to undertake to comply with the proposed rule (e.g., installation of treatment technologies to remove PFAS), and the costs associated with primacy agency implementation and administration of the proposed rule. National quantified cost estimates are provided for PFOA, PFOS, and PFHxS treatment. Due to occurrence data limitations, EPA has quantified the national treatment and monitoring costs associated with the HI for PFHxS only and has not quantified the national cost impacts associated with HI exceedances resulting from PFNA, PFBS, and HFPO-DA. Because these costs are unquantified, national costs are underestimated. In instances where concentrations of PFNA, PFBS, and HFPO-DA are high enough to cause or contribute to a HI exceedance when the concentrations of PFOA, PFOS, and PFHxS would not have already otherwise triggered treatment, the quantified costs may be underestimated. If these PFAS occur in isolation at levels that affect treatment decisions, or if these PFAS occur in combination with PFHxS when PFHxS concentrations are otherwise below the HI in isolation (i.e., <9.0 ppt) then the quantified costs underestimate the impacts of the proposed rule. To characterize the costs associated with treatment of other PFAS chemicals that are not included in the national cost estimates, EPA used a model system approach to look at the potential differences in system level treatment costs that could arise from the presence of PFNA, PFBS, and HFPO-DA which would cause HI exceedances at systems precipitating additional systems to treat. EPA also use this model system approach to estimate the incremental system level treatment expense resulting from cooccurrence of PFNA, PFBS, and HFPO-DA at systems already required to treat because of PFOA and/or PFOS MCLs and/or PFHxS HI exceedances. Additional discussion of the methodology and results of this analysis can be found in Chapter 5, section 5.3.1.4 and Appendix N.3.

EPA identified effective treatment technologies as part of the NPDWR, and consistent with SDWA requirements found in Section 1412(b)(3)(C)(II) to consider benefits likely to occur from reductions in co-occurring compounds, EPA estimated expected benefits from reductions in co-occurring compounds as a result of PFAS treatment. Moreover, EPA developed a quantitative analysis for reductions in bladder cancer morbidity and mortality that stem from removal of DBP precursors. Disinfection byproducts, specifically trihalomethanes, are formed when disinfectants interact with organic material in drinking water distribution systems. Since PFAS treatment has been demonstrated to remove DBP precursors, the Agency anticipates that disinfection byproducts, including trihalomethanes, will be reduced with PFAS treatment. EPA provides a qualitative discussion of benefits for other potential water quality improvements that stem from PFAS treatment, including those benefits associated with reductions in other co-occurring contaminants besides DBPs.

In the tables below, quantified benefits and costs of the proposed NPDWR ("proposed option") and alternative MCLs considered are presented. Table ES-1 presents the total estimated national annualized benefits associated with the proposed option and regulatory alternatives considered. Table ES-2 presents the total estimated national annualized costs associated with the proposed option and regulatory alternatives considered. Quantitative estimates are presented using 3 percent and 7 percent discount rates. Throughout this EA, benefits and costs are presented using mean (or "expected value"), 5th, and 95th percentile results to characterize key sources of uncertainty, including but not limited to PFAS baseline occurrence and health effect slope factor uncertainty, which is consistent with OMB and EPA guidance (OMB Circular A-4, 2003; U.S. EPA, 2010a). All significant limitations and uncertainties of this economic analysis are described in the pages that follow.

Table ES-1: Quantified Total National Annualized Benefits, All Options (Million \$2021)

Option	3% Discount Rate ^a			7% Discount Rate ^a		
	5 th Percentile ^b	Expected Value	95 th Percentile ^b	5 th Percentile ^b	Expected Value	95 th Percentile ^b
Proposed Option ^c	\$659.91	\$1,232.98	\$1,991.51	\$477.69	\$908.11	\$1,462.43
Option 1a ^d	\$651.19	\$1,216.08	\$1,971.01	\$471.53	\$895.36	\$1,456.23
Option 1be	\$553.37	\$1,046.91	\$1,706.81	\$398.21	\$773.33	\$1,292.96
Option 1c ^f	\$280.42	\$584.80	\$1,030.56	\$208.71	\$436.24	\$784.59

Notes: Detail may not add exactly to total due to independent rounding.

^aSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

^bThe 5th and 95th percentile range is based on modeled variability and uncertainty described in Section 6.1.2 and Table 6-1 for benefits. This range does not include the uncertainty described in Table 6-48 for benefits.

^cThe proposed option sets PFOA and PFOS MCLs of 4.0 ppt and an HI of 1.0.

^dOption 1a sets PFOA and PFOS MCLs of 4.0 ppt.

^eOption 1b sets PFOA and PFOS MCLs of 5.0 ppt.

^fOption 1c sets PFOA and PFOS MCLs of 10.0 ppt.

Table ES-2: Quantified Total National Annualized Costs, All Options (Million \$2021)

	3% Discount Rate ^{a,b}			7% Discount Rate ^{a,b}		
Option	5 th Percentile ^c	Expected Value	5 th Percentile ^c	5 th Percentile ^c	Expected Value	95 th Percentile ^c
Proposed Option ^{d,e}	\$704.53	\$771.77	\$850.40	\$1,106.01	\$1,204.61	\$1,321.01
Option 1a ^f	\$688.09	\$755.82	\$833.48	\$1,078.51	\$1,177.31	\$1,292.01
Option 1bg	\$558.71	\$611.01	\$674.32	\$864.74	\$942.28	\$1,035.56
Option 1c ^h	\$269.36	\$292.57	\$320.76	\$396.22	\$430.87	\$472.20

Notes: Detail may not add exactly to total due to independent rounding.

^aSee Table 7-6 for a list of the nonquantifiable costs, and the potential direction of impact these costs would have on the estimated monetized total annualized costs in this table.

^bPFAS-contaminated wastes are not considered hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See Appendix N, Section N.2 for additional detail.

^cThe 5th and 95th percentile range is based on modeled variability and uncertainty described in Section 5.1.2 and Table 5-1 for costs. This range does not include the uncertainty described in Table 5-22 for costs.

^dTotal quantified national cost values do not include the incremental treatment costs associated with the cooccurrence of HFPO-DA, PFBS, and PFNA at systems required to treat for PFOA, PFOS, and PFHxS. The total quantified national cost values do not include treatment costs for systems that would be required to treat based on HI exceedances apart from systems required to treat because of PFHxS occurrence alone. See Appendix N, Section N.3 for additional detail on cooccurrence incremental treatment costs and additional treatment costs at systems with HI exceedances.

 $^{^{\}mathrm{e}}\mathrm{The}$ proposed option sets PFOA and PFOS MCLs of 4.0 ppt and an HI of 1.0.

^fOption 1a sets PFOA and PFOS MCLs of 4.0 ppt.

^gOption 1b sets PFOA and PFOS MCLs of 5.0 ppt.

^hOption 1c sets PFOA and PFOS MCLs of 10.0 ppt.

2 Introduction

Per- and polyfluoroalkyl substances (PFAS) are a class of synthetic chemicals that have been manufactured and in use since the 1940s (AAAS, 2020; U.S. EPA, 2022j). PFAS are most commonly used to make products resistant to water, heat, and stains and are consequently found in industrial and consumer products like clothing, food packaging, cookware, cosmetics, carpeting, and fire-fighting foam (AAAS, 2020). PFAS manufacturing and processing facilities, facilities using PFAS in the production of other products, airports, and military installations have been associated with PFAS releases into the air, soil, and water (U.S. EPA, 2016b; U.S. EPA, 2016c). People may be exposed to PFAS by using certain consumer products, through occupational exposure, and/or through consuming contaminated food or contaminated drinking water (Domingo et al., 2019; Fromme et al., 2009).

Perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA) are part of a subset of PFAS referred to as perfluorinated alkyl acids (PFAA) and are two of the most widely studied and longest-used PFAS. Due to their widespread use and persistence in the environment, most people have been exposed to PFAS, including PFOA and PFOS (U.S. EPA, 2016b; U.S. EPA, 2016c). PFOA and PFOS have been detected in up to 98 percent of blood serum samples taken in biomonitoring studies that are representative of the U.S. general population (CDC, 2019). Following the voluntary phase-out of PFOA by eight major chemical manufacturers and processors in the U.S. under EPA's 2010/2015 PFOA Stewardship Program and reduced manufacturing of PFOS (last reported in 2002 under Chemical Data Reporting), serum concentrations have been declining. The National Health and Nutrition Examination Survey (NHANES) data exhibited that 95th-percentile serum PFOS concentrations have decreased over 75 percent, from 75.7 μ g/L in the 1999-2000 cycle to 18.3 μ g/L in the 2015-2016 cycle (CDC, 2019; Jain, 2018; Calafat et al., 2007; Calafat et al., 2019).

Despite voluntary phase-outs and reduced exposure to some PFAS chemicals, PFAS are still used in a wide range of consumer products and industrial applications. EPA's analysis of drinking water monitoring data shows widespread occurrence of PFAS compounds in multiple geographic locations. Most known exposures are relatively low, but some can be high, particularly when people are exposed to a concentrated source over long periods of time. Studies indicate that PFAS exposure above certain levels may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants, cancer, and other immunologic-related effects.

Under the Safe Drinking Water Act (SDWA), the U.S. Environmental Protection Agency (EPA or the Agency) is proposing to regulate PFAS in drinking water distributed by all community water systems (CWSs)² and non-transient non-community water systems (NTNCWSs). In 2021, EPA determined that a NPDWR for PFAS would result in a meaningful opportunity to reduce health risks (U.S. EPA, 2021b). Section 2.1 provides further detail on the proposed NPDWR for PFAS.

² Systems that supply water to the same population year-round.

2.1 Summary of the Proposed PFAS Rule and Regulatory Alternatives

EPA is proposing to regulate six PFAS in finished drinking water: (1) perfluorooctanesulfonic acid (PFOS), (2) perfluorooctanoic acid (PFOA), (3) perfluorononanoic acid (PFNA), (4) hexafluoropropylene oxide dimer acid (HFPO-DA or HFPO-DA), (5) perfluorohexanesulfonic acid (PFHxS), and (6) perfluorobutanesulfonic acid (PFBS). The proposed regulation utilizes compound-specific MCLs for PFOA and PFOS with a group MCL based on a hazard index (HI) for PFNA, HFPO-DA, PFHxS, and PFBS. This regulatory approach utilizes the combined toxicity framework peer reviewed by EPA's Science Advisory Board (SAB; U.S. EPA, 2022k) and builds a framework for inclusion of additional PFAS through future rulemaking as new data become available (U.S. EPA, 2023a). For more information on the HI approach, see EPA's Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) (U.S. EPA, 2023a).

Based on the best available scientific information on the health effects of PFOA and PFOS, EPA is proposing maximum contaminant level goals (MCLGs) of 0 ppt for PFOA and 0 ppt for PFOS. EPA has determined that it is feasible to set enforceable maximum contaminant levels (MCLs) for PFOA and PFOS at 4.0 ppt each. Additionally, EPA has determined it is feasible to set an MCL for four PFAS with a HI limit of 1.0. As such, EPA is proposing enforceable MCLs of 4.0 ppt for PFOA, 4.0 ppt for PFOS, and a unitless HI of 1.0 for the group including PFNA, HFPO-DA, PFHxS, and PFBS. For additional details about the MCLGs and MCLs in the proposed rule, see the federal notice for this rulemaking. This proposed rule framework is referred to as the "proposed option" within this EA.

Additionally, in this EA, EPA presents benefits and costs for the proposed rule as well as three regulatory alternatives. The regulatory alternatives that EPA evaluated present individual MCLG and enforceable MCL values for PFOA and PFOS. MCL values for PFOA and PFOS vary for each alternative considered: 4.0 ppt in Option 1a, 5.0 ppt in Option 1b, and 10.0 ppt in Option 1c. EPA evaluated benefits and costs for Option 1a to determine the difference in costs between alternatives for PFOA and PFOS MCLs only versus MCLs for PFOA and PFOS and an HI for four additional PFAS. EPA considered benefits and costs under Option 1b—MCLs of 5.0 ppt for PFOA and PFOS—because it is 25 percent above the compliance quantitation limit of 4.0 ppt established for today's regulation. Lastly, EPA considered benefits and costs of Option 1c—MCLs of 10.0 ppt for PFOA and PFOS—to provide information on whether the Agency should consider utilizing its authority under Section 1412(b)(6) to set an alternative MCL at the level at which the benefits would justify the costs.

The Agency is also inviting comment on whether establishing a traditional MCLG and MCL for PFHxS, HFPO-DA, PFNA, and PFBS instead of or in addition to the HI approach would change public health protection, improve clarity for the rule, or change costs. EPA has not separately presented changes in quantified costs and benefits for these approaches. If EPA adds individual MCLs in addition to using the HI approach, EPA anticipates there will be no change in costs and benefits relative to the proposed rule (i.e., the same number of systems will incur identical costs to the proposed option and the same benefits will be realized). EPA has not separately quantified the benefits and costs for the approach to regulate PFHxS, PFNA, PFBS, and HFPO-DA with individual MCLs instead of the HI. However, EPA expects both the costs and benefits would be

reduced under this approach as fewer systems may be triggered into treatment and its associated costs. Additionally, systems that exceed one or more of the individual MCLs will treat to a less stringent and public health-protective standard. Furthermore, under the proposed option, PWSs are required to treat based on the combined occurrence of PFAS included in the HI which considers the known and additive toxic effects and occurrence and likely co-occurrence of PFAS compounds in the HI, providing more public health protection compared to an individual MCL approach.

2.2 Economic Analysis Assumptions

2.2.1 Compliance Schedule and Period of Analysis for Proposed Rule

For purposes of this EA, EPA assumes that the NPDWR will be promulgated by the end of 2023. This analysis follows the standard NPDWR compliance schedule with regulatory requirements taking effect three years after the date on which the regulation is promulgated. Therefore, EPA assumes that actions to comply with the rule will begin taking place by 2026. In addition to this initial time window, EPA's period of analysis includes the 80 years following the assumed compliance date. This time span is based on an assumed median human lifespan of 80 years. In this EA, EPA evaluates costs and benefits under the proposed rule for the period of analysis from 2023 through 2104. EPA selected this period of analysis to estimate human health risk reduction to capture health effects from chronic illnesses that are typically experienced later in life (i.e., cardiovascular disease and cancer). Capital costs for installation of treatment technologies are spread over the useful life of the technologies. EPA does not capture effects of compliance with the proposed rule beyond the year 2104.

2.2.2 Dollar Year and Discount Rates

EPA presents estimated costs and benefits under the proposed rule in 2021 U.S. dollars. Appendix J provides additional details on the price indices used for inflation adjustments.

The proposed rule analysis estimates the annualized value of future benefits using two discount rates: 3 percent and 7 percent. The 3 percent discount rate reflects society's valuation of differences in the timing of consumption; the 7 percent discount rate reflects the opportunity cost of capital to society. In Circular A-4, the Office of Management and Budget (OMB) recommends that 3 percent be used when a regulation affects private consumption, and 7 percent be used when evaluating a regulation that would mainly displace or alter the use of capital in the private sector (OMB, 2003; updated 2009). OMB's Circular A-4 indicates that a 3 percent discount rate represents the rate that an average saver uses to discount future consumption and is therefore more appropriate for this rulemaking. EPA presents costs and benefits at both 3 and 7 percent.

The same discount rates are used for both benefits and costs. All future cost and benefit values are discounted back to the initial year of the analysis, 2023, providing the present value of the cost or benefit.

2.2.3 Annualization

Consistent with the timing of the proposed rule and associated reductions in PFAS levels, EPA uses the following equation to annualize the future costs and benefits:

Equation 1:

$$AV = \frac{r(PV)}{(1+r)[1-(1+r)^{-n}]}$$

Where AV is the annualized value, PV is the present value, $^3 r$ is the discount rate (3% or 7%), and n is the number of years (82 years).

2.2.4 Population

To determine the number of people expected to benefit from actions under the proposed rule, EPA uses population data from the Safe Drinking Water Information System (SDWIS) 2021 Quarter 4 (Q4) database (U.S. EPA, 2021h). The SDWIS data provide the population served by each PWS in the U.S. For analyses that rely on age-, sex-, and race/ethnicity-specific populations, EPA uses county-level population proportions based on 2021 estimates from the U.S. Census Bureau (2020a). EPA does not consider population growth during the period of analysis (2023–2104). For more information on the SDWIS and U.S. Census Bureau (2020a) data, see Appendix B.

2.2.5 Valuation

To estimate the economic value of avoided premature deaths, EPA uses Value of Statistical Life (VSL) estimates. EPA follows *Guidelines for Preparing Economic Analyses* (U.S. EPA, 2010a) and approximates Value of Statistical Life growth using a compound annual growth rate of projected Value of Statistical Life values to obtain a Value of Statistical Life suitable for valuation of mortality risk reductions during the period of analysis, 2023-2104. As the base value, EPA used the Value of Statistical Life estimate of \$4.8 million (\$1990, 1990 income year), which is the central tendency of the Value of Statistical Life distribution recommended for use in EPA's regulatory impact analyses (U.S. EPA, 2010a). The base Value of Statistical Life estimate is adjusted for inflation and income growth as described in Appendix J. The Value of Statistical Life estimates employed in EPA's analysis range from \$10.7 million (\$2021) in 2023 to \$17.7 million (\$2021) in 2104.⁴

To estimate the economic value of avoided morbidity (i.e., non-fatal heart attacks and ischemic strokes, birth weight decrements, and cancers), EPA used the cost of illness (COI) valuation approach. The COI-based values used in this analysis reflect medical care expenditures and opportunity costs associated with managing/treating the condition. The health endpoint-specific morbidity valuation details are provided in Sections 6.4.4, 6.5.4, 6.6.4, and 6.7.2.5.

2.3 Document Organization

The remainder of this EA is organized into the following chapters:

• Chapter 2: Introduction summarizes the proposed PFAS rule and regulatory alternatives, including the economic assumptions made in developing the rule.

³ The present value is the current value of a future sum of benefits given a specified discount rate. The present value represents the expected value of benefits determined at the date of valuation.

⁴ Income growth projections from the U.S. Energy Information Administration (2021) are available through 2050.

- Chapter 3: Need for the Rule summarizes the statutory requirements, regulatory actions, and national EPA initiatives affecting PFAS in drinking water. It also explains the contributors to the PFAS rule proposal, statutory authority, and the economic rationale for the regulatory approach.
- Chapter 4: Baseline Drinking Water System Conditions describes the systems subject to the proposed PFAS rule, PFAS water concentration levels, and data sources used to characterize the baseline before the EPA models estimated changes that result from complying with the proposed PFAS requirements.
- Chapter 5: Estimating Public Water System Costs provides a description of the estimated costs for the proposed regulatory changes affecting systems and Primary Agencies.
- Chapter 6: Benefits Analysis provides an estimate of the potential health benefits of the proposed PFAS regulatory alternatives relative to the baseline, including quantification and monetization where possible.
- Chapter 7: Comparison of Costs to Benefits provides a summary of costs and benefits associated with the provisions of the proposed PFAS rule.
- Chapter 8: Environmental Justice Analysis provides a description of how the proposed PFAS rule addresses Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations.
- Chapter 9: Statutory and Administrative Requirements discusses analyses performed to evaluate the effects of the proposed PFAS regulatory alternatives on different segments of the population in accordance with 12 federal mandates and statutory reviews, including but not limited to the Final Regulatory Flexibility Analysis (RFA/SBREFA), Unfunded Mandates Reform Act (UMRA), and Executive Order 14008: Tackling the Climate Crisis at Home and Abroad.
- Chapter 10: References includes a list of references cited throughout the proposed PFAS rule economic analysis.

2.4 Supporting Documentation

This EA involves numerous detailed and complex analyses, and the following appendices are provided to help the reader understand how those analyses were conducted and their underlying data and assumptions:

- Appendix A: Framework of Bayesian Hierarchical Markov Chain Monte Carlo Occurrence Model
- Appendix B: Affected Population
- Appendix C: Cost Analysis Results
- Appendix D: PFOA and PFOS Serum Concentration-Birth Weight Relationship
- Appendix E: Effects of Reduced Birth Weight on Infant Mortality
- Appendix F: Serum Cholesterol Dose-Response Functions
- Appendix G: CVD Benefits Model Details and Input Data
- Appendix H: Cancer Benefits Model Details and Input Data
- Appendix I: Trihalomethane Co-Removal Model Details and Analysis
- Appendix J: Value of a Statistical Life Updating
- Appendix K: Benefits Sensitivity Analyses

- Appendix L: Uncertainty Characterization Details and Input Data
- Appendix M: Environmental Justice
- Appendix N: Supplemental Cost Analyses
- Appendix O: Appendix References

3 Need for the Rule

This section provides the statutory and economic rationales for choosing a regulatory approach to address the public health consequences of PFAS contamination in drinking water. EPA's statutory requirements, regulatory actions, and Agency initiatives impacting PFAS in drinking water are discussed.

3.1 Previous EPA Nonregulatory and Regulatory Actions Potentially Affecting PFAS Drinking Water Management

This section provides a summary of actions and initiatives affecting PFAS in drinking water prior to the publication of the proposed NPDWR for PFAS. Additionally, states have begun proposing and promulgating their own regulatory and non-regulatory standards for PFAS in drinking water. For more information on these state actions, see the Environmental Council of the States' *Processes & Considerations for Setting State PFAS Standards* (ECOS, 2022).

3.1.1 PFAS Strategic Roadmap and PFAS Council

EPA Administrator Michael Regan established the EPA Council on PFAS in April 2021 and charged it to develop a bold, strategic, whole-of-EPA strategy to protect public health and the environment from the impacts of PFAS. The PFAS Council developed the PFAS Strategic Roadmap to lay out EPA's whole-of-Agency approach to tackling PFAS and set timelines by which the Agency plans to take concrete actions during the first term of the Biden-Harris administration to deliver results for the American people. The Council comprises senior technical and policy leaders from across EPA program offices and regions and is chaired by Assistant Administrator for Water Radhika Fox and Acting Region 1 Administrator Deb Szaro (U.S. EPA, 2021e).

On October 18, 2021, Administrator Regan announced the Agency's PFAS Strategic Roadmap—laying out a whole-of-agency approach to addressing PFAS. The PFAS Strategic Roadmap sets timelines by which EPA plans to take specific actions and commits to bolder new policies to safeguard public health, protect the environment, and hold polluters accountable. Described in the Roadmap are key commitments the Agency made toward addressing these contaminants in the environment. With this proposal, EPA is delivering on a key commitment in the Roadmap to "establish a National Primary Drinking Water Regulation" for proposal and is working toward promulgating the final NPDWR in Fall of 2023 (U.S. EPA, 2021e).

3.1.2 EPA PFAS Health Advisories

In 2016, EPA published health assessments (Health Effects Support Documents or HESDs) for PFOA and PFOS based on the Agency's evaluation of the peer reviewed science available at that time. The lifetime Health Advisory (HA) of 70 ppt was used as the Health Reference Level (HRL) for Regulatory Determination 4 and reflected the maximum combined concentration of PFOA and PFOS in drinking water at which adverse health effects were not anticipated to occur over a lifetime. Studies indicate that exposure to PFOA and/or PFOS above certain exposure levels may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast-fed infants (e.g., low birth weight, accelerated puberty, skeletal variations), cancer (e.g., testicular, kidney), liver effects (e.g., tissue damage), immune effects

(e.g., antibody production and immunity), and other effects (e.g., cholesterol changes). Both PFOA and PFOS are known to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk. Both compounds were also associated with tumors in long-term animal studies (U.S. EPA, 2016e; U.S. EPA, 2016f; NTP, 2020). For specific details on the potential for adverse health effects and approaches used to identify and evaluate information on hazard and dose-response, see Drinking Water Health Advisories for PFOA and PFOS and Health Effects Support Documents for PFOA and PFOS (U.S. EPA, 2016b; U.S. EPA, 2016c; U.S. EPA, 2016f).

On June 15, 2022, EPA released four drinking water HAs for PFAS, including interim updated HAs for PFOA and PFOS (U.S. EPA, 2022h). The HA levels for PFOA and PFOS are 0.004 ppt and 0.02 ppt, respectively. These updated HA values are based on human studies in populations exposed to PFOA and PFOS; studies have found associations between PFOA and/or PFOS exposure and effects on the immune system, cardiovascular system, human development, and cancer (U.S. EPA, 2022h).

Additionally, EPA issued final HAs for HFPO-DA and PFBS based on animal studies following oral exposure to these chemicals. Exposure to HFPO-DA have been linked to health effects on the liver, kidney, immune system, developmental effects, and cancer (U.S. EPA, 2022h). Exposure to PFBS has been linked to health effects on the kidney, thyroid, reproductive system, and developmental effects. The final HAs for HFPO-DA and PFBS are 10 ppt and 2,000 ppt, respectively (U.S. EPA, 2022h).

3.1.3 Final Regulatory Determinations on the Fourth Drinking Water Contaminant Candidate List

Section 1412(b)(1)(B)(i) of SDWA requires EPA to publish the CCL every five years after public notice and an opportunity to comment. The CCL is a list of contaminants which are not subject to any proposed or promulgated NPDWRs but are known or anticipated to occur in PWSs and may require regulation under SDWA. SDWA section 1412(b)(1)(B)(ii) directs EPA to determine, after public notice and an opportunity to comment, whether to regulate at least five contaminants from the CCL every five years.

Under Section 1412(b)(1)(A) of SDWA, EPA will regulate a contaminant in drinking water if the EPA Administrator determines that:

- a) The contaminant may have an adverse effect on the health of persons;
- b) The contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in PWSs with a frequency and at levels of public health concern; and
- c) In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

If after considering public comment on a preliminary determination, the decides to regulate a contaminant, EPA will initiate the process to propose and promulgate a NPDWR. In that case, the statutory time frame provides for Agency proposal of a regulation within 24 months and action on a final regulation within 18 months of proposal.

On March 10, 2020, EPA published preliminary positive regulatory determinations for PFOS and PFOA (85 FR 14098) (U.S. EPA, 2020a). On March 3, 2021, EPA published final regulatory determinations for PFOS and PFOA (86 FR 12272) (U.S. EPA, 2021b). In doing so, EPA also committed to evaluating a broader range of PFAS, including new monitoring and occurrence data, and other information being developed by EPA, other federal agencies, state governments, international organizations, industry groups, and other stakeholders (U.S. EPA, 2021b).

3.1.4 Unregulated Contaminant Monitoring Rule

As part of its responsibilities under the SDWA, EPA implements Section 1445(a)(2), Monitoring Program for Unregulated Contaminants. This section requires that once every five years, EPA issue a list of no more than 30 unregulated contaminants to be monitored by PWSs. This monitoring is implemented through the Unregulated Contaminant Monitoring Rule (UCMR), which collects data from community water systems and non-transient non-community water systems. For each UCMR cycle, EPA establishes a new list of contaminants for monitoring, specifies which systems are required to monitor, identifies the sampling locations, and defines the analytical methods to be used.

The third Unregulated Contaminant Monitoring Rule (UCMR 3) was published on May 2, 2012. UCMR 3 required monitoring for six PFAS: PFOA, PFOS, PFNA, PFHxS, PFBS, and PFHpA. UCMR 3 data were used in the development of this economic analysis: see sections 4.2.2 and 4.4 for further discussion of these data.

On December 17, 2021, EPA Administrator Michael Regan signed the final Revisions to the Unregulated Contaminant Monitoring Rule (UCMR 5) for Public Water Systems, and the rule was subsequently published in the Federal Register on December 27, 2021 (86 FR 73131). The five-year UCMR 5 cycle spans from 2022 to 2026, with preparations in 2022, sample collection from 2023 to 2025, and completion of data reporting in 2026. UCMR 5 includes all 29 PFAS that are within the scope of EPA Methods 533 and 537.1 (U.S. EPA, 2021b).

3.2 Statutory Authority for Promulgating the Rule

Section 1412(b)(1)(A) of SDWA authorizes EPA to establish NPDWRs for contaminants that may have an adverse public health effect, that are known to occur or that present a substantial likelihood of occurring in PWSs at a frequency and level of public health concern, and that present a meaningful opportunity for health risk reduction for persons served by PWSs.

Section 1445(a) of SDWA authorizes the EPA Administrator to establish monitoring, recordkeeping, and reporting regulations that the Administrator can use to establish regulations under the SDWA, determine compliance with SDWA, and advise the public of the risks of unregulated contaminants (42 U.S.C. § 300j-4(a)). In requiring a PWS to monitor under Section 1445(a), the Administrator may take into consideration the water system size and the contaminants likely to be found in the system's drinking water (42 U.S.C. § 300j-4(a)). Section 1445(a)(1)(C) of the SDWA provides that "every person who is subject to a national primary drinking water regulation" under section 1412 must provide such information as the Administrator may reasonably require to assist the Administrator in establishing regulations under section 1412 (42 U.S.C § 300j-4(a)(1)(C)).

Section 1413(a)(1) of the SDWA allows EPA to grant a state primary enforcement responsibility ("primacy") for NPDWRs when EPA has determined that the state has, among other things, adopted regulations that are no less stringent than EPA's (42 U.S.C. § 300g-2(a)(1)). To obtain primacy for this rule, states must adopt comparable regulations within two years of the EPA's promulgation of the final rule, unless EPA grants the state a two-year extension (40 CFR 142.12(b)). State primacy requires, among other things, adequate enforcement (including monitoring and inspections) and reporting. EPA must approve or deny state primacy applications within 90 days of submission to EPA (42 U.S.C. § 300g-2(b)(2)). In some cases, a state submitting revisions to adopt a NPDWR has interim primary enforcement authority for the new regulation while EPA's decision on the revision is pending (42 U.S.C. § 300g-2(c)).

Section 1450 of the SDWA authorizes the Administrator to prescribe such regulations as are necessary or appropriate to carry out his or her functions under the Act (42 U.S.C § 300j-9).

3.3 Economic Rationale

The OMB Circular A-4 (OMB, 2003) states that "in order to establish the need for the proposed action, the analysis should discuss whether the problem constitutes a significant market failure." This section describes the types of market failures that NPDWRs address.

In a perfectly competitive market, market forces guide buyers and sellers to attain the most efficient social outcome. A perfectly competitive market occurs when both buyers and sellers are price takers, usually when there are many producers and buyers of a product and both producers and buyers have complete knowledge about that product. Also, there must not be any barriers to entry into the industry, and existing producers in the industry must not have any advantage over potential new producers. Several factors in the public water supply industry preclude it from being a perfectly competitive market and lead to market failures that may require regulation.

First, it is not economically efficient to have multiple suppliers who would, for example, compete by building multiple systems of pipelines, reservoirs, wells, and other facilities. Instead, economic efficiency leads to a single firm or government entity performing these functions generally under public control. Under these monopoly conditions, consumers are provided only one level of service with respect to drinking water quality. If consumers do not believe that the quality of tap water is adequate, they cannot simply switch to another water utility. Consumers may purchase bottled water, but this option can be much more expensive due to the inefficiencies of bottling and transporting bottled water. Consumers may also install and operate home treatment systems, but this can also be considerably more expensive without the economies of scale of large, centralized water systems. Additionally, home treatment systems potentially can lead to increased health risks when not regularly maintained by the consumer.

Second, high information and transaction costs impede the public's understanding of health and safety issues concerning drinking water quality. The health risks potentially posed by trace quantities of drinking water contaminants requires EPA to analyze and distill complex toxicological and health sciences data. EPA promulgated the Consumer Confidence Report (CCR) rule to make water quality information more easily available to consumers. The CCR rule requires CWSs to mail their customers an annual report on local drinking water quality.

The report provides customers with information on levels of detected contaminants in their drinking water, limited health risk information associated with contaminant exposure when

levels exceed MCLs, and utility contact information. Even if informed consumers can engage utilities regarding these health issues, the costs of such engagement, known as "transaction costs" (in this case measured in personal time and commitment), can be a barrier to efficient market outcomes.

SDWA regulations are intended to provide a level of protection from exposure to drinking water contaminants that would not otherwise occur in the existing market environment of public water supply. The regulations set minimum performance requirements for all public water supplies to reduce the risk confronted by all consumers from exposure to drinking water contaminants. SDWA regulations are not intended to restructure market mechanisms or establish competition in supply; rather, SDWA standards establish the level of service needed to better reflect the public's preference for safety. Federal regulations remove the high information and transaction costs by acting on behalf of all consumers in balancing the risk reduction and social costs of achieving this reduction.

4 Baseline Drinking Water System Conditions

4.1 Introduction

In its *Guidelines for Preparing Economic Analyses*, EPA characterizes the baseline as a reference point that reflects the world without the proposed regulation (U.S. EPA, 2010a); this baseline is the starting point for estimating the potential benefits and costs of the proposed PFAS NPDWR.

This chapter presents a characterization of PWSs and their current operations (i.e., the baseline) before changes are made to meet the proposed PFAS NPDWR. Section 4.2 identifies each major data source used to develop the baseline. Section 4.3 explains the derivation of each baseline characteristic and presents results in detailed tables. Section 4.4 describes the Bayesian model developed to estimate national PFAS occurrence in drinking water supplies. Section 4.5 summarizes limitations of the major data sources and uncertainties in the baseline characterization (both quantified and nonquantifiable) in table format.

4.2 Data Sources

EPA used a variety of data sources to develop the baseline. Section 4.2.1 explains the relevant information provided in the federal version of the Safe Drinking Water Information System (SDWIS/Fed) and measures EPA has taken to verify the data. Section 4.2.2 describes the purpose of the third Unregulated Contaminant Monitoring Rule (UCMR 3) data. Section 4.2.3 describes the independent state sampling program data. Sections 4.2.4 and 4.2.5 describe two data sources used to develop key characteristics of system treatment plants. Section 4.2.6 explains the purpose of the 2006 Community Water System Survey (CWSS) and the representativeness of the data. Table 4-1 identifies each major data source and the baseline data element(s) derived from them.

Table 4-1: Data Sources Used to Develop the Water System Characteristics

Data Source	Baseline Data Derived from the Source						
	• Water System Inventory (Section 4.3.1): PWS inventory, including system unique identifier, population served, number of service connections, source water type, and system type.						
SDWIS/Fed fourth quarter 2021 Q4 "frozen" dataset ^a	 Population and Households Served (Section 4.3.2): PWS population served. 						
	 Treatment Plant Characterization (Section 4.3.3.1): Number of unique treatment plant facilities per system, which are used as a proxy for entry points when UCMR 3 sampling site data are not available. 						
LICMD 2 (LLC EDA 2017)	• Treatment Plant Characterization (Section 4.3.3): Number of unique entry point sampling sites, which are used as a proxy for entry points.						
UCMR 3 (U.S. EPA, 2017)	• Treatment Plant Characterization (Section 4.3.3): PFAS concentration data collected as part of UCMR 3.						
Independent state sampling programs	 Treatment Plant Characterization (Section 4.3.3): PFAS concentration data collected by states. These data supplemented the occurrence modeling for systems included in UCMR 3. 						

Data Source

SYR4 ICR Occurrence
Dataset (2012-2019)

Geometries and
Characteristics of PWSs
(U.S. EPA, 2000)

2006 CWSS (U.S. EPA, 2009)

Baseline Data Derived from the Source

• Treatment Plant Characterization (Section 4.3.3): TOC.

• Treatment Plant Characterization (Section 4.3.3): Design and average daily flow per system.

• PWS Labor Rates (Section 4.3.4): PWS labor rates.

Table 4-1: Data Sources Used to Develop the Water System Characteristics

Abbreviations: CWSS – Community Water System Survey; ICR – Information Collection Request; PFAS – per- and polyfluoroalkyl substances; PWS – public water system; SDWIS/Fed – Safe Drinking Water Information System/federal version; SYR – Six-Year Review; TOC – total organic carbon; UCMR 3 – Third Unregulated Contaminant Monitoring Rule. Note:

4.2.1 SDWIS/Fed 2021

SDWIS/Fed (U.S. EPA, 2021h) is EPA's national regulatory compliance database for the drinking water program. It contains system inventory, treatment facility, violation, and enforcement information for PWSs as reported by primacy agencies, EPA regions, and EPA headquarters personnel. Primacy agencies report data quarterly to EPA. The information presented in the EA is based on the fourth quarter 2021 "frozen" dataset that was extracted on January 14, 2022.

SDWIS/Fed contains information to characterize the inventory of PWSs, namely: system name and location; retail population served, source water type, and PWS type.

4.2.1.1 PWS Type

EPA defines a PWS as a system that provides water for human consumption through pipes or other constructed conveyances to at least 15 service connections or regularly serves an average of at least 25 individuals per day for at least 60 days per year (U.S. EPA, 2021h). Systems are categorized as follows:

- CWSs are systems that supply water to the same population year-round.
- Non-community water systems (NCWSs) are systems that supply water to a varying population or one that is served less than year-round; these are sub-categorized as:
 - Non-transient non-community water systems (NTNCWSs) are systems that are not CWSs and that regularly supply water to at least 25 of the same people at least six months per year (e.g., schools).
 - Transient non-community water systems (TNCWSs) are NCWSs that do not meet the non-transient criterion; they provide water in places such as gas stations or seasonal campgrounds where people do not remain for long periods of time.

^aContains information extracted on January 14, 2022.

A proposed rule to limit PFAS in drinking water would not apply to TNCWSs. Therefore, system inventories in this analysis are classified into two categories: CWSs and NTNCWSs.

4.2.1.1.1 Population Served

Systems are also categorized by the number of people they serve.⁵ The following nine categories of populations served by systems are used throughout this EA:

- ≤ 100
- 101-500
- 501–1,000
- 1,001–3,300
- 3,301–10,000
- 10,001–50,000
- 50,001–100,000
- 100,001–1,000,000 (1M)
- >1M

EPA uses these system size categorizes based on distinctions in the way systems operate as the amount of water supplied and number of service connections increases. Systems within each size category can be expected to face similar implementation and cost challenges when complying with the new regulatory requirements proposed for this regulatory effort.

4.2.1.1.2 Source Water Type

SDWIS/Fed classifies system by source water using the following six categories:

- Ground water (Ground Water)
- Ground water purchased
- Ground water under the direct influence (GWUDI)⁶
- Ground water under the direct influence purchased (purchased GWUDI)
- Surface water (Surface Water)
- Surface water purchased

For this analysis, EPA broadly categorized systems as Surface Water if any of their sources are surface water, surface water purchased, GWUDI, or purchased GWUDI. Systems are classified as Ground Water if they exclusively used Ground Water or purchased Ground Water.⁷

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⁵ SDWIS/Fed classifies systems according to "retail" population that does not include the population served by other systems that purchase water from them.

⁶ 40 CFR section 141.2 defines ground water under the direct influence of surface water as "any water beneath the surface of the ground with significant occurrence of insects or other macroorganisms, algae, or large-diameter pathogens such as *Giardia lamblia* or *Cryptosporidium*, or significant and relatively rapid shifts in water characteristics such as turbidity, temperature, conductivity, or pH which closely correlate to climatological or surface water conditions."

⁷ 23 CWS and 11 NTNCWS have an unknown primary water source. For purposes of this analysis, EPA assigned these systems to the source type ground water.

4.2.1.1.3 Facilities

SDWIS/Fed provides additional information on system facilities, including the type of facility, its activity status, and a unique facility identification number.

4.2.1.2 Verification of SDWIS/Fed Data

EPA routinely conducts program reviews to verify whether information in the primacy agencies' databases and files, such as inventory and violations for all regulations are correctly represented in SDWIS/Fed. Between 2006 and 2016, EPA recorded the findings from these reviews in the national Error Code Tracking Tool (ECTT) (U.S. EPA, 2007b). The ECTT contains, as individual records, all actions assessed during each program review. EPA identifies records as confirmed actions (correct compliance determinations and correct reporting to SDWIS/Fed), compliance determination discrepancies (incorrect compliance determinations), or data flow discrepancies (correct compliance determination but incorrect reporting). This section presents data from the ECTT from program reviews conducted from 2006 to 2016 related to system inventory.

It is important to note that treatment data (objective codes and process codes for plants in SDWIS) are not evaluated during program reviews and therefore have more uncertainty associated with the data as compared to inventory and compliance data.

4.2.1.2.1 System Inventory

From 2006 to 2016 EPA evaluated inventory data for a total of 2,180 systems. Prior to August 2007, the program reviews evaluated eight inventory fields: system type, system status, activity status, source type, population, service connection, administrative contact, and administrative address. After August 2007, the reviews did not include administrative contact or address. In addition, in August 2007, the review policy changed so that discrepancies for inventory were only identified if they affected monitoring requirements (e.g., a change in population that would increase or decrease the minimum number of required samples).

Of the inventory fields evaluated from 2006 to 2016, only 82 (<1%) inventory discrepancies were identified. Furthermore, some of these discrepancies, such as those related to administrative contact and address, may not impact the PWS baseline characterization. The inventory data in ECTT indicate a high degree of completeness and accuracy in SDWIS/Fed, and that the information is largely representative of the regulated PWS.

4.2.2 Third Unregulated Contaminant Monitoring Rule

Every five years, EPA issues a new list of no more than 30 unregulated contaminants to be monitored by PWSs. UCMR 3 was published in 2012 and required monitoring for six PFAS from 2013-2015: PFOA, PFOS, PFBS, PFNA, PFHxS, and PFHpA.. The final UCMR 3 dataset of analytical results was released in January 2017.

Under UCMR 3, all CWSs and NTNCWSs with more than 10,000 retail customers and a representative sample of 800 systems serving 10,000 or fewer retail customers were required to conduct assessment monitoring to collect occurrence data for the listed contaminants suspected to be present in drinking water but that do not have health-based standards set under the SDWA.

Systems conducted assessment monitoring over one consecutive 12-month period between January 2013 and December 2015. Ground Water systems were required to monitor twice during that period, with sampling events occurring five to seven months apart. Surface Water systems were required to monitor in four consecutive quarters, with sampling events occurring three months apart. For the PFAS compounds, sampling was conducted at the entry point to the distribution system post treatment.

4.2.3 Independent State Sampling Programs

EPA used state monitoring data from 12 states (Alabama, Colorado, Illinois, Kentucky, Massachusetts, Michigan, New Hampshire, New Jersey, North Dakota, Ohio, South Carolina, and Vermont). These states conducted non-targeted monitoring (i.e., random sampling) of finished drinking water for one or more of the four PFAS in this analysis.

4.2.4 Six-Year Review Data

EPA used information from the fourth Six-Year Review Information Collection Request (ICR) Dataset ("SYR4 ICR dataset") to characterize the total organic carbon (TOC) level for individual systems. The SYR4 ICR dataset is the most comprehensive and current national drinking water occurrence dataset, containing millions of records of water system compliance monitoring data and treatment technique information for regulated chemical, radiological, and microbiological contaminants collected from 2012 through 2019. The portion of the dataset containing the TOC information was made publicly available in August 2022.⁸

4.2.5 Geometries and Characteristics of Public Water Systems (2000)

An important factor in determining costs of treatment is average daily flow and design flow, measured in gallons per day or million gallons per day (MGD), at a treatment plant. EPA estimated the average daily flow and design flow for each entry point in the system based on the relationship between retail population and flow as derived in EPA's *Geometries and Characteristics of Public Water Systems* report (U.S. EPA, 2000).

Utilizing data from the 1995 CWSS, EPA conducted an extensive data-cleaning process⁹ to develop a dataset of 1,734 records with paired responses for population and total average daily flow. These data were then weighted to account for non-responses to individual questions from the CWSS. EPA used this dataset to develop regression equations that predict average daily flow based on retail population served (for both publicly-owned and privately-owned systems). The data show a very good correlation as indicated by a high R value of 0.90. Additional information and background data are provided in Chapter 4 of the *Geometries and Characteristics of Public Water Systems* report (U.S. EPA, 2000).

 $^{{}^{8}\,}Available\ at: \underline{https://www.epa.gov/dwsixyearreview/microbial-and-disinfection-byproduct-data-files-2012-2019-epas-fourth-\underline{six-year}$

⁹ EPA adjusted the dataset to remove non-zero values; adjusted flow if needed to represent retail flow only removing wholesale water flow; and adjusted for reporting discrepancies in population, flow, or service connections.

4.2.6 Community Water System Survey (2006)

EPA periodically conducts the CWSS to obtain data to support the Agency's development and evaluation of drinking water regulations. The 2006 CWSS is the most recent survey. For this EA, EPA relied on the national average estimates of unit labor from the 2006 CWSS to derive the unit labor rates.

EPA selected the CWSS as a data source because it is based on a nationally representative sample of CWSs. The sample was drawn from SDWIS/Fed, which includes approximately 50,000 systems in the 50 states and the District of Columbia. The survey used a stratified random sample design to ensure the sample was representative. EPA selected a survey sample of 2,210 systems, including all systems serving populations of 100,000 or more. In the 2006 CWSS, the Agency took additional steps to improve response rates, ensure accurate responses, and reduce the burden of the survey on systems, especially systems serving 3,300 or fewer persons. EPA sent water system experts to collect data from systems serving 3,300 or fewer persons. For systems serving more than 3,300 people, the Agency mailed the survey, made available a spreadsheet and Web-based version of the questionnaire, and provided extensive assistance through e-mail and a toll-free telephone hotline. The survey was designed to collect data for the year 2006. Full-scale data collection occurred from June to December 2007. The overall response rate was 59 percent with a total of 1,314 systems responding; 95 percent of selected systems serving 3,300 or fewer persons (representing 571 of 600 systems sampled) participated in the survey (U.S. EPA, 2009).

4.3 Drinking Water System Baseline/Industry Profile

This section presents the following baseline characterizations for the purposes of estimating costs and benefits for the proposed rule. Section 4.3.1 provides a characterization of the inventory of systems subject to the proposed rule (CWSs and NTNCWSs). Section 4.3.2 includes the population served by CWSs and NTNCWSs and the number of households served by CWSs. Section 4.3.3 provides treatment plant characteristics used to determine treatment costs. Section 4.3.4 describes the derivation of PWS labor rates. Finally, Section 4.3.5 describes the cost of capital rates used to estimate household-level costs. Each section includes a characterization of the baseline for CWSs, followed by NTNCWSs, if applicable, and a characterization of data limitations and uncertainty. TNCWSs are not subject to the proposed rule.

4.3.1 Water System Inventory

A key component of the baseline is the inventory of systems—both CWSs and NTNCWSs—subject to the proposed rule. As shown in Table 4-2, approximately 81 percent of all CWSs serve 3,300 or fewer people (39,746 of the total systems), and those serving 500 or fewer account for about 54 percent of all CWSs (26,742 of the total systems). CWSs serving 3,301–50,000 people represent about 17 percent of all CWSs (8,422 of the total systems), and those serving more than 50,000 people account for only about 2 percent (1,025 of the total systems). Most CWSs (about 77 percent or 37,733 systems) use Ground Water as their primary source. Most systems serving more than 10,000 people, however, are classified as Surface Water systems (about 63 percent or 2,817 systems).

Table 4-2: Inventory of CWSs

	CWSs ^a								
System Size (Population Served)	Ground Water	Surface Water	Total						
	A	В	C = A + B						
≤ 100	10,654	739	11,393						
101–500	13,037	2,042	15,079						
501-1,000	4,132	1,179	5,311						
1,001–3,300	5,503	2,460	7,963						
3,301–10,000	2,784	2,223	5,007						
10,001-50,000	1,385	2,030	3,415						
50,001-100,000	162	417	579						
100,001-1M	74	347	421						
> 1M	2	23	25						
TOTAL	37,733	11,460	49,193						

Abbreviations: CWS - community water systems.

Notes

Source: SDWIS/Fed fourth quarter 2021 "frozen" dataset that contains information reported through January 14, 2022. Includes all active CWSs.

As shown in Table 4-3, approximately 99 percent of all NTNCWSs serve 3,300 or fewer people (17,135 of the total). NTNCWSs serving 3,301 – 50,000 people account for about 1 percent of all NTNCWSs (200 of the total). Only two NTNCWSs serve more than 50,000 people, and none serve more than 1 million people. Most NTNCWSs (about 95 percent or 16,531 systems) use Ground Water as their primary source. Approximately 51 percent (21 systems) of those serving 10,001–100,000 people use Surface Water versus Ground Water and the one system serving 100,001–1 million people is classified as a Surface Water system.

^aIncludes 23 CWSs serving 10,000 or fewer people for which no primary source water type was reported to SDWIS/Fed. EPA assigned these systems to the source type of Ground Water.

Table 4-3: Inventory of NTNCWSs

	${ m NTNCWS}{ m s}^{ m a}$							
System Size (Population Served)	Ground Water	Surface Water	Total					
	A	В	C=A+B					
≤ 100	8,084	252	8,336					
101–500	6,111	257	6,368					
501-1,000	1,476	91	1,567					
1,001-3,300	743	121	864					
3,301–10,000	97	63	160					
10,001-50,000	20	20	40					
50,001-100,000	0	1	1					
100,001–1M	0	1	1					
> 1M	0	0	0					
TOTAL	16,531	806	17,337					

Abbreviations: NTNCWS – non-transient non-community water systems.

Includes all active NTNCWSs.

^aIncludes 11 NTNCWSs serving 3,300 or fewer people for which no primary source type was reported to SDWIS/Fed. EPA assigned these systems to the source water type of Ground Water.

Sources: SDWIS/Fed fourth quarter 2021 "frozen" dataset that contains information reported through January 14, 2022.

There is uncertainty in the approach used to assign source water type to the 23 CWSs and 11 NTNCWSs where no primary source type was reported to SDWIS/Fed. This analysis assumes that these systems have Ground Water as their primary source based on the preponderance of ground water systems in the inventory. This could result in an under- or overestimate of costs in those instances where the cost model inputs vary by source type (e.g., number of entry points per system); however, EPA expects the impact to be low because the systems without a source type in SDWIS/Fed represent a small proportion of systems subject to the rule (23 of the total 49,193 CWSs and 11 of the total 17,337 NTNCWSs or 0.05 percent of all systems subject to the rule) and all serve fewer than 10,000 people.

4.3.2 Population and Households Served

It is necessary to have an accurate characterization of population served by water systems when assessing the potential benefits of a proposed regulation. Population is also an input for estimating treated water volumes and associated granular activated carbon (GAC) or ion exchange (IX) costs.

SDWIS/Fed tracks "retail" population served, meaning that it counts only the population that purchases water directly from the water system, not the population of a system's wholesale customers. The systems that purchase water appear in SDWIS/Fed as a separate system with a unique PWS identification (PWSID) number.

Table 4-4 and Table 4-5 show the total population served and average population served per system by size category for CWSs and NTNCWSs, respectively. Each exhibit is organized by source water type (Surface Water or Ground Water) and is based on the SDWIS/Fed fourth quarter 2021 "frozen" dataset that contains information reported by primacy agencies through January 14, 2022.

Because systems often pass some or all of their costs onto customers in the form of rate increases, the proposed rule cost analysis also includes analyses to assess the impact of the proposed requirements on annual household expenditures. EPA estimated the number of households served by affected CWSs by dividing the population for each system size category by the average number of people per household. For CWSs, EPA assumed an average of 2.53 persons per household based on 2020 U.S. Census data (U.S. Census Bureau, 2020b). This information is also included in Table 4-4 by system size and source type. NTNCWSs do not serve households, thus, this information is not included in Table 4-5.

As shown in Table 4-4, although CWSs serving 3,300 or fewer people account for approximately 81 percent of all CWSs, they serve fewer than 8 percent of the population and households that receive their water from a CWS. Although CWSs serving more than 50,000 people account for only 2 percent of all CWSs, they serve more than half (59 percent) of the population and households that receive their water from a CWS.

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Table 4-4: Population and Number of Households Served by CWSs

	Ground Water ^c				Surface Water			TOTAL			
System Size (Population Served)	Population Served	Average Population Per System	Number of Households Served	Population Served	Average Population Per System	Number of Households Served	Population Served	Average Population Per System	Number of Households Served		
	A	B ^a	$C = A/2.53^{b}$	D	Eª	F=D/2.53b	G	H ^a	I=G/2.53b		
≤ 100 ^d	652,335	61	257,840	45,231	61	17,878	697,566	61	275,718		
101-500	3,254,293	250	1,286,282	576,601	282	227,906	3,830,894	254	1,514,187		
501-1,000	3,032,366	734	1,198,564	883,656	749	349,271	3,916,022	737	1,547,835		
1,001-3,300	10,264,020	1,865	4,056,925	4,935,965	2,006	1,950,974	15,199,985	1,909	6,007,899		
3,301–10,000	15,794,291	5,673	6,242,803	13,633,206	6,133	5,388,619	29,427,497	5,877	11,631,422		
10,001-50,000	28,665,202	20,697	11,330,119	46,262,480	22,789	18,285,565	74,927,682	21,941	29,615,685		
50,001-100,000	10,889,918	67,222	4,304,315	29,350,794	70,386	11,601,104	40,240,712	69,500	15,905,420		
100,001–1M	15,082,760	203,821	5,961,565	84,675,709	244,022	33,468,660	99,758,469	236,956	39,430,225		
>1M	3,400,000	1,700,000	1,343,874	44,266,001	1,924,609	17,496,443	47,666,001	1,906,640	18,840,317		
TOTALe	91,035,185	2,413	35,982,287	224,629,643	19,601	88,786,420	315,664,828	6,417	124,768,707		

Abbreviations: Ground Water – ground water; CWS – community water systems. Notes:

^aB, E, and H: Derived by dividing the population served by the number of systems presented in Table 4-2.

^bC, F, and I: The average of 2.53 persons per household is from 2020 U.S. Census data (Table AVG1. Average Number of People per Household, by Race and Hispanic Origin/1, Marital Status, Age, and Education of Householder: 2020).

^cCWSs with unreported primary source were assumed to be Ground Water systems. Thus, the Ground Water column reflects an additional 23 CWSs with unreported primary source type.

^dEPA removed any CWS wholesaler serving less than 25 people from the analysis and assumed that any remaining CWS had a minimum possible population of 25.

^eNumbers may not sum to total because of rounding.

Source for A, D, and G: SDWIS/Fed fourth quarter 2021 "frozen" dataset that contains information reported through January 14, 2022.

As previously discussed, NTNCWSs serving 3,300 or fewer people account for approximately 99 percent of all NTNCWSs. As shown in Table 4-5, these systems serve approximately 70 percent of the population that receives their water from an NTNCWS. Those serving 3,301–50,000 people and more than 50,000 people serve approximately 26 percent and 4 percent of the population that receives water from an NTNCWS, respectively.

Table 4-5: Population Served by NTNCWSs

	Ground	d Water ^b	Surface	e Water	TOTAL		
System Size (Population Served)	Population Served Average Population Per System		Population Served	Average Population Per System	Population Served	Average Population Per System	
	A	Ba	D	E ^a	F	Ga	
≤ 100°	452,516	56	12,534	50	465,050	56	
101-500	1,513,562	248	69,046	269	1,582,608	249	
501-1,000	1,049,638	711	68,235	750	1,117,873	713	
1,001-3,300	1,241,973	1,672	239,516	1,979	1,481,489	1,715	
3,301–10,000	511,494	5,273	377,219	5,988	888,713	5,554	
10,001-50,000	397,246	19,862	414,099	20,705	811,345	20,284	
50,001-100,000	0	0	71,963	71,963	71,963	71,963	
100,001-1M	0	0	203,375	203,375	203,375	203,375	
> 1M	0	0	0	0	0	0	
$TOTAL^d$	5,166,429	313	1,455,987	1,806	6,622,416	382	

Abbreviations: NTNCWS – non-transient non-community water systems. Notes:

As noted previously, EPA consistently classifies systems in SDWIS/Fed according to the retail population served by the system and does not include the population served by wholesale customers. Wholesale customers who purchase water from another system and meet the PWS definition have their own unique PWSID, retail population, and associated regulatory requirements under SDWA. EPA uses retail population to estimate design and average daily flow parameters, which are then used to estimate treatment costs associated with the rule. Use of retail population may overestimate aggregate costs by assuming that each system will have an individual treatment plant instead of the more common scenario of the seller having one large plant and selling treated water to their wholesale customers. Because of returns to scale in treatment capital costs, the cost of a single large plant will be less than the sum of the costs across several small plants treating the same aggregate flow.

^aB, E, and G: Derived by dividing the population served by the number of systems presented in Table 4-3.

^bNTCWSs with unreported primary source were assumed to be Ground Water systems. Thus, the "Ground Water" column reflects an additional 11 NTCWSs with unreported primary source type.

cEPA assumed any non-wholesale NTNCWS had a minimum possible population of 25.

^dNumbers may not sum to total because of rounding.

Source for A, D, and F: SDWIS/Fed fourth quarter 2021 "frozen" dataset that contains information reported through January 14, 2022.

In addition, given that some of the reported population values would create inconsistencies in the analysis, EPA removed any CWS wholesaler serving less than 25 people from its analysis and assumed that any remaining CWS had a minimum possible population of 25. EPA assumed any non-wholesale NTNCWS had a minimum possible population of 25.

4.3.3 Treatment Plant Characterization/Production Profile

This section explains the baseline inputs for the following treatment-related PWS characteristics. Section 4.3.3.1 discusses the entry points per system characterization. Section 4.3.3.2 discusses EPA's TOC baseline assumptions and Section 4.3.3.3 presents the estimation method and the computed average daily flows and design flows by system type and size.

4.3.3.1 Entry Points Per System

Entry points are the point of compliance for the proposed rule and systems can have multiple entry points. EPA developed estimates of entry points per system using UCMR 3 unique sampling points, SDWIS/Fed facility data, and a modeled frequency distribution.

UCMR 3 required a subset of CWSs and NTNCWSs to conduct assessment monitoring for six PFAS compounds.¹⁰ The data record a unique identifying number for the entry point sample location(s) for each system. Given the information provided, EPA assumes that the number of unique sample point IDs per system approximates the total number of entry points per system.

For systems without UCMR 3 occurrence data, EPA developed estimates based on SDWIS/Fed facilities data. The SDWIS/Fed data include unique identification numbers for system facilities, as well as facility type and activity status. This analysis relies on active facilities identified as treatment plants. Using the assumption that treatment plants are associated with one entry point, the SDWIS/Fed facility data provide an approximation for the number of entry points per system when a system does not have UCMR 3 occurrence data. EPA considers the UCMR 3 sampling point data to be of higher quality than the SDWIS/Fed treatment facility data. If the SDWIS/Fed treatment facility data value for a system exceeded the maximum number found for the equivalent system size and source water combination in the UCMR 3 data, EPA limited the system entry point value to the UCMR3 maximum number of entry points.

For systems without UCMR 3 occurrence data or SDWIS/Fed facility data, EPA relies on an estimate of the number of entry points. The estimated value for each system with missing entry point count data was imputed from known entry point counts for stratified SDWIS/Fed data. Within each stratum, defined by a combination of system size and source water, EPA sampled from systems with known entry point counts. Sampling was done with replacement after truncating the entry point counts to the maximum recorded in UCMR 3. For reproducibility, EPA performed this sample-based imputation in R using the 'base::sample' function (R Core Team, 2021).

Following this process, EPA relies on sample point values recorded in UCMR 3 for 5,419 systems, SDWIS/Fed facility data for 43,563 systems, and imputed entry point values for 17,523

¹⁰ UCMR 3 required all systems serving more than 10,000 people to collect and analyze samples for PFOA, PFOS, PFNA, PFHxS, PFBS, and PFHpA at each distribution system entry point. EPA also identified a stratified random sample of 800 small systems serving up to 10,000 people to collect samples for these six PFAS.

systems. All systems have at least one entry point. Among CWSs, the maximum number of entry points is 202, and the mean is 1.80. Among NTNCWSs, the maximum number of entry points is 22, and the mean is 1.31.

Table 4-6 summarizes the final frequency distribution of entry point input ranges for each CWS stratum of size and source water combination. Table 4-7 summarizes the final frequency distribution of entry point input ranges for each NTNCW stratum of size and source water combination. These distributions are used to proportionally assign numbers of entry points to systems in each system size and type category.¹¹

cost analysis, please see Section 5.2.

¹¹ The SDWIS/Fed data provide information on the PWS characteristics that typically define PWS categories, or strata, for which EPA develops costs in rulemakings. These characteristics include system type (CWS, NTNCWS), number of people served by the PWS, PWS's primary raw water source (ground water or surface water), PWS's ownership type (public or private), and PWS state. For more information on the use of baseline and compliance characteristics to define model systems in EPA's

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Table 4-6: Frequency Distribution of Entry Point Inputs for CWSs

Ground Water							Surface Water							
System Size	1 EP	2–5 EP	6–10 EP	11–15 EP	16–20 EP	21– 100 EP	> 100 EP	1 EP	2–5 EP	6–10 EP	11–15 EP	16–20 EP	21– 100 EP	> 100 EP
≤ 100	90%	10%	0.1%	0	0	0	0	87%	13%	0	0	0	0	0
101-500	76%	24%	0	0	0	0	0	84%	16%	0	0	0	0	0
501-1,000	62%	38%	0.5%	0	0	0	0	76%	23%	0.8%	0	0	0	0
1,001-3,300	48%	50%	1%	0	0	0	0	70%	30%	0.7%	0	0	0	0
3,301-10,000	32%	59%	8%	0.9%	0.1%	0	0	54%	43%	3%	0.5%	0.04%	0	0
10,001-50,000	3%	58%	28%	7%	3%	1%	0.07%	3%	82%	10%	2%	1%	0.6%	0
50,001-100,000	0	51%	25%	8%	8%	9%	0	0.2%	74%	13%	6%	2%	4%	0
100,001-1M	0	34%	22%	11%	8%	24%	1%	0.3%	67%	13%	4%	9%	6%	0.3%

Abbreviations: CWS – community water systems; EP – entry point.

Table 4-7: Frequency Distribution of Entry Point Inputs for NTNCWSs

Ground Water							Surface Water				
System Size	1 EP	2–5 EP	6–10 EP	11-20 EP	> 20 EP	1 EP	2–5 EP	6–10 EP	11–20 EP	> 20 EP	
≤ 100	84%	16%	0.4%	0	0	82%	18%	0	0	0	
101-500	81%	19%	0	0	0	74%	26%	0	0	0	
501-1,000	0	0	0	0	0	0	0	0	0	0	
1,001-3,300	68%	30%	2%	0	0	61%	31%	8%	0	0	
3,301-10,000	53%	44%	2%	1%	0	35%	44%	14%	6%	0	
10,001-50,000	10%	80%	0	10%	0	30%	40%	5%	20%	5%	
50,001-100,000	0	0	0	0	0	0	100%	0	0	0	
100,001–1M	0	0	0	0	0	0	100%	0	0	0	

Abbreviations: NTNCWS – non-transient non-community water systems; EP – entry point.

4.3.3.2 Total Organic Carbon

The effectiveness of the GAC treatment process varies with the level of TOC in the influent water. There is no national dataset containing TOC values for every CWS or NTNCWS. Therefore, EPA randomly assigned a TOC level to each system based on two distributions of TOC in 'finished' water. The Agency developed distributions using TOC data voluntarily submitted by states in response to the SYR4 ICR drinking water regulations. Because TOC levels in Ground Water are lower on average than TOC levels in Surface Water, EPA separated the data by system primary source water. TOC levels can also vary throughout a system. Source water TOC measurements can be higher than finished water estimates if a treatment process removes TOC. For each system, EPA identified TOC measurements that best represented finished water quality. Using the resulting distribution of Ground Water or Surface Water estimates, EPA identified decile midpoint values to randomly assign to each system.

4.3.3.3 Average Daily Production Flow and Design Flow

Average daily production flow and design flow per system are based on regression equations from EPA's *Geometries and Characteristics of Public Water Supplies* report (U.S. EPA, 2000). The average daily flow and design flow are functions of the population served, with different equations for source water type (Surface Water or Ground Water). Table 4-8 presents these flow equations. The flow was then divided by the number of entry points to calculate the flow per treatment plant for the system (assuming each entry point has one treatment plant). EPA does not have comparable flow-population regression equations for NTNCWSs and, therefore, used the CWS relationships to estimate flow for NTNCWSs.

Table 4-8: Functions for Design and Average Daily Flow by System Types

Design Flow Functions (kgal)						
Surface Water system	Design Flow = $0.59028 \times Population^{0.94573}$					
Surface water system	(or 2 x Average Flow, whichever is greater)					
Ground Water system	Design Flow = $0.54992 \times Population^{0.95538}$					
Ground Water System	(or 2 x Average Flow, whichever is greater)					
	Average Daily Flow Functions (kgal)					
Surface Water system	Average Flow = $0.14004 \times Population^{0.99703}$					
Ground Water system	Average Flow = $0.08575 \times Population^{1.05839}$					

 $Abbreviations: Ground\ Water-ground\ water;\ Surface\ Water-surface\ water,\ kgal-1000\ gallons.$

As an example, Table 4-9 shows the design flow and average daily flow results when applying the regression equations to the average population per system for each CWS system stratum. The results for NTNCWSs are in Table 4-10. Note that these results are examples only. In practice, EPA applied the regression equations to the population served of individual systems, instead of the stratum average population. In addition, for systems serving more than 1 million people, EPA obtained publicly available system-specific information on the average daily flow and design flow for each entry point whenever possible (e.g., annual Consumer Confidence Reports).

Table 4-9: Design and Average Daily Flow for CWSs

	(Fround Water		Surface Water			
System Size	Average Design Flow (MGD)		Average Flow (MGD)	Average Population	Design Flow (MGD)	Average Flow (MGD)	
≤ 100	61	0.028	0.007	61	0.029	0.008	
101-500	250	0.107	0.030	282	0.123	0.039	
501–1,000	734	0.301	0.093	749	0.309	0.103	
1,001-3,300	1,865	0.733	0.248	2,006	0.784	0.275	
3,301-10,000	5,673	2.121	0.806	6,133	2.255	0.837	
10,001-50,000	20,697	7.305	3.171	22,789	7.804	3.098	
50,001-100,000	67,222	22.512	11.031	70,386	22.671	9.535	
100,001-1M	203,821	71.371	35.685	244,022	73.470	32.937	

Abbreviations: CWS – community water systems; MGD – million gallons per day.

Table 4-10: Design and Average Daily Flow for NTNCWSs

		Ground Water	r	Surface Water			
System Size	Average Design Flow (MGD)		Average Flow (MGD)	Average Population	Design Flow (MGD)	Average Flow (MGD)	
≤ 100	56	0.026	0.006	50	0.024	0.007	
101-500	248	0.107	0.029	269	0.117	0.037	
501-1,000	711	0.292	0.089	750	0.309	0.103	
1,001-3,300	1,672	0.660	0.221	1,979	0.774	0.271	
3,301-10,000	5,273	1.978	0.746	5,988	2.205	0.817	
10,001-50,000	19,862	7.023	3.035	20,705	7.127	2.815	
50,001-100,000	Not	Not	Not	71,963	23.151	9.748	
	applicable	applicable	applicable				
100,001–1M	Not applicable	Not applicable	Not applicable	203,375	61.841	27.465	

Abbreviations: NTNCWS - non-transient non-community water systems; MGD - million gallons per day.

4.3.4 Public Water System Labor Rates

EPA recognizes that there may be variation in labor rates across all systems. However, for purposes of this EA, EPA used national average estimates of unit labor from the 2006 CWSS, with a few modifications described below. Prior labor unit costs for managerial, technical, and

clerical labor in EPA's work breakdown structure¹² (WBS) were based on a review of data from three sources:

- The Occupational Employment Survey (OES), a semi-annual Bureau of Labor Statistics (BLS) survey that provides hourly wage estimates by occupation and industry (BLS, 2022).
- The Water Utility Compensation Survey, an annual American Water Works Association (AWWA) survey that provides hourly wage estimates for the water and wastewater industry by occupation. Data are in 2008 dollars.
- The 2006 CWSS, a periodic EPA survey that obtains employment information from a sample of CWSs.

There are more recent wage data from the OES and AWWA surveys, but there has not been a CWSS since 2006. A 2020 review of the WBS labor rates found that the WBS wage rates in 2019 dollars overstate labor costs for clerical labor hours as well as potentially overstate labor costs for technical labor hours (Abt Associates, 2020). Following these findings, EPA adjusted the labor costs used in the WBS to reflect occupation-specific escalation factors rather than the seasonally adjusted employment cost index (ECI) for all civilian employees. The WBS labor costs for managerial hours were not clearly over- or understated compared to OES data but were consistently lower than the AWWA wage estimates (Abt Associates, 2020).

Table 4-11 presents the labor rate estimates used in the WBS in 2007 dollars. Labor rates were calculated for three occupation categories: technical, managerial, and clerical. The rates do not include benefits.

Table 4-11: Hourly Wage Rates Based on CWSS Data (\$2007)

Occupation	≤ 500	501- 3,300	3,301– 10,000	10,001– 50,000	50,001- 100,000	> 100,000
Technical	\$16.97	\$16.97	\$18.10	\$19.11	\$19.95	\$23.32
Managerial	\$24.06	\$24.06	\$27.52	\$30.65	\$35.76	\$38.21
Clerical	\$16.21	\$16.21	\$16.21	\$20.93	\$20.93	\$20.93

Abbreviations: CWSS - Community Water System Survey.

Source: Abt Associates, 2020

A review of updated BLS Employer Cost for Employee Compensation (ECEC) data indicated that benefits account for a higher proportion of total compensation today than they did at the end of 2006 (Abt Associates, 2020). The WBS assumes a benefit multiplier of 1.45, which is the 2020 multiplier for all civilians working in service-producing industries (Abt Associates, 2020). The benefit-loaded wage rates are shown in Table 4-12.

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¹² To estimate treatment costs, EPA uses several engineering models using a bottom-up approach known as work breakdown structure (WBS). The WBS models derive system-level costs and provide EPA with comprehensive, flexible and transparent tools to help estimate treatment costs.

Table 4-12: Hourly Labor Costs Including Wages Plus Benefits (\$2007)

Occupation	≤ 500	501- 3,300	3,301– 10,000	10,001– 50,000	50,001– 100,000	> 100,000
Technical	\$24.61	\$24.61	\$26.25	\$27.71	\$28.93	\$33.81
Managerial	\$34.89	\$34.89	\$39.90	\$44.44	\$51.85	\$55.40
Clerical	\$23.50	\$23.50	\$23.50	\$30.35	\$30.35	\$30.35

Source: Abt Associates, 2020

Because the WBS relies on 2020 dollar values, EPA escalated the CWSS values using the OES occupation-specific change in mean wage rate from 2007 to 2020 instead of the general civilian ECI escalation rate. The escalation for the technical rate is 35.2 percent and the escalation for the clerical rate is 36.3 percent. The WBS managerial wage rates are consistent with OES rates, but slightly lower than AWWA rates (Abt Associates, 2020). At the time of the analysis in 2020, the OES occupation-specific wage escalation rate for the managerial rate was comparable to the ECI rate (Abt Associates, 2020). Therefore, the WBS retains the ECI escalated managerial labor rates, which for 2020 is 41.4 percent. The national cost-benefit analysis method described in Section 5.2 presents all values in 2021 dollars. The method uses the gross domestic product (GDP) implicit price deflator to adjust values in other dollar years to 2021 dollars. Therefore, the labor costs including wages and benefits in 2021 dollars shown in Table 4-13 reflect an additional adjustment for dollar year. EPA applied the same system labor rates to both CWSs and NTNCWSs.

Table 4-13: Hourly Labor Costs Escalated to \$2021

Occupation	≤ 500	501- 3,300	3,301–10,000	10,001– 50,000	50,001- 100,000	> 100,000
Technical	35.48	35.48	37.84	39.94	41.70	48.74
Managerial	52.60	52.60	60.16	67.02	78.19	83.55
Clerical	34.17	34.17	34.17	44.12	44.12	44.12

Note

EPA escalated the 2020 labor costs in the WBS models to 2021 dollars for use in the national cost-benefit analysis. The adjustment multiplier based on the GDP implicit price deflator was 1.066, equal to the October 2021 value of 121.188 divided by the 2020 annual value of 113.633 (U.S. Bureau of Economic Analysis, 2022).

There is uncertainty in the derivation of labor rates that could result in an over- or underestimate of national costs of the proposed rule. The mean labor rate is based on findings of the 2006 CWSS. The labor rate mix may have changed since the time of the survey. EPA accounted for general changes in cost of labor by adjusting 2007 values to 2020 using occupation-specific escalators and the ECI where appropriate. There is also uncertainty in assuming a 1.45 benefits multiplier; this may cause an under- or overestimation of cost of the proposed rule.

4.3.5 Cost of Capital

For the social cost-benefit analysis, EPA uses two alternative social discount rates, 3 percent and 7 percent to discount future values and annualize discounted present value over the period of analysis. These rates are in accordance with EPA policy and guidance from OMB.

When evaluating the economic impacts on PWSs and households, however, EPA uses estimated cost of capital to discount future costs and annualize the discounted present value over the analysis period. This rate best represents the actual costs of compliance that systems will incur

over time. To estimate PWS cost of capital, EPA used data from the 2006 CWSS. The CWSS defined the following categories of funding sources:

- Current revenue;
- Equity or other funds from private investors;
- Department of Homeland Security (DHS) grant;
- Other government grants;
- Drinking Water State Revolving Fund (DWSRF), including loans and Principal Repayment Forgiveness;
- Other borrowing from public sector sources; and
- Borrowing from private sectors sources.

EPA calculated the overall weighted average cost of capital (across all funding sources and loan periods) for each size/ownership category, weighted by the percentage of funding from each source. Table 4-14 shows the cost of capital for each CWS size category and ownership type. Similar cost of capital information is not available for NTNCWS. Therefore, EPA used the CWS cost of capital when calculating the annualized cost per NTNCWS.

Table 4-14: Weighted Average Cost of Capital by PWS Ownership and Size Category

Size Category	Publicly Owned CWS	Privately Owned CWS
≤100	3.8%	7.8%
101–500	5.5%	8.2%
501-1,000	4.0%	8.6%
1,001–3,300	4.7%	7.1%
3,301–10,000	5.8%	7.0%
10,001–50,000	6.1%	7.0%
50,001-100,000	4.9%	6.9%
100,001-500,000	4.7%	3.9%
Over 500,000	3.7%	7.8%

Abbreviations: PWS – public water system; CWS – community water system.

Since the CWSS data collection, Congress established new programs and expanded funding for existing programs. These funding sources allow PWSs to lower their cost of capital. These include the DWSRF, the Water Infrastructure Finance and Innovation (WIFIA) program, the Water Infrastructure Improvements for the Nation Act of 2016 (WIIN Act), and the Bipartisan Infrastructure Law of 2021 (BIL).

Through the DWSRF Program, the EPA allocates annual capitalization grants to states. The grants, along with state matching monies, support a dedicated loan fund to finance eligible water system infrastructure improvement projects. States are permitted to use funding from their DWSRF to help PWS finance water treatment through low-interest loans. The WIFIA program provides creditworthy PWSs access to low-interest direct federal loans for water treatment investment. The WIIN Act established a grant program to help small, underserved, and disadvantaged communities achieve compliance with drinking water standards. Additionally, the

¹³ See "Cost of Capital Approach.doc" in the docket for details of how the cost of capital estimates were developed.

Bipartisan Infrastructure Law (BIL) (P.L. 117-58) authorizes \$5 billion as part of the Emerging Contaminants in Small or Disadvantaged Communities grant program that can be used to reduce PFAS in drinking water in communities facing disproportionate impacts. BIL funds will be provided as grants and loan forgiveness associated with PFAS drinking water treatment capital expenditures. Therefore, the actual cost of capital faced by some PWSs may be lower than those used in this analysis.

4.4 Occurrence of PFAS

EPA's Technical Support Document for PFAS Occurrence provides estimates of the baseline PFAS occurrence in PWSs (U.S. EPA, 2023g). After reviewing the available data on PFAS in drinking water, EPA determined that the data from the UCMR 3 are the best available nationally representative data to characterize the occurrence of multiple PFAS in drinking water. Consistent with the Agency's commitment in the final regulatory determination for PFOA and PFOS and EPA's PFAS Strategic Roadmap to present the best available occurrence information, the Agency supplemented the UCMR 3 data with data collected by states that have made their data publicly available (U.S. EPA, 2021b; U.S. EPA, 2021e).

This section summarizes the EPA's PFAS occurrence analysis (U.S. EPA, 2023g). Section 4.4.1 provides an overview of UCMR 3 and its PFAS occurrence data. Section 4.4.2 provides an overview of state PFAS monitoring data. Section 4.4.4 summarizes EPA's analysis of PFAS drinking water occurrence data. Section 4.4.5 summarizes the national PFAS occurrence estimates used in the cost and benefit analyses.

4.4.1 Overview of UCMR 3 Data

The UCMR is a national drinking water monitoring program administered by EPA. The UCMR 3 monitoring cycle included a census of all large CWSs and NTNCWSs (i.e., those serving more than 10,000 people) and a statistical sample of 800 small CWSs and NTNCWSs (i.e., those serving 10,000 people or fewer). Monitoring under UCMR 3 occurred from 2013 to 2015. More information on the UCMR 3 study design and data analysis can be found in U.S. EPA (2012) and U.S. EPA (2019c).

EPA collected the UCMR 3 data from PWSs in all 50 states and seven additional primacy agencies. UCMR 3 monitoring occurrence data are available for six PFAS: PFOS, PFOA, PFNA, PFHxS, PFHpA, and PFBS. For the individual PFAS contaminants, EPA collected nearly 37,000 finished water samples from 4,920 PWSs.

Systems collected PFAS samples at each entry point to their customer distribution system. Entry points are the point of compliance for the proposed rule, and systems can have multiple entry points. The sampling frequency varied by source water: four quarterly samples in a one-year period for surface water systems, and two samples at least six months apart for ground water systems.

EPA's Technical Support Document for PFAS Occurrence (U.S. EPA, 2023g) describes the data and analyses that EPA used to develop national estimates of PFAS occurrence in public drinking water systems using UCMR 3 data.

4.4.2 Overview of State PFAS Data

Outside of the UCMR 3 data collection, many states have undertaken individual efforts to monitor for PFAS in both source and finished drinking water. EPA collected data from 23 states that made their data publicly available as of August 2021; this action was in alignment with the Agency's commitment in the final regulatory determination for PFOA and PFOS and its PFAS Strategic Roadmap to present the best available information on sampling for PFAS in water systems. EPA notes that this data collection cutoff was made to allow sufficient time for the Agency to conduct analyses on the state information for the proposed NPDWR. Due to the limitations in representation and reporting of some of the available data, EPA conducted technical analyses using a subset of the available state data. These more recent state data, collected using improved analytical methods that have lower reporting limits than under UCMR 3, show widespread occurrence of PFOA, PFOS, PFBS, PFNA, and PFHxS in multiple geographic locations. These data also show that these PFAS occur with substantial frequency at lower concentrations than were analyzed under UCMR 3, as demonstrated within EPA's Technical Support Document for PFAS Occurrence (U.S. EPA, 2023g). Furthermore, these state data include results for more PFAS than were included in the UCMR 3, including HFPO-DA.

EPA's analysis of state PFAS data shows occurrence in multiple geographic locations consistent with what was observed during UCMR 3 monitoring. The Agency notes that the data vary in terms of quantity and coverage; for example, some of these available data are from targeted sampling efforts (i.e., monitoring in areas of known or potential contamination) and thus may not be representative of levels found in all PWSs within the state. Summaries on the non-targeted state PFAS finished water data are available in Table 4-15 and Table 4-16. Specifically, a summary on the percent of samples in state datasets that were above detection limits for select PFAS is provided in Table 4-15, and a summary on the number of systems in state datasets that had detections for select PFAS is available in Table 4-16. Comprehensive summaries of state data are available within EPA's Technical Support Document for PFAS Occurrence (U.S. EPA, 2023g).

Table 4-15: Non-Targeted State PFAS Finished Water Data – Summary of Samples with Detections of PFAS Proposed for Regulation

State	PFHxS	PFNA	PFBS	HFPO-DA ^a
Colorado	10.8%	0.9%	11.0%	0.2%
Illinois	5.1%	0.2%	7.8%	0.0%
Kentucky	8.6%	2.5%	13.3%	13.6%
Massachusetts	31.9%	4.6%	35.5%	0.0%
Michigan	2.9%	0.1%	5.2%	0.04%
New Hampshire	12.9%	2.5%	22.7%	1.8%
New Jersey	24.7%	8.0%	24.9%	N/A
North Dakota	1.6%	0.0%	0.0%	0.0%
Ohio	5.8%	0.3%	4.7%	0.1%
South Carolina	13.5%	2.1%	38.3%	6.0%
Vermont	2.2%	1.7%	4.8%	0.2%

Abbreviations: PFAS – per- and polyfluoroalkyl substances.

^aN/A indicates that no data are available. 0.0 % indicates that monitoring data were available for the compound/state but there were no detections.

State **PFHxS PFBS PFNA** HFPO-DA^a Colorado 13.4% 1.0% 0.3% 13.4% 4.3% 6.6% 0.0% Illinois 0.2% Kentucky 8.6% 2.5% 12.3% 13.6% Massachusetts 30.2% 8.4% 39.4% 0.0% Michigan 3.0% 0.2% 5.3% 0.1% New Hampshire 17.6% 4.4% 26.1% 1.7% New Jersey 32.6% 13.3% 34.0% N/A North Dakota 1.6% 0.0% 0.0% 0.0% Ohio 2.2% 0.3% 2.4% 0.1% South Carolina 20.0% 6.1% 56.0% 10.9% Vermont 1.6% 1.3% 5.2% 0.5%

Table 4-16: Non-Targeted State PFAS Finished Water Data – Summary of Systems with Detections of Select PFAS

 $Abbreviations: PFAS-per- and polyfluoroalkyl \ substances.$

Note:

4.4.3 Overview of PFAS Co-Occurrence

Co-occurrence of multiple PFAS has been reported in drinking water, ambient surface waters, aquatic organisms, biosolids (sewage sludge), and other environmental media. PFOA and PFOS have historically been target analytes, which has partly contributed to their prevalence in environmental monitoring studies, although some recent monitoring studies have begun to focus on additional PFAS via advanced analytical instruments/methods and non-targeted analysis (McCord et al., 2019; McCord et al., 2020).

EPA's analysis on PFAS co-occurrence using UCMR 3 data found that 4 percent of PWSs reported results for which one or more of the six UCMR 3 PFAS were measured at or above their respective minimum reporting levels. Additionally, several studies have demonstrated PFAS co-occurrence in finished drinking water (Adamson et al., 2017; Cadwallader et al., 2022; Guelfo et al., 2018). One study in particular used UCMR 3 data to demonstrate that two or more of the six PFAS monitored under UCMR 3 co-occurred in 48 percent (285/598) of sampling events with PFAS detected, and PFOA and PFOS co-occurred in 27 percent (164/598) of sampling events with two or more PFAS detected (Guelfo et al., 2018).

For additional discussion and analysis on PFAS co-occurrence, reference EPA's Technical Support Document for PFAS Occurrence (U.S. EPA, 2023g).

4.4.4 Summary of PFAS Occurrence Data Analysis

Identifying the systems and population exposed to PFAS exceeding the limits under the proposed option and the three regulatory alternatives is a key step to estimating benefits and costs of the proposed NPDWR. EPA used a Bayesian hierarchical Markov chain Monte Carlo (MCMC) occurrence model to estimate national PFAS occurrence in PWSs. EPA used the MCMC occurrence model output to estimate the PWSs and entry points with PFAS occurrence exceeding the limits under the proposed option and regulatory alternatives. EPA assumed that the

^aN/A indicates that no data are available. 0.0 % indicates that monitoring data were available for the compound/state but there were no detections.

populations served by these PWSs were exposed to the PFAS concentration estimates generated by the MCMC occurrence model.

This section summarizes the occurrence model and EPA's use of the model to identify the systems and entry points with PFAS occurrence exceeding the regulatory alternatives considered within the EA, as well as the corresponding populations exposed. Further details on the MCMC model are available in Appendix A, Cadwallader et al. (2022), and U.S. EPA (2023g).

Data collected under UCMR 3 served as the primary dataset for the MCMC occurrence model due to its nationally representative design. Additionally, EPA incorporated state PFAS monitoring datasets to supplement UCMR 3 data in the occurrence model. These state datasets, for which the monitoring has been conducted more recently than UCMR 3, generally have lower reporting limits because the analytical methods have improved over the last 10 years, allowing laboratories to reliably measure PFAS at concentrations approximately 5 to 20 times lower than for UCMR 3. Thus, state datasets with lower reporting limits than those in UCMR 3 helped inform the model by enabling observation of PFAS occurrence at lower concentrations. State datasets also consist of more-recent samples than UCMR 3, which broadened the temporal range of data used to fit the model. The supplemental state data were limited to samples collected from systems that were also in UCMR 3 to prevent biasing the dataset toward states for which the data from additional PWSs were available as well as maintain the nationally representative set of systems selected for UCMR 3. Using these criteria, 17 states were identified as having some state monitoring data to be included in fitting the national occurrence model.

The dataset used to fit the model included all data available in the final UCMR 3 dataset for PFOS, PFOA, PFHpA, and PFHxS. This amounted to 36,972 samples each for PFOS, PFOA, and PFHpA, and 36,971 samples for PFHxS. Of these four PFAS, 1,114 samples had results reported at or above the UCMR 3 MRLs. The additional state datasets included to supplement the UCMR 3 data contained 6,645 PFOS samples, 6,656 PFOA samples, 4,715 PFHpA samples, and 5,114 PFHxS samples collected at systems that were included in UCMR 3. Of these samples, 2,200 (33%) were reported values for PFOS, 2,694 (40%) were reported values for PFOA, 932 (20%) were reported values for PFHpA, and 1,269 (25%) were reported values for PFHxS. The remainder were listed as being below their respective reporting limits. A summary of the state data used in the occurrence model, including system and sample counts, is available in Appendix A.

Some states have promulgated drinking water standards for PFAS since the UCMR 3 monitoring. EPA reviewed state websites and identified states with enacted standards for the PFAS compounds considered within the regulatory alternatives discussed in the EA. Table 4-17 summarizes state regulations on PFAS in drinking water, which are current as of July 2022. The state PFAS regulation summary in Table 4-17 is reflective of only those states that have promulgated PFAS drinking water regulations and does not include information from states that have proposed PFAS drinking water regulations or issued guidance for PWSs.

Table 4-17: State PFAS Regulations

	Regulated PFAS Levels (ppt)									
State	PFOA	PFOS	PFBS	PFHpA	PFHxA	PFHxS	PFNA	PFDA	HFPO- DA	Sum
New Jersey	14	13					13			
Vermont ^a	*	*		*		*	*			20
New Hampshire	12	15				18	11			
Massachusetts ^a	*	*		*		*	*	*		20
Michigan	8	16	420		400,000	51	6		370	
New York	10	10								

 $Abbreviations: PFAS-per-and polyfluoroalkyl \ substances. \\$

Notes:

(https://www.nj.gov/health/ceohs/documents/pfas_drinking%20water.pdf), Vermont (https://dec.vermont.gov/water/drinking-water/water-quality-monitoring/pfas), New Hampshire (https://www.nhwwa.org/wp-content/uploads/NHWWA-Water-is-Essential-Seminar-Oct-20-2020-PFAS-Arsenic-Rule-Updates.pdf), Massachusetts (https://www.mass.gov/lists/development-of-a-pfas-drinking-water-standard-mcl#final-pfas-mcl-regulations-), Michigan

(https://www.michigan.gov/pfasresponse/drinking-water/mcl), New York

(https://www.health.ny.gov/environmental/water/drinking/docs/water_supplier_fact_sheet_new_mcls.pdf).

To estimate the costs and benefits of the proposed rule, EPA assumed that all MCMC occurrence model estimates exceeding state limits are equivalent to the state-enacted limit. For these states, EPA assumed that the state MCL is the maximum baseline PFAS occurrence value for all entry points in the state. This adjustment was made to the MCMC occurrence model PFAS estimates for PFOA, PFOS, and PFHxS in this EA. Since the proposed rule standards are more stringent than current state drinking water standards, systems in states with PFAS regulations are still expected to incur incremental costs to comply with the proposed rule, although the estimated compliance costs will be less compared to costs that do not adjust the MCMC occurrence data to reflect the state MCLs. Similarly, populations served by PWSs in the states with PFAS regulations are expected to benefit from further reductions in PFAS exposures, although the incremental benefits for these populations will be less compared to benefits that do not adjust the MCMC occurrence data to reflect the state MCLs.

EPA used system-level distributions, as described in Cadwallader et al. (2022), to simulate entry point concentrations and estimate PFAS occurrence relative to the regulatory alternatives and proposed option limits. EPA assumed entry point concentrations were constant. Simulated sample data are composed of a set of 4,000 iterations with the number of simulated samples per system within each iteration equal to the number of entry points. EPA estimated within system variation from all available samples within each system as part of the model fitting process. Although the data used to fit the model may have included multiple samples over time or entry points, this simulation strategy assumes that all within-system variability is related to entry point.

For 4,920 systems with means fitted by the model (i.e., systems with PFAS data in UCMR 3), EPA simulated system-specific samples based on the best-fit model. EPA simulated from the high level multivariate normal distribution to produce means for each chemical at each non-UCMR system and then used those distributions to simulate system-specific samples. The Agency then generated random samples from the multivariate distribution and the value of the fixed parameters for each iteration. The exception to this approach was systems serving more

^aAsterisks (*) indicate states that regulate PFAS compounds at an overall threshold value, as indicated in the Sum column. Sources: State websites are as follows – New Jersey

than 1 million people. For these systems, EPA used UCMR 3 and more recent monitoring data to identify the entry points that might require PFAS removal. These relatively few very large systems have the potential to affect aggregate costs and, therefore, require more precision in baseline occurrence estimates.

4.4.5 Summary of National PFAS Occurrence

Using the MCMC occurrence model, EPA estimated baseline occurrence to understand changes in occurrence and exposure for the proposed option and the regulatory alternative MCLs under Options 1a-1c. These estimates vary across the 4,000 MCMC occurrence model iterations, thereby characterizing baseline occurrence uncertainty. In addition, for PWSs in states with existing MCLs for PFOA, PFOS, and PFHxS, EPA capped contaminant concentrations at the state MCLs.

The estimated number of PWSs with at least one entry point above the MCL or HI are provided in Table 4-18 through Table 4-21, while the total estimated number of entry points above the MCL or HI are provided in Table 4-22 through Table 4-25. In Table 4-26 through Table 4-29, EPA provides the population served by PWSs with at least one entry point above the MCL or HI. The population served by entry points above the MCL or HI are provided in Table 4-30 through Table 4-33. Each table provides expected value estimates as well as 5th percentile and 95th percentile estimates that characterize the uncertainty of baseline PFAS occurrence.

Table 4-18: Total Systems Impacted, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0)

	5 th Percentile	Mean	95 th Percentile
Small Systems			
Total Number of PWSs	61,463	61,463	61,463
PWSs With PFOS Exceedance	1,801	2,905	4,260
PWSs With PFOA Exceedance	836	1,520	2,422
PWSs With Hazard Index Exceedance ^a	145	320	563
PWSs That Exceed One or More MCLs	2,115	3,259	4,699
Large Systems			
Total Number of PWSs	4,433	4,433	4,433
PWSs With PFOS Exceedance	721	791	868
PWSs With PFOA Exceedance	803	878	959
PWSs With Hazard Index Exceedance ^a	178	207	239
PWSs That Exceed One or More MCLs	978	1,062	1,150
All Systems			
Total Number of PWSs	65,896	65,896	65,896
PWSs With PFOS Exceedance	2,522	3,696	5,128
PWSs With PFOA Exceedance	1,639	2,399	3,381
PWSs With Hazard Index Exceedance ^a	323	528	802
PWSs That Exceed One or More Limits	3,093	4,321	5,849

 $Abbreviations: PFOA-perfluorooctanoic acid; PFOS-perfluorooctanesulfonic acid; PWS-public water system; MCL-maximum contaminant level; HI-hazard index. \\ Note:$

Table 4-19: Total Systems Impacted, Option 1a (PFOA and PFOS MCLs of 4.0 ppt) $\,$

	5 th Percentile	Mean	95 th Percentile
Small Systems			
Total Number of PWSs	61,463	61,463	61,463
PWSs With PFOS Exceedance	1,801	2,905	4,260
PWSs With PFOA Exceedance	836	1,520	2,422
PWSs That Exceed One or More MCLs	2,111	3,251	4,676
Large Systems			
Total Number of PWSs	4,433	4,433	4,433
PWSs With PFOS Exceedance	721	791	868
PWSs With PFOA Exceedance	803	878	959
PWSs That Exceed One or More MCLs	975	1,060	1,145
All Systems			

^aHazard Index exceedance is triggered by perfluorohexane sulfonate (PFHxS) occurrence estimates from the Markov chain Monte Carlo (MCMC) occurrence model.

Table 4-19: Total Systems Impacted, Option 1a (PFOA and PFOS MCLs of 4.0 ppt)

	5 th Percentile	Mean	95 th Percentile
Total Number of PWSs	65,896	65,896	65,896
PWSs With PFOS Exceedance	2,522	3,696	5,128
PWSs With PFOA Exceedance	1,639	2,399	3,381
PWSs That Exceed One or More MCLs	3,086	4,310	5,821

Abbreviations: PFOA-perfluorooctanoic acid; PFOS-perfluorooctanesulfonic acid; PWS-public water system; MCL-maximum contaminant level.

Table 4-20: Total Systems Impacted, Option 1b (PFOA and PFOS MCLs of 5.0 ppt)

	5 th Percentile	Mean	95 th Percentile
Small Systems	_		
Total Number of PWSs	61,463	61,463	61,463
PWSs With PFOS Exceedance	1,307	2,197	3,268
PWSs With PFOA Exceedance	542	1,025	1,683
PWSs That Exceed One or More MCLs	1,518	2,428	3,557
Large Systems			
Total Number of PWSs	4,433	4,433	4,433
PWSs With PFOS Exceedance	597	657	722
PWSs With PFOA Exceedance	634	696	762
PWSs That Exceed One or More MCLs	803	871	947
All Systems			
Total Number of PWSs	65,896	65,896	65,896
PWSs With PFOS Exceedance	1,904	2,855	3,990
PWSs With PFOA Exceedance	1,176	1,721	2,445
PWSs That Exceed One or More MCLs	2,321	3,300	4,504

 $Abbreviations: PFOA-perfluorooctanoic\ acid; PFOS-perfluorooctanesulfonic\ acid; PWS-public\ water\ system;\ MCL-maximum\ contaminant\ level.$

Table 4-21: Total Systems Impacted, Option 1c (PFOA and PFOS MCLs of 10.0 ppt)

	5 th Percentile	Mean	95 th Percentile
Small Systems			
Total Number of PWSs	61,463	61,463	61,463
PWSs With PFOS Exceedance	437	801	1,275
PWSs With PFOA Exceedance	107	238	429

Table 4-21: Total Systems Impacted, Option 1c (PFOA and PFOS MCLs of 10.0 ppt)

	5 th Percentile	Mean	95 th Percentile
PWSs That Exceed One or More MCLs	473	852	1,347
Large Systems			
Total Number of PWSs	4,433	4,433	4,433
PWSs With PFOS Exceedance	293	330	369
PWSs With PFOA Exceedance	256	288	322
PWSs That Exceed One or More MCLs	382	422	464
All Systems			
Total Number of PWSs	65,896	65,896	65,896
PWSs With PFOS Exceedance	730	1,130	1,644
PWSs With PFOA Exceedance	363	526	751
PWSs That Exceed One or More MCLs	855	1,274	1,811

 $Abbreviations: PFOA-perfluorooctanoic\ acid; PFOS-perfluorooctanesulfonic\ acid; PWS-public\ water\ system;\ MCL-maximum\ contaminant\ level.$

Table 4-22: Total Entry Points Impacted, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0)

	5 th Percentile	Mean	95 th Percentile
Small Systems			
Total Number of Entry Points	87,895	87,895	87,895
Entry Points With PFOS Exceedance	2,294	3,768	5,520
Entry Points With PFOA Exceedance	1,051	1,913	3,040
Entry Points With Hazard Index Exceedance ^a	166	379	674
Entry Points That Exceed One or More MCLs	2,803	4,354	6,269
Large Systems			
Total Number of Entry Points	22,441	22,441	22,441
Entry Points With PFOS Exceedance	1,812	1,981	2,156
Entry Points With PFOA Exceedance	1,932	2,107	2,296
Entry Points With Hazard Index Exceedance ^a	467	533	600
Entry Points That Exceed One or More MCLs	3,110	3,356	3,613
All Systems			
Total Number of Entry Points	110,336	110,336	110,336
Entry Points With PFOS Exceedance	4,106	5,749	7,676
Entry Points With PFOA Exceedance	2,983	4,019	5,336
Entry Points With Hazard Index Exceedance ^a	633	912	1,274
Entry Points That Exceed One or More MCLs	5,913	7,710	9,882

 $Abbreviations: PFOA-perfluorooctanoic acid; PFOS-perfluorooctanesulfonic acid; PWS-public water system; MCL-maximum contaminant level; HI-hazard index. \\ Note:$

Table 4-22: Total Entry Points Impacted, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0)

5th Percentile	Mean	95 th
		Percentile

^aHazard Index exceedance is triggered by perfluorohexane sulfonate (PFHxS) occurrence estimates from the Markov chain Monte Carlo (MCMC) occurrence model.

Table 4-23: Total Entry Points Impacted, Option 1a (PFOA and PFOS MCLs of 4.0 ppt)

	5 th Percentile	Mean	95 th Percentile
Small Systems			
Total Number of Entry Points	87,895	87,895	87,895
Entry Points With PFOS Exceedance	2,294	3,768	5,520
Entry Points With PFOA Exceedance	1,051	1,913	3,040
Entry Points That Exceed One or More MCLs	2,760	4,327	6,208
Large Systems			
Total Number of Entry Points	22,441	22,441	22,441
Entry Points With PFOS Exceedance	1,812	1,981	2,156
Entry Points With PFOA Exceedance	1,932	2,107	2,296
Entry Points That Exceed One or More MCLs	3,004	3,238	3,487
All Systems			
Total Number of Entry Points	110,336	110,336	110,336
Entry Points With PFOS Exceedance	4,106	5,749	7,676
Entry Points With PFOA Exceedance	2,983	4,019	5,336
Entry Points That Exceed One or More MCLs	5,764	7,564	9,695

 $Abbreviations: PFOA-perfluorooctanoic\ acid; PFOS-perfluorooctanesulfonic\ acid; PWS-public\ water\ system;\ MCL-maximum\ contaminant\ level.$

Table 4-24: Total Entry Points Impacted, Option 1b (PFOA and PFOS MCLs of 5.0 ppt)

	5 th Percentile	Mean	95 th Percentile
Small Systems			
Total Number of Entry Points	87,895	87,895	87,895
Entry Points With PFOS Exceedance	1,704	2,840	4,242
Entry Points With PFOA Exceedance	668	1,286	2,077
Entry Points That Exceed One or More MCLs	2,000	3,220	4,730
Large Systems			
Total Number of Entry Points	22,441	22,441	22,441
Entry Points With PFOS Exceedance	1,464	1,603	1,751

Table 4-24: Total Entry Points Impacted, Option 1b (PFOA and PFOS MCLs of 5.0 ppt)

	5 th Percentile	Mean	95 th Percentile
Entry Points With PFOA Exceedance	1,467	1,603	1,748
Entry Points That Exceed One or More MCLs	2,386	2,579	2,777
All Systems			
Total Number of Entry Points	110,336	110,336	110,336
Entry Points With PFOS Exceedance	3,168	4,443	5,993
Entry Points With PFOA Exceedance	2,135	2,889	3,825
Entry Points That Exceed One or More MCLs	4,386	5,799	7,507

 $Abbreviations: PFOA-perfluorooctanoic\ acid; PFOS-perfluorooctanesulfonic\ acid; PWS-public\ water\ system;\ MCL-maximum\ contaminant\ level.$

Table 4-25: Total Entry Points Impacted, Option 1c (PFOA and PFOS MCLs of 10.0 ppt)

	5 th Percentile	Mean	95 th Percentile
Small Systems			
Total Number of Entry Points	87,895	87,895	87,895
Entry Points With PFOS Exceedance	547	1,026	1,662
Entry Points With PFOA Exceedance	136	299	541
Entry Points That Exceed One or More MCLs	638	1,119	1,762
Large Systems			
Total Number of Entry Points	22,441	22,441	22,441
Entry Points With PFOS Exceedance	678	756	836
Entry Points With PFOA Exceedance	534	595	658
Entry Points That Exceed One or More MCLs	1,039	1,134	1,235
All Systems			
Total Number of Entry Points	110,336	110,336	110,336
Entry Points With PFOS Exceedance	1,225	1,782	2,498
Entry Points With PFOA Exceedance	670	893	1,199
Entry Points That Exceed One or More MCLs	1,677	2,253	2,997

 $Abbreviations: PFOA-perfluorooctanoic\ acid; PFOS-perfluorooctanesulfonic\ acid; PWS-public\ water\ system;\ MCL-maximum\ contaminant\ level.$

Table 4-26: Total Population at PWSs Impacted, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0)

	5 th Percentile	Mean	95 th Percentile
G NG (Percentile
Small Systems			
Total Population	57,897,900	57,897,900	57,897,900
Population Impacted by PFOS Exceedance	2,087,271	3,264,073	4,701,130
Population Impacted by PFOA Exceedance	1,146,222	1,938,415	2,971,819
Population Impacted by Hazard Index Exceedance ^a	234,852	493,057	840,765
Population Impacted by One or More MCL Exceedances	2,510,966	3,752,014	5,199,508
Large Systems			
Total Population	215,603,000	215,603,000	215,603,000
Population Impacted by PFOS Exceedance	40,925,500	46,523,900	52,256,600
Population Impacted by PFOA Exceedance	44,865,200	50,710,300	56,793,900
Population Impacted by Hazard Index Exceedance ^a	11,250,000	13,769,700	16,474,900
Population Impacted by One or More MCL Exceedances All Systems	54,331,100	60,630,000	67,160,000
Total Population	273,500,900	273,500,900	273,500,900
Population Impacted by PFOS Exceedance	43,012,771	49,787,973	56,957,730
Population Impacted by PFOA Exceedance	46,011,422	52,648,715	59,765,719
Population Impacted by Hazard Index Exceedance ^a	11,484,852	14,262,757	17,315,665
Population Impacted by One or More MCL Exceedances	56,842,066	64,382,014	72,359,508

Abbreviations: PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid; PWS – public water system; MCL – maximum contaminant level; HI – hazard index. Note:

Table 4-27: Total Population at PWSs Impacted, Option 1a (PFOA and PFOS MCLs of 4.0 ppt)

	5 th Percentile	Mean	95 th Percentile
Small Systems			
Total Population	57,897,900	57,897,900	57,897,900
Population Impacted by PFOS Exceedance	2,087,271	3,264,073	4,701,130
Population Impacted by PFOA Exceedance	1,146,222	1,938,415	2,971,819
Population Impacted by One or More MCL Exceedances Large Systems	2,482,756	3,735,146	5,174,268
Total Population	215,603,000	215,603,000	215,603,000

^aHazard Index exceedance is triggered by perfluorohexane sulfonate (PFHxS) occurrence estimates from the Markov chain Monte Carlo (MCMC) occurrence model.

Table 4-27: Total Population at PWSs Impacted, Option 1a (PFOA and PFOS MCLs of 4.0 ppt)

	5 th Percentile	Mean	95 th Percentile
Population Impacted by PFOS Exceedance	40,925,500	46,523,900	52,256,600
Population Impacted by PFOA Exceedance	44,865,200	50,710,300	56,793,900
Population Impacted by One or More MCL Exceedances All Systems	54,219,800	60,480,200	67,106,000
Total Population	273,500,900	273,500,900	273,500,900
Population Impacted by PFOS Exceedance	43,012,771	49,787,973	56,957,730
Population Impacted by PFOA Exceedance	46,011,422	52,648,715	59,765,719
Population Impacted by One or More MCL Exceedances	56,702,556	64,215,346	72,280,268

Abbreviations: PFOA-perfluorooctanoic acid; PFOS-perfluorooctanesulfonic acid; PWS-public water system; MCL-maximum contaminant level.

Table 4-28: Total Population at PWSs Impacted, Option 1b (PFOA and PFOS MCLs of 5.0 ppt)

	5 th Percentile	Mean	95 th
	3 Tercentile	Mean	Percentile
Small Systems			
Total Population	57,897,900	57,897,900	57,897,900
Population Impacted by PFOS Exceedance	1,547,309	2,495,969	3,630,458
Population Impacted by PFOA Exceedance	767,919	1,339,283	2,091,861
Population Impacted by One or More MCL	1,845,024	2,821,792	4,008,112
Exceedances Large Systems			
Total Population	215,603,000	215,603,000	215,603,000
Population Impacted by PFOS Exceedance	34,492,900	39,513,400	44,694,900
Population Impacted by PFOA Exceedance	36,129,300	41,217,600	46,370,500
Population Impacted by One or More MCL	45,034,700	50,937,000	56,823,600
Exceedances All Systems			
Total Population	273,500,900	273,500,900	273,500,900
Population Impacted by PFOS Exceedance	36,040,209	42,009,369	48,325,358
Population Impacted by PFOA Exceedance	36,897,219	42,556,883	48,462,361
Population Impacted by One or More MCL Exceedances	46,879,724	53,758,792	60,831,712

Abbreviations: PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid; PWS – public water system; MCL – maximum contaminant level.

Table 4-29: Total Population at PWSs Impacted, Option 1c (PFOA and PFOS MCLs of $10.0~\rm ppt)$

	5 th Percentile	Mean	95 th
			Percentile
Small Systems			
Total Population	57,897,900	57,897,900	57,897,900
Population Impacted by PFOS Exceedance	540,037	950,658	1,469,750
Population Impacted by PFOA Exceedance	169,217	344,601	579,202
Population Impacted by One or More MCL Exceedances	599,217	1,032,176	1,574,182
Large Systems			
Total Population	215,603,000	215,603,000	215,603,000
Population Impacted by PFOS Exceedance	17,858,800	21,145,500	24,589,600
Population Impacted by PFOA Exceedance	15,387,800	18,369,100	21,638,200
Population Impacted by One or More MCL Exceedances All Systems	23,155,800	26,728,800	30,481,500
Total Population	273,500,900	273,500,900	273,500,900
Population Impacted by PFOS Exceedance	18,398,837	22,096,158	26,059,350
Population Impacted by PFOA Exceedance	15,557,017	18,713,701	22,217,402
Population Impacted by One or More MCL Exceedances	23,755,017	27,760,976	32,055,682

Abbreviations: PFOA-perfluoro octanoic acid; PFOS-perfluoro octane sulfonic acid; PWS-public water system; MCL-maximum contaminant level.

Table 4-30: Total Population at Entry Points Impacted, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0)

	5 th Percentile	Mean	95 th
a			Percentile
Small Systems			
Total Population	57,897,900	57,897,900	57,897,900
Population Impacted by PFOS Exceedance	1,522,862	2,491,841	3,659,561
Population Impacted by PFOA Exceedance	716,698	1,283,316	2,040,113
Population Impacted by Hazard Index Exceedance ^a	110,444	256,444	463,178
Population Impacted by One or More MCL Exceedances	1,898,416	2,905,970	4,124,296
Large Systems			
Total Population	215,603,000	215,603,000	215,603,000
Population Impacted by PFOS Exceedance	15,309,500	17,333,700	19,400,000
Population Impacted by PFOA Exceedance	17,494,600	19,653,500	21,865,800
Population Impacted by Hazard Index Exceedance ^a	3,242,290	3,991,870	4,817,620
Population Impacted by One or More MCL Exceedances	26,877,800	29,883,500	32,989,200

Table 4-30: Total Population at Entry Points Impacted, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0)

	5 th Percentile	Mean	95 th Percentile
All Systems			_
Total Population	273,500,900	273,500,900	273,500,900
Population Impacted by PFOS Exceedance	16,832,362	19,825,541	23,059,561
Population Impacted by PFOA Exceedance	18,211,298	20,936,816	23,905,913
Population Impacted by Hazard Index Exceedance ^a	3,352,734	4,248,314	5,280,798
Population Impacted by One or More MCL Exceedances	28,776,216	32,789,470	37,113,496

 $Abbreviations: PFOA-perfluorooctanoic\ acid; PFOS-perfluorooctanesulfonic\ acid;\ MCL-maximum\ contaminant\ level;\ HI-hazard\ index.$

Note

^aHazard Index exceedance is triggered by perfluorohexane sulfonate (PFHxS) occurrence estimates from the Markov chain Monte Carlo (MCMC) occurrence model.

Table 4-31: Total Population at Entry Points Impacted, Option 1a (PFOA and PFOS MCLs of 4.0 ppt)

	5 th Percentile	Mean	95 th
			Percentile
Small Systems			
Total Population	57,897,900	57,897,900	57,897,900
Population Impacted by PFOS Exceedance	1,522,862	2,491,841	3,659,561
Population Impacted by PFOA Exceedance	716,698	1,283,316	2,040,113
Population Impacted by One or More MCL Exceedances	1,876,207	2,885,852	4,135,782
Large Systems			
Total Population	215,603,000	215,603,000	215,603,000
Population Impacted by PFOS Exceedance	15,309,500	17,333,700	19,400,000
Population Impacted by PFOA Exceedance	17,494,600	19,653,500	21,865,800
Population Impacted by One or More MCL	26,160,300	29,117,300	32,135,400
Exceedances			
All Systems			
Total Population	273,500,900	273,500,900	273,500,900
Population Impacted by PFOS Exceedance	16,832,362	19,825,541	23,059,561
Population Impacted by PFOA Exceedance	18,211,298	20,936,816	23,905,913
Population Impacted by One or More MCL Exceedances	28,036,507	32,003,152	36,271,182

 $Abbreviations: PFOA-perfluoro octanoic\ acid; PFOS-perfluoro octane sulfonic\ acid; MCL-maximum\ contaminant\ level.$

Table 4-32: Total Population at Entry Points Impacted, Option 1b (PFOA and PFOS MCLs of 5.0 ppt)

	5 th Percentile	Mean	95 th
			Percentile
Small Systems			
Total Population	57,897,900	57,897,900	57,897,900
Population Impacted by PFOS Exceedance	1,098,901	1,877,218	2,830,317
Population Impacted by PFOA Exceedance	456,340	862,265	1,409,382
Population Impacted by One or More MCL Exceedances	1,332,730	2,145,682	3,143,289
Large Systems			
Total Population	215,603,000	215,603,000	215,603,000
Population Impacted by PFOS Exceedance	12,230,900	13,904,100	15,676,000
Population Impacted by PFOA Exceedance	13,161,700	14,889,700	16,671,200
Population Impacted by One or More MCL Exceedances All Systems	20,620,500	23,031,100	25,487,300
Total Population	273,500,900	273,500,900	273,500,900
Population Impacted by PFOS Exceedance	13,329,801	15,781,318	18,506,317
Population Impacted by PFOA Exceedance	13,618,040	15,751,965	18,080,582
Population Impacted by One or More MCL Exceedances	21,953,230	25,176,782	28,630,589

Abbreviations: PFOA-perfluoro octanoic acid; PFOS-perfluoro octane sulfonic acid; MCL-maximum contaminant level.

Table 4-33: Total Population at Entry Points Impacted, Option 1c (PFOA and PFOS MCLs of 10.0 ppt)

	5th Percentile	Mean	95 th
			Percentile
Small Systems	·		_
Total Population	57,897,900	57,897,900	57,897,900
Population Impacted by PFOS Exceedance	361,876	680,278	1,092,021
Population Impacted by PFOA Exceedance	86,354	199,750	359,333
Population Impacted by One or More MCL Exceedances	409,590	745,161	1,179,156
Large Systems			
Total Population	215,603,000	215,603,000	215,603,000
Population Impacted by PFOS Exceedance	5,239,470	6,228,730	7,268,400
Population Impacted by PFOA Exceedance	4,414,550	5,309,960	6,230,660
Population Impacted by One or More MCL Exceedances All Systems	8,491,400	9,750,100	11,090,400
Total Population	273,500,900	273,500,900	273,500,900
Population Impacted by PFOS Exceedance	5,601,346	6,909,008	8,360,421
Population Impacted by PFOA Exceedance	4,500,904	5,509,710	6,589,993

Table 4-33: Total Population at Entry Points Impacted, Option 1c (PFOA and PFOS MCLs of 10.0 ppt)

	5 th Percentile	Mean	95 th Percentile
Population Impacted by One or More MCL Exceedances	8,900,990	10,495,261	12,269,556

Abbreviations: PFOA-perfluorooctanoic acid; PFOS-perfluorooctanesulfonic acid; PWS-public water system; MCL-maximum contaminant level.

4.5 Uncertainties in the Baseline and Compliance Characteristics of Systems

This section summarizes limitations and uncertainties of the baseline analysis. In the chapter, EPA described how the quantitative analysis incorporates some sources of uncertainty. The agency also noted data limitations that introduce uncertainty because information is not available for the baseline analysis. Table 4-34 provides a summary of sources that have quantifiable uncertainty and data limitations.

EPA notes that in most cases it is not possible to determine the extent to which a particular limitation or uncertainty can affect the magnitude of the baseline conditions. EPA notes the potential direction of the impact on baseline inputs to the costs and/or benefits analysis when possible, but the Agency does not prioritize the entries with respect to the impact magnitude.

Table 4-34: Limitations and Uncertainties That Apply to the Baseline Analysis for the Proposed PFAS Rule

Uncertainty/ Assumption	Effect on Quantitative Analysis	Notes
The Agency assigned Ground Water as the source to systems missing source water information.	Underestimate costs	The design and average flow equations for Ground Water systems result in lower flow estimates than the equations for Surface Water systems. If any of the systems assigned Ground Water source are in fact Surface Water systems, then the flow estimates used in the cost analysis will be underestimated. In addition, initial monitoring costs will be underestimated for small Surface Water systems that are assigned as a Ground Water source.
SDWIS/Fed retail populations used for baseline analysis	Overestimate costs	EPA did not reallocate populations for purchased water systems to the wholesale suppliers. All systems are in the inventory with their respective retail populations. In general, this will result in extra systems with small populations in the analysis and smaller populations at the wholesale systems. Both results will tend to increase cost estimate because the cost curves reflect economies of scale.
SDWIS/Fed data quality	Uncertain impact on baseline number of systems and entry points	EPA periodically reviews inventory information in SDWIS/Fed (U.S. EPA, 2021h) and has generally found a high level of completeness and accuracy. There is uncertainty, however, in some of the population and facility data reported per system. To address this, EPA removed any CWS wholesaler serving fewer than 25

Table 4-34: Limitations and Uncertainties That Apply to the Baseline Analysis for the Proposed PFAS Rule

Uncertainty/ Assumption	Effect on Quantitative Analysis	Notes
		people from the analysis and assumed any remaining CWSs had a minimum possible population of 25. EPA also assumed any non-wholesale NTNCWSs had a minimum possible population of 25. The maximum number of entry points per system was limited to the maximum number found for the equivalent system size and source water combination in the UCMR 3 data.
Flow relationships for CWS	Uncertain impact on flow inputs to cost analysis	The equations used to estimate design and average daily flow based on service population may over- or underestimate actual system flows. In general, average per capita household water consumption has declined since the source data were collected because of increased water efficiency. ^a The change in nonresidential consumption is unknown.
CWS flow curves applied to NTNCWS	Uncertain impact on flow inputs to cost analysis	EPA applied the CWS population-flow equations to NTNCWSs. This approach may result in an over- or underestimate of flow, and therefore cost for NTNCWSs.
Uniform entry point population distribution	Uncertain impact on flow inputs to cost analysis and population inputs to benefits analysis	EPA assumed a uniform distribution of system population across system entry points. Actual entry point population may be greater or lower than the modeled estimates.
System wage rates are based on old survey data	Uncertain impact on cost analysis	National average wage rates are based on CWSS data finalized in 2006. EPA escalated the values to \$2021 to reflect current national industry averages, but actual wage rates at affected systems may be greater or less than national averages.
Baseline occurrence based on MCMC occurrence model outputs	Uncertain effect on occurrence and exposure	The modeled occurrence values may over- or underestimate actual occurrence at individual entry points. The 4,000 iterations attempt to bound the range of uncertainty.
Baseline occurrence limited to four PFAS	Underestimate occurrence and exposure	Excluding occurrence estimates for PFNA, HFPO-DA, and PFBS (three of the four HI contaminants) underestimates the number of systems that would exceed the HI and exposed population for the quantified SafeWater model runs. In Appendix N, EPA evaluates the potential increase in system level treatment costs for systems that exceed the HI in addition to the PFOA and PFOS MCLs, and for systems that do not exceed the PFOA and PFOS MCLs but do exceed the HI.

Abbreviations: CWS – community water systems; CWSS– community water system survey; HI– hazard index; MCMC – Markov chain Monte Carlo; NTNCWS – non-transient, non-community water systems; PFAS – per- and polyfluoroalkyl substances; PFOA– perfluorooctanoic acid; PFOS– perfluorooctane sulfonate; SDWIS– safe drinking water information system. Note:

There is uncertainty in using the equations from EPA's *Geometries and Characteristics of Public Water Systems* report (U.S. EPA, 2000) to predict future average daily and design flow based on a system's retail population. Water use efficiency has increased substantially since the 1980s, with a major improvement between 2005 and 2010 (Rockaway et al., 2011). A 2016 Water Research Foundation study reported a 22 percent decline in indoor water use (Water Research Foundation, 2016). Several factors have contributed to increases in water efficiency. Technological changes, supported by policy, increased the efficiency of water use. For example, the Energy Policy Act of 1992 required water efficiency standards for fixtures, including shower heads, toilets, and washing machines. Water recycling and increased efficiency of power generation also reduces freshwater use. The economic downturn of 2008 contributed to the drop in water use and the increase in use of water-efficient fixtures and xeriscaping. Other demand-side management measures contributed to reduction in per capita use as well. The trend of lower

Table 4-34: Limitations and Uncertainties That Apply to the Baseline Analysis for the Proposed PFAS Rule

Uncertainty/ Assumption Effect on Quantitative Analysis	Notes
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residential water use could result in lower flow per population and lower treatment costs as compared to predicted values in this

5 Cost Analysis

5.1 Introduction

In this chapter, EPA presents its cost analysis for the proposed PFAS National Primary Drinking Water Regulation (the proposed rule) and other alternative rule options considered by the Agency as part of the rulemaking process (Options 1a through 1c). The contents include the national cost estimates for the proposed rule as well as options and the approach EPA used to derive those estimates. The estimates include the cost that PWSs, households, and primacy agencies may incur in response to the proposed rule requirements.

5.1.1 Chapter Overview

This chapter has seven main sections including this introductory section. Section 5.2 provides an overview of EPA's approach to estimate the cost of the proposed rule and options. In Section 5.3, EPA provides the data and algorithms used to calculate the cost of activities PWSs will undertake to comply with the proposed rule. Section 5.4 provides the data and assumptions used to calculate the cost activities primacy agencies will undertake to implement and administer the proposed rule. Sections 5.1.3, 5.5, and 5.6 provide the cost estimates at the national, PWS, and household level, respectively. As indicated below, some additional details on the approach and data used to calculate the costs of the proposed rule are in Appendix C.

5.1.2 Uncertainty Characterization

Many of the input values used to calculate the costs of drinking water regulations are not known with certainty. For example, estimated technology unit costs and contaminant occurrence values are uncertain to some degree given imperfect information. EPA determined it does have enough information about the level or distribution of uncertainty to conduct a Monte-Carlo based uncertainty analysis as part of the SafeWater Multi-Contaminant Benefit-Cost Model (MCBC). With respect to the cost analysis, EPA modeled the sources of uncertainty summarized in Table 5-1.

Table 5-1: Quantified Sources of Uncertainty in Cost Estimates

Source	Description of Uncertainty
Total organic carbon concentration	The TOC value assigned to each system is from a distribution derived from the fourth Six-Year Review Information Collection Request database (see Section 5.3.1.1)
Compliance technology unit cost curve selection	Cost curve selection varies with baseline PFAS concentrations and also includes a random selection from a distribution across feasible technologies (see Section 5.3.1.1), and random selection from a triangular distribution of low-, mid-, and high-cost equipment (25%, 50%, and 25%, respectively).

 $Abbreviations: MCBC-Multi-Contaminant\ Benefit-Cost\ Model;\ PFAS-per-\ and\ polyfluoroalkyl\ substances;\ TOC-total\ organic\ carbon.$

For each iteration, SafeWater MCBC assigned new values to the two sources of modeled uncertainty as described in Table 5-1, and then calculated costs for each of the model PWSs. This was repeated 4,000 times to reach an effective sample size for each parameter. At the end of the 4,000 iterations, SafeWater MCBC outputs the expected value as well as the 90 percent

confidence interval for each cost metric (i.e., bounded by the 5th and 95th percentile estimates for each cost component). Detailed information on the data used to model uncertainty is provided in Appendix L.

5.1.3 Summary of Quantified National Cost Estimates of the Proposed Rule

In Table 5-2, EPA summarizes the total annualized cost of the proposed option at both a 3 percent and 7 percent discount rate. The first three rows show the annualized PWS sampling costs, the annualized PWS implementation and administrative costs, and the annualized PWS treatment costs. The fourth row shows the sum of the annualized PWS costs. At a 3 percent discount rate, the expected annualized PWS costs are \$764 million. The uncertainty range for annualized PWS costs is \$698 million to \$842 million. Finally, annualized primacy agency implementation and administrative costs are added to the annualized PWS costs to calculate the total annualized cost of the proposed option. At a 3 percent discount rate, the expected total annualized cost of the proposed option is \$772 million with an uncertainty range of \$705 million to \$850 million. At a 7 percent discount rate, the expected total annualized cost of the proposed option is \$1.205 billion, while the uncertainty range is \$1.106 billion to \$1.321 billion. As discussed in Section 2.1, for purposes of this analysis, EPA is considering the cost analysis for the proposed option to be representative of the alternate regulatory approach where PFHxS, PFNA, PFBS, and HFPO-DA would be regulated by individual MCLs in addition to or instead of using the HI approach.

Table 5-2: National Annualized Costs, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0; Million \$2021)

	3%	6 Discount Ra	ate	7% Discount Rate			
	5 th Expected 95 th		5 th Expected		95 th		
	Percentile ^a	Value	Percentile ^a	Percentile ^a	Value	Percentile ^a	
Annualized PWS Sampling Costs	\$76.33	\$88.64	\$102.15	\$78.71	\$91.27	\$105.00	
Annualized PWS Implementation and Administration Costs	\$1.71	\$1.71	\$1.71	\$3.52	\$3.52	\$3.52	
Annualized PWS Treatment Costs	\$619.29	\$673.59	\$741.17	\$1,012.54	\$1,101.26	\$1,206.49	
Total Annualized PWS Costs	\$697.54	\$763.93	\$841.97	\$1,098.59	\$1,195.99	\$1,311.59	
Primacy Agency Rule Implementation and Administration Cost	\$6.91	\$7.83	\$8.86	\$7.68	\$8.64	\$9.69	
Total Annualized Rule Costs ^{b,c,d}	\$704.53	\$771.77	\$850.40	\$1,106.01	\$1,204.61	\$1,321.01	

Notes: Detail may not add exactly to total due to independent rounding. Percentiles cannot be summed because cost components are not perfectly correlated.

^dPFAS-contaminated wastes are not considered hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See Appendix N, Section N.2 for additional detail.

In Table 5-3, Table 5-4, and Table 5-5 EPA summarizes the total annualized cost of Options 1a, 1b, and 1c, respectively.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty described in Section 5.1.2 and Table 5-1. This range does not include the uncertainty described in Table 5-22.

^bSee Table 7-6 for a list of the nonquantifiable costs, and the potential direction of impact these costs would have on the estimated monetized total annualized costs in this table.

control quantified national cost values do not include the incremental treatment costs associated with the cooccurrence of HFPO-DA, PFBS, and PFNA at systems required to treat for PFOA, PFOS, and PFHxS. The total quantified national cost values do not include treatment costs for systems that would be required to treat based on HI exceedances apart from systems required to treat because of PFHxS occurrence alone. See Appendix N, Section N.3 for additional detail on cooccurrence incremental treatment costs and additional treatment costs at systems with HI exceedances.

Table 5-3: National Annualized Costs, Option 1a (PFOA and PFOS MCLs of 4.0 ppt; Million \$2021)

	3%	6 Discount Ra	ate	7% Discount Rate			
	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Annualized PWS Sampling Costs	\$75.70	\$87.84	\$101.27	\$78.14	\$90.45	\$104.11	
Annualized PWS Implementation and Administration Costs	\$1.71	\$1.71	\$1.71	\$3.52	\$3.52	\$3.52	
Annualized PWS Treatment Costs	\$604.25	\$658.51	\$726.21	\$985.22	\$1,074.85	\$1,176.48	
Total Annualized PWS Costs	\$681.28	\$748.05	\$824.44	\$1,068.69	\$1,168.79	\$1,282.69	
Primacy Agency Rule Implementation and Administration Cost	\$6.81	\$7.77	\$8.79	\$7.59	\$8.56	\$9.61	
Total Annualized Rule Costs ^{b,c}	\$688.09	\$755.82	\$833.48	\$1,078.51	\$1,177.31	\$1,292.01	

Notes: Detail may not add exactly to total due to independent rounding. Percentiles cannot be summed because cost components are not perfectly correlated.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty described in Section 5.1.2 and Table 5-1. This range does not include the uncertainty described in Table 5-22.

^bSee Table 7-6 for a list of the nonquantifiable costs, and the potential direction of impact these costs would have on the estimated monetized total annualized costs in this table.

[°]PFAS-contaminated wastes are not considered hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See Appendix N, Section N.2 for additional detail.

Table 5-4: National Annualized Costs, Option 1b (PFOA and PFOS MCLs of 5.0 ppt; Million \$2021)

	3%	6 Discount Ra	ate	7% Discount Rate			
	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Annualized PWS Sampling Costs	\$66.38	\$77.03	\$89.08	\$68.71	\$79.54	\$91.74	
Annualized PWS Implementation and Administration Costs	\$1.71	\$1.71	\$1.71	\$3.52	\$3.52	\$3.52	
Annualized PWS Treatment Costs	\$481.16	\$525.41	\$577.23	\$781.55	\$851.63	\$935.08	
Total Annualized PWS Costs	\$550.41	\$604.16	\$666.81	\$857.47	\$934.69	\$1,025.67	
Primacy Agency Rule Implementation and Administration Cost	\$6.04	\$6.84	\$7.75	\$6.76	\$7.59	\$8.47	
Total Annualized Rule Costs ^{b,c}	\$558.71	\$611.01	\$674.32	\$864.74	\$942.28	\$1,035.56	

Notes: Detail may not add exactly to total due to independent rounding. Percentiles cannot be summed because cost components are not perfectly correlated.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty described in Section 5.1.2 and Table 5-1. This range does not include the uncertainty described in Table 5-22.

^bSee Table 7-6 for a list of the nonquantifiable costs, and the potential direction of impact these costs would have on the estimated monetized total annualized costs in this table.

[°]PFAS-contaminated wastes are not considered hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See Appendix N, Section N.2 for additional detail.

Table 5-5: National Annualized Costs, Option 1c (PFOA and PFOS MCLs of 10.0 ppt; Million \$2021)

	3%	6 Discount Ra	ate	7% Discount Rate			
	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Annualized PWS Sampling Costs	\$46.27	\$52.21	\$59.29	\$48.37	\$54.49	\$61.57	
Annualized PWS Implementation and Administration Costs	\$1.71	\$1.71	\$1.71	\$3.52	\$3.52	\$3.52	
Annualized PWS Treatment Costs	\$215.41	\$233.93	\$256.36	\$337.86	\$367.50	\$402.16	
Total Annualized PWS Costs	\$265.05	\$287.86	\$315.46	\$391.00	\$425.51	\$466.68	
Primacy Agency Rule Implementation and Administration Cost	\$4.31	\$4.72	\$5.20	\$4.93	\$5.36	\$5.85	
Total Annualized Rule Costs ^{b,c}	\$269.36	\$292.57	\$320.76	\$396.22	\$430.87	\$472.20	

Notes: Detail may not add exactly to total due to independent rounding. Percentiles cannot be summed because cost components are not perfectly correlated.

5.2 Overview of SafeWater Multi-Contaminant Benefit Cost Model (MCBC)

The SafeWater Cost Benefit Model (SafeWater CBX) was designed to calculate the costs and benefits associated with setting a new or revised MCL. Since the proposed PFAS rule simultaneously regulates multiple PFAS contaminants, EPA developed a new model version called the SafeWater MCBC to estimate the costs and benefits associated with regulating more than one contaminant. The following modifications were made to the SafeWater CBX model to create the SafeWater MCBC model:

1. Instead of tracking a single contaminant's level and comparing to the proposed MCL to determine if the PWS must take compliance actions, SafeWater MCBC tracks each PWS's level of multiple PFAS contaminants and compares against proposed MCLs for each contaminant (or group of contaminants).

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty described in Section 5.1.2 and Table 5-1. This range does not include the uncertainty described in Table 5-22.

^bSee Table 7-6 for a list of the nonquantifiable costs, and the potential direction of impact these costs would have on the estimated monetized total annualized costs in this table.

[°]PFAS-contaminated wastes are not considered hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See Appendix N, , Section N.2 for additional detail.

- 2. The structure of the occurrence data input to the model was updated to not only handle multiple contaminants, but to incorporate all information from the PFAS occurrence model on the predicted co-occurrence of contaminants.
- 3. The model structure allows for assignment of one or more compliance technologies that achieve all regulatory requirements and estimates costs and benefits associated with multiple PFAS contaminant reductions and calculates before and after treatment concentrations of each contaminant for use in estimation of benefits.

5.2.1 Modeling PWS Variability in SafeWater MCBC

The costs incurred by a PWS depend on water system characteristics. The data describing some of these characteristics for PWSs are in SDWIS/Fed. The SDWIS/Fed data provide information on the PWS characteristics that typically define PWS categories, or strata, for which EPA develops costs in rulemakings:

- System type (CWS, NTNCWS)
- Number of people served by the PWS
- PWS's primary raw water source (ground water or surface water)
- PWS's ownership type (public or private).
- PWS state.

Because EPA does not have complete PWS-specific data across the 49,193 CWSs and 17,337 NTNCWS in SDWIS/Fed for many of the baseline and compliance characteristics necessary to estimate costs and benefits, such as design and average daily flow rates, water quality characteristics, treatment in-place, and labor rates, EPA adopted a "model PWS" approach. SafeWater MCBC creates model PWSs by combining the PWS-specific data available in SDWIS/Fed with data on baseline and compliance characteristics available at the PWS category level. In some cases, the categorical data are simple point estimates. In this case, every model PWS in a category is assigned the same value. In other cases, where more robust data representing system variability are available, the category-level data include a distribution of potential values. In the case of distributional information, SafeWater MCBC assigns each model PWS a value sampled from the distribution. These distributions are assumed to be independent. Table 5-6 provides a list of all the PWS characteristics that impact model PWS compliance costs. These data include inventory data specific to each system and categorical data for which randomly assigned values are based on distributions that vary by category (e.g., ground water and surface water TOC distributions or compliance forecast distributions that vary by system size category).

Table 5-6: Model PWS Variability Characteristics and Data Sources

PWS Characteristic	Data Type and Description
System Type	Known SDWIS/Fed Inventory
Primary Source Water	Known: SDWIS/Fed Inventory
Ownership	Known: SDWIS/Fed Inventory
Population Served	Known: SDWIS/Fed Inventory
Number of Entry Points	Known: UCMR 3, SDWIS/Fed Inventory, and modeled from SDWIS/Fed Inventory distribution (see Section 4.3.3.1)
PFAS Contaminant Concentration at each Entry Point	Sampled from EPA Occurrence Model (see Section 4.3.3.2)
Influent TOC Level	Assigned from distribution derived from fourth Six-Year Review Information Collection Request database (see Section 5.3.1.1)
Compliance Technology Forecast at each Entry Point	Assigned from distribution derived from full-scale compliance actions analyzed by EPA (see Section 5.3.1.1)

Abbreviations: EPA – U.S. Environmental Protection Agency; PFAS – per-and polyfluoroalkyl substances; SDWIS/Fed – Safe Drinking Water Information System/Federal version; TOC – Total Organic Carbon; UCMR 4 – Fourth Unregulated Contaminant Monitoring Rule.

As illustrated in Figure 5-1, once all the model PWSs are created and assigned baseline and compliance characteristics, SafeWater MCBC estimates the quantified costs and benefits of compliance for each model PWS under the proposed rule. Because of this model PWS approach, SafeWater MCBC does not output any results at the PWS-level. Instead, the outputs are cost and benefit estimates for 36 PWS categories, or strata. Each PWS category is defined by the system type (CWS and NTNCWS), primary water source (ground or surface), and size category (there are nine). Note EPA does not report state specific strata although state location is utilized in the SafeWater MCBC model (e.g., current state level regulatory limits on PFAS in drinking water).

For each PWS category, the model then calculates summary statistics that describe the costs and quantified benefits associated with the proposed rule compliance. These summary statistics include total quantified costs of the proposed regulatory requirement, total quantified benefits of the proposed regulatory requirement, the variability in PWS-level costs (i.e., 5th and 95th percentile system costs), and the variability in household-level costs.

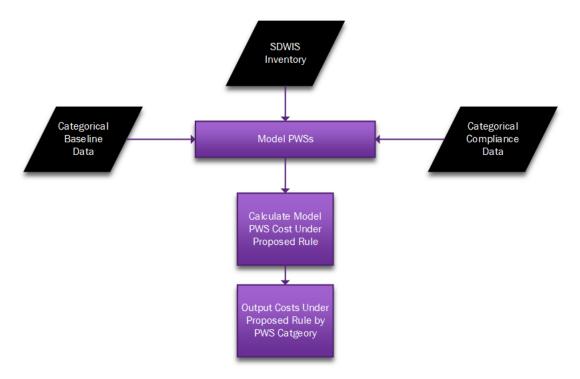


Figure 5-1: Approach Used by SafeWater MCBC to Model PWS Variability

5.3 Estimating Public Water System Costs

EPA estimated PWS compliance activities that result in treatment costs, and administrative and monitoring costs associated with the proposed rule. Each major regulatory component consists of required activities, which EPA details here. EPA presents the costs associated with treatment addition and non-treatment actions that could be taken in lieu of treatment in Section 5.3.1. EPA presents the costs associated with the administrative and monitoring requirements associated with the proposed rule in Section 5.3.2.

5.3.1 PWS Treatment Costs

This section describes how EPA estimated costs associated with:

- Engineering, installing, operating, and maintaining PFAS removal treatment technologies, including treatment media replacement and spent media destruction or disposal
- Non-treatment actions that some PWSs might take in lieu of treatment, such as
 constructing new wells in an uncontaminated aquifer or interconnecting with and
 purchasing water from a neighboring PWS.

EPA used SafeWater MCBC to apply costs for one of these treatment technologies or non-treatment alternatives at each entry point in a PWS estimated to be out of compliance with the regulatory option under consideration. First, for each affected entry point, SafeWater MCBC selected from among the compliance alternatives using the decision tree procedure described in

Section 5.3.1.1. Next, SafeWater MCBC estimated the cost of the chosen compliance alternative using outputs from EPA's WBS cost estimating models. Specifically, SafeWater MCBC used cost equations generated from the following models:

- The GAC WBS model
- The PFAS-selective IX WBS model
- The centralized reverse osmosis/nanofiltration (RO/NF) WBS model¹⁴
- The non-treatment WBS model.

The national cost analysis reflects the assumption that PFAS-contaminated wastes are not considered hazardous wastes. As a general matter, EPA notes that such wastes are not currently regulated under federal law as a hazardous waste. However, EPA anticipates proposing certain PFAS be designated as Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) hazardous substances to require reporting of PFOA and PFOS releases, enhance the availability of data, and ensure agencies can recover cleanup costs. 15 Stakeholders have expressed concern to EPA that a hazardous substance designation for certain PFAS may limit their disposal options for drinking water treatment residuals (e.g., spent media, concentrated waste streams) and/or potentially increase costs. Although designating chemicals as hazardous substances under CERCLA would not result in new requirements for disposal of PFAS drinking water treatment residuals, to address stakeholder concerns, including those raised during the SBREFA process, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. EPA has estimated national costs, both assuming nonhazardous disposal options and assuming hazardous waste disposal at 100 percent of systems treating for PFAS to assess the effects of potential increased disposal costs. EPA acknowledges that if federal authorities later determine that PFAS-contaminated wastes require handling as hazardous wastes, the residuals management costs are expected to be higher. For a discussion of the findings from this sensitivity analysis, see Appendix N.

Section 5.3.1.2 describes the WBS models. Section 5.3.1.2.2 describes the form of the resulting cost equations and their application in SafeWater MCBC. The Technologies and Costs (T&C) document (U.S. EPA, 2023h) provides a comprehensive discussion of each of the treatment technologies, their effectiveness, and the WBS cost models. It also presents the cost equations themselves in tabular form.

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¹⁴ At this time, EPA is not including point-of-use (POU) RO in the national cost estimates because the regulatory options under consideration require treatment to concentrations below 70 ng/L total of PFOA and PFOS, the current NSF/ANSI certification standard for POU devices. However, POU treatment is reasonably anticipated to become a compliance option for small systems in the future if NSF/ANSI or other independent third-party certification organizations develop a new certification standard that mirrors EPA's proposed regulatory standard. Costs presented here reflect the costs of devices certified under the current testing standard, not a future standard, which may change dependent on future device design. In the event POU treatment becomes a valid compliance option, national costs could be lower than estimated in this application of the SafeWater MCBC.

¹⁵ The pre-publication in the Federal Register Notice version of the proposed rule entitled "Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances" is available at https://www.epa.gov/system/files/documents/2022-08/FRL% 207204-02-OLEM% 20_% 20 Designating% 20 PFOA% 20 and % 20 PFOS% 20 as % 20 HSs% 20_NPRM_20220823.pdf.

5.3.1.1 Decision Tree for Technology Selection

For entry points at which baseline PFAS concentrations exceed regulatory thresholds, the decision tree selects a treatment technology or non-treatment alternative using a two-step process that:

- 1. Determines whether to include or exclude each alternative from consideration given the entry point's characteristics and the regulatory option selected
- 2. Selects from among the alternatives that remain viable based on percentage distributions derived, in part, from data on recent PWS actions in response to PFAS contamination.

Inputs to the decision tree include the following:

- Influent concentrations of individual PFAS contaminants in ppt (ng/L);
- Entry point design flow in MGD; and
- TOC influent to the new treatment process in mg/L.

Section 4.4 describes EPA's method for estimating PFAS influent concentrations and Section 4.3.3.3 describes how EPA derived entry point flow estimates. SafeWater MCBC selects influent TOC using the distribution shown in Table 5-7.

Table 5-7: Frequency Distribution to Estimate Influent TOC in mg/L

Percentile	Surface Water	Ground Water
0.05	0.65	0.35
0.15	1.1	0.48
0.25	1.38	0.5
0.35	1.6	0.5
0.45	1.85	0.58
0.5	1.97	0.69
0.55	2.14	0.75
0.65	2.54	1
0.75	3.04	1.39
0.85	3.63	2.01
0.95	4.81	3.8

Abbreviations: TOC - total organic carbon.

Source: EPA's analysis of total organic carbon concentrations in the fourth Six-Year Review Information Collection Request database.

Step 1 of the decision tree uses these inputs to determine whether to include or exclude each treatment alternative from consideration in the compliance forecast. For the treatment technologies (GAC, IX, and RO/NF), this determination is based on estimates of each technology's performance given available data about influent water quality and the regulatory option under consideration. Section 5.3.1.1.1 describes this process for GAC and IX. Section 5.3.1.1.2 describes this process for RO.

EPA assumes a small number of PWSs may be able to take non-treatment actions in lieu of treatment. The viability of non-treatment actions (interconnection with neighboring system or new wells) is likely to depend on the quantity of water being replaced. Therefore, the decision

tree considers non-treatment only for entry points with design flows less than or equal to 3.536 MGD. EPA's WBS model for non-treatment does not generate costs for flows greater than this value, so the decision tree excludes non-treatment actions from consideration above this flow.

Step 2 of the decision tree selects a compliance alternative for each entry point from among the alternatives that remain in consideration after Step 1. Table 5-8 shows the initial compliance forecast that is the starting point for this step. The percentages in Table 5-8 consider data presented in the T&C document (U.S. EPA, 2023h) on actions PWSs have taken in response to PFAS contamination.

Table 5-8: Initial Compliance Forecast Including POU RO

	Design flow MG		than 1 Design flow 1 to less than 10 MGD			Design flow greater than or equal to 10 MGD	
Compliance Alternative	TOC less than or equal to 1.5 mg/L	TOC greater than 1.5 mg/L	TOC less than or equal to 1.5 mg/L	TOC greater than 1.5 mg/L	TOC less than or equal to 1.5 mg/L	TOC greater than 1.5 mg/L	
GAC	65%	50%	77%	50%	85%	50%	
PFAS-selective IX	10%	25%	10%	37%	10%	45%	
Central RO/NF	4%	4%	5%	5%	5%	5%	
POU RO	13%	13%	0%	0%	0%	0%	
Interconnection	6%	6%	6%	6%	0%	0%	
New Wells	2%	2%	2%	2%	0%	0%	

Abbreviations: GAC – granular activated carbon; PFAS – per-and polyfluoroalkyl substances; MGD – million gallons per day; IX – ion exchange; RO/NF – reverse osmosis/nanofiltration; POU – point of use; RO – reverse osmosis; TOC – total organic carbon.

Source: EPA's analysis of total organic carbon concentrations in the fourth Six-Year Review Information Collection Request database.

To date, the majority of PWSs for which data are available have installed GAC (U.S. EPA, 2023h). The first full-scale system treating drinking water using PFAS-selective IX began operation in 2017 (WWSD, 2018). The data in the T&C document (U.S. EPA, 2023h) suggest that an increasing share of PWSs have selected IX in response to PFAS since that first installation. EPA expects this trend to continue, so the initial percentages include adjustments to account for this expectation. In addition, as discussed in Section 5.3.1.1.1, the performance of GAC is affected by the presence of TOC. Accordingly, the table includes adjusted distributions for systems with higher influent TOC.

The initial percentages in Table 5-8 estimate that some small systems will choose POU RO as a compliance alternative. At this time, EPA is not including POU RO in the national cost estimates because the regulatory options under consideration require treatment to concentrations below 70 ppt PFOA and PFOS summed, the current certification standard for POU devices. ¹⁶ Therefore, the decision tree excludes POU RO from consideration and proportionally redistributes the

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¹⁶POU treatment might become a compliance option for small systems in the future if NSF/ANSI develop a new certification standard that mirrors EPA's proposed regulatory standard. In the event POU treatment becomes a valid compliance option, national costs could be lower than estimated here.

percentages among the other alternatives. Table 5-9 shows the final compliance forecast after this redistribution.

Table 5-9: Initial Compliance Forecast Excluding POU RO

	Design flow less than 1 MGD		Design flow 1 10 M		Design flow greater than or equal to 10 MGD	
Compliance Alternative	TOC less than or equal to 1.5 mg/L	TOC greater than 1.5 mg/L	TOC less than or equal to 1.5 mg/L	TOC greater than 1.5 mg/L	TOC less than or equal to 1.5 mg/L	TOC greater than 1.5 mg/L
GAC	75%	57%	77%	50%	85%	50%
PFAS-selective IX	11%	29%	10%	37%	10%	45%
Central RO/NF	5%	5%	5%	5%	5%	5%
Interconnection	7%	7%	6%	6%	0%	0%
New Wells	2%	2%	2%	2%	0%	0%

Abbreviations: GAC – granular activated carbon; PFAS – per-and polyfluoroalkyl substances; MGD – million gallons per day; IX – ion exchange; RO/NF – reverse osmosis/nanofiltration; POU – point of use; RO – reverse osmosis; TOC – total organic carbon.

If all the compliance alternatives (other than POU RO) remain in consideration after Step 1, the decision tree uses the forecast shown in Table 5-9. If Step 1 eliminated on one or more of the alternatives, the decision tree proportionally redistributes the percentages among the remaining alternatives and uses the redistributed percentages.

5.3.1.1.1 Estimating GAC and IX Performance

The viability of GAC and IX depends on bed life, which is the length of time the technology can maintain a target removal percentage (e.g., 80 percent, 95 percent). Bed life can vary depending on factors including type of media used (GAC or IX), specific PFAS contaminants targeted, influent water quality, and removal performance required to meet regulatory option thresholds. Bed life determines media replacement frequency and, therefore, affects both the practicality and operation and maintenance (O&M) cost of these technologies. This analysis estimates bed life in bed volumes (BV), which is a measure of throughput: the volume of water treated during the bed life divided by the volume of the media bed.

The bed life estimates use linear equations derived as described in the T&C document (U.S. EPA, 2023h). EPA estimated the equations based on pooled data from several studies of GAC as well as IX performance and reflect central tendency results under varying water quality conditions. As such, EPA believes they represent the best approach currently available for use in a national cost estimation. However, they should not be used in lieu of site-specific engineering analyses or pilot studies to guide the design or operation of specific treatment systems.

The bed life equations are technology-specific and shown below:

Equation 2:

$$BV_{contam,GAC} = A_{TOC} \times TOC + A_{R,GAC} \times \%R_{contam} + B_{contam,GAC}$$

 $BV_{contam,IX} = A_{PFAS} \times PFAS_{total} + A_{R,IX} \times \%R_{contam} + B_{contam,IX}$

Where:

 $BV_{contam,tech}$ = bed life of the given technology for a given PFAS contaminant in BV; tech = GAC or IX

TOC = TOC influent to the new treatment process in mg/L

PFAS_{total} = total influent concentration of all PFAS contaminants (regulated or unregulated) in ppt

 $R_{contam} = \text{target percent removal of a given PFAS as a decimal (e.g., 0.8, 0.95)}$

Table 5-10 shows the estimated values of the parameter coefficients A_{TOC} , A_{PFAS} , $A_{R,tech}$, and intercepts $B_{contam,tech}$

Table 5-10: Estimated Parameter Values for Technology-Specific Bed Life Equations

Parameter	GAC Model Value	IX Model Value
A _{TOC}	-37,932	Not applicable ^a
A _{PFAS}	Not applicable ^a	-6.04
A_R	-36,309	-198,242
$\mathrm{B}_{\mathrm{HFPO-DA}}$	113,034	Data not available
B_{PFHxA}	113,967	212,867
B_{PFBS}	129,357	439,515
$\mathrm{B}_{\mathrm{PFHpA}}$	129,357	319,511
B_{PFHxS}	129,357	439,515
$\mathrm{B}_{\mathrm{PFOA}}$	139,862	390,787
B_{PFOS}	143,731	439,515

Note:

^aTotal PFAS is not a significant parameter in GAC performance; TOC is not a significant parameter in IX performance. Source: Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water (U.S. EPA, 2023h)

The bed life equations are only applicable over a specific range of water quality conditions (TOC up to 3.2 mg/L for GAC; total PFAS up to 7,044 ppt for IX). Data are not available to estimate performance beyond these limits. Therefore, the decision tree excludes GAC from consideration if an entry point's influent TOC concentration is greater than 3.2 mg/L. It excludes IX if total influent PFAS is greater than 7,044 ppt.

If GAC and/or IX remain in consideration, the decision tree calculates the percent removal required for the regulatory option under consideration and uses the linear equations above to estimate bed life. These calculations vary depending on the regulatory option. Section 5.3.1.1.1.1

describes the calculations under Option 1 (individual MCLs for PFOS and PFOA). Section 5.3.1.1.2 describes the calculations under the proposed option (#2) (individual MCLs for PFOS and PFOA plus group standard based on HI).

Based on data presented in the T&C document (U.S. EPA, 2023h), the decision tree assumes the maximum PFAS removal achievable by GAC or IX is 99 percent. Therefore, if the relevant regulatory option requires removal at an entry point greater than this maximum, the decision tree removes GAC and IX from consideration, as described in the sections below. Additionally, the decision tree assumes that bed lives less than 5,000 BV for GAC and less than 20,000 BV for IX are impractical. These bed lives correspond to media replacement frequencies of two to five months depending on the average flow of the entry point. If the relevant regulatory option results in a final operating bed life below these limits, the decision tree removes the corresponding technology from consideration. For entry points that ultimately select GAC or IX, the final operating bed life is also an input to the cost estimates (see Section 5.3.1.3) and the calculation of post-treatment PFAS concentrations used to estimate reduction in health risks).¹⁷

5.3.1.1.1 Bed Life Under Option 1

Under Option 1, PWSs must meet individual MCLs for PFOS and PFOA. For these options, the decision tree calculates the percent removal required to meet each individual MCL:

$$\%R_{contam} = \frac{C_{0,contam} - MCL_{contam} \times SF}{C_{0,contam}}$$

Where:

%R_{contam} = target percent removal of a given PFAS as a decimal (e.g., 0.8, 0.95)

 $C_{0.\text{contam}}$ = influent concentration of the given PFAS in ppt

 $MCL_{contam} = MCL$ for the given PFAS in ppt

SF = 0.8, a safety factor that assumes PWSs will design and operate treatment processes to achieve 80 percent of the MCL

The decision tree performs this calculation for each contaminant that occurs at an entry point and has an MCL in the regulatory option, even if the contaminant occurs at a concentration below the MCL. Including contaminants that are below their respective MCLs helps to account for chromatographic peaking¹⁸; which is a concern in GAC along with IX and is discussed in greater

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¹⁷ As shown in Equation 2, bed life and percent removal are directly related. SafeWater uses the same equation to back-calculate final percent removal for each PFAS compound from final operating bed life. It then uses the final removal efficiency to calculate post-treatment concentrations.

¹⁸ Chromatographic peaking is a phenomenon in which less strongly sorbed contaminants are detached from sorbents by more strongly bound sorbents and the less tightly bound sorbent re-enters drinking water. Direct competition with stronger sorbing constituents can lead to effluent PFAS concentrations temporarily exceeding influent concentrations. Some PFAS species sorb more strongly than other PFAS species which can cause more weakly sorbed species to re-enter drinking water.

detail in the T&C document (U.S. EPA, 2023h). The calculations here are designed to account for and avoid it.

If the percent removal required for any contaminant ($\%R_{contam}$) is greater than 0.99 (99 percent), the decision tree removes GAC and IX from consideration. If the technologies remain in consideration, the decision tree estimates the bed life for each contaminant using the linear equations presented in Section 5.3.1.1.1. The final operating bed life is the minimum of the individual contaminant-specific bed life estimates. If this final operating bed life is less than 5,000 BV for GAC or less than 20,000 BV for IX, the decision tree removes the corresponding technology from consideration.

5.3.1.1.1.2 Bed Life Under the Proposed Option

Under the proposed rule, PWSs must meet a group standard based on HI, plus individual MCLs for PFOS and PFOA. Due to limitations in occurrence data, the national cost estimates account for only one of the contaminants included in the HI: PFHxS. Therefore, for this option, the decision tree calculates the percent removal required to meet the individual health benchmark for PFHxS:

$$\%R_{PFHxS} = \frac{C_{0,PFHxS} - HB_{PFHxS} \times SF}{C_{0,PFHxS}}$$

Where:

%R_{PFHxS} = target percent removal of PFHxS as a decimal (e.g., 0.8, 0.95)

 $C_{0,PFHxS}$ = influent concentration of PFHxS in ppt

 HB_{PFHxS} = heath benchmark for PFHxS in ppt

SF = 0.8, a safety factor that assumes PWSs will design and operate treatment processes to achieve 80 percent of the health benchmark

The decision tree performs this calculation even when PFHxS occurs at a concentration below its health benchmark. Including contaminants that are below their respective MCLs prevents the subsequent bed life calculations from selecting a bed life that results in a preferred PFAS displacing a less preferred PFAS from the treatment media to the extent that the less preferred PFAS periodically exceeds its MCL. This phenomenon is sometimes a concern in GAC as well as IX design and operation and is discussed in greater detail in the T&C document (U.S. EPA, 2023h). The calculations here are designed to account for and avoid it.

If the percent removal required to meet the health benchmark for PFHxS is greater than 0.99 (99 percent), the decision tree removes GAC and IX from consideration. If the technologies remain in consideration, the decision tree estimates the bed life for PFHxS using the linear equations presented in Section 5.3.1.1.1. It also calculates the bed lives necessary to meet the individual MCLs for PFOS and PFOA, as described in Section 5.3.1.1.1.1. The final operating bed life is the minimum of all the bed life estimates resulting from the calculations for all three contaminants (PFOS, PFOA, and PFHxS). If this final operating bed life is less than 5,000 BV for GAC or less than 20,000 BV for IX, the decision tree removes the corresponding technology from consideration.

5.3.1.1.2 Estimating the Performance of RO/NF

Designed and operated correctly, central RO/NF provides steady-state PFAS removal. The technology's effectiveness does not vary substantially among PFAS compounds of similar molecular size. There is no concept like bed life to consider for an RO membrane design. The calculation of the required removal from RO/NF (%Rfinal,RO) varies depending on the regulatory option, as described in Sections 5.3.1.1.2.1 through 5.3.1.1.1.2 below. For entry points that ultimately select RO, the required removal is also an input to the cost estimates (see Section 5.3.1.3) and the calculation of post-treatment PFAS concentrations.¹⁹

5.3.1.1.2.1 Required Removal Under Option 1

Under Option 1, PWSs must meet individual MCLs for PFOS and PFOA. For these options, the decision tree calculates the percent removal required to meet each individual MCL²⁰:

Equation 5:

$$\%R_{contam} = \frac{C_{0,contam} - MCL_{contam} \times SF}{C_{0,contam}}$$

Where:

 $%R_{contam}$ = target percent removal of a given PFAS as a decimal (e.g., 0.8, 0.95)

 $C_{0,contam}$ = influent concentration of the given PFAS in ppt

 $MCL_{contam} = MCL$ for the given PFAS in ppt

SF = 0.8, a safety factor that assumes PWSs will design and operate treatment processes to achieve 80 percent of the MCL

The final removal required from RO/NF (%_{Rfinal,RO}) is the maximum percent removal required for any contaminant (%_{Rcontam}) that exceeds its MCL.

5.3.1.1.2.2 Required Removal Under the Proposed Option

Under the proposed rule, PWSs must meet a group standard based on HI, plus individual MCLs for PFOS and PFOA. The national SafeWater modelled cost estimates account for only one of the contaminants included in the HI: PFHxS. Therefore, for this option, the decision tree calculates the percent removal required to meet the individual health benchmark for PFHxS:

$$\%R_{PFHxS} = \frac{C_{0,PFHxS} - HB_{PFHxS} \times SF}{C_{0,PFHxS}}$$

Where:

%R_{PFHxS} = target percent removal of PFHxS as a decimal (e.g., 0.8, 0.95)

 $C_{0,PFHxS}$ = influent concentration of PFHxS in ppt

 HB_{PFHxS} = heath benchmark for PFHxS in ppt

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¹⁹ SafeWater uses Equations 5 and 6 to back-calculate final percent removal for each PFAS compound given the maximum percent removal across the affected PFAS. It then uses the final removal efficiency to calculate post-treatment concentrations.

²⁰ Equations 5 and 6 in this section are the same as Equations 3 and 4, respectively.

SF = 0.8, a safety factor that assumes PWSs will design and operate treatment processes to achieve 80 percent of the health benchmark

The decision tree also calculates the percent removal required to meet the individual MCLs for PFOS and PFOA ($\%R_{PFOS}$ and $\%R_{PFOA}$), as described in Section 5.3.1.1.2.1. The final removal required from RO/NF ($\%R_{final.RO}$) is the maximum of $\%R_{PFMxS}$, $\%R_{PFOS}$, and $\%R_{PFOA}$.

5.3.1.2 WBS Models

The WBS models are spreadsheet-based engineering models for individual treatment technologies, linked to a central database of component unit costs. EPA developed the WBS model approach as part of an effort to address recommendations made by the Technology Design Panel (TDP), which convened in 1997 to review the Agency's methods for estimating drinking water compliance costs (U.S. EPA, 1997). The TDP consisted of nationally recognized drinking water experts from EPA, water treatment consulting companies, public as well as private water utilities along with suppliers, equipment vendors, and Federal along with State regulators in addition to cost estimating professionals.

In general, the WBS approach involves breaking a process down into discrete components for the purpose of estimating unit costs. The WBS models represent improvements over past cost estimating methods by increasing comprehensiveness, flexibility, and transparency. By adopting a WBS-based approach to identify the components that should be included in a cost analysis, the models produce a more comprehensive assessment of the capital and operating requirements for a treatment system.

Section 5.3.1.2.1 is a brief overview of the common elements of all the WBS models. Section 5.3.1.2.2 provides information on the anticipated accuracy of the models. Sections 5.3.1.2.3 through 5.3.1.2.6 identify technology-specific cost elements included in each model and discuss key inputs. The documentation for the individual WBS models (U.S. EPA, 2023i; U.S. EPA, 2023k; U.S. EPA, 2023j), provides more complete details on the structure, content, and use of each model.

5.3.1.2.1 Common Model Components and Inputs

Each WBS model contains the work breakdown for a particular treatment process and preprogrammed engineering criteria and equations that estimate equipment requirements for user-specified design requirements (e.g., system size and influent water quality). Each model also provides unit and total cost information by component (e.g., individual items of capital equipment) and totals the individual component costs to obtain a direct capital cost. Additionally, the models estimate add-on costs (e.g., permits and land acquisition), indirect capital costs, and annual O&M costs, thereby producing a complete compliance cost estimate.

Primary inputs common to all the WBS models include design flow and average daily flow in MGD. Each WBS model has default designs (input sets) that correspond to specified categories of flow, but the models can generate designs for many other combinations of flows. To estimate costs for PFAS compliance, EPA fit cost curves to the WBS estimates across a range of flow rates, as described in Section 5.3.1.3.

Another input common to all the WBS models is "component level" or "cost level." This input drives the selection of materials for items of equipment that can be constructed of different

materials. For example, a low-cost system might include fiberglass pressure vessels and PVC piping. A high-cost system might include stainless steel pressure vessels and stainless-steel piping. The component level input also drives other model assumptions that can affect the total cost of the system, such as building quality and heating and cooling. The component level input has three possible values: low cost, mid cost, and high cost. To estimate costs for PFAS treatment, EPA generated separate cost equations for each of the three component levels, thus creating a range of cost estimates for use in national compliance cost estimates.

The third input common to all the WBS models is system automation, which allows the design of treatment systems that are operated manually or with varying degrees of automation (i.e., with control systems that reduce the need for operator intervention). The cost equations described in Section 5.3.1.3 are for systems that are fully automated, minimizing the need for operator intervention and reducing operator labor costs.

The WBS models generate cost estimates that include a consistent set of capital, add-on, indirect, and O&M costs. Table 5-11 identifies these cost elements, which are common to all the WBS models and included in the cost estimates below. Sections 5.3.1.2.3 through 5.3.1.2.6 identify the technology-specific cost elements included in each model. The documentation for the WBS models (U.S. EPA, 2023i; U.S. EPA, 2023k; U.S. EPA, 2023l; U.S. EPA, 2023j) provide more information on the methods and assumptions used in the WBS models to estimate the costs for both the technology-specific and common cost elements.

Table 5-11: Cost Elements Included in All WBS Models

Cost Category	Components Included		
Direct Capital Costs	• Technology-specific equipment (e.g., vessels, basins, pumps, treatment media, piping, valves)		
	• Instrumentation and system controls		
	• Buildings		
	• Residuals management equipment		
Add-on Costs	• Land		
	• Permits		
	• Pilot testing		
Indirect Capital	Mobilization and demobilization		
Costs	 Architectural fees for treatment building 		
	• Equipment delivery, installation, and contractor's overhead and profit		
	• Sitework		
	• Yard piping		
	• Geotechnical		
	• Standby power		
	• Electrical infrastructure		
	• Process engineering		
	• Contingency		
	Miscellaneous allowance		
	 Legal, fiscal, and administrative 		
	• Sales tax		

Table 5-11: Cost Elements Included in All WBS Models

Cost Category	Components Included		
	• Financing during construction		
	Construction management		
O&M Costs: Technology-	 Operator labor for technology-specific tasks (e.g., managing backwash and media replacement) 		
specific	• Materials for O&M of technology-specific equipment		
	• Technology-specific chemical usage		
	• Replacement of technology-specific equipment that occurs on an annual basis (e.g., treatment media)		
	• Energy for operation of technology-specific equipment (e.g., mixers)		
O&M Costs: Labor	• Operator labor for O&M of process equipment		
	Operator labor for building maintenance		
	Managerial and clerical labor		
O&M Costs:	• Materials for maintenance of booster or influent pumps		
Materials	Materials for building maintenance		
O&M Costs:	• Energy for operation of booster or influent pumps		
Energy	• Energy for lighting, ventilation, cooling, and heating		
O&M Costs:	Residuals management operator labor, materials, and energy		
Residuals	Residuals disposal and discharge costs		

Abbreviations: O&M – operation & maintenance; WBS – work breakdown structure.

5.3.1.2.2 WBS Model Accuracy

Costs for a given system can vary depending on site-specific conditions (e.g., raw water quality, climate, local labor rates, and location relative to equipment suppliers). The costs presented here are based on national average assumptions and include a range (represented by low-, mid-, and high-cost equations) intended to encompass the variation in costs that systems would incur to remove PFAS. To validate the engineering design methods used by the WBS models and increase the accuracy of the resulting cost estimates, EPA has subjected the individual models to a process of external peer review by nationally recognized technology experts.

The GAC model underwent peer review in 2006. Two of the three reviewers expressed the opinion that resulting cost estimates would be in the range of budget estimates (+30 to -15 percent). The other reviewer did not provide a precise estimate of the model's accuracy range but commented that the resulting cost estimates were reasonable. EPA made substantial revisions to the GAC model in response to the peer review.

The IX model underwent peer review in 2005, during an early stage of its development. One peer reviewer responded that resulting cost estimates were in the range of budget estimates (+30 to -15 percent). The other two reviewers thought the estimates were order of magnitude estimates (+50 to -30 percent), with an emphasis on the estimates being high. The IX model has since undergone extensive revision, both in response to the peer review and to adapt it for PFAS treatment using selective resin.

The RO/NF model underwent peer review in 2007. The majority of peer reviewers who evaluated the model expressed the opinion that resulting cost estimates would be in the range of budget estimates (+30 to -15 percent). The RO/NF model has since undergone substantial revision in response to the peer review comments.

EPA received peer review comments on the non-treatment model in May 2012. The first reviewer responded that cost estimates resulting from the non-treatment model were in the range of budget estimates (+30 to -15 percent). The second reviewer thought the cost estimates were order of magnitude estimates (+50 to -30 percent). The third reviewer felt the cost estimates were definitive (+15 to -5 percent), except for land costs, which were difficult to assess due to regional variations. EPA revised the nontreatment model in response to the peer review recommendations.

5.3.1.2.3 GAC Model

Work Breakdown Structure-Based Cost Model for Granular Activated Carbon Drinking Water Treatment provides a complete description of the engineering design process used by the WBS model for GAC (U.S. EPA, 2023i). The model can generate costs for two types of design:

- Pressure designs where the GAC bed is contained in stainless steel, carbon steel, or fiberglass pressure vessel
- Gravity designs where the GAC bed is contained in open concrete basins.

Table 5-12 shows the technology-specific capital equipment and O&M requirements included in the GAC model. These items are in addition to the common WBS cost elements listed in Table 5-11.

Table 5-12: Technology-Specific Cost Elements Included in the GAC Model

Cost Category	ory Major Components Included		
Direct Capital Costs	 Booster pumps for influent water Contactors (either pressure vessels or concrete basins) that contain the GAC bed Tanks and pumps for backwashing the contactors 		
	 GAC transfer and storage equipment Spent GAC reactivation facilities (if on-site reactivation is selected) Associated piping, valves and instrumentation 		
O&M Costs: Labor	 Operator labor for contactor maintenance (for gravity GAC designs) Operator labor for managing backwash events Operator labor for backwash pump maintenance (if backwash occurs weekly or more frequently) Operator labor for GAC transfer and replacement 		
O&M Costs: Materials	 Materials for contactor maintenance (accounts for vessel relining in pressure designs, because GAC can be corrosive, and for concrete and underdrain maintenance in gravity designs) Materials for backwash pump maintenance (if backwash occurs weekly or more frequently) Replacement virgin GAC (loss replacement only if reactivation is selected) 		

Cost Category

Major Components Included

O&M Costs:
Energy
O&M Costs:

Residuals

Objecting energy for backwash pumps

Discharge fees for spent backwash
Fees for reactivating spent GAC (if off-site reactivation is selected)

Labor, materials, energy, and natural gas for regeneration facility (if on-site reactivation is selected)

Disposal of spent GAC (if disposal is selected)

Table 5-12: Technology-Specific Cost Elements Included in the GAC Model

Abbreviations: GAC - granular activated carbon; O&M - operation & maintenance; WBS - work breakdown structure.

For small systems (less than 1 MGD) using pressure designs, the GAC model assumes the use of package treatment systems that are pre-assembled in a factory, mounted on a skid, and transported to the site. The model estimates costs for package systems by costing all individual equipment line items (e.g., vessels, interconnecting piping and valves, instrumentation, and system controls) in the same manner as custom-engineered systems. This approach is based on vendor practices of partially engineering these types of package plants for specific systems (e.g., selecting vessel size to meet flow and treatment criteria). The model applies a variant set of design inputs and assumptions that are intended to simulate the use of a package plant and that reduce the size and cost of the treatment system. U.S. EPA (2023i) provides complete details on the variant design assumptions used for package plants.

To generate the cost equations discussed in Section 5.3.1.3, EPA used the following key inputs in the GAC model:

- For pressure designs, two vessels in series with a minimum total empty bed contact time (EBCT) of 20 minutes
- For gravity designs, contactors in parallel with a minimum total EBCT of 20 minutes
- Bed life varying over a range from 5,000 to 150,000 BV, estimated as discussed in Section 5.3.1.1.1

EPA generated separate cost equations for two spent GAC management scenarios:

- Off-site reactivation under current RCRA non-hazardous waste regulations
- Off-site disposal as a hazardous waste and replacement with virgin GAC (i.e., single use operation).

The T&C document (U.S. EPA, 2023h) provides a comprehensive discussion of these and other key inputs and assumptions.

5.3.1.2.4 PFAS-selective IX Model

Work Breakdown Structure-Based Cost Model for Ion Exchange Treatment of Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water provides a complete description of the engineering design process used by the WBS model for PFAS-selective IX (U.S. EPA, 2023j). Table 5-13 shows the technology-specific capital equipment and O&M requirements included in the model. These items are in addition to the common WBS cost elements listed in Table 5-11.

Table 5-13: Technology-Specific Cost Elements Included in the PFAS-Selective IX Model

Cost Category	Major Components Included		
Direct Capital	Booster pumps for influent water		
Costs	Pre-treatment cartridge filters		
	 Pressure vessels that contain the resin bed 		
	 Tanks and pumps for initial rinse and (optionally) backwash of the resin bed 		
	 Tanks (with secondary containment), pumps and mixers for delivering sodium hydroxide for use in post-treatment corrosion control (optional) 		
	 Associated piping, valves, and instrumentation 		
O&M Costs: Labor	Operator labor for pre-treatment filters		
	 Operator labor for managing backwash/rinse events 		
	 Operator labor for backwash pump maintenance (only if backwash occurs weekly or more frequently) 		
	 Operator labor for resin replacement 		
O&M Costs:	Replacement cartridges for pre-treatment filters		
Materials	 Materials for backwash pump maintenance (only if backwash occurs weekly or more frequently) 		
	 Chemical usage (if post-treatment corrosion control is selected) 		
	Replacement virgin PFAS-selective resin		
O&M Costs: Energy	Operating energy for backwash/rinse pumps		
O&M Costs:	 Disposal of spent cartridge filters 		
Residuals	 Discharge fees for spent backwash/rinse 		
	 Disposal of spent resin 		

 $Abbreviations: IX-ion\ exchange;\ O\&M-operation\ \&\ maintenance;\ PFAS-per-and\ polyfluoroalkyl\ substances.$

For small systems (less than 1 MGD), the PFAS-selective IX model assumes the use of package treatment systems that are pre-assembled in a factory, mounted on a skid, and transported to the site. The IX model estimates costs for package systems using an approach similar to that described for the GAC model, applying a variant set of inputs and assumptions that reduce the size and cost of the treatment system (see Section 5.3.1.2.3). U.S. EPA (2023j) provides complete details on the variant design assumptions used for IX package plants.

To generate the cost equations discussed in Section 5.3.1.3, EPA used the following key inputs in the PFAS-selective IX model:

- Two vessels in series with a minimum total EBCT of 6 minutes
- Bed life varying over a range from 20,000 to 440,000 BV, estimated as discussed in Section 5.3.1.1

EPA generated separate cost equations for two spent resin management scenarios:

• Spent resin managed as non-hazardous and sent off-site for incineration

• Spent resin managed as hazardous and sent off-site for incineration.

The T&C document (U.S. EPA, 2023h) provides a comprehensive discussion of these and other key inputs and assumptions.

5.3.1.2.5 RO/NF Model

Work Breakdown Structure-Based Cost Model for Reverse Osmosis/Nanofiltration Drinking Water Treatment provides a complete description of the engineering design process used by the WBS model for RO/NF (U.S. EPA, 2023l). Table 5-14 shows the technology-specific capital equipment and O&M requirements included in the model. These items are in addition to the common WBS cost elements listed in Table 5-11.

Table 5-14: Technology-Specific Cost Elements Included in the RO/NF Model

Cost Category	Major Components Included		
Direct Capital Costs	High-pressure pumps for influent water and (optionally) interstage pressure boost		
	Pre-treatment cartridge filters		
	Tanks, pumps, and mixers for pretreatment chemicals		
	• Pressure vessels, membrane elements, piping, connectors, and steel structure for the membrane racks		
	 Valves for concentrate control and (optionally) per-stage throttle 		
	• Tanks, pumps, screens, cartridge filters, and heaters for membrane cleaning		
	• Equipment, including dedicated concentrate discharge piping, for managing RO/NF concentrate and spent cleaning chemicals		
	 Associated pipes, valves, and instrumentation 		
O&M Costs: Labor	Operator labor for pre-treatment filters		
	 Operator labor for routine O&M of membrane units 		
	Operator labor to maintain membrane cleaning equipment		
O&M Costs:	Replacement cartridges for pre-treatment filters		
Materials	Chemical usage for pretreatment		
	 Maintenance materials for pre-treatment, membrane process, and cleaning equipment 		
	Replacement membrane elements		
	Chemical usage for cleaning		
O&M Costs: Energy	Energy for high-pressure pumping		
O&M Costs: Residuals	Disposal costs for spent cartridge filters and membrane elements		

 $Abbreviations: O\&M-operation \&\ maintenance;\ PFAS-per-and\ polyfluoroalkyl\ substances;\ RO/NF-reverse\ osmosis/nanofiltration.$

The RO/NF model includes three default ground waters and three default surface waters, ranging from high to low quality (i.e., from low to high total dissolved solids and scaling potential). To generate the cost equations discussed in Section 5.3.1.3, EPA used the model's default high-

quality influent water parameters to reflect the incremental cost of removing PFAS from otherwise potable water. EPA used the following additional key inputs and assumptions:

- For systems larger than approximately 0.5 MGD, target recovery rates of 80 percent for ground water and 85 percent for surface water²¹
- Target recovery rates of 70 to 75 percent for smaller systems
- Flux rates of 19 gallons per square foot per day (gfd) for ground water and 15 to 16 gfd for surface water
- Direct discharge of RO/NF concentrate to a permitted outfall on a non-potable water body (e.g., ocean or brackish estuary) via 10,000 feet of buried dedicated piping.

The T&C document (U.S. EPA, 2023h) provides a comprehensive discussion of these and other key inputs and assumptions.

5.3.1.2.6 Non-treatment Model

Work Breakdown Structure-Based Cost Model for Nontreatment Options for Drinking Water Compliance provides a complete description of the engineering design process used by the WBS model for nontreatment actions (U.S. EPA, 2023k). The model can estimate costs for two nontreatment alternatives: interconnection with another system and drilling new wells to replace a contaminated source. Table 5-15 shows the technology-specific capital equipment and O&M requirements included in the model for each alternative. The interconnection alternative does not include any buildings. It includes all the indirect capital costs shown in Table 5-15 except for yard piping, site work, and architectural fees. The new well alternative includes a small shed or other low-cost building at the well site along with materials and labor for maintenance of this building. It includes all the indirect capital costs shown in Table 5-15 except for yard piping.

Table 5-15: Technology-Specific Cost Elements Included in the Non-Treatment Model

Cost Category	Major Components Included for Interconnection	Major Components Included for New Wells	
Direct Capital Costs	 Booster pumps or pressure reducing valves (depending on pressure at supply source) Concrete vaults (buried) for booster pumps or pressure reducing valves Interconnecting piping (buried) and valves 	 Well casing, screens, and plugs Well installation costs including drilling, development, gravel pack, and surface seals Well pumps Piping (buried) and valves to connect the new well to the system 	
O&M Costs: Labor	Operator labor for O&M of booster pumps or pressure reducing valves (depending on pressure at supply source) and interconnecting valves	Operator labor for operating and maintaining well pumps and valves	

²¹ Recovery rate is the percent of flow influent to RO that is recovered as useable treated water (permeate), as opposed to lost as residual concentrate. It is not directly related to percent removal of PFAS.

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Table 5-15: Technology-Specific Cost Elements Included in the Non-Treatment Model

Cost Category	Major Components Included for Interconnection	Major Components Included for New Wells	
O&M Costs: Materials	 Cost of purchased water Materials for maintaining booster pumps (if required by pressure at supply source) 	Materials for maintaining well pumps	
O&M Costs: Energy	 Energy for operating booster pumps (if required by pressure at supply source) 	Energy for operating well pumps	

Abbreviations: O&M – operation & maintenance.

To generate the cost equations discussed in Section 5.3.1.3, EPA used the following key inputs in the non-treatment model for interconnection:

- An interconnection distance of 10,000 feet
- Minimal differences in pressure between the supplier and the purchasing system, so that neither booster pumps nor pressure reducing valves are needed
- An average cost of purchased water of \$3.00 per thousand gallons in 2020 dollars.²²

For new wells, EPA used the following key inputs:

- A maximum well capacity of 500 gallons per minute (gpm), such that one new well is installed per 500 gpm of water production capacity required
- A well depth of 250 feet
- 500 feet of distance between the new wells and the distribution system.

The T&C document (U.S. EPA, 2023h) provides a comprehensive discussion of these and other key inputs and assumptions.

5.3.1.3 WBS Cost Equations

EPA developed the cost estimates for PFAS treatment using outputs from the WBS models. Outputs from these models are point estimates of total capital and O&M cost that correspond to a given set of inputs that include design flow and average daily flow in MGD. Separately for total capital and annual O&M cost, EPA fit cost equations to the WBS outputs for up to 49 different flow rates. EPA choose from among several possible equation forms: linear, quadratic, cubic, power, exponential, and logarithmic. For each equation, EPA selected the form that resulted in the best correlation coefficient (R²), subject to the requirement that the equation must be monotonically increasing over the appropriate range of flow rates (i.e., within the flow rate category, the equation must always result in higher estimated costs for higher flow systems than

²² The WBS model presents costs in 2020 dollars, but the economic analysis is adjusted to present all costs and benefits in 2021 dollars.

for lower flow systems). The resulting cost equations take one of the following forms, identified by which coefficients (C1 through C10) are nonzero:

Equation 7:

$$Cost = C1 Q^{C2}$$
or = C3 Ln(Q) + C4
or = C5 e^(C6 Q)
or = C7 Q³ + C8 Q² + C9 Q + C10

In each case, Q is design flow in MGD for total capital costs, or average flow in MGD for annual O&M costs. The resulting costs are in 2020 dollars.²³

The equations are categorized by water source (surface water or ground water) and component level (low, mid, or high cost). EPA developed separate equations for small, medium, or large systems. These equations apply as follows:

- Small system equations apply where design flow (Q) is less than 1 MGD
- Medium system equations apply where design flow (Q) is 1 MGD or greater, but less than 10 MGD
- Large system equations apply where design flow (Q) is 10 MGD or greater.

SafeWater MCBC selects from among the small, medium, and large equations and applies the equations using the treated flow of the entry point. For GAC, IX, and non-treatment alternatives, the treated flow is the entire flow of the entry point. Because RO/NF can continuously achieve high removal efficiencies for PFAS, PWSs that require lower removals may be able to treat a portion of their total flow and blend treated water and untreated water to meet regulatory standards. EPA assumes systems using RO/NF will employ blending when they require less than 95 percent removal. Data presented in the T&C document (U.S. EPA, 2023h) show that RO/NF can achieve greater than 95 percent removal efficiency for most PFAS compounds. Therefore, this assumption errs on the side of higher costs. Accordingly, for entry points using RO/NF that require less than 95 percent removal, SafeWater MCBC calculates a blending ratio and treated design and average flow as follows:

²³ The WBS model presents costs in 2020 dollars, but the economic analysis is adjusted to present all costs and benefits in 2021 dollars.

Equation 8:

$$B = \frac{\%R_{final,RO}}{0.95}$$

$$Q_{treated,design} = B \times Q_{total,design}$$

$$Q_{treated,average} = B \times Q_{total,design}$$

Where:

B = the blending ratio expressed as a decimal

 $%R_{final,RO}$ = removal required from RO/NF expressed as a decimal and calculated as described in Section 5.3.1.1.2

0.95 = the continuous removal achieved by RO/NF; an assumption based on data presented in the T&C document (U.S. EPA, 2023h)

Q_{treated} = treated portion of entry point flow in MGD

 $Q_{total} = total entry point flow in MGD$

SafeWater MCBC assumes that entry points using RO/NF that require 95 percent removal or greater will not employ blending and treat their entire flow.

For GAC and IX, EPA developed separate equations that vary according to the estimated bed life. These equations are in increments of 5,000 BV for GAC and 20,000 BV for IX. Each bed life increment corresponds to a change in media replacement frequency of two to five months, depending on the average flow of the entry point. For entry points using GAC or IX, SafeWater MCBC selects from among these equations based on the final operating bed life calculated as described in Section 5.3.1.1.1, rounded down to the nearest increment of 5,000 BV for GAC and 20,000 BV for IX.

For GAC, there are separate equations for pressure designs and gravity designs. For ground water entry points using GAC, EPA assumed PWSs would always use pressure designs to maintain their existing pressure head. For surface water entry points using GAC, EPA assumed PWSs would choose between pressure and gravity based on the design that results in the lower annualized cost.

In total, there are almost 3,500 individual cost equations across the categories of capital and O&M cost, water source, component level, flow, bed life (for GAC and IX), residuals management scenario (for GAC and IX), and design type (for GAC). The T&C document (U.S. EPA, 2023h) presents the equations in tabular form.

5.3.1.4 Incremental Treatment Costs of Other PFAS

EPA has estimated the national level costs of the proposed rule associated with PFOA, PFOS and PFHxS. There are limitations with nationally representative occurrence information for the other compounds in the proposed rule (PFNA, HFPO-DA and PFBS), therefore the additional treatment cost, from co-occurrence of PFNA, HFPO-DA, PFBS or other PFAS, at systems already required to treat because of PFOA, PFOS, or PFHxS MCL and HI exceedances are not quantitatively assessed in the national cost estimates. Nor are treatment costs for systems that

exceed the HI based on the combined occurrence of PFNA, HFPO-DA, PFBS, and PFHxS (where PFHxS itself does not exceed its HBWC of 9.0 ppt) included in the national monetized cost estimates. This section discusses EPA's model system approach for estimating potential incremental treatment costs associated with co-occuring PFAS at systems already required to treat in the national model framework and the potential per system costs for the set of systems triggered into treatment as a result of HI exceedances not already captured in the national analysis.

EPA's approach utilizes unit treatment cost information on three types of systems:

- 1. Baseline System: this model system has occurrence of PFAS included in the national analysis (PFOA, PFOS, and PFHxS). It reflects the costs that are covered in the national analysis and provides a basis for comparison.
- 2. System Type 1: this model system has no detections of PFOA, PFOS, or PFHxS. However, it has occurrence of all the other PFAS considered in the HI. EPA considered two scenarios for this system type: high occurrence of the other HI PFAS and medium occurrence of the other HI PFAS. This system type represents additional systems that are not currently captured in the national costs but would incur treatment costs because they exceed the HI requirement under the proposed option.
- 3. System Type 2: this model system has occurrence of PFOA, PFOS, and/or PFHxS identical to the baseline system. It also has occurrence of the other HI PFAS considered in the proposed option. Like System Type 1, EPA considered two scenarios: high occurrence of the other PFAS and medium occurrence of the other PFAS. This system type illustrates a range of potential incremental treatment costs for systems that are already treating in the national analysis.

Model System Type 1 cost estimate results characterize the system level costs that accrue as a result of HI exceedances at locations that are not already treating for PFOA, PFOS, and/or PFHxS in the national cost analysis. Model System Type 2 costs minus those of the Baseline System provides the incremental system level cost for PWSs that are treating for PFOA, PFOS, and/or PFHxS in the national model but also have significant concentrations of the other HI PFAS that must be removed.

In this analysis, concentrations for PFOA, PFOS, and PFHxS correspond to the median for each contaminant from the UCMR3 data, considering detected values only. Concentrations for the other PFAS are 95th percentile and median values based on EPA's analysis of state-level occurrence data. For more information on assumed baseline characteristics See Appendix N.3.

Given this occurrence information and basic system characteristics by system size category, EPA estimated a range of costs for model systems in each size category for each of the three treatment technologies (GAC, IX, and RO/NF). The range of costs reflects all combinations of two source waters (ground and surface) and two cost levels (low and high). For GAC and IX, the range of costs also incorporates two bed life scenarios corresponding to a range of influent TOC.

EPA has conducted additional occurrence modeling that indicates that 100-500 systems are estimated to not exceed the PFOA and/or PFOS MCLs but are estimated to exceed the HI. In the national model approximately 500 systems are estimated to exceed the HI based on PFHxS data

alone. However, some of these systems are also estimated to exceed the PFOA and/or PFOS MCLs. Therefore, a subset of the estimated 100-500 systems estimated to exceed the HI only have already been captured in the national analysis because EPA includes an estimate of systems where PFHxS exceeds 9.0 ppt in the national cost analysis. EPA does not capture HI related treatment costs associated with HFPO-DA, PFNA, and PFBS in the national cost analysis. Instead, EPA assesses Type 1 model systems, which represent additional systems that are not currently captured in the national costs but would incur treatment costs because they exceed the HI requirement. These systems are estimated to incur treatment costs in general ranging from 0.70 to 1.77 times the estimated baseline system costs. Type 1 systems with moderate occurrence for HFPO-DA, PFNA, and PFBS have estimated costs that are the same as or somewhat lower than systems captured in the national analysis (0.70 to 1.00 times baseline). Type 1 systems with high occurrence (95th percentile) have estimated costs slightly lower to somewhat higher than systems captured in the national analysis (0.92 to 1.77 times baseline).

EPA's national cost model estimated number of systems which exceed one or more limits (MCLs for PFOA and/or PFOS and/or the HI for PFHxS alone) is approximately 4,300. Some fraction of these systems may incur increased treatment costs because of the co-occurrence of additional PFAS. As explained above, EPA used the UCMR3 median and 95th percentile HFPO-DA, PFBS, and PFNA (the HI PFAS not already included in the national analysis) data to characterize the potential change in treatment cost at the system level given co-occurrence. The modeled Type 2 systems are designed to assess these impacts. Overall, the need to remove these other HI compounds could increase treatment costs by 0 to 77 percent on a per-system basis. For both IX and RO/NF there is no appreciable increase in the cost of treatment when the additional PFAS are found, even when concentrations of HFPO-DA, PFBS, and PFNA are all present at the 95th percentile level. Only systems using GAC are expected to incur increased per system costs. At the upper bound of the GAC cost range, the high TOC influent combined with the need to remove the other HI compounds (particularly HFPO-DA) results in a shorter bed life and increased costs of operation. Type 2 modeled systems with median co-occurrence for HFPO-DA, PFNA, and PFBS experience increases in estimated GAC treatment costs that range from 0 to 9 percent. For Type 2 systems that with high co-occurrence (95th percentile of the additional HI PFAS) GAC treatment costs increased from 0 to 77 percent. Based on EPA's national model results, EPA estimates that of those 4,300 systems that are required to treat because of MCL and/or HI exceedances GAC will be installed at approximately 50-85 percent of entry points, depending on source water type and other factors (see Section 5.3.1.1).

For further detail on the assumptions and findings of EPA's analysis of incremental costs of other PFAS, see Appendix N.3.

5.3.2 Estimating PWS Sampling and Administrative Costs

This section details how EPA estimated the costs of compliance with the system sampling and administrative activities associated with the proposed rule. In the subsections of 5.3.2, EPA organizes and presents the cost information based on the series of activities that are required to comply with the proposed PFAS NPDWR, with tables for each data element used to calculate the proposed rule component costs. These tables include the data element name and a description of the data variable, as well as any relevant sources for the data. EPA presents the costs categorized as follows:

- Administrative costs associated with implementation (Section 5.3.2.1);
- Sampling costs (Section 5.3.2.2); and
- Administrative costs associated with treatment (Section 5.3.2.3).

Consistent with standard Agency practice, EPA assumes compliance with the rule throughout the economic analysis, and as a result, SafeWater MCBC does not accrue costs to any system for the Tier 2 and 3 public notifications. Nevertheless, EPA presents a qualitative discussion of the public notification costs potentially associated with the proposed rule in Section 5.3.2.4.

5.3.2.1 Implementation Administration Costs

Systems conduct the following one-time actions to begin implementation of the rule:

- Reading and understanding the rule; and
- Attending training provided by primacy agencies.

EPA assumes that systems will conduct these activities during years one through three of the period of analysis. Table 5-16 lists the data elements and provides descriptions, values, and sources for these costs. The cost per system for each activity is the product of the hourly labor cost (labor_sys_rate) and the hours (hrs_sys_adopt_rule and hrs_sys_initial_ta), which vary by system size. The total cost is the sum of per-system costs.

Table 5-16: Implementation Administration Startup Costs (\$2021)

Data Element Name	Data Element Description	Data Element Value	Data Element Source
labor_sys_rate	The labor rate per hour for systems	\$35.48 (systems \(\leq 3,300\) \$37.84 (systems 3,301-10,000) \$39.94 (systems 10,001-50,000) \$41.70 (systems 50,001- 100,000) \$48.74 (systems >100,000)	WBS Technical Labor Cost
hrs_sys_adopt_rule	The average hours per system to read and adopt the rule	4 hours per system	Arsenic in Drinking Water Rule Economic Analysis (EPA 815-R-00- 026)
hrs_sys_initial_ta	The average hours per system to attend one-time training provided by primacy agencies	16 hours per system (systems ≤3,300) 32 hours per system (systems >3,300)	Arsenic in Drinking Water Rule Economic Analysis (EPA 815-R-00- 026)

Abbreviation: WBS – work breakdown structure.

5.3.2.2 Sampling Costs

EPA assumes that there will be initial and long-term monitoring for the proposed rule. As Table 5-17 shows, surface and ground water systems serving 10,000 or more people will collect one sample each quarter, at each entry point, during the initial 12-month monitoring period. Surface water systems serving 10,000 or fewer people are also required to collect a quarterly sample at each entry point during the initial 12-month period. Ground water systems that serve 10,000 or fewer people will be required to sample once at each entry point on a semi-annual basis for the first 12-month monitoring period.

Long-term monitoring requirements differ based on two factors: (1) system size, and (2) whether a system can demonstrate during the initial monitoring period that they are "reliably and consistently" below the proposed MCLs for PFAS. EPA has set the PWS size threshold at systems serving 3,300 or fewer people. The threshold for systems to demonstrate that they are "reliably and consistently" below the proposed MCLs is set at a trigger level of one-third the MCLs for PFOA or PFOS (1.3 ppt) or the HI (0.33). For systems below the trigger level values during the initial 12-month monitoring period and in future long-term monitoring periods may conduct triennial monitoring. Systems serving 3,300 or fewer people will collect one triennial sample per entry point. Systems providing water for more than 3,300 people will take one sample in two consecutive quarters at each entry point, totaling two samples in each triennial period. For systems with concentration values at or above the trigger level regardless of system size, a quarterly sample must be taken at each entry point.

For any samples that have a detection, the system will analyze the field reagent blank samples collected at the same time as the monitoring sample. Systems that have an MCL exceedance will collect one additional sample from the relevant entry point to confirm the results (i.e., a confirmation sample) (U.S. EPA, 2004).

Long-Term Initial Monitoring^a: Long-Term Initial 12-Long-Term **Monitoring PFAS** Monitoring^a: PFAS Month **Monitoring Detection < 1.3 System** Detection ≥ 1.3 ppt **Monitoring System Size** Size ppt (PFOA or (PFOA or PFOS) or Period Category PFOS) or HI < HI ≥0.33 Category 0.33 Surface Water: 1 sample every quarter $\leq 10,000$ \leq 3,300 1 triennial sample 1 sample every quarter Ground Water: 1 sample every 6month period Surface Water 2 triennial samples and Ground (1 sample in two >10,000 >3.300 1 sample every quarter Water: 1 sample consecutive

Table 5-17: Initial and Long-Term Sampling Frequencies Per System Entry Point

Abbreviations: HI – hazard index; PFAS – per-and polyfluoroalkyl substances.

every quarter

quarters)

For the national cost analysis, EPA assumes that systems with either UCMR 5 data or monitoring data in the State PFAS Database will not need to conduct the initial year of monitoring (See Chapter 3.1.4). As a simplifying assumption for the cost analysis, EPA assumes all systems serving a population of greater than 3,300 have UCMR 5 data and those with 3,300 or less do not. For the State PFAS Database, EPA relied on the PWSIDs stored in the database and exempted those systems from the first year of monitoring in the cost analysis.

EPA assumes that systems with an MCL exceedance will implement actions to comply with the MCL by the compliance date. As indicated in 5.3.1, EPA assumes a treatment target, for systems required to treat for PFAS, that includes a margin of safety so finished water PFAS levels at these systems are 80 percent of the MCL or HI. This target is insufficient to meet the triennial monitoring threshold. Therefore, systems implementing treatment will continue with quarterly monitoring. All other systems that do not have PFAS concentrations at or below the trigger level threshold will also continue quarterly monitoring.

For all systems, the activities associated with the sample collection in the initial 12-month monitoring period are the labor burden and cost for the sample collection and analysis, as well as a review of the sample results. Table 5-18 presents the data needs associated with the implementation monitoring period. The cost per entry point for each sampling activity is the product of the hourly labor cost and the hours plus the laboratory analysis cost. The laboratory analysis cost will include the additional field blank cost when occurrence values exceed method detection limits. The total cost is the sum of per-entry point costs.

^aEPA used the following thresholds to distinguish whether PFAS concentrations are reliably and consistently below the maximum contaminant level (MCL): PFOA and PFOS – one-third the MCL for each option; PFHxS – one-third the health benchmark of 9 ng/L or 3 ng/L.

Table 5-18: Sampling Costs (\$2021)

Data Element Name	Data Element Description	Data Element Value	Data Element Source
labor_sys_rate	The labor rate per hour for systems	\$35.48 (systems \(\leq 3,300\) \$37.84 (systems 3,301- 10,000) \$39.94 (systems 10,001- 50,000) \$41.70 (systems 50,001- 100,000) \$48.74 (systems >100,000)	WBS Technical Labor Cost
numb_intial_samples	The number of samples per entry point per monitoring round for the initial monitoring in Year 1	2 samples (Ground Water systems ≤10,000) 4 samples (all other systems) ^a	Proposed rule
numb_quarterly_samples	The number of samples per entry point per long-term monitoring year for entry points that exceed the triennial monitoring threshold	4 samples (all systems)	Proposed rule
numb_triennial_samples	The number of samples per entry point per long-term monitoring round for entry points that meet the triennial threshold	1 sample (systems ≤3,300) 2 samples (systems >3,300)	Proposed rule
hrs_samp	The hours per sample to travel to sampling locations, collect samples, record any additional information, submit samples to a laboratory, and review results	1 hour	UCMR5 ICR (EPA- HQ-OW-2020- 0530-00141)
EPA533_cost	The laboratory analysis cost per sample for EPA Method 533	\$376	UCMR5 ICR (EPA- HQ-OW-2020- 0530-0141)
EPA537_cost	The laboratory analysis cost per sample for EPA Method 537.1	\$302	UCMR5 ICR (EPA- HQ-OW-2020- 0530-0141)
EPA533_fieldblank_cost	The laboratory analysis cost per sample for field reagent blank under EPA Method 533	\$327 ^b	,
EPA537_fieldblank_cost	The laboratory analysis cost per sample for the field reagent blank under EPA Method 537.1	\$266 ^b	

 $Abbreviations: EPA-U.S.\ Environmental\ Protection\ Agency;\ Ground\ Water-ground\ water\ ICR-Information\ Collection\ Request;\ UCMR-Unregulated\ Contaminant\ Monitoring\ Rule;\ WBS-work\ breakdown\ structure.$ Notes:

 $^{^{}a}$ Systems greater than 3,300 will rely on UCMR 5 data and a subset of other systems will rely on data in the State PFAS Monitoring Database.

^bThis incremental sample cost applies to all samples that exceed method detection limits. EPA used the Method 537.1 detection limits to apply this cost because Method 533 does not include detection limits.

5.3.2.3 Treatment Administration Costs

As described in Section 5.3.1, any system with an MCL exceedance adopts either a treatment or non-treatment alternative to comply with proposed rule. The majority of systems are anticipated to install treatment technologies while a subset, described in Section 5.3.1.1, will choose alternative methods. EPA assumes that systems will have administrative costs associated with obtaining permits for either the treatment or non-treatment methods. The costs vary depending on whether the system installs treatment or selects a non-treatment method. For the economic analysis, EPA assumes that systems install treatment in the fourth year of the period of analysis. Table 5-19 presents the data elements and sources for these costs. The cost per entry point requiring treatment or changing water source is the product of the hourly labor cost and the hours per the relevant permit request. The total cost is the sum of per-entry point costs.

Table 5-19: Treatment Administration Costs (\$2021)

Data Element Name	Data Element Description	Data Element Value	Data Element Source
labor_sys_rate	The labor rate per hour for systems	\$35.48 (systems ≤3,300) \$37.84 (systems 3,301- 10,000) \$39.94 (systems 10,001- 50,000) \$41.70 (systems 50,001- 100,000) \$48.74 (systems	WBS Technical Labor Cost
hrs_sys_treat	The hours per entry point for a system to notify, consult, and submit a permit request for treatment installation ^a	>100,000) 3 hours (systems ≤100) 5 hours (systems 101- 500) 7 hours (systems 501- 1,000) 12 hours (systems 1,001- 3,300) 22 hours (systems 3,301- 50,000) 42 hours (systems >50,000)	Lead and Copper Rule Revisions Support Material (EPA-HQ-OW- 2017-0300-1701)
hrs_sys_source	The hours per entry point for a system to notify, consult, and submit a permit request for source water change or alternative method ^a	6 hours	Lead and Copper Rule Revisions Support Material (EPA-HQ-OW- 2017-0300-1700)

Abbreviations: WBS – work breakdown structure.

5.3.2.4 Public Notification Costs

While EPA assumes full compliance with the rule and does not include public notification costs in the cost estimates, there are public notification requirements in the proposed rule for systems with certain violations. The proposed rule designates MCL violations for PFAS as Tier 2, which

^aThe Lead and Copper Rule Revisions presents this burden per system, but EPA applied the cost per entry point for this economic analysis because the notification, consultation, and permitting process occurs for individual entry points.

requires systems to provide public notification as soon as practical, but no later than 30 days after the system learns of the violation. The system must repeat notice every three months if the violation or situation persists unless the primacy agency determines otherwise. At a minimum, systems must give repeat notice at least once per year.

The proposed rule designates monitoring and testing procedure violations as Tier 3, which requires systems to provide public notice not later than one year after the system learns of the violation. The system must repeat the notice annually for as long as the violation persists. The system may use an annual report detailing all violations that occurred during the previous year if the timing requirements of the public notification are met.

To provide an approximate estimate of the burden associated with the Tier 2 and 3 violations, EPA reviewed the ICR for the Public Water System Supervision (PWSS) Program, which includes Tier 2 and 3 notifications. Table 5-20 presents the PWSS Program ICR burdens for the preparation and delivery of the Tier 2 and 3 public notifications.

Table 5-20: Public Notification Burden Estimate

Data Element ^a	Data Element Value	Data Element Source
Preparation of initial Tier 2 notices	3.5 hours	PWSS Program ICR (EPA-HQ- OW-2011-0433-0003)
Preparation of initial Tier 3 notices	3 hours (CWS) 3.5 hours (NTNCWS)	PWSS Program ICR (EPA-HQ-OW-2011-0433-0003)
Delivery of initial Tier 2 notices	9 hours (CWS ≤500) 30 hours (CWS >500) 9 hours (NTNCWS)	PWSS Program ICR (EPA-HQ-OW-2011-0433-0003)
Development and delivery of repeated Tier 2 and 3 notices	3 hours	PWSS Program ICR (EPA-HQ-OW-2011-0433-0003)

Abbreviations: CWS – community water system; PWSS – public water systems.

5.4 Estimating Primacy Agency Costs

In addition to the PWS costs associated with the rule implementation, EPA assumes primacy agencies will have upfront implementation costs as well as costs associated with the system actions related to sampling and treatment. The activities associated with primacy agencies under the proposed rule include:

- Reading and understanding the rule, as well as adopting regulatory requirements;
- Providing internal training for the rule implementation
- Providing systems with training and technical assistance during the rule implementation;
- Reporting to EPA on an ongoing basis any PFAS-specific information under 40 CFR 142.15 regarding violations as well as enforcement actions and general operations of public water supply programs;

^aDelivery of Tier 3 notices must occur not later than one year after the system learns of the violation. EPA assumes systems will include this notice with the Consumer Confidence Reports sent to all customers annually, therefore Tier 3 delivery costs are assumed to be zero.

- Reviewing the sample results during the implementation monitoring period and the SMF monitoring period; and
- Reviewing and consulting with systems on the installation of treatment technology or alternative methods, including source water change.

With the exception of the first four activities listed above, the primacy agency burdens are incurred in response to an action taken by a system. For example, the cost to primacy agencies of reviewing any sample result depends on the number of samples taken at each entry point by each system under the jurisdiction of the primacy agency. Table 5-21 presents the data elements and sources for all primacy agency costs. The data element descriptions indicate whether the cost is per primacy agency, per sample, per system, or per entry point. In each instance, the primacy agency labor rate is multiplied by the number of relevant hours and the activity frequency.

Table 5-21: Primacy Agency Costs (\$2021)

Data Element Name	Data Element Description	Data Element Value	Data Element Source
labor_pa_rate	The labor rate per hour for primacy agencies	\$58.14	Loaded labor rate (including the cost of benefits) derived from the Bureau of Labor Statistics ^a
hrs_pa_adopt_rule	The average hours per primacy agency to read and understand the rule, as well as adopt regulatory requirements	416 hours per primacy agency	Arsenic in Drinking Water Rule Economic Analysis (EPA 815-R-00-026)
hrs_pa_train	The average hours per primacy agency to provide initial training to internal staff	250 hours per primacy agency	Arsenic in Drinking Water Rule Economic Analysis (EPA 815-R-00-026)
hrs_pa_initial_ta	The average hours per primacy agency to provide initial training and technical assistance to systems	2,080 hours per primacy agency	Arsenic in Drinking Water Rule Economic Analysis (EPA 815-R-00-026)
hrs_sdwis	The average hours per primacy agency to report annually to EPA information under 40 CFR 142.15 regarding violations, variances and exemptions, enforcement actions and general operations of State public water supply programs	0	EPA assumes that the proposed PFAS rule will have no discernable incremental burden for quarterly or annual reports to SDWIS/Fed
hrs_pa_report_ep	The hours per sample for a primacy agency to review sample results	1 hour	Arsenic in Drinking Water Rule Economic Analysis (EPA 815-R-00-026)
hrs_pa_treat	The hours per entry point for a primacy agency to review and consult on installation of a treatment technique ^b	3 hours (systems ≤100) 5 hours (systems 101- 500) 7 hours (systems 501- 1,000) 12 hours (systems 1,001-3,300) 22 hours (systems 3,301-50,000) 42 hours (systems >50,000)	Lead and Copper Rule Revisions Support Material (EPA-HQ-OW-2017-0300- 1701)

Table 5-21: Primacy Agency Costs (\$2021)

Data Element Name	Data Element Description	Data Element Value	Data Element Source
hrs_pa_source	The hours per entry point for a primacy agency to review and consult on a source water change ^b	4 hours	Lead and Copper Rule Revisions Support Material (EPA-HQ-OW-2017-0300- 1700)

Notes:

a State employee wage rate of \$33.91 from National Occupational Employment and Wage Estimates, United States, BLS SOC Code 19-2041, "State Government, excluding schools and hospitals - Environmental Scientists and Specialists, Including Health," hourly mean wage rate. May 2020 data (published in March 2021): https://www.bls.gov/oes/current/oes192041.htm. Wages are loaded using a factor of 62.2 from the BLS Employer Costs for Employee Compensation report, Table 3, March 2020. Percent of total compensation - Wages and Salaries - All Workers - State and Local Government Workers (https://www.bls.gov/news.release/archives/ecec_06182020.pdf). See worksheet BLS Table 3. The final loaded wage is adjusted for inflation.

^bThe Lead and Copper Rule Revisions present this burden per system, but EPA has applied the cost per entry point for this economic analysis because the notification, consultation, and permitting process occurs for individual entry points.

In addition to the costs described above, a primacy agency may also have to review the certification of any Tier 2 or 3 public notifications sent out by systems. EPA assumes full compliance with the proposed rule but provides a brief discussion of the possible system costs associated with this component in Section 5.3.2.4. The public notification burden associated with primacy agencies is between 0.33 and 0.5 hours per system to review the system certification of the public notification. The burden is derived from the LCRR estimates for a similar activity.

5.5 PWS-Level Cost Estimates

PWS-level cost estimates for the proposed rule (proposed option) and other regulatory options are provided in Appendix C. PWS-level cost are provided for all PWSs by PWS-type, size category, primary source water type, and ownership. In addition, a second set of PWS-level costs are provided for PWSs that must take an action to comply with the rule (treat or change water source).

5.6 Household-Level Cost Estimates

Household-level cost estimates for the proposed rule and other regulatory options are provided in Appendix C. Household-level cost are provided for all CWSs by size category, primary source water type, and ownership. In addition, a second set of household-level costs are provided for households served by CWSs that must take an action to comply with the rule (treat or change water source).²⁴

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Note that EPA does compute per household technology cost values in the separate national small system affordability determination analysis. These household values are distinct from the values generated in the national cost estimates as they include only small system compliance technology cost. For three small system size categories (systems serving 25-500, 501-3,300, and 3,301-10,000) EPA estimates a per household treatment technology cost range including the minimum and maximum cost values. These cost estimates are based on system characteristics, contaminant reduction requirements, and technology efficacy, across the set of small system compliance technology options. See Chapter 9.12 the EA for additional information on the national small system affordability determination.

5.7 Discussion of Data Limitations and Uncertainty

The preceding sections identify the nonquantifiable costs and the uncertainty information incorporated in the quantitative cost analysis. There are also data limitations that could not be incorporated in this analysis. Chapter 7 and Table 7-6 outline the nonquantifiable costs associated with the regulatory requirements of the proposed option as well as Options 1a-c. Table 5-22 lists the data limitations and characterizes the impact on the quantitative cost analysis. EPA notes that in most cases it is not possible to judge the extent to which a particular limitation or uncertainty could affect the cost analysis. EPA provides the potential direction of the impact on the cost estimates when possible but does not prioritize the entries with respect to the impact magnitude.

Table 5-22: Limitations that Apply to the Cost Analysis for the Proposed PFAS Rule

Uncertainty/ Assumption	Effect on Quantitative Analysis	Notes
WBS engineering cost model assumptions and component costs	Uncertain	The WBS engineering cost models require many design and operating assumptions to estimate treatment process equipment and operating needs. Section 5.3.1 addressed the bed life assumption. The Technologies and Costs document (U.S. EPA, 2023h) and individual WBS models in the rule docket provide additional information. The component-level costs approximate national average costs, which can over- or under-estimate costs at systems affected by the proposed rule.
Compliance forecast	Uncertain	The forecast probabilities are based on historical full-scale compliance actions. Site-specific water quality conditions, changes in technology, and changes in market conditions can result in future technology selections that differ from the compliance forecast.
Total organic carbon concentration	Uncertain	The randomly assigned values from the two national distributions are based on a limited dataset. Actual TOC concentrations at systems affected by the proposed rule can be higher or lower than the assigned values.
National occurrence data for HFPO-DA, PFBS, and PFNA not available	Underestimate	The hazard index in the proposed option would regulate PFBS, PFNA, and HFPO-DA in addition to the modeled PFAS. In instances when concentrations of PFBS, PFNA, and/or HFPO-DA are high enough to cause a hazard index exceedance, the modeled costs may be underestimated. If these PFAS occur in isolation at levels that affect treatment decisions, or if they occur in sufficient concentration to result in an exceedance when the concentration of PFHxS alone would be below the HI, then costs would be underestimated. Note that EPA has conducted an analysis of the potential changes in system level treatment cost associated with the occurrence of PFBS, PFNA, and HFPO-DA using a model system approach which is discussed in detail in Section 5.3.1.4 and Appendix N.3.
POU not included in compliance forecast	Overestimate	If POU devices can be certified to meet concentrations that satisfy the proposed rule, then small systems may be able to reduce costs by using a POU compliance option instead of centralized treatment or source water changes.
Process wastes not classified as hazardous	Underestimate	The national cost analysis reflects the assumption that PFAS-contaminated wastes are not considered hazardous

Table 5-22: Limitations that Apply to the Cost Analysis for the Proposed PFAS Rule

Uncertainty/ Assumption	Effect on Quantitative Analysis	Notes
		wastes. As a general matter, EPA notes that such wastes are not currently regulated under federal law as a hazardous waste. To address stakeholder concerns, including those raised during the SBREFA process, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. As part of this analysis, EPA generated a second full set of unit cost curves that are identical to the curves used for the national cost analysis with the exception that spent GAC and spent IX resin are considered hazardous. EPA acknowledges that if federal authorities later determine that PFAS-contaminated wastes require handling as hazardous wastes, the residuals management costs in the WBS treatment cost models are expected to be higher. See Appendix N for a sensitivity analysis describing the potential increase in costs associated with hazardous waste disposal at 100 percent of systems treating for PFAS. The costs estimated in Appendix N are consistent with EPA OLEM's "Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances" (U.S. EPA, 2020b).

Abbreviations: HFPO-DA – hexafluoropropylene oxide dimer acid; PFAS – per and polyfluoroalkyl substances; PFBS – perfluorobutanesulfonic acid; PFNA – perfluorononanoic acid; POU – point-of-use; WBS – work breakdown structure.

6 Benefits Analysis

6.1 Introduction

This chapter discusses the potential quantified and nonquantifiable²⁵ benefits to human health resulting from changes in PFAS levels in drinking water due to implementation of the proposed rule, as well as several regulatory alternatives. EPA's quantification of health benefits resulting from reduced PFAS exposure in drinking water was driven by PFAS occurrence estimates, pharmacokinetic (PK) model availability, information on exposure-response relationships, and available information to monetize avoided cases of illness. EPA either quantitatively assesses or qualitatively discusses health endpoints associated with exposure to PFAS. EPA assesses potential benefits quantitatively if evidence of exposure and health effects is likely, it is possible to link the outcome to risk of a health effect, and there is no overlap in effect with another quantified endpoint in the same outcome group. Only a subset of the avoided morbidity and mortality stemming from reduced PFAS levels in drinking water can be quantified and monetized. The monetized benefits evaluated in the Economic Analysis for the proposed rule include changes in human health risks associated with cardiovascular disease (CVD) and infant birth weight from reduced exposure to PFOA and PFOS in drinking water and renal cell carcinoma from reduced exposure to PFOA. EPA also quantified benefits from reducing bladder cancer risk due to the co-removal of non-PFAS pollutants via the installation of drinking water treatment, discussed in greater detail in Section 6.7. EPA was not able to quantify or monetize other benefits, including those related to possible immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, or other outcomes. EPA discusses these benefits qualitatively in more detail below in Section 6.2 of the Economic Analysis.

EPA analyses the quantified costs and benefits of setting individual MCLs for PFOA and PFOS at 4.0 ppt, 5.0 ppt, and 10.0 ppt, referred to as Options 1a through 1c respectively. As discussed in Section 2.1, the regulatory options include treatment thresholds that would reduce PFAS levels in finished drinking water by various amounts. The change in PFAS levels at a particular water system depends on baseline PFAS levels estimated using the occurrence model (Section 4.4) and the PFAS treatment threshold specified under each regulatory alternative.

EPA notes that the quantified benefits alone of this analysis are a significant underestimate of the total benefits expected to result from this rule. Hence, as mandated by SDWA section 1412(b)(3)(C), EPA has considered both quantifiable and nonquantifiable benefits in informing its decision making that the costs of this rule are clearly justified by the benefits.

6.1.1 Chapter Overview

Section 6.2 provides an overview of the health benefits categories considered in the analysis of reductions of PFAS in drinking water. In addition to describing the benefits EPA is able to quantify, this section includes a robust qualitative discussion of nonquantifiable benefits. Because of the broad adverse health impacts of PFAS on many endpoints, the nonquantifiable benefits of this proposed rule are likely substantial. Section 6.3 describes the application of EPA's pharmacokinetic models for PFAS to estimate changes in blood serum concentrations under each regulatory alternative. Section 6.4 presents the methodology and results of the

²⁵ Nonquantifiable benefits are discussed qualitatively.

impacts of the PFAS regulatory alternatives on a subset of developmental outcomes, namely infant birth weight. Section 6.5 presents the methodology and results of the impacts of the PFAS regulatory alternatives on cardiovascular disease (CVD) incidence. Section 6.6 presents the methodology and results of the impacts of the PFAS regulatory alternatives on the incidence of Renal Cell Carcinoma (RCC), one of the cancers with known association to PFAS exposure. Section 6.7 presents the methodology and results of the impacts of the PFAS regulatory alternatives on DBP formation and the associated incidence of bladder cancer. Finally, Section 6.8 describes limitations and uncertainties of the benefits analyses.

6.1.2 Uncertainty Characterization

EPA characterizes sources of uncertainty in its analysis of potential quantified benefits resulting from changes in PFAS levels in drinking water. The analysis reports uncertainty bounds for benefits estimated in each health endpoint category modeled for the proposed rule. Each lower (upper) bound value is the 5th (95th) percentile of the category-specific benefits estimate distribution represented by 4,000 Monte Carlo draws. Table 6-1 provides an overview of the specific sources of uncertainty that EPA quantified in this benefits analysis. In addition to these sources of uncertainty, reported uncertainty bounds also reflect the following upstream sources of uncertainty: baseline PFAS occurrence (Section 4.4), affected population size and demographic composition (Section 4.3), and the magnitude of PFAS concentration reductions (Section 4.4). These analysis-specific sources of uncertainty are further described in Appendix L.

Table 6-1: Quantified Sources of Uncertainty in Benefits Estimates

Source	Description of Uncertainty
Health effect-serum PFAS slope factors	The slope factors that express the effects of serum PFOA and serum PFOS on health outcomes (birth weight, CVD, and RCC) are based either on EPA meta-analyses or high-quality studies that provide a central estimate
	and a confidence interval for the slope factors. To characterize uncertainty, EPA assumed that these slope factors have a normal distribution with a mean set at the central estimate and the standard deviation set at the estimated standard error.
RCC risk reduction cap	EPA implemented a cap on the cumulative RCC risk reductions due to reductions in serum PFOA based on the PAF estimates for a range of cancers and environmental contaminants. This parameter is treated as uncertain; its uncertainty is characterized by a log-uniform distribution with a minimum set at the smallest PAF estimate identified in the literature and a maximum set at the largest PAF estimate identified in the literature.
	The central estimate for the PAF is the mean of this log-uniform distribution.

Abbreviations: PFAS – per and polyfluoroalkyl substances; PFOA – perfluorooctanoic acid; PFOS – perfluorooctane sulfonic acid; RCC – renal cell carcinoma; PAF – population attributable fraction.

^aThe slope factors contributing to the CVD benefits analysis include the relationship between total cholesterol and PFOA and PFOS, and the relationship between blood pressure and PFOS.

EPA did not characterize the following sources of potentially quantifiable uncertainty: U.S. population life tables (see Section 6.1.4), annual all-cause and health outcome-specific mortality rates, coefficients of the CVD risk model linking total cholesterol (TC), high-density lipoprotein cholesterol (HDLC), and blood pressure (BP) to cardiovascular event incidence (Goff et al., 2014), CVD risk model predictors (e.g., share of smokers) estimated from health survey data,

prevalence of CVD event history in the U.S. population, distribution of CVD events by type, the estimated infant mortality-birth weight slope factor (See Section 6.4.3.1), state-level distributions of infant births and infant deaths over discrete birth weight ranges, the 200-g cap on birth weight changes estimated under the rule, cost of illness estimates for all modeled non-fatal health outcomes, the Value of Statistical Life reference value, the Value of Statistical Life income elasticity value used to approximate the Value of Statistical Life income growth adjustment, and the gross domestic product per capita projection used for the Value of Statistical Life income growth adjustment (see Appendix J). EPA expects that the sources listed in Table 6-1, in addition to uncertainty surrounding the estimates of PFAS occurrence, affected population size, and the magnitude of PFAS reduction, account for a substantial portion of the uncertainty in the benefits analysis.

6.1.3 Summary of Quantified National Benefits Estimates of the Proposed Rule

This section provides summary outputs for the benefits analysis of the proposed rule as well as Options 1a-c. Total annual benefits include human health risk reduction benefits for the health outcomes listed in Section 6.1.1. EPA annualized benefit values for each endpoint at two discount rates, 3 percent and 7 percent. Both the expected value and the 90 percent confidence interval is provided.

As discussed in Section 2.1, for purposes of this analysis, EPA is considering the benefits analysis for the proposed option to be representative of the alternate regulatory approach where PFHxS, PFNA, PFBS, and HFPO-DA would be regulated by individual MCLs in addition to or instead of using the HI approach.

Table 6-2: National Annualized Benefits, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0; Million \$2021)

	3% Discount Rate			7% Discount Rate			
	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Annualized CVD Benefits	\$111.78	\$533.48	\$1,051.00	\$85.94	\$421.10	\$822.88	
Annualized Birth Weight Benefits	\$97.36	\$177.66	\$279.49	\$74.62	\$139.01	\$219.43	
Annualized RCC Benefits	\$54.23	\$300.56	\$758.03	\$45.36	\$217.37	\$515.89	
Annualized Bladder Cancer Benefits	\$173.09	\$221.30	\$273.62	\$102.08	\$130.63	\$161.56	
Total Annualized Rule Benefits ^b	\$659.91	\$1,232.98	\$1,991.51	\$477.69	\$908.11	\$1,462.43	

Abbreviations: CVD – cardiovascular disease; RCC – renal cell carcinoma.

Note: Detail may not add exactly to total due to independent rounding. Percentiles cannot be summed because health effects are not perfectly correlated.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 6-3: National Annualized Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ppt; Million \$2021)

	3% Discount Rate			7% Discount Rate			
	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Annualized CVD Benefits	\$110.45	\$525.05	\$1,035.36	\$86.32	\$414.45	\$817.79	
Annualized Birth Weight Benefits	\$95.73	\$175.05	\$276.44	\$74.66	\$136.97	\$217.02	
Annualized RCC Benefits	\$52.92	\$295.53	\$744.64	\$45.09	\$213.78	\$508.56	
Annualized Bladder Cancer Benefits	\$171.72	\$220.48	\$274.24	\$101.34	\$130.15	\$161.56	
Total Annualized Rule Benefits ^b	\$651.19	\$1,216.08	\$1,971.01	\$471.53	\$895.36	\$1,456.23	

Abbreviations: CVD - cardiovascular disease; RCC - renal cell carcinoma.

Note: Detail may not add exactly to total due to independent rounding. Percentiles cannot be summed because health effects are not perfectly correlated.

Table 6-4: National Annualized Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ppt; Million \$2021)

	3%	% Discount Ra	ıte	7% Discount Rate			
	5th Percentile ^a	Expected Value	95th Percentile ^a	5th Percentile ^a	Expected Value	95th Percentile ^a	
Annualized CVD Benefits	\$99.73	\$459.09	\$908.82	\$72.72	\$362.42	\$717.85	
Annualized Birth Weight Benefits	\$83.27	\$154.13	\$246.43	\$64.94	\$120.59	\$193.47	
Annualized RCC Benefits	\$42.28	\$250.60	\$643.71	\$36.32	\$182.24	\$446.80	
Annualized Bladder Cancer Benefits	\$141.17	\$183.10	\$227.85	\$83.31	\$108.08	\$135.37	
Total Annualized Rule Benefits ^b	\$553.37	\$1,046.91	\$1,706.81	\$398.21	\$773.33	\$1,292.96	

Abbreviations: CVD – cardiovascular disease; RCC – renal cell carcinoma.

Note: Detail may not add exactly to total due to independent rounding. Percentiles cannot be summed because health effects are not perfectly correlated.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 6-5: National Annualized Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ppt; Million \$2021)

	3% Discount Rate			7% Discount Rate			
	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Annualized CVD Benefits	\$51.00	\$268.78	\$571.32	\$41.85	\$212.18	\$450.51	
Annualized Birth Weight Benefits	\$43.22	\$92.70	\$164.19	\$34.18	\$72.51	\$125.80	
Annualized RCC Benefits	\$18.58	\$131.44	\$367.38	\$17.34	\$97.30	\$260.54	
Annualized Bladder Cancer Benefits	\$68.26	\$91.90	\$118.64	\$40.29	\$54.25	\$70.10	
Total Annualized Rule Benefits ^b	\$280.42	\$584.80	\$1,030.56	\$208.71	\$436.24	\$784.59	

Abbreviations: CVD – cardiovascular disease: RCC – renal cell carcinoma.

Note: Detail may not add exactly to total due to independent rounding. Percentiles cannot be summed because health effects are not perfectly correlated.

6.1.4 Life Table Modeling Background

EPA uses a life table modeling approach to evaluate reductions in CVD and cancer risk. This approach allows for internally consistent estimation of the path-dependent health effects for regulatory alternatives, including annual incidence of CVD events or cancers among those without prior history of these conditions, which is dependent on the population prevalence of these chronic conditions and survival over time.

The life table is a statistical tool used to analyze the mortality experience of a population over time. Specifically, using data on the age-specific probability of death and the initial population size (e.g., 100,000 persons), the life table computes the number of persons surviving to a specific age, the number of deaths occurring at a given age, the number of person-years lived at a given age, the number of person-years lived beyond a given age, and age-specific life expectancy. The details of standard life table calculations can be found in Anderson (1999).

The life table modeling approach extends the standard life table calculations to characterize populations with respect to their chronic condition status and estimate transitions into the subpopulation affected by the chronic condition. ²⁶ EPA has previously used life table approaches in regulatory analyses, including the analysis of lead-associated health effects in the 2015 Benefit and Cost Analysis for the Effluent Limitations Guidelines, Standards for the Steam Electric

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

²⁶ For example, a benefits model that evaluates the impact of contaminant exposure on incidence of cancer—a chronic condition—would need to estimate the number of persons who are cancer free and, therefore, are eligible for the estimation of new cancer risk (i.e., the risk of transition into the subpopulation affected by the chronic condition).

Power Generating Point Source Category (U.S. EPA, 2015), and PM_{2.5}-related health effects in revisions to the National Ambient Air Quality Standards for ground-level ozone (U.S. EPA, 2008). Other examples of the use of a life table approach among federal agencies include EPA's analysis of Benefits and Costs of the Clean Air Act from 1990 to 2020 (U.S. EPA, 2011a) and the Occupational Safety and Health Administration (OSHA) assessment of lifetime excess lung cancer, nonmalignant respiratory disease mortality, and silicosis risks from exposure to respirable crystalline silica (OSHA, 2010; OSHA, 2016). Additionally, the Agency sought advice from the EPA Science Advisory Board on the use of the life table in this application and they supported this approach (U.S. EPA, 2022k). See Appendix G for details on application of the life table for the CVD benefits analysis. See Appendix H for details on application of the life table for cancer benefits analyses.

6.2 Overview of Benefit Categories

EPA notes that much of the information included in this section is based on draft MCLG documents, which are expected to be finalized by the time of rule finalization. Therefore, statements on evidence of associations between PFOA/PFOS and health effects may be updated. Statements on evidence of associations between other PFAS compounds and health effects may be updated as additional assessments are conducted and finalized. EPA's decision to quantify health benefits resulting from reduced PFAS exposure in drinking water is driven by the availability of PFAS related occurrence estimates, pharmacokinetic (PK) models, and information on exposure-response relationships. In this benefits analysis, EPA either quantitatively assesses or qualitatively discusses the health endpoints associated with exposure to PFAS; EPA assesses potential benefits quantitatively if (1) there is indicative (likely) evidence of a relationship between exposure and a health effect response, (2) it is possible to link the health outcome (e.g., CVD) to risk of a health effect (e.g., increased total cholesterol), and (3) there is no overlap in effect with another quantified endpoint in the same outcome group.

EPA describes occurrence modeling information in Section 4.4. Table 6-6 presents an overview of the categories of health benefits expected to result from the implementation of treatment that reduces PFAS levels in drinking water. The PFAS compounds that EPA identified as having indicative evidence linking exposure to a particular health endpoint, as well as compounds having reliable PK models estimating the distribution to PFAS compounds throughout the body, include PFOA, PFOS, and PFNA.²⁷

As seen in Table 6-6, only a small subset of the potential health effects of reduced PFAS levels in drinking water can be quantified and monetized. The monetized benefits evaluated in this proposed rulemaking include CVD, infant birth weight, and RCC. EPA also quantified benefits from reducing bladder cancer risk due to the reduction of DBP formation as a result of the coremoval of organic carbon via the installation of additional treatment for PFAS (Cantor et al., 1998; Crittenden et al., 1993; Regli et al., 2015; Weisman et al., 2022). EPA notes that the Agency anticipates additional benefits resulting from installing drinking water treatment for PFAS chemicals and the subsequent removal of co-occurring non-PFAS contaminants, including source water metals (e.g., chromium (VI)), organic regulated and unregulated contaminants, (e.g., cyanotoxins (Foreman et al., 2021)), and certain pesticides. EPA was not able to quantify

²⁷ EPA relies on the serum PFNA calculator from Lu et al. (2020). PFNA effects are described as part of a sensitivity analysis for birth weight-related benefits in Appendix K.

or monetize other benefits, including those related to possible immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, many cancers, or other outcomes discussed in Section 6.1.2. EPA discusses these benefits qualitatively in Sections 6.2.2.2 and 6.2.4.

Table 6-6: Overview of Health Benefits Categories Considered in the Analysis of Changes in PFAS Drinking Water Levels

	Health Outcome	PI	FAS Compoun	$\mathbf{d}^{\mathrm{a,b}}$	Benefits	Analysis
Category	Endpoint	PFOA	PFOS	PFNA ^d	Discussed Quantitatively	Discussed Qualitatively
Lipids	Total cholesterol (TC)	X	X	X	X	
	High-density lipoprotein cholesterol (HDLC)	X^c	X^{c}		X	
	Low-density lipoprotein cholesterol (LDLC)	X	X			X
CVD	Blood pressure (BP)		X		X	
Developmental	Birth weight	X	X	X	X	
	Small for gestational age (SGA), non-birth weight developmental	X				X
Hepatic	Alanine transaminase (ALT)	X	X			X
Immune	Antibody response (tetanus, diphtheria)	X	X			X
Metabolic	Leptin	X				X
Musculoskeletal	Osteoarthritis, bone mineral density	X				X
Cancer	Renal Cell Carcinoma (RCC)	X			X	
	Testicular	X				X

Abbreviations: PFAS – per- and polyfluoroalkyl substances.

Notes:

^aFields marked with "X" indicate the PFAS compound for which there is evidence of an association with a given health outcome in humans.

bOutcomes with indicative (likely) evidence of an association between a PFAS compound and a health outcome are assessed quantitatively unless (1) there is an overlap within the same outcome group (e.g., low density lipoprotein cholesterol overlaps with total cholesterol and small for gestational age overlaps with low birth weight), or (2) it is not possible to link the outcome to the risk of the health effect (e.g., evidence is inconclusive regarding the relationship between PFOS exposure, leptin levels and associated health outcomes). Such health outcomes are discussed qualitatively.

^cAlthough evidence of associations between HDLC and PFOA and PFOS was mixed, certain individual studies reported robust associations in general adult populations (See Section 6.2.2.1.2 on Cardiovascular Effects). Based on comments and recommendations from the EPA SAB (U.S. EPA, 2022k), EPA assessed HDLC in a sensitivity analysis (see Appendix K).

^dNote that only PFOA and PFOS effects were modeled in the assessment of benefits under the proposed rule. PFNA was modeled only in sensitivity analyses of birth weight benefits because some studies show a slight association between PFNA and birth weight effects, although the associations were not consistent (ATSDR, 2021; U.S. EPA, 2023d) and Lu et al. (2020) provides an approach for estimating PFNA blood serum levels resulting from PFNA exposures in drinking water (see Appendix K).

In Table 6-7, EPA presents an overview of the epidemiology and toxicology evidence regarding the effects of exposure to PFAS compounds on health outcomes that were examined in various EPA and ATSDR assessments. Health outcomes are classified as having:

- No evidence of an association²⁸ (signified with a dot in the table);
- Evidence of an association noted as suggestive or slight (signified with an X in the table);
- Indicative (likely) evidence of an association (signified with a green-highlighted X in the table);
- Health outcomes that are quantified in the benefits analysis for the proposed rule are signified with a bold **X***.

EPA further describes the associations, and supporting evidence of associations, in Section 6.2.2 for PFOA and PFOS and in Section 6.2.3 for additional PFAS compounds.

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²⁸ No evidence of an association is listed in instances where an absence of evidence precludes definitive conclusions about the relationship between exposure and a given health effect and also when there is evidence demonstrating that exposure does not result in a given health effect.

Table 6-7: Overview of Epidemiology and Toxicology Evidence of PFAS Effects on Health Outcomes

	Evidence Type								Н	ealth (Outcome	es									
PFAS		Lipids		CVD		CAD		Hepatic	Immune	Endocrine	Metabolic	Renal	Reproductive	Musculoskeletal	Hematologic	Other non-cancer		Cancer		Data Source(s)	Notes
IFAU	Eviden	TC	HDLC	LDLC	BP ^a (human)Heart histopathology (animal)	Birth weight	SGA, non-birth weight developmental	ALT (human) Organ weight, cell death (animal)	AbR ^a (tetanus, diphtheria) (human) Various endpoints (animal)	Thyroid hormone disruption	Leptin, body weight (human)Body fat, body weight (animal)	Uric acid (human) Organ weight (animal)	Gestational hypertension/pre- eclampsia (human)Various endpoints (animal)	Osteoarthritis, bone mineral density	Vitamin D levels, hemoglobin levels, albumin levels	Other non-cancer	RCC®	Testicular	Other		
PFOAg	Epi	X *	X	X	•	X*	X	X	X	X	X	•	X	X	•	•	X *	Xb	•	Draft MCLG 2021; ATSDR 2021; NASEM, 2022	Other non-cancer: neurological effects, respiratory effects, gastrointestinal
	Tox	•	•	•	•	X *	X	X	X	X	•	•	X	X	•	X	•	•	•	Draft MCLG 2021; ATSDR 2021	Other non-cancer: neurological effects, respiratory effects, gastrointestinal
PFOS ^g	Epi	X*	X	X	X	X * ^c	•	X	X	X	•	•	Xe	•	•	•	X	•	X	Draft MCLG 2021; ATSDR 2021; NASEM, 2022	Other non-cancer: neurological effects, gastrointestinal
	Tox	•	•	•	•	X	X	X	X	X	•	•	X	•	•	X	•	•	X	Draft MCLG 2021; ATSDR 2021	Other non-cancer: neurological effects, gastrointestinal

Table 6-7: Overview of Epidemiology and Toxicology Evidence of PFAS Effects on Health Outcomes

	Evidence Type									ealth (Outcome	es									
PFAS			Lipids			Developmental		Hepatic	Immune	Endocrine	Metabolic	Renal	Reproductive	Musculoskeletal	Hematologic	Other non-cancer		Cancer		Data Source(s)	Notes
ITAU	Eviden	TC	HDLC	LDLC	BP ^a (human)Heart histopathology (animal)	Birth weight	SGA, non-birth weight developmental	ALT (human) Organ weight, cell death (animal)	AbR ^a (tetanus, diphtheria) (human) Various endpoints (animal)	Thyroid hormone disruption	Leptin, body weight (human)Body fat, body weight (animal)	Uric acid (human) Organ weight (animal)	Gestational hypertension/pre- eclampsia (human)Various endpoints (animal)	Osteoarthritis, bone mineral density	Vitamin D levels, hemoglobin levels, albumin levels	Other non-cancer	RCC*	Testicular	Other		
PFBAg	Epi	•	•	•	•	•	•	•		•)	•	•							IRIS Assessment 2022; ATSDR 2021; NASEM, 2022	No associations in humans
	Tox	•			•		X	X	•	X	•	•	•	•	•	•				IRIS Assessment 2022; ATSDR 2021	Other non-cancer: ocular, respiratory (ATSDR)
PFNA ^h	Epi	X	•	X	•	X	•	•	•	•	•	•	•	•				•		ATSDR 2021; NASEM, 2022	Other non-cancer: respiratory effects
ITNA	Tox	•	•	•	•	•	•	•	X		•		•			•				ATSDR 2021	Other non-cancer: general toxicity
PFDA h	Epi	X	•	X	•	•	X	•	X	•	•	•	•	•		•		•		ATSDR 2021; NASEM, 2022	
PFDA ^h	Tox	•	•	•	•	X	X	X	X	•	•	•			•	•	•	•	•	ATSDR 2021	Other non-cancer: general toxicity

Table 6-7: Overview of Epidemiology and Toxicology Evidence of PFAS Effects on Health Outcomes

										ealth (Outcome	es									
PFAS	Evidence Type	Lipids			CVD	CVD Developmental		Hepatic	Immune	Endocrine	Metabolic	Renal	Reproductive	Musculoskeletal	Hematologic	Other non-cancer		Cancer		Data Source(s)	Notes
ITAS	Eviden	TC	HDLC	LDLC	BP ^a (human)Heart histopathology (animal)	Birth weight	SGA, non-birth weight developmental	ALT (human) Organ weight, cell death (animal)	AbR ^a (tetanus, diphtheria) (human) Various endpoints (animal)	Thyroid hormone disruption	Leptin, body weight (human)Body fat, body weight (animal)	Uric acid (human) Organ weight (animal)	Gestational hypertension/pre- eclampsia (human)Various endpoints (animal)	Osteoarthritis, bone mineral density	Vitamin D levels, hemoglobin levels, albumin levels	Other non-cancer	RCC*	Testicular	Other		
prov. ch	Epi	•		•	•	•	•	•	X	•	•	•	•	•		•		•		ATSDR 2021; NASEM, 2022	
PFHxS ^h	Tox	•	•		•	•	•	X	•	•	•		•	•	•	•				ATSDR 2021	Other non-cancer: respiratory effects
PFHxA ^g	Epi				•			•		•	•	•								IRIS Draft Assessment 2022; ATSDR 2021; NASEM, 2022	No associations in humans
	Tox	•	•	•	•	X	•	X	•	X	•	•	•	•	•	•		•		IRIS Draft Assessment 2022; ATSDR 2021	Other non-cancer: nervous, respiratory (ATSDR)
PFBS ^f	Epi	•	•	•	•						•	•	٠							EPA Human Health Toxicity Study 2021; ATSDR 2021; NASEM, 2022	No associations in humans

Table 6-7: Overview of Epidemiology and Toxicology Evidence of PFAS Effects on Health Outcomes

									Н	ealth (Outcome	es									
PFAS	Evidence Type	Lipids			CVD	CVD Developmental		Hepatic	Immune	Endocrine	Metabolic	Renal	Reproductive	Musculoskeletal	Hematologic	Other non-cancer		Cancer		Data Source(s)	Notes
TTAG	Eviden	TC	HDLC	LDLC	BP ^a (human)Heart histopathology (animal)	Birth weight	SGA, non-birth weight developmental	ALT (human) Organ weight, cell death (animal)	AbR ^a (tetanus, diphtheria) (human) Various endpoints (animal)	Thyroid hormone disruption	Leptin, body weight (human)Body fat, body weight (animal)	Uric acid (human) Organ weight (animal)	Gestational hypertension/pre- eclampsia (human)Various endpoints (animal)	Osteoarthritis, bone mineral density	Vitamin D levels, hemoglobin levels, albumin levels	Other non-cancer	RCC®	Testicular	Other		
	Tox		•	•	•	•	X	•	•	X	•	X	•	•	•	•				EPA Human Health Toxicity Study 2021; ATSDR 2021	Other non-cancer: respiratory effects (ATSDR)
PFHpA	Epi	•	•	•	•	•	•	•	•							•		•		ATSDR 2021; NASEM, 2022	No associations in humans
	Tox																			ATSDR 2021	
PFUnA	Epi	•	•	•	•	•	•	•	•	•	•		•			•		•		ATSDR 2021; NASEM, 2022	No associations in humans
	Tox					X		•				•			•					ATSDR 2021	
PFDoDA	Epi	•	•	•	•	•	•	•	•	•	•	•	•					•		ATSDR 2021; NASEM, 2022	No associations in humans
	Tox	•			•	•	•	•			•	•	•		•					ATSDR 2021	
FOSA	Epi				•	•	•				•		•			•		•		ATSDR 2021; NASEM, 2022	No associations in humans

Table 6-7: Overview of Epidemiology and Toxicology Evidence of PFAS Effects on Health Outcomes

									Н	ealth (Outcome	es									
PFAS	e Type	Lipids			CVD	Developmental		Hepatic	Immune	Endocrine	Metabolic	Renal	Reproductive	Musculoskeletal	Hematologic	Other non-cancer	Cancer		Data Source(s)		Notes
	Evidence Type	TC	HDLC	LDLC	BP ^a (human)Heart histopathology (animal)	Birth weight	SGA, non-birth weight developmental	ALT (human) Organ weight, cell death (animal)	AbR ^a (tetanus, diphtheria) (human) Various endpoints (animal)	Thyroid hormone disruption	Leptin, body weight (human)Body fat, body weight (animal)	Uric acid (human) Organ weight (animal)	Gestational hypertension/pre- eclampsia (human)Various endpoints (animal)	Osteoarthritis, bone mineral density	Vitamin D levels, hemoglobin levels, albumin levels	Other non-cancer	RCCª	Testicular	Other		
	Tox							•			•									ATSDR 2021	
HFPO- DA ^f	Epi																			EPA HFPO-DA 2021 final toxicity assessment	No data from epidemiology studies
	Tox	•		•		X		X	X			X	•		X			X		EPA HFPO-DA 2021 final toxicity assessment	Cancer: liver tumors

Notes:

[•] Health outcomes examined, no evidence of associations (also noted as inadequate, or equivocal evidence).

X Health outcomes examined, slight or suggestive evidence of associations.

X Health outcomes examined, indicative (likely) evidence of associations (also noted as supports a hazard in IRIS assessments, evidence indicates, or evidence demonstrates).

X* Health outcomes quantified in benefits analyses, indicative (likely) evidence of associations.

[[]Blank cell] Health outcome was not examined.

^aAbR: antibody response; BP: blood pressure; Epi: epidemiology; Tox: toxicology; RCC: renal cell carcinoma.

^bSupported based on PFOA HESD (2016) and Bartell et al. (2021) meta-analysis.

^cSupported by Dzierlenga et al. (2020) meta-analysis.

^dDevelopmental delays: IRIS Draft Assessments (2021).

^eAlso supported by recent meta-analysis from Gao et al. (2021) (PFOS and preeclampsia risk).

^fPublished final EPA assessments.

^gPublished draft EPA assessments.

^hUnpublished draft EPA assessments.

6.2.1 Availability of Pharmacokinetic (PK) Models

PK models describe the distribution of chemicals in the body and pharmacodynamic relation between blood concentration and clinical effects. EPA evaluated existing PFOA and PFOS PK models for their utility in predicting internal doses for use in both cancer and non-cancer doseresponse assessments (U.S. EPA, 2023d; U.S. EPA, 2023e). PFOA and PFOS PK models typically take one of three forms:

- Classical compartment models, where modelers define the body as a one- or two-compartment system with volumes and intercompartmental transfer fit specifically to the PFAS PK dataset. The most common approach for prediction of serum PFAS levels is to apply a simple single-compartment model.
- **Modified compartment models**, where modelers attempt to characterize absorption, distribution, metabolism, and/or excretion through protein-binding, cardiac output, and known renal elimination. These models also rely on fitting PFAS data to non-physiological parameters.
- Physiological-based pharmacokinetic (PBPK) models, where tissues and organs of the body are described as physiological-based compartments. In these models, transport between compartments is informed by measures of blood flow and tissue perfusion.
 These models are fit to time-course concentration data.

EPA's *Toxicity Assessment and Proposed Maximum Contaminant Level Goal for PFOA in Drinking Water* (U.S. EPA, 2023e) and *Toxicity Assessment and Proposed Maximum Contaminant Level Goal for PFOS in Drinking Water* (U.S. EPA, 2023d)²⁹ describe existing PFOA and PFOS PK models. Briefly, EPA developed single-compartment PK models for adult males and females to estimate blood serum PFOA and PFOS concentrations. These models are described in U.S. EPA (2023e, 2023d), and the application of these models in health risk benefits modeling is described in Section 6.3.

6.2.2 Benefits of PFOA and PFOS Exposure Reduction

This section provides an overview of the potential health benefits of reduced exposure to PFOA and PFOS in drinking water. These benefits are expected to be realized as avoided adverse health effects as a result of the proposed NPDWR, in addition to the benefits that EPA has quantified. EPA identified a wide range of potential health effects associated with exposure to PFOA and PFOS using five comprehensive federal government documents that summarize the recent literature on PFAS (mainly PFOA and PFOS) exposure and its health impacts: EPA's *Health Effects Support Document for PFOA and Health Effects Support Document for PFOS*, hereafter referred to as the EPA HESDs (U.S. EPA, 2016e; U.S. EPA, 2016f); EPA's *Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water* (U.S. EPA, 2023d; U.S. EPA, 2023e); and the U.S. Department of Health and Human Services Agency for Toxic Substances and Disease Registry's (ATSDR) *Toxicological Profile for Perfluoroalkyls* (ATSDR, 2021). Each source presents comprehensive literature reviews on adverse health effects associated with PFOA and PFOS.

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²⁹ For brevity, these documents are described throughout as EPA's *Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water*.

The most recent literature reviews on PFAS exposures and health impacts, which are included in EPA's *Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water*, discuss the weight of evidence supporting PFOA and PFOS associations with health outcomes as indicative (likely), inadequate, or suggestive (U.S. EPA, 2023d; U.S. EPA, 2023e). For the purposes of the reviews conducted to develop the proposed MCLGs, an association is deemed indicative when findings are consistent and supported by substantial evidence. The association is inadequate if there is a lack of information or an inability to interpret the available evidence (e.g., findings across studies). The association is suggestive if findings are consistent but supported by a limited number of studies or analyses, or only observed in certain populations or species. Note that these determinations are based on information available as of February 2022. Section 6.2.2.1 discusses PFAS-related health effects that were considered quantitatively (modeled and monetized) in the benefits analysis, while Section 6.2.2.2 discusses PFAS-related health effects that were considered only qualitatively in the benefits analysis. These sections specify whether evidence is based on animal (toxicology) or human (epidemiology) studies, or both.

6.2.2.1 Quantitative benefits of PFOA and PFOS Exposure Reduction

In this section, EPA discusses some of the health benefits expected to result from reduced exposure to PFOA and PFOS in drinking water. These benefits are expected to be realized as avoided adverse health effects as a result of the proposed NPDWR and are quantified in Sections 6.4, 6.5, and 6.6 respectively.

6.2.2.1.1 Developmental Effects

Exposure to PFOA and PFOS is linked to developmental effects such as infant birth weight, birth length, head circumference at birth, and other effects (Verner et al., 2015; U.S. EPA, 2016e; U.S. EPA, 2016f; Negri et al., 2017; ATSDR, 2018; Waterfield et al., 2020; U.S. EPA, 2023d; U.S. EPA, 2023e). Low birth weight (LBW) is an important health outcome affected by PFOA/PFOS exposure because it is a significant factor in survival rates and medical care costs among infants (ATSDR, 2021). Infants are exposed prenatally to PFOA and PFOS through maternal serum via the placenta.

Because data on the cost of incremental changes in birth weight are available from Klein et al. (2018), EPA selected birth weight as a key developmental health effect when assessing the health impacts of reduced PFOA and PFOS exposures. Epidemiology studies on PFOA supported an increased risk of LBW in infants with PFOA exposures (U.S. EPA, 2023e). Similarly, epidemiology studies on PFOS showed an increased risk of LBW infants with PFOS exposures. Overall, most epidemiology studies evaluating the association between maternal serum PFOA/PFOS and birth weight reported negative relationships (i.e., increased exposure is associated with decreased birth weight) (Darrow et al., 2013; Verner et al., 2015; Govarts et al., 2016; Negri et al., 2017; Starling et al., 2017; Sagiv et al., 2018; Chu et al., 2020; Dzierlenga et al., 2020; Wikström et al., 2020; Yao et al., 2021). Toxicology studies on PFOA further supported an association between decreased offspring weight and PFOA exposure; several studies conducted on rodents showed decreased fetal and pup weight with gestational PFOA

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³⁰ Recent evidence indicates that relationships between maternal serum PFOA/PFOS and birth weight may be impacted by changes in pregnancy hemodynamics (Sagiv et al., 2018; Steenland et al., 2018).

exposure (U.S. EPA, 2023e). Toxicology studies also reported that increased exposure to PFOS was associated with decreased body weight in rodent fetuses and pups (U.S. EPA, 2023d). For additional details on developmental effects studies and their individual outcomes, see Chapter 3.4.1 (Developmental) in U.S. EPA (2023d) and U.S. EPA (2023e). See Section 6.4 for EPA's analysis of avoided infant birth weight impacts as a result of reduced PFOA and PFOS exposure from the proposed rule.

6.2.2.1.2 Cardiovascular Effects

CVD is one of the leading causes of premature mortality in the U.S. (D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017). As discussed in EPA's *Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water*, exposure to PFOA and PFOS through drinking water contributes to increased serum PFOA and PFOS concentrations and potentially elevated levels of TC, changes in levels of HDLC, and elevated levels of systolic BP (U.S. EPA, 2023e; U.S. EPA, 2023d). Changes in TC, HDLC, and BP are associated with changes in incidence of CVD events such as myocardial infarction (MI, i.e., heart attack), ischemic stroke (IS), and cardiovascular mortality occurring in populations without prior CVD event experience (D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017).

Overall, epidemiology evidence suggested a positive association between PFOS/PFOA exposure and TC levels (i.e., increased exposure is associated with increased TC levels) (ATSDR, 2021; U.S. EPA, 2023d; U.S. EPA, 2023e). While most epidemiology studies reported positive associations between exposure to PFOA and TC, some results were not statistically significant. Epidemiology studies observed consistent positive associations between PFOA and LDLC (U.S. EPA, 2023e). Most epidemiology studies on PFOS exposure pointed to a positive association between exposure and TC levels (ATSDR, 2021). This association was observed in children as well as in the general adult population and pregnant women (U.S. EPA, 2023d). Toxicology studies generally reported decreases in serum lipids from oral exposure to PFOA and PFOS (U.S. EPA, 2023e; U.S. EPA, 2023d). Although the biological significance of the decrease in various serum lipid levels observed in animal models regardless of species, sex, or exposure paradigm is unclear, these effects do indicate a disruption in lipid metabolism, which is coherent with effects observed in humans. For additional details on the TC studies and their individual outcomes, see Chapter 3.4.4 (Cardiovascular) in U.S. EPA (2023d) and U.S. EPA (2023e).

Existing epidemiology and toxicology studies provided inadequate evidence of associations between PFOA and PFOS exposures and HDLC levels, with a mix of positive and some inverse associations in adult populations (ATSDR, 2021; U.S. EPA, 2023d; U.S. EPA, 2023e). A single study reported a statistically significant positive association between PFOA and HDLC in pregnant women (Starling et al., 2017). In children, prenatal exposure was associated with lower HDLC, especially in boys, whereas childhood exposure was associated with higher HDLC (ATSDR, 2021; U.S. EPA, 2023e). Similarly, studies did not report consistent associations between PFOS and HDLC levels (ATSDR, 2021; U.S. EPA, 2023d). Most of the evidence in adults involved cross-sectional assessments, although associations between PFOS and lower HDLC were also observed in the cohort study by P.-I. D. Lin et al. (2019). The available evidence is currently limited to a single study that reported null associations between PFOS and HDLC in pregnant women (Starling et al., 2017, U.S. EPA, 2023d). Toxicology studies of oral exposure to PFOA and PFOS reported decreases in serum lipids levels, including HDLC, after

exposure (U.S. EPA, 2023d; U.S. EPA, 2023e). Although evidence of associations between PFOA and PFOS exposures and HDLC were mixed, certain individual studies reported robust associations in general adult populations. Based on comments and recommendations from the EPA SAB on EPA's analysis of CVD risk reductions resulting from changes in PFOA/PFOS exposures (U.S. EPA, 2021a), EPA assessed HDLC in a sensitivity analysis (see Appendix K). For additional details on the HDLC studies and their individual outcomes, see Chapter 3.4.4 (Cardiovascular) of U.S. EPA (2023d) and U.S. EPA (2023e).

Epidemiology studies observed inconsistent associations between PFOA exposure and BP (ATSDR, 2021; U.S. EPA, 2023d; U.S. EPA, 2023e). Some epidemiology studies reported positive associations between PFOA exposure and risk of hypertension (defined as elevated BP) in adults, but the data were inconsistent (U.S. EPA, 2023e). Five studies in children, adolescents, and pregnant women suggested no association between PFOA exposure and elevated BP (U.S. EPA, 2023e). In adults, there was evidence of positive associations between PFOS exposure and BP, although the results were not always consistent between systolic BP and diastolic BP, and one study reported an inverse association (U.S. EPA, 2023d). However, there was overall consistent evidence of an association between PFOS and BP in studies conducted in general adult populations (U.S. EPA, 2023d). Evidence for associations between PFOS exposure and BP in children and adolescents was limited and did not suggest an association with elevated BP (U.S. EPA, 2023d). However, exposure duration was a limitation in these studies, and evidence of an association between PFOS and increased risk of hypertension, specifically, was limited and inconsistent (U.S. EPA, 2023d). ATSDR reported a single toxicology study that evaluated the association between PFOS exposure and BP; systolic BP was significantly increased in female and male offspring of exposed pregnant female rats (Rogers et al., 2014; ATSDR, 2021). For additional details on the BP studies and their individual outcomes, see Chapter 3.4.4 (Cardiovascular) in U.S. EPA (2023d) and U.S. EPA (2023e).

Given the breadth of evidence linking PFOA and PFOS exposure to effects on TC and BP in general adult populations, EPA quantified public health impacts of changes in these wellestablished CVD risk biomarkers (D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017) by estimating changes in incidence of several CVD events. Specifically, EPA assumed that PFOA/PFOS-related changes in TC and BP had the same effect on the CVD risk as the changes unrelated to chemical exposure and used the Pooled Cohort Atherosclerotic Cardiovascular Disease (ASCVD) model (Goff et al., 2014) to evaluate their impacts on the incidence of MI, IS, and cardiovascular mortality occurring in populations without prior CVD event experience (see Section 6.5). EPA observed that the direct evidence of associations between PFOA/PFOS exposure and CVD risk was limited and inconsistent (U.S. EPA, 2023e; U.S. EPA, 2023d), with mixed findings reported by one high-quality longitudinal epidemiology study (Mattsson et al., 2015) and four medium-quality cross-sectional epidemiology studies (Huang et al., 2018; Shankar et al., 2012; Hutcheson et al., 2019; Fry et al., 2017). However, inconclusive evidence of the direct association between PFOA/PFOS exposure and CVD effects from a limited collection of studies does not imply the absence of such an association. Future analyses of CVD effects using large longitudinal studies, such as the ones used to develop the ASCVD model (Goff et al., 2014), could help elucidate whether there is a consistent direct association between PFOA/PFOS and CVD risk. See Section 6.5 for EPA's analysis of reduced CVD impacts as a result of reduced PFOA and PFOS exposure from the proposed rule.

6.2.2.1.3 Renal Cell Carcinoma

Data on the association between PFOA exposure and kidney cancer (i.e., RCC) suggest a positive association between exposure and increased risk of RCC. Epidemiology studies indicated that exposure to PFOA was associated with an increased risk of RCC (CalEPA, 2021; U.S. EPA, 2016f; ATSDR, 2021 ATSDR, 2021; U.S. EPA, 2023e). In the HESD for PFOA (U.S. EPA, 2016f), EPA determined that PFOA is likely to be carcinogenic to humans (U.S. EPA, 2005c) based in part on evidence of associations between PFOA exposure and kidney cancer in humans. PFOA exposure effects on RCC were shown in two occupational population studies (Raleigh et al., 2014; Steenland et al., 2012) and two high-exposure community studies (Vieira et al., 2013; Barry et al., 2013). A recent study of the relationship between PFOA and RCC in the U.S. general population found strong evidence of a positive association between exposure to PFOA and RCC in humans (Shearer et al., 2021). In EPA's Toxicity Assessment and Proposed Maximum Contaminant Level Goal for PFOA in Drinking Water, the agency reviewed the weight of the evidence and determined that PFOA is Likely to Be Carcinogenic to Humans, as "the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor Carcinogenic to Humans." This determination is based on the evidence of kidney and testicular cancer in humans and Leydig cell tumors (LCTs), pancreatic acinar cell tumors (PACTs), and hepatocellular adenomas in rats. See Section 6.6 for EPA's analysis of the benefits of reduced RCC as a result of reduced PFOA exposures from the proposed rule.

Evidence of a positive association between PFOS exposure and kidney cancer was inconclusive; the small number and limited scope of studies at the time were inadequate to make definitive conclusions (U.S. EPA, 2016e; U.S. EPA, 2023d). One recent study observed an association between PFOS and an increased risk of RCC in the highest exposed quartile and per doubling of PFOS concentration (Shearer et al., 2021; U.S. EPA, 2023d). However, the association was no longer statistically significant after adjusting for other PFAS (Shearer et al., 2021). EPA did not report any PFOA or PFOS toxicology studies specifically relating to RCC, although there was evidence of other cancer types in rodent models treated with PFOA (U.S. EPA, 2023d; U.S. EPA, 2023e). For additional details on cancer studies and their individual outcomes, see Chapter 3.5 (Cancer) in U.S. EPA (2023d) and U.S. EPA (2023e).

6.2.2.2 Nonquantifiable Benefits of PFOA and PFOS Exposure Reduction

In this section, EPA qualitatively discusses the potential health benefits resulting from reduced exposure to PFOA and PFOS in drinking water. These nonquantifiable benefits are expected to be realized as avoided adverse health effects as a result of the proposed NPDWR, in addition to the benefits that EPA has quantified. EPA anticipates additional benefits associated with developmental, cardiovascular, hepatic, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects beyond those benefits that EPA has quantified. The evidence for these adverse health effects is briefly summarized below.

6.2.2.2.1 Developmental Effects

In addition to the infant birth weight impacts that EPA has quantified (see Section 6.4), small for gestational age (SGA) is a developmental health outcome of interest when studying potential effects of PFOA/PFOS exposure, because infants who are SGA face increased health risks during pregnancy and delivery as well as post-delivery (Osuchukwu et al., 2022). Epidemiology

evidence related to PFOA/PFOS exposure was mixed; some studies indicated increased risk of SGA with PFOA/PFOS exposure, while other studies observed null results (U.S. EPA, 2023e; U.S. EPA, 2023d). For instance, some studies suggested a potentially positive association between PFOA exposure and SGA (Govarts et al., 2018; Lauritzen et al., 2017; Y. Wang et al., 2016; U.S. EPA, 2023e). For PFOS, few patterns were discernible, and overall confidence of an association between the two factors was low (U.S. EPA, 2023d). Similarly, ATSDR found no strong associations between PFOA or PFOS exposures and increases in risk of SGA infants (ATSDR, 2021). Toxicology studies on PFOS exposures in rodents demonstrated relationships with multiple developmental endpoints including increased offspring mortality, decreased maternal body weight and body weight change, skeletal and soft tissue effects, and delayed eyeopening (U.S. EPA, 2023d). For additional details on developmental studies and their individual outcomes, see Chapter 3.4.1 (Developmental) in U.S. EPA (2023d) and U.S. EPA (2023e).

6.2.2.2.2 Cardiovascular Effects

In addition to the CVD effects that EPA quantified associated with changes in TC and BP from exposure to PFOA and PFOS (see Section 6.5), available evidence suggests an association between exposure to PFOA and PFOS and increased LDLC (ATSDR, 2021; U.S. EPA, 2023e; U.S. EPA, 2023d). High levels of LDLC lead to the buildup of cholesterol in the arteries, which can raise the risk of heart disease and stroke. Epidemiology studies showed a positive association between PFOA and PFOS exposure and LDLC levels in children (U.S. EPA, 2023e; U.S. EPA, 2023d). In particular, the evidence suggested positive associations between serum PFOA and PFOS levels and LDLC levels in adolescents ages 12–18, while positive associations between serum levels and LDLC levels in younger children were observed only for PFOA (ATSDR, 2021). Studies conducted on PFOS showed evidence of an association between exposure and LDLC levels in adults. For instance, all five epidemiology studies evaluated in EPA's *Toxicity* Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water reported positive associations, although the association was only statistically significant in obese women. Available evidence regarding the impact of PFOA and PFOS exposure on pregnant women was too limited for EPA to determine an association (ATSDR, 2021; U.S. EPA, 2023e; U.S. EPA, 2023d). Toxicology studies generally reported alterations in LDLC levels in mice and rats following oral exposure to PFOA (U.S. EPA, 2023e) or PFOS (U.S. EPA, 2023d). Although the biological significance of the decrease in various serum lipid levels observed in animal models regardless of species, sex, or exposure paradigm is unclear, these effects do indicate a disruption in lipid metabolism, which is coherent with effects observed in humans. For additional details on LDLC studies and their individual outcomes, see Chapter 3.4.4 (Cardiovascular) in U.S. EPA (2023d) and U.S. EPA (2023e).

6.2.2.2.3 Hepatic Effects

Several biomarkers can be used clinically to diagnose liver diseases, including the alanine aminotransferase (ALT). High levels of serum ALT may indicate liver damage. Epidemiology data provides consistent evidence of a positive association between PFOS/PFOA exposure and ALT levels in adults (ATSDR, 2021; U.S. EPA, 2023d; U.S. EPA, 2023e). Studies of adults showed consistent evidence of a positive association between PFOA exposure and elevated ALT levels at both high exposure levels and exposure levels typical of the general population (U.S. EPA, 2023e). There is also consistent epidemiology evidence of associations between PFOS and elevated ALT levels, although the associations observed were not large in magnitude. Study

results showed inconsistent evidence on whether the observed changes led to changes in specific liver disease (U.S. EPA, 2023d).

Associations between PFOS/PFOA exposure and ALT levels in children were less consistent than in adults (U.S. EPA, 2023d; U.S. EPA, 2023e), and PFOA toxicology studies showed increases in ALT and other liver enzymes across multiple species, sexes, and exposure paradigms (U.S. EPA, 2023e). Toxicology studies on the impact of PFOS exposure also reported increases in ALT and other liver enzyme levels in rodents, though these increases were modest (U.S. EPA, 2023d). For additional details on the ALT studies and their individual outcomes, see Chapter 3.4.2 (Hepatic) in U.S. EPA (2023d) and U.S. EPA (2023e).

6.2.2.2.4 Immune Effects

Proper antibody response helps maintain the immune system by recognizing and responding to antigens. Evidence indicates a relationship between PFOA exposure and immunosuppression; epidemiology studies showed suppression of at least one measure of the antibody response for tetanus and diphtheria among people with higher prenatal, childhood, and adult serum concentrations of PFOA (U.S. EPA, 2023e). It is less clear whether PFOA exposure impacts antibody response to vaccinations other than tetanus and diphtheria (ATSDR, 2021; U.S. EPA, 2023e). Epidemiology evidence suggests that children with preexisting immunological conditions are particularly susceptible to immunosuppression associated with PFOA exposure (U.S. EPA, 2023e). Available studies supported an association between PFOS exposure and immunosuppression in children, where increased PFOS serum levels were associated with decreased antibody production (U.S. EPA, 2023d). However, an association between PFOS and immunosuppression has not been observed to date in adults (U.S. EPA, 2023d).³¹ Other potential associations with PFOS exposure with a high degree of uncertainty included asthma and infectious diseases (e.g., the common cold, lower respiratory tract infections, pneumonia, bronchitis, ear infections; U.S. EPA, 2023d). Toxicology evidence suggested that PFOA and PFOS exposure results in effects similarly indicating immune suppression, such as reduced response of immune cells (e.g., natural killer cell activity and immunoglobulin production) (U.S. EPA, 2023d; U.S. EPA, 2023e). For additional details on antibody studies and their individual outcomes, see Chapter 3.4.3 (Immune) in U.S. EPA (2023d) and U.S. EPA (2023e).

Because evidence indicates that PFOA and PFOS exposure results in immune effects, EPA expects those impacts to potentially impact immune response to other diseases. For instance, the coronavirus disease 2019 (COVID-19) caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) rapidly evolved into a global pandemic after its first report in Wuhan, China, in December 2019. A few recent studies have considered the association between PFOA and PFOS exposure and COVID-19 infection, severity, or mortality (Catelan et al., 2021; Grandjean et al., 2020; Ji et al., 2021).

A case-control study in China (Ji et al., 2021) showed increased risks for COVID-19 infection with high urinary PFOS, PFOA, and total PFASs after adjusting for potential confounding factors including age, gender, diabetes, cardiovascular disease, and urine albumin-to-creatinine ratio. Adjusted odds ratios (ORs) were 1.94 (95% CI: 1.39, 2.96) for PFOS and 2.73 (1.71, 4.55) for PFOA. Using metabolome-wide association analysis, Ji et al. (2021) found that PFOA and

³¹ This may be due to the lack of high-quality data at present.

PFOS exposure in COVID-19 patients was associated with metabolic disturbances in biochemical pathways involved in mitochondria stress signaling and the regulation of immune function, including fatty acid oxidation, tricarboxylic acid cycle, eicosanoid, and kynurenine pathways. One cross-sectional study in Denmark (Grandjean et al., 2020) observed no association between PFOA or PFOS concentrations and severity of COVID-19 development.³² In a spatial ecological analysis, Catelan et al. (2021) showed higher mortality risk for COVID-19 in a population heavily exposed to PFAS (including PFOA, PFOS, PFHxS, PFBS, PFBA, PFPeA, PFHxA, and PFHpA) via drinking water in Veneto, Italy.

Although these studies provide a suggestion of possible associations, the body of evidence does not permit any conclusions about the relationship between COVID-19 and exposures to PFAS.

6.2.2.2.5 Endocrine Effects

Elevated thyroid hormone levels can accelerate metabolism and cause irregular heartbeat; low levels of thyroid hormone can cause neurodevelopmental effects, tiredness, weight gain, and susceptibility to the common cold. There is suggestive evidence of a positive association between PFOA/PFOS exposure and thyroid hormone disruption (ATSDR, 2021; U.S. EPA, 2023d; U.S. EPA, 2023e). Epidemiology studies reported inconsistent evidence regarding associations between PFOA and PFOS exposure and general endocrine outcomes, such as thyroid disease, hypothyroidism, and hypothyroxinemia (U.S. EPA, 2023d; U.S. EPA, 2023e). However, studies reported suggestive evidence of positive associations for thyroid stimulating hormone (TSH) in adults, and the thyroid hormone thyroxine (T4) in children (U.S. EPA, 2023d; U.S. EPA, 2023e). Toxicology studies indicated that PFOA and PFOS exposure leads to decreases in thyroid hormone levels³³ and adverse effects to the endocrine system (ATSDR, 2021; U.S. EPA, 2023e; U.S. EPA, 2023d). Despite uncertainty around the applicability of animal studies in this area, changes in thyroid hormone levels in animals did indicate PFOS and PFOA toxicity relevant to humans (U.S. EPA, 2023e; U.S. EPA, 2023d). For additional details on endocrine effects studies and their individual outcomes, see Chapter C.2 (Endocrine) in U.S. EPA (2023b) and U.S. EPA (2023c).

6.2.2.2.6 Metabolic Effects

Leptin is a hormone that balances hunger, and high leptin levels are associated with obesity, overeating, and inflammation (e.g., of adipose tissue, the hypothalamus, blood vessels, and other areas). Evidence suggests a direct association between PFOA exposure and leptin levels in the general adult population (ATSDR, 2021; U.S. EPA, 2023e). Based on a review of 69 human epidemiology studies, evidence of associations between PFOS and metabolic outcomes appears inconsistent, but in some studies, suggestive evidence was observed between PFOS exposure and leptin levels (U.S. EPA, 2023d). Studies examining newborn leptin levels did not find associations with maternal PFOA levels (ATSDR, 2021). Maternal PFOS levels were also not associated with alterations in leptin levels (ATSDR, 2021). For additional details on metabolic effect studies and their individual outcomes, see Chapter C.3 (Metabolic/Systemic) in U.S. EPA (2023b) and U.S. EPA (2023c).

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³² Note that the authors found that PFBA exposure was associated with increasing severity of COVID-19.

³³ Decreased thyroid hormone levels are associated with effects such as changes in thyroid and adrenal gland weight, hormone fluctuations, and organ histopathology (ATSDR, 2021; U.S. EPA, 2023d).

6.2.2.2.7 Reproductive Effects

Studies of the reproductive effects from PFOA/PFOS exposure have focused on associations between exposure to these contaminants and increased risk of gestational hypertension and preeclampsia in pregnant women (ATSDR, 2021; U.S. EPA, 2023d; U.S. EPA, 2023e). Gestational hypertension (high BP during pregnancy) can lead to fetal problems such as poor growth and stillbirth. Preeclampsia—instances of gestational hypertension where the mother also has increased levels of protein in her urine—can similarly lead to potentially fatal fetal problems and maternal complications. The epidemiology evidence yields mixed (positive and non-significant) associations, with some suggestive evidence supporting positive associations between PFOA/PFOS exposure and both preeclampsia and gestational hypertension (ATSDR, 2021; U.S. EPA, 2023d; U.S. EPA, 2023e). For additional details on reproductive effects studies and their individual outcomes, see Chapter C.1 (Reproductive) in U.S. EPA (2023b) and U.S. EPA (2023c).

6.2.2.2.8 Musculoskeletal Effects

Adverse musculoskeletal effects such as osteoarthritis and decreased bone mineral density impact bone integrity and cause bones to become brittle and more prone to fracture. There is limited evidence from studies pointing to effects of PFOS on skeletal size (height), lean body mass, and osteoarthritis (U.S. EPA, 2023d). Epidemiology evidence suggested that PFOA exposure may be linked to decreased bone mineral density, bone mineral density relative to bone area, height in adolescence, osteoporosis, and osteoarthritis (ATSDR, 2021; U.S. EPA, 2023e). Evidence from four PFOS studies suggested that PFOS exposure has a harmful effect on bone health, particularly measures of bone mineral density, with more statistically significant effects occurring among females (U.S. EPA, 2023d). Some studies found that PFOA/PFOS exposure was linked to osteoarthritis, in particular among women under 50 years of age (ATSDR, 2021). However, other reviews reported mixed findings on the effects of PFOS exposure including decreased risk of osteoarthritis, increased risk for some demographic subgroups, or no association (ATSDR, 2021). For additional details on musculoskeletal effects studies and their individual outcomes, see Chapter C.8 (Musculoskeletal) in U.S. EPA (2023b) and U.S. EPA (2023c).

6.2.2.2.9 Cancer Effects

In EPA's *Toxicity Assessment and Proposed Maximum Contaminant Level Goal for PFOA in Drinking Water* the Agency evaluates the evidence for carcinogenicity of PFOA that has been documented in both epidemiological and animal toxicity studies. The evidence in epidemiological studies is primarily based on the incidence of kidney and testicular cancer, as well as potential incidence of breast cancer in genetically susceptible subpopulations. Other cancer types have been observed in humans, although the evidence for these is generally limited to *low* confidence studies. The evidence of carcinogenicity in animal models is provided in three chronic oral animal bioassays in Sprague-Dawley rats which identified neoplastic lesions of the liver, pancreas, and testes (U.S. EPA, 2023e). EPA determined that PFOA is *Likely to Be Carcinogenic to Humans*, as "the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor *Carcinogenic to Humans*." This determination is based on the evidence of kidney and testicular cancer in humans and LCTs, PACTs, and hepatocellular adenomas in rats (U.S. EPA, 2023e). EPA's benefits analysis for avoided RCC cases from reduced PFOA exposure is detailed in Section 6.6.

In EPA's *Toxicity Assessment and Proposed Maximum Contaminant Level Goal for PFOS in Drinking Water* the Agency evaluates the evidence for carcinogenicity of PFOS and concluded that several epidemiological studies and a single chronic cancer bioassay comprise the evidence database for the carcinogenicity of PFOS (U.S. EPA, 2023d). The available epidemiology studies report elevated risk of bladder, prostate, kidney, and breast cancers after chronic PFOS exposure. However, in developing this proposal, EPA did not identify information to quantify the benefits that reducing PFOS would have on reducing various cancers in humans. The sole animal chronic cancer bioassay study provides support for multi-site tumorigenesis in male and female rats. EPA reviewed the weight of the evidence and determined that PFOS is *Likely to Be Carcinogenic* to Humans, as "the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor *Carcinogenic to Humans*."

EPA anticipates there are additional nonquantifiable benefits related to potential testicular, bladder, prostate, kidney, and breast carcinogenic effects summarized above. For additional details on cancer studies and their individual outcomes, see Chapter 3.5 (Cancer) in U.S. EPA (2023e) and U.S. EPA (2023d).

6.2.3 Summary of Health Information Considered in the Economic Analysis

After assessing available health and economic information, EPA was unable to quantify the benefits of avoided health effects discussed above. The Agency prioritized health endpoints with the strongest weight of evidence conclusions for this assessment and readily available data for monetization, namely cardiovascular effects, developmental effects, and carcinogenic effects. Several other health endpoints that had indicative evidence of associations with exposure to PFOA and PFOS have not been selected for the economic analysis:

- While immune effects had indicative evidence of associations with exposure to PFOA and PFOS, EPA did not identify the necessary information to connect the measured biomarker responses (i.e., decrease in antibodies) to a clinical effect that could be valued in the economic analysis;
- Evidence indicates associations between PFOA and PFOS exposure and hepatic effects, such as increases in ALT. However, EPA is not able to model this health endpoint because ALT is a non-specific biomarker.³⁴ Similar challenges with non-specificity of the biomarkers representing metabolic effects (i.e., leptin) and musculoskeletal effects (i.e., bone density) prevented economic analysis of these endpoints;
- There is indicative evidence of association with exposure to PFOA for testicular cancer; however, the available slope factor implied small changes in the risk of this endpoint. Furthermore, testicular cancer is rarely fatal which implies low expected economic value

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³⁴ Elevated ALT levels could be one of several contributors to the non-alcoholic fatty liver disease. Additionally, high ALT levels can be associated with alcohol consumption, heart failure, hepatitis (A, B, and C), medication use (e.g., Tylenol and statins), and obesity (Mayo Clinic, 2022) and this wide range of associations makes it difficult to model economic benefits of non-specific ALT level changes in response to reduced exposures.

- of reducing this risk because Value of Statistical Life is the driver of economic benefits evaluated in the EA;
- Finally, other health endpoints, such as small for gestational age and LDLC effects, were not modeled in the EA because they overlap with effects that EPA did model. For example, SGA infants are often born at low birth weight or receive similar care to infants born at low birth weight. LDLC is a component of total cholesterol and could not be modeled separately as EPA used total cholesterol as an input to the ASCVD model to estimate CVD outcomes.

6.2.4 Nonquantifiable Benefits of PFAS in Proposed Rule and PFAS Expected to be Co-Removed

EPA also qualitatively summarized the potential health benefits resulting from reduced exposure to PFAS other than PFOA and PFOS in drinking water. The proposed option and all regulatory alternatives are expected to result in additional benefits that have not been quantified. The proposed option will reduce exposure to PFHxS, HFPO-DA, PFNA, and PFBS to below their respective Health Based Water Concentrations (HBWCs). Benefits from avoided cases of the adverse health effects discussed below are expected from the proposed rule due to co-occurrence of these contaminants in source waters containing PFOA and/or PFOS, documented in detail in the *Technical Support Document - Per- and Polyfluoroalkyl Substances (PFAS) Occurrence & Contaminant Background* (U.S. EPA, 2023g). EPA also expects that compliance actions taken under the proposed rule will remove additional unregulated co-occurring PFAS contaminants where present because the best available technologies have been demonstrated to co-remove additional PFAS. Treatment responses implemented to reduce PFOA and PFOS exposure under the proposed option and Options 1a-c are likely to remove some amount of additional PFAS contaminants where they co-occur.

Ion exchange (IX) and granulated activated carbon (GAC) are effective at removing PFAS; there is generally a linear relationship between PFAS chain length and removal efficiency, shifted by functional group (McCleaf et al., 2017; Sörengård, 2020). Perfluoroalkyl sulfonates (PFSAs), such as PFOS, are removed with greater efficiency than corresponding perfluoroalkyl carboxylates (PFCAs), such as PFOA, of the same carbon backbone length (Appleman et al., 2014; Du, 2014; Eschauzier et al., 2012; Ochoa-Herrera et al., 2008; Zaggia et al., 2016). Generally, for a given water type and concentration, PFSAs are removed approximately as effectively as PFCAs, which have two additional fully perfluorinated carbons in the carbon backbone. For example, PFHxS (i.e., sulfonic acid with a six-carbon backbone) is removed approximately as well as PFOA (i.e., carboxylic acid with an eight-carbon backbone) and PFHxA (i.e., carboxylic acid with a six-carbon backbone). Further, PFAS compounds with longer carbon chains display lower percentage decreases in average removal efficiency over time (McCleaf et al., 2017).

In cases where the six PFAS included in the proposed rule occur at concentrations above their respective regulatory standards, there is also an increased probability of co-occurrence of additional unregulated PFAS. Further, as the same technologies also remove other long-chain and higher carbon/higher molecular weight PFAS, EPA expects that treatment will provide

additional public health protection and benefits due to co-removal of unregulated PFAS that may have adverse health effects. While EPA has not quantified these additional benefits, the Agency believes these important co-removal benefits further enhance public health protection.

EPA identified a wide range of potential health effects associated with exposure to PFAS compounds other than PFOA and PFOS using documents that summarize the recent literature on exposure and associated health impacts: ATSDR's Toxicology Profile for Perfluoroalkyls (ATSDR, 2021); EPA's summary of HFPO-DA toxicity (U.S. EPA, 2021c); publicly available IRIS assessment for PFBA and draft IRIS assessments for PFDA, and PFHxA (; U.S. EPA, 2022f; U.S. EPA, 2022g); a human health assessment for PFBS (U.S. EPA, 2021d); and the recent National Academies of Sciences, Engineering, and Medicine Guidance on PFAS Exposure, Testing, and Clinical Follow-up (NASEM, 2022). Note that the determinations of associations between PFAS compounds and associated health effects are based on information available as of May 2022, and that the finalization of the IRIS assessments may result in slight changes to the discussion of evidence.

Developmental effects: Toxicology and/or epidemiology studies observed evidence of associations between birth weight and/or other developmental effects and exposure to PFBA, PFDA, PFHxS, HFPO-DA, PFNA, and PFBS. Specifically, data from toxicology studies support this association for PFBS, PFBA, and HFPO-DA, while both toxicology and epidemiology studies support this association for PFDA and PFNA (ATSDR, 2021; U.S. EPA, 2021c; U.S. EPA, 2022e; U.S. EPA, 2022f) although some mixed results have been found for birth outcomes, particularly birth weight. In general, epidemiological studies did not find associations between perfluoroalkyl exposure and adverse pregnancy outcomes (miscarriage, preterm birth, or gestational age) for PFHxS, PFNA, PFDA, or PFUnA (ATSDR, 2021; NASEM, 2022).

Cardiovascular effects: Epidemiology and/or toxicology studies observed evidence of associations between PFNA and PFDA exposures and total cholesterol, LDLC, and HDLC. Evidence for associations between PFNA exposure and serum lipids levels in epidemiology studies was mixed; associations have been observed between serum PFNA levels and total cholesterol in general populations of adults but not in pregnant women, and evidence in children is inconsistent (ATSDR, 2021). Most epidemiology studies did not observe associations between PFNA and LDLC or HDLC. Similarly inconsistent evidence was observed for PFDA (ATSDR, 2021). Other PFAS for which lipid outcomes were examined in toxicology or epidemiology studies observed limited to no evidence of associations. Studies have examined possible associations between various PFAS and blood pressure in humans or heart histopathology in animals. However, studies did not find suggestive or likely evidence for any PFAS in this summary except for PFOS.

Hepatic effects: Toxicology studies reported associations between exposure to PFAS compounds (PFBA, PFDA, PFHxA, PFHxS, HFPO-DA, and PFBS) and hepatotoxicity following inhalation, oral, and dermal exposure in animals. The results of these studies provide strong evidence that the liver is a sensitive target of PFHxS, PFNA, PFDA, PFUnA, PFBS, PFBA, PFDoDA, and PFHxA toxicity. Observed effects in rodents include increases in liver weight, hepatocellular hypertrophy, hyperplasia, and necrosis (ATSDR, 2021; U.S. EPA, 2021c; U.S. EPA, 2022f; U.S. EPA, 2022f; U.S. EPA, 2022g). Increases in serum enzymes (such as

ALT) and decreases in serum bilirubin were observed in one epidemiologic study of PFHxS, and mixed effects were observed in epidemiologic studies for PFNA (ATSDR, 2021).

Immune effects: Epidemiology studies have reported evidence of associations between PFDA and PFHxS exposure and antibody response to tetanus or diphtheria. There is also some limited evidence for decreased antibody response for PFNA, PFUnA, and PFDoDA, although many of the studies did not find associations for these compounds. There is limited evidence for associations between PFHxS, PFNA, PFDA, PFBS, and PFDoDA and increased risk of asthma due to the small number of studies evaluating the outcome and/or conflicting study results. The small number of studies investigating immunotoxicity in humans following exposure to PFHpA and PFHxA did not find associations (ATSDR, 2021; U.S. EPA, 2022g, NASEM, 2022). Toxicology studies have reported evidence of associations between HFPO-DA exposure and various immune-related endpoints in animals (ATSDR, 2021; U.S. EPA, 2021c). No laboratory animal studies were identified for PFUnA, PFHpA, PFDoDA, or FOSA. A small number of toxicology studies evaluated the immunotoxicity of other perfluoroalkyls and most did not evaluate immune function. No alterations in spleen or thymus organ weights or morphology were observed in studies on PFHxS, PFBA, and PFDA. A study on PFNA found decreases in spleen and thymus weights and alterations in splenic lymphocyte phenotypes (ATSDR, 2021).

COVID-19: A cross-sectional study in Denmark (Grandjean et al., 2020) showed that PFBA exposure was associated with increasing severity of COVID-19, with an OR of 1.77 [95%] Confidence Interval (CI): 1.09, 2.87] after adjustment for age, sex, sampling site, and interval between blood sampling and diagnosis. However, the study design does not allow for causal determinations. A case-control study showed increased risk of COVID-19 infection with high urinary PFAS (including PFOA, PFOS, PFHxA, PFHpA, PFHxS, PFNA, PFBS, PFDA, PFUnA, PFDoA, PFTrDA, PFTeDA) levels (Ji et al., 2021). Adjusted odds ratios were 1.94 (95% CI: 1.39, 2.96) for PFOS, 2.73 (95% CI: 1.71, 4.55) for PFOA, and 2.82 (95% CI: 1.97–3.51) for sum PFAS, while other PFAS were not significantly associated with COVID-19 susceptibility after adjusting for confounders. In a spatial ecological analysis, Catelan et al. (2021) showed higher mortality risk for COVID-19 in a population heavily exposed to PFAS (including PFOA, PFOS, PFHxS, PFBS, PFBA, PFPeA, PFHxA, and PFHpA) via drinking water. Overall, results suggested a general immunosuppressive effect of PFAS and/or increased COVID-19 respiratory toxicity due to a concentration of PFBA in the lungs; however, the study design precludes causal determinations. Although these studies provide a suggestion of possible associations, the body of evidence does not permit any conclusions about the relationship between COVID-19 infection, severity, or mortality, and exposures to PFAS.

Endocrine effects: Epidemiology studies have observed associations between serum PFHxS, PFNA, PFDA, and PFUnA and thyroid stimulating hormone (TSH), triiodothyronine (T3), or thyroxine (T4) levels or thyroid disease, however the results are not consistent across studies and a larger number of studies have not found associations (ATSDR, 2021; NASEM, 2022). Toxicology studies have reported associations between thyroid hormone disruption in animals and exposure to PFBA, PFHxA, and PFBS (U.S. EPA, 2021d; U.S. EPA, 2022e; U.S. EPA, 2022g).

Metabolic effects: Epidemiology and toxicology studies have examined possible associations between various PFAS and metabolic effects, including leptin, body weight, or body fat in

humans or animals (ATSDR, 2021). However, evidence of associations was not suggestive or likely for any PFAS in this summary except for PFOA. Evidence did not include changes such as body weight gain, pup body weight, or other developmentally focused weight outcomes (ATSDR, 2021; NASEM, 2022).

Renal effects: A small number of epidemiology studies with inconsistent results evaluated possible associations between PFHxS, PFNA, PFDA, PFBS, PFDoDA, or PFHxA and renal functions (including estimated glomerular filtration rate and increases in uric acid levels) (ATSDR, 2021; NASEM 2022). Toxicology studies have not observed impaired renal function or morphological damage following exposure to PFHxS, PFDA, PFUnA, PFBS, PFBA, PFDoDA, or PFHxA. Associations with kidney weight in animals were observed for PFBS and HFPO-DA (ATSDR, 2021; U.S. EPA, 2021c; U.S. EPA, 2021d).

Reproductive effects: A small number of epidemiology studies with inconsistent results evaluated possible associations between reproductive hormone levels and PFHxS, PFNA, PFUnA, PFDoDA, or PFHxA. Some associations between PFAS (PFHxS, PFNA, PFDA) exposures and sperm parameters have been observed, but often only one sperm parameter was altered. While there is suggestive evidence of an association between PFHxS or PFNA exposure and an increased risk of early menopause, this may be due to reverse causation since an earlier onset of menopause would result in a decrease in the removal of PFAS in menstrual blood. Epidemiological studies provide mixed evidence of impaired fertility (increased risks of longer time to pregnancy and infertility), with some evidence for PFHxS PFNA, PFHpA, and PFBS but the results are inconsistent across studies or were only based on one study (ATSDR, 2021). Toxicology studies have evaluated the potential histological alterations in reproductive tissues, alterations in reproductive hormones, and impaired reproductive functions. No effect on fertility was observed for PFBS, PFHxS or PFDoDA, and no histological alterations were observed for PFBS, PFHxS, and PFBA. One study found alterations in sperm parameters and decreases in fertility in mice exposed to PFNA, and one study for PFDoDA observed ultrastructural alterations in the testes (ATSDR, 2021).

Musculoskeletal effects: Epidemiology studies observed evidence of associations between PFNA and PFHxS and musculoskeletal effects including osteoarthritis and bone mineral density, but data are limited to two studies (ATSDR, 2021). Epidemiology studies reported limited to no evidence of associations between exposure to PFDA and musculoskeletal effects. Toxicology studies reported no morphological alterations in bone or skeletal muscle in animals exposed to PFBA, PFHxA, PFHxS, or PFBS (ATSDR, 2021).

Hematological effects: A single epidemiologic study reported on blood counts in pregnant women exposed to PFHxA (U.S. EPA, 2023d). Epidemiological data were not identified for the other PFAS (ATSDR, 2021). A limited number of toxicology studies observed alterations in hematological indices following exposure to higher doses of PFHxS, PFDA, PFUnA, PFBS, PFBA, PFDoDA, or PFHxA (ATSDR, 2021). Toxicology studies observed evidence of association between HFPO-DA exposure and hematological effects, including decreases in RBC number, hemoglobin, and percentage of RBCs in the blood (U.S. EPA, 2021c).

Other non-cancer effects: A limited number of epidemiology and toxicology studies have examined possible associations between various PFAS and dermal, ocular, and other non-cancer effects. However, the evidence does not support associations for any PFAS compound in this

summary except for PFOA and PFOS (ATSDR, 2021; U.S. EPA, 2021d; U.S. EPA, 2022e; U.S. EPA, 2022f; U.S. EPA, 2022g).

Cancer effects: A small number of epidemiology studies reported limited associations between multiple PFAS and cancer effects. No consistent associations were observed for breast cancer risk for PFHxS, PFNA, PFHpA, or PFDoDA; increased breast cancer risks were observed for PFDA and FOSA, but this was based on a single study (Bonefeld-Jorgensen et al., 2014). No associations between PFHxS, PFNA, PFDA, or PFUnA and prostate cancer risk were observed. However, among men with a first-degree relative with prostate cancer, associations were observed for PFHxS, PFDA, and PFUnA, but not for PFNA (ATSDR, 2021). Epidemiological studies examining potential cancer effects were not identified for PFBS, PFBA, or PFHxA (ATSDR, 2021; U.S. EPA, 2022e). Aside from a study that suggested an increased incidence of liver tumors in rats exposed to high doses of HFPO-DA, toxicology studies reported no evidence of associations between exposure to other PFAS (i.e., PFDA and PFHxA) and risk of cancer (ATSDR, 2021; U.S. EPA, 2021c).

6.2.5 Sensitive Populations

SDWA section 1412(b)(3)(C) establishes requirements for EPA to develop a health risk reduction and cost analysis (HRRCA) that presents both quantifiable and nonquantifiable benefits and costs likely to occur as a result of compliance with the NPDWR. In developing this HRRCA, EPA considered adverse health effects to sensitive populations and subpopulations.

Adverse health effects of PFAS such as cancer, developmental, hepatic, immune, and serum lipid effects (see Sections 6.2.2 and 6.2.3) have been observed in the general population, including women of reproductive age. Effects have been observed in vulnerable populations of groups who have relatively high exposures, for example workers and their families who worked at and/or lived near facilities that used PFOA (such as the C8 Health Project³⁵ populations). However, data for the elucidation of differential susceptibility dependent on life stage (e.g., developing embryo/fetus, or pregnant women) are very limited or not available. Children are frequently more vulnerable to contaminants than the average adult because of the differences in their behaviors and biology. These differences can result in greater exposure and/or unique windows of developmental susceptibility during the prenatal and postnatal periods for both the pregnant mother and the developing fetus.

In determining MCLGs, EPA considers the adverse health risks to infants/children, individuals who are immunologically compromised, and the elderly to ensure the most sensitive population groups are protected. In conducting risk analyses and assessments, other agencies and organizations consider sensitive subpopulations to be pregnant women, infants/children, individuals who are immunologically compromised, and the elderly (ATSDR, 2021; CalEPA, 2021; Minnesota Pollution Control Agency, 2021). CalEPA (2021) and the Minnesota Pollution Control Agency (2021) also identify the timing of exposure to PFAS to be critical in the development of adverse health effects. There is evidence of associations with birth weight effects and exposure to PFDA, PFHxS, PFNA, PFOA, PFOS, or PFUnA (see Sections 6.2.2 and 6.2.3). There is some sex-specific variation in the toxicokinetics of PFOA in hamsters, rabbits, and rats,

³⁵ The C8 Health Project studied over 60,000 individuals who had lived, worked, or attended school for more than one year in one of six water districts contaminated by PFOA between 1950 and 2004 (Frisbee et al., 2010).

with females excreting PFOA faster than males (U.S. EPA, 2016c). Lactation and menstruation were noted as important excretory routes in females; however, further research is needed to determine whether those differences in toxicokinetics are relevant to toxicity of PFOA in humans (U.S. EPA, 2016c).

Overall, given that evidence of exposure and adverse health effects of PFAS is observed in the general population, not all potentially sensitive populations are quantified in developing this HRRCA. However, the modeled endpoints, including birth weight (Section 6.4), CVD (Section 6.5), and renal cell carcinoma (Section 6.6), are prevalent in sensitive populations (i.e., infants and the elderly).

6.2.6 Co-Removal of Additional Contaminants

Additional co-removal benefits can occur with the advanced treatment options for PFAS removal. Advanced treatment technologies including granular activated carbon (GAC), ion exchange (IX), as well as high-pressure membranes such as nanofiltration (NF) and reverse osmosis (RO) can remove many contaminants in addition to those specifically targeted by the Proposed PFAS Rule, including other contaminants that EPA may regulate in the future (Chowdhury et al., 2013; de Abreu Domingos et al., 2018; McNamara et al., 2018; Pramanik et al., 2015; Yu et al., 2012). For example, membrane technology (depending on pore size), can be used to lower DBP formation by the removal of organic carbon, and can also remove many microbial contaminants (e.g., bacteria and protozoans) of public health concern (Park et al., 2019).

Organic matter can also be removed by IX and GAC (Crittenden et al., 1993; Kim et al., 1997; Yapsakli et al., 2010; Dickenson et al., 2016; Yuan et al., 2022). Removing TOC, which functions as a DBP precursor, may also help address DBP issues, including regulated and nonregulated DBPs. Epidemiological studies have shown that increased exposure to chlorinated DBPs is associated with higher risk of bladder cancer and other adverse health outcomes (Cantor et al., 1998; Freeman et al., 2017). Weisman et al. (2022) found that approximately 8,000 of the 79,000 annual bladder cancer cases in the U.S. were potentially attributable to chlorinated DBPs in drinking water systems.

TOC removal also lowers disinfectant demand and could lower disinfectant dose requirements (Hooper et al., 2002). Membrane technology, IX, and GAC also lower nutrient availability for bacterial growth, produce a more biologically stable finished water, and facilitate management of water quality in the distribution system. Lower organic matter concentration is also associated with lower assimilable organic carbon (AOC) and nutrient availability for biofilm growth, helping maintain disinfectant residual in the distribution system, and reduce microbial risk (U.S. EPA, 2005b).

A major concern for drinking water systems is biofilm control in reducing microbial risk. One opportunistic pathogen of concern is *Legionella*, which can grow and multiply in amoeba that live in biofilms and sediments (National Academies of Sciences, 2020). Certain conditions in the distribution and plumbing systems can also support its proliferation, including low disinfectant residual (U.S. EPA, 2016i; LeChevallier, 2020). *Legionella* exposure can lead to legionellosis, Pontiac fever, or a form of pneumonia called Legionnaires' disease (National Academies of Sciences, 2020). Collier et al. (2021) estimated that in 2014 there were 11,000 cases of

Legionnaires' disease due to waterborne exposure in the U.S., with an estimated one in 10 cases leading to death.

Since membrane technology and GAC also remove SOCs, these advanced treatment options provide additional protection from exposure to chemicals associated with accidental spills or environmental runoff. EPA has previously used the term SOC to include volatile organic carbons, herbicides, pesticides, and other anthropogenic organic compounds (U.S. EPA, 1998d). One example of a volatile organic carbon that can be co-removed by GAC is dichloromethane, which has been linked to liver, neurological, and blood cell damage in addition to various cancers (U.S. EPA, 2014). EPA also identified alachlor as a herbicide that can be removed by GAC and has been linked to liver, kidneys, and spleen damage (U.S. EPA, 1998a). Another SOC example that can be removed by GAC treatment is atrazine, a pesticide that targets the endocrine system and has been associated with adverse developmental reproductive effects (U.S. EPA, 2007a). Removal of any contaminants that may face current and/or future regulation could result in additional public health protection and cost savings to a water system. As public water systems move to advanced treatment, other non-health benefits are also anticipated including better-tasting and smelling water.

6.3 Blood Serum Concentration Modeling for PFAS

6.3.1 Introduction

The U.S. EPA developed PK models to evaluate blood serum PFOA and PFOS levels in adults resulting from exposure to PFAS via drinking water. This section discusses the application of the PFOA and PFOS PK models in the context of the benefits analysis.

6.3.2 Application of PK Models to Benefits Analyses

EPA used baseline and regulatory alternative PFOA/PFOS drinking water concentrations as inputs to its PK models to estimate blood serum PFOA/PFOS concentrations for adult males and females. In this analysis, the Agency implemented an earlier version PFOA/PFOS PK model version in SafeWater MCBC. ³⁶ See EPA's *Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water* for further information on the model (U.S. EPA, 2023d; U.S. EPA, 2023e) and https://github.com/USEPA/OW-PFOS-PFOA-MCLG-support-PK-models. The PK models require total PFOA/PFOS dose in mg/kg of body weight per day to be provided as an input. EPA multiplied PFOA/PFOS drinking water concentrations in mg/L by a water intake of 0.013 L/kg of body weight per day based on EPA's Exposure Factors Handbook (U.S. EPA, 2011b) in order to compute the PFOA/PFOS dose from drinking water sources.

To estimate the total daily dose, consistent with the 2016 PFOA and PFOS health advisories (U.S. EPA, 2016e; U.S. EPA, 2016f) and EPA's *Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water* (U.S. EPA, 2023d; U.S. EPA, 2023e), EPA assumed that the dose from drinking water sources comprises 20 percent of the total daily PFOA/PFOS dose under the baseline scenario (see Section 6.3.3 for discussion of

³⁶ SafeWater MCBC was programmed for maximal computational efficiency. The implementation is mathematically consistent with what is described in the SAB documentation and associated R code, however, SafeWater performs a series of precalculations to reduce model runtime.

contributions from other sources). EPA notes that the assumed baseline percent contribution from drinking water sources does not affect the estimated changes in serum PFOA/PFOS, which is the key quantity of interest to the benefits estimation. For the PK model in humans, EPA selected a "linear" approach in which the rates in the model are all proportional to concentration. In this type of model, predicted serum concentration is proportional to the dose, with a proportionality constant that is dependent on time, but not dose. Holding the age, exposure duration, and other features of a scenario constant, doubling the dose will double the predicted serum concentration.³⁷ This implies that the change in predicted serum concentration is dependent only on the change in drinking water dose and independent of the dose from non-drinking water sources. EPA additionally assumed that non-drinking water exposure is independent of the drinking water PFOA/PFOS concentration and estimated the total regulatory alternative dose as the sum of the baseline non-drinking water dose and the regulatory alternative drinking water dose.³⁸

EPA used the PK models to evaluate the following PWS entry point (EP)-specific exposure scenarios in male and female subpopulations:

- **Lifetime baseline exposure scenario:** Lifetime exposure to baseline PFOA/PFOS drinking-water dose for cohorts of all ages alive at the start of the evaluation period in 2023 and cohorts born after 2023;
- **Lifetime regulatory alternative exposure scenario:** Lifetime exposure to regulatory alternative PFOA/PFOS drinking-water dose for cohorts born during or after 2026 (i.e., the year of full regulatory alternative implementation);
- Partial lifetime treatment exposure scenario: Exposure to baseline PFOA/PFOS drinking-water dose until age A-1 years and regulatory alternative PFOA/PFOS dose thereafter for cohorts aged A > 0 years in 2026.

EPA selected the annual midpoint (the value on June 1 of each year) of the PK-modeled serum PFOA/PFOS concentration time series to represent the annual average serum PFOA/PFOS concentrations under the baseline and regulatory options. EPA estimated changes in annual average serum PFOA/PFOS concentrations under the regulatory alternatives by subtracting baseline cohort-specific serum PFOA/PFOS concentrations from either full or partial lifetime cohort-specific serum PFOA/PFOS concentrations (as appropriate) under the regulatory alternatives. EPA applied the PFOA/PFOS blood serum concentration time series estimated

³⁷ Specifically, let $C = \alpha \cdot D_t$, where C is serum concentration, α is a proportionality constant, and D_t is the total dose. This can be expanded to $C = \alpha \cdot D_t = \alpha \cdot (D_{dw} + D_o)$, where the total dose is the sum of the dose from drinking water, D_{dw} , and from other sources, D_o . The change in concentration due to a change in dose from drinking water is then $\Delta C = \alpha \cdot \Delta D_{dw} + \alpha \cdot \Delta D_o = \alpha \cdot \Delta D_{dw}$, given that the dose from other sources is constant, $\Delta D_o = 0$.

³⁸ EPA used the fraction of exposure from drinking water under baseline conditions to estimate the total daily dose of PFOA/PFOS and the exposure from sources other than drinking water (i.e., 80 percent of the total daily dose), which did not change upon implementation of the treatment scenario. While the total change in exposure is independent of the amount of exposure from other sources, the relative change in exposure does depend on the relative amount of exposure from non-drinking water sources. A greater fraction of exposure from drinking water sources will result in a greater relative change in total exposure upon implementation of the treatment scenario. EPA also notes that, in reality, some portion of the non-drinking water exposure will be related to drinking water concentration (e.g., water used for cooking). This portion is difficult to estimate, and, depending on the relationship, there may be a time lag between the decrease in drinking water concentration and the decrease in the non-drinking water exposure.

using the PK models to all benefits analyses that considered changes in PFOA/PFOS drinking water concentrations.

The birth weight analysis focuses only on women of childbearing age defined by the CDC as those aged 15 to 44 (Ellington et al., 2020) and thus considers only maternal serum PFOA/PFOS levels. As described above, the PK models provide estimates of changes in serum PFOA/PFOS levels by PWS EP, age, and sex for each year during the period of analysis (2023 to 2104). The birth weight analysis requires a single estimate of change in maternal serum levels for each PFAS compound per year and location to evaluate potential changes in birth weight resulting from the regulatory alternatives. Therefore, EPA used the race/ethnicity-specific distribution of populations of women of childbearing age during the period of analysis to estimate average annual race/ethnicity-specific change in PFOA/PFOS levels at each PWS EP and for each year. EPA relied on the average age of race/ethnicity-specific women of childbearing age when determining PFOA/PFOS serum levels to reflect differences in maternal age across these groups. The population of women of childbearing age per PWS, race/ethnicity, age, and sex are based on population estimates for women aged 15 to 44 based on county-level data from the U.S. Census (U.S. Census Bureau, 2020a; see Appendix B).³⁹

6.3.3 Contributions from Other Sources

The regulatory alternatives considered in this economic analysis are based on potential reductions in PFOA/PFOS levels in drinking water. However, human exposures to PFOA and PFOS may also result from sources other than drinking water, including diet, ambient and indoor air, incidental soil/dust ingestion, consumer products, and others (U.S. EPA, 2023d; U.S. EPA, 2023e). In development of an MCLG for PFOA and PFOS, EPA applies a relative source contribution (RSC) to provide a margin of safety that ensures that an individual's total exposure from PFOA or PFOS does not exceed the chronic oral reference dose (RfD) derived for each contaminant's MCLG. EPA assumes that 20 percent of the exposure equal to the RfD is from drinking water and that the remaining 80 percent is from other potential sources (U.S. EPA, 2023d; U.S. EPA, 2023e).

Following a systematic review of the PFOA and PFOS source contribution literature, EPA identified ingestion of food as the dominant source of both PFOA and PFOS exposures (U.S. EPA, 2023d; U.S. EPA, 2023e). This pathway is particularly dominant due to bioaccumulation of PFOA and PFOS in food from environmental emissions, large amounts of foods being consumed, and high gastrointestinal uptake. PFOA and PFOS may be present in food due to contact with non-stick cookware or grease-proofing agents in food packaging. PFOA and PFOS have also been shown to bioaccumulate in fish and shellfish. Consumer products, including certain cosmetics, textiles, and other household goods, are also a source of PFOA and PFOS exposure. While PFAS have been detected in ambient air globally, concentrations vary widely depending on location. PFAS have been detected in soils and dust from carpets and upholstered furniture. Incidental exposures from soils and dust are particularly important exposure routes for small children, who have a higher level of hand-to-mouth behavior compared to adults. PFAS

³⁹ County-level population estimates are linked to PWSs based on the "counties served" field provided by the SDWIS 2021 Q4 database.

levels in soils and surface water can also impact PFAS levels found in air particulates, fish, dairy products, meat/poultry, and produce (ATSDR, 2021; U.S. EPA, 2023d; U.S. EPA, 2023e).

6.4 Developmental Effects

Research indicates that exposure to PFOA and PFOS is linked to developmental effects, including infant birth weight (Verner et al., 2015; Negri et al., 2017; ATSDR, 2018; Waterfield et al., 2020; U.S. EPA, 2016e; U.S. EPA, 2016f; U.S. EPA, 2023d; U.S. EPA, 2023e). The route through which infants are exposed prenatally to PFOA and PFOS is maternal blood serum via the placenta. Most studies of the association between maternal serum PFOA/PFOS and birth weight report negative relationships (Verner et al., 2015; Negri et al., 2017; Dzierlenga et al., 2020). This chapter outlines the overall methodology, assumptions, and data used for estimating changes in birth weight among infants whose mothers were exposed to PFOA and PFOS in drinking water during or prior to pregnancy. 41

EPA also considered the potential benefits from reduced exposure to PFNA that may be realized as a direct result of the proposed rule. The Agency explored the birth weight impacts of PFNA in a sensitivity analysis, using a unit PFNA reduction scenario (i.e., 1 ppt change) and Lu et al. (2020) to estimate PFNA blood serum levels resulting from PFNA exposures in drinking water. To estimate blood serum PFNA based on its drinking water concentration, EPA used a first-order single-compartment model whose behavior was previously demonstrated to be consistent with PFOA pharmacokinetics in humans (Bartell et al., 2010). In addition to the PFOA-birth weight and PFOS-birth weight effects analyzed in the EA, EPA examined the effect of inclusion of PFNA-birth weight effects using estimates from two studies (Lenters et al., 2016; Valvi et al., 2017). EPA found that inclusion of a 1 ppt PFNA reduction could increase annualized birth weight benefits 5.4-7.7-fold, relative to the scenario that quantifies a 1 ppt reduction in PFOA and a 1 ppt reduction in PFOS only. The range of estimated PFNA-related increases in benefits is driven by the exposure-response, with smaller estimates produced using the slope factors from Lenters et al. (2016), followed by Valvi et al. (2017). EPA notes that the PFNA slope factor estimates are orders of magnitude larger than the slope factor estimates used to evaluate the impacts of PFOA/PFOS reductions. EPA also notes that the PFNA slope factor estimates are not precise, with 95% CIs covering wide ranges that include zero (i.e., serum PFNA slope factor estimates are not statistically significant at 5% level). Caution should be exercised in making judgements about the potential magnitude of change in the national benefits estimates based on the results of these sensitivity analyses, although conclusions about the directionality of these effects can be inferred. EPA did not include PFNA effects in the national benefits estimates for the proposed rulemaking because of limitations associated with the UCMR 3 PFNA occurrence data and the slope factor estimates are less precise. For EPA's PFNA sensitivity analysis, see Appendix K.

6.4.1 Overview of the Birth Weight Risk Reduction Analysis

Figure 6-1 provides an overview of the approach used to quantify and value the changes in birth weight-related risks associated with reductions in exposure to PFOA and PFOS via drinking

⁴⁰ Note that recent evidence indicates that relationships between maternal serum PFOA/PFOS and birth weight may be impacted by changes in pregnancy hemodynamics (Sagiv et al., 2018; Steenland et al., 2018).

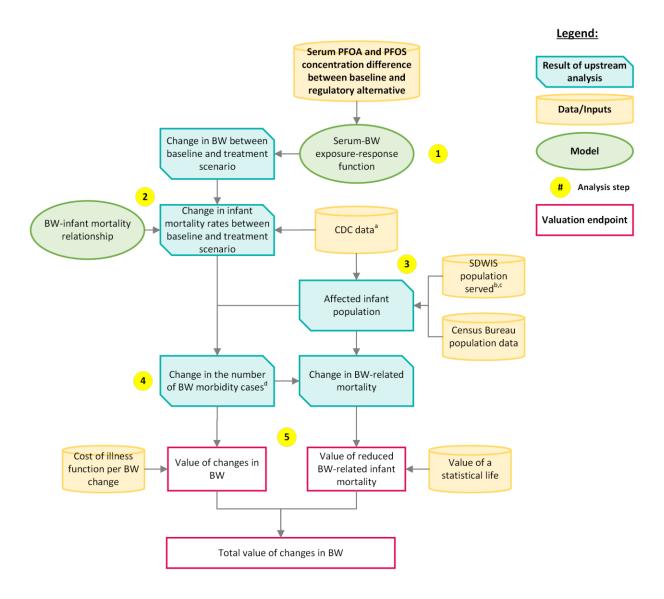
⁴¹ The PK model assumes that mothers were exposed to PFOA/PFOS from birth to the year in which pregnancy occurred.

water. Section 4.4 and Section 6.3 detail the PWS entry point (EP)-specific PFOA/PFOS drinking water occurrence estimation and modeling of serum PFOA/PFOS concentrations, respectively. EP-specific time series of the differences between serum PFOA/PFOS concentrations under baseline and regulatory alternatives are inputs into this analysis. For each EP, evaluation of the changes in birth weight impacts involves the following key steps:

- Estimating the changes in birth weight based on modeled changes in serum PFOA/PFOS levels and exposure-response functions for the effect of serum PFOA/PFOS on birth weight;
- 2. Estimating the difference in infant mortality probability between the baseline⁴² and regulatory alternatives based on changes in birth weight under the regulatory alternatives and the association between birth weight and mortality;
- 3. Identifying the infant population affected by reduced exposure to PFOA/PFOS in drinking water under the regulatory alternatives;
- 4. Estimating the changes in the expected number of infant deaths under the regulatory alternatives based on the difference in infant mortality rates and the population of surviving infants affected by increases in birth weight due to reduced PFOA/PFOS exposure; and
- 5. Estimating the economic value of reducing infant mortality based on the Value of Statistical Life and infant morbidity based on reductions in medical costs associated with changes in birth weight for the surviving infants based on the cost of illness.

Section 6.4.2 discusses the exposure-response modeling for birth weight. Section 6.4.3 describes estimation of birth weight-related mortality and morbidity impacts in the affected population. Section 6.4.4 discusses EPA's valuation methodology for reductions in birth weight-related mortality and morbidity. Section 6.4.5 presents the results of the analysis.

⁴² Based on mortality rates per state and 500 g birth weight increment from the Centers for Disease Control and Prevention (CDC) from 2012 to 2018.



Notes:

SDWIS – Safe drinking water information system, CDC – Centers for Disease Control, BW – birth weight, VSL – value of a statistical life

^aIncludes baseline state-level birth rate and average BW (varies by 100-gm BW increment) and infant mortality rate (varies by 500-gm BW increment) data distributed based on national-level race/ethnicity-specific data.

Baseline infant mortality rates, along with the BW-infant mortality relationship, are used to determine the change in infant mortality rate between the baseline and policy scenario. Birth rate and average BW data describe the affected population of infants.

Figure 6-1: Overview of Analysis of Birth Weight-Related Benefits

^bIncludes both large and small surface water and ground water systems.

^cSmall public water system exposures are extrapolated to represent exposure at the stratum and national level based on ratios of sampled to total populations served at small public water systems.

^dMorbidity cases refer to the total affected population minus infant mortality cases under the regulatory alternatives.

6.4.2 Estimation of Birth Weight Changes Between Baseline and Regulatory Alternatives

To estimate changes in birth weight resulting from reduced exposure to PFOA and PFOS under the regulatory alternatives, EPA relied on the estimated time series of changes in serum PFOA/PFOS concentrations specific to women of childbearing age and serum-birth weight exposure-response functions provided in recently published meta-analyses. The estimation of the time series of changes in serum PFOA/PFOS concentrations is explained in Section 6.3.2. EPA reviewed five recent meta-analyses of PFAS-birth weight relationships in detail. As described in Table 6-8, two of the analyses used well-documented systematic review and risk of bias (ROB) procedures to identify relevant studies in the literature (Johnson et al., 2014; Negri et al., 2017). The three other studies did not document ROB protocols and study quality evaluation criteria, however, EPA's Office of Science and Technology (EPA/OST) evaluated most of the studies used in these meta-analyses for study quality (Verner et al., 2015; Dzierlenga et al., 2020; Steenland et al., 2018). As discussed below, there was extensive overlap in the studies used in the various meta-analyses. Two of the meta-analyses included exposure-response modeling for both PFOS and PFOA (Verner et al., 2015; Negri et al., 2017), while one addressed only PFOS (Dzierlenga et al., 2020) and the remaining two addressed only PFOA (Johnson et al., 2014; Steenland et al., 2018).

Table 6-8: Summary of Studies Relating PFOA or PFOS to Birth Weight

Author	PFOA	PFOS	Documented ROB Protocols
Johnson et al. (2014)	X		X
Verner et al. (2015)	X	X	
Negri et al. (2017)	X	X	X
Steenland et al. (2018)	X		
Dzierlenga et al. (2020)		X	

Abbreviations: PFOS - perfluorooctane sulfonic acid; PFOA - perfluorooctanoic acid; ROB - risk of bias.

EPA evaluated the applicability of these studies for use in the evaluation of birth weight changes resulting from reduced PFOS and PFOA exposure based on the following criteria: number of studies, homogeneity among studies, and sensitivity analyses. Based on these considerations, the Agency selected results from Steenland et al. (2018) as the birth weight exposure-response function for PFOA and results from Dzierlenga et al. (2020) as the birth weight exposure-response function for PFOS.

Steenland et al. (2018) conducted a random effects meta-analysis based on 24 studies. The authors estimated a slope of -10.5 g birth weight per ng PFOA/mL with significant heterogeneity ($I^2 = 63\%$)⁴³ (p-value for heterogeneity <0.0001). The Agency chose the results from this study for use in the risk assessment from exposure to PFOA and benefits analysis of reducing PFOA in drinking water because it is the most recent meta-analysis on PFOA-birth weight, and it included a large number of studies.

Dzierlenga et al. (2020) conducted a random effects meta-analysis based on 32 results from 29 studies. An EPA reanalysis of this study⁴⁴ estimated a slope of -3.0 g birth weight per ng PFOS/mL with significant heterogeneity ($I^2 = 58\%$) (p-value for heterogeneity <0.001). The Agency chose the results from this study for use in the risk assessment from exposure to PFOS and benefits analysis of reducing PFOS in drinking water because it is the most recent meta-analysis on PFOS-birth weight and included a large number of the most recent studies. While sensitivity analyses suggested that results may be sensitive to the timing of blood draw, the authors observed consistent inverse associations with birth weight among those with blood measurements in early pregnancy and in later pregnancy.

Changes in serum PFOA and PFOS concentrations are calculated for each PWS EP during each year in the analysis period. EPA assumes that, given long half-lives of PFOS and PFOA, any one-time measurement during or near pregnancy is reflective of a critical window and not subject to considerable error. The mean change in birth weight per increment in long-term PFOA and PFOS exposure is calculated by multiplying each annual change in PFOA and PFOS serum concentration (ng/mL serum) by the PFOA and PFOS serum-birth weight exposure-response slope factors (g birth weight per ng/mL serum) provided in Table 6-9, respectively. The mean annual change in birth weight attributable to changes in both PFOA and PFOS exposure is the sum of the annual PFOA- and PFOS-birth weight change estimates. Appendix D provides additional details on the derivation of the exposure-response functions. Appendix K presents an analysis of birth weight risk reduction considering slope factors specific to the first trimester.

Table 6-9: Serum Exposure-Birth Weight Response Estimates

Compound	g Birth Weight/ng/mL Serum (95% CI)
PFOA ^a	-10.5 (-16.7, -4.4)
PFOS ^b	-3.0 (-4.9, -1.1)

Abbreviations: g - gram.

Notes:

^aThe serum-birth weight slope factor for PFOA is based on the main random effects estimate from Negri et al. (2017); Steenland et al. (2018).

^bThe serum-birth weight slope factor for PFOS is based on an EPA reanalysis of Dzierlenga et al. (2020).

⁴³ I² represents the proportion of total variance in the estimated model due to inter-study variation.

⁴⁴ In the original Dzierlenga et al. (2020) estimate, the authors duplicated an estimate from M. H. Chen et al. (2017) in the pooled estimate. EPA reran the analysis excluding the duplicated estimate.

EPA places a cap on estimated birth weight changes in excess of 200 g based on existing studies that found that changes to environmental exposures result in relatively modest birth weight changes (Windham et al., 2008; Klein et al., 2018; Kamai et al., 2019). 45 Modest changes in birth weight even as a result of large changes in PFOA/PFOS serum concentrations may be due to potential bias from studies only including live births (Liew et al., 2015). Additionally, the magnitude of birth weight changes may be correlated with other developmental outcomes such as preterm birth, gestational duration, fetal loss, birth defects, and developmental delays. As described in Section 6.2, these developmental outcomes have limited epidemiology and toxicology evidence showing associations with PFOA/PFOS exposure and due to this uncertainty, these outcomes were not further assessed.

6.4.3 Estimation of Birth Weight Impacts

LBW is linked to a number of health effects that may be a source of economic burden to society in the form of medical costs, infant mortality, parental and caregiver costs, labor market productivity loss, and education costs (Chaikind et al., 1991; J. R. Behrman et al., 2004; R. E. Behrman et al., 2007; Joyce et al., 2012; Kowlessar et al., 2013; Colaizy et al., 2016; Nicoletti et al., 2018; Klein et al., 2018). Recent literature also linked LBW to educational attainment and required remediation to improve student outcomes, childhood disability, and future earnings (Jelenkovic et al., 2018; Temple et al., 2010; Elder et al., 2020; Hines et al., 2020 Chatterji et al., 2014; Dobson et al., 2018). EPA's analysis focuses on two categories of birth weight impacts that are amenable to monetization associated with incremental changes in birth weight: (1) medical costs associated with changes in infant birth weight and (2) the value of avoiding infant mortality at various birth weights.

The birth weight literature related to other sources of economic burden to society (e.g., parental and caregiver costs and productivity losses) is limited in geographic coverage, population size, and range of birth weights evaluated and therefore cannot be used in the economic analysis of birth weight effects from exposure to PFOA/PFOS in drinking water (ICF, 2021). The following sections summarize the relationship between infant mortality and birth weight as well as methods used to estimate changes in the number of infant deaths and the number of surviving infants whose birth weight is affected by reduced PFOA/PFOS exposures.

6.4.3.1 Impacts of Birth Weight on Infant Mortality

Infant mortality is defined as the deaths among infants who were delivered alive but passed before their first birthday. Birth weight is a significant factor in infant survival (Jacob, 2016). Epidemiology studies in the U.S. have reported relationships between birth weight and mortality. Most of these studies typically evaluate relationships between infant mortality and birth weight above or below various birth weight thresholds (e.g., McIntire et al., 1999; Lau et al., 2013). However, even small changes in birth weight could result in substantial avoided mortality benefits.

⁴⁵ Klein et al. (2018) indicate that birth weight changes in response to reduced environmental exposures are likely to be small and simulated changes in birth weight up to 100 g. Kamai et al. (2019) found maximum changes in birth weight in response to reduced exposures to cigarette smoke of 150 g, while Windham et al. (2008) found a maximum decrement in mean birth weight of 200 g for infants of smokers.

Two studies showed statistically significant relationships between incremental changes in birth weight and infant mortality: Almond et al. (2005) and Ma et al. (2010). Ma et al. (2010) used 2001 National Center for Health Statistics (NCHS) linked birth/infant death data for singleton and multiple birth infants among subpopulations defined by sex and race/ethnicity to estimate a regression model assessing the associations between 14 key birth outcome measures, including birth weight, and infant mortality. They found notable variation in the relationship between birth weight and mortality across race/ethnicity subpopulations, with odds ratios for best-fit birth weight-mortality models ranging from 0.8-1 (per 100 g birth weight change). Almond et al. (2005) used 1989-1991 NCHS linked birth/infant death data for multiple birth infants to analyze relationships between birth weight and infant mortality within birth weight increment ranges. For their preferred model, they reported coefficients in deaths per 1,000 births per 1 g increase in birth weight that range from -0.420 to -0.002. However, the data used in these studies (Almond et al., 2005 and Ma et al., 2010) are outdated (1989-1991 and 2001, respectively). Given the significant decline in infant mortality over the last 30 years (ICF, 2020) and other maternal and birth characteristics that are likely to influence infant mortality (e.g., average maternal age and rates of maternal smoking), the birth weight-mortality relationship estimates from Almond et al. (2005) and Ma et al. (2010) are likely to overestimate the benefits of birth weight changes.

Considering the discernible changes in infant mortality over the last 30 years, EPA developed a regression analysis to estimate the relationship between birth weight and infant mortality using the most recently available Period/Cohort Linked Birth-Infant Death Data Files published by NCHS from the 2017 period/2016 cohort and the 2018 period/2017 cohort (CDC, 2017, 2018). These data provide information on infants who are delivered alive and receive a birth certificate. EPA selected variables of interest for the regression analysis, including maternal demographic and socioeconomic characteristics, maternal risk and risk mitigation factors (e.g., number of prenatal care visits, smoker status), and infant birth characteristics. EPA included several variables used in Ma et al. (2010) (maternal age, maternal education, marital status, and others – see Appendix E for the complete list) as well as additional variables to augment the set of covariates included in the analyses. In addition, EPA developed separate models for different race/ethnicity categories (non-Hispanic Black, non-Hispanic White, and Hispanic) and interacted birth weight with categories of gestational age, similar to Ma et al. (2010). Appendix E provides details on model development and regression results.

Table 6-10 presents the resulting odds ratios and marginal effects (in terms of deaths per 1,000 births for every 1 g increase in birth weight) estimated for changes in birth weight among different gestational age categories in the mortality regression models for non-Hispanic Black, non-Hispanic White, and Hispanic race/ethnicity subpopulations. Marginal effects for birth weight among different gestational age categories indicate the change in the incidence of infant

 $^{^{46}}$ These data do not include information on miscarriages or stillbirths.

⁴⁷ Note that Ma et al. (2010) developed a model for infants with Mexican heritage, rather than the Hispanic population, and interacted birth weight with gestational age as a continuous interaction variable, rather than developing different birth weight variables per gestational age category. Ma et al. (2010) did not consider the Hispanic paradox, a term for the epidemiological finding that Hispanic and Latino Americans often have lower risk of poor health outcomes compared to race/ethnicity groups with higher income and education levels. Note that Ma et al. (2010) developed a model for infants with Mexican heritage, rather than the Hispanic population, and interacted birth weight with gestational age as a continuous interaction variable, rather than developing different birth weight variables per gestational age category. Ma et al. (2010) did not consider the Hispanic paradox, a term for the epidemiological finding that Hispanic and Latino Americans often have lower risk of poor health outcomes compared to race/ethnicity groups with higher income and education levels.

mortality per 1 g increase in birth weight.⁴⁸ Marginal effects for birth weight among gestational age categories vary across different race/ethnicity subpopulations. As shown in Figure 6-2, the marginal effects for birth weight among different gestational age categories are higher in the non-Hispanic Black model than in the non-Hispanic White and Hispanic models, particularly for extremely and very preterm infants, indicating that LBW increases the probability of mortality within the first year more so among non-Hispanic Black infants than among non-Hispanic White and Hispanic infants.

EPA relies on odds ratios estimated using the birth weight-mortality regression model to assess mortality outcomes of reduced exposures to PFOA/PFOS in drinking water under the regulatory alternatives. To obtain odds ratios specific to each race/ethnicity and 100 g birth weight increment considered in the birth weight benefits model, 49 EPA averaged the estimated odds ratios for 1 g increase in birth weight over the gestational age categories using the number of infants (both singleton and multiple birth) that fall into each gestational age category as weights. Separate gestational age category weights were computed for each 100 g birth weight increment and race/ethnicity subpopulation within the 2017 period/2016 cohort and 2018 period/2017 cohort Linked Birth-Infant Death Data Files. The weighted birth weight odds ratios are then used in conjunction with the estimated change in birth weight and baseline infant mortality rates to determine the probability of infant death under the regulatory alternatives, as described further in Section 6.4.3.1.

⁴⁸ All marginal effect values for birth weight among different gestational age categories are negative and decrease in magnitude with each higher gestational age category, indicating that the probability of mortality decreases as gestational age and birth weight increase. For example, using marginal effects from the non-Hispanic Black model, for extremely preterm infants a 100 g birth weight increase on average would translate to 20 fewer infant deaths per 1,000 births in this gestational age category or a 2% decrease in the probability of mortality within one year of birth. The same birth weight increase at a higher gestational age would still decrease mortality risk but to a lesser extent.

 $^{^{49}}$ The birth weight risk reduction model evaluates changes in birth weight in response to PFOA/PFOS drinking water level reductions for infants who fall into 100 g birth weight increments (e.g., birth weight 0-99 g, 100-199 g, 200-299 g... 8,000-8,099 g, 8,100-8,165 g).

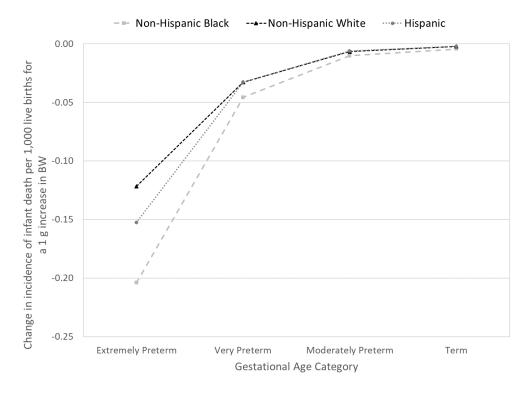


Figure 6-2: Comparison of Change in Incidence of Infant Death per 1 g Increase in birth weight by Gestational Age Category and Race/Ethnicity (Deaths per 1,000 Births)

Notes: Gestational age categories defined as extremely preterm (<=28 weeks), very preterm (>28 weeks and <=32 weeks), moderately preterm (>32 weeks and <=37 weeks), and term (>37 weeks). Data based on the 2016/17 and 2017/18 CDC Period Cohort Linked Birth-Infant Death Data Files obtained from NCHS/NVSS. Marginal effects and odds ratios are estimated using a regression model that also includes covariates representative of infant birth characteristics in addition to birth weight, maternal demographic characteristics, and maternal risk factors. Details are included in Appendix E.

Table 6-10: Race/Ethnicity- and Gestational Age-Specific Birth Weight Marginal Effects and Odds Ratios from the Mortality Regression Models

Race	Gestational Age Category ^b	Marginal Effect per 1,000 births (95% CI)	Odds Ratio (95% CI)
Non-Hispanic Black	Extremely Preterm	-0.20400 (-0.21910, -0.18890)	0.99817 (0.99802, 0.99832)
	Very Preterm	-0.04580 (-0.04820, -0.04340)	0.99816 (0.99804, 0.99827)
	Moderately Preterm	-0.01030 (-0.01080, -0.009850)	0.99852 (0.99846, 0.99857)
	Term	-0.00453 (-0.00472, -0.00434)	0.99856 (0.99851, 0.9986)
Non-Hispanic White	Extremely Preterm	-0.12160 (-0.13080, -0.11240)	0.99866 (0.99855, 0.99878)
	Very Preterm	-0.03290	0.9985

Table 6-10: Race/Ethnicity- and Gestational Age-Specific Birth Weight Marginal Effects and Odds Ratios from the Mortality Regression Models

Race	Gestational Age Category ^b	Marginal Effect per 1,000 births (95% CI)	Odds Ratio (95% CI)
		(-0.03430, -0.03140)	(0.99842, 0.99858)
	Madaustala Dustaus	-0.00677	0.99867
	Moderately Preterm	(-0.00702, -0.00652)	(0.99863, 0.99872)
	Term	-0.00228	0.99865
	Term	(-0.00236, -0.00221)	(0.99861, 0.99868)
Hispanic	Evituaria de Duatama	-0.15260	0.99835
	Extremely Preterm	(-0.16770, -0.13750)	(0.99817, 0.99853)
	Varra Duata ma	-0.03290	0.99846
	Very Preterm	(-0.03510, -0.03070)	(0.99835, 0.99858)
	M. L. at I. Data	-0.00626	0.99856
	Moderately Preterm	(-0.00659, -0.00592)	(0.99849, 0.99862)
	T	-0.00219	0.99849
	Term	(-0.00229, -0.00208)	(0.99844, 0.99855)

Notes:

^aData based on the 2016/17 and 2017/18 CDC Period Cohort Linked Birth-Infant Death Data Files obtained from NCHS/NVSS. Marginal effects and odds ratios are estimated using a regression model that also includes covariates representative of infant birth characteristics in addition to birth weight, maternal demographic characteristics, and maternal risk factors. All effects were statistically significant at the 5% level. Additional details are included in Appendix E. ^bGestational age categories defined as extremely preterm (<=28 weeks), very preterm (>28 weeks and <=32 weeks), moderately preterm (>32 weeks and <=37 weeks), and term (>37 weeks).

EPA weighted the race/ethnicity-specific mortality odds ratios in Table 6-10 by the proportions of the infant populations who fell into each gestational age within a 100 g birth weight increment, based on the 2016/17 and 2017/18 period cohort data, to obtain a weighted mortality odds ratio estimate for each modeled race/ethnicity subpopulation and 100 g birth weight increment. The weighted mortality odds ratios are shown in Figure 6-3. ⁵⁰

⁵⁰ Note that weighted mortality odds ratios for the Hispanic population at larger birth weight increments fluctuate between 0.99849 and 0.99856. Due to the small sample size of the Hispanic infant population within these birth weight increments, 100 percent of infants in a specific birth weight increment is associated with either moderately preterm or term gestational age categories. For instance, all Hispanic infants included in the analysis who were between 7,800 and 7,899 g were full-term, while all Hispanic infants who were between 7,900 and 7,999 g were moderately preterm. Therefore, the weighted mortality odds ratio for Hispanic infants between 7,800 and 7,899 g is equal to the full-term mortality odds ratio estimated for the Hispanic infant population, while the weighted mortality odds ratio for Hispanic infant between 7,900 and 7,999 g is equal to the moderately preterm mortality odds ratio estimated for the Hispanic infant population.

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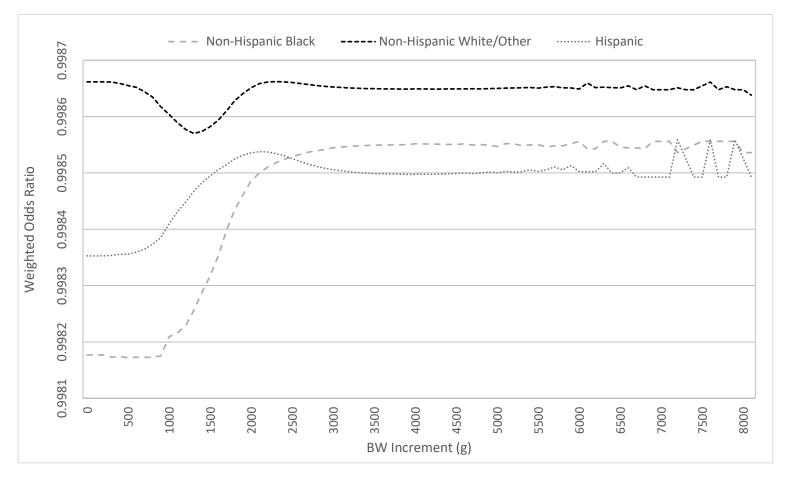


Figure 6-3: Weighted Mortality Odds Ratios Based on Populations of Infants Falling into 100 g Birth Weight Increments and Four Gestational Age Categories

Note: Weighted mortality odds ratios refer to the exponentiation of the sum of odds ratios estimated for each gestational age category and race/ethnicity-specific infant population multiplied by the proportions of the infant populations who fell into each gestational age within a 100 g birth weight increment, based on the 2016/17 and 2017/18 CDC Period Cohort Linked Birth-Infant Death Data Files obtained from NCHS/NVSS, to obtain a weighted odds ratio estimate for each modeled race/ethnicity and 100 g birth weight increment. EPA applies the weighted mortality odds ratios estimated for the non-Hispanic White subpopulation to the "other" race/ethnicity subpopulation because of similarities in infant death rates from 2016 to 2018 among non-Hispanic White infants (4.75 deaths per 1,000) and non-Hispanic other infants (4.45 deaths per 1,000).

Note that EPA did not model the relationship between birth weight and infant mortality for other race/ethnicity subpopulations because doing so for each individual race/ethnicity or combination of all "other" races/ethnicities is precluded by very low sample sizes (i.e., imprecise coefficients and imprecise marginal effects). EPA applies the weighted mortality odds ratios estimated for the non-Hispanic White subpopulation to the "other" race/ethnicity subpopulation because of similarities in infant death rates from 2016 to 2018 among non-Hispanic White infants (4.75 deaths per 1,000) and non-Hispanic other infants (4.45 deaths per 1,000).

6.4.3.2 Estimating the Number of Infants Affected by Birth Weight Changes and Changes in Infant Mortality

Based on reduced serum PFOA/PFOS exposures under the regulatory alternatives and the estimated relationship between birth weight and infant mortality, EPA estimates the subsequent change in birth weight for those infants affected by decreases in PFOA/PFOS and changes in the number of infant deaths. EPA evaluates these changes at each PWS EP affected by the regulatory alternatives and the calculations are performed for each race/ethnicity group, 100 g birth weight category, and year of the analysis.

6.4.3.2.1 Changes in Birth Weight

EPA combined estimated average annual changes in PFOA and PFOS serum levels for women of childbearing age (15 to 44 years old) by analysis year, race/ethnicity group, and PWS EP (see Section 6.3.2) with the serum PFOA/PFOS-birth weight exposure-response slope factors (see Table 6-9) to compute average annual changes in birth weight per newborn as follows:

Equation 9:

$$\Delta BW_{y,r,p} = \max\left(CAP, SF_{BW,PFOA} \cdot \Delta PFOA_Serum_{y,r,p} + SF_{BW,PFOS} \cdot \Delta PFOS_{Serum_{y,r,p}}\right)$$

Where ΔBW is the change in birth weight under the regulatory alternatives, y is the analysis year, r is the race/ethnicity group, p is the PWS EP analyzed; $\Delta PFOA_Serum$ is the change in PFOA serum for women of childbearing age under the regulatory alternatives; $\Delta PFOS_Serum$ is the change in PFOS serum for women of childbearing age under the regulatory alternatives; $SF_{BW,PFOA}$ and $SF_{BW,PFOS}$ are the serum-birth weight exposure-response slope factors for PFOA and PFOS, respectively; and CAP is the 200 g cap placed on the birth weight changes.

6.4.3.2.2 Changes in Infant Death Rate

EPA used average annual changes in birth weight under the regulatory alternatives (Equation 9) to estimate the associated infant mortality odds ratios, $OR_{v,i,r,p}$:

Equation 10:

$$OR_{y,i,r,p} = \exp(\Delta BW_{y,r,p} \cdot \ln(OR_{i,r}))$$

Where y is the analysis year, i is the 100 g birth weight increment, r is the race/ethnicity group, p is the PWS EP analyzed, and $OR_{i,r}$ is the weighted odds ratio for a 1 g birth weight increase associated with each 100 g birth weight increment for a given race/ethnicity category (see Section 6.4.3).

EPA combined the result of Equation 10 with the baseline infant death rate to estimate the infant death rate under the regulatory alternatives, $DR_{Regulatory\ Alternative,y,i,r,p}$:

Equation 11:

$$DR_{Regulatory\;Alternative,y,i,r,p} = \frac{OR_{y,i,r,p} \cdot DR_{Baseline,y,i,r,p}}{1 + OR_{y,i,r,p} \cdot DR_{Baseline,y,i,r,p}}$$

Where $DR_{Baseline,y,i,r,p}$ is the baseline death rate per birth computed from 2012-2018 death rates per 500 g birth weight increment (CDC, 2020a),⁵¹ y is the analysis year, i is 100 g birth weight increment, r is the race/ethnicity group, p is the PWS EP analyzed, and $OR_{y,i,r,p}$ is the mortality odds ratio associated with the annual change in birth weight under the regulatory alternatives.

6.4.3.2.3 Affected Infant Population Size

The annual race/ethnicity- and PWS EP-specific number of infants affected by changes in PFOA/PFOS drinking water levels is based on the 2021 retail population served at each PWS from the SDWIS and 2021 race/ethnicity-specific population estimates from the U.S. Census (U.S. Census Bureau, 2020a; see Appendix B). Because birth rates per race/ethnicity group and 100 g birth weight increment are often suppressed due to lack of data, EPA multiplied state-level birth rates per race/ethnicity group from the Centers for Disease Control and Prevention (CDC) Linked Birth/Infant Death records from 2012 to 2018 (CDC, 2020a) by the ratio of infants falling within each 100 g birth weight increment per state (not specific to race/ethnicity) to the total number of infants per state to distribute the number of affected infants in each state. EPA imputed state-level data that was missing from the 2012-2018 CDC Linked Birth/Infant Death records with data at the census region level. EPA used the same approach to assign average birth weights per race/ethnicity group over the 100 g birth weight increments for use in COI data matching (See Section 6.4.4). Using the 2012-2018 imputed state-level birth rate data, EPA computed the share of births that correspond to each 100 g birth weight increment (i), race/ethnicity (r), and PWS EP (p) as the ratio of race/ethnicity- and state-specific (s) birth rates⁵² in a particular birth weight increment to the sum of birth rates associated with all birth weight increments:

Equation 12:

Share of
$$Births_{i,r,p} = \frac{(BR_{2012-2018,i,r,s})}{sum(BR_{2012-2018,i,r,s})}$$

Next, EPA assumed that the share of births within each 100 g birth weight increment (from Equation 12) would remain constant throughout the period of analysis and estimated the annual

⁵¹ EPA assumed that the same death rate applies to infants in all 100 g birth weight increments falling in the 500 g birth weight range.

⁵² In this analysis, EPA applies state-specific birth rates that correspond to the state for which each PWS EP is located.

affected infant population size for each future analysis year (y), 100 g birth weight increment (i), race/ethnicity group (r), and PWS EP (p), $Births_{v,i,r,p}$ as follows:

Equation 13:

$$Births_{y,i,r,p} = Births_{y,r,p} \cdot Share \ of \ Births_{i,r,p}$$

6.4.3.2.4 Infant Deaths Avoided and the Number of Surviving Infants

EPA used the estimated annual infant population size, $Births_{y,i,r,p}$, along with infant death rates, $DR_{Baseline,y,i,r,p}$ and $DR_{Regulatory\,Alternative,y,i,r,p}$, to compute the annual number of deaths expected at baseline (Equation 14) and the annual number of deaths expected under the regulatory alternatives (Equation 15):

Equation 14:

 $Deaths_{Baseline,y,i,r,p} = Births_{y,i,r,p} \cdot DR_{Baseline,y,i,r,p}$

Equation 15:

 $Deaths_{Regulatory\ Alternative,y,i,r,p} = Births_{y,i,r,p} \cdot DR_{Regulatory\ Alternative,y,i,r,p}$

EPA estimated the annual number of avoided infant deaths, Avoided Deaths_{v,i,r,n}, as:

Equation 16:

 $Avoided\ Deaths_{y,i,r,p} = Deaths_{Baseline,y,i,r,p} - Deaths_{Regulatory\ Alternative,y,i,r,p}$

EPA computed the population of surviving infants whose birth weight would be affected by changes in PFOA/PFOS exposure ($Survivors_{Regulatory\ Alternative,y,i,r,p}$) as the number of births less the number of deaths under the regulatory alternatives. EPA estimated the annual number of avoided infant deaths, $Avoided\ Deaths_{y,i,r,p}$, as:

Equation 17:

 $Survivors_{Regulatory\ Alternative,y,i,r,p} = Births_{y,i,r,p} \cdot (1 - DR_{Regulatory\ Alternative,y,i,r,p})$

6.4.4 Valuation of Reduced Birth Weight Impacts

EPA uses the Value of Statistical Life to estimate the benefits of reducing infant mortality and COI to estimate the economic value of increasing birth weight in the population of surviving infants born to mothers exposed to PFOA and PFOS in drinking water. Value of Statistical Life updating information is provided in Section 2.2.

EPA's approach to monetizing benefits associated with incremental increases in birth weight resulting from reductions in drinking water PFOA/PFOS levels relies on avoided medical costs associated with various ranges of birth weight. Although the economic burden of treating infants at various birth weights also includes non-medical costs, very few studies to date have quantified

such costs (Klein et al., 2018; ICF, 2021). EPA selected the medical cost function from Klein et al. (2018) to monetize benefits associated with the estimated changes in infant birth weight resulting from reduced maternal exposure to PFOA/PFOS.⁵³ EPA selected the cost function from Klein et al. (2018) because it is based on recent data on birth weight, healthcare utilization, and healthcare costs that encompass a longer time period and a larger population than data used in other studies (e.g., Almond et al., 2005). Additional studies that EPA reviewed provided only an incremental cost for LBW infants compared to normal birth weight (NBW) infants (greater or equal to 2,500 g; e.g., Almond et al., 2010 and Malits et al., 2018). Klein et al. (2018), on the other hand, estimated incremental medical costs as a function of birth weight over the range from 900 to 4,500 g and used a continuous spline function (Figure 6-4), rather than allowing for a discontinuity at the very low birth weight level (i.e., < 1,500 grams). Table 6-11 summarizes the incremental cost changes associated with birth weight increases from Klein et al. (2018).

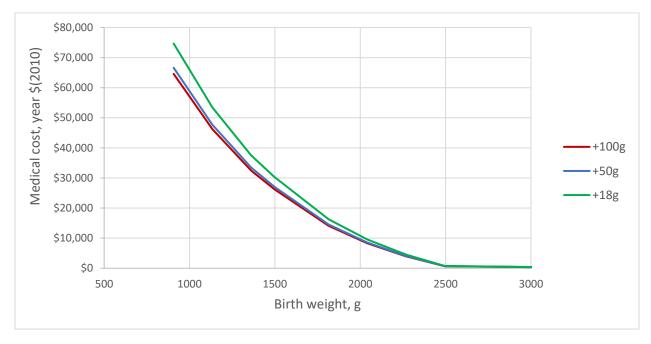


Figure 6-4: Piecewise Medical Cost Function Calculated by Klein and Lynch (2018) for Three Increments in Increased Birth Weight (18 g, 50 g, and 100 g)

⁵³ The Klein et al. (2018) report was externally peer reviewed by three experts with qualifications in economics and public health sciences. EPA's charge questions to the peer reviewers sought input on the methodology for developing medical cost estimates associated with changes in birth weight. The Agency's charge questions and peer reviewer responses are available in the docket (see No. EPA-HQ-OW-2022-0114 at https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114).

Table 6-11: Simulated Cost Changes for Birth Weight Increases (\$2021) (Based on Klein and Lynch, 2018 Table 8)

Birth Weight ^{a,b}	Simulated Cost Changes for Birth Weight Increases, Dollars per Gram (\$2021) ^c				
	+0.04 lb (+18 g)	+0.11 lb (+50 g)	+0.22 lb (+100 g)		
2 lb (907 g)	-\$126.53	-\$112.87	-\$109.39		
2.5 lb (1,134 g)	-\$94.88	-\$84.64	-\$82.03		
3 lb (1,361 g)	-\$71.15	-\$63.47	-\$61.51		
3.3 lb (1,497 g)	-\$59.86	-\$53.40	-\$51.75		
4 lb (1,814 g)	-\$40.00	-\$35.69	-\$34.59		
4.5 lb (2,041 g)	-\$30.00	-\$26.76	-\$25.93		
5 lb (2,268 g)	-\$22.49	-\$20.07	-\$19.45		
5.5 lb (2,495 g)	-\$0.93	-\$0.84	-\$0.84		
6 lb (2,722 g)	-\$0.91	-\$0.83	-\$0.83		
7 lb (3,175 g)	-\$0.88	-\$0.80	-\$0.80		
8 lb (3,629 g)	-\$0.85	-\$0.77	-\$0.77		
9 lb (4,082 g)	\$3.15	\$2.87	\$2.89		
10 lb (4,536 g)	\$3.54	\$3.23	\$3.26		

Notes:

Using the incremental cost changes from Klein et al. (2018), EPA calculates the change in medical costs resulting from changes in birth weight among infants in the affected population who survived the first year following birth. To do so, EPA linearly interpolates between the birth weight and cost values presented in Klein et al. (2018) to obtain a cost value for every 1 g birth weight increment, as shown in Figure 6-5. EPA then matches this interpolated birth weight value to the nearest baseline average birth weight value in each 100 g birth weight increment to obtain the simulated cost change for birth weight increases that are estimated to be between zero and 18 g, between 19 and 50 g, and between 51 and 100 g or more.⁵⁴

^aValues for birth weight have been converted from lb to g.

^bNote that simulated medical costs increase, rather than decrease, in response to increased birth weight changes among high birth weight infants (those greater than 8 lb). Among HBW infants, there is a higher risk of birth trauma, metabolic issues, and other health problems (Klein et al., 2018).

cValues scaled from \$2010 to \$2021 using the medical care Consumer Price Index (U.S. Bureau of Labor Statistics, 2021).

 $^{^{54}}$ Note that EPA caps birth weight changes at 200 g, as described in earlier sections. EPA assumes that the cost of illness estimates for birth weight increases between 51 and 100 g apply to birth weight increases greater than 100 g.

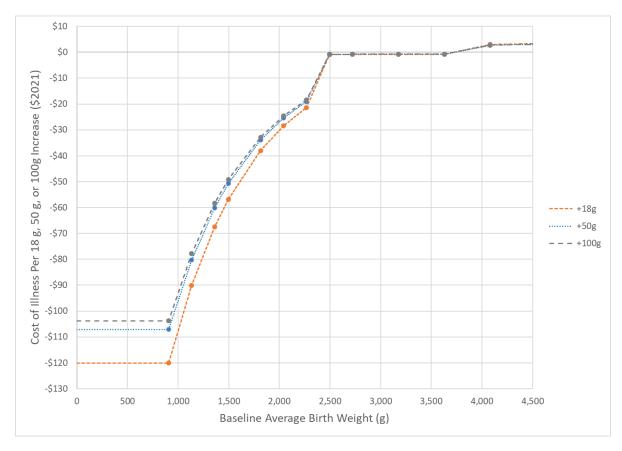


Figure 6-5. Interpolated Cost of Illness at Baseline Average Birth Weights, by Estimated Change in Birth Weight Under the Proposed Rule

6.4.5 Results

Table 6-12 to Table 6-15 provide the health effects avoided and valuation associated with birth weight impacts.

Table 6-12: National Birth Weight Benefits, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0)

	3%	6 Discount Ra	ite	7%	7% Discount Rate		
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Increase in Birth Weight (millions of grams)	114.2	209.3	329.7	114.2	209.3	329.7	
Number of Birth Weight- Related Deaths Avoided	676.8	1,232.7	1,941.0	676.8	1,232.7	1,941.0	
Total Annualized Birth Weight Benefits (Million \$2021) ^b	\$97.36	\$177.66	\$279.49	\$74.62	\$139.01	\$219.43	

Note: Detail may not add exactly to total due to independent rounding.

Table 6-13: National Birth Weight Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ppt)

	3%	6 Discount Ra	iscount Rate 79			6 Discount Rate	
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Increase in Birth Weight (millions of grams)	111.7	206.3	326.9	111.7	206.3	326.9	
Number of Birth Weight- Related Deaths Avoided	665.4	1,214.7	1,915.4	665.4	1,214.7	1,915.4	
Total Annualized Birth Weight Benefits (Million \$2021) ^b	\$95.73	\$175.05	\$276.44	\$74.66	\$136.97	\$217.02	

Note: Detail may not add exactly to total due to independent rounding.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 6-14: National Birth Weight Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ppt)

	3%	6 Discount Ra	ite	6 Discount Rate		
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a
Increase in Birth Weight (millions of grams)	97.6	181.9	292.1	97.6	181.9	292.1
Number of Birth Weight- Related Deaths Avoided	578.9	1,069.5	1,707.3	578.9	1,069.5	1,707.3
Total Annualized Birth Weight Benefits (Million \$2021) ^b	\$83.27	\$154.13	\$246.43	\$64.94	\$120.59	\$193.47

Note: Detail may not add exactly to total due to independent rounding.

Table 6-15: National Birth Weight Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ppt)

	3%	6 Discount Ra	ite	7%	6 Discount Rate		
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Increase in Birth Weight (millions of grams)	51.0	109.2	195.3	51.0	109.2	195.3	
Number of Birth Weight- Related Deaths Avoided	299.5	643.3	1,140.5	299.5	643.3	1,140.5	
Total Annualized Birth Weight Benefits (Million \$2021) ^b	\$43.22	\$92.70	\$164.19	\$34.18	\$72.51	\$125.80	

Note: Detail may not add exactly to total due to independent rounding.

6.5 Cardiovascular Disease

6.5.1 Overview of the Cardiovascular Disease Risk Analysis

Figure 6-6 provides an overview of the approach used to quantify and value the changes in CVD risk associated with reductions in exposure to PFOA and PFOS via drinking water. Section 4.4 details the PWS EP-specific PFOA/PFOS drinking water occurrence estimation and Section 6.3 describes modeling of serum PFOA/PFOS concentrations. EP-specific time series of the differences between serum PFOA/PFOS concentrations under baseline and regulatory

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

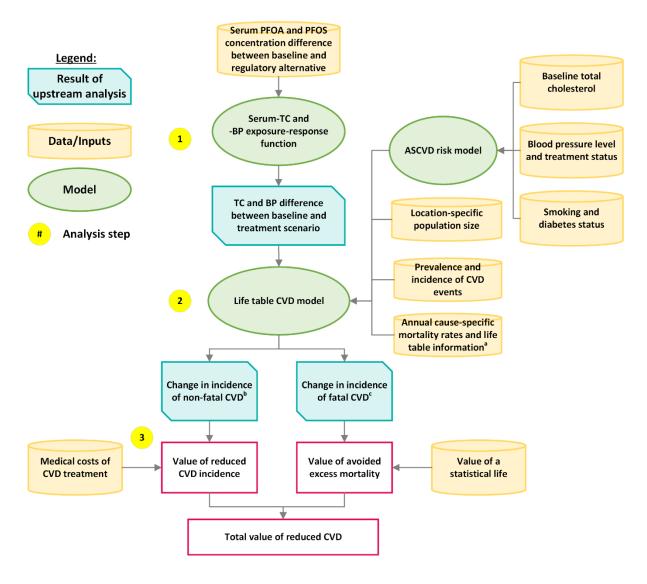
^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

alternatives are inputs into this analysis. For each EP, evaluation of the changes in CVD risk involves the following key steps:

- 1. Estimation of annual changes in TC⁵⁵ and BP levels using exposure-response functions for the potential effects of serum PFOA/PFOS on these biomarkers;
- 2. Estimation of the annual incidence of fatal and non-fatal first hard CVD events, defined as fatal and non-fatal myocardial infarction (MI; i.e., heart attack), fatal and non-fatal ischemic stroke (IS), or other coronary heart disease (CHD) death occurring in populations without prior CVD event experience (D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017), and post-acute CVD mortality corresponding to baseline and regulatory alternative TC and BP levels in all populations alive during or born after the start of the evaluation period; and
- Estimation of the economic value of reducing CVD mortality and morbidity from baseline to regulatory alternative levels, using the Value of Statistical Life and COI measures, respectively.

Section 6.5.2 discusses the exposure-response models for TC and BP. Section 6.5.3 details the estimated CVD risk reductions using the Pooled Cohort ASCVD risk model (Goff et al., 2014) and the life table approach. Section 6.5.4 discusses EPA's valuation methodology for fatal and non-fatal CVD events. Section 6.5.5 presents the results of the analysis.

⁵⁵ EPA discusses the relationship between PFOA/PFOS exposure and other forms of cholesterol in Appendix F.



Abbreviations: PFOA – perfluorooctanoic acid, PFOS – perfluorooctanesulfonic acid, TC – total cholesterol, BP – blood pressure, CVD – cardiovascular disease, ASCVD – atherosclerotic cardiovascular disease, MI – myocardial infarction, IS – ischemic stroke, CHD – coronary heart disease

Notes:

Figure 6-6: Overview of the CVD Risk Model

^aData from the Centers for Disease Control (CDC) and Prevention.

^bNon-fatal CVD includes non-fatal first MI and non-fatal first IS.

Fatal CVD includes fatal first MI, fatal first IS, other fatal first CHD events, and post acute CVD mortality among survivors of the first MI and the first IS.

6.5.2 Cardiovascular Disease Exposure-Response Analyses 6.5.2.1 Estimation of Cholesterol Changes

The ASCVD model includes TC as a predictor of first hard CVD events. EPA did not identify any readily available relationships for PFOA or PFOS and TC that were specifically relevant to the age group of interest (40-89 years, the years for which the ASCVD model estimates the probability of a first hard CVD event). Therefore, the Agency developed a meta-analysis of studies reporting associations between serum PFOA or PFOS and TC in general populations (e.g., populations that are not a subset of workers or pregnant women). Statistical analyses that combine the results of multiple studies, such as meta-analyses, are widely applied to investigate the associations between contaminant levels and associated health effects. Such analyses are suitable for economic assessments because they can improve precision and statistical power (Engels et al., 2000; Deeks, 2002; Rücker et al., 2009). Appendix F provides details on the studies selection criteria, meta-data development, meta-analysis results, and discussion of the uncertainty and limitations inherent in EPA's exposure-response analysis.

EPA identified studies for inclusion in the meta-analysis using data from literature reviews, including those performed by ATSDR in the development of their Toxicological Review Public Comment Draft (ATSDR, 2018), which included literature through mid-2017, and those performed for developing EPA's *Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water* (U.S. EPA, 2023d; U.S. EPA, 2023e), which included studies published from 2016 through September 2020. EPA included studies in the meta-data if they reported quantitative estimates (e.g., regression coefficients) and measures of uncertainty (e.g., standard errors, confidence intervals) of associations between serum PFOA or PFOS and TC in general population adults aged 20 years and older. EPA included a total of 14 studies in the meta-analysis. Of these, 12 studies were used to develop exposure-response relationships for serum PFOA or PFOS and TC (i.e., not all relevant studies report the effects for both PFOA and PFOS). The unit in the meta-analysis was change in TC in mg/dL per increases in serum PFOA or PFOS. EPA conducted four separate meta-analyses for each chemical (PFOA or PFOS).

Table 6-16 summarizes the 14 studies that EPA identified from literature reviews and used to derive slope estimates for PFOA and PFOS associations with serum TC levels. ⁵⁶ Six of the studies that EPA retained for use in the meta-analysis were based on serum PFAS and serum TC measurements from the U.S. general population (National Health and Nutrition Examination Survey [NHANES]) (Dong et al., 2019; Fan et al., 2020; He et al., 2018; Jain et al., 2019; Liu et al., 2018; Nelson et al., 2010); there were also general population studies from Canada (Fisher et al., 2013), Sweden (Y. Li et al., 2020), Taiwan (Yang et al., 2018; C. Y. Lin et al., 2020), and Henan Province, China (Fu et al., 2014). Château-Degat et al. (2010) reported on the association between PFOS and TC in a Canadian Inuit population. EPA also retained the results from a study of a highly exposed population in the U.S. (the C8 cohort) (Steenland et al., 2009) and from a study using participants in a U.S. diabetes prevention program (P.-I. D. Lin et al., 2019). EPA retained results from Steenland et al. (2009) because serum levels in the examined cohort were only modestly elevated compared to less exposed populations (e.g., the median serum PFOA

⁵⁶ For this effort, EPA focused on PFOA and PFOS, since these are by far the most well-studied perfluorinated compounds.

concentration in this cohort was 27 ng/mL, with an interquartile range of 13.1 to 67 ng/mL). EPA retained results from P.-I. D. Lin et al. (2019) because the examined cohort included prediabetic adults enrolled in a diabetes prevention program; thus, this cohort was representative of a large portion of the U.S. adult population.

Table 6-16: Studies Selected for Inclusion in the Meta-Analyses

Author and Year	Title	TC and Serum PFAS Relationship Evaluated in Study		
	_	PFOA	PFOS	
Steenland et al., 2009 ^{a,d}	Association of Perfluorooctanoic Acid and Perfluorooctane Sulfonate With Serum Lipids Among Adults Living Near a Chemical Plant	X	X	
Château-Degat et al., 2010 ^{a,d}	Effects of Perfluorooctanesulfonate Exposure on Plasma Lipid Levels in the Inuit Population of Nunavik (Northern Quebec)		X	
Nelson et al., 2010 ^{a,d}	Exposure to Polyfluoroalkyl Chemicals and Cholesterol, Body Weight, and Insulin Resistance in the General U.S. Population	X	X	
Fisher et al., 2013	Do Perfluoroalkyl Substances Affect Metabolic Function and Plasma Lipids? —Analysis of the 2007–2009, Canadian Health Measures Survey (CHMS) Cycle 1	X	X	
Fu et al., 2014 ^{a,d}	Associations Between Serum Concentrations of Perfluoroalkyl Acids and Serum Lipid Levels in a Chinese Population	X	X	
He et al., 2018 ^c	PFOA is Associated with Diabetes and Metabolic Alteration in US Men: National Health and Nutrition Examination Survey 2003-2012	X	X	
Liu et al., 2018 ^c	Association Among Total Serum Isomers of Perfluorinated Chemicals, Glucose Homeostasis, Lipid Profiles, Serum Protein and Metabolic Syndrome in Adults: NHANES, 2013–2014	X	X	
Dong et al., 2019 ^b	Using 2003–2014 U.S. NHANES Data to Determine the Associations Between Per- and Polyfluoroalkyl Substances and Cholesterol: Trend and Implications	X	X	
Jain et al., 2019 ^b	Roles of Gender and Obesity in Defining Correlations Between Perfluoroalkyl Substances and Lipid/Lipoproteins	X	X	
PI. D. Lin et al., 2019 ^b	Per- and Polyfluoroalkyl Substances and Blood Lipid Levels in Pre-Diabetic Adults—Longitudinal Analysis of the Diabetes Prevention Program Outcomes Study	X	X	
Fan et al., 2020 ^b	Serum Albumin Mediates the Effect of Multiple Per- and Polyfluoroalkyl Substances on Serum Lipid Levels	X	X	
Y. Li et al., 2020 ^b	Associations Between Perfluoroalkyl Substances and Serum Lipids in a Swedish Adult Population With Contaminated Drinking Water	X	X	

Abbreviations: TC – total cholesterol; PFOS – perfluorooctane sulfonic acid; PFOA – perfluorooctanoic acid; PFAS – per and polyfluoroalkyl substances; PFAS – per-and polyfluoroalkyl substances. Notes:

EPA developed exposure-response relationships between serum PFOA/PFOS and TC for use in the CVD analysis using the meta-analyses restricted to studies of adults in the general population reporting similar models. EPA used untransformed serum PFOA/PFOS to reduce bias due to

^aStudies identified based on ATSDR literature review.

^bStudies identified based on EPA literature review.

^cStudies available in both assessments.

^dStudies available in PFOA and/or PFOS health effects support documents (U.S. EPA, 2016e; U.S. EPA, 2016f).

back-transformations of effect estimates. For studies that provided results only for logtransformed serum PFOA/PFOS (five studies) or log-transformed outcomes (two studies), or both log-transformed serum PFOA/PFOS and outcomes (two studies), EPA approximated the results for an untransformed analysis using the approach outlined by Rodríguez-Barranco et al. (2017) and Dzierlenga et al. (2020). When using studies reporting linear associations between TC and serum PFOA or PFOS, EPA estimated a positive increase in TC of 1.57 (95% CI: 0.02, 3.13) mg/dL per ng/mL serum PFOA (p-value=0.048), and of 0.08 (95% CI: -0.01, 0.16) mg/dL per ng/mL serum PFOS (p-value=0.064). EPA selected the pooled slope estimate based on the studies using linear models to ease interpretability and to reduce bias due to backtransformations of effect estimates with log-transformed outcomes or exposures (see Appendix F for details). While the association for PFOS and TC is not significant at the 0.05 confidence level, it is significant at the 0.10 confidence level (p-value=0.064). Furthermore, the literature provides sufficient support of a positive association (e.g., Château-Degat et al., 2010; Dong et al., 2019; U.S. EPA, 2023d; U.S. EPA, 2023e). The studies are large with more than 700 and 8,900 participants, respectively (Château-Degat et al., 2010; Dong et al., 2019) and have low risk of bias. In addition, the estimated values are supported by sensitivity analyses and by the estimates from potential candidate studies from exposure-response modeling for ongoing Agency efforts (Dong et al., 2019). Based on the systematic review conducted by EPA of 39 epidemiologic studies published between 2016 and September 2020 for developing EPA's Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water, the available evidence supports a positive association between PFOS and TC in the general population (U.S. EPA, 2023d; U.S. EPA, 2023e). For more information on the systematic review and results, see EPA's Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water (U.S. EPA, 2023d; U.S. EPA, 2023e).

Note that EPA sought comments from the EPA Science Advisory Board on the cardiovascular disease exposure-response approach (U.S. EPA, 2022k). The Science Advisory Board recommended that EPA evaluate how the inclusion of HDLC effects would influence results. EPA evaluated the inclusion of HDLC effects in a sensitivity analysis, described in Appendix K.

6.5.2.2 Estimation of BP Changes

PFOS exposure has been linked to other cardiovascular outcomes, such as systolic BP and hypertension (Liao et al., 2020; U.S. EPA, 2023d). Because systolic BP is another predictor used by the ASCVD model, EPA included the estimated changes in BP from reduced exposure to PFOS in the CVD analysis. EPA selected the slope from the Liao et al. (2020) study — a high confidence study conducted based on U.S. general population data from NHANES cycles 2003-2012. Liao et al. (2020) estimated an increase of 1.35 (95% CI: 0.18, 2.53) in mmHg systolic BP per log10(ng/mL) PFOS among those not using antihypertensive medications. For the purposes of this analysis, EPA converted this slope to 0.044 (95% CI: 0.006, 0.083) mmHg per ng/mL. The evidence on the associations between PFOA and BP is not as consistent as for PFOS (see Section 6.2.2.1.2). Therefore, EPA is not including effect estimates for the serum PFOA-BP associations in the CVD analysis.

6.5.3 Estimation of Cardiovascular Disease Risk Reductions

EPA relies on the life table-based approach to estimate CVD risk reductions because (1) changes in serum PFOA/PFOS in response to changes in drinking water PFOA/PFOS occur over multiple years, (2) CVD risk, relying on the ASCVD model, can be modeled only for those older than 40 years without prior CVD history, and (3) individuals who have experienced non-fatal CVD events have elevated mortality implications immediately and within at least five years of the first occurrence.⁵⁷ Recurrent life table calculations are used to estimate a PWS EP-specific annual time series of CVD event incidence for a population cohort characterized by sex, race/ethnicity, birth year, age at the start of the PFOA/PFOS evaluation period (i.e., 2023), and age- and sex-specific time series of changes in TC and BP levels obtained by combining serum PFOA/PFOS concentration time series (Section 6.3) with exposure-response information (Section 6.5.3). Baseline and regulatory alternatives are evaluated separately, with regulatory alternative TC and BP levels estimated using baseline information on these biomarkers from external statistical data sources and modeled changes in TC and BP due to conditions under the regulatory alternatives (see Appendix G for detailed information on data sources used in CVD modeling).

EPA estimated the incidence of first hard CVD events based on TC serum and BP levels using the ASCVD model (Goff et al., 2014), which predicts the 10-year probability of a hard CVD event to be experienced by a person without a prior CVD history (see Section 6.5.3.2).⁵⁸ EPA adjusted the modeled population cohort to exclude individuals with pre-existing conditions, as the ASCVD risk model does not apply to these individuals. For BP effects estimation, EPA further restricts the modeled population to those not using antihypertensive medications for consistency with the exposure-response relationship (see Section 6.5.3.2 for detail). Modeled first hard CVD events include fatal and non-fatal MI, fatal and non-fatal IS, and other CHD mortality. EPA also has estimated the incidence of post-acute CVD mortality among survivors of the first MI or IS within 6 years of the initial event (Section 6.5.3.3).

The estimated CVD risk reduction resulting from reducing serum PFOA and serum PFOS concentrations is the difference in annual incidence of CVD events (i.e., mortality and morbidity associated with first-time CVD events and post-acute CVD mortality) under the baseline and regulatory alternatives. Appendix G provides detailed information on all CVD model components, computations, and sources of data used in modeling.

6.5.3.1 Life Table Calculations

The CVD model integrates the ASCVD model predictions and post-acute CVD mortality rates in the series of recurrent calculations that produce a life table estimate for the affected population cohort (e.g., non-Hispanic White females aged 70 years at the beginning of the evaluation period). For each PWS EP, EPA evaluates population cohorts defined by a combination of birth year, age, sex (males and females), and race/ethnicity (non-Hispanic White, non-Hispanic Black, Hispanic, Other). In addition to the key standard life table components (i.e., the number of persons surviving to a specific age and the number of all-cause deaths occurring at a given age)

⁵⁷ EPA notes that elevated mortality for hard CVD event survivors may persist beyond five years of the initial event. However, EPA did not identify U.S. based studies with sufficiently long follow-up to quantify mortality impacts beyond five years of the initial event.

⁵⁸ EPA did not identify studies that found statistically significant associations between the modeled biomarkers (TC, BP) and CVD events in populations with prior CVD history. Discussion of the relevant literature is provided in Appendix G.

for ages 40 years or older, the CVD model estimates the number of surviving persons with and without a history of hard CVD events, the number of persons experiencing hard CVD events at a given age, and the deaths from CVD and non-CVD causes at a given age.

Figure 6-7 summarizes the CVD model calculations for a population cohort age 0 at the start of the evaluation period. The CVD model calculations are identical across race/ethnicity and sex demographic subgroups but use subgroup-specific parameters. For cohorts born prior to or in 2023, the CVD model is initialized using the PWS-specific number of persons estimated to be alive at the beginning of 2023. For cohorts born after 2023 (i.e., 2024–2104), the CVD model is initialized using the PWS EP-, race/ethnicity-, sex, and scenario-specific number of persons who died in the previous calendar year of the analysis, thereby ensuring that the size of the modeled population remains constant throughout the analysis period. Additional PWS EP- and sex, race/ethnicity, and age-specific population estimation assumptions are provided in Section 2.2; additional details are included in Appendix B.

Once the model is initialized, the following types of calculations occur for each year within the simulation period:⁶¹

- **Recurrent standard life table calculations** that rely on the all-cause, age-specific annual mortality rates to evaluate the number of deaths among persons of a specific integer age and the number of survivors to the beginning of the next integer age.⁶² These calculations are executed whenever the current cohort age is in the 0–39 range. They are represented by the navy blue segment of the timeline shown in Figure 6-7.
- Recurrent life table calculations that separately track subpopulations with and without a history of hard CVD events, including estimation of the number of annual CVD and non-CVD deaths (in either subpopulation), as well as the number of annual post-acute CVD deaths experienced by survivors of the first hard CVD events that occurred, at most, 5 years ago. These calculations are executed whenever the current cohort age is 40 years or older. These calculations are represented by the blue segment of the timeline. Figure 6-7 and Figure 6-8 further illustrates the year-specific calculations required for explicit tracking of subpopulations with and without a hard CVD event history.

⁵⁹ This initial population cohort age is chosen because it allows for illustration of the full set of calculation types used in the CVD model.

⁶⁰ There are different ASCVD model coefficients for non-Hispanic White and non-Hispanic Black males and females. The figure shows the generalized approach of the CVD model.

⁶¹ EPA notes that the simulation period is the lifespan of individuals relevant to the analysis. The simulation period is distinct from the period of analysis in that some parts of the simulation period may fall outside the period of analysis. For example, for a person aged 40 years at the start of the analysis period, the period of analysis will not capture the first 40 years of simulation results.

⁶² Life table calculations are based on the present-day information about life expectancy, disease, environmental exposure, and other factors

⁶³ People 85 years or older, are treated as a single cohort in the model. The mortality rate for this cohort is assumed to be the average mortality rate for those age 85-100 years. This cohort also used serum PFOA/PFOS values at age 85.

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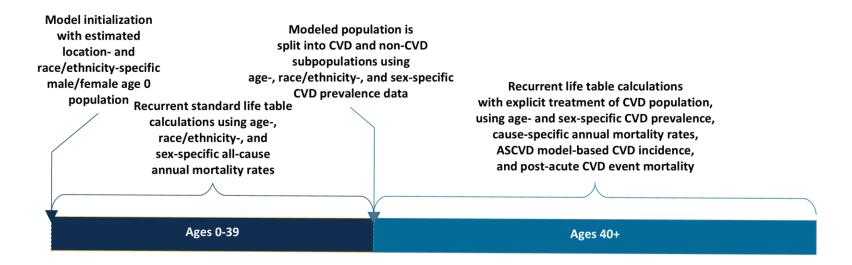


Figure 6-7: Overview of Life Table Calculations in the CVD Model

Note: The figure illustrates the model for population cohort age 0 years at the beginning of the evaluation period (i.e., calendar year 2023). The model is initialized using the age 0 PWS EP-specific population (see Appendix B for PWS population estimation details).

Figure 6-8 provides additional information on the post-acute CVD mortality estimation. Each person included in the surviving current age-specific incident CVD subpopulation⁶⁴ (corresponding to the group F result in Figure 6-8) is tracked for 5 additional years to estimate the number of CVD deaths occurring in that timeframe. The recurrent estimates rely on age-specific non-CVD mortality rates, estimated based on the CDC's life table data and annual CVD mortality rates, and on post-acute CVD mortality rates, estimated based on Thom et al. (2001) and S. Li et al. (2019).

Further details of the life table calculations are provided in Appendix G. The outputs of the life table calculations and application of the ASCVD model are the PWS EP-specific estimates of the annual number of persons experiencing their first non-fatal MI or IS event and the number of deaths among those who have experienced their first hard CVD event, at most, 6 years ago. Note that the ASCVD model does not predict risks separately by type of first hard CVD event (i.e., non-fatal MI, non-fatal IS, and fatal CVD). The distribution of these events by type is estimated using data publicly available on CVD prevalence, incidence, and hospital mortality statistics as described in Section 6.5.3.2 and integrated into the overall CVD impacts modeling.

⁶⁴ For example, persons who experienced their first non-fatal MI or IS at age 70 and survived through the first post-event year.

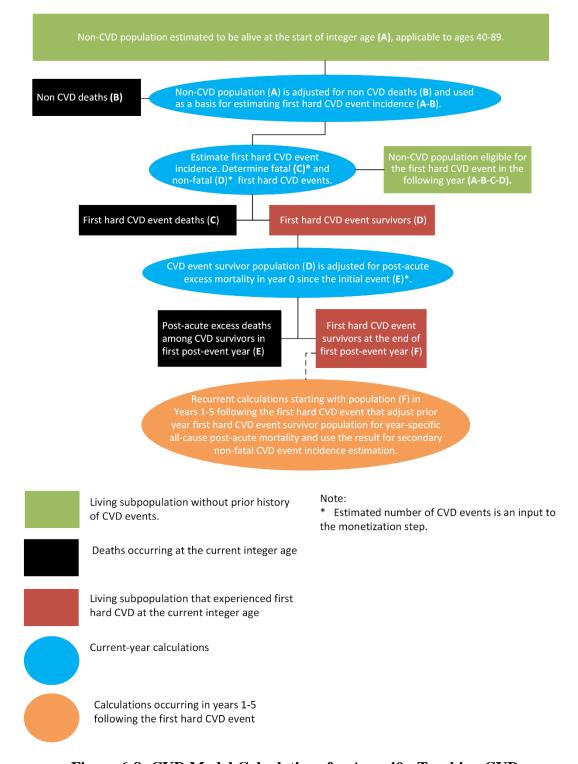


Figure 6-8: CVD Model Calculations for Ages 40+ Tracking CVD

6.5.3.2 Risk and Distribution of First Hard Cardiovascular Disease Event

The first hard CVD event incidence estimates are generated by the Pooled Cohort ASCVD model (Goff et al., 2014). The ASCVD model is commonly used in clinical practice to estimate

CVD risk for those between ages 40 and 80, as well as for overall population risk management (Lloyd-Jones et al., 2017). The ASCVD model predicts the 10-year probability of a hard CVD event—fatal and non-fatal MI, fatal and non-fatal IS, or CHD death—to be experienced by a person without a prior history of MI, IS, congestive heart failure, percutaneous coronary intervention, coronary bypass surgery, or atrial fibrillation. The ASCVD model is a survival model that links predictor levels at the start of the 10-year follow-up period to the first hard CVD event incidence during the follow-up period; the modeling does not account for changes in CVD risk predictors over time.

Four large longitudinal community-based epidemiologic cohort studies were combined to develop a geographically and racially diverse dataset used for the ASCVD model estimation.⁶⁵ The predictors of the ASCVD model include age, TC and HDLC concentrations, systolic BP, current smoking, diagnosed diabetes, and whether the participant is undergoing treatment for high BP. The model was fit separately to four population subgroups: non-Hispanic White females, non-Hispanic Black females, non-Hispanic Black males.

Several studies assessed predictive performance of the ASCVD risk model in racial and ethnic groups other than other non-Hispanic White and non-Hispanic Black populations, as well as in various sociodemographic subgroups in the U.S. Two studies concluded that the ASCVD risk model overestimated CVD risk among Asian and Hispanic groups, while noting that these groups were not included in the development and validation of the ASCVD model (Mongraw-Chaffin et al., 2018; Rodriguez et al., 2019). Five studies acknowledged limitations for the ASCVD risk model in terms of performance among individuals with high levels of CVD risk, diabetes, older adults with frailty and multimorbidity, smokers, and women (Muntner et al., 2014; Leigh et al., 2019; Mora et al., 2018; Q. D. Nguyen et al., 2020; Raghavan et al., 2020). Overall, the literature across different sociodemographic subgroups concluded that the ASCVD risk model tended to overestimate risk but suggested the model may improve through additional input variables and recalibration given contemporary ASCVD prevalence, especially if the prevalence differs significantly across geographic locations to which the model is applied (Mora et al., 2018; (Muntner et al., 2014). Extended discussion of ASCVD risk model performance and availability of alternative CVD risk prediction models for national analysis is provided in ICF (2022a).

In light of these findings, EPA does not follow the Goff et al. (2014) recommendation that the ASVCD risk model for non-Hispanic White populations be used for other race/ethnicity groups. In the development and parameterization of the CVD model for Hispanic, Asian American, and American Indian/Alaska Native populations, EPA applies the model for non-Hispanic Black populations based on the ASCVD model validation relative to reported CVD prevalence and mortality statistics (EPA analysis based on Medical Expenditure Panel Surveys from 2010–2017), as described in Appendix G. The results of this validation exercise showed that the ASCVD model coefficients for the non-Hispanic Black model are more consistent with data on CVD prevalence and mortality for Hispanic and non-Hispanic other race subpopulations than the ASCVD model coefficients for the non-Hispanic White model. The all-cause and CVD mortality

⁶⁵ These studies include the Atherosclerosis Risk in Communities (ARIC) study (Williams, 1989) and the Cardiovascular Health Study (Fried et al., 1991), along with applicable data from the Coronary Artery Risk Development in Young Adults (CARDIA) study (Friedman et al., 1988) and the Framingham Original and Offspring cohort data (D'Agostino et al., 2008).

was obtained from CDC's National Vital Statistics System, whereas CVD prevalence was estimated using Agency for Healthcare Research and Quality survey data (see Appendix G for details). As explained in Appendix G, race/ethnicity and sex-specific CVD incidence consistent with these reported statistics was compared with the incidence estimated using the ASCVD model, where the baseline race/ethnicity- and sex-specific values for the ASCVD model predictors were obtained from CDC's public health surveys (see Appendix G for details).

The ASCVD model generates predictions of the 10-year probability of the first hard CVD event without differentiation across CVD event types. The specifics of annual first hard CVD event probability derivation, which is needed for the life table calculations in Section 6.5.3.1, are provided in Appendix G. As is also detailed in Appendix G, EPA combined the Medical Expenditure Panel Survey (MEPS) 2010–2017 data and the Healthcare Cost and Utilization Project (HCUP) 2017 data to derive the ASCVD event distribution over the following event types: non-fatal MI, non-fatal IS, and fatal CVD events. The fatal CVD events include fatal MI, fatal IS, and other fatal CHD events. EPA used the MEPS data to identify the subpopulation of persons without a prior CVD event history and estimate the rate of new CVD events by type (i.e., MI, IS, and other CHD) in this subpopulation. The probabilities of in-hospital death for MI, IS, and other CHD were obtained from HCUP.

Table 6-17 shows the derived race/ethnicity-, sex-, and age group-specific shares of first hard CVD events for the following event types: non-fatal MI, fatal MI, non-fatal IS, fatal IS, other non-fatal CHD, and other fatal CHD. For males, looking across race/ethnicity and age categories, the share of non-fatal MI events is 4.9 percent to 28 percent, the share of non-fatal IS events is 9.4 percent to 38 percent, and the share of other non-fatal CHD events is 44 percent to 78 percent. For females, across race/ethnicity and age categories, the share of non-fatal MI events is 6.4 percent to 19 percent, the share of non-fatal IS events is 8.7 percent to 29 percent, and the share of other non-fatal CHD events is 51 percent to 76 percent. For both sexes, shares of all fatal events increase with age. The share of fatal CVD events is largest for Hispanic and non-Hispanic other race subpopulations of both sexes. Table 6-17 also shows derived race/ethnicity-, sex-, and age group-specific shares of first hard CVD events over ASCVD event types (i.e., non-fatal MI, non-fatal IS, and fatal CVD). Note that these shares were re-normalized to sum to 100 percent after exclusion of other non-fatal CHD not predicted by the ASCVD model. The CVD model relies on the re-normalized shares to allocate the total number of first hard CVD events predicted by the ASCVD model.

Table 6-17: Estimated Shares of Fatal and Non-Fatal First Hard CVD Events Based on MEPS and HCUP Data

Sex			N	on-Fatal CV	D (%)	Fatal CVD (%)		
	Age (in years)	Race/ Ethnicity	Non-Fatal MI (%)	Non-Fatal IS (%)	Other Non- Fatal CHD (%)	Fatal MI (%)	Fatal IS	Other Fatal CHD (%)
			Shares of F	irst Hard CV	D Events			
Males	18–44	NH White	14	9.4	77	0.19	0.17	0
	45-64	NH White	16	15	69	0.39	0.34	0.44
	65-84	NH White	13	20	64	0.71	0.75	0.76
	85 or older	NH White	13	20	63	1.3	1.4	1.9
	18–44	NH Black	4.9	17	78	0.067	0.31	0
	45-64	NH Black	11	38	50	0.28	0.88	0.32
	65-84	NH Black	8.9	22	67	0.48	0.8	0.79
	85 or older	NH Black	8.5	21	66	0.87	1.5	2
	18-44	Hispanic	23	17	59	0.31	0.31	0
	45-64	Hispanic	19	29	51	0.48	0.67	0.32
	65–84	Hispanic	20	17	60	1.1	0.65	0.71
	85 or older	Hispanic	19	17	59	2	1.2	1.8
	18–44	NH Other	26	30	44	0.35	0.54	0
	45–64	NH Other	28	19	52	0.71	0.43	0.33
	65–84	NH Other	13	25	60	0.71	0.92	0.71
	85 or older	NH Other	12	24	59	1.3	1.7	1.8
Females	18–44	NH White	8.1	19	72	0.13	0.41	0
1 Ciliaics	45–64	NH White	6.9	20	72	0.13	0.55	0.54
	65–84	NH White	11	28	58	0.68	1.2	
	85 or older	NH White	10	27	57	1.2	2.3	2.1
	18–44	NH Black	15	8.7	76	0.23	0.18	0
	45–64	NH Black	10	27	61	0.29	0.18	0.46
	65–84	NH Black	6.7	29	62	0.29	1.2	0.40
	85 or older	NH Black	6.4	28	61	0.42		2.2
	18–44		8.8	18	73	0.76	0.38	0
		Hispanic	13	27	59	0.14	0.38	0.45
	45–64 65–84	Hispanic Hispanic	19	26	52			0.43
				25	51	1.2	1.1 2.1	1.9
	85 or older	Hispanic	18			2.1		
	18–44	NH Other	11	13	75 55	0.17	0.27	0 42
	45–64	NH Other	14	29	55	0.42	0.78	0.42
	65–84	NH Other	12	28	58	0.74	1.2	0.81
	85 or older	NH Other	11	27	56	1.3	2.3	2.1
					redicted by the	ASCVD M		
Males	18–44	NH White	58	40	_		1.5	
	45–64	NH White	50	47	_		3.7	
	65–84	NH White	37	57	_		6.2	
	85 or older	NH White	34	53	_		13	
	18–44	NH Black	22	77	_		1.7	
	45–64	NH Black	22	75	_		2.9	
	65–84	NH Black	27	66	_		6.4	
	85 or older	NH Black	25	62	_		13	
	18–44	Hispanic	56	42	_		1.5	
	45-64	Hispanic	38	59	_		3.0	
	65-84	Hispanic	50	44	_		6.1	
	85 or older	Hispanic	47	41	_		12	
	18-44	NH Other	46	53	_		1.6	

Table 6-17: Estimated Shares of Fatal and Non-Fatal First Hard CVD Events Based on MEPS and HCUP Data

		Race/ Ethnicity	No	on-Fatal CV	D (%)	Fatal CVD (%)		
Sex	Age (in years)		Non-Fatal MI (%)	Non-Fatal IS (%)	Other Non- Fatal CHD (%)	Fatal MI (%)	Fatal IS	Other Fatal CHD (%)
	45–64	NH Other	58	39	_		3.1	
	65-84	NH Other	33	62	_		5.8	
	85 or older	NH Other	30	58	_		12	
Females	18–44	NH White	29	69	_		1.9	
	45-64	NH White	24	71	_		4.6	
	65-84	NH White	26	67	_		6.5	
	85 or older	NH White	24	63	_		13	
	18–44	NH Black	62	36	_		1.7	
	45-64	NH Black	26	70	_		3.9	
	65-84	NH Black	18	76	_		6.7	
	85 or older	NH Black	16	70	_		14	
	18-44	Hispanic	32	66	_		1.9	
	45-64	Hispanic	31	65	_		3.8	
	65-84	Hispanic	40	54	_		6.4	
	85 or older	Hispanic	37	51	_		12	
	18-44	NH Other	45	53	_		1.8	
	45-64	NH Other	32	64	_		3.6	
	65-84	NH Other	28	66	_		6.5	
	85 or older	NH Other	26	61	_		13	

Abbreviations: CVD – cardiovascular disease; CHD – coronary heart disease; fatal CVD – includes fatal MI, fatal IS, and fatal other coronary heart disease events; HCUP – Healthcare Cost and Utilization Project; IS – ischemic stroke; MEPS – Medical Expenditure Panel Survey; MI – myocardial infarction; NH – non-Hispanic.

6.5.3.3 Risk of Post-Acute Cardiovascular Disease Mortality

Persons who have experienced non-fatal MI and non-fatal IS have an elevated risk of post-acute CVD mortality and morbidity (Roger et al., 2012). Studies focusing on secondary hard CVD events point to an elevated risk of these events among survivors of the first hard CVD event (e.g., Beatty et al., 2015; S. Li et al., 2019; Thom et al., 2001), but do not support the link between these risks and TC/BP levels (Beatty et al., 2015). (See Appendix G for details.) Therefore, the CVD model evaluates post-acute CVD mortality among survivors of the initial MI/IS event under baseline and regulatory alternatives using the baseline post-acute mortality rates that do not depend on the levels of modeled biomarkers. The CVD model does not explicitly evaluate secondary CVD morbidity because available first non-fatal MI/IS valuation measures (e.g., O'Sullivan et al., 2011) incorporate incidence of these secondary events.

For survivors of the first hard CVD event at ages 40–65, EPA uses estimates of sex- and race/ethnicity-specific all-cause post-acute mortality for MI survivors at 1- and 5-year follow-up from Thom et al. (2001). Because Thom et al. (2001) reports all-cause post-acute mortality rates, EPA adjusted these rates to exclude deaths from non-CVD causes. To this end, EPA used general population integer age- and sex-specific all-cause mortality from U.S. Life Tables, 2017 (Arias et al., 2019), U.S. CVD mortality rates (CDC, 2020b), and U.S. Life Tables Eliminating

^aThe distribution is derived by (1) excluding the other non-fatal CHD category; (2) aggregating fatal MI, fatal IS, and other fatal CHD categories into the fatal CVD category; and (3) re-normalizing the data to sum to 100%.

Certain Causes of Death, 1999–2000 (Arias et al., 2013). Appendix G provides additional estimation details. Although EPA was unable to identify comparable post-acute mortality statistics for non-fatal IS, an analysis of the Medicare population by S. Li et al. (2019) suggests that post-acute MI mortality is a reasonable approximation for post-acute IS mortality. ⁶⁶ Table 6-18 shows estimated post-acute CVD mortality rates for survivors of the first MI or IS at ages 40–65 that are used to parameterize the CVD model.

For survivors of the first hard CVD event at ages 66+, EPA uses the results in S. Li et al. (2019) to estimate the number of post-acute CVD deaths within 6 years of the initial event. Because S. Li et al. (2019) reports only all-cause post-acute mortality rates, EPA adjusted these rates to exclude deaths from non-CVD causes. Integer age- and sex-specific probability of death from non-CVD causes was derived from U.S. Life Tables, 2017 (Arias et al., 2019), U.S. CVD mortality rates (CDC, 2020b), and U.S. Life Tables Eliminating Certain Causes of Death, 1999–2000 (Arias et al., 2013). The sex-specific probabilities of death from non-CVD causes were average using the demographic information for the cohorts analyzed by S. Li et al. (2019). See Appendix G for additional estimation details. Table 6-18 shows estimated post-acute CVD mortality rates for survivors of the first MI and survivors of the first IS at ages 66 years or older that are used to parameterize the CVD model. 67

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⁶⁶ For those age 65 or older, S. Li et al. (2019) have estimated the probability of death within 1 year after non-fatal IS to be 32.07 percent and the probability of death within 1 year after non-fatal MI to be 32.09 percent.

⁶⁷ These rates are applied to all those aged 66+ in the SafeWater MCBC implementation of the model.

Table 6-18: Estimated Risk of Post-Acute CVD Mortality Following the First Non-Fatal Hard CVD Event

Type of First Non-	Demographic Group	Post-Acute CVD Mortality Rate per 100,000 by Integer Year Since the First Non-Fatal Hard CVD Event							
Fatal Hard CVD Event		0	1	2	3	4	5		
Source: Thom et al. (2001)									
	Non-Hispanic White b males aged 45–65 years	4,500	910	860	820	760	_		
MI ICa	Non-Hispanic Black males aged 45–65 years	12,000	1,200	1,100	1,100	1,000	_		
MI, IS ^a	Non-Hispanic White b females aged 45–65 years	8,600	1,900	1,900	1,900	1,800	_		
	Non-Hispanic Black females aged 45–65 years	7,700	4,300	4,200	4,100	4,100	_		
	Sour	rce: S. Li et	al. (2019)						
MI	Persons aged 66+ years	27,000	11,000	9,600	9,040	8,600	8,040		
IS	Persons aged 66+ years	28,000	9,900	10,000	9,800	8,900	8,030		

Abbreviations: CVD – cardiovascular disease; IS – ischemic stroke (International Classification of Disease Ninth Revision [ICD9]=433, 434; International Classification of Disease Tenth Revision [ICD10]=I63), MI – myocardial infarction (ICD9=410; ICD10=I21).

Notes:

6.5.4 Valuation of Cardiovascular Disease Risk Reductions

EPA uses the Value of Statistical Life to estimate the benefits of reducing mortality associated with hard CVD events in the population exposed to PFOA and PFOS in drinking water. Value of Statistical Life updating information is provided in Section 2.2. EPA relies on COI-based valuation that represents the medical costs of treating or mitigating non-fatal first hard CVD events (MI, IS) during the three years following an event among those without prior CVD history, adjusted for post-acute mortality.

The annual medical expenditure estimates for MI and IS are based on O'Sullivan et al. (2011). The estimated expenditures do not include long-term institutional and home health care. For nonfatal MI, O'Sullivan et al. (2011) estimated medical expenditures are \$51,173 (\$2021) ⁶⁸ for the initial event and then \$31,871, \$14,065, \$12,569 annually within 1, 2, and 3 years after the initial event, respectively. For non-fatal IS, O'Sullivan et al. (2011) estimated medical expenditures are \$15,861 (\$2021) for the initial event and then \$11,521, \$748, \$1,796 annually within 1, 2, and 3 years after the initial event, respectively. Annual estimates within 1, 2, and 3 years after the initial event include the incidence of secondary CVD events among survivors of first MI and IS events.

To estimate the present discounted value of medical expenditures within 3 years of the initial non-fatal MI, EPA combined O'Sullivan et al. (2011) MI-specific estimates with post-acute

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^aThom et al. (2001) reported data for the first MI survivors only for aged 45–64 years. The CVD model applies these rates to both the first MI and first IS survivors.

^bEstimates for non-Hispanic White populations are applied to other ethnic groups.

⁶⁸ Original values from the source were inflated to \$2019 using the medical care Consumer Price Index (U.S. Bureau of Labor Statistics, 2021).

survival probabilities based on Thom et al. (2001) (for MI survivors aged 40-64) and S. Li et al. (2019) (for MI survivors aged 65+). To estimate the present discounted value of medical expenditures within 3 years of the initial non-fatal IS, EPA combined O'Sullivan et al. (2011) IS-specific estimates with post-acute survival probabilities based on Thom et al. (2001) (for IS survivors aged 40-64, assuming post-acute MI survival probabilities reasonably approximate post-acute IS survival probabilities) and S. Li et al. (2019) (for IS survivors aged 65+). EPA did not identify post-acute IS mortality information in this age group, but instead applied post-acute MI mortality estimates for IS valuation. ⁶⁹ Table 6-19 presents the resulting MI and IS unit values.

Table 6-19: Cost of Illness of Non-Fatal First CVD Event Used in Modeling

Type of First Non-fatal	Age Group	Present Discounted Value of 3-Year Medical Expenditures (\$2021) ^{a,b} Adjusted for Post-Acute Mortality ^c					
Hard CVD Event	rige Group	3% discount rate	7% discount rate				
MI	40-64 years	\$105,419	\$104,155				
	65+ years	\$92,658	\$91,881				
IS	40-64 years	\$29,154	\$29,017				
	65+ years	\$26,844	\$26,762				

Abbreviations: CVD – cardiovascular disease; MI – myocardial infarction (ICD9=410; ICD10=I21), IS – ischemic stroke (ICD9=433, 434; ICD10=I63).

Notes:

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^a Estimates of annual medical expenditures are from O'Sullivan et al. (2011).

^bOriginal values from O'Sullivan et al. (2011) were inflated to \$2021 using the medical care Consumer Price Index (U.S. Bureau of Labor Statistics, 2021).

^cPost-acute MI mortality data for those aged 40-64 years is from Thom et al. (2001); probabilities to survive 1 year, 2 years, and 3 years after the initial event are 0.93, 0.92, and 0.90, respectively. EPA applies these mortality values to derive the IS value in this age group. Post-acute MI mortality data and post-acute IS mortality data for persons aged 65 years and older are from S. Li et al. (2019). For MI, probabilities to survive 1 year, 2 years, and 3 years after the initial event are 0.68, 0.57, and 0.49, respectively. For IS, probabilities to survive 1 year, 2 years, and 3 years after the initial event are 0.67, 0.57, and 0.48, respectively.

⁶⁹ Post-acute mortality estimates for IS and MI were very close in the Medicare population (S. Li et al., 2019). For those ages 65 years or older, Li et al. (2019) have estimated probability of death within 1 year after non-fatal IS to be 32.07 percent and probability of death within 1 year after non-fatal MI to be 32.09 percent. Therefore, reliance on the post-acute mortality for MI to approximate the same for stroke is reasonable.

6.5.5 Results

Table 6-20 to Table 6-23 provide the health effects avoided and valuation associated with cardiovascular disease.

Table 6-20: National CVD Benefits, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0)

	3%	% Discount Ra	te	7% Discount Rate			
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Number of Non-Fatal MI Cases Avoided	1,251.5	6,081.0	11,738.7	1,251.5	6,081.0	11,738.7	
Number of Non-Fatal IS Cases Avoided	1,814.0	8,870.8	17,388.5	1,814.0	8,870.8	17,388.5	
Number of CVD Deaths Avoided	753.6	3,584.6	7,030.9	753.6	3,584.6	7,030.9	
Total Annualized CVD Benefits (Million \$2021) ^b	\$111.78	\$533.48	\$1,051.00	\$85.94	\$421.10	\$822.88	

Abbreviations: CVD - cardiovascular disease, MI - myocardial infarction, IS - Ischemic Stroke.

Notes: Detail may not add exactly to total due to independent rounding.

Table 6-21: National CVD Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ppt)

	3%	6 Discount Ra	te	7% Discount Rate			
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Number of Non-Fatal MI Cases Avoided	1,248.7	5,983.8	11,614.9	1,248.7	5,983.8	11,614.9	
Number of Non-Fatal IS Cases Avoided	1,786.4	8,729.6	17,149.5	1,786.4	8,729.6	17,149.5	
Number of CVD Deaths Avoided	744.6	3,527.8	6,951.5	744.6	3,527.8	6,951.5	
Total Annualized CVD Benefits (Million \$2021) ^b	\$110.45	\$525.05	\$1,035.36	\$86.32	\$414.45	\$817.79	

Abbreviations: CVD - cardiovascular disease, MI - myocardial infarction, IS - Ischemic Stroke.

Notes: Detail may not add exactly to total due to independent rounding.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 6-22: National CVD Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ppt)

	39	% Discount Ra	te	7% Discount Rate			
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Number of Non-Fatal MI Cases Avoided	1,105.9	5,220.7	10,215.4	1,105.9	5,220.7	10,215.4	
Number of Non-Fatal IS Cases Avoided	1,609.3	7,624.2	15,029.5	1,609.3	7,624.2	15,029.5	
Number of CVD Deaths Avoided	645.9	3,084.6	6,102.2	645.9	3,084.6	6,102.2	
Total Annualized CVD Benefits (Million \$2021) ^b	\$99.73	\$459.09	\$908.82	\$72.72	\$362.42	\$717.85	

Abbreviations: CVD - cardiovascular disease, MI - myocardial infarction, IS - Ischemic Stroke.

Notes: Detail may not add exactly to total due to independent rounding.

Table 6-23: National CVD Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ppt)

	3%	6 Discount Ra	te	7% Discount Rate			
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Number of Non-Fatal MI Cases Avoided	619.0	3,032.5	6,320.7	619.0	3,032.5	6,320.7	
Number of Non-Fatal IS Cases Avoided	878.1	4,445.9	9,439.4	878.1	4,445.9	9,439.4	
Number of CVD Deaths Avoided	343.8	1,806.7	3,835.8	343.8	1,806.7	3,835.8	
Total Annualized CVD Benefits (Million \$2021) ^b	\$51.00	\$268.78	\$571.32	\$41.85	\$212.18	\$450.51	

Abbreviations: CVD - cardiovascular disease, MI - myocardial infarction, IS - Ischemic Stroke.

Notes: Detail may not add exactly to total due to independent rounding.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable costs, and the potential direction of impact these costs would have on the estimated monetized total annualized costs in this table.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

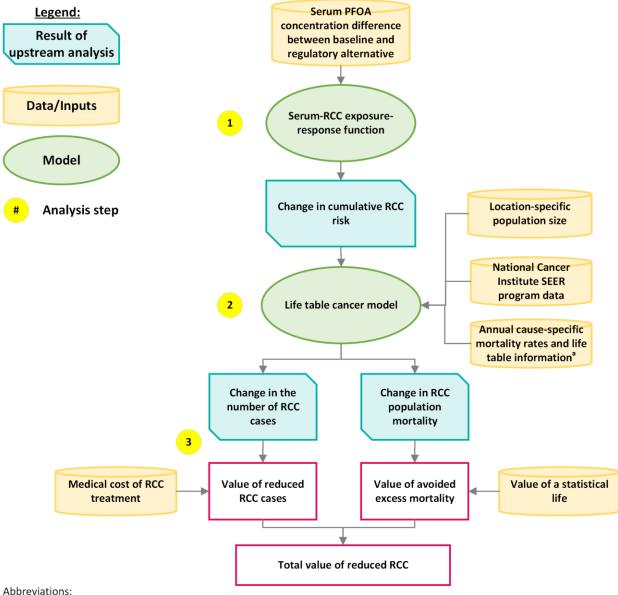
6.6 Renal Cell Carcinoma

6.6.1 Overview of the RCC Risk Reduction Analysis

Figure 6-9 illustrates the approach used to quantify and value the changes in RCC risk associated with lowered serum PFOA levels from reductions in drinking water PFOA concentrations under the regulatory alternatives. Section 4.4 and Section 6.3 detail the PWS EP-specific PFOA drinking water occurrence estimation and modeling of serum PFOA concentrations, respectively. PWS EP-specific time series of the differences between serum PFOA concentrations under baseline and regulatory alternatives are inputs into this analysis. For each PWS EP, evaluation of the changes in RCC impacts involves the following key steps:

- 1. Estimating the changes in RCC risk based on modeled changes in serum PFOA levels and the exposure-response function for the effect of serum PFOA on RCC;
- 2. Estimating the annual incidence of RCC cases and excess mortality among those with RCC in all populations corresponding to baseline and regulatory alternative RCC risk levels, as well as estimating the regulatory alternative-specific reduction in cases relative to the baseline; and
- 3. Estimating the economic value of reducing RCC mortality from baseline to regulatory alternative levels, using the Value of Statistical Life and COI measures, respectively.

Section 6.6.2 discusses the exposure-response modeling for RCC. Section 6.6.3 summarizes the life table-based approach for estimation of RCC risk reductions. Section 6.6.4 discusses EPA's valuation methodology for RCC mortality and morbidity. Section 6.6.5 presents the results of the analysis.



PFOA – perfluorooctanoic acid, RCC – renal cell carcinoma, SEER - Surveillance, Epidemiology, and End Results program

(a) Data from the Centers for Disease Control (CDC) and Prevention.

Figure 6-9: Overview of Analysis of Reduced RCC Risk

6.6.3 RCC Exposure-Response Modeling

To identify an exposure-response function, EPA reviewed studies highlighted in the HESD for PFOA (U.S. EPA, 2016f) and a recent study discussed in both the California Environmental Protection Agency's Office of Environmental Health Hazard Assessment (OEHHA) PFOA Public Health Goals report (CalEPA, 2021) and EPA's *Toxicity Assessment and Proposed Maximum Contaminant Level Goal for PFOA in Drinking Water* (U.S. EPA, 2023e). Steenland et al. (2015) observed an increase in kidney cancer deaths among workers with high exposures to PFOA. Vieira et al. (2013) found that kidney cancer was positively associated with high and very high PFOA exposures. Barry et al. (2013) found a slight trend in cumulative PFOA serum exposures and kidney cancer among the C8 Health Project population.⁷⁰ In a large case-control general population study of the relationship between PFOA and kidney cancer in 10 locations across the U.S., Shearer et al. (2021) found strong evidence that exposure to PFOA causes RCC, the most common form of kidney cancer, in humans.

To evaluate changes between baseline and regulatory alternative RCC risk resulting from reduced exposure to PFOA, EPA relied on the estimated time series of changes in serum PFOA concentrations (Section 6.3) and the serum-RCC exposure-response function provided by Shearer et al. (2021): 0.00178 (95% CI: 0.00005, 0.00352) per ng/mL. The analysis from Shearer et al. (2021) was designed as a case-control study with population controls based on 10 sites within the U.S. population. Shearer et al. (2021) included controls for age, sex, race, ethnicity, study center, year of blood draw, smoking, and hypertension. Results showed a strong and statistically significant association between PFOA and RCC. EPA selected the exposure-response relationship from Shearer et al. (2021) because it included exposure levels typical in the general population and was found to have a low risk of bias when assessed in EPA's *Toxicity Assessment and Proposed Maximum Contaminant Level Goal for PFOA in Drinking Water* (U.S. EPA, 2023e).

The linear slope factor based on Shearer et al. (2021) enables estimation of the changes in the lifetime RCC risk associated with reduced lifetime serum PFOA levels:

Equation 18:

$$LR(x) = LR(z) + 0.00178 \cdot (x - z)$$

Where LR(x) is the probability of lifetime RCC incidence for an individual exposed to a lifetime average serum PFOA concentration of x ng/mL, and LR(z) is the probability of lifetime RCC at the baseline lifetime average serum PFOA concentration of z ng/mL.

Because baseline RCC incidence statistics are not readily available from the National Cancer Institute public use data, EPA used kidney cancer statistics in conjunction with an assumption that RCC comprises 90 percent of all kidney cancer cases to estimate baseline lifetime probability of RCC (U.S. EPA, 2023e). EPA estimated the baseline lifetime RCC incidence for males at 1.89 percent and the baseline lifetime RCC incidence for females at 1.05 percent. Details of these calculations are provided in Appendix H. Because the Shearer et al. (2021) slope

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⁷⁰ The C8 Health Project collected data to ascertain the amount of C8 (otherwise known as PFOA) in blood among Mid-Ohio Valley communities from 2005-2013. Mean PFOA at enrollment 24 ng/mL.

factor is not sex-specific, EPA averaged sex-specific baseline lifetime RCC estimates to obtain LR(z) = 0.0147 for use in the estimation of annual RCC risk changes.

To enable annual RCC risk estimation, EPA further assumed that the relative risk relationship implied by Equation 18, i.e., $RR(x,z) = LR(x)/LR(z) = 1 + 0.00178 \cdot (x-z)/LR(z) = 1 + 0.00178 \cdot (x-z)/0.0147$, also holds for the cumulative RCC risk and cumulative average exposure to serum PFOA from birth to a specific age.

A person's cumulative serum PFOA exposure by age a—denoted by x_a —is defined as:

Equation 19:

$$x_a = \frac{1}{a} \sum_{i=0}^{a-1} serum \, PFOA_i$$
, $x_0 = 0$

EPA estimated the relative risk of RCC by a particular age from a change in average serum PFOA experienced by this age as follows:

Equation 20:

$$RR(x_a, z_a) = max \left(1 - PAF, 1 + \frac{0.00178 \cdot (x_a - z_a)}{0.0147}\right)$$

Where $RR(x_a, z_a)$ is the relative cumulative risk of RCC by age a associated with a change from baseline cumulative exposure z_a to treatment cumulative exposure x_a and PAF is the environmental exposure-related population attributable fraction of RCC incidence set at 0.0394. As such, this equation implies that EPA caps the magnitude of PFOA-related cumulative RCC risk reduction at the PAF of 3.94 percent to ensure plausibility of the estimated RCC benefits size. EPA developed this PAF estimate based on its review of literature on environmental contaminant-attributable risk estimates for cancers (ICF, 2022b). In calculations of the annual RCC risk changes, EPA continued to assume that RCC comprises 90 percent of annual kidney cancer incidence.

6.6.3 Estimation of RCC Risk Reductions

EPA relies on the life-table approach to estimate RCC risk reductions because:

- Changes in serum PFOA in response to changes in drinking water PFOA occur over multiple years;
- Annual risk of new RCC should be quantified only among those not already experiencing this chronic condition;
- RCC has elevated mortality implications.

EPA used recurrent life table calculations to estimate PWS EP-specific time series of RCC incidence for a population cohort characterized by sex, race/ethnicity, birth year, and age at the beginning of the evaluation period (i.e., 2023) under the baseline scenario and the regulatory alternatives. The life-table analysis accounts for the gradual changes in lifetime exposures to

PFOA following implementation of treatment under the regulatory alternatives compared to the baseline.⁷¹ Details of the life-table calculations are provided in Appendix H. The outputs of the life-table calculations are the PWS EP-specific estimates of the annual change in the number of RCC cases and the annual change in RCC population mortality.

Although the change in PFOA exposure likely affects the risk of developing RCC beyond the end of the analysis period (the majority of RCC cases manifest during the latter half of the average individual lifespan; see Appendix H), EPA does not capture effects after the end of the period of analysis, 2104. Individuals alive after the end of the period of analysis likely benefit from lower lifetime exposure to PFOA. Lifetime health risk model data sources include EPA SDWIS; age-, sex-, and race/ethnicity-specific population estimates from the U.S. Census Bureau (U.S. Census Bureau, 2020a); the Surveillance, Epidemiology, and End Results (SEER) program database (National Cancer Institute),⁷² and the CDC National Center for Health Statistics.⁷³ Appendix H provides additional detail on the data sources and information used in this analysis as well as baseline kidney cancer statistics. Appendix B describes estimation of the affected population.

6.6.4 Valuation of RCC Risk Reductions

EPA uses the Value of Statistical Life to estimate the benefits of reducing mortality associated with RCC in the population exposed to PFOA in drinking water. Section 2.2 provides information on updating Value of Statistical Life for inflation and income growth. EPA uses the COI-based valuation to estimate the benefits of reducing morbidity associated with RCC.

EPA used the medical cost information from a recent RCC cost-effectiveness study by Ambavane et al. (2020) to develop COI estimates for RCC morbidity. Ambavane et al. (2020) used a discrete event simulation model to estimate the lifetime treatment costs of several RCC treatment sequences, which included first and second line treatment medication costs, medication administration costs, adverse effect management costs, and disease management costs on- and off-treatment. To this end, the authors combined RCC cohort data from a *CheckMate 214* clinical trial and recent US-based healthcare cost information assembled from multiple sources (see supplementary information from Ambavane et al. (2020)).

Table 6-24 summarizes RCC morbidity COI estimates derived by EPA using Ambavane et al. (2020)-reported disease management costs on- and off-treatment along with medication, administration, and adverse effect management costs for the first line treatment that initiated the most cost-effective treatment sequences as identified by Ambavane et al. (2020), i.e., the nivolumab / ipilimumab drug combination. This is a forward-looking valuation approach in that it assumes that the clinical practice would follow the treatment recommendations in Ambavane et al. (2020) and other recent studies cited therein. EPA notes that the second line treatment costs

⁷¹ As described above, EPA models PFAS changes under the regulatory alternatives as being in effect for the years 2023 through 2104, with nonzero PFAS changes first occurring in 2026, the year when all PWSs are assumed to comply with PFAS treatment requirements.

⁷² For cancer incidence and stage distribution data, EPA relies on SEER 21 (2009-2018); for cancer survival data, EPA relies on SEER 18 (2000-2017).

⁷³ CDC WONDER data on 1999-2019 all-cause and kidney cancer mortality by age and sex.

⁷⁴ Second line cancer treatment is a treatment implemented after the failure of the initial treatment (i.e., first line treatment). The first line treatment may fail because it stops working or has side effects that are not tolerated.

are not reflected in EPA's COI estimates, because Ambavane et al. (2020) did not report information on the expected durations of the treatment-free interval (between the first line treatment discontinuation and the second line treatment initiation) and the second line treatment phase, conditional on survival beyond discontinuation of the second line treatment. As such, EPA valued RCC morbidity at \$251,007 (\$2021) during year 1 of the diagnosis, \$190,969 (\$2021) during year 2 of the diagnosis, and \$1,596 (\$2021) starting from year 3 of the diagnosis. Additionally, EPA assumed that for individuals with RCC who die during the specific year, the entire year-specific cancer treatment regimen is applied prior to the death event. This may overestimate benefits if a person does not survive the entire year.

Table 6-24: RCC Morbidity Valuation

Time Interval	First Line Medication (\$2018) ^a	First Line Administration (\$2018)ª	First Line Adverse Effect Management (\$2018) ^{a.c}	Disease Management (\$2018)ª	Total (\$2018)	Total (\$2021) ^d
Monthly cost, month 1-3 from diagnosis ^{a,e}	32,485	516	78	73	33,152	35,927
Monthly cost, month 4-24 from diagnosis ^{b,f}	13,887	647	78	73	14,685	15,914
Monthly cost, month 25+ from diagnosis ^g	-	-	-	123	123	133
Annual cost, year 1 from diagnosis	222,438	7,371	934	878	231,621	251,007
Annual cost, year 2 from diagnosis	166,644	7,764	934	878	176,220	190,969
Annual cost, year 3+ from diagnosis	-	-	-	1,473	1,473	1,596

Abbreviations: RCC – renal cell carcinoma.

Notes:

6.6.5 Results

Table 6-25 to Table 6-28 provide the health effects avoided and valuation associated with renal cell carcinoma.

^aAmbavane et al. (2020) Table 1;

^bAmbavane et al. (2020) p. 41, a maximum treatment duration assumption of 2 years;

^cThe adverse effect management costs of \$1,868 in Ambavane et al. (2020) Table 1 were reported for the treatment duration.

EPA used the treatment duration of 24 months (i.e., 2 years) to derive monthly costs of \$77.83;

^dTo adjust for inflation, EPA used U.S. Bureau of Labor Statistics Consumer Price Index for All Urban Consumers: Medical Care Services in U.S. (City Average).

^eFirst line treatment induction

^fFirst line treatment maintenance

gTreatment-free interval

Table 6-25: National RCC Benefits, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0)

	3%	6 Discount Ra	ate	7% Discount Rate			
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Number of Non-Fatal RCC Cases Avoided	1,313.6	6,872.0	17,387.8	1,313.6	6,872.0	17,387.8	
Number of RCC-Related Deaths Avoided	308.7	1,927.8	5,049.3	308.7	1,927.8	5,049.3	
Total Annualized RCC Benefits (Million \$2021) ^b	\$54.23	\$300.56	\$758.03	\$45.36	\$217.37	\$515.89	

Abbreviations: RCC – Renal Cell Carcinoma.

Notes: Detail may not add exactly to total due to independent rounding.

Table 6-26: National RCC Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ppt)

	3%	6 Discount Ra	ate	7% Discount Rate			
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Number of Non-Fatal RCC Cases Avoided	1,289.6	6,753.3	17,147.8	1,289.6	6,753.3	17,147.8	
Number of RCC-Related Deaths Avoided	300.5	1,895.2	4,960.4	300.5	1,895.2	4,960.4	
Total Annualized RCC Benefits (Million \$2021) ^b	\$52.92	\$295.53	\$744.64	\$45.09	\$213.78	\$508.56	

Abbreviations: RCC - Renal Cell Carcinoma.

Notes: Detail may not add exactly to total due to independent rounding.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 6-27: National RCC Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ppt)

	3%	6 Discount Ra	ite	7% Discount Rate			
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Number of Non-Fatal RCC Cases Avoided	1,017.6	5,681.7	14,962.1	1,017.6	5,681.7	14,962.1	
Number of RCC-Related Deaths Avoided	235.9	1,602.1	4,317.6	235.9	1,602.1	4,317.6	
Total Annualized RCC Benefits (Million \$2021) ^b	\$42.28	\$250.60	\$643.71	\$36.32	\$182.24	\$446.80	

Abbreviations: RCC - Renal Cell Carcinoma.

Notes: Detail may not add exactly to total due to independent rounding.

Table 6-28: National RCC Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ppt)

	3%	6 Discount Ra	ate	7% Discount Rate			
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Number of Non-Fatal RCC Cases Avoided	433.5	2,903.0	8,205.4	433.5	2,903.0	8,205.4	
Number of RCC-Related Deaths Avoided	101.1	831.8	2,406.2	101.1	831.8	2,406.2	
Total Annualized RCC Benefits (Million \$2021) ^b	\$18.58	\$131.44	\$367.38	\$17.34	\$97.30	\$260.54	

Abbreviations: RCC - Renal Cell Carcinoma.

Notes: Detail may not add exactly to total due to independent rounding.

6.7 Benefits from Co-Removal of Disinfection Byproducts

As part of its health risk reduction and cost analysis, EPA is directed by SDWA to evaluate quantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur from reductions in co-occurring contaminants that may be attributed solely to compliance with the maximum contaminant level (SDWA 1412(b)(3)(C)(II)). These co-occurring contaminants are expected to include additional PFAS contaminants not directly regulated by the proposed PFAS NPDWR, co-occurring chemical contaminants such as SOCs, VOCs, and DBP precursors. In this section,

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

EPA presents a quantified estimate of the reductions in DBP formation potential that are likely to occur as a result of compliance with the proposed PFAS NPDWR.⁷⁵

6.7.1 Overview of Reduced Disinfection Byproduct Formation

DBPs are formed when disinfectants react with naturally occurring materials in water. Under the Stage 2 Disinfectants and Disinfection Byproducts Rule (Stage 2 DBP Rule, U.S. EPA, 2006b), EPA regulates 11 individual DBPs from three subgroups: four trihalomethanes, five haloacetic acids, and two inorganic compounds (bromate and chlorite). Under the Stage 2 DBP Rule, compliance is based on a locational running annual average (LRAA) calculation, where the annual average at each sampling location in the distribution system is used to determine compliance with the MCL of 0.08 mg/L for THM4 (regulated as TTHM, bromodichloromethane, bromoform, chloroform, and dibromochloromethane). There is a substantial body of literature on DBP precursor occurrence and THM4 formation mechanisms in drinking water treatment. The formation of THM4 in a particular drinking water treatment plant is a function of several factors including disinfectant type, disinfectant dose, bromide concentration, organic material type and concentration, temperature, pH, and system residence times. Epidemiology studies have shown that THM4 exposure, a surrogate for chlorinated drinking water, is associated with an increased risk of bladder cancer, among other diseases (Cantor et al., 1998; Cantor et al., 2010; Costet et al., 2011; Freeman et al., 2017; King et al., 1996; Regli et al., 2015; Villanueva et al., 2004; Villanueva et al., 2006) and U.S. EPA (2019d). These studies considered THM4 as surrogate measures for DBPs formed from the use of chlorination that may co-occur. Reductions in exposure to THM4 is expected to yield significant public health benefits (Regli et al., 2015). In what Richardson (2022) describes as the "largest risk assessment of DBPs in the U.S. to date, focusing on bladder cancer cases associated with chlorinated drinking water", Weisman et al. (2022) estimated that 8,000 of 79,000 national cases of bladder cancer are attributable to DBPs in drinking water.

EPA used the following data sources for the DBP co-removal analysis (see Table 6-29).

Table 6-29: Data Sources and How the Information Derived from each Source is Used in the DBP Co-Removal Analysis

Data Source	Acronym	How Specific Data was Used in Analysis		
Consumer Confidence Reports		• Identify GAC treatment start date/year.		
		 Identify intended purpose for GAC treatment. 		
	CCR	 Estimate baseline THM4 (four regulated trihalomethanes) concentrations at systems when SYR4 data were unavailable. 		
		 Calculate THM4 reduction at systems when SYR4 data were unavailable. 		

⁷⁵ The methodology detailed in Section 6.7.1 on estimated DBP reductions was externally peer reviewed by three experts in GAC treatment for PFAS removal and DBP formation potential. The external peer reviewers supported EPA's approach and edits based on their recommendations for clarity and completeness are reflected in the following analysis and discussion. Some peer reviewer comments suggested EPA provide additional baseline data summaries for TOC and THM4 occurrence information. EPA will include these additional summaries in the EA for the final rule.

Table 6-29: Data Sources and How the Information Derived from each Source is Used in the DBP Co-Removal Analysis

the DDI Co-Removal III	idiysis	
Data Source	Acronym	How Specific Data was Used in Analysis
DBP Information Collection Rule Treatment Study Database	DBP ICR TSD	• Estimate changes in THM4 levels based on implementing GAC treatment.
DBP ICR Aux 1 (1998)	Aux 1	 Evaluate changes in DBP precursor occurrence over time by comparing TOC data to SYR3 TOC data.
Six-Year Review 3, Information Collection Rule (2011)	SYR3 ICR	• Evaluate raw water TOC data.
Six-Year Review 4, Information Collection Rule (2019)	SYR4 ICR	Evaluate raw water TOC data.Estimate baseline THM4 concentrations.Calculate THM4 reductions.
Unregulated Contaminant Monitoring Rule 3	UCMR 3	 Inform a Bayesian occurrence model to identify PWSs expected to implement treatment under the NPDWR. Identify PWSIDs that had a detectable level of PFOA and/or PFOS to identify systems used in trihalomethane reduction comparison.
Unregulated Contaminant Monitoring Rule 4	UCMR 4	Identify plants that indicated GAC treatment.Inform disinfectant type.

Abbreviations: THM4 – Four Regulated Trihalomethanes; DBP – disinfection byproduct; NPDWR – National Primary Drinking Water Regulation; PWS – public water system; PWSID – Public water system identifier; SYR – Six Year Review; GAC – Granular Activated Carbon; PFOS – perfluorooctane sulfonic acid; PFOA – perfluorooctanoic acid.

6.7.1.1 Overview of PFAS Treatment with Disinfection Byproduct Reduction

GAC adsorption has been used to remove synthetic organic chemicals, taste and odor compounds, and natural organic matter (NOM) during drinking water treatment (Chowdhury et al., 2013). Recently, many water utilities have installed or are considering installing GAC and/or other advanced technologies as a protective or mitigation measure to remove various contaminants of emerging concern, such as PFAS (Dickenson et al., 2016). Because NOM often exists in a much higher concentration (in mg/L) than trace organics (in µg/L or ng/L) in water, NOM, often measured as TOC, can interfere with the adsorption of trace organics by outcompeting the contaminants for adsorption sites and by general fouling (blockage of adsorption pores) of the GAC.

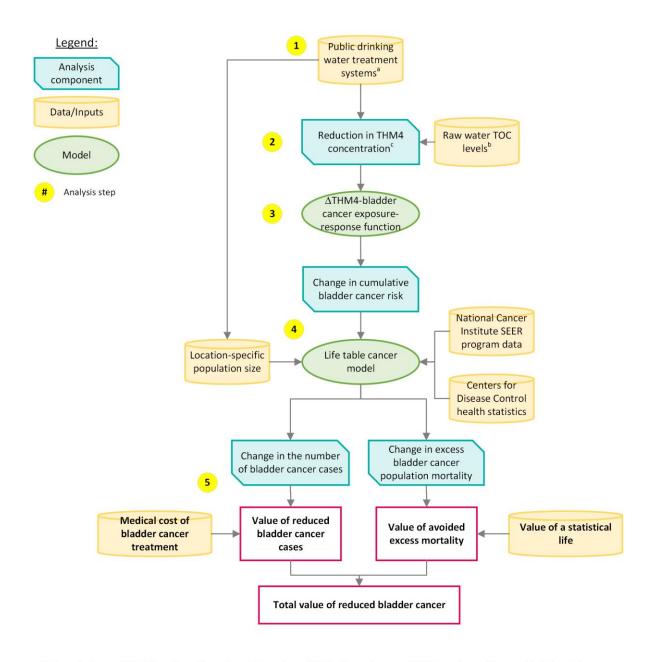
NOM and inorganic matter are precursors for the formation of THMs and other DBPs when water is disinfected using chlorine and other disinfectants to control microbial contaminants in finished drinking water. Removal of DBP precursors through adsorption onto GAC has been included as a treatment technology for compliance with the existing DBP Rules and is a best available technology (BAT) for the Stage 2 DBP Rule. Dissolved organic matter can be removed

by GAC through adsorption and biodegradation (Crittenden et al., 1993; Kim et al., 1997; Yapsakli et al., 2010). Upon startup, the initial removal is via adsorption of the DBP precursors; GAC is well-established for removal of THM and HAA precursors (Dastgheib et al., 2004; Cheng et al., 2005; Iriarte-Velasco et al., 2008; Summers et al., 2013; Cuthbertson et al., 2019; L. Wang et al., 2019). However, biodegradation becomes the predominant mechanism over time as adsorption capacity is exhausted and microbial growth within the GAC column establishes itself (Speitel Jr et al., 1989; Velten et al., 2007). In addition to removal of organic DBPs, GAC also exhibits some capacity for removal of inorganic DBPs such as bromate and chlorite (Kirisits et al., 2000; Sorlini et al., 2005) and removal of preformed organic DBPs via adsorption and biodegradation (Jiang et al., 2017; Terry et al., 2018). Further, GAC may offer limited removal of dissolved organic nitrogen (Chili et al., 2012).

Based on an extensive review of published literature in sampling studies where both contaminant groups (PFAS and DBPs) were sampled, few direct studies examined both PFAS and DBP coremoval. To help inform its economic analysis, EPA relied on the DBP Information Collection Rule Treatment Study Database and DBP formation studies to estimate reductions in THM4 (Δ THM4) that may occur when GAC is used to remove PFAS. Subsequently, these results were compared to THM4 data from PWSs that have detected PFAS and have indicated use of GAC.

The objective of the co-removal benefits analysis is to determine the reduction in bladder cancer cases associated with the decrease of regulated THM4 in treatment plants due to the installation of GAC for PFAS removal. Figure 6-10 illustrates EPA's approach for quantifying the human health benefits of reducing THM4 levels in drinking water. The analysis entails:

- 1. Estimating the number of systems expected to install GAC treatment in compliance with the proposed PFAS NPDWR and affected population size;
- 2. Estimating changes in THM4 levels that may occur when GAC is installed for PFAS removal based on influent TOC levels;
- 3. Estimating changes in the cumulative risk of bladder cancer using an exposure-response function linking lifetime risk of bladder cancer to THM4 concentrations in residential water supply (Regli et al., 2015);
- 4. Estimating annual changes in the number of bladder cancer cases and mortality in the bladder cancer population corresponding to changes in THM4 levels under the regulatory alternative in all populations alive during or born after the start of the evaluation period;
- 5. Estimating the economic value of reducing bladder cancer morbidity and mortality from baseline to regulatory alternative levels, using COI measures and the VSL, respectively.



Abbreviations: THM4 = Four Regulated Species of Trihalomethanes; SEER = Surveillance, Epidemiology, and End Results; TOC = Total Organic Carbon

Figure 6-10: Overview of Analysis of Co-Removal Benefits

^aSystems expected to be triggered into PFAS treatment using either granular activated carbon (GAC) or ion exchange (IX) treatment technologies.

^bBased on median raw water TOC annual system-means for non-purchased water systems.

Based on THM4 reductions due to GAC installation from the disinfection byproduct (DBP) information collection rule (ICR) treatment studies. Reductions dependent on empty bed contact time (EBCT) and source water type (surface water or groundwater).

6.7.1.2 Baseline Information on DBP Precursors and Trihalomethane Formation

DBP precursors are the chemical constituents that are reactants or intermediates in the formation of DBPs. Precursors can be characterized by their origin and the nature of their chemistry (inorganic vs. organic). Precursors include NOM and anthropogenic organic matter (i.e., wastewater) from watersheds, organic matter contaminants within treatment processes, and biofilm growth within the distribution system. Additional precursors include inorganic matter present in source water from anthropogenic and natural sources, or chemical additives introduced during treatment. The presence of DBP precursors is site-specific and dependent on many factors such as, but not limited to, environment, location, watershed, and treatment.

EPA evaluated raw water TOC data included in the SYR3 and SYR4 ICR datasets (U.S. EPA, 2016j; U.S. EPA, 2022i). The fourth Unregulated Contaminant Monitoring Rule (UCMR 4) TOC data were not used since that dataset did not include THM4 information. In addition, EPA compared the DBP ICR Aux 1 TOC data (pre-Stage 1 DBP Rule⁷⁶) to the SYR3 ICR TOC data to evaluate changes in DBP precursor occurrence over time. PWSs (specifically subpart H systems⁷⁷) are required to achieve a certain percentage of TOC removal; occurrence estimates for TOC are typically evaluated at the plant-level. The SYR3 ICR dataset contains TOC data for 33 states and systems of all sizes. The SYR4 ICR dataset contains TOC data for 49 states/tribes and systems of all sizes. To be consistent with SYR3 and SYR4 data management protocols, non-detections of TOC were assigned a value of 0.0 mg/L for all plant-mean calculations (U.S. EPA, 2016a).

In U.S. EPA (2005b), EPA reviewed the raw water TOC levels for Ground Water plants included in the DBP ICR Aux 1 data. The results shown in Table 6-30 represent the distribution of Ground Water plant-mean data as calculated using ICR Aux 1 monthly data from the year 1998. Only plants with reported data for at least 9 of the 12 months are included in this summary table. Note that the table does not include results for blended, mixed, or purchased water plants. Table 6-31shows the distribution of plant-mean TOC concentrations in raw water for non-purchased Surface Water plants. Segmenting the plants with raw water TOC means provides some indication of the percentage of plants that would be within each THM4 reduction category outlined in Section 6.7.1.3. The levels in Ground Water plants tended to be lower compared to concentrations in Surface Water plants (Table 6-30 and Table 6-32 compared to Table 6-31 and Table 6-33). As mentioned above, TOC non-detections were assumed to be zero for plant-mean calculations.

⁷⁶ Stage 1 Disinfectants and Disinfection Byproducts Rule was promulgated by EPA in December 1998 (U.S. EPA, 1998e).

⁷⁷ Subpart H systems are defined as public water systems using surface water or ground water under the direct influence of surface water as a source that are subject to the requirements of subpart H of the National Primary Drinking Water Regulations (U.S. EPA, 2006a).

Table 6-30: DBP ICR (1998), SYR3 ICR (2011), and SYR4 ICR (2019) – Summary of Raw Water TOC Annual System Means for Ground Water Systems

Data Source (Year) ^a	Source Water Type	Count of Systems	Median (mg/L)	Mean (mg/L)	90%ile (mg/L)	Range of System- Means ^b
DBP ICR (1998)	Ground Water	103	0.19	1.46	3.36	0.0 - 16.1
SYR3 ICR (2011)	Ground Water	68	2.19	3.33	5.85	0.42 - 17.0
SYR4 ICR (2019)	Ground Water	80	1.50	2.54	7.11	0.0 - 15.73

Notes:

Abbreviations: DBP – Disinfection Byproduct; ICR – Information Collection Rule; SYR – Six-Year Review; TOC – Total Organic Carbon.

Source: ICR AUX1 database; table extracted from Exhibit 3.6 of U.S. EPA (2005b).

Table 6-31: DBP ICR (1998), SYR3 ICR (2011), and SYR4 ICR (2019) – Summary of Raw Water TOC Annual System Means for Surface Water Systems

Data Source (Year) ^a	Source Water Type	Count of Systems	Median (mg/L)	Mean (mg/L)	90%ile (mg/L)	Range of System- Means ^b
DBP ICR (1998)	Surface Water	307	2.71	3.14	5.29	0.0 - 21.4
SYR3 ICR (2011)	Surface Water	756	2.89	3.45	6.45	0.0 - 29.3
SYR4 ICR (2019)	Surface Water	802	3.29	3.88	6.93	0.0 - 38.9

Abbreviations: ICR – Information Collection Rule; SYR – Six-Year Review; TOC – Total Organic Carbon. Notes:

EPA reviewed the finished water TOC levels included in SYR3 ICR and SYR4 ICR data. The results shown in Table 6-32 represent the distribution of TOC concentrations for Ground Water plants. Note that Ground Water plants are not federally required to report finished water TOC data. In addition, EPA reviewed finished water TOC levels for Surface Water plants included in SYR3 and SYR4 ICR data. Table 6-33 displays the distribution of TOC levels in finished water for Surface Water plants. Similar to the raw water comparison, TOC levels tended to be higher among Surface Water plants compared to Ground Water plants.

^aUsing SYR3 cutoff values, values > 100 mg/L were excluded from calculations.

^bValues below the minimum reporting level (MRL) were converted to 0.0 mg/L to calculate system-means.

^aUsing SYR3 cutoff values, values > 100 mg/L were excluded from calculations.

^bValues below the MRL were converted to 0.0 mg/L to calculate system-means.

Table 6-32: SYR3 ICR (2011) and SYR4 ICR (2019) – Summary of Finished Water TOC Annual System Means for Ground Water Systems

Data Source (Year) ^a	Source Water Type	Count of Systems	Median (mg/L)	Mean (mg/L)	90%ile (mg/L)	Range of System- Means ^b
SYR3 ICR (2011)	Ground Water	78	1.86	2.30	4.53	0.0 - 11.4
SYR4 ICR (2019)	Ground Water	113	0.73	2.77	3.63	0.0 - 93.0

Notes:

Abbreviations: ICR - Information Collection Rule; SYR - Six-Year Review; TOC - Total Organic Carbon.

Table 6-33: SYR3 ICR (2011) and SYR4 ICR (2019) – Summary of Finished Water TOC Annual System Means for Surface Water Systems

Data Source (Year) ^a	Source Water Type	Count of Systems	Median (mg/L)	Mean (mg/L)	90%ile (mg/L)	Range of System- Means ^b
SYR3 ICR (2011)	Surface Water	756	1.93	2.32	3.99	0.0 - 25.1
SYR4 ICR (2019)	Surface Water	802	1.89	2.24	3.90	0.0 - 74.4

 $Abbreviations: ICR-Information\ Collection\ Rule;\ SYR-Six-Year\ Review;\ TOC-Total\ Organic\ Carbon.$ Notes:

EPA compared the levels of raw water TOC between the DBP ICR and SYR3 ICR to evaluate the changes in TOC occurrence over time (U.S. EPA, 2016g). EPA used 1998 data from the DBP ICR Aux 1 database and 2011 data from the SYR3 ICR dataset and included only the data from systems that were found in both datasets (referred to as "common systems"). The evaluation of TOC changes over time was limited to large Surface Water systems (≥100,000 population served) because the DBP ICR only covered large systems.

Table 6-34 below presents plant-level summary statistics for finished water TOC from common systems in the Aux 1 database and SYR3 ICR. The common systems were distributed across 14 states (Alabama, Alaska, Illinois, Indiana, Iowa, Kentucky, Nevada, New Jersey, North Carolina, Oklahoma, Pennsylvania, South Carolina, Virginia, and West Virginia). The comparison of data for large Surface Water supplies between 1998 and 2011 shows a small decrease in treated water TOC levels. The median finished water TOC concentrations at large systems were 1.76, 1.75, and 1.51 mg/L in the Aux 1 database, SYR3 ICR dataset, and SYR4 ICR dataset, respectively.

^aUsing SYR3 cutoff values, values > 100 mg/L were excluded from calculations.

^bValues below the MRL were converted to 0.0 mg/L to calculate system-means.

^aUsing SYR3 cutoff values, values > 100 mg/L were excluded from calculations.

^bValues below the MRL were converted to 0.0 mg/L to calculate system-means.

Table 6-34: DBP ICR (Aux 1; 1998), SYR3 ICR (2011), and SYR4 ICR (2019) – Finished Water Annual System Mean TOC; Common Surface Water Systems

Data Source (Year)	Count of Systems ^a	Median (mg/L)	Mean (mg/L)	90%ile (mg/L)	95%ile (mg/L)	% Means > 2 mg/L	% Means > 3 mg/L
DBP ICR (1998)		1.76	1.77	2.90	3.23	34%	8%
SYR3 ICR (2011)	80	1.75	1.74	2.78	3.24	30%	8%
SYR4 ICR (2019)	80	1.51	1.49	2.44	2.81	21%	5%

Abbreviations: DBP – disinfection byproduct; ICR – Information Collection Rule; SYR – Six-Year Review; TOC – Total Organic Carbon.

Note:

^aSome systems included data for multiple plants.

Source: Table extracted from Exhibit 6.11 of U.S. EPA, 2016g

Table 6-35 summarizes THM4 baselines under DBP ICR, which represents pre-Stage 1 and Stage 2 DBP Rules. Prior to evaluating the SYR4 ICR THM4 data, EPA removed values greater than 10 times the MCL (800 µg/L) due to potential data entry errors. Additionally, EPA converted values below the MRL (10 µg/L) to 0 µg/L, which is consistent with previous SYR data analysis (U.S. EPA, 2016a). Average THM4 values were higher for Surface Water plants compared to Ground Water plants across the two datasets. Within the DBP ICR dataset, representing PWSs serving populations >100,000, 82 Ground Water plants had a median THM4 concentration of 6.8 µg/L with a range of 0-123 µg/L. For the 213 Surface Water plants in the DBP ICR, the median THM4 concentration was 40 µg/L with a range of 0 to 117 µg/L. In comparison, post- Stage 1 and 2 DBP Rules SYR4 ICR data show median THM4 concentrations of 5.0 µg/L and 41.4 µg/L and mean THM4 concentrations of 13.4 µg/L and 41.1 µg/L in Ground Water and Surface Water, respectively. Plant means ranged from 0 to 371.4 µg/L and from 0 to 263.8 µg/L for Ground Water and Surface Water, respectively. Note that the SYR4 dataset was from voluntary submissions and includes data from systems of all sizes. The SYR4 ICR reduced dataset, limited to PWSs serving populations >100,000, shows median THM4 concentrations of 24.4 and 36.1 µg/L and mean THM4 concentrations of 25.0 and 35.1 µg/L for Ground Water and Surface Water, respectively. Plant means ranged from 0 to 66.6 µg/L and from 0 to 62.0 µg/L for Ground Water and Surface Water, respectively.

Table 6-35: Summary of THM4 Baseline Comparing DBP ICR and SYR4 ICR

Data Source	Source Water Type	Count of Systems ^c	THM4 Median (µg/L)	THM4 Mean (μg/L)	90%ile (μg/L)	Range of System-Means ^d
DBP ICR (1998) ^a	Ground Water	82	6.8	15.4	37	0-123
DBP ICR (1998) ^a	Surface Water	213	40	42	70	0-117
SYR4 ICR Reduced (2012- 2019) ^{b,e,f}	Ground Water	84	24.4	25.0	53.1	0 – 66.6
SYR4 ICR Reduced (2012- 2019) ^{b,e,f}	Surface Water	291	36.1	35.1	50.2	0 – 62.0

THM4 THM4 90%ile Range of **Source Water** Count of Mean Median **Data Source** Type Systems^c $(\mu g/L)$ System-Means^d $(\mu g/L)$ $(\mu g/L)$ SYR4 ICR (2012-5.0 13.4 38.5 0 - 371.426,243 Ground Water 2019)b,e SYR4 ICR (2012-9,618 41.4 41.1 64.1 0 - 263.8Surface Water 2019)b,e

Table 6-35: Summary of THM4 Baseline Comparing DBP ICR and SYR4 ICR

 $Abbreviations: DBP-Disinfection\ Byproduct; ICR-Information\ Collection\ Rule; SYR-Six-Year\ Review;\ THM4-Four\ Regulated\ Trihalomethanes.$

Notes:

In the Economic Analysis (EA) for the Stage 2 DBP Rule, EPA estimated a combined average THM4 reduction for all systems of 7.8 percent, with Surface Water systems ranging from 9.2 percent (systems serving ≥10,000) to 7.2 percent (systems serving <10,000), and Ground Water systems ranging from 1.4 percent (systems serving >10,000) to 2.0 percent (systems serving <10,000) (U.S. EPA, 2005b). Comparisons of the DBP ICR THM4 baseline data and the SYR4 data that reflects Stage 1 and Stage 2 DBP Rule changes indicate that the Stage 2 EA slightly overestimated the ΔTHM4 for Surface Water systems (40 to 41.4 μg/L, 3.5% increase) and underestimated the ΔTHM4 for Ground Water systems (6.8 to 5.0 μg/L, 26.5% reduction). Comparing all systems (Surface Water and Ground Water) serving ≥100,000, no statistically significant difference (P = 0.2) was observed between the DBP ICR and SYR4 dataset means. Comparing Ground Water systems in the DBP ICR dataset to those in the reduced SYR4 dataset showed a statistically significant difference (P = 0.0003) in THM4 means, with THM4 increasing in the more recent years (SYR4). Comparing Surface Water systems in the DBP ICR dataset to those in the reduced SYR4 dataset showed no statistically significant difference (P =0.3) in THM4 means. The lack of statistically significant differences in THM4 means between the DBP ICR and SYR4 datasets for Surface Water systems indicates that TOC and THM4 trends support the use of the DBP ICR dataset to predict ΔTHM4 resulting from GAC treatment. For large Ground Water systems (populations ≥100,000), reductions in THM4 mean concentrations may be underestimated due to the increase in THM4 baseline concentrations observed from data reported in the DBP ICR to the SYR4 ICR. Based on the TOC and THM4 trends over time and the percent differences observed between the DBP ICR and SYR4 dataset means, EPA determined that using the DBP ICR Treatment Study Database results for ΔTHM4 to predict future ΔTHM4 resulting from GAC treatment was justified and reasonable. Additionally, with this focus on GAC treatment and the reduction of THM4, it is important to note that the DBP ICR treatment study required systems to conduct DBP precursor removal studies (Treatment Study Database), which contains the most extensive amount of data on GAC treatment and DBP formation potentials (U.S. EPA, 1996; L. Wang et al., 2019).

Larger datasets, such as SYR ICRs, have not included data on both disinfectant type and DBP formation. The DBP ICR collected this information in addition to other source and water quality

^aStage 2 DBP Rule Economic Analysis (U.S. EPA, 2005b), screened data from Exhibit 3.15 and 3.20

^bUsing SYR3 cutoff values, values > 10 times the MCL were excluded from calculations.

^cNA values and blanks were removed prior to calculations.

^dValues below the MRL were converted to 0.0 μg/L to calculate system-means.

^eSYR4 data collected from 2012 to 2019. All years were included in calculations.

^fSYR4 reduced dataset included only PWSs serving populations ≥100,000

parameters. Table 6-36 shows mean THM4 concentrations in the DBP ICR per disinfectant type and source water type.

Table 6-36: DBP ICR (Aux 1) Summary of THM4 Concentrations Based on Disinfectant and Source Water Type

Disinfectant Type	Source Water Type	Count of Plants / Facilities	Mean THM4 concentration (μg/L)
Chi.	Ground Water	15	29.2
Chloramine	Surface Water	77	43.2
E 011 '	Ground Water	34	21.3
Free Chlorine	Surface Water	164	45.0
Free Chlorine +	Ground Water	1	18.7
Chloramine (DS)	Surface Water	20	53.2

Abbreviations: DBP – disinfection byproduct; THM4 – Four Regulated Trihalomethanes; DS – Distribution System.

Despite the significant public health improvements provided by EPA's Stage 2 Disinfectant and Disinfection Byproducts Rule (D/DBPR), DBPs are still estimated to cause approximately 8,000 cases of drinking water-attributable bladder cancer cases every year (Weisman et al., 2022). Hence, there are still public health benefits to be realized when DBPs are reduced when feasible. Where systems install activated carbon, the PFAS rule will, for many systems, further reduce DBP concentrations because of precursor removal. While the Stage 1 and Stage 2 D/DBPRs were effective at reducing THM4, there are remaining risks associated with DBP exposure that could be further reduced as shown in the baseline analysis above. The Stage 2 D/DBPR was promulgated in 2006 and since the rule implementation there have been numerous peer-reviewed studies that have shown an increased weight of evidence supporting a correlation between chlorination DBPs and bladder cancer with updated estimates on attributable cases (Weisman et al., 2022; Regli et al., 2015). Additionally, there is an increased understanding of the role of genetically susceptible populations and exposure routes for THMs (i.e., oral, inhalation, and dermal) that impact risk assessments. This comparison between the SYR4 ICR (2019) and DBP ICR (1998) showed that the DBP ICR THM4 data were still relevant for the post Stage 2 D/DBPR baselines for both TOC (i.e., DBP precursors) and THM4. Because the baseline was pre-Stage 1 (DBP ICR), EPA took the low-end estimate for THM4 reduction to reduce possible overestimation. Further reduction in TOC concentrations in finished water could be achieved if additional treatment is added (i.e., PFAS removal using GAC treatment).

6.7.1.3 Estimation of Trihalomethane Reduction using Treatment Models

6.7.1.3.1 DBP Information Collection Rule Treatment Study Database

The Information Collection Rule Treatment Study Database (ICR TSD) contains results of the most extensive GAC study conducted on a national scale. The ICR TSD contains treatment study data submitted by systems required to conduct DBP precursor removal studies under the DBP ICR (U.S. EPA, 1996). The systems included in the ICR TSD were considered "challenged" in their ability to achieve compliance with potential Stage 2 DBP rule revision MCLs. The

participating systems included Surface Water systems (and Ground Water systems under the direct influence of Surface Water) serving 100,000 or more people and having ≥ 4 mg/L of TOC in source water, and Ground Water systems serving 50,000 or more people and having ≥ 2 mg/L of TOC in finished water. Both free chlorine and chloramine systems were included in the treatment study (U.S. EPA, 1996; L. Wang et al., 2019).

Data from the ICR TSD study from these "challenged systems" can be used to identify conservative estimates of TOC reduction and associated Δ THM4. Due to upstream pollution, drought, and/or climate change, individual drinking water sources may be as challenged as when the ICR TSD data were collected (Hashempour et al., 2020; McDonough et al., 2020). While the GAC treatment dataset dates are from 1998, the physical/chemical relationships observed have only improved with the current application of GAC being at least as effective for THM4 as was observed in the ICR TSD (Yuan et al., 2022). While source water parameters and treatments at individual plants have changed over time, as seen in the baseline characterization in Section 6.7.1.2, EPA determined the ICR TSD was still appropriate to inform estimates of Δ THM4 formation potential given the lack of available data to directly inform Δ THM4 from PFAS adsorption studies and the low percent difference in TOC changes on a national scale between the DBP ICR and SYR4 collection efforts.

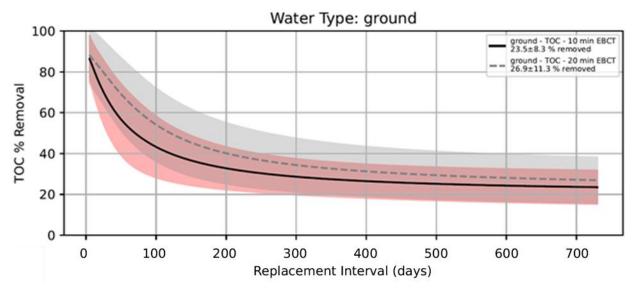
From the 63 GAC systems included in the ICR TSD, a total of 182 pilot/rapid small-scale column test (RSSCT) studies were conducted to develop breakthrough curves of TOC and DBP formation changes. Two EBCTs, 10 and 20 min, were evaluated for treated water that had passed through any full-scale treatment processes previously in place at each drinking water treatment plant to remove precursors (i.e., coagulation/flocculation, sedimentation, filtration) but before any disinfectant was added. To determine the effect of GAC treatment on DBP formation, these studies evaluated TOC removal and THM4 formation potential for the treated water before and after GAC treatment. Uniform formation condition procedures were standardized across each study, with a reaction time of 24 ± 1 hours, temperature of $20.0 \pm 1.0^{\circ}$ C, buffered pH at 8.0 ± 0.2 , and 24-hr chlorine residual of 1.0 ± 0.4 mg/L as Cl_2 (U.S. EPA, 1996; Summers et al., 1996).

The pilot/RSSCT studies were timed to account for seasonal changes and an "averaging" approach was used to remove temporal variations. This approach was consistent with analysis used to characterize different GAC options for compliance with the MCLs under the Stage 2 DBP Rule (Hooper et al., 2002). Additional details on the GAC study design specifications under the ICR TSD are available in the "ICR Manual for Bench and Pilot Scale Treatment Studies" (U.S. EPA, 1996).

For drinking water systems in the ICR TSD that used chloramines (n=123 pilots/RSSCTs) in their distribution system, free chlorine was still used in the DBP formation tests, therefore the pilot and RSSCT systems were not compared based on disinfectant type used by the individual treatment system. For reference, a summary of the THM4 estimates by disinfectant type is provided in Appendix I Table I-1. Additionally, if the comparison categories were further parsed by source water type, disinfectant type, and TOC concentrations, then the number of systems in each bin would not provide sufficient studies to compare the ΔTHM4 estimates. Therefore, EPA analyzed the THM4 reductions based on raw-water TOC.

The TOC and THM4 formation potential reductions data from the ICR TSD were modeled with a logistic equation using results from 182 pilot plant/RSSCT studies. EPA fit the logistic function parameters for each EBCT and did not consider feed water quality parameters. Results were categorized by TOC level and source water type. Further subdivision of these or additional categories would have resulted in very small numbers of systems in bins and some bins not being filled (see Appendix I Table I-1 for example of "disinfection type" added as a category). The model calculated individual system TOC removal for the EBCT and results were averaged for each subset of systems for the GAC replacement interval. The model was not intended to simulate the dynamics of TOC removal by GAC or the formation of THM4, but it simulated the TOC ranges within the pilot/RSSCT studies and the changes in THM4 due to the reduction in TOC observed in the ICR TSD. EPA used Python to individually fit data from each pilot or RSSCT study in the ICR TSD to a logistic equation and the performance was then averaged. Additional details on the data model are included in Appendix I.

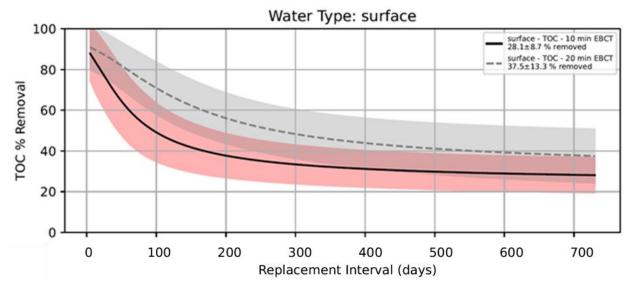
To conservatively estimate national scale THM4 reduction due to GAC treatment to reduce levels of PFAS compounds, EPA chose a 2-year GAC replacement time. EPA assumes that this is the longest amount of time before replacement would be required and percent removals are approximately at their long-term removal level with minimal further changes. The PFAS NPDWR will likely result in some systems replacing GAC media more frequently than 2 years, which EPA expects would result in a greater average TOC reduction since TOC removal decreases over time with GAC treatment (see Figure 6-11 and Figure 6-12 for Ground Water and Surface Water respectively). The overall trends seen in Figure 6-11 and Figure 6-12 show greatest TOC removal in the first 200 days of use, after which the predicted TOC removal becomes consistent for Ground Water with 26.9 percent (EBCT 20 min) and Surface Water with 37.5 percent (EBCT 20 min). EPA solicits public comment on whether the GAC replacement interval of 2-years was too conservative an approach for estimating benefits in this DBP coremoval analysis.



 $Abbreviations: TOC-total\ organic\ carbon;\ GAC-granular\ activated\ carbon;\ EBCT-empty\ bed\ contact\ times.$ Notes:

Pink shaded area represents ± 1 standard deviation for Ground Water TOC with a GAC EBCT of 10 min Gray shaded area represents ± 1 standard deviation for Ground Water TOC with a GAC EBCT of 20 min

Figure 6-11: Estimated TOC Percent Removal in Ground Water Using GAC Based on Logistic Equation Model



Abbreviations: TOC – total organic carbon; GAC – granular activated carbon; EBCT – empty bed contact times.

Pink shaded area represents ± 1 standard deviation for Ground Water TOC with a GAC EBCT of 10 min Gray shaded area represents ± 1 standard deviation for Ground Water TOC with a GAC EBCT of 20 min

Figure 6-12: Estimated TOC Percent Removal in Surface Water Using GAC Based on Logistic Equation Model

To estimate the TOC reduction, the ICR TSD pilot/RSSCT studies (n = 182) were partitioned into five potential bins based on TOC concentrations in raw water (Very Low ≤ 1 mg/L, Low > 1 to ≤ 2 mg/L TOC, Mid > 2 to ≤ 3.5 mg/L, High-Mid > 3.5 to ≤ 5 mg/L, High TOC > 5mg/L TOC). There were no systems in the ICR TSD that fell into very low TOC bin. Based on the logistic equation for TOC reduction, higher raw water TOC concentrations yield greater TOC reductions (in absolute value) following to GAC treatment. Table 6-37 shows the TOC reduction for all waters (both Ground Water and Surface Water) for a 20 min EBCT.

Table 6-37: TOC Reduction for All Waters (Both Surface Water and Ground Water) with GAC EBCT of 20 Min and a 2-year Replacement Time

TOC Bin	Number of Studies in GAC Treatment Dataset	TOC Reduction ± 1- Standard Deviation (%)	TOC Reduction (mg/L)
TOC 1-2 mg/L	20	41.9 ± 23.2	0.75 ± 0.39
TOC 2-3.5 mg/L	103	37.1 ± 11.6	1.06 ± 0.36
TOC 3.5-5 mg/L	44	32.0 ± 9.6	1.31 ± 0.39
TOC above 5mg/L	15	26.3 ± 14.2	1.83 ± 0.91

Abbreviations: TOC – Total Organic Carbon; GAC – Granular Activated Carbon; EBCT – Empty Bed Contact Time. Notes: The model calculated individual system TOC removal and results were averaged for each influent TOC bin for a two-year GAC replacement interval and the standard deviation was calculated for each subset average.

Using the same raw water TOC bins, EPA estimated national scale $\Delta THM4$ values resulting from GAC treatment. The selected $\Delta THM4$ estimate was based on a conservative approach (mean concentration minus one standard deviation), since the DBP ICR systems included in the treatment studies were "challenged systems" (i.e., systems that had difficulty meeting regulatory compliance requirements) that may experience increased TOC reduction due to GAC installation.

The analysis here assumes operation of GAC with a replacement interval of 730 days (2 years). Although some systems will operate with longer replacement intervals, after 730 day (2 years), the modeled TOC reduction due to GAC shows consistent removal when further extending the replacement interval (Figure 6-11 and Figure 6-12). While systems may replace GAC at shorter time intervals, the 2-year replacement assumption also approximates blended systems (i.e., multiple GAC treatment trains in parallel with varying replacement intervals) and TOC long term removal by adsorption since GAC treatment for PFAS uses adsorption rather than biodegradation (Kempisty et al., 2022). Therefore, the estimated TOC reduction at 730 days (2 years) should also be representative for systems with longer replacement intervals or systems with intermittent use. If GAC replacement occurred more frequently due to PFAS treatment needs, higher average TOC removal would occur, resulting in greater THM4 reduction as shown in the 6-month GAC replacement time-steps (1/2, 1, 1 ½, and 2 years) shown in Appendix I (Tables I-2, I-3, I-4, and I-5). Using the longer replacement time of 2 years is consistent with EPA's conservative approach to estimating ΔTHM4 even when the presence of PFAS compounds and other source water conditions may affect GAC replacement frequency.

Based on common treatment designs, EPA expects GAC treatment parameters for PFAS removal to be 20 min EBCTs (U.S. EPA, 2023h). Table 6-38 and Table 6-39 provide estimates of THM4 reductions in the modeled 182 pilot/RSSCT systems broken out by Surface Water vs Ground Water and 20 min EBCT. The number of GAC systems included in each TOC bin is provided along with the average Δ THM4 and the "conservative" Δ THM4 (defined as average Δ THM4 minus 1-standard deviation) with a GAC replacement time of 2 years.

Table 6-38: Estimation of $\Delta THM4$ in Surface Water with a 20 Min EBCT, and a 2-year GAC Replacement Time

Raw Water TOC Bin	Number of Studies in GAC Treatment Dataset	Average ΔTHM4 ± 1- Standard Deviation (μg/L)	Conservative ΔTHM4 (μg/L)
TOC 1-2 mg/L	12	14.23 ± 7.34	6.9
TOC 2-3.5 mg/L	89	31.54 ± 24.02	7.5
TOC 3.5-5 mg/L	37	48.55 ± 31.81	16.7
TOC above 5mg/L	7	67.2 ± 18.3	48.9

Abbreviations: EBCT – Empty Bed Contact Time; TOC – Total Organic Carbon; THM4 – Four Regulated Trihalomethanes; GAC – Granular Activated Carbon.

Table 6-39: Estimation of $\Delta THM4$ in Ground Water with a 20 Min EBCT, and a 2-year GAC Replacement Time

Raw Water TOC Bin	Number of Studies in GAC Treatment Dataset	Average $\Delta THM4 \pm 1$ -Standard Deviation ($\mu g/L$)	Conservative ΔTHM4 (μg/L)
TOC 1–2 mg/L	8	15.14 ± 8.98	6.2
TOC 2-3.5 mg/L	14	22.02 ± 17.48	4.5
TOC 3.5-5 mg/L	7	27.46 ± 8.33	19.1
TOC above 5mg/L	8	56.66 ± 38.69	18.0

Abbreviations: EBCT – Empty Bed Contact Time; TOC – Total Organic Carbon; THM4 – Four Regulated Trihalomethanes; GAC – Granular Activated Carbon.

For the Low (1–2mg/L), Mid (2–3.5mg/L), and High-Mid (3.5–5mg/L) TOC bins, the conservative Δ THM4 estimates were reasonable compared to the mean concentrations reported into the SYR4 baseline occurrence data. Conservative ΔTHM4 estimates in the High TOC bin (>5mg/L) were higher due to the greater reduction in TOC. For the THM4 reduction observed in the High TOC bin (>5mg/L), the conservative THM4 reduction estimates were higher due to the greater reduction in TOC and may not be plausible based on the baseline occurrence information and if it is assumed that all systems are currently in compliance (THM4 <80 µg/L). However, based on SDWIS violations, not all systems are currently in compliance with the Stage 2 DBP Rule. EPA assumes that these larger ΔTHM4 estimates would be observed only in the 90th percentile of TOC data. Ground Water systems in the High TOC bin may also be mischaracterized during the ICR TSD and should be more accurately described as Ground Water under the direct influence of Surface Water (GWUDI) (Brunke et al., 1997; Chin et al., 2000). The GWUDI provisions of the 1989 Surface Water Treatment Rule instituted the concept of Ground Water that is so closely connected to Surface Water that public water supply wells should be regulated as Surface Water rather than as Ground Water (U.S. EPA, 1989). If one or more Ground Water systems were mischaracterized, then this could overestimate the ΔTHM4

estimate since these systems make act more like a Surface Water system in terms of TOC removal.

Since these conservative $\Delta THM4$ estimates were based on the longest assumed time period for GAC use (i.e., GAC replacement time) in the current regulatory options, EPA assumes that the estimated $\Delta THM4$ values are conservative, considering that shorter replacement times would increase the average TOC removal during that operation time.

Since these Surface Water and Ground Water systems have already been identified as "challenged" in the ICR TSD (pre-Stage 1 and Stage 2 DBP Rules), this indicates the specific advantages of using GAC to reduce THM4 precursors in comparison to conventional treatment (i.e., coagulation/flocculation followed by sedimentation and filtration). When GAC treatment is used for additional contaminant removal such as PFAS, TOC reduction benefits will also be observed. Since there is a lack of PFAS and TOC co-removal data, the ICR TSD can provide the largest dataset on TOC reduction and THM4 formation changes in drinking water to provide a national estimate of Δ THM4.

The limitations and uncertainties for using this method to quantify ΔTHM4 due to GAC treatment for PFAS are listed in Section 6.8. One major limitation of using the ICR TSD was that this dataset only used chlorine as a disinfectant and does not capture THM reduction in chloraminating systems. This limitation may lead to an overestimate of THMs formed in systems that used chloramines in the distribution system since THM4 can continue to form within the distribution system and formation tends to be lower when chloramines are used in comparison to free chlorine (Hua et al., 2008). Most chlorinating systems use free chlorine as a primary disinfectant followed by the addition of ammonia to form chloramines for the secondary disinfectant. Of the 9,838 Ground Water entry points to distribution systems included in UCMR 3, chlorine disinfection was used 8.8 times more often than chloramine (n=7,881 for chlorine exclusively and n=896 for chloramines or both chlorine and chloramines) (U.S. EPA, 2016g). For the 3,179 Surface Water entry points to distribution systems in UCMR 3, chlorine was used 1.9 times more than chloramine (n=1,648 for chlorine exclusively and n=879 for chloramines or both chlorine and chloramines) (U.S. EPA, 2016g).

By assuming the use of free chlorine only, the estimates of $\Delta THM4$ from pilot/RSSCTs studies may provide an overestimation when factoring in use of both free chlorine and chloramines. Thus, using the conservative free chlorine THM4 formation potential (average $\Delta THM4$ minus 1-standard deviation) rather than the average $\Delta THM4$, EPA attempted to address the overestimation and provide a reasonable national estimate of $\Delta THM4$.

In a separate DBP formation study under the ICR TSD, individual DBP formation conditions were selected to represent simulated distribution systems for each individual plant that accounted for the disinfectant differences (i.e., chlorine versus chloramine) by using only chlorine as the disinfectant and varying the reaction times. The simulated distribution system studies were not included in the estimated $\Delta THM4$ provided in this document since including them would have further increased the uncertainty error for systems using chloramine due to the longer reaction times.

6.7.1.3.2 Trihalomethane Reduction Comparison to Fourth Six Year Review PFAS Plants with GAC Treatment

EPA compared Δ THM4 estimates from the ICR TSD to the SYR4 data for PFAS-associated plants that have installed GAC. The objective of this analysis was to compare the ICR TSD modeled predictions of Δ THM4 to the observed Δ THM4 concentrations from PWSs that installed GAC for PFAS treatment.

EPA identified systems that had detectable levels of PFOA and/or PFOS in UCMR 3. Subsequently, EPA used UCMR 4 data to identify which systems indicated use of GAC treatment. Finally, EPA used consumer confidence reports (CCRs) for all systems that detected PFAS and specified GAC treatment for PFAS to approximate the year that GAC treatment was installed and the purpose for installation. While this approach limited the number of systems available for comparison (n = 7), it allowed EPA to pinpoint, approximately, which samples were taken before and after GAC installation. EPA obtained THM4 compliance monitoring data through the SYR4 ICR, based on data collected between 2012 and 2019. EPA calculated the ΔTHM4 values based on observed THM4 levels before and after GAC installation.

EPA identified plants using the following criteria (see Table 6-40):

- 1. Detectable level of PFAS in UCMR 3 (i.e., detections of PFOA and/or PFOS above their respective minimum reporting level (MRL) values).
- 2. GAC installed as indicated in UCMR 4 and confirmed for PFAS treatment by using CCR information.
- 3. Ability to identify the year GAC was installed using CCR information.
- 4. THM4 data available from SYR4 (CCR THM4 data were used as an alternative when SYR4 data were unavailable).

Table 6-40: Selected Distribution Systems from SYR4 Based on Outlined Criteria

PWSID	Source Water Type	Disinfectant Type	Year GAC Began	
AL0000577	Surface Water	Free Chlorine ^a	2018	
AL0000377 AL0001092	Surface Water	Free Chlorine, Chlorine Dioxide	2016	
AZ0407046	Ground Water	Free Chlorine	2017	
MI0005370	Surface Water	Free Chlorine	2018	
NY3503549	Surface Water	Free Chlorine	2018	
OH2903412	Ground Water	Free Chlorine	2017	
PA1090069	Ground Water	Free Chlorine	2017	

 $Abbreviations: PWSID-Public \ water \ system \ identifier; SYR-Six \ Year \ Review; GAC-Granular \ Activated \ Carbon.$ Note:

^aFree chlorine includes gaseous chlorine, offsite generated hypochlorite, or onsite generated hypochlorite.

EPA chose sampling years to represent conditions before and after GAC treatment based on the following criteria:

- If source water type was Surface Water, one year before and one year after the year in which GAC treatment began was used.
- If source water type was Ground Water, two years before and two years after the year in which GAC treatment began was used. Since Ground Water plants have fewer samples, this was done to offset the lower sample number. (Note that Ground Water quality typically has fewer fluctuations than does Surface Water quality, so EPA expects fewer changes in year-to-year data for Ground Water systems.)

EPA extracted and matched sampling point IDs for the years that represent before and after GAC treatment (see Appendix I). Only sampling point IDs with the same number of samples for before and after GAC treatment were used to determine THM4 averages. The seasonality and quantity of samples were considered, and EPA found that samples were taken consistently and remained at the same frequency throughout the years selected to represent before and after GAC treatment.

EPA calculated Δ THM4 concentrations for each system at matched sampling point locations using THM4 data collected before and after GAC installation. EPA also estimated Δ THM4 concentrations at the broader plant level by aggregating all THM4 locational sampling data collected before and after GAC installation (see Table 6-41).

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Table 6-41: Information on Selected Distribution System and Corresponding ΔTHM4 Values

PWSID	Source Water Type	Disinfectant Type	Sampling Point ID ^b	Average THM4 (Before) (μg/L)	Average THM4 (After) (µg/L)	ΔΤΗΜ4 (μg/L)	Average ΔΤΗΜ4 (μg/L) ^c
AL0000577	Surface Water	Free Chlorine	12975	16.5	10.9	5.7	9.8
AL0001092	Surface Water	Free Chlorine, Chlorine Dioxide	23592	16.6	6.4	10.2	15.7
AZ0407046	Ground Water	Free Chlorine	33997	28.8	21.6	7.3	4.8
MI0005370	Surface Water	Free Chlorine	CCR	84.9	66.4	18.5	18.5
NY3503549	Surface Water	Free Chlorine	334940	39.1	7.6	31.5	31.5
OH2903412	Ground Water	Free Chlorine	541452	8.9	7.0	1.9	-4.1
PA1090069	Ground Water	Free Chlorine	892902	21.0	21.3	-0.3	-10.7

Abbreviations: THM4 – Four Regulated Trihalomethanes.

Notes:

^aΔTHM4= THM4 Average (Before) – THM4 Average (After).

bSampling point IDs that have a sampling point type of entry point (EP) were used when available. When unavailable, the first listed sampling point ID was used. cAverage delta of pairwise changes in THM4 for each location in the entire distribution system.

Based on available data, the EBCT for the seven plants from SYR4 is unknown. EPA used TOC values from SYR4 when available and used CCR TOC data as an alternative when TOC data were missing from SYR4. TOC values for SYR4 Ground Water plants were missing from the SYR4 dataset and corresponding CCRs, and due to this limitation, EPA did not use raw water TOC bins, but instead used a range of Δ THM4 values for comparison between SYR4 and ICR TSD.

EPA compared Δ THM4 values from the SYR4 to the ICR TSD dataset conservative approach (see Table 6-42). Among SYR4 Ground Water plants, a THM4 change between -10.7 µg/L to 4.8 µg/L was observed. ICR TSD Ground Water Δ THM4 values ranged from 3.5 µg/L to 67.2 µg/L. SYR4 Ground Water averages were between -7.2 µg/L to 62.4 µg/L lower than ICR TSD Surface Water averages.

Table 6-42: Comparison Between ICR TSD Conservative Δ THM4 and SYR4 Δ THM4 for Surface Water Systems

Raw Water TOC Bin	Surface Water				
	ICR TSD Conservative $\Delta THM4$ (µg/L)	PWSID	SYR4 ΔTHM4 (μg/L)		
TOC 0-1 mg/L	No available data	AL0000577, AL0001092	5.7, 15.7		
TOC 1-2 mg/L	6.9	NY3503549	31.5		
TOC 2-3.5 mg/L	7.5	MI0005370	18.5		
TOC 3.5-5 mg/L	16.7	No available data	No available data		
TOC >5mg/L	48.9	No available data	No available data		

Abbreviations: TOC – Total Organic Carbon; THM4 – Four Regulated Trihalomethanes; ICR – Information Collection Rule; TSD – Treatment Study Database.

Notes:

Two of the three Ground Water systems showed increased THM4 formation after the installation of GAC. Possible reasons for increased formation may include source water changes (i.e., increased sediment runoff or spore concentration fluctuations in Ground Water), operational challenges of the GAC treatment, changes to other treatments within the PWS, or changes in retention time within the distribution system. The four Surface Water systems had $\Delta THM4$ values ranging from 5.7 to 31.5 $\mu g/L$.

Three out of the seven plants had no available TOC data in SYR4 or CCRs. TOC data for the SYR4 THM4 analysis were only available for Surface Water plants. SYR4 Surface Water plants with influent TOC concentrations between 1–2 mg/L had an average Δ THM4 of 31.5 μ g/L compared to the ICR TSD conservative Δ THM4 estimate of 6.9 μ g/L. For SYR4 Surface Water plants with influent TOC concentrations between 2–3.5 mg/L, EPA observed an average Δ THM4 of 18.5 μ g/L compared to the ICR TSD conservative Δ THM4 estimate of 7.5 μ g/L. Both comparisons of TOC bins for Surface Water show that the conservative estimates for THM4

^aThree of the seven surface water PWSs had no TOC measurements.

^bEBCTs were unknown.

^c20 min EBCT was used to determine best-case and conservative ΔTHM4 values.

reduction are plausible. Note that this finding is based on a small subset of systems (n = 4) and may not be representative of systems nationally.

Due to lack of TOC data for SYR4 Ground Water plants, EPA compared Ground Water plants to the lowest TOC bin (1–2 mg/L) with ICR TSD data available. SYR4 Ground Water plants had an average Δ THM4 between ICR TSD Ground Water plants with influent TOC concentrations between 1–2 mg/L had an average change in THM4 between -10.7 µg/L to 4.8 µg/L compared to the ICR TSD conservative THM4 reduction estimate of 4.5 µg/L. Limitations on the comparison between the ICR TSD Δ THM4 estimates and the SYR4 THM changes are described in Section 6.8.

6.7.2 Estimation of Bladder Cancer Risk Reductions

Evaluation of the expected reductions in bladder cancer risk resulting from treatment of PFAS in drinking water involves five steps listed in Section 6.7.1.1. Section 6.7.1.3.2 provides details on the estimation of changes in THM4, while Section 6.7.2.1 provides details on selecting the changes in THM4 specific to the modeled scenarios.⁷⁸

6.7.2.1 Application of Changes in THM4 to PFAS PWSs

EPA expects PWSs that exceed the PFAS regulatory threshold to consider both treatment and non-treatment options to achieve compliance with the drinking water standard. EPA assumes that the populations served by systems with entry points expected to install GAC based on the compliance forecast detailed in Section 5.3 will receive the DBP exposure reduction benefits. EPA notes that other compliance actions included in the compliance forecast could result in DBP exposure reductions, including installation of RO. However, these compliance actions are not included in the DBP benefits analysis because this DBP exposure reduction function is specific to GAC. Switching water sources may or may not result in DBP exposure reductions, therefore EPA assumed no additional DBP benefits for an estimated percentage of systems that elect this compliance option. Lastly, EPA assumed no change in DBP exposure at water systems that install IX, as that treatment technology is not expected to remove a substantial amount of DBP precursors. Finally, EPA also assumed that PWSs included in this analysis use chlorine only for disinfection and have conventional treatment in place prior to GAC installation.

As described in Section 6.7.1.3, EPA used the relationship between median raw water TOC levels and changes in THM4 levels estimated in the 1998 DBP ICR to estimate changes in THM4 concentrations in the finished water of PWSs fitted with GAC treatment. EPA applied changes in THM4 levels to PWS treating for PFAS using the following steps:

1. Identifying the PWSs expected to be triggered into PFAS treatment under various thresholds and the associated PWS populations served by source water type: Surface Water and Ground Water;

⁷⁸ The benefits analyses described herein relied on methodology implemented in R software (R Core Team, 2021) and differ slightly from SafeWater MCBC methods. Specifically, SafeWater performs a set of pre-calculations to maximize computational efficiency and, as such, the order of analytical steps across R and SafeWater models differs. However, results across models are mathematically consistent.

- Estimating the TOC levels associated with each source water type, based on median raw water TOC data collected among non-purchased Surface Water and Ground Water systems from the 2019 SYR4 dataset; and
- 3. Identifying the associated THM4 reduction value based on relationships between raw water TOC levels and changes in THM4 levels estimated in the 1998 DBP ICR.

As shown in the Section 6.7.1.3 tables, EPA estimated changes in THM4 levels that vary based on the following characteristics:

- **Replacement time:** Assumed to be 730 days;
- **EBCT:** 20 min;
- Source water type: Surface Water, Ground Water;
- **THM4 change scenario:** Conservative (mean DBP ICR THM4 reduction minus one standard deviation per TOC bin).

For the DBP risk reduction modeling, EPA focused on the following treatment scenario (See Table 6-38 and Table 6-39):

- **PWS treatment threshold:** PFOA or PFOS mean concentration exceeds threshold defined by regulatory alternatives;
- **EBCT:** 20 min;
- Source water type: Surface Water, Ground Water;
- **THM4 change scenario:** Conservative.

As described in Section 2.2.4, EPA models a scenario where reduced exposures to THM4 begin in 2026. Therefore, EPA assumed that the population affected by reduced THM4 levels resulting from implementation of GAC treatment is exposed to baseline THM4 levels prior to actions to comply with the rule (i.e., prior to 2026) and to reduced THM4 levels from 2026 through 2104.

6.7.2.2 Affected Population

Information on PWS attributes required for estimating changes in population-level bladder cancer is obtained from EPA's 2021 Q4 SDWIS database (U.S. EPA, 2021h). This information includes data on PWS primary sources of water (e.g., whether a PWS relies primarily on Ground Water or Surface Water for their source water), operational status, and population served. Some PWSs have multiple entry points delivering drinking water to the distribution network. As discussed in Section 6.7.2.1, the analysis assumes that PWSs will reduce PFAS levels by fitting individual entry points for either GAC or IX treatment and therefore changes in NOM and THM4 will also be specific to entry points.

Rather than modeling individual locations (e.g., PWS), EPA evaluates changes in bladder cancer cases among the aggregate population per treatment scenario and source water type that is expected to install GAC treatment to reduce PFAS levels. Because of this aggregate modeling approach, EPA used national-level population estimates to distribute the SDWIS populations based on single-year age and sex and to grow the age- and sex-specific populations to future years. Section 5.3 describes the decision tree for GAC technology selection. Appendix B provides additional details on estimation of the affected population.

6.7.2.3 Bladder Cancer Exposure-Response Modeling

The relationship between exposure to DBPs, specifically trihalomethanes and other halogenated compounds resulting from water chlorination, and bladder cancer has been the subject of multiple epidemiology studies (Cantor et al., 2010; U.S. EPA, 2016g; NTP, 2018), meta-analyses (Villanueva et al., 2003; Costet et al., 2011), and pooled analysis (Villanueva et al., 2004). EPA used the relationship between THM4 levels and bladder cancer in the Villanueva et al. (2004) study to support the benefits analysis for the Stage 2 DBP Rule⁷⁹ which specifically aimed to reduce the potential health risks from DBPs (U.S. EPA, 2005b).

Regli et al. (2015) analyzed the potential lifetime bladder cancer risks associated with increased bromide levels in surface source water resulting in increased THM4 levels in finished water. ⁸⁰ To account for variable levels of uncertainty across the range of THM4 exposures from the pooled analysis of Villanueva et al. (2004), they derived a weighted mean slope factor from the odds ratios reported in Villanueva et al. (2004). They showed that, while the original analysis deviated from linearity, particularly at low concentrations, the overall pooled exposure-response relationship for THM4 could be well-approximated by a linear slope factor that predicted an incremental lifetime cancer risk of 1 in ten thousand exposed individuals (10^{-4}) per 1 μ g/L increase in THM4. The linear slope factor developed by Regli et al. (2015) is 0.00427 per 1 μ g/L. Using a fixed effects meta-analysis model assumed by Regli et al. (2015), EPA estimated a

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⁷⁹ See DBP Rule documentation at https://www.epa.gov/dwreginfo/stage-1-and-stage-2-disinfectants-and-disinfection-byproducts-rules

The Regli et al. (2015) slope factor was utilized in the recently peer-reviewed Weisman et al. (2022) study, which estimates that 8,000 of 79,000 US bladder cancer cases are attributable to bladder cancer. Among other things, the authors found that there is a stronger weight of evidence linking DBPs and bladder cancer since the promulgation of the 2006 Stage 2 DBP regulations and even since publication of Regli et al. (2015).

95% CI of 0.00331–0.00522 per 1 μ g/L. This slope enables estimation of the changes in the lifetime bladder cancer risk associated with lifetime exposures to reduced THM4 levels:

Equation 21:

$$Odds(x) = Odds(0) \cdot exp(0.00427 * x)$$

Where Odds(x) are the odds of lifetime bladder cancer incidence for an individual exposed to a lifetime average THM4 concentration in residential water supply of $x \mu g/L$ and Odds(0) are the odds of lifetime bladder cancer in the absence of exposure to THM4 in residential water supply. The relationship (Equation 21) has the advantage of being independent from the baseline THM4 exposure level, which is highly uncertain for most affected individuals due to lack of historical data.

To enable annual bladder cancer risk estimation, EPA assumed that the relationship (Equation 21) also holds for the cumulative bladder cancer risk and cumulative average exposure to residential water THM4 from birth to a specific age. A person's cumulative THM4 exposure from drinking water by age a—denoted by x_a —is defined as:

Equation 22:

$$x_a = \frac{1}{a} \sum_{i=0}^{a-1} THM4_i$$
 , $x_0 = 0$

EPA estimated the relative risk of bladder cancer by a particular age from a change in average THM4 experienced by this age as follows:

Equation 23:

$$RR(x_a, z_a) = \frac{exp(0.00427 * [x_a - z_a])}{exp(0.00427 * [x_a - z_a]) * LR(z_a) + 1 - LR(z_a)}$$

Where $RR(x_a, z_a)$ is the relative cumulative risk of bladder cancer associated with a change from baseline cumulative exposure z_a to treatment cumulative exposure x_a . This calculation requires an estimate of baseline cumulative bladder cancer risk $LR(z_a)$ which is described in Appendix H.

6.7.2.4 Estimation of Bladder Cancer Risk Reductions

EPA estimated changes in annual bladder cancer cases and annual mortality in the bladder cancer population due to estimated reductions in lifetime THM4 exposure using a life table-based approach. This approach was used because (1) annual risk of new bladder cancer should be quantified only among those not already experiencing this chronic condition, and (2) bladder cancer has elevated mortality implications.

EPA used recurrent life table calculations to estimate a water source type-specific time series of bladder cancer incidence for a population cohort characterized by sex, birth year, and age at the beginning of the PFOA/PFOS evaluation period under the baseline scenario and the GAC regulatory alternative described in Section 6.7.2.1. The estimated risk reduction from lower exposure to DBPs in drinking water is calculated based on changes in THM4 levels used as

inputs to the Regli et al. (2015)-based health impact function, as shown in Section 6.7.2.3. The life-table analysis accounts for the gradual changes in lifetime exposures to THM4 following implementation of GAC treatment under the regulatory alternative compared to the baseline. ⁸¹ Details of the life-table calculations are provided in Appendix H. The outputs of the life-table calculations are the water source type-specific estimates of the annual change in the number of bladder cancer cases and the annual change in bladder cancer population mortality.

Although the change in THM4 exposure likely affects the risk of developing bladder cancer beyond the end of the analysis period (the majority of cancer cases manifest during the latter half of the average individual life span; Hrudey et al., 2015), EPA does not capture effects after the end of the period of analysis, 2104. Individuals alive after the end of the period of analysis likely benefit from lower lifetime exposure to THM4. Lifetime health risk model data sources include; EPA SDWIS; age- and sex-specific population estimates from the U.S. Census Bureau (U.S. Census Bureau, 2020a); the Surveillance, Epidemiology, and End Results (SEER) program database (National Cancer Institute),⁸² and the CDC National Center for Health Statistics. Appendix H provides additional detail on the data sources and information used in this analysis as well as baseline bladder cancer statistics. Appendix B provides additional details on the estimation of the affected population.

6.7.2.5 Valuation of Bladder Cancer Risk Reductions

EPA uses the Value of Statistical Life to estimate the benefits of reducing mortality associated with bladder cancer in the affected population. Section 2.2 provides information on updating Value of Statistical Life for inflation and income growth. EPA uses COI-based valuation to estimate the benefits of reducing morbidity associated with bladder cancer. Specifically, EPA used bladder cancer treatment-related medical care and opportunity cost⁸⁴ estimates from Greco et al. (2019). Table 6-43 shows the original COI estimates from Greco et al. (2019) which were reported in \$2010, along with the values updated to \$2021 used in this analysis. EPA further notes that the estimates for non-invasive bladder cancer subtype were used to value local, regional, and unstaged bladder cancer morbidity reductions, while the estimates for the invasive bladder cancer subtype were used to value distant bladder cancer morbidity reductions.⁸⁵

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⁸¹ As described above, EPA models THM4 changes under the treatment scenario as being in effect for the years 2023 through 2104, with nonzero THM4 changes first occurring in 2026, the year when all PWS are assumed to comply with PFAS treatment requirements.

⁸² For cancer incidence and stage distribution data, EPA relies on SEER 21 (2009-2018); for cancer survival data, EPA relies on SEER 18 (2000-2017).

⁸³ CDC Wonder data on 1999-2019 all-cause and bladder cancer mortality by age and sex.

⁸⁴ Opportunity (or indirect) costs modeled by this study were represented by the value of time needed to undergo the cancer treatment, which could otherwise have been dedicated to work or leisure activities.

⁸⁵ Local cancer is a malignant cancer confined entirely to the organ where the cancer began. Remote cancer refers to cancer that has grown beyond the original (primary) tumor to nearby lymph nodes or organs and tissues. Distant cancer refers to cancer that has spread from the original (primary) tumor to distant organs or distant lymph nodes; it is also called a distant metastasis. Finally, unstaged cancer is a cancer whose subtype is unknown.

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Table 6-43: Bladder Cancer Morbidity Valuation

Bladder Cancer Subtype ^a	Type of Cost	Cost in First Year (\$2010) ^b	Cost in Subsequent Years (\$2010) ^b	Cost in First Year (\$2021) ^c	Cost in Subsequent Years (\$2021) ^c
	Medical care	9,133	916	12,350	1,239
Non-invasive	Opportunity cost	4,572	24	5,921	31
	Total cost	13,705	941	18,272	1,270
	Medical care	26,951	2,455	36,445	3,320
Invasive	Opportunity cost	10,513	77	13,616	100
	Total cost	37,463	2,532	50,061	3,420

Notes:

^aThe estimates for non-invasive bladder cancer subtype were used to value local, regional, and unstaged bladder cancer morbidity reductions, while the estimates for the invasive bladder cancer subtype were used to value distant bladder cancer morbidity reductions

^bThe estimates come from Greco et al. (2019).

[°]To adjust for inflation, EPA used U.S. Bureau of Labor Statistics Consumer Price Index for All Urban Consumers: Medical Care Services in U.S. (City Average).

6.7.3 Results

Table 6-44 to Table 6-47 provide the health effects avoided and valuation associated with bladder cancer.

Table 6-44: National Bladder Cancer Benefits, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0)

	3%	3% Discount Rate 7% Discount Rate		e 7% Discount Rate		ate
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a
Number of Non-Fatal Bladder Cancer Cases Avoided	4,079.1	5,238.6	6,475.3	4,079.1	5,238.6	6,475.3
Number of Bladder Cancer- Related Deaths Avoided	1,436.0	1,844.4	2,280.0	1,436.0	1,844.4	2,280.0
Total Annualized Bladder Cancer Benefits (Million \$2021) ^b	\$173.09	\$221.30	\$273.62	\$102.08	\$130.63	\$161.56

Notes

Table 6-45: National Bladder Cancer Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ppt)

	3%	6 Discount Ra	ate	7%	6 Discount Ra	Discount Rate	
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Number of Non-Fatal Bladder Cancer Cases Avoided	4,066.1	5,219.4	6,488.8	4,066.1	5,219.4	6,488.8	
Number of Bladder Cancer- Related Deaths Avoided	1,431.5	1,837.6	2,284.9	1,431.5	1,837.6	2,284.9	
Total Annualized Bladder Cancer Benefits (Million \$2021) ^b	\$171.72	\$220.48	\$274.24	\$101.34	\$130.15	\$161.56	

Notes

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

Table 6-46: National Bladder Cancer Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ppt)

	3%	6 Discount Ra	ate	7% Discount Rate		
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a
Number of Non-Fatal Bladder Cancer Cases Avoided	3,342.7	4,334.3	5,382.5	3,342.7	4,334.3	5,382.5
Number of Bladder Cancer- Related Deaths Avoided	1,176.8	1,526.0	1,895.3	1,176.8	1,526.0	1,895.3
Total Annualized Bladder Cancer Benefits (Million \$2021) ^b	\$141.17	\$183.10	\$227.85	\$83.31	\$108.08	\$135.37

Notes:

Table 6-47: National Bladder Cancer Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ppt)

	3%	6 Discount Ra	ate	7%	ate	
Benefits Category	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a
Number of Non-Fatal Bladder Cancer Cases Avoided	1,615.9	2,175.5	2,807.4	1,615.9	2,175.5	2,807.4
Number of Bladder Cancer- Related Deaths Avoided	568.9	766.0	988.6	568.9	766.0	988.6
Total Annualized Bladder Cancer Benefits (Million \$2021) ^b	\$68.26	\$91.90	\$118.64	\$40.29	\$54.25	\$70.10

Notes:

6.8 Limitations and Uncertainties of the Benefits Analysis

This section describes limitations of the quantified benefits analysis, along with uncertainties that could not be modeled quantitatively as part of the national benefits analysis. The sources of uncertainty characterized quantitatively are presented in Section 6.1.2. In the tables below, EPA summarizes limitations and uncertainties that apply to:

- All quantitative benefits analyses implemented for the proposed PFAS rule (Table 6-48);
- Application of PK models for blood serum PFAS concentration estimation (Table 6-49);

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized total annualized benefits in this table.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty. This range does not include the uncertainty described in Table 6-48.

^bSee Table 7-6 for a list of the nonquantifiable costs, and the potential direction of impact these costs would have on the estimated monetized total annualized costs in this table.

- Developmental effects (i.e., infant birth weight) modeling (Table 6-50);
- CVD impacts modeling (Table 6-51);
- RCC impacts modeling (Table 6-52); and
- Modeling of bladder cancer impacts from GAC treatment related THM4 reductions (Table 6-53).

EPA notes that in most cases it is not possible to judge the extent to which a particular limitation or uncertainty could affect the magnitude of the estimated benefits. Therefore, in each table below, EPA notes the potential direction of the impact on the quantified benefits (*e.g.*, a source of uncertainty that tends to underestimate quantified benefits indicates expectation for larger quantified benefits) but does not prioritize the entries with respect to the impact magnitude.

Table 6-48: Limitations and Uncertainties that Apply to Benefits Analyses Considered for the Proposed PFAS Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
EPA has quantified benefits for three health endpoints for PFOA and PFOS.	Underestimate	For various reasons, EPA has not quantified the benefit of removing PFOA and PFOS from drinking water for most of the health endpoints PFOA and PFOS are expected to impact. See discussion in Section 6.2.2. for more information about these nonquantifiable benefits.
EPA has quantified benefits for one co-removed contaminant group (THM4).	Underestimate	Treatment technologies that remove PFAS can also numerous other contaminants, including some other PFAS compounds, additional regulated and unregulated DBPs, heavy metals, organic contaminants, pesticides, among others. These co-removal benefits may be significant, depending on co-occurrence, how many facilities install treatment and which treatment option they select.
EPA has not quantified benefits for any health endpoint for PFHxS, PFNA, PFBS, and HFPO- DA.	Underestimate	PFHxS, PFNA, PFBS, and HFPO-DA each have substantial health impacts on multiple health endpoints.
The analysis does not explicitly consider changes in PFOA/PFOS and THM4 concentrations for systems that purchase their drinking water from other PWSs.	Uncertain	Many PWSs purchase their primary source water from PWSs that are likely to implement treatment under the rule. The SDWIS/Fed inventory of PWSs includes these systems with their retail populations instead of allocating those populations to the wholesale systems. The MCMC occurrence analysis outputs for the wholesale system and purchasing system may vary from one another, resulting in either an under- or over-estimate of affected population in any iteration. The net effect on total benefits is uncertain.
The analysis does not account for populations that consume bottled water as their primary drinking water source.	Uncertain	Studies indicate that between 13 percent and 33 percent of the U.S. population consumes bottled water as their primary drinking water source (Z. Hu et al., 2011; Rosinger et al., 2018; Vieux et al., 2020). The benefits models do not consider these populations. This could result in an overestimate of avoided cases of health effects and associated benefits. However, bottled water

Table 6-48: Limitations and Uncertainties that Apply to Benefits Analyses Considered for the Proposed PFAS Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
		consumers can also be CWS customers and may still be exposed to PFAS by using water for cooking etc., therefore, would benefit from PFAS removal. (U.S. FDA, 2022; Aquafina, 2022). Finally, the benefits may also be underestimated because those using bottled water as a primary drinking water source may switch to CWS supply as a result of the proposed rule; EPA did not model this behavioral response and hence the benefits do not account for the potential cost savings to those consuming bottled water at baseline.
The analysis considers PFOA/PFOS concentrations from NTNCWSs.	Overestimate	Some SDWIS population served estimates for NTNCWSs represent the both the population that has regular exposure to the NTNCWS' drinking water (e.g., the employees at a location) and the peak day transient population (e.g., customers) who have infrequent exposure to the NTNCWS' drinking water. Estimating the demographic distribution and the share of daily drinking water consumption for these two types of NTNCWS populations would be difficult across many of the industries which operate NTNCWSs. The inclusion of NTNCWS results is an overestimate of benefits because daily drinking water consumption for these populations is also modeled at their residential CWS.
EPA assumes that the effects of PFOA and PFOS exposures are independent.	Uncertain	The exposure-response functions used in benefits analyses assume that the effects of serum PFOA/PFOS on the health outcomes considered are independent and therefore additive. Due to limited evidence, EPA does not consider synergies or antagonisms in PFOA/PFOS exposure-response.
The derivation of PFOA/PFOS exposure-response functions for the relationship between PFOA/PFOS serum and associated health outcomes assumes that there are no threshold serum concentrations below which effects do not occur.	Overestimate	The new data and EPA's proposed MCLGs indicate that the levels at which adverse health effects could occur are much lower than previously understood when EPA issued the 2016 health advisories for PFOA and PFOS (70 parts per trillion or ppt) – including near zero for certain health effects. Therefore, the exposure-response functions used in benefits analyses assume that there are no threshold serum concentrations below which effects do not occur. This could result in a slight overestimate of benefits for certain health endpoints.
The exposure-response functions used to estimate risk assume causality.	Overestimate	Analyses evaluating the evidence on the associations between PFAS exposure and health outcomes are ongoing and EPA has not conclusively determined causality. As described in Section 6.2, EPA modeled health risks from PFOA/PFOS exposure for endpoints for which the evidence of association was found to be likely. These endpoints include birth weight, TC, and RCC. While the evidence supporting causality between DBP exposure and bladder cancer has increased since EPA's Stage 2 DBP

Table 6-48: Limitations and Uncertainties that Apply to Benefits Analyses Considered for the Proposed PFAS Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
		Rule (NTP, 2021; Weisman et al., 2022), causality has not yet been conclusively determined (Regli et al., 2015).
The analysis assumes that quantified benefits categories are additive.	Uncertain	EPA did not model birth weight, CVD, RCC, and bladder cancer benefits jointly, in a competing risk framework. Therefore, reductions in health risk in a specific benefits category do not influence health risk reductions in another benefits category. For example, lower risk of CVD and associated mortality implies a larger population that could benefit from cancer risk reductions, because cancer incidence grows considerably later in life.
The scope of the analysis does not include intra- or international migration throughout the evaluation period.	Uncertain	Throughout the analysis period people may migrate from one place to another. If persons migrate to locations with larger decreases in PFOA/PFOS under the regulatory alternative, EPA would be underestimating the impacts. The opposite is true if persons migrate to locations with smaller decreases in PFOA/PFOS under the regulatory alternative.
The analysis does not take into account population growth and other changes in long-term trends.	Underestimate	The benefits analysis does not reflect the effects of growing population that may benefit from reduction in PFOA/PFOS exposure. Furthermore, EPA uses present-day information on life expectancy, disease, environmental exposure, and other factors, which are likely to change in the future.
		There are two potential datasets that could inform population growth under the final rule. EPA has described these datasets below.
		Population projections by year, county, single-year age, sex, and race/ethnicity are available through 2050 from the Woods & Poole Economics Inc. (2021) dataset and could be used for the final rule. This dataset has been used in prior rulemakings, such as the National Ambient Air Quality Standards, the Steam Electric Effluent Limitations Guidelines, and the Federal Recreational Water Quality Criteria Applicable to Certain Waters in New York (unpublished; currently on hold until January 2023 at the earliest). Woods & Poole Economics Inc. (2021) population growth data are also used in EPA's air quality benefits programs BenMAP-CE and COBRA. EPA could project the county-, sex-, race/ethnicity-, and age-specific distribution of Woods & Poole Economics Inc. (2021) data from 2051 to 2104 using a transition ratio approach with normalization to obtain population projections throughout the period of analysis relevant to the NPDWR.

Table 6-48: Limitations and Uncertainties that Apply to Benefits Analyses Considered for the Proposed PFAS Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
		Additional population projection estimates are available from the Socioeconomic Data and Applications Center (SEDAC) by county, age, sex, and race/ethnicity in five-year intervals through the year 2100. These projections were used in EPA's recent Waters of the United States rulemaking. If implemented in the PFAS NPDWR, EPA would need to distribute population within five-year intervals and project population estimates from 2101 to 2104.
The analysis does not include the impacts of COVID-19 on future population health and economic growth.	Uncertain	Impacts of the COVID-19 pandemic have had resulting effects on conception, pregnancy, and birth rates (Aassve et al., 2021; McLaren Jr et al., 2021; Ullah et al., 2020). Some studies suggest that the economic recession caused by the COVID-19 pandemic may impose long-term impacts on fertility rates (McLaren Jr et al., 2021; Ullah et al., 2020). Such impacts are not accounted for in this benefits analysis.
For PWSs with multiple entry points, the analysis assumes a uniform population distribution across the entry points.	Uncertain	Data on the populations served by each entry point are not available and EPA therefore uniformly distributes system population across entry points. Effects of the regulatory alternative may be greater or smaller than estimated, depending on actual populations served by affected entry points. For one large system serving more than one million customers EPA has sufficient data on entry point flow to proportionally assign effected populations.
Valuation of mortality risk reductions assumes that per capita income will grow at the constant rate.	Uncertain	EPA uses Value of Statistical Life adjusted for income growth to estimate economic value of the premature mortality avoided in the future. Per capita income growth projections were available through 2050. EPA estimated the compound annual growth rate in per capita income during 2023-2050 and applied it to project Value of Statistical Life over the analysis period 2023-2104.
EPA does not characterize uncertainty associated with the Value of Statistical Life reference value or Value of Statistical Life elasticity.	Uncertain	EPA did not quantitatively characterize the uncertainty for the Value of Statistical Life reference value and income elasticity. Because the economic value of avoided premature mortality comprises the majority of the overall benefits estimate, not considering uncertainty surrounding the Value of Statistical Life is a limitation.

Abbreviations: COVID-19 – coronavirus disease 2019; CVD – cardiovascular disease; CWS – community water system; DBP – disinfection byproduct; MCLG - maximum contaminant level goal; PFOA – perfluorooctanoic acid; PFOS – perfluorooctane sulfonic acid; PWS – public water system; RCC – renal cell carcinoma; RO – reverse osmosis; UCMR – Unregulated Contaminant Monitoring Rule.

Table 6-49: Limitations and Uncertainties in the PK Model Application

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
The benefits analysis assumes that there are no reductions in PFOA/PFOS exposure from other sources associated with treatment-related reductions in PFOA/PFOS drinking water concentrations.	Underestimate	Some portion of the non-drinking water PFOA/PFOS exposure could be related to drinking water concentration (e.g., food affected by water concentrations). This portion is difficult to estimate, and, depending on the relationship, there may be a time lag between the decrease in drinking water concentration and the decrease in the non-drinking water exposure.
The birth weight analysis uses the adult female PK model to estimate changes in serum PFOA/PFOS from changes in drinking water PFOA/PFOS.	Overestimate	Evidence from epidemiology studies connects birth weight to serum PFOA/PFOS levels throughout pregnancy: The serum PFOS-birth weight slope factor in the birth weight benefits module comes from the meta-analysis of 29 studies by Dzierlenga et al. (2020). Table 1 in Dzierlenga et al. (2020) summarizes the timing of the serum samples for the contributing studies, including prepregnancy (2 studies), first trimester (6 studies), second trimester (5 studies), third trimester (5 studies), and cord blood samples/delivery (11 studies). The serum PFOA-birth weight slope factor comes from the meta-analysis of 24 studies by Steenland et al. (2018). Steenland et al. (2018) summarizes the timing of the serum samples for the contributing studies, including prepregnancy (2 studies), first trimester (4 studies), straddling first and second trimester (1 study), second trimester (2 studies), straddling second and third trimester (2 studies), third trimester (4 studies), and cord blood samples/delivery (9 studies). Because the slope factors included epidemiological evidence throughout pregnancy, a developmental version of the PK model may be a more appropriate choice. A developmental PK model would allow the observed decrease in serum levels that occurs during pregnancy to be captured by accounting for maternal physiological changes. For example, Glynn et al. (2012) found a mean decrease of 16 percent for PFOA and 11 percent for PFOS between serial measurements taken in the 1st trimester and 3rd trimester of pregnancy. This decrease is associated with increases in maternal plasma volume and transfer of the chemicals to the placenta and fetus. EPA expects that the use of the adult PK model overestimates the additive difference in serum concentrations between baseline and regulatory alternative (and, therefore, the birth weight benefits of the regulatory alternative) because of the expected larger volume of distribution for pregnant females and, therefore, proportionally lower serum concentrations.

Abbreviations: PFOA – perfluorooctanoic acid; PFOS – perfluorooctane sulfonic acid; PK – pharmacokinetic.

^aFor PFOS, EPA used 4 high confidence studies (Chu et al., 2020; Sagiv et al., 2018; Starling et al., 2017; and Wikström et al., 2019) with a variety of PFOS exposure measures across the fetal and neonatal window. Sagiv et al. (2018) collected maternal

Table 6-49: Limitations and Uncertainties in the PK Model Application

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
Assumption	Estimate	

samples in trimester 1, while Wikström et al. (2020) collected them in trimesters 1 and 2. The samples from Starling et al. (2017) were from trimesters 2 and 3, while Chu et al. (2020) collected exclusively in trimester 3. Of these studies, only Sagiv et al. (2018) and Starling et al. (2017) were part of the Dzierlenga et al. (2020) meta-analysis.

^bFor PFOA, EPA used 5 high confidence studies (Chu et al., 2020; Govarts et al., 2016; Sagiv et al., 2018; Starling et al., 2017; and Wikström et al., 2020) with a variety of PFOA exposure measures across the fetal and neonatal window. Sagiv et al. (2018) collected maternal samples in trimester 1, while Wikström et al. (2020) collected them in trimesters 1 and 2. The samples from Starling et al. (2017) were from trimesters 2 and 3, while Chu et al. (2020) collected exclusively in trimester 3. The samples in the Govarts et al. (2016) study were collected from umbilical cords. None of these studies were part of the Negri et al. (2017) meta-analysis.

Table 6-50: Limitations and Uncertainties in the Analysis of Birth Weight Benefits Under the Proposed Rule

the Froposcu Ruic	T	_				
Uncertainty/ Assumption	Effect on Benefits Estimate	Notes				
Characterizing the Exposed Population						
The analysis does not consider the effects of PFOA/PFOS exposure on fertility rates.	Uncertain	Studies have shown that exposure to PFAS may lead to reduced fertility rates among women (Fei et al., 2009; Waterfield et al., 2020), while the evidence supporting PFAS effects on the male reproductive system is inconclusive (C. C. Bach et al., 2016; U.S. EPA, 2023d; U.S. EPA, 2023e). The birth weight risk reduction analysis does not account for any potential differences in birth rates among the baseline and treatment scenario due to PFAS-related changes in fertility.				
EPA uses state-specific birth rate data, distributed based on census region-level race/ethnicity-specific birth rates, to determine the share of infants born to women of childbearing age at each PWS and within each 100 gram birth weight increment.	Uncertain	County-level birth rates from CDC by 100 gram birth weight increment are often tagged as "unreliable" by CDC in cases where there are low infant counts per birth weight increment. State-specific 100 gram increment-specific birth rates may not reflect the number of infants born in each 100 birth weight increment in PWS service area that is affected by PFOA/PFOS through the pregnant mother's ingestion of drinking water. Using state-specific birth rates may over- or underestimate the number of infants falling into each 100 gram birth weight increment born to mothers who experience PWS specific changes in drinking water PFOA/PFOS levels. This in turn may over- or underestimate benefits associated with changes in PFOA/PFOS levels.				
EPA uses state-specific death rate data, distributed based on national-level race/ethnicity-specific infant mortality rates, as the baseline infant mortality rate (i.e., number	Uncertain	State-specific death rates may not reflect the baseline number of infants who die in each PWS that is affected by PFOA/PFOS in mother's drinking water. Using state-specific baseline death rates may over- or underestimate the post-regulation death rates determined using the birth weight-mortality relationship and changes in birth weight, and result				

Table 6-50: Limitations and Uncertainties in the Analysis of Birth Weight Benefits Under the Proposed Rule

the Proposed Rule			
Uncertainty/ Assumption	Effect on Benefits Estimate	Notes	
of deaths per 1,000 births) of infants born to women of childbearing age at each PWS.		in an over- or underestimate of benefits associated with changes in PFOA/PFOS levels.	
Baseline infant death rates per location are held constant throughout the years of the analysis.	Uncertain	Although changes in infant death rates may not be consistent across race/ethnicity and location in the US, medical advances in infant care will likely reduce infant mortality in future years.	
EPA uses county-specific percentages of the population that fall within four race/ethnicity categories (non-Hispanic White, non-Hispanic Black, Hispanic, and other) to separate total PWS-specific populations into race categories for application of the birth weightmortality marginal effects estimates.	Uncertain	County-specific population percentages may not accurately represent the race/ethnicity makeup of PWS-level populations served. PWS populations served may span multiple counties or may represent a portion of a single county.	
	Modeling Changes	in Health Risks	
The analysis does not model variability in pregnancy stage-specific serum PFOA/PFOS concentrations and exposure-response relationships.	Overestimate	The studies estimating the link between maternal serum PFOA/PFOS and infant birth weight use serum PFOA/PFOS measurements from various stages of pregnancy. EPA used a constant, adult PK model-based estimate of serum PFOA/PFOS concentration to represent exposure during pregnancy, which is more consistent with early pregnancy exposures and likely overestimates the reduction in serum PFOA/PFOS exposure later in pregnancy. In a sensitivity analysis (Appendix K), EPA estimated birth weight benefits using exposure-	

birth weight benefits.

response functions that evaluated the association between early pregnancy serum PFOA/PFOS and birth weight. EPA found that using an early

pregnancy-based exposure-response function would result in approximately a 60 percent reduction in

Table 6-50: Limitations and Uncertainties in the Analysis of Birth Weight Benefits Under the Proposed Rule

the Froposed Kule				
Uncertainty/ Assumption	Effect on Benefits Estimate	Notes		
The analysis assumes that birth weight changes resulting from changes in PFAS serum levels will not exceed 200 g.	Underestimate	EPA places a cap on estimated birth weight changes in excess of 200 g based on existing studies that found that changes to environmental exposures result in relatively modest birth weight changes (Windham et al., 2008; Klein et al., 2018; Kamai et al., 2019).		
	Economic Valuation of Cl	hanges in Health Risk		
Some possible benefits from increased birth weight in infants are omitted from the analysis.	Underestimate	Omitted benefit categories include reduction in IQ loss, special education costs, early intervention costs, and labor market productivity losses associated with specific developmental diseases, among others. EPA's analysis omitted these categories because the available studies documenting relationships between birth weight and non-medical effects either did not identify methods for determining the associated economic burden of such effects or had other limitations such as older (pre-2000s) data, limited geographical coverage, small sample sizes, small ranges of birth weight evaluated, performed outside of the U.S., or lack of statistical significance. See ICF (2021) for additional details.		
The analysis does not monetize medical treatment costs for infants who die within 1 year of birth.	Underestimate	This limitation likely results in an underestimate of total benefits. The magnitude of this underestimate is likely to be small because the number of infants who do not survive represent a small percentage of the total number of LBW infants. In addition, the medical cost function is based on estimated treatment expenses over a two-year period after birth and thus EPA would have to scale down medical costs to account for the distribution of infant death timing within 1-year (e.g., within 28 days of birth or 3 months). Based on the 2016-2018 NCHS/NVSS data, approximately 50 percent of LBW infant deaths occur within the first 28 days of birth. Thus, it is likely that only a small portion of medical costs from Klein et al. (2018) is applicable to infants who die within 1 year of birth.		
Simulated medical cost changes from Klein and Lynch (2018) do not reflect	Uncertain	Preliminary modeling indicates that reductions in PFOA/PFOS concentrations based on the regulatory alternatives may lead to birth weight changes greater		

Table 6-50: Limitations and Uncertainties in the Analysis of Birth Weight Benefits Under the Proposed Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
birth weight changes greater than 100 g.		than 100 g. Although EPA caps birth weight change estimates at 200 g, EPA uses the COI estimates associated with a 100 g change in birth weight for all birth weight changes between 100 and 200 g to avoid extrapolation outside of the data range.

Abbreviations: birth weight – birth weight; CDC – Centers for Disease Control and Prevention; COI – cost of illness; g – gram; LBW – low birth weight; NCHS – National Center for Health Statistics; NTNCWS - non-transient non-community water system; NVSS – National Vital Statistics System; PFAS – per-and polyfluoroalkyl substances; PFOA – perfluorooctanoic acid; PFOS – perfluorooctane sulfonic acid; PWS – public water system; SDWIS - Safe Drinking Water Information System.

Table 6-51: Limitations and Uncertainties in the Analysis of CVD Benefits Under the Proposed Rule

Froposed Kille			
Uncertainty/ Assumption	Effect on Benefits Estimate	Notes	
	Characterizing the	Exposed Population	
The analysis uses national- level estimates of CVD prevalence and incidence rates, life tables, and ASCVD model inputs (e.g., prevalence of treated and untreated hypertension, diabetes, smoking).	Uncertain	Using national-level baseline health data may over- or underestimate the effects of regulatory alternatives on CVD morbidity and mortality overall and in specific PWSs.	
The effects of statin use on changes in CVD risk were not modeled in this analysis.	Uncertain	Because statin medications lower LDL cholesterol, statin use may impact the relationship between serum PFOA/PFOS levels and TC and, ultimately, the estimated changes in CVD risk. EPA did not model population variability with respect to this factor for two reasons. First, as described in Appendix F, not all studies modeling serum PFOA/PFOS levels and TC consider and/or control for statin use. Exclusion of persons who rely on statins for LDL control from the modeled population would underestimate CVD benefits if serum PFOA/PFOS-TC effect represents an average across statin user and non-user groups. Second, there are challenges in estimating statin use prevalence. Depending on age, sex, race/ethnicity, and disease status, approximately 20 percent-40 percent of the U.S. population relies on statins (Robinson et al., 2010). Factors such as overt CVD, healthcare, and demographics are significantly associated with statin use (Leino et al., 2020; Electricwala et al., 2020). While statin therapy is intended to be permanent, many individuals who are prescribed statins take them irregularly (Colantonio, 2019; Lewey et al., 2013; Ellis et al., 2004; Goldstein et	

Table 6-51: Limitations and Uncertainties in the Analysis of CVD Benefits Under the Proposed Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
		al., 2016; Toth et al., 2019); Toth et al. (2019) found a <25 percent rate of adherence 5 years after initiation of therapy.
	Modeling Char	nges in Health Risks
The analysis assumes that there is no lag between changes in serum PFOA/PFOS concentrations and changes in TC and BP. Likewise, the analysis assumes that there is no lag between changes in TC/BP and changes in CVD risk.	Overestimate	The studies estimating the link between serum PFOA/PFOS and TC/BP and the ASCVD model are not dynamic, and hence do not provide insights into whether TC/BP may respond gradually to changes in serum PFOA/PFOS and/or if CVD risk may respond gradually to changes in TC/BP. The analysis assumes immediate adjustment, which may overestimate impacts to the exposed population. Note, however, that reductions in TC/BP and CVD risk do not instantaneously follow the reductions in PFOA/PFOS drinking water concentrations, because the reductions in serum PFOA/PFOS are gradual, as predicted by the PK model.
The derivation of PFOA/PFOS exposure-response functions for the relationship between PFOA/PFOS serum and TC levels assumes that the studies used in the meta-analysis represent the PFOA/PFOS effects on serum TC levels in general population adults.	Uncertain	The exposure-response function was developed based on six general population studies reporting linear serum PFAS-TC level associations. Four of these studies were high quality as reflected by the lower risk of bias evaluations. These studies may not capture all possible relationships between PFOA/PFOS and serum TC levels.
The analysis excludes exposure-response relationships between serum PFOA/PFOS and HDLC.	Uncertain	The relationship between serum PFOA/PFOS and HDLC is uncertain. As shown in Section 6.5.2 and Appendix F, the meta-analysis-based estimate of the effect of serum PFOA/PFOS on HDLC concentration is positive but not statistically significant. Single-study analyses of this relationship have generated both positive (Dong et al. (2019) serum PFOS-HDLC relationship) and negative (Dong et al. (2019) serum PFOA-HDLC relationship, PI. D. Lin et al. (2019) serum PFOA-HDLC and serum PFOS-HDLC relationship) effect estimates that were not statistically significant. To better understand the impact of incorporating HDLC in the CVD risk model, EPA has implemented a sensitivity analysis (see details in Appendix K). EPA found that, using the meta-analysis results, inclusion of HDLC would decrease benefits by approximately 23-25%.
The analysis assumes that the CVD risk impact of changes in TC/BP from	Uncertain	While the CVD risk impacts of changes in TC/BP from behavioral and medical interventions is well documented (Lloyd-Jones et al., 2017), there is no information on

Table 6-51: Limitations and Uncertainties in the Analysis of CVD Benefits Under the Proposed Rule

Proposed Rule			
Uncertainty/ Assumption	Effect on Benefits Estimate	Notes	
reductions in serum PFOA/PFOS is the same as the CVD risk impact of changes in these biomarkers due to other reasons such as behavioral changes or medication.		whether changes in serum PFOS/PFOA leading to changes in these biomarkers would result in similar outcomes.	
The CVD risk analysis assumes that person's TC/BP level history does not have an impact on changes in CVD risk due to changes in the levels of these biomarkers.	Uncertain	The ASCVD model links TC/BP levels at the start of the 10-year follow-up period to first hard CVD event incidence during the follow-up period. The modeling does not account for TC/BP changes over time, which could have an impact on the CVD event risk.	
The ASCVD model was not recalibrated for the contemporary CVD incidence and prevalence.	Overestimate	Assessments of ASCVD risk model performance across different sociodemographic subgroups (Asian populations, Hispanic populations, persons with high levels of CVD risk, diabetes, older adults with frailty and multimorbidity, smokers, and women) indicated that the model tended to overestimate risk but suggested that the model may improve through additional input variables and recalibration given contemporary CVD incidence and prevalence (Mora et al., 2018; Muntner et al., 2014).	
The analysis uses the ASCVD model developed for non-Hispanic Black populations to assess potential CVD risks for race/ethnicity groups other than non-Hispanic Black and non-Hispanic White populations.	Uncertain	The ASCVD model documentation encourages the use of equations for non-Hispanic White populations for other race/ethnicity categories, specifying that estimated risks may be biased upward, especially for Hispanic and Asian American populations. EPA's model validation analysis detailed in Appendix G shows that the non-Hispanic Black model is a better fit for these race/ethnicity groups. However, the ultimate impact of this assumption is uncertain.	
EPA uses the fraction of the population who smokes and has diabetes as inputs into the ASCVD model.	Underestimate	The ASCVD model uses binary values to indicate whether a person is a current smoker or has diabetes. EPA simplifies calculations by using the fraction of the population who smokes and has diabetes as inputs to the ASCVD model. EPA has implemented a targeted evaluation of the effect of this assumption and confirmed that this simplification likely underestimates impacts by approximately 5 percent to 10 percent, depending on the age group, due to the non-linearity of the estimated model.	
The analysis assumes that the threshold for high BP is a systolic/diastolic measurement of 140/90.	Underestimate	In November 2017, the threshold defined for high BP was reduced to 130/80. The analysis relies on high BP prevalence data and treated, untreated, and normal BP measurements that are based on NHANES surveys from 2011 to 2016. Therefore, EPA adheres to the pre-2017 threshold. Furthermore, the ASCVD model was developed prior to the change in high BP definition.	

Table 6-51: Limitations and Uncertainties in the Analysis of CVD Benefits Under the Proposed Rule

Proposed Rule	Proposed Kule			
Uncertainty/ Assumption	Effect on Benefits Estimate	Notes		
		Adhering to the pre-2017 threshold may affect the number of people sorted into the high BP population category, potentially underestimating CVD risk.		
The analysis assumes independence among the prevalence of high BP, smoking, and diabetes.	Overestimate	Smoking and high BP are often related, and smoking is a risk factor for Type 2 diabetes. Assuming independence among the prevalence of high BP, smoking, and diabetes may result in overestimated CVD risk impacts.		
The analysis assumes that deaths from causes other than hard CVD events occur first.	Underestimate	By assuming that deaths from causes other than hard CVD events occur first, EPA underestimates the eligible population (e.g., population without CVD history) evaluated for the first hard CVD event estimation.		
The analysis does not account for survivors of first hard CVD events that are neither MI nor IS. The analysis does not account for persons who were younger than 40 years at the time of their first hard CVD event.	Underestimate	The ASCVD model captures risk of non-fatal MI, non-fatal IS, and fatal CVD; however, it does not capture other non-fatal CHD. The ASCVD model can be used to predict the annual probability of a first hard CVD event for persons aged 40–89 years; EPA applied this model to populations aged 40 years and older. The prevalence of CVD history before age 40 is low (<7% based on estimates from the Medical Expenditure Panel Survey) and likely includes persons whose CVD arises from genetic factors (Zhang et al., 2019). Early life PFAS exposures and TC are inconclusively associated for PFOA and positively associated for PFOS (U.S. EPA, 2023d; U.S. EPA, 2023e). TC later in life is highly positively correlated with early TC as seen in Pletcher et al. (2016) and Zhang et al. (2019). This analysis does not directly capture effects of early life increases in TC due to PFAS exposures. The analysis does capture the effects of early life TC indirectly to the extent that early and later in life TC levels are correlated.		
The analysis does not capture post-acute CVD mortality beyond 5 years of the first MI or IS for those ages 40–65 at the time of the initial event nor does it capture post-acute CVD mortality beyond 6 years of the first MI or IS for those ages 66–89 at the time of the initial event.	Underestimate	The risk of post-acute CVD mortality was estimated based on Thom et al. (2001) for those aged 40–65 years and on S. Li et al. (2019) for those older than 65 years. Neither study reported post-acute mortality information for a longer follow-up period. The reported information does not support complete post-acute mortality risk elimination beyond the longest follow-up period. EPA did not identify U.S. population-based MI/IS survivor studies that had a longer follow-up time and, thus, has no reliable quantitative basis to estimate post-acute mortality impacts beyond 6 years of the initial event.		
The analysis assumes that post-acute CVD mortality for survivors of IS at ages 40–65 is the same as post-acute CVD mortality for survivors of MI at ages 40–65.	Uncertain	Post-acute mortality estimates for IS and MI were very close in the Medicare population (S. Li et al., 2019). For those aged 65 years or older, S. Li et al. (2019) have estimated the probability of death within 1 year after non-fatal IS to be 32.07 percent and the probability of death within 1 year after non-fatal MI to be 32.09 percent.		

Table 6-51: Limitations and Uncertainties in the Analysis of CVD Benefits Under the Proposed Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
		Therefore, reliance on the post-acute mortality for MI to approximate the same for stroke is reasonable.
The analysis models the 85+ year old group jointly and applies average mortality rate for those aged 85+ in this age group.	Uncertain	The effect of this modeling approximation on the CVD benefits is not certain because the integer age-specific mortality rates may be above or below the average mortality rate.
The analysis models the 85+ year old group jointly and uses serum PFOA/PFOS estimates for age 85 in initiate calculations in this age group.	Underestimate	Because the impacts of changes in PFOA/PFOS drinking water concentrations on serum PFOA/PFOS levels increase over time, the use of serum PFOA/PFOS concentrations at 85 years to model the 85+ age group will underestimate the CVD risk impacts in this group.
The analysis applies the ASCVD model to those older than 80 years.	Overestimate	The ASCVD model evaluates first hard CVD event risk for adults aged 40-80. Applying the predicted hard CVD event risk for those aged 80 years or older results in an overestimate of benefits.
EPA does not characterize uncertainty associated with ASCVD model parameters.	Uncertain	EPA treats the coefficients of the ASCVD risk model as certain. However, uncertainty surrounding race/ethnicity-and sex-specific ASCVD model parameters could be characterized by multivariate normal distribution using the ASCVD model coefficient estimates, and the variance-covariance matrix shared by the ASCVD model authors. Assuming that ASCVD model parameters are certain is a limitation of this analysis.
	Economic Valuation o	f Changes in Health Risk
The analysis monetized changes in non-fatal first MI/IS risk using medical expenditures that do not cover long-term institutional or at-home care. Furthermore, the COI estimates do not include lost productivity. Finally, the COI-based approach does not account for the pain and suffering associated with non-fatal CVD events.	Underestimate	This analysis likely understates morbidity benefits since hard CVD events, particularly IS, require a longer rehabilitation period. According to HCUP 2017 data, 65 percent of IS survivors and 33 percent of MI survivors are discharged to a long-term care facility or to a home healthcare setting. Lost productivity impacts are also likely (Cropper et al., 2000; Skolarus et al., 2014). MI/IS survivors also experience significant reductions in the health-related quality of life (J. P. Bach et al., 2011; Kirchberger et al., 2020; Martino Cinnera et al., 2020; Mollon et al., 2017).

Abbreviations: ASCVD – Atherosclerotic cardiovascular disease; BP – blood pressure; CVD – cardiovascular disease; HDLC – high-density lipoprotein; IS – ischemic stroke (ICD9=433, 434; ICD10=I63); MI – myocardial infarction (ICD9=410; ICD10=I21); NHANES – National Health and Nutrition Examination Survey; PFOA – perfluorooctanoic acid; PFOS – perfluorooctane sulfonic acid; TC – total cholesterol.

Table 6-52: Limitations and Uncertainties in the Analysis of RCC Benefits Under the Proposed Rule

Uncertainty/Assumption	Effect on Benefits Estimate	Notes
	Characterizing the Expos	ed Population
The analysis uses national-level estimates of kidney cancer incidence, prevalence, stage distribution, and relative survival data, as well as national-level life tables.	Uncertain	Using national-level baseline health data may over- or underestimate the effects of regulatory alternatives on RCC morbidity and mortality in specific PWSs and well as overall.
EPA assumed that RCC comprises 90 percent of kidney cancer incidence.	Uncertain	Because baseline RCC incidence statistics are not readily available from the National Cancer Institute public use data, EPA used kidney cancer statistics in conjunction with an assumption that RCC comprises 90 percent of all kidney cancer cases to estimate baseline lifetime probability of RCC. This assumption was used in RCC exposure-response modeling by U.S. EPA (2023e).
RCC risks are estimated for populations for which reductions in PFOA exposures relative to baseline exposures start at different ages, including children.	Uncertain	The relative cancer potency of PFOA in children is unknown, which may bias benefits estimates either upward or downward. Because RCC incidence in children is very small, we assess any bias to be negligible.
	Modeling Changes in H	ealth Risks
The analysis assumes that the magnitude of RCC risk reductions resulting from reductions in serum PFOA levels will not exceed a PAF of 3.94 percent.	Uncertain	EPA placed a cap of 3.94 percent on the magnitude of the estimated cumulative RCC risk reduction resulting from reductions in serum PFOA levels, based on its analysis of PAF values found in the literature on environmental contaminants and cancers (ICF, 2022b). This review found that changes in environmental exposures result in relatively modest PAFs (between 0.2 percent and 17.9%); however, few of the studies provided PAFs related specifically to RCC or kidney cancer. EPA characterized the uncertainty surrounding this parameter using a log-uniform distribution with a minimum of 0.2 percent and a maximum of 17.9 percent. For the central estimate of RCC benefits, EPA used a PAF of 3.94 percent, which is the mean of the PAF uncertainty distribution. As such, EPA assumed that RCC risk reduction estimates in excess of the PAF are unreasonable even as a result of large changes in serum PFOA concentrations. Because this PAF cap is not based on RCC studies specifically, it is uncertain whether the RCC impacts are under-or overestimated.

Table 6-52: Limitations and Uncertainties in the Analysis of RCC Benefits Under the Proposed Rule

Uncertainty/Assumption	Effect on Benefits Estimate	Notes
The analysis assumes that there is no lag between changes in serum PFOA concentrations and changes in RCC incidence.	Overestimate	The studies estimating the link between serum PFOA and RCC are not dynamic, and hence do not provide insights into whether RCC incidence may respond gradually to changes in serum PFOA. The PK model estimates daily serum levels, which are averaged annually for the purposes of modeling gradual serum changes for the RCC risk reduction analysis. The RCC risk reduction analysis assumes immediate RCC incidence adjustment within each year, which may overestimate impacts to the exposed population.
The analysis relies on public-access SEER 18 10-year relative kidney cancer survival data to model mortality patterns in the kidney cancer population.	Uncertain	Reliance on these data generates both a downward and an upward bias. The downward bias is due to the short, 10-year excess mortality follow-up window. Survival rates beyond 10 years following the initial diagnosis are likely to be lower. The upward bias comes from the inability to determine how many of the excess deaths were deaths from kidney cancer.
The analysis assumes that RCC incidence patterns and survival are reasonably approximated by the kidney cancer statistics.	Uncertain	The exposure-response function provides information on changes in RCC risk, while detailed race/ethnicity-, sex-, and age-specific cancer incidence, stage, and survival information is available for kidney cancer only. For consistency with the RCC exposure-response modeling (U.S. EPA, 2023e), EPA assumed that RCC comprises 90 percent of kidney cancer cases. In absence of RCC-specific detailed information, the model relies on patterns based on kidney cancer statistics.
The analysis models the 85+ year old group jointly and applies the average mortality rate for those aged 85+ in this age group.	Uncertain	The effect of this modeling approximation on the RCC benefits is not certain because integer age-specific mortality rates may be above or below the average mortality rate.
The analysis models the 85+ year old group jointly and uses serum PFOA estimates for those aged 85 to initiate calculations in this age group.	Underestimate	Because the impacts of changes in PFOA drinking water concentrations on serum PFOA levels increase over time, the use of serum PFOA concentrations at 85 years to model the 85+ age group will underestimate the RCC risk impacts in this group.

Table 6-52: Limitations and Uncertainties in the Analysis of RCC Benefits Under the Proposed Rule

Uncertainty/Assumption	Effect on Benefits Estimate	Notes
Econ	omic Valuation of Chang	ges in Health Risk
RCC morbidity valuation is based on medical costs associated with the first line treatment that resulted in the most cost-effective treatment sequences, as reported in Ambavane et al. (2020).	Uncertain	The valuation is biased downward because it does not account for (1) the second line treatments that may also be applied; (2) lost productivity by the person experiencing RCC and family caregivers; and (3) the pain and suffering associated with experiencing RCC and/or adverse effects of RCC treatment. The valuation is biased upward because (1) the full year-specific cancer treatment is assumed to occur prior to the year-specific cancer population death; and (2) the first line treatment may be discontinued prior to the assumed maximum treatment duration of 2 years. The effect of using costs associated with the most cost-effective treatment from Ambavane et al. (2020) rather than costs for treatments currently prevalent in clinical practice is uncertain. EPA could not assess the impact of this assumption because EPA is not aware of publicly available information on the frequency of various kidney cancer treatments in the U.S. population.

Abbreviations: PFOA-perfluoro octano ic acid; PFOS-perfluoro octane sulfonic acid; PK-pharmacokinetic; RCC-renal cell carcinoma.

Table 6-53: Limitations and Uncertainties in the Analysis of DBP Quantified Benefits Under the Proposed Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes	
Modeling Reduced THM4 in PWSs			
Reductions in THM4 formation depend only on the relationship between raw water TOC levels and THM4 levels as estimated in the 1998 DBP ICR. Other source water quality parameters were not modeled.	Uncertain	EPA assumes that PWSs affected by implementation of PFAS treatment technologies have similar characteristics as those evaluated in the 1998 DBP ICR. Source water parameters and treatments at individual plants may have changed over time.	

Table 6-53: Limitations and Uncertainties in the Analysis of DBP Quantified Benefits Under the Proposed Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
EPA uses available TOC data to estimate reduced THM4 concentration.	Uncertain	Due to the lack of site-specific information on factors affecting THM4 formation at each potentially affected drinking water treatment plant, EPA uses relationships between TOC levels and changes in THM4 levels among GAC-treating systems from the 1998 DBP ICR and median raw water TOC levels for each source water type from the 2019 SYR4 dataset. Actual changes in THM4 concentrations for a given change in treatment at any specific PWS could be higher or lower than that estimated using EPA's approach.
EPA assigned TOC values at the system level based on Ground Water or Surface Water distributions.	Uncertain	Because the TOC levels for all systems is not available, EPA used TOC data provided by states in response to the fourth Six-Year Review to derive TOC probability distributions for influent into a PFAS treatment process; one distribution for Ground Water systems and another for Surface Water systems. EPA randomly assigned values from these distributions to each Ground Water or Surface Water system, respectively. The actual TOC values may be higher or lower than the assigned values. For systems using GAC for PFAS removal, the corresponding impact would be under-stating or over-stating costs.
EPA estimates THM4 reduction based on free chlorine formation potential but does not estimate the reduction based on chloramine use.	Overestimate	The 1998 DBP ICR TSD provided information for systems that only used free chlorine as a disinfectant and did not capture THM4 reduction in chloraminating systems. This limitation likely leads to an overestimate of THM4 formed in systems that used chloramines in the distribution system because THM4 formation within the distribution system is lower when chloramines are used, compared to when free chlorine is used (Hua et al., 2008). Based on SYR3 data, 36 percent of surface water systems and 4 percent of ground water systems use chloramination (U.S. EPA, 2016j). Chloramines may produce greater amounts of genotoxic and carcinogenic DBPs, but a reduction in the TOC prior to disinfection will also yield a reduction in DBP formation (Cuthbertson et al., 2019).

Table 6-53: Limitations and Uncertainties in the Analysis of DBP Quantified Benefits Under the Proposed Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
THM4 is assumed to be a surrogate for other chlorination DBPs, some of which are more genotoxic and cytotoxic than THMs.	Uncertain	EPA's analysis relies on the slope factor from Regli et al. (2015), which links lifetime risk of bladder cancer to THM4 concentrations in finished water. Regli et al. (2015) did not explicitly account for brominated or nitrogenous DBPs, but instead used THM4 as a surrogate for the broad suite of chlorination DBPs. This is consistent with the approach used in numerous epidemiolocal studies (Costet et al., 2011; Freeman et al., 2017) since insufficient data are available to estimate the co-occurrence and coremoval of specific genotoxic or cytotoxic DBPs.
EPA estimates THM4 reduction based on GAC use but does not estimate the reduction in individual THM4 species.	Uncertain	GAC has been shown to shift the speciation among THM4 and can result in a relatively larger fraction of brominated species (THM3) compared to chloroform. However, studies show that even as speciation shifts, the absolute concentrations of each species is reduced (Cuthbertson et al., 2019; L. Wang et al., 2019).
The logistic model uses pilot/RSSCT results to predict ΔTHM4.	Overestimate	RSSCTs may overpredict full-scale adsorption capacity of GAC (Kempisty et al., 2022; Zachman et al., 2010)
	SYR4 Compari	son
Estimates of reductions in THM4 formation assume that GAC treatment is the only treatment change in a distribution system.	Uncertain	Uncertainty exists if other changes (i.e., new source water, chemical dosing, other treatments added such as pre-chlorination, existing treatments changed such as new filter media) that could have been made in public water systems beyond GAC treatment could potentially over- or underestimate THM4 reduction.
EPA analyzed only systems that were sampled under UCMR 3 and indicated GAC treatment under UCMR 4.	Uncertain	Assessing only UCMR GAC systems limited the sample to PWS serving ≥ 10,000 people. Therefore, EPA was unable to compare THM4 reduction estimates to measured data for small systems.
EPA relied on available CCRs to estimate the GAC treatment start date to determine before and after treatment years.	Uncertain	Available CCRs were used to inform the GAC start date. When CCRs were unavailable, EPA searched the web to identify information about the timeline of treatment for individual PWSs. While installation dates were found, the exact date for when the GAC systems went into full-scale use was not always specified.

Table 6-53: Limitations and Uncertainties in the Analysis of DBP Quantified Benefits Under the Proposed Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
EPA obtained THM4 values from multiple data sources.	Uncertain	For PWSs that met criteria outlined in Section 6.7.1.3.2 but had no THM4 data available in SYR4, EPA relied on CCR THM4 data. Reporting on THM4 levels is inconsistent across CCRs. If a CCR listed "Amount Detected" instead of the THM4 average, then EPA used the "Amount Detected" value to represent the THM4 average.
	Characterizing the Expo	sed Population
Analysis assumes that systems implementing IX do not accrue benefits associated with bladder cancer risk reductions.	Underestimate	Systems using IX for PFAS removal will also benefit from some TOC removal, but the removal will be limited in comparison to GAC treatment because PFAS-selective IX can show preferential removal of PFAS over organic matter (de Abreu Domingos et al., 2018).
The analysis does not model location-specific demographics.	Uncertain	Because EPA models impacts to aggregate populations based on systems triggered into treatment under various scenarios, EPA relies on national-level demographic and bladder cancer data. The impact of this limitation is uncertain. For instance, populations with a large portion of elderly or male individuals will be more sensitive to changes in THM4 levels due to the high baseline bladder cancer incidence among elderly and male populations, compared to younger and female populations.
The analysis does not model variability by race/ethnicity.	Uncertain	Because EPA models impacts based on a national-level distribution of finished water TOC levels, specific TOC levels at actual PWSs are not available. Therefore, these impacts were not included in EPA's DBP analysis. Accordingly, EPA did not pursue race/ethnicity-specific modeling of health risk because it would not provide meaningful insight into distributional effects.
Bladder cancer risks are estimated for populations for which reductions in THM4 exposures relative to baseline exposures start at different ages, including children.	Uncertain	The relative cancer potency of THM4 in children is unknown, which may bias estimates either upward or downward. Past reviews found no clear evidence that children are at greater risk of adverse effects from bromoform or dibromochloromethane exposure (U.S. EPA, 2005a), although certain modes of action and health effects may be associated with exposure to THM4 during childhood (U.S. EPA, 2016g). Because bladder cancer incidence in children is very small, EPA assesses any bias to be negligible.

Table 6-53: Limitations and Uncertainties in the Analysis of DBP Quantified Benefits Under the Proposed Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes
	Modeling Changes in H	lealth Risks
Analysis assumes an immediate and full reduction in bladder cancer risk following THM4 exposure reduction.	Overestimate	EPA did not model the transitional dynamics in relative annual risk of bladder cancer following the THM4 exposure reduction. Regli et al. (2015) do not provide pertinent information; as such, this is a cross-sectional analysis quantifying the relationship between lifetime cancer risk and lifetime average exposure. Existing cancer risk cessation lag studies focused on smoking and arsenic exposure (e.g., Hrubec et al., 1997, Hartge et al., 1987, and C. W. Chen et al., 2003); show that, annual cancer risk drops within the first 25 years after exposure cessation, yet it may never reach the annual cancer risk of persons who were always exposed to the treatment contaminant levels. In EPA's modeling this issue pertains to those alive at the start of the evaluation period who have been exposed to the pre-treatment THM4 levels for a considerable amount of time, such as persons older than 60 years at the start of the evaluation period. This subpopulation comprises approximately 20 percent of the affected population alive in 2023.
The analysis relies on public-access SEER 18 10-year relative bladder cancer survival data to model mortality patterns in the bladder cancer population.	Uncertain	Reliance on these data generates both a downward and an upward bias. The downward bias is due to the short, 10-year excess mortality follow-up window. Survival rates beyond 10 years following the initial diagnosis are likely to be lower. The upward bias comes from the inability to determine how many of the excess deaths were deaths from bladder cancer.
The relationship from Regli et al. (2015) is a linear approximation of the odds ratios reported in Villanueva et al. (2004).	Uncertain	Given the uncertainty about the historical, location-specific THM4 baselines, Regli et al. (2015) provides a reasonable approximation of the risk. However, depending on the baseline THM4 exposure level, the impact computed based on Regli et al. (2015) may be larger or smaller than the impact computed using the Villanueva et al. (2004)-reported odds ratios directly.

Table 6-53: Limitations and Uncertainties in the Analysis of DBP Quantified Benefits Under the Proposed Rule

Uncertainty/ Assumption	Effect on Benefits Estimate	Notes	
The analysis does not apply a PAF-based cap on the magnitude of bladder cancer relative risk reductions from reductions in THM4 exposure.	Overestimate	While, for the RCC analysis, EPA placed a cap of 3.94 percent on the magnitude of the estimated cumulative RCC risk reduction resulting from reductions in serum PFOA levels, a similar cap was not implemented for the bladder cancer model. This is because the relative bladder cancer risk reductions from reductions in THM4, estimated in this analysis, have been modest, generally not exceeding 4 percent. Because the PAF cap developed by EPA is not based on bladder cancer studies specifically, it is uncertain to what extent the bladder cancer impacts may have been overestimated.	
Ecor	nomic Valuation of Chang	ges in Health Risk	
Bladder cancer morbidity valuation is based on medical costs and indirect/time costs (by cancer stage), as reported in Greco et al. (2019).	Uncertain	The valuation is biased downward because it does not account for (1) lost productivity by the family caregivers and volunteers; (2) broader labor market participation effects for those experiencing bladder cancer and/or providing care; and (3) the pain and suffering associated with experiencing bladder cancer and/or adverse effects of bladder cancer treatment. The valuation is biased upward because (1) the full year-specific cancer treatment is assumed to occur prior to the year-specific cancer population death; and (2) the treatment may be discontinued if it is no longer effective.	

Abbreviations: CCR – consumer confidence reports; DBP – disinfection byproduct; GAC – Granular Activated Carbon; ICR – Information Collection Request; PFAS – per-and polyfluoroalkyl substances; PFOA – perfluorooctanoic acid; PFOS – perfluorooctane sulfonic acid; PWS – public water system; SYR – Six Year Review; THM4 – Four Regulated Trihalomethanes; TOC – Total Organic Carbon; TSD – Treatment Study Database; UCMR – Unregulated Contaminant Monitoring Rule, PAF – population attributable fraction.

7 Comparison of Costs to Benefits

This chapter provides a comparison of the incremental costs and benefits of the proposed rule, as described in Chapter 5 and Chapter 6.⁸⁶ The incremental cost is the difference between costs that will be incurred if the proposed rule is enacted over and above current baseline conditions. Incremental benefits reflect the avoided future adverse health outcomes attributable to PFAS reductions and co-removal of additional contaminants due to actions undertaken to comply with the proposed rule. This chapter also provides benefits and costs for the alternatives to the proposed option that EPA considered. Results for the proposed option precede estimates for the alternatives.

Table 7-1 provides the incremental quantified costs and benefits of the proposed option at both a 3 percent and a 7 percent discount rate in 2021 dollars. The first row shows total monetized annualized costs including total PWS costs and primacy agency costs. The second row shows total monetized annualized benefits including all endpoints that could be quantified and valued. For both discount rates, the estimates are the expected values, and the 5th percentile and 95th percentile estimates are derived from the uncertainty distribution. These percentile estimates come from the distributions of annualized costs and annualized benefits generated by the 4,000 iterations of SafeWater MCBC, as described in Sections 5.1.2 and 6.1.2. Therefore, these distributions reflect the joint effect of the multiple sources of variability and uncertainty for costs identified in Section 5.1.2 and for benefits identified in Section 6.1.2 as well as the baseline uncertainties discussed throughout Chapter 4 such as baseline PFAS occurrence.

The third row shows net benefits (benefits minus costs). At a 3 percent discount rate, the net annual incremental benefits are \$461 million. The uncertainty range for net benefits is negative \$45 million to \$1.14 billion. At a 7 percent discount rate, the net annual incremental benefits are negative \$297 million. The uncertainty range for net benefits is negative \$628 million to \$141 million.

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⁸⁶ The cost-benefit analysis results for each option reflect the variability and uncertainties that could be quantified given the best available scientific data. There are many factors that EPA could not quantify because of data limitations. For example, benefits will be underestimated if the PFOA and PFOS reductions result in avoided adverse health outcomes that cannot be quantified and valued. Chapters 5 and 6 identify these limitations and the potential effect on the cost or benefit estimates, respectively.

Table 7-1: Annualized Quantified National Costs and Benefits, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0; Million \$2021)

	3% Discount Rate			7% Discount Rate			
	5 th Expected 95 th Percentile ^a Value Percentile ^a		5 th Percentile ^a	Expected Value	95 th Percentile ^a		
Total Annualized Rule Costs	\$704.53	\$771.77	\$850.40	\$1,106.01	\$1,204.61	\$1,321.01	
Total Annualized Rule Benefits	\$659.91	\$1,232.98	\$1,991.51	\$477.69	\$908.11	\$1,462.43	
Total Net Benefits ^{b,c,d}	-\$44.62	\$461.21	\$1,141.11	-\$628.31	-\$296.50	\$141.42	

Notes: Detail may not add exactly to total due to independent rounding.

Table 7-2 to Table 7-4 summarize the monetized total annual costs and benefits for Options 1a, 1b, and 1c, respectively.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty described in Section 5.1.2 and Table 5-1 for costs and Section 6.1.2 and Table 6-1 for benefits. This range does not include the uncertainty described in Table 5-22 for costs and Table 6-48 for benefits.

^bSee Table 7-6 for a list of the nonquantifiable benefits and costs, and the potential direction of impact these benefits and costs would have on the estimated monetized total annualized benefits and costs in this table.

^cTotal quantified national cost values do not include the incremental treatment costs associated with the cooccurrence of HFPO-DA, PFBS, and PFNA at systems required to treat for PFOA, PFOS, and PFHxS. The total quantified national cost values do not include treatment costs for systems that would be required to treat based on HI exceedances apart from systems required to treat because of PFHxS occurrence alone. See Appendix N, Section N.3 for additional detail on cooccurrence incremental treatment costs and additional treatment costs at systems with HI exceedances.

^dPFAS-contaminated wastes are not considered hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See Appendix N, Section N.2 for additional detail.

Table 7-2: Annualized Quantified National Costs and Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ppt; Million \$2021)

	3% Discount Rate			7% Discount Rate		
2 Expected 50		95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Total Annualized Rule Costs	\$688.09	\$755.82	\$833.48	\$1,078.51	\$1,177.31	\$1,292.01
Total Annualized Rule Benefits	\$651.19	\$1,216.08	\$1,971.01	\$471.53	\$895.36	\$1,456.23
Total Net Benefits ^{b,c}	-\$36.90	\$460.26	\$1,137.53	-\$606.97	-\$281.95	\$164.22

Notes: Detail may not add exactly to total due to independent rounding.

Table 7-3: Annualized Quantified National Costs and Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ppt; Million \$2021)

	3% Discount Rate			7% Discount Rate		
	5 th Percentile ^a	Expected Value	95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a
Total Annualized Rule Costs	\$558.71	\$611.01	\$674.32	\$864.74	\$942.28	\$1,035.56
Total Annualized Rule Benefits	\$553.37	\$1,046.91	\$1,706.81	\$398.21	\$773.33	\$1,292.96
Total Net Benefitsb,c	-\$5.34	\$435.90	\$1,032.49	-\$466.53	-\$168.95	\$257.40

Notes: Detail may not add exactly to total due to independent rounding.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty described in Section 5.1.2 and Table 5-1 for costs and Section 6.1.2 and Table 6-1 for benefits. This range does not include the uncertainty described in Table 5-22 for costs and Table 6-48 for benefits.

^bSee Table 7-6 for a list of the nonquantifiable benefits and costs, and the potential direction of impact these benefits and costs would have on the estimated monetized total annualized benefits and costs in this table.

^cPFAS-contaminated wastes are not considered hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See Appendix N, Section N.2 for additional detail.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty described in Section 5.1.2 and Table 5-1 for costs and Section 6.1.2 and Table 6-1 for benefits. This range does not include the uncertainty described in Table 5-22 for costs and Table 6-48 for benefits.

^bSee Table 7-6 for a list of the nonquantifiable benefits and costs, and the potential direction of impact these benefits and costs would have on the estimated monetized total annualized benefits and costs in this table.

PFAS-contaminated wastes are not considered hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See Appendix N, Section N.2 for additional detail.

Table 7-4: Annualized Quantified National Costs and Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ppt; Million \$2021)

	3% Discount Rate			7% Discount Rate			
	5 th Expected 95 th Percentile ^a Value Percentile ^a		95 th Percentile ^a	5 th Percentile ^a	Expected Value	95 th Percentile ^a	
Total Annualized Rule Costs	\$269.36	\$292.57	\$320.76	\$396.22	\$430.87	\$472.20	
Total Annualized Rule Benefits	\$280.42	\$584.80	\$1,030.56	\$208.71	\$436.24	\$784.59	
Total Net Benefits ^{b,c}	\$11.06	\$292.23	\$709.80	-\$187.51	\$5.36	\$312.39	

Notes: Detail may not add exactly to total due to independent rounding.

The reported dollar figures in this benefit-cost analysis reflect benefits and costs that could be quantified for each regulatory alternative given the best available scientific data. EPA notes that the quantified benefit-cost results presented above are not representative of all benefits and costs anticipated under the proposed NPDWR. Due to limited data on occurrence, health, and economic information, there are several adverse health effects associated with PFAS exposure and costs associated with treatment that EPA could not estimate in a quantitative manner.

PFAS are associated with a wide range of adverse health effects including reproductive issues such as decreased fertility or increased high blood pressure in pregnant women; developmental effects or delays in children, including low birth weight, accelerated puberty, bone variations, or behavioral changes; increased risk of some cancers, including prostate, kidney, and testicular cancers; reduced ability of the body's immune system to fight infections, including reduced vaccine response; interference with the body's natural hormones; and increased cholesterol levels and/or risk of obesity. EPA is only able to quantify three PFOA- and PFOS-related health endpoints in this analysis. All regulatory alternatives are expected to produce substantial benefits that have not been quantified. Treatment responses implemented to remove PFOA and PFOS under Options 1a-c are likely to remove some amount of additional PFAS contaminants where they co-occur. Co-occurrence among PFAS compounds has been observed frequently as discussed in the PFAS Occurrence Technical Support Document (U.S. EPA, 2023g). The proposed option is expected to produce the greatest reduction in exposure to PFAS compounds because it includes PFHxS, HFPO-DA, PFNA, and PFBS in the regulation. Inclusion of the HI will trigger more systems into treatment (as shown in Section 4.4.4) and provides enhanced public health protection by ensuring reductions of these additional compounds when present above the HI of 1.0. For further discussion of the quantitative and qualitative benefits associated with the proposed rule, see Section 6.2.

^aThe 5th and 95th percentile range is based on modeled variability and uncertainty described in Section 5.1.2 and Table 5-1 for costs and Section 6.1.2 and Table 6-1 for benefits. This range does not include the uncertainty described in Table 5-22 for costs and Table 6-48 for benefits.

^bSee Table 7-6 for a list of the nonquantifiable benefits and costs, and the potential direction of impact these benefits and costs would have on the estimated monetized total annualized benefits and costs in this table.

[°]PFAS-contaminated wastes are not considered hazardous wastes at this time and therefore total costs reported in this table do not include costs associated with hazardous waste disposal of spent filtration materials. To address stakeholder concerns about potential costs for disposing PFAS-contaminated wastes as hazardous should they be regulated as such in the future, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See Appendix N, Section N.2 for additional detail.

EPA also expects that the proposed option will result in additional nonquantifiable costs in comparison to Options 1a-c. As noted above, the HI is expected to trigger more systems into more frequent monitoring and treatment. Due to occurrence data limitations, EPA has quantified the national treatment and monitoring costs associated with the HI for PFHxS only and has not quantified the cost impacts associated with HI exceedances resulting from HFPO-DA, PFNA, and PFBS. In cases where these compounds co-occur at locations where PFAS treatment is implemented because of nationally modeled PFOA, PFOS, and PFHxS MCLs or HI exceedances, treatment costs are likely to be marginally higher as treatment media estimated bed-life is shortened. In instances where concentrations of HFPO-DA, PFNA, and PFBS are high enough to cause or contribute to an HI exceedance when the concentrations of PFOA, PFOS, and PFHxS would not have already otherwise triggered treatment, the modeled costs may be underestimated. If these PFAS occur in isolation at levels that affect treatment decisions, or if these PFAS occur in combination with PFHxS when PFHxS concentrations were otherwise below the HI in isolation (i.e., less than 9.0 ppt) then the quantified costs underestimate the impacts of the proposed rule. As such, EPA conducted a semi-quantitative analysis of the anticipated incremental costs associated with regulating HFPO-DA, PFNA, and PFBS (discussed in Section 5.3.1.4 and Appendix N).

Another potential source of nonquantified cost comes from the fact that EPA has proposed designating PFOA and PFOS as CERCLA hazardous substances (U.S. EPA, 2022b). Stakeholders have expressed concern to EPA that a hazardous substance designation for certain PFAS may limit their disposal options for drinking water treatment residuals (e.g., spent media, concentrated waste streams) and/or potentially increase costs. In its estimated national costs, EPA has maintained the assumption that disposal does not have to occur in accordance with hazardous waste standards thus national costs may be underestimated. EPA has conducted a sensitivity analysis that assumes hazardous waste disposal at all systems treating for PFAS to assess the potential increase in costs (see Appendix N). Table 7-5 summarizes benefits and costs that are quantified and nonquantified under the proposed NPDWR.

Table 7-5: Summary of Quantified and Nonquantified Benefits and Costs					
Category	Quantified	Non-quantified	Methods (Report Section where Analysis is Detailed)		
	Costs				
PWS treatment costs ^a	✓		Section 5.3.1		
PWS sampling costs	✓		Section 5.3.2.2		
PWS implementation and administration costs	✓		Section 5.3.2.1		
Primacy agency rule implementation and administration costs	✓		Section 5.3.2		
Hazardous waste disposal for treatment media		✓	Section 5.6		
POU not in compliance forecast		\checkmark	Section 5.6		
	Benefits				
PFOA and PFOS birth weight effects	✓		Section 6.4		
PFOA and PFOS cardiovascular effects	✓		Section 6.5		

Table 7-5: Summary of Quan	Table 7-5: Summary of Quantified and Nonquantified Benefits and Costs					
Category	Quantified	Non-quantified	Methods (Report Section where Analysis is Detailed)			
PFOA and PFOS renal cell carcinoma	✓		Section 6.6			
Health effects associated with disinfection byproducts	✓		Section 6.7			
Other PFOA and PFOS health effects		✓	Section 6.2.2.2			
Health effects associated with HI compounds HFPO-DA, PFNA, PFBS, and PFHxS		✓	Section 6.2			
Health effects associated with other PFAS		✓	Section 6.2			

Abbreviations: HFPO-DA – hexafluoropropylene oxide dimer acid; PFAS – per and polyfluoroalkyl substances; PFBS – perfluorobutanesulfonic acid; PFHxS – perfluorohexane sulfonate; PFNA – perfluorononanoic acid; PFOA – Perfluorooctanoic Acid; PFOS– Perfluorooctane Sulfonate; POU – point of use; PWS– public water system Notes:

^aDue to occurrence data limitations, EPA quantified the national treatment and monitoring costs associated with the HI for PFHxS only and has not quantified the national cost impacts associated with HI exceedances resulting from PFNA, PFBS, and HFPO-DA

Table 7-6 provides a summary of the potential impact of nonquantifiable benefit-cost categories. In each case, EPA notes the potential direction of the impact on costs and/or benefits. For example, benefits are underestimated if the PFOA and PFOS reductions result in avoided adverse health outcomes that cannot be quantified and valued. Sections 5.7 and 6.8 identify the key methodological limitations and the potential effect on the cost or benefit estimates, respectively.

Table 7-6: Potential Impact of Nonquantifiable Benefits and Costs

Source	Proposed Option	Option 1a	Option 1b	Option 1c
Nonquantifiable PFOA and PFOS health endpoints	B: underestimate	B: underestimate	B: underestimate	B: underestimate
Limitations with nationally representative HFPO-DA, PFNA, and PFBS occurrence data (HI)	C: underestimate	N/A	N/A	N/A
Nonquantifiable HFPO- DA, PFNA, PFHxS, and PFBS health endpoints (HI)	B: underestimate	N/A	N/A	N/A
Limitations with nationally representative occurrence data for additional PFAS compounds	B&C: underestimate	B&C: underestimate	B&C: underestimate	B&C: underestimate
Removal of co-occurring non-PFAS contaminants	B&C: underestimate	B&C: underestimate	B&C: underestimate	B&C: underestimate
POU not in compliance forecast	C: overestimate	C: overestimate	C: overestimate	C: overestimate
Unknown future hazardous waste management requirements for PFAS (HI)	C: underestimate	C: underestimate	C: underestimate	C: underestimate

 $Abbreviations:\ B-benefits;\ C-costs;\ POU-point\ of\ use;\ PFAS-per-and\ polyfluoroalkyl\ substances$

When proposing an NPDWR, the Administrator shall publish a determination as to whether the benefits of the maximum contaminant level justify, or do not justify, the costs based on the analysis conducted under paragraph 1412(b)(3)(C). With this proposed rule, the Administrator has determined that the quantified and nonquantifiable benefits of the proposed PFAS NPDWR justify the costs.

As indicated in Table 7-1, the monetized costs and benefits result in expected annualized incremental benefits of \$1,233 million at a 3 percent discount rate. At a 7 percent discount rate, the expected annualized incremental benefits are \$908 million. The Agency views the 3 to 7 percent range of costs and benefits as characterizing the significant portion of the uncertainty in the discount rate and views the quantified endpoint values with equal weight.

Table 7-1 through Table 7-6 summarize the results of this proposed rule analysis. As indicated in Section 2.2.2 of this EA, EPA discounted the estimated monetized cost and benefit values using both 3 and 7 percent discount rates. In federal regulatory analyses, EPA follows OMB Circular A-4 (OMB, 2003) guidance which recommends using both 3 percent and 7 percent to account for

the different streams of monetized benefits and costs affected by regulation. The 7 percent discount rate is intended to represent the estimated rate of return on capital in the U.S. economy, to reflect the opportunity cost of capital when the main effect of a regulation is to displace or alter the use of capital in the private sector. Regulatory effects, however, can fall on both capital and private consumption.⁸⁷ In 2003, Circular A-4 estimated the rate appropriate for discounting consumption effects at 3 percent. The estimated monetized costs and benefits of this rulemaking result in expected annual net benefits (total monetized annual benefits minus total monetized annual costs) of \$461.21 million at a 3 percent discount rate and \$-296.50 at a 7 percent discount rate. There are a variety of considerations with respect to the capital displacement in this particular proposal. For example, a meaningful number of PWSs may not be managed as profitmaximizing private sector investments, which could impact the degree to which the rate of return on the use of capital in the private sector applies to PWS costs. Federal funding is expected to defray many such PWS costs; 88 where that occurs, such costs are transferred to the government. Additionally, to the extent that the benefits extend over a long time period into the future, including to future generations, Circular A-4 advises agencies to consider conducting sensitivity analyses using lower discount rates. Regardless, the impacts in this rulemaking are such that costs are expected to occur in the nearer term, and in particular that larger one-time capital investments are expected to occur in the near term; and public health benefits are expected to occur over the much longer term. Discounting across an appropriate range of rates can help explore how sensitive net benefits are to assumptions about whether effects fall more to capital or more to consumption.

EPA has followed Circular A-4's default recommendations to use 3 and 7 percent rates to represent the range of potential impacts accounting for diversity in stakeholders' time preferences. The Agency views the 3 to 7 percent range of costs and benefits as characterizing a significant portion of the uncertainty in the discount rate and views the quantified endpoint values as demonstrating a range of monetized costs and benefits which encompass a significant portion of the uncertainty associated with discount rates. Material unquantified benefits expected as a result of this proposed rulemaking are discussed in greater detail later in this section.

The quantified analysis is limited in its characterization of uncertainty. In Table 7-1, EPA provides 5th and 95th percentile values associated with the 3 and 7 percent discounted expected values for net benefits. These values represent the quantified, or modeled, potential range in the expected net benefit values associated with the variability in system characteristics and the uncertainty resulting from the following variables: the baseline PFAS occurrence; the affected population size; the compliance technology unit cost curves, which are selected as a function of baseline PFAS concentrations and population size, the distribution of feasible treatment technologies, and the three alternative levels of treatment capital costs; the concentration of total organic carbon in a system's source water, which impacts GAC O&M costs; the demographic composition of the systems population; the magnitude of PFAS concentration reductions; the health effect-serum PFOA and PFOS slope factors that quantify the relationship between changes in PFAS serum level and health outcomes for birth weight, CVD, and renal cell

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⁸⁷ Private consumption is the consumption of goods and services by households for the direct satisfaction of individual needs (rather than for investment).

⁸⁸ As noted above in this preamble, "Infrastructure Investment and Jobs Act, also referred to as the Bipartisan Infrastructure Law (BIL), invests over \$11.7 billion in the Drinking Water State Revolving Fund (SRF); \$4 billion to the Drinking Water SRF for Emerging Contaminants; and \$5 billion to Small, Underserved, and Disadvantaged Communities Grants."

carcinoma; and the cap placed on the cumulative renal cell carcinoma risk reductions due to reductions in serum PFOA. These modeled sources of uncertainty are discussed in more detail in Sections 5.1.2 and 6.1.2. What the quantified 5th and 95th percentile values do not include are a number of factors which impact both costs and benefits but for which the Agency did not have sufficient data to include in the quantification of uncertainty. The factors influencing the proposed rule cost estimates that are not quantified in the uncertainty analysis are detailed in Table 5-22. These uncertainty sources include: the specific design and operating assumptions used in developing treatment unit cost; the use of national average costs that may differ from the geographic distribution of affected systems; the possible future deviation from the compliance technology forecast; and the degree to which actual TOC source water values differ from EPA's estimated distribution. EPA has no information to indicate a directional influence of the estimated costs with regard to these uncertainty sources. To the degree that uncertainty exists across the remaining factors it would most likely influence the estimated 5th and 95th percentile range and not significantly impact the expected value estimate of costs.

Table 6-48 discusses the sources of uncertainty affecting the estimated benefits not captured in the estimated 5th and 95th reported values. The modeled values do not capture the uncertainty in: the exposure that results from daily population changes at NTNCWSs or routine population shifting between PWSs, for example spending working hours at a NTNCWS or CWS and home hours at a different CWS; the exposure-response functions used in benefits analyses assume that the effects of serum PFOA/PFOS on the health outcomes considered are independent, additive, and that there are no threshold serum concentrations below which effects do not occur; the distribution of population by size and demographics across entry points within modeled systems and future population size and demographic changes; and the Value of Statistical Life reference value or income elasticity used to update the VSL. Given information available to the Agency, four of the listed uncertainty sources would not affect the benefits expected value but the dispersion around that estimate. They are the unmodeled movements of populations between PWS which potentially differing PFAS concentrations; the independence and additivity assumptions with regard to the effects of serum PFOA/PFOS on the health outcomes; the uncertainty in the population and demographic distributions among entry points within individual systems; and the VSL value and the income elasticity measures. Two of the areas of uncertainty not captured in the analysis would tend to indicate that the quantified benefits numbers are overestimates. First, the data available to EPA with regard to population size at NTNCWs, while likely capturing peaks in populations utilizing the systems, does not account for the variation in use and population and would tend to overestimate the exposed population. The second uncertainty, which definitionally would indicate overestimates in the quantified benefits values, is the assumption that there are no threshold serum concentrations below which health effects do not occur. One factor not accounted for in the quantified analysis associated with the underestimation of benefits is the impact of general population growth over the extended period of analysis.

In addition to the quantified cost and benefit expected values, the modeled uncertainty associated within the 5th and 95th percentile values, and the un-modeled uncertainty associated with a number of factors listed above, there are also significant nonquantifiable costs and benefits, which are important to the overall weighing of costs and benefits. Table 7-6 provides a summary of these nonquantifiable cost and benefit categories along with an indication of the directional

impact each category would have on total costs and benefit. Table 5-22 and Table 6-48 also provide additional information on a number of these nonquantifiable categories.

On the nonquantifiable costs side of the equation, EPA had insufficient nationally representative data to precisely characterize occurrence of HFPO-DA, PFNA, and PFBS at the national level and therefore could not include complete treatment costs associated with: the co-occurrence of these PFAS at systems already required to treat as a result of estimated PFOA, PFOS, or PFHxS levels, which would shorten the filtration media life and therefore increase operation costs; and the occurrence of HFPO-DA, PFNA, and/or PFBS at levels high enough to cause systems to exceed the HI and have to install PFAS treatment. The quantified national costs are marginally underestimated as a result of this lack of sufficient nationally representative occurrence data for purposes of model integration. In an effort to better understand the costs associated with treatment of potentially co-occurring HFPO-DA, PFNA, and PFBS at systems already required to treat and the potential costs resulting from an HI exceedance associated with the same chemicals, EPA estimated the potential unit treatment costs for model systems under both scenarios for differing assumed HI PFAS concentrations. The analysis is discussed in Section 5.3.1.4 and Appendix N. Two additional nonquantifiable cost impacts stemming from insufficient co-occurrence data could also potentially shorten filtration media life and increase operation costs. The co-occurrence of other PFAS and other non-PFAS contaminants not regulated in the proposed rule could both increase costs to the extent that they reduce media life. EPA did not include POU treatment in the compliance technology forecast because current POU units are not certified to remove PFAS to the standards required in the proposed rule. Once certified, this technology may be a low cost treatment alternative for some subset of small systems. Not including POU treatment in this analysis has resulted in a likely overestimate of cost values. Appendix N contains a sensitivity analysis that estimates there may be a national annual cost of \$30 to \$61 million, discounted at 3 and 7 percent, respectively, which would accrue to systems if the waste filtration media from GAC and IX were handled as hazardous waste. This sensitivity analysis includes only disposal costs and does not consider other potential environmental costs associated with the disposal of the waste filtration.

There are significant nonquantifiable sources of benefits that were not captured in the quantified benefits estimated for the proposed rule. While EPA was able to monetize some of the PFOA and PFOS benefits related to cardiovascular disease, infant birth weight, and renal cell carcinoma effects, the Agency was unable to quantify additional negative health impacts. EPA did not quantify PFOA and PFOS benefits related to health endpoints including developmental, cardiovascular, hepatic, immune, endocrine, metabolic, reproductive, musculoskeletal, and other types of carcinogenic effects. Section 6.2.2 provides additional information on the nonquantifiable impacts of PFOA and PFOS. Further, the Agency did not quantify any health endpoint benefits associated with the potential reductions in HI PFAS, which include PFHxS, HFPO-DA, PFNA, and PFBS, or other co-occurring non-regulated PFAS which would be removed by the installation of required filtration technology at those systems with PFOA, PFOS, or HI exceedances. The nonquantifiable benefits impact categories associated with PFHxS, HFPO-DA, PFNA, and PFBS include developmental, cardiovascular, immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects. In addition, EPA did not quantify the potential developmental, cardiovascular, immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic impacts related to the removal of other co-occurring non-regulated PFAS. See Section 6.2.4 for additional information on the

nonquantifiable impacts of PFHxS, HFPO-DA, PFNA, and PFBS, and other non-regulated co-occurring PFAS.

The treatment technologies installed to remove PFAS can also remove numerous other non-PFAS drinking water contaminants which have negative health impacts including additional regulated and unregulated DBPs (the quantified benefits assessment does estimate benefits associated with THM4), heavy metals, organic contaminants, and pesticides among others. The removal of these co-occurring non-PFAS contaminants could have significant positive health benefits. In total these nonquantifiable benefits are anticipated to be significant and are discussed qualitatively in Section 6.2.

To fully weigh the costs and benefits of the action the Agency considered the totality of the monetized values, the potential impacts of the unquantified uncertainties described above, and the nonquantifiable costs and benefits. The Administrator has determined that the benefits of this proposed regulation justify the costs.

8 Environmental Justice Analysis

8.1 Introduction

EPA defines environmental justice (EJ) as "the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies" (U.S. EPA, 2016h). The concept of fair treatment includes not just the distribution of burdens across populations but also the distribution of risk reduction from EPA actions. EPA reviews potential EJ concerns regarding minority populations, low-income populations, and/or indigenous peoples (U.S. EPA, 2016h).

The framework used to evaluate the anticipated EJ impacts of the proposed rule for per— and polyfluoroalkyl substances (PFAS) comes from the *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (U.S. EPA, 2016h), which provides the following guiding questions:

- Are there potential EJ concerns associated with environmental stressors affected by the regulatory action for population groups of concern in the baseline?
- Are there potential EJ concerns associated with environmental stressors affected by the regulatory action for population groups of concern for the regulatory options under consideration?
- For the regulatory options under consideration, are potential EJ concerns created or mitigated compared to the baseline?

Contextualizing these questions for the proposed PFAS rule, EPA evaluated the following questions:

- Are population groups of concern (i.e., people of color and low-income populations) disproportionately exposed to PFAS compounds in drinking water delivered by PWSs?
- Are population groups of concern disproportionately affected by the proposed option and regulatory alternatives under consideration for the proposed PFAS NPDWR?
- If any disproportionate impacts are identified, do they create or mitigate baseline EJ concerns?

As part of the proposal process for the PFAS NPDWR, EPA conducted the EJ analyses in this chapter to assess the demographic distribution of baseline PFAS drinking water exposure and impacts that are anticipated to result from the proposed rule. EPA conducted two separate analyses to address the research questions presented above. To inform the first question, EPA conducted an analysis using EJScreen, the Agency's Environmental Justice Screening and Mapping Tool (U.S. EPA, 2019a). To inform the second and third questions above, EPA conducted an EJ analysis of EPA's proposed regulatory option and regulatory alternatives using SafeWater MCBC.

Section 8.2 provides an overview of EPA's EJ literature review. Sections 8.3 and 8.4 describe the EJ analyses EPA conducted. Section 8.5 presents the conclusions from EPA's EJ analyses.

8.2 Literature Review

EPA conducted a literature review to develop a broad understanding of current research at the intersection of drinking water quality, PFAS exposure, and communities with related EJ concerns. The literature covered a range of specific topics including the likelihood of exposure based on proximity to sites of contamination, sociodemographic characteristics of communities exposed to PFAS in region-specific studies and understanding the sociodemographic distribution of health outcomes associated with exposure to PFAS. EPA's literature review also examined the relationship between PFAS exposure via drinking water in vulnerable communities and a range of health outcomes.

8.2.1 Methods

EPA conducted its literature review to evaluate and synthesize findings from studies that explored associations between PFAS exposure via drinking water in vulnerable communities and associated health outcomes, including those health endpoints EPA quantified as part of its benefits analysis: changes in infant birth weight, CVD, and kidney cancer.

EPA applied a variety of search terms for the literature review, including: CVD; disparities; disproportionate exposure; disproportionate impact; drinking water quality/contamination; environmental justice; equity; forever chemicals; inequity; infant birth weight; kidney cancer; low-income; minority; over-burdened; people of color; PFAS; PFAS interactions; PFC(s); PFOA; PFOS; race differences in health effects after PFAS exposure; race disparities in health effects, immune effects, and PFAS exposure; race ethnicity and health effects of PFAS exposure and interactions; sociodemographic differences in health effects after PFAS exposure; social justice; and tribal.

From the literature review, EPA found that there are a limited number of studies that focus on the association between disproportionate exposure to PFAS via drinking water and health outcomes for vulnerable communities on a national level. The Agency excluded studies that examined exposure routes apart from drinking water and/or did not evaluate race/ethnicity within their participant demographics. Of the studies that EPA identified as part of its literature review, all but two studies were published in peer reviewed journals (with the remaining two studies appearing in gray literature).

8.2.2 Findings

To contextualize its analysis of EJ impacts related to PFAS in drinking water, EPA reviewed studies that evaluate overall EJ concerns related to environmental contamination. In 1987, EPA reported in a nationwide study that roughly twice as many people of color resided in proximity to a commercial hazardous waste facility compared to communities without a facility (U.S. EPA, 1994). Later research indicated that communities of low socioeconomic status are more likely to reside in proximity to environmental hazardous facilities, thereby potentially facing a disproportionate impact of exposure to toxic chemicals than communities of higher socioeconomic status (Brown, 1995; Brulle et al., 2006). A 2010 study showed 63 percent of

large polluters in a North Carolina county were operating in census tracts with per capita income below \$21,000, as identified in EPA's Toxics Release Inventory (TRI) (Banzhaf et al., 2019).

When specifically examining studies related to PFAS in drinking water, available literature showed associations between PFAS contamination in drinking water and proximity to sites including those critical for transportation infrastructure, industry, and national defense (Black et al., 2021; X. C. Hu et al., 2016; Johnston et al., 2020; Sunderland et al., 2019). Researchers noted that identifiable sources of PFAS are often prevalent at aforementioned locations and are more frequently located in vulnerable communities (Black et al., 2021; X. C. Hu et al., 2016; Stoiber et al., 2020).

PFAS have characteristics—namely high aqueous solubility and persistence within the environment that allow them to travel readily between ecological zones (ATSDR, 2021; X. C. Hu et al., 2016; Kotlarz et al., 2020). As such, PFAS contamination can negatively impact drinking water sources downstream from an original contamination site, putting residents in communities surrounding known sources of PFAS at a disproportionate risk of exposure. A 2019 study in Michigan by Desikan et al. (2019) evaluated the proportion of low-income households and households with people of color in communities within five miles of PFAS-contaminated sites compared to census projections for those areas. It found that 38,962 more low-income households and 294,591 more households with people of color reside within five miles of a site contaminated with PFAS than expected, based on U.S. Census data.

In California, Lee et al. (2021) demonstrated that vulnerable communities are more likely to be served by PWSs with higher levels of PFAS. PFAS data were integrated with results from CalEnviroScreen 3.0, a statewide EJ screening tool (OEHHA, 2016). Of the 7,896 PWSs in the state, about 3 percent (n=248) had been monitored for PFAS, serving 42 percent of California's total population. Results from the study showed that PFAS was detected in 160 of 248 PWSs, or roughly 65 percent of systems monitored. Lee, Kar, et al. (2021) overlaid the upper 25 percent of disadvantaged communities as identified by CalEnviroScreen 3.0 with water systems experiencing the highest levels of PFAS contamination. Among the communities in the top quartile for people of color and low-income demographic groups, 69 percent had PFAS detected in their water system. Further, PWSs in 20 percent of vulnerable communities with PFAS contamination fell within the highest quartile of PFAS concentration levels in the state of California, suggesting that PFAS occurrence is disproportionately higher in drinking water serving already vulnerable communities. Only 2 of the 10 water systems with the highest PFAS concentrations fell below the state average for all relevant demographic indicators included in the study (people of color, education level, unemployment, poverty, and housing burden).

At least two studies identified the use of aqueous film forming foam (AFFF) as a predictor of PFAS concentrations in U.S. drinking water (Johnston et al., 2020; Sunderland et al., 2019). Using nationally representative PFAS occurrence data from UCMR 3, a study from X. C. Hu et al. (2016) found that the presence of a military fire training area using AFFF within a watershed's eight-digit hydraulic unit code (HUC) increased the frequency of exposure to at least one PFAS analyte in drinking water from 10.4 percent to 28.2 percent . For each additional military site within a HUC, drinking water samples with detectable levels of PFAS found a 20 percent increase in PFHxS, a 10 percent increase in both PFHpA and PFOA, and a 35 percent increase in PFOS.

To remain consistent with the health endpoints associated with PFAS exposure that are monetized as part of the proposed PFAS NPDWR's benefits analysis, the health outcomes of focus in this literature review included CVD, kidney cancer, and impacts on infant birth weight. For more information on EPA's quantified benefits analysis, see Chapter 6.

Literature showed that vulnerable communities experience relatively higher adverse health outcomes compared to communities with fewer people of color (Driscoll et al., 2021; Fryar et al., 2017; Pinheiro et al., 2021). Literature also showed that risk of CVD, kidney cancer, and changes in infant birth weight are associated with PFAS exposure (Almond et al., 2005; Barry et al., 2013; Goff et al., 2014; Ma et al., 2010; Raleigh et al., 2014; Steenland et al., 2012; Vieira et al., 2013; U.S. EPA, 2016d; U.S. EPA, 2016h; U.S. EPA, 2021a; U.S. EPA, 2023d; U.S. EPA, 2023e), discussed in more detail in Chapter 6.

The Centers for Disease Control and Prevention (CDC) identified hypertension (HTN) as a substantial risk factor for CVD (Fryar et al., 2017). Using the 140/90 mmHg threshold for HTN diagnosis, the CDC reported that African American adults reported a higher burden of HTN (40.3%) compared to White (27.8%), Asian (25.0%), or Hispanic (27.8%) adults (Fryar et al., 2017). Additionally, a comprehensive narrative literature review by Graham (2015) found disproportionate rates of CVD among minority subpopulations in the U.S., particularly the African American population. African American subpopulations were found to have higher incidence of myocardial infarction, heart failure, stroke, among other cardiovascular events and experience the highest overall death rate from CVD among various minority population groups.

With regards to cancer, a study by Uche et al. (2021) showed statistically significantly greater cumulative cancer risk was identified in communities in which small and large CWSs serve higher proportions of Hispanic/Latino and Black/African American residents in Texas and California⁸⁹. In Texas, greater cumulative cancer risk was statistically significantly greater for small and medium CWSs serving relatively higher proportions of Hispanic/Latino community members. Additionally, small CWSs serving relatively higher proportions of Black/African American residents had statistically significantly greater cumulative cancer risk. In California, cumulative cancer risk was statistically significantly greater for very large CWSs serving relatively higher proportions of Black/African American community members, followed by small CWSs serving relatively higher proportions of Hispanic/Latino residents.

Pinheiro et al. (2021) studied kidney cancer rates in White, Black, Asian/Pacific Islander (API), American Indian, all non-Hispanic, and Hispanic populations of any race by using reported cancer deaths in California and Florida (2008–2018) and New York (2008–2017). This study's methodology directly compared results for specific race/ethnicity groups to White populations. Results indicated that American Indian individuals experience the highest mortality (54%), and mortality is 53 percent higher for men and women when compared to mortality among White participants (Pinheiro et al., 2021). Conversely, API populations showed significantly lower mortality than White populations, with 45 percent lower mortality among males and 43 percent lower mortality among females. Kidney cancer mortality among Black populations and all-combined Hispanic populations (i.e., Cuban, Puerto Rican, and Mexican) was also significantly lower than among White populations, but by smaller margins: mortality was 12 percent and 16

⁸⁹ A CWS was defined as small if it served 501-3,300 people, medium if it served 3,301-10,000 people, large if it served 10,001-100,000 people, and very large if it served more than 100,000 people.

percent lower for Black males and females and 11 percent and 8 percent lower for Hispanic males and females, respectively.

Additionally, the CDC's National Vital Statistics Reports used the 2020 birth file from the National Vital Statistic System to display distributions in prepregnancy body mass index (BMI), including three classes of obesity, by maternal race and Hispanic origin for women who gave birth in 2020 (Driscoll et al., 2021). Infants born to non-Hispanic Black women had the highest rate of low birth weight (14.19%), followed by infants of Hispanic women (7.40%). Infants of non-Hispanic White women had the lowest rate of low birth weight (6.84%) (Driscoll et al., 2021).

Furthermore, EPA reviewed studies that examine blood serum levels of PFAS across various demographic groups. Studies analyzing biomarker data indicate some demographic disparities that exist in blood serum levels across certain PFAS analytes (Boronow et al., 2019; Calafat et al., 2007; Eick et al., 2021; C. Y. Lin et al., 2020; Nelson et al., 2012; V. K. Nguyen et al., 2020; Park et al., 2019). Specifically, blood serum levels of PFNA and PFOS were found to be elevated in Black adults (Boronow et al., 2019; Calafat et al., 2007; Eick et al., 2021; C. Y. Lin et al., 2020; Nelson et al., 2012; Park et al., 2019). PFNA was also found to be elevated in Asian American mothers, when compared to all other races (Eick et al., 2021). Additionally, PFDA was found to be elevated in Asian American women, when compared to non-Hispanic White populations (V. K. Nguyen et al., 2020). Finally, Me-FOSAA was found to be elevated in Black women at some but not all study sites analyzed (Park et al., 2019).

However, many studies indicate lower average blood serum PFAS levels among people of color. Three studies in particular demonstrated that non-Hispanic White populations had the highest concentrations of PFAS across all analytes (Barton et al., 2020; Kato et al., 2014; Kingsley et al., 2018). It should be noted, however, that the study design for Barton et al. (2020), Kato et al. (2014), and Kingsley et al. (2018) each had majority non-Hispanic White participant demographics of 75 percent, 63 percent, and 61 percent of study participants, respectively. The literature also indicates that higher socioeconomic status (e.g., income) is associated with higher PFAS blood serum levels (Buekers et al., 2018).

8.2.3 Discussion and Limitations

EPA's purpose in conducting its literature review was to examine the relationship between PFAS exposure via drinking water in vulnerable communities and health outcomes related to CVD, changes in infant birth weight, and kidney cancer. Presented studies indicate that higher percentages of low-income and minority communities reside near a range of PFAS-contaminated sites. Such contamination is also shown to occur at higher levels in low-income and minority communities. Further, EPA's literature review analysis indicates that PFAS contamination occurs more often and/or at higher levels in vulnerable communities.

It should be noted there are substantial gaps in current literature on PFAS exposure and health outcomes in vulnerable communities. One substantial gap in the available literature is a dearth of studies that examine differential impacts of health outcomes associated with PFAS exposure, as reported by race or ethnicity. Potential gaps in understanding also relate to determining whether the rate of developed risk for one or more of the aforementioned health endpoints is related to exposure to PFAS contamination in drinking water rather than other exposure pathways.

The blood serum PFAS studies evaluated as part of this literature review have their limitations in extrapolating to the potential disproportionate impacts of PFAS drinking water exposure given their focus on overall PFAS exposure across many exposure routes rather than drinking water-specific exposures. Wilder et al. note that national average PFAS blood serum levels are influenced by a variety of major exposure pathways, including diet and consumer products in addition to exposure via drinking water (Wilder et al., 2017). As such, this limits conclusions that can be drawn about the demographic breakdown of PFAS blood serum levels due to drinking water exposure alone. Additional information on exposure via drinking water alone is necessary to better understand the impacts of PFAS drinking water contamination on PFAS blood serum levels within vulnerable communities.

Another limitation of these blood serum-based studies is their inequitable representation of study participants by race. The participant demographic makeup of three published studies that examined PFAS blood serum levels was highly biased toward the non-Hispanic White population, resulting in an incomplete understanding of people of color's exposure to PFAS. Statisticians can adjust the results if certain participant demographic groups are disproportionately represented. However, these adjustments are based on assumptions about the underlying demographic makeup of the study population.

8.3 EJ PFAS Exposure Analysis

This section describes the data sources and approach EPA used to characterize the demographic distribution of PFAS exposure in drinking water. This analysis is designed to answer the question posed in the beginning of the chapter: Are population groups of concern (i.e., people of color and low-income populations) disproportionately exposed to PFAS compounds in drinking water delivered by PWSs? This analysis estimates exposure rates above various PFAS concentrations for four PFAS analytes, where occurrence of these is used as a proxy for co-occurrence of many other PFAS compounds. In some cases, the thresholds that EPA uses in this analysis overlap with regulatory alternatives considered by EPA in the proposed regulatory action. This analysis does not evaluate the anticipated costs and benefits of the proposed option and regulatory alternatives. EPA's analysis of the anticipated demographic distribution of costs and benefits of the proposed option and regulatory alternatives can be found in Section 8.4.

EPA estimated the sociodemographic characteristics of populations that EPA anticipates are exposed to levels higher than various threshold concentrations of four PFAS analytes (PFOA, PFOS, PFHxS, and PFHpA). For this analysis, EPA had sufficient information on PFAS occurrence and PWS service area boundaries in the sample population, which was a subset of PWSs. ⁹⁰ PWSs were first categorized by available data (Section 8.3.1), using availability of UCMR 3 sampling data, state sampling data, and availability of service area boundary information (Table 8-1).

EPA used PWS service area data in conjunction with the EJSCREENbatch R package to obtain sociodemographic characteristics of the populations served by PWSs (U.S. EPA, 2022a). The EJSCREENbatch R package allows analysts to conduct EJ screening analyses for multiple geographies using environmental and sociodemographic data from EJScreen and the American Community Survey. EPA estimated the rate of exposure to PFAS across demographic groups

⁹⁰ PWS service area boundaries are defined as the spatial extent of the geographic area served by a PWS.

using PFAS occurrence data and the sociodemographic characteristics of populations served with designated service area boundaries. EPA conducted this analysis using several thresholds: Method 537.1 detection limits (also referred to as baseline occurrence level for this analysis), UCMR 5 minimum reporting levels (MRLs), and 10.0 ppt. This analysis serves as an estimate of possible exposure to PFAS levels over these thresholds, as EPA cannot confirm that these populations consumed the water at the time of elevated PFAS occurrence at each PWS.

8.3.1 Data Sources and Approach

8.3.1.1 Categorization of Public Water Systems

EPA designated distinct categories for PWSs based on data availability for PFAS occurrence and estimated PWS service area boundaries. The Agency used two types of PFAS occurrence data sources in this analysis: (1) simulated PFAS occurrence data for PWSs with sampled PFAS occurrence data under UCMR 3; and (2) state-collected PFAS occurrence data for PWSs not sampled under UCMR 3 (U.S. EPA, 2017). PWS service area boundary data are distinguished by three types: (1) those with predelineated PWS service area boundaries, (2) those where zip codes served by PWSs were used as a proxy to approximate and delineate PWS service area boundaries, and (3) those with no available PWS service area boundary information. Table 8-1 describes the characteristics of each of the six distinct PWS categories examined in this analysis.

For the EJ exposure analysis, EPA focused on reporting results for PWSs in categories 1 and 2, which were sampled for PFAS under UCMR 3. The PWSs in categories 4 and 5 include systems with state PFAS occurrence data, and EPA has summarized the results for these categories in Appendix M. EPA used data from EJScreen (U.S. EPA, 2022a) and the American Community Survey along with PWS service area boundary data to characterize the sociodemographic characteristics of PWSs.

PWSs in categories 1 and 2 account for 239.6 million people served (n=4,723 PWSs), and PWSs in categories 4 and 5 account for approximately 1.2 million people served (n=459 PWSs). PWSs in categories 3 and 6 were not included in the exposure analysis, as PWS service area boundaries or zip codes served by the PWS were unavailable.

Table 8-1: Categorizing of PWSs Based on Data Availability for PFAS Occurrence and PWS Service Area Boundaries

	PWS Included in UCMR 3	PWS State PFAS Occurrence Data Available and Not Included in UCMR 3
PWS Service Areas Available	Category 1	Category 4
PWS Service Area Boundary Estimates from Zip Codes	Category 2	Category 5
No PWS Service Area Information Available	Category 3	Category 6

Abbreviations: PWS - public water system; UCMR - Unregulated Contaminant Monitoring Rule.

8.3.1.2 Data Sources

8.3.1.2.1 PFAS Occurrence

The two data source categories used to derive PFAS occurrence estimates for this analysis are described in more detail below. All PFAS occurrence data are presented in parts per trillion (ppt).

Generally, if a system was sampled for PFAS under UCMR 3, EPA used simulated occurrence data that were based on system-specific results. For PWSs in categories 1 and 2 (n=4,723 PWSs), EPA simulated PFAS occurrence data using a hierarchical Bayesian model that was optimized with PFAS occurrence data from UCMR 3 and, where available, state data (see Cadwallader et al., 2022, and Section 4.4 for further description). EPA calculated the system-level geometric mean occurrence value for each PWS from the simulated water sample concentrations. All simulated values (i.e., simulated samples for PWSs in categories 1 and 2) were above zero because the occurrence model assumes a log-normal distribution for water concentration. The system-level geometric mean occurrence values for the category 1 and 2 PWSs ranged from 0.01 to 254.65 ppt.

For other systems, EPA used state sampling data. EPA used state monitoring data from 12 states⁹¹, which generally conducted nontargeted monitoring (i.e., random sampling) of finished drinking water for one or more of the four PFAS in this analysis. PWSs that had state sampling data but were not sampled under UCMR 3 fell into categories 4 and 5 (n=459). EPA calculated the system-level geometric means of measured PFAS water sample concentrations to characterize PFAS occurrence for each PWS. For this dataset, the Agency did not pursue Bayesian estimation of non-detection concentrations due to a limited sample size and non-standardized sampling regime. Instead, for these data, EPA set non-detections to a small

⁹¹ States include: Alabama, Colorado, Illinois, Kentucky, Massachusetts, Michigan, New Hampshire, New Jersey, North Dakota, Ohio, South Carolina, and Vermont.

constant, 10 percent of the lowest analyte sample value (i.e., 0.02 ppt for each analyte), before calculating the system-level geometric mean. 92

Among the 12 state occurrence datasets used in this analysis to characterize PFAS occurrence for category 4 and 5 PWS service areas, EPA noted that different states utilized various reporting, quantification, and/or detection limits when analyzing and presenting data, and for some states, no clearly defined limits were publicly provided as part of the dataset. Further, the limits often varied within the data for each state depending on the specific PFAS analyte. In some cases, states reported detection, quantification, or reporting limits and/or presented data at concentrations below EPA's proposed rule detection limits and/or practical quantitation limits provided in the federal register notice for this proposed regulatory action. In addition to variable reporting limits and PFAS analytes evaluated, sample collection routines across state datasets also lacked uniformity. For more information on the collection and analysis of occurrence data, see U.S. EPA (2023g).

For both simulated occurrence data and state-sampled occurrence data, system-level geometric means were calculated to represent a typical concentration of a single sample for each PFAS analyte in a system. The concentrations of samples are log-normally distributed for all four PFAS analytes (PFOA, PFOS, PFHxS, PFHpA), meaning that while most samples have low concentrations, some may have much higher concentrations.

8.3.1.2.2 PWS Service Area Boundaries

For CWSs and NTNCWSs that had PFAS occurrence data sampled under UCMR 3 or PFAS occurrence data collected by states, EPA acquired or estimated service area boundaries. Since transient noncommunity water systems (TNCWSs) have changing populations throughout the year, they were not included in this analysis. Data were categorized by the availability of PWS service areas, those with predelineated PWS service areas (categories 1 and 4), and those where zip codes served by PWSs were used to approximate PWS service area boundaries (categories 2 and 5). When available, predelineated PWS service areas were prioritized over zip codeapproximated PWS service area boundaries. EPA used the federal version of the Safe Drinking Water Information System (SDWIS/Fed) to inform the type of water system (e.g., CWS, NTNCWS), population served, identify Native American-owned PWSs, and determine activity status for PWSs included in the analysis. Only active systems, as identified in SDWIS/Fed fourth quarter 2021, were included.

For predelineated PWS service area boundaries, EPA aggregated spatial data from a variety of sources spanning multiple file formats into one ESRI file geodatabase. ⁹³ Data sources are provided in Table 8-2.

⁹² EPA evaluated the difference between using 10 percent (0.02 ppt) and 50 percent (1 ppt) of the minimum reported sample concentration for all analytes. The difference in population estimates from this change was less than 0.5 percent for all analytes. 10 percent of the minimum reported value was used in the analysis (0.02 ppt).

⁹³ File formats included: ESRÎ ArcGIS Online (AGOL) layers, shapefiles, and GeoJSON.

Table 8-2: Data Sources for Predelineated PWS Service Areas

Accessed Through State Sources or EPA Correspondence										
State	Source Name	Link	Date							
CO	State of Colorado – Water District Boundaries	https://data.colorado.gov/Water/Water-District- Boundaries/82ke-q8t2	Accessed 1/26/2022							
CA	State of California – Division of Drinking Water, California Water Resources Control Board	https://gispublic.waterboards.ca.gov/portal/home/item.html?id=fbba842bf134497c9d611ad506ec48cc	Accessed 1/31/2022							
NJ	EPA correspondence	EPA Office of Ground Water and Drinking Water	Accessed 1/31/2022							
NM	State of New Mexico – water data	https://catalog.newmexicowaterdata.org/dataset/5d06 9bbb-1bfe-4c83-bbf7- 3582a42fce6e/resource/037d915d-4a28-4c39-9922- 3556ec492698/download/nm_pws_areas.zip	Accessed 1/26/2022							
NY	State of New York – Department of Health	https://water.ny.gov/doh2/applinks/waterqual/assets/ PWS_GeoJson3.json	Accessed 1/31/2022							
OK	State of Oklahoma – Water Resources Board	https://www.owrb.ok.gov/maps/data/layers/Water%2 0Supply/ws_system_service_areas.htm; https://owrb.maps.arcgis.com/apps/webappviewer/in dex.html?id=68c5f3fd492a43ee8386f39a80f88afb	Accessed 1/26/2022							
PA	State of Pennsylvania – Department of Environmental Protection	https://newdata-padep- 1.opendata.arcgis.com/datasets/public-water- systems-public-water-supplier-service- areas/explore?location=40.917958%2C- 77.621150%2C8.24	Accessed 1/12/2022							
RI	EPA correspondence	EPA Office of Ground Water and Drinking Water	Accessed 1/31/2022							
	Accessed through	EPA ArcGIS Online Portal								
State	Source	Link	Date							
AR	EPA ArcGIS – Portal									
AZ	EPA ArcGIS – Portal									
CT	EPA ArcGIS – Portal									
KS	EPA ArcGIS – Portal	https://epa.maps.arcgis.com/home/item.html?id=59e	Accessed							
MO	EPA ArcGIS – Portal	b7810caa044678f1e26e637b4fa79	12/7/2021							
MS	EPA ArcGIS – Portal									
TX	EPA ArcGIS – Portal									
UT	EPA ArcGIS – Portal									
		https://www.nconemap.gov/search?groupIds=9eb59a								

Under UCMR 3 and 4, PWSs sampled were asked to report U.S. Postal Service zip code(s) for all areas being served water by a PWS. As such, when pre-delineated PWS service area boundaries were unavailable, EPA used zip codes served by PWSs to delineate approximated boundaries using the following steps:

- EPA joined zip codes served—as specified for PWSs in UCMR 3 (U.S. EPA, 2017) and UCMR 4 (U.S. EPA, 2022c)—to a zip code polygon layer that represented postal service delivery areas.
- EPA projected zip codes served by PWSs.
- In cases where zip codes did not have polygons (i.e., zip codes for post offices and large volume mail customers), to map these zip codes as approximate service areas, EPA selected and overlaid zip code points for each service area with zip code polygons to select the polygon at that location. Then, EPA merged and dissolved all zip codes (both point- and polygon-based) to map each service area.
- EPA aggregated all zip code polygons served by each PWS into one boundary representative of PWS service area boundaries.
- In instances where one zip code was served by multiple PWSs, EPA included the zip code boundary in all corresponding PWS service area boundaries. For example, if one zip code was served by two PWSs, both PWS service area boundaries would contain the same zip code region represented in their boundaries. In some cases, this resulted in EPA double-counting population demographic characteristics; however, the populations were not double-counted because population-served data were obtained from SDWIS/Fed and were unique to each PWS.
- PWSs with pre-delineated PWS service areas (categories 1 and 4), account for 38.8 percent of all PWSs included in the analysis. PWSs with zip code delineated boundaries (categories 2 and 5), account for 61.2 percent of all PWSs included in the analysis.

Because there is greater accuracy with the predelineated PWS service areas, and to reduce double-counting of affected populations, EPA removed the portion of the zip code boundaries that were already accounted for within the predelineated PWS service area boundaries.

For example, in rural areas, the zip code boundaries can be relatively large and therefore overlap with predelineated PWS service area boundaries. To avoid redundancy and reduce double-counting populations, EPA used the following approach:

- EPA used predelineated PWS service area boundaries (including overlap⁹⁴) when available.
- If predelineated PWS service areas were not available, EPA used zip code-approximated PWS service area boundaries (as provided in UCMR 3 and UCMR 4).

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⁹⁴ For PWSs with predelineated PWS service area boundaries, EPA conducted a sensitivity analysis of the results of EPA's EJ exposure analysis to evaluate the impact of retaining PWS boundaries including overlapping areas versus removing overlapping boundaries. The impact on the results of EPA's EJ exposure analysis showed very few differences across the two approaches. As such, EPA used service area boundaries with overlapping areas included.

EPA carved out or removed predelineated PWS service area boundaries from the zip codeapproximated PWS service area boundaries to reduce the risk of double-counting the demographic composition of the populations served.

EPA used predelineated PWS service area boundaries and zip code-approximated PWS service area boundaries as inputs to the EJSCREENbatch R package to estimate the sociodemographic characteristics of PWS service areas included in the analysis (see Section 8.3.1.2.3 for more detail on this process) (U.S. EPA, 2022a). The population served counts were obtained from SDWIS/Fed for each PWS. Further description of the population-served data and sociodemographic characteristics of the population served by PWS service areas is provided in Section 8.3.2.1 and in Appendix M.

8.3.1.2.2.1 Categories 1 and 2

Categories 1 and 2 contained PWSs that had sampled PFAS occurrence data from UCMR 3. Category 1 (n=1,699 PWSs) comprised PWSs that had predelineated PWS service area boundaries, whereas category 2 (n=3,024 PWSs) comprised PWSs that had zip codeapproximated PWS service area boundaries.

The exposure analysis included service areas for 1,699 category 1 PWSs and 3,024 category 2 PWSs, for a total of 4,723 PWSs. There were 4,920 PWSs that conducted PFAS sampling under UCMR 3, and categories 1 and 2 PWSs accounted for approximately 96 percent of all PWSs that participated in UCMR 3. Of the 4,920 PWSs that participated in UCMR 3, 10 PWSs did not have predelineated PWS service area boundaries or zip code-served data available to approximate PWS service area boundaries. Systems were excluded from the analysis if they were classified as "inactive" in SDWIS/Fed (67 PWSs). Additionally, PWSs could not be evaluated if there were errors processing the EJSCREENbatch R package (120 PWSs). In such instances, the EJSCREENbatch R package did not provide sociodemographic characteristics for a given PWS service area.

Category 1 and 2 PWSs account for 239.6 million people served, or approximately 73 percent of the U.S. population. However, the subset of category 1 and 2 PWSs captured in the analysis represented roughly 3 percent of active PWSs.⁹⁵

8.3.1.2.2.2 Categories 4 and 5

EPA used state PFAS occurrence data for PWSs in categories 4 and 5 because these systems did not monitor for PFAS under UCMR 3. Category 4 (n=311 PWSs) included PWSs that had predelineated PWS service areas, whereas category 5 (n=148 PWSs) included PWSs that had zip code-approximated PWS service area boundaries.

The EJ exposure analysis includes PWS service areas for 311 category 4 PWSs and 148 category 5 PWSs. Category 4 and 5 PWSs account for approximately 7 percent of all PWSs with state PFAS sample occurrence data. Ninety-three PWSs with state PFAS occurrence data have PFAS occurrence data available in UCMR 3, and therefore are included in the analysis under categories 1 and 2. In addition, EPA included PWSs with state PFAS occurrence data in the analysis only if finished water samples were available for at least one of the four PFAS analytes. The Agency

⁹⁵ The number of active public water systems was retrieved from SDWIS Q4 2021/Fed fourth quarter 2021.

could not include many of the PWSs with state PFAS occurrence data because predelineated PWS service areas or zip code approximated PWS service area boundaries were not available.

Category 4 and 5 PWSs account for 1.2 million people served, or approximately 0.4 percent of the U.S. population. EPA summarized the results for these PWSs in Appendix M.

8.3.1.2.2.3 Categories 3 and 6

EPA did not include category 3 and 6 PWSs in the EJ exposure analysis because predelineated PWS service areas and information containing zip codes served by PWSs were both unavailable.

8.3.1.2.3 Sociodemographic Data

EPA used the Agency's EJSCREENbatch R package to characterize the sociodemographic makeup of populations living in PWS service areas, as described in Section 8.3.1.2.2 (U.S. EPA, 2022a). The EJSCREENbatch R package offers functions to extract and process Census block group EJScreen data within user-provided geographies. EJScreen uses U.S. Census Bureau's American Community Survey (ACS) 2015–2019 five-year estimates (U.S. EPA, 2022a). EJScreen data are input into a function that spatially apportions (i.e., using areal apportionment) data to service areas using a 1 km resolution raster population dataset from NASA's Socioeconomic Data and Applications Center.

EPA used the following data outputted from the EJSCREENbatch package on the race, ethnicity, and poverty status of populations served by the PWSs:

- Race: Percent American Indian or Alaska Native; percent Asian and Pacific Islander; percent Black or African American; and percent non-Hispanic White. 96
- Ethnicity: Percent Hispanic.
- Income: Percent of the population below twice the Federal poverty level; percent of the population above twice the Federal poverty level.

In addition, the Agency identified PWSs that are Native American-owned and within EPA's tribal primacy program using SDWIS/Fed data (U.S. EPA, 2021h).

Note that sociodemographic information used for EPA's EJ exposure analysis differs from that used in EPA's benefits analysis, which relies on SDWIS/Fed and race/ethnicity-specific population estimates from the U.S. Census Bureau (2020a). In particular, this analysis presents race and ethnicity separately such that most race categories (Asian and Pacific Islander, American Indian or Alaskan Native, and Black) include individuals who identify as Hispanic, while the ethnicity category Hispanic includes individuals who identify as White or a race other than White. Population estimates from the U.S. Census Bureau are available at the county level, but more granular location-specific population data was needed for EPA's EJ exposure analysis. For further information on the use of U.S. Census Bureau population proportions in EPA's benefits analysis, see Appendix B.

⁹⁶ In an effort to avoid double counting populations, race/ethnicity categories reported here do not account for people who selected "some other race alone" or "two or more races" in the ACS.

8.3.1.3 EJ Exposure Analytic Approach

EPA conducted a baseline analysis of populations served by PWS service areas in categories 1 and 2 to evaluate the demographic characteristics of systems exposed to PFAS concentrations above a baseline set of thresholds and two hypothetical regulatory thresholds.

For purposes of this baseline analysis, EPA assumed the following baseline thresholds, based on Method 537.1 detection limits (U.S. EPA, 2018):^{97,98,99}

• PFHpA: 0.71 ppt

• PFHxS: 1.4 ppt

• PFOS: 1.1 ppt

• PFOA: 0.53 ppt

EPA also evaluated the rate of exposure using two hypothetical regulatory thresholds: (1) the UCMR 5 MRL values for each PFAS analyte, and (2) 10.0 ppt. For the purpose of this analysis, these values are assumed to be individual regulatory thresholds for each contaminant. EPA notes that while these thresholds are not exactly set at the proposed or alternate MCL values, EPA began this analysis prior to refinement of those regulatory options. This analysis is not intended to determine the demographic breakdown of costs and benefits expected to result from the proposed regulatory option and alternatives; rather, this analysis determines whether vulnerable communities are disproportionately exposed to PFAS over baseline conditions and these hypothetical thresholds. The UCMR 5 MRL values for PFOA, PFOS, PFHpA, and PFHxS are as follows:

• PFHpA: 3 ppt

• PFHxS: 3 ppt

• PFOS: 4 ppt

• PFOA: 4 ppt

EPA compared the estimated population served in each demographic group anticipated to experience reductions in PFAS exposure under each hypothetical regulatory threshold to the total

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⁹⁷ There are no detection limits reported for Method 533 (U.S. EPA, 2019b).

⁹⁸ EPA used these detection limits solely as baseline thresholds for purposes of its EJ analysis. EPA has defined the Rule Detection Limit for purposes of consideration of monitoring data to determine monitoring schedules as 1/3 the MCL for PFOA and PFOS, or 1.3 ppt. Refer to Sections VI, VIII, and IX of the federal register notice for this proposed regulatory action for further discussion on EPA's analytical methods and the determination of practical quantitation limits (PQLs).

⁹⁹ As noted in Section 8.3.1.2.1, different states utilized various reporting, quantification, and/or detection limits when analyzing and presenting data, and for some states, no clearly defined limits were publicly provided as part of the dataset. Further, the limits often varied within the data for each state depending on the specific PFAS analyte. In some cases, states reported detection, quantification, or reporting limits and/or presented data at concentrations below EPA's proposed rule detection limits and/or practical quantitation limits provided in the federal register notice for this proposed regulatory action. For more information on the collection and analysis of occurrence data, see U.S. EPA (2022j).

population served across all demographic groups. This analysis seeks to answer the following question: When PFAS occurs in drinking water over a certain threshold, will vulnerable communities be disproportionately exposed to PFAS compared to the total population that is exposed to PFAS over the same threshold?

As described above, EPA's EJ exposure analysis for the proposed rule uses data from EJScreen and the American Community Survey to examine anticipated exposure above set baseline and theoretical regulatory thresholds using system-level mean occurrence data. As the literature shows, the degree to which a community is above a specific PFAS threshold can vary. As such, EPA also characterized population-weighted mean concentrations of PFAS to evaluate the extent to which the levels of potential exposure correlate with community characteristics. EPA requests comment on whether considering additional thresholds, metrics, or analyses would further elucidate relative demographic disparities. In particular, EPA requests comment on whether further investigation of pockets of concern, such as a detailed break-out analysis for one or more demographic groups, would improve the analysis.

8.3.2 EJ Exposure Analysis Results

This section describes the demographic characterization of category 1 and 2 PWS service areas in the baseline as well as the results of the analysis exploring the EJ implications of two hypothetical regulatory thresholds. EPA focused on category 1 and 2 PWS service areas due to the availability of spatial boundaries (from both predelineated PWS service area boundaries and zip code-approximated PWS service area boundaries) and PFAS occurrence data from UCMR 3. Results from categories 4 and 5 are reported in Appendix M.

8.3.2.1 Demographic Profile of PWS Service Areas

Table 8-3 summarizes the breakdown of category 1 and 2 PWS service areas by state and by size, where small systems are those serving fewer than or equal to 10,000 people. In total, these PWSs account for roughly 240 million people served, or approximately 73 percent of the U.S. population. Category 1 and 2 PWSs span all states in the continental U.S. Category 1 and 2 PWSs included in this analysis capture roughly 3 percent of active PWSs. Among the 3 percent of active PWSs captured by EPA's analysis (i.e., category 1 and 2 PWSs), there are 28 PWSs within EPA's tribal primacy program, serving a population of approximately 314,182 people. Additionally, approximately 19 percent of the systems are defined as small (serving fewer than 10,000 people), accounting for 1.4 percent of the total population served.

Table 8-4 summarizes the demographic profile for category 1 and 2 PWS service areas and compares it to the demographic characteristics of the overall U.S. population. There are slight differences in the demographic characteristics of the population served by PWS service areas included in EPA's analysis compared to the overall U.S. population, with percent differences all being less than +/- 3 percent. The population served by these PWSs has slightly higher percentages of Asian and Pacific Islander (+0.9%) and Black (+1.8%) populations compared to the overall U.S. population. The percentage of American Indian or Alaska Native populations is consistent with the percent of these populations across the U.S. The Hispanic population served by category 1 and 2 PWSs is slightly higher (+1.3%) and the non-Hispanic White population is lower (-3%) than that of the overall U.S. population. When examining income demographics, Table 8-4 shows that category 1 and 2 PWSs have a slightly higher percentage of populations

with income below twice the poverty level (+2.2%) and a slightly lower percentage of population with income above twice the poverty level (-2.2%) compared to the overall U.S. population.

Table 8-3: Number of Category 1 and 2 PWSs and Populations Served by Size and State

State	Number of Service Areas	Percent Small Service Areas	Total Population Served ^a	Population Served in Small Systems ^a	Population Served in Medium and Large Systems	
Tribal Service Areas	28	50%	314,182	44,571	269,611	
Alabama	124	15%	4,488,042	86,106	4,401,936	
Arizona	68	19%	5,561,792	44,818	5,516,974	
Arkansas	57	32%	1,449,872	81,217	1,368,655	
California	412	9%	34,438,454	146,260	34,292,194	
Colorado	200	61%	5,756,473	227,838	5,528,635	
Connecticut	42	14%	2,457,248	13,799	2,443,449	
Delaware	13	23%	642,261	13,535	628,726	
District of Columbia	2	0%	648,013	-	648,013	
Florida	258	11%	19,355,085	111,293	19,243,792	
Georgia	126	16%	8,816,216	77,382	8,738,834	
Idaho	26	23%	991,096	16,854	974,242	
Illinois	252	13%	9,703,392	121,219	9,582,173	
Indiana	100	19%	3,791,557	62,381	3,729,176	
Iowa	57	26%	1,810,021	52,241	1,757,780	
Kansas	40	33%	1,424,944	41,732	1,383,212	
Kentucky	118	21%	3,572,262	169,375	3,402,887	
Louisiana	87	28%	3,353,978	86,822	3,267,156	
Maine	16	19%	411,385	16,456	394,929	
Maryland	39	21%	4,980,513	20,084	4,960,429	
Massachusetts	171	9%	6,236,022	74,117	6,161,905	
Michigan	158	16%	5,895,618	122,403	5,773,215	
Minnesota	98	14%	3,478,561	40,952	3,437,609	
Mississippi	78	32%	1,400,826	88,145	1,312,681	
Missouri	86	24%	3,879,698	87,393	3,792,305	
Montana	15	40%	416,576	10,070	406,506	
Nebraska	21	33%	1,136,091	12,642	1,123,449	

Table 8-3: Number of Category 1 and 2 PWSs and Populations Served by Size and State

State	Number of Service Areas	Percent Small Service Areas	Total Population Served ^a	Population Served in Small Systems ^a	Population Served in Medium and Large Systems	
Nevada	16	25%	2,826,471	10,200	2,816,271	
New Hampshire	23	22%	570,449	10,907	559,542	
New Jersey	163	9%	7,567,370	54,089	7,513,281	
New Mexico	22	18%	590,288	6,862	583,426	
New York	167	18%	15,963,267	96,915	15,866,352	
North Carolina	145	14%	6,706,695	82,447	6,624,248	
North Dakota	12	25%	425,637	4,903	420,734	
Ohio	183	15%	8,969,887	112,278	8,857,609	
Oklahoma	62	24%	2,482,622	49,472	2,433,150	
Oregon	65	17%	2,875,275	33,730	2,841,545	
Pennsylvania	170	20%	8,424,012	130,731	8,293,281	
Rhode Island	17	12%	934,307	12,485	921,822	
South Carolina	81	11%	3,487,233	46,773	3,440,460	
South Dakota	18	28%	458,464	17,065	441,399	
Tennessee	136	12%	6,114,639	86,951	6,027,688	
Texas	329	26%	15,408,123	319,661	15,088,462	
Utah	62	13%	2,595,756	32,847	2,562,909	
Vermont	12	50%	142,888	23,438	119,450	
Virginia	81	16%	6,291,660	48,692	6,242,968	
Washington	132	15%	6,304,525	70,712	6,233,813	
West Virginia	32	31%	818,159	35,605	782,554	
Wisconsin	92	20%	2,920,851	82,496	2,838,355	
Wyoming	11	18%	268,828	3,341	265,487	
TOTAL	4,723	19%	239,557,584	3,242,305	236,315,279	

Abbreviations: PWS – public water system.

Note:

Table 8-3: Number of Category 1 and 2 PWSs and Populations Served by Size and State

State	Number of Service Areas	Percent Small Service Areas	Total Population Served ^a	Population Served in Small Systems ^a	Population Served in Medium and Large Systems
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^aPopulation served by PWSs was obtained from SDWIS/Fed fourth quarter 2021. Small systems include those serving fewer than or equal to 10,000 people. Medium and large systems serve populations more than 10,000 people.

Table 8-4: Population Served by Category 1 and 2 PWSs Compared to Percent of U.S. Population by Demographic Group

Results		Ra	Inco					
	American Indian or Alaska Native	Non-Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served			
Population Served	1,518,369	16,087,571	34,583,262	46,573,256	136,673,130	76,716,883	162,840,701	239,557,584
Percent of Total Population Served	0.6%	6.7%	14.4%	19.4%	57.1%	32.0%	68.0%	100.0%
U.S. Population Percent by Demographic Group ^a	0.8%	5.8%	12.6%	18.2%	60.1%	29.8%	70.2%	-
Percent Difference Between Population Served and U.S. Population	-0.2%	0.9%	1.8%	1.3%	-3%	2.2%	-2.2%	-

Note:

^aU.S. population estimates were obtained from the U.S. Census Bureau's American Community Survey 2016–2020 five-year estimates.

8.3.2.2 Exposure Analysis Results

8.3.2.2.1 Baseline Scenario

To evaluate impacts of the proposed rule on population groups of concern, the percent of a specific demographic group with modeled PFAS above baseline thresholds needs to be presented in relation to another group, typically referred to as a comparison group. The way in which the comparison group is defined can have important implications for identifying differences in potential exposure across population groups of concern in an EJ analysis. The Agency's *Technical Guidance for Assessing Environmental Justice in Regulatory* Analysis notes that the comparison group can be defined as individuals with similar socioeconomic characteristics across different areas in the state, region or nation (i.e., within-group comparison) or as affected individuals with different socioeconomic characteristics (i.e., across-group comparison) (U.S. EPA, 2016h).

For this proposed regulatory action, EPA is examining individuals served by PWSs with modeled PFAS exposure above the baseline concentration threshold or a specific hypothetical alternative policy threshold. EPA presents the total affected population as a possible metric of comparison, noting however that each affected demographic group is reflected also within the total affected population. It is possible that EPA understates the magnitude of disproportionate baseline exposure to PFAS for populations of concern by using the total affected population as the basis of comparison.

As currently defined, race and ethnicity classifications are generally presented separately such that the race categories include individuals who identify as Hispanic, while Hispanic ethnicity includes individuals who identify as a race other than White. In aggregate, those who identify as a race or ethnicity other than White and/or Hispanic are considered "people of color" when considering potential EJ concerns. Thus, the disaggregated race and ethnicity categories in the current analysis reflect some double counting among affected populations that ultimately compose the aggregate category, people of color. EPA has therefore included the category non-Hispanic White in the analysis, as this category does not include individuals who identify as a race or ethnicity included within people of color. EPA requests comment on all aspects of the environmental justice analysis, including its choice of comparison groups to help identify potential demographic disparities in anticipated PFAS exposure.

The results of EPA's analysis of baseline exposure are shown in Table 8-5 and Table 8-6. Table 8-5 summarizes the population served by category 1 and 2 PWSs with modeled PFAS occurrence above baseline thresholds based on the Method 537.1 detection limits. The second set of rows in Table 8-5 summarizes the percentage of the total population served by demographic group with modeled PFAS occurrence above these baseline thresholds by demographic group. Table 8-7 shows average population-weighted PFAS concentrations across demographic groups. In Table 8-5, percentages are bolded and italicized when the percentage of the population in a specific demographic group with modeled PFAS above the baseline threshold is greater than the percentage of the total population across all demographic groups exposed to modeled PFAS above this threshold (right-hand column). In Table 8-5, the highlighted numbers represent where percentages of the population served in a particular demographic group are more than 1 percent greater than percentages of the total population. In Table 8-6, highlighted cells represent whether the average concentration for a given demographic group is higher than the average for the total

population served across all demographic groups (right-hand column). Higher percentages or concentrations indicate higher PFAS exposure for a given demographic group compared to the percentage of the population served across all demographic groups. Between 7.1 percent and 12.6 percent of the total population served for category 1 and 2 PWS service areas, depending on the analyte, are exposed to modeled PFAS occurrence above baseline thresholds based on the Method 537.1 detection limits.

The following are findings from EPA's baseline EJ exposure analysis: 100

- The percentage of Asian and Pacific Islander and Hispanic populations served with exposure to PFAS above baseline thresholds is higher across all four PFAS analytes compared to the percentage of the total population served across all demographic groups with anticipated PFAS exposure above the baseline thresholds. These percentages are also higher than those of non-Hispanic White populations. Most percentages are more than 1 percent greater than percentages exposed across the total population.
- The percentage of Asian and Pacific Islander populations served with exposure above baseline thresholds is 0.7 percent to 2.2 percent points higher (depending on the analyte) than the percentages of the population served across all demographic groups. When compared to non-Hispanic White populations, the percentages are 1.8 to 3.4 percentage points higher.
- The percentage of Hispanic populations served with exposure above baseline thresholds is 3.1 percent to 3.6 percentage points higher (depending on the analyte) than the percentage of the population served across all demographic groups. When compared to non-Hispanic White populations, the percentages are 4.0 to 4.8 percentage points higher.
- While the percentage of American Indian or Alaska Native and Black populations served have similar PFAS exposure above the baseline thresholds for PFAS compared to the percentages of the population served across all demographic groups, they are somewhat higher than those of non-Hispanic White populations for three of the four PFAS analytes.
- Other demographic groups, including those representing relative income status, are anticipated to experience percentages of PFAS occurrence above baseline thresholds similar to (within 0.5%) the percentage of the population served across all demographic groups.

Table 8-6 characterizes population-weighted mean concentrations of PFAS by demographic group. In addition to having a higher percentage of population served by PWSs with above baseline concentrations of PFAS, Asian and Pacific Islander and Hispanic populations are also exposed to higher mean concentrations than is typical for the total population served. Hispanic populations are the most highly exposed across all four PFAS. On average, they are exposed to 0.2-0.3 ppt more of each of the four analyzed PFAS than non-Hispanic White populations served. The results also suggest that Black, American Indian and Alaska Native, and low-income individuals are exposed to higher average concentrations than the total population served for at least two PFAS in each case. This finding suggests that, while these populations may not always be more likely to be served by public water systems with above baseline concentrations of PFAS, they may be exposed to higher average concentrations when exposure does occur. Collectively,

¹⁰⁰ Although differences in anticipated exposure between a particular demographic group and the entire sample population are <5%, all results are reported in EPA's summary of results regardless of magnitude.

people of color are potentially exposed to 0.1-0.2 ppt more of each of the four PFAS analyzed than non-Hispanic White populations served.

Table 8-5: Baseline Scenario: Population Served by Category 1 and 2 PWS Service Areas Above Baseline Thresholds and as a Percent of Total Population Served

			Race and Ethnicity					Income		
Results	PFAS	American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	Non-Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served	
Population	PFOS	148,381	1,958,054	3,469,513	6,612,120	12,941,535	7,879,907	17,530,418	25,410,325	
Served Above	PFHxS	114,653	1,492,095	2,454,674	4,817,842	8,024,430	5,400,599	11,675,163	17,075,762	
Baseline	PFHpA	141,360	1,697,425	3,295,139	6,330,047	12,073,566	7,553,195	16,239,858	23,793,053	
Threshold	PFOA	163,560	2,276,202	4,019,351	7,346,397	16,125,251	9,341,681	20,956,016	30,297,697	
Population	PFOS	9.8%	12.2%	10.0%	14.2%	9.5%	10.3%	10.8%	10.6%	
Served Above	PFHxS	7.6%	<mark>9.3%</mark>	7.1%	10.3%	5.9%	7.0%	7.2%	7.1%	
Baseline Threshold as a	PFHpA	9.3%	10.6%	9.5%	13.6%	8.8%	9.8%	10.0%	9.9%	
Percent of Total Population Served	PFOA	10.8%	<u>14.1%</u>	11.6%	<u>15.8%</u>	11.8%	12.2%	12.9%	12.6%	

Abbreviations: PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid.

Table 8-6: Modeled Average PFAS Concentrations (ppt) by Demographic Group in the Baseline, Category 1 and 2 PWS Service Areas

			Race and l	Ethnicity	Income				
PFAS	American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	People of Color ^a	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served
PFOS	0.73	0.77	0.71	0.92	0.81	0.62	0.73	0.69	0.70
PFHxS	0.59	0.53	0.51	0.62	0.56	0.44	0.52	0.48	0.49
PFHpA	0.39	0.40	0.44	0.51	0.46	0.39	0.42	0.42	0.42
PFOA	0.79	0.93	0.89	1.03	0.95	0.83	0.87	0.88	0.88

Abbreviations: PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid. Note:

^aThe demographic group people of color includes individuals who identify as Hispanic and/or a race other than White. It is calculated from EJScreen's percent minority indicator and is non-duplicative across race and ethnicity categories.

8.3.2.2.2 Hypothetical Regulatory Scenario #1: UCMR 5 MRLs

Table 8-7 and Table 8-8 summarize the results for population served by category 1 and 2 PWSs with PFAS occurrence above UCMR 5 MRL values. For this hypothetical regulatory scenario, EPA assumed that PWSs with PFAS system-level means above the MRL value will reduce PFAS levels to comply with the proposed rule. The first set of rows in Table 8-7 summarizes populations served by category 1 and 2 PWS service areas with modeled PFAS occurrence above the UCMR 5 MRLs. The second set of rows provides these estimates as a percentage of the total population served by PWSs included in EPA's analysis. Table 8-8 summarizes the population-weighted average reductions in PFAS assuming all PWSs reduce their concentrations to UCMR 5 MRL levels.

In Table 8-7, percentages are bolded and italicized when the percentage of the population in a specific demographic group with PFAS occurrence above the MRL value is greater than the percentage of the total population across all demographic groups with PFAS occurrence above the MRL (right-hand column). In Table 8-7, the highlighted numbers represent where percentages of the population served in a particular demographic group are more than 1 percent greater than percentages of the total population. In Table 8-8, highlighted cells represent whether the average reduction in PFAS concentrations for a given demographic group is higher than the average for the total populations served across all demographic groups (right-hand column). The percentages that are bolded, italicized, or highlighted indicate higher PFAS exposure above the MRL for a given demographic group; EPA anticipates that relatively higher reductions in PFAS exposure will accrue to these demographic groups under this hypothetical regulatory scenario compared to the percentage of the population across all demographic groups. EPA provides additional details on anticipated exposure above UCMR 5 MRL values in Appendix M.

Between 2.7 percent and 4.8 percent of the population served by category 1 and 2 PWS service areas, depending on the PFAS analyte, are exposed to modeled PFAS concentrations above the MRL for PFOS, PFOA, PFHpA, and PFHxS. Under this hypothetical regulatory scenario, where MCLs are assumed to be equal to UCMR 5 MRL values, EPA expects these populations to experience reductions in PFAS exposure to below the hypothetical regulatory thresholds. EPA's analysis of the demographic distribution of anticipated health benefits and household costs due to reductions in PFAS exposure resulting from the proposed PFAS rule and regulatory alternatives is discussed in Section 8.4.2.

Based on this analysis, American Indian or Alaska Native, Asian and Pacific Islander, Black, Hispanic, and low-income populations are estimated to face higher rates of system-level mean PFAS exposure above UCMR 5 MRL values compared to rates of exposure over these thresholds for the population served across all demographic groups. The differences are even greater when compared to the rates of exposure over these thresholds for non-Hispanic White populations. Specifically, American Indian or Alaska Native populations served have higher exposure above the UCMR 5 MRL values for PFOS, PFHxS, and PFHpA compared to the percent of the population served across all demographic groups. These differences in exposure are larger when compared to non-Hispanic White populations. Asian and Pacific Islander populations served have higher exposure above the UCMR 5 MRL values for PFOS and PFOA compared to the percent of the population served across all demographic groups. For PFOA and PFOS, the percentage of Asian and Pacific Island populations exposed is over 1% greater than for non-Hispanic White populations. Black populations served have higher exposure above the

UCMR 5 MRL values for PFHpA and PFOA, compared to the percent of the population served across all demographic groups, and they have higher exposure above the UCMR 5 MRLs for PFOS and PFHxS compared to non-Hispanic White populations. Hispanic populations served have higher exposure above the UCMR 5 MRL values across all four PFAS analytes compared to the percent of the population served across all demographic groups. The percent of Hispanic populations served with exposure above the UCMR 5 MRL values is generally at least double the percent of non-Hispanic White populations with exposure above the UCMR 5 MRL values. This is the most notable difference in exposure. The percent differences observed suggest that, in this analysis, Hispanic populations are estimated to face nearly twice the level of exposure for all four PFAS analytes compared to the entire sample population across all demographic groups. As such, Hispanic populations could also be expected to experience the greatest reductions in PFAS exposure under this hypothetical regulatory scenario. Populations served with income less than twice the poverty level have higher PFAS exposure above the UCMR 5 MRL values across all four PFAS analytes compared to the percent of the population served across all demographic groups. Exposure percentages for populations served with income less than twice the poverty level are at least 1% greater than exposure for non-Hispanic White populations. Table 8-8 displays population-weighted reductions in PFAS exposure in a hypothetical regulatory scenario where system-level means are reduced to UCMR 5 MRLs to comply with the proposed rule. Hispanic populations see the greatest reductions in concentrations for three PFAS in this hypothetical regulatory scenario, which is consistent with Table 8-7. However, despite having lower percentage of population affected than Hispanic populations, American Indian and Alaska Native populations see the greatest reduction in PFHxS of any demographic group in this hypothetical regulatory scenario. Black populations also see greater reductions in PFOS and PFHxS than the average across the total population served, even though the percentage of Black individuals with exposure above UCMR 5 MRLs is the same as the percentage of the population served across all demographic groups. Collectively, people of color and those with income less than twice the poverty level see greater reductions in PFAS exposure across all four analytes in comparison to the total population served. These differences in PFAS reductions are larger when compared to the non-Hispanic White population.

Table 8-7: Hypothetical Regulatory Scenario #1: Demographic Breakdown of Population Served by Category 1 and 2 PWS Service Areas Above UCMR 5 MRLs and as a Percent of Total Population Served

			Ra		Inco				
Results	PFAS	American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	Non-Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served
Population	PFOS	82,997	861,159	1,585,417	3,612,399	4,900,864	3,739,513	7,384,230	11,123,742
Served Above	PFHxS	81,981	656,539	1,419,167	3,161,527	4,492,124	3,268,486	6,613,772	9,882,258
UCMR5	PFHpA	43,064	386,810	1,075,549	2,309,203	2,648,871	2,275,173	4,229,947	6,505,119
MRL	PFOA	60,023	867,254	1,809,985	3,500,258	5,245,421	3,737,007	7,846,216	11,583,222
Population Served	PFOS	5.5%	5.4%	4.6%	7.8%	3.6%	4.9%	4.5%	4.6%
Above UCMR 5 MRL as a	PFHxS	5.4%	4.1%	4.1%	6.8%	3.3%	4.3%	4.1%	4.1%
Percent of Total	PFHpA	2.8%	2.4%	3.1%	5.0%	1.9%	3.0%	2.6%	2.7%
Population Served	PFOA	4.0%	5.4%	5.2%	<mark>7.5%</mark>	3.8%	4.9%	4.8%	4.8%

 $Abbreviations: MRL-minimum\ reporting\ level; PFHpA-perfluoroheptanoic\ acid; PFHxS-perfluorohexane sulfonic\ acid; PFOA-perfluorooctanoic\ acid; PFOA-perfluorooctanoic\ acid; PFOS-perfluorooctane sulfonic\ acid; UCMR-Unregulated\ Contaminant\ Monitoring\ Rule.$

Table 8-8: Reductions in Average PFAS Concentrations (ppt) by Demographic Group in a Hypothetical Regulatory Scenario with Maximum Contaminant Level at the UCMR 5 MRLs, Category 1 and 2 PWS Service Areas

			Race and	Ethnicity					
PFAS	American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	People of Color ^a	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served
PFOS	0.26	0.25	0.25	0.33	0.28	0.18	0.26	0.21	0.22
PFHxS	0.25	0.16	0.18	0.19	0.18	0.13	0.18	0.14	0.15
PFHpA	0.04	0.03	0.06	0.07	0.06	0.04	0.06	0.05	0.05
PFOA	0.16	0.22	0.19	0.25	0.22	0.16	0.19	0.18	0.18

Abbreviations: PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid. Note:

^aThe demographic group people of color includes individuals who identify as Hispanic and/or a race other than White. It is calculated from EJScreen's percent minority indicator and is non-duplicative across race and ethnicity categories.

8.3.2.2.3 Hypothetical Regulatory Scenario #2: 10.0 ppt

Table 8-9 and Table 8-10 summarize the results of the population served by category 1 and 2 PWS service areas with modeled PFAS occurrence above 10.0 ppt. The first set of rows in Table 8-9 summarizes populations served by PWSs with PFAS occurrence above 10.0 ppt. The second set of rows displays these estimates as a percent of the total population served for PWSs included in EPA's analysis. Table 8-10 shows the population-weighted average reduction in PFAS concentrations assuming all PWSs reduce their concentrations to 10.0 ppt.

In Table 8-9, percentages are bolded and italicized when the percentage of the population in a specific demographic group with PFAS occurrence above 10.0 ppt is greater than the percentage of the total population served across all demographic groups with PFAS occurrence above 10.0 ppt (right-hand column). In Table 8-10, highlighted cells represent whether the average reduction in PFAS concentrations for a given demographic group is higher than the average for the total populations served across all demographic groups (right-hand column). The percentages that are bolded, italicized, or highlighted indicate greater PFAS exposure above 10.0 ppt for a given demographic group compared to the total population served across all demographic groups; EPA anticipates potentially relatively higher reductions in PFAS exposure to accrue to these demographic groups under this hypothetical regulatory scenario compared to the percentage of population across all demographic groups. Unlike the results from EPA's exposure analysis where UCMR 5 MRLs are used as hypothetical MCL values, percentages in particular demographic groups are less than 1 percent greater than percentages across the total population. Between 0.2 percent and 1.1 percent of the population served by category 1 and 2 PWS service areas, depending on the PFAS analyte, is exposed to PFAS occurrence above 10.0 ppt.

The following are findings from the EJ exposure analysis for PFAS occurrence above 10.0 ppt:

- American Indian or Alaska Native, Asian and Pacific Islander, Black, Hispanic, and low-income populations have slightly higher PFAS exposure above 10.0 ppt for some PFAS analytes compared to the population served across all demographic groups. These results are essentially unchanged when comparing exposures above 10.0 ppt to non-Hispanic White populations.
- The most notable difference is for PFHxS exposure for American Indian or Alaska Native populations served, with 1.0 percent of American Indian and Alaska Native populations served with PFAS exposure above 10.0 ppt compared to 0.4 percent of population served across all demographic groups.

Table 8-10 characterizes population-weighted average reductions of PFAS by demographic group in a hypothetical regulatory scenario where system-level means are reduced to 10.0 ppt. This analysis reinforces the results for PFOS in Table 8-9, showing that people of color see greater reductions in PFOS than the average for the total population served. Notably, for PFHxS, Asian and Pacific Islander, Black, and Hispanic populations see greater reductions than the total population served despite having similar percentages exposed above 10.0 ppt. Collectively, people of color and populations with income below twice the poverty level see greater reductions in PFOS and PFHxS than the total population served across all demographic groups.

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Table 8-9: Hypothetical Regulatory Scenario #2: Demographic Breakdown of Population Served by Category 1 and 2 PWS Service Areas Above 10.0 ppt and as a Percent of Total Population Served

	PFAS		Race and Ethnicity					Income		
Results		American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Population Served	
	PFOS	18,295	189,271	431,476	602,304	1,275,424	931,413	1,623,668	2,555,081	
Population	PFHxS	14,897	70,637	133,867	174,242	564,113	357,196	620,248	977,444	
Served Above 10.0 ppt	PFHpA	2,535	10,837	82,138	52,059	220,554	131,151	244,513	375,664	
10.0 ррі	PFOA	7,502	139,046	230,168	213,670	796,015	437,039	972,748	1,409,787	
Population	PFOS	1.2%	1.2%	1.2%	1.3%	0.9%	1.2%	1.0%	1.1%	
Served Above	PFHxS	1.0%	0.4%	0.4%	0.4%	0.4%	0.5%	0.4%	0.4%	
10.0 ppt as a Percent of Total	PFHpA	0.2%	0.1%	0.2%	0.1%	0.2%	0.2%	0.2%	0.2%	
Population Served	PFOA	0.5%	0.9%	0.7%	0.5%	0.6%	0.6%	0.6%	0.6%	

Abbreviations: PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid; ppt – parts per trillion.

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Table 8-10: Reductions in Average PFAS Concentrations (ppt) by Demographic Group in a Hypothetical Regulatory Scenario with Maximum Contaminant Level at 10.0 ppt, Category 1 and 2 PWS Service Areas

			Race and l	Ethnicity					
PFAS	American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	People of Color ^a	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served
PFOS	0.10	0.11	0.11	0.12	0.11	0.08	0.11	0.08	0.09
PFHxS	0.06	0.07	0.08	0.07	0.07	0.05	0.08	0.05	0.06
PFHpA	0.00	0.00	0.01	0.00	0.00	0.01	0.01	0.00	0.00
PFOA	0.04	0.04	0.06	0.04	0.05	0.05	0.05	0.04	0.05

Abbreviations: PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid. Note:

^aThe demographic group people of color includes individuals who identify as Hispanic and/or a race other than White. It is calculated from EJScreen's percent minority indicator and is non-duplicative across race and ethnicity categories.

8.3.2.3 Comparison of Results by PWS Size

8.3.2.3.1 Demographic Profile of PWS Service Areas

Table 8-11 and Table 8-12 summarize the demographic profile for category 1 and 2 PWS service areas by system size for large and small PWS service areas, respectively. Small systems are defined as systems serving fewer than or equal to 10,000 people while large systems serve more than 10,000 people. Table 8-11 and Table 8-12 also provide a comparison to the demographic characteristics of the overall U.S. population. Because category 4 and 5 PWS service areas make up a relatively smaller proportion of the sample of PWS service areas included in EPA's analysis, results for category 4 and 5 PWS service areas are not compared by size due to inadequate sample size to conduct this analysis.

Table 8-11 shows that the population served by large category 1 and 2 PWS service areas has slight differences in demographic characteristics compared to the overall U.S. population, with percent differences all being less than +/- 3.3 percent. PWS service areas have higher percentages of Black (+1.9%), Hispanic (+1.35%), and Asian and Pacific Islander populations (+0.98%) populations and populations with income below twice the poverty level (+2.2%) compared to the overall U.S. population. Additionally, the population served by large category 1 and 2 PWS service areas has lower percentages of non-Hispanic White (-3.3%) populations and populations with income above twice the poverty level (-2.2%) compared to the overall U.S. population. The percentage of American Indian or Alaska Native populations is relatively consistent with the percent of these populations across the U.S.

Table 8-12 shows that the population served by small category 1 and 2 PWS service areas has considerable differences in the demographic characteristics of the population served compared to the overall U.S. population, with percent differences being generally greater than +/- 2.5 percent, and the greatest difference being +13.09 percent. The population served by small category 1 and 2 PWS service areas has lower percentages of Asian and Pacific Islander (-3.7%), Black (-2.79%), and Hispanic (-6.59%) populations and populations with income above twice the poverty level (-4.07%) compared to the overall U.S. population. Additionally, the population served by small category 1 and 2 PWS service areas has higher percentages of American Indian or Alaska Native (+1%), non-Hispanic White (+13.09%) populations, and populations with income below twice the poverty level (+4.07%) compared to the overall U.S. population.

Table 8-11: Population Served by Category 1 and 2 PWSs and Percent of U.S. Population by Demographic Group, Large Systems

		Ra	ce and Ethnicit	y		Inc	ome	_
	American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served
Population Served	1,460,058	16,019,564	34,265,272	46,196,824	134,300,144	75,618,752	160,696,528	236,315,280
Percent of Total Population Served	0.62%	6.78%	14.50%	19.55%	56.83%	32.00%	68.00%	100.00%
U.S. Population Percent	0.80%	5.80%	12.60%	18.20%	60.10%	29.80%	70.20%	-
Percent Difference Between Population Served Percent and U.S. Percent	-0.18%	0.98%	1.90%	1.35%	-3.27%	2.20%	-2.20%	-

Table 8-12: Population Served by Category 1 and 2 PWSs and Percent of U.S. Population by Demographic Group, Small Systems

		Rac	e and Ethnici	ty		Inco	ome	
	American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served
Population Served	58,311	68,007	317,990	376,431	2,372,983	1,098,134	2,144,171	3,242,305
Percent of Total Population Served	1.80%	2.10%	9.81%	11.61%	73.19%	33.87%	66.13%	100.00%
U.S. Population Percent	0.80%	5.80%	12.60%	18.20%	60.10%	29.80%	70.20%	_
Percent Difference between Population Served Percent and U.S. Percent	1.00%	-3.70%	-2.79%	-6.59%	13.09%	4.07%	-4.07%	-

8.3.2.3.2 Baseline Scenario

Table 8-13 and Table 8-14 summarize the populations served by large and small category 1 and 2 PWS service areas with modeled PFAS occurrence above baseline thresholds based on the Method 537.1 detection limits. The second set of rows in Table 8-13 and Table 8-14 summarize the percentage of the total population served by demographic group with modeled PFAS occurrence above baseline thresholds. Percentages are bolded when the percentage of the population in a specific demographic group with modeled PFAS above baseline thresholds is greater than the percentage of the total population across all demographic groups exposed to modeled PFAS above the baseline thresholds. Additionally, percentages are highlighted when the percentage of the population in a specific demographic group with modeled PFAS above the baseline threshold represents greater than a 1 percent difference compared to the total population across all demographic groups. Table 8-15 characterizes population-weighted average PFAS concentrations across demographic groups in large and small category 1 and 2 PWSs. Highlighted cells represent whether the average concentration for a given demographic group is higher than the average concentration for the total population served across all demographic groups (right-hand column).

Depending on the PFAS analyte, between 7.2 percent and 12.8 percent of the total population served by large category 1 and 2 PWS service areas are exposed to modeled PFAS occurrence above baseline thresholds based on the Method 537.1 detection limits. Depending on the PFAS analyte, between 1.5 percent and 3.4 percent of the total population served by small category 1 and 2 PWS service areas is exposed to modeled PFAS occurrence above baseline thresholds based on the Method 537.1 detection limits.

For large systems, the percentage of Asian and Pacific Islander and Hispanic populations served by category 1 and 2 PWS service areas is higher across all four PFAS analytes compared to the percentage of the total population served across all demographic groups with anticipated PFAS exposure above baseline thresholds. Depending on the PFAS analyte, the percentage of Asian and Pacific Islander populations served with exposure above baseline thresholds is 0.6 percent to 2.1 percentage points higher than percentages of the population served across all demographic groups, or 1.6 to 3.3 percentage points higher than for non-Hispanic White populations. Depending on the PFAS analyte, the percent of Hispanic populations served with exposure above baseline thresholds is 3.1 percent to 4.7 percent higher than for the population served across all demographic groups. This difference is 3.7 to 4.7 percentage points greater when compared to the non-Hispanic White population.

For small systems, the percentage of Black populations served by category 1 and 2 PWS service areas with PFAS above baseline thresholds is higher across all four PFAS analytes compared to the percentage of the total population served across all demographic groups with anticipated PFAS exposure above baseline thresholds. Depending on the PFAS analyte, the percent of Black populations served with exposure above baseline thresholds is 0.2 percent to 2.2 percentage points higher than percentages of the population served across all demographic groups. Given the data gaps in occurrence information among small systems, extrapolating these results to small systems across the country is not possible.

Table 8-15 provides detail on average concentrations across these demographic groups for large and small water systems, respectively. The first panel of Table 8-15 supports the previous

findings in Table 8-13 that, for large PWSs, Asian and Pacific Islander as well as Hispanic populations served have greater exposure across at least three PFAS in comparison to exposure for the total population served across all demographic groups. In addition, Table 8-15 demonstrates that Black and American Indian or Alaska Native populations have greater exposure to PFOS and PFHxS in comparison to average exposure for the total population served across all demographic groups for large PWSs, even though these groups have similar or even lower percentages of exposure in comparison to the total population served. Collectively, people of color and populations with income less than twice the poverty level have greater average exposure to at least three PFAS in comparison to the total population served across all demographic groups for large PWSs. These differences in potential exposure are greater when compared to the non-Hispanic White population across all four PFAS.

The second panel of Table 8-15 shows that Black and non-Hispanic White populations have greater potential exposure to PFOS and PFOA in comparison to the total population served across all demographic groups served by small PWSs. Non-Hispanic White populations also see greater exposure to PFHxS in comparison to the total population served in small PWSs. Of note, Asian and Pacific Islander populations have somewhat higher average concentrations of PFOA than the total population served across all demographic groups for small PWSs, despite the fact that these populations have a 0.6 percentage point lower exposure rate in comparison to the total population served across small PWSs.

Table 8-13: Baseline Scenario: Demographic Breakdown of Population Served by Category 1 and 2 PWS Service Areas Above Baseline Thresholds and as a Percent of Total Population Served, Large Systems

			R	ace and Ethni	city		Inc	ome		
		American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served	System Count
Population	PFOS	148,105	1,956,415	3,459,772	6,608,365	12,885,593	7,863,869	17,475,594	25,339,463	306
Served Above	PFHxS	114,411	1,491,117	2,449,433	4,816,112	7,984,226	5,390,515	11,637,142	17,027,657	200
Baseline	PFHpA	140,992	1,696,341	3,281,454	6,326,676	12,024,400	7,535,110	16,190,763	23,725,873	297
Threshold	PFOA	162,058	2,274,278	4,001,945	7,341,699	16,040,854	9,308,772	20,878,534	30,187,306	411
Population	PFOS	10.14%	12.21%	10.10%	14.30%	9.59%	10.40%	10.87%	10.72%	-
Served Above	PFHxS	7.84%	9.31%	7.15%	10.43%	5.95%	7.13%	7.24%	7.21%	-
Baseline Threshold as a	PFHpA	9.66%	10.59%	9.58%	13.70%	8.95%	9.96%	10.08%	10.04%	-
Percentage of Total Population Served	PFOA	11.10%	14.20%	11.68%	15.89%	11.94%	12.31%	12.99%	12.77%	-
Total Population in Sampled Pop		1,460,058	16,019,564	34,265,272	134,300,144	134,300,144	75,618,752	160,696,528	236,315,280	

Abbreviations: PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid.

Table 8-14: Baseline Scenario: Demographic Breakdown of Population Served by Category 1 and 2 PWS Service Areas Above Baseline Thresholds and as a Percent of Total Population Served, Small Systems

			Rac	e and Ethnici	ty		Inco	me		System Count
		American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served	
Population	PFOS	276	1,639	9,741	3,756	55,942	16,038	54,823	70,861	15
Served	PFHxS	241	978	5,241	1,730	40,203	10,084	38,021	48,105	9
Above Baseline	PFHpA	367	1,084	13,685	3,371	49,166	18,085	49,095	67,180	12
Threshold	PFOA	1,502	1,924	17,406	4,699	84,397	32,909	77,481	110,390	21
Population	PFOS	0.47%	2.41%	3.06%	1.00%	2.36%	1.46%	2.56%	2.19%	_
Served	PFHxS	0.41%	1.44%	1.65%	0.46%	1.69%	0.92%	1.77%	1.48%	_
Above Baseline	PFHpA	0.63%	1.59%	<mark>4.30%</mark>	0.90%	2.07%	1.65%	2.29%	2.07%	_
Threshold as a	1	2.58%	2.83%	5.47%	1.25%	3.56%	3.00%	3.61%	3.40%	
Percentage of Total	PFOA									-
Population Served										
Served Total Popula Served in Sar Population		58,311	68,007	317,990	376,431	2,372,983	1,098,134	2,144,171	3,242,305	-

Abbreviations: PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid.

Table 8-15: Modeled Average PFAS Concentrations (ppt) by Demographic Group and System Size in the Baseline, Category 1 and 2 PWS Service Areas

			Ra	ce and Ethnicit	y		Inco	ome	
PFAS	American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	People of Color ^a	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served
Large Systems	3								
PFOS	0.75	0.77	0.71	0.92	0.81	0.62	0.73	0.69	0.70
PFHxS	0.61	0.53	0.52	0.63	0.57	0.44	0.52	0.49	0.50
PFHpA	0.40	0.40	0.44	0.51	0.46	0.39	0.43	0.42	0.42
PFOA	0.81	<mark>0.94</mark>	0.89	1.03	0.96	0.83	0.88	0.89	0.89
Small Systems									
PFOS	0.25	0.34	0.44	0.27	0.33	0.40	0.34	0.40	0.38
PFHxS	0.13	0.15	0.16	0.13	0.14	0.18	0.15	0.18	0.17
PFHpA	0.12	0.14	0.15	0.12	0.13	0.14	0.13	0.14	0.14
PFOA	0.30	0.39	0.41	0.32	0.35	0.38	0.34	0.39	0.37

Abbreviations: PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid. Note:

^aThe demographic group people of color includes individuals who identify as Hispanic and/or a race other than White. It is calculated from EJScreen's percent minority indicator and is non-duplicative across race and ethnicity categories.

8.3.2.3.3 Hypothetical Regulatory Scenario #1: UCMR 5 MRLs

Table 8-16, Table 8-17, and Table 8-18 summarize the results for populations served by large and small category 1 and 2 PWS service areas with PFAS occurrence above UCMR 5 MRL values, respectively. EPA assumed that PWS service areas with PFAS system-level means above the UCMR 5 MRL value will reduce PFAS levels to comply with the proposed rule.

The first set of rows in Table 8-16 and Table 8-17 summarize populations served by large and small category 1 and 2 PWSs with modeled PFAS occurrence above the UCMR 5 MRLs. respectively. The second set of rows provides these estimates as a percentage of the total population served by PWS service areas included in EPA's analysis. In Table 8-16 and Table 8-17, percentages are bolded and italicized when the percentage of the population in a specific demographic group with PFAS occurrence above the MRL value is greater than the percentage of the total population across all demographic groups with PFAS occurrence above the MRL. Additionally, percentages are highlighted when the percentage of the population in a specific demographic group with modeled PFAS above the MRL represents greater than a 1 percentage point difference compared to the total population across all demographic groups exposed to modeled PFAS above the MRL value. Table 8-17 characterizes population-weighted average reductions in PFAS concentrations across demographic groups in large and small category 1 and 2 PWSs. Highlighted cells represent whether the average reduction for a given demographic group is higher than the average reduction for the total population served across all demographic groups (right-hand column). The percentages that are bolded, italicized, or highlighted indicate more PFAS exposure above the MRL for a given demographic group; EPA anticipates relatively higher reductions in PFAS exposure will accrue to these demographic groups under this hypothetical regulatory scenario compared to the percentage of the population across all demographic groups.

Depending on the PFAS analyte, between 2.8 percent and 4.9 percent of the total population served by large category 1 and 2 PWS service areas are exposed to at least one of the modeled four PFAS occurrence above UCMR 5 MRL values. For small category 1 and 2 PWS service areas, depending on the PFAS analyte, between 0.3 percent and 1.2 percent of the total population served is exposed to modeled PFAS occurrence above UCMR 5 MRL values.

Findings for large systems are as follows:

- American Indian or Alaska Native populations served have higher exposure above UCMR 5 MRL values for PFOS, PFHpA, and PFHxS compared to the percent of the population served across all demographic groups. American Indian or Alaska Native populations also have higher PFOA exposure than the non-Hispanic White population.
- Asian and Pacific Islander populations served have higher exposure above UCMR 5
 MRL values for PFOS and PFOA compared to the percent of the population served
 across all demographic groups. These populations also have higher exposure for PFHpA
 and PFHxS in comparison to the non-Hispanic White population.
- Black populations served have higher exposure above the UCMR 5 MRL for PFHpA and PFOA compared to the percent of the population served across all demographic groups. Black populations also have higher exposures for PFOA, PFHxS, and PFHpA compared to the non-Hispanic White population.

 Hispanic populations served have higher exposure above the UCMR 5 MRL values for all four PFAS analytes compared to the percent of the population served across all demographic groups. Hispanic populations have at least double the exposure above UCMR 5 MRL values in comparison to non-Hispanic White populations across all four PFAS.

Findings for small systems are as follows:

- Asian and Pacific Islander populations served have higher exposure above UCMR 5
 MRL values for PFHpA and PFOA compared to the percent of the population served
 across all demographic groups.
- Black populations served have higher exposure above the UCMR 5 MRL for PFOS compared to the percent of the population served across all demographic groups.
- Non-Hispanic White populations served have higher exposure above the UCMR 5 MRL values across all four PFAS analytes compared to the percent of the population served across all demographic groups.
- Populations with income above twice the poverty level have higher exposure above the UCMR 5 MRL values for PFOS, PFHpA, and PFOA compared to the percent of the population served across all demographic groups.

Table 8-18 characterizes population-weighted average reductions in PFAS exposures anticipated to occur for large and small PWSs in a hypothetical regulatory scenario where system-level means are reduced to UCMR 5 MRLs. As in Table 8-16, Hispanic populations have the greatest exposures above UCMR 5 MRLs of any demographic group among large PWSs. The results also show that Black populations have higher average exposures to PFOS and PFHxS than the total population served across all demographic groups in large PWSs, although a lower percentage of this population experiences exposure to PFAS above MRL levels in large PWSs. Collectively, people of color served by large PWSs see larger reductions in exposure across all four PFAS in this hypothetical regulatory scenario than the total population served across all demographic groups. For small systems, Black and non-Hispanic White populations have larger reductions in PFOS than the total population served across all demographic groups, and non-Hispanic White populations also see somewhat larger reductions in PFOA. In general, however, differences in PFAS reductions across demographic groups are slight for small systems.

It should be noted that the sample size of small PWS service areas included in categories 1 and 2 with PFAS exposure above UCMR 5 MRL values is limited and could meaningfully impact the results presented herein. The population served by small category 1 and 2 PWS service areas included in this analysis captures roughly 1 percent of the total U.S. population. Given that approximately 20 percent of the U.S. population is served by small systems, this subset of systems may not be representative of small systems across the U.S., and results from this analysis cannot be extrapolated to be representative of small systems nationwide. Additionally, the population served by the subset of small systems in categories 1 and 2 is disproportionately non-Hispanic White, with 13.09 higher percentage point representation compared to the overall U.S. population. The population served is also less Hispanic, with representation of this group being 6.59 percentage points lower than the overall U.S. population. Further evaluation is needed to demonstrate whether the sample population served by small category 1 and 2 PWS service areas is representative of the demographic breakdown of all small systems nationwide.

Table 8-16: Hypothetical Regulatory Scenario #1: Demographic Breakdown of Population Served by Category 1 and 2 PWS Service Areas Above UCMR 5 MRLs and as a Percent of Total Population Served, Large Systems

			Ra	ce and Ethni	city		Inc	come		
		American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served	System Count
	PFOS	82,776	860,437	1,581,076	3,610,906	4,867,952	3,731,804	7,352,841	11,084,645	306
Population	PFHxS	81,853	656,474	1,419,053	3,161,347	4,481,038	3,264,982	6,605,550	9,870,532	200
Served Above UCMR 5 MRL	PFHpA	43,053	386,554	1,075,433	2,308,921	2,640,787	2,274,284	4,221,951	6,496,235	297
	PFOA	59,931	866,578	1,809,639	3,498,968	5,225,904	3,734,032	7,827,235	11,561,267	411
Population	PFOS	5.67%	5.37%	4.61%	7.82%	3.62%	4.94%	4.58%	4.69%	-
Served Above UCMR 5 MRL as	PFHxS	<mark>5.61%</mark>	4.10%	4.14%	<mark>6.84%</mark>	3.34%	4.32%	4.11%	4.18%	-
a Percentage of	PFHpA	2.95%	2.41%	3.14%	5.00%	1.97%	3.01%	2.63%	2.75%	-
Total Population Served	PFOA	4.10%	5.41%	5.28%	<mark>7.57%</mark>	3.89%	4.94%	4.87%	4.89%	-
Total Population Se Sampled Population		1,460,058	16,019,564	34,265,272	46,196,824	134,300,144	75,618,752	160,696,528	236,315,280	-

Abbreviations: MRL – minimum reporting level; PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid; UCMR – Unregulated Contaminant Monitoring Rule.

Table 8-17: Hypothetical Regulatory Scenario #1: Demographic Breakdown of Population Served by Category 1 and 2 PWS Service Areas Above UCMR 5 MRLs and as a Percent of Total Population Served, Small Systems

			Rac	e and Ethnic	ity		Inc	ome		
		American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served	System Count
	PFOS	221	722	4,341	1,494	32,911	7,708	31,389	39,097	15
Population	PFHxS	128	65	113	181	11,086	3,504	8,222	11,726	9
Served Above UCMR 5 MRL	PFHpA	11	256	116	282	8,084	889	7,996	8,885	12
	PFOA	93	676	346	1,290	19,517	2,974	18,981	21,955	21
Population Served Above	PFOS	0.38%	1.06%	1.37%	0.40%	1.39%	0.70%	1.46%	1.21%	-
UCMR 5 MRL	PFHxS	0.22%	0.10%	0.04%	0.05%	0.47%	0.32%	0.38%	0.36%	-
as a Percentage of Total	PFHpA	0.02%	0.38%	0.04%	0.07%	0.34%	0.08%	0.37%	0.27%	-
Population Served	PFOA	0.16%	0.99%	0.11%	0.34%	0.82%	0.27%	0.89%	0.68%	-
Total Population Sampled Populat		58,311	68,007	317,990	376,431	2,372,983	1,098,134	2,144,171	3,242,305	

Abbreviations: MRL – minimum reporting level; PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid; UCMR – Unregulated Contaminant Monitoring Rule.

Table 8-18: Reductions in Average PFAS Concentrations (ppt) by Demographic Group in a Hypothetical Regulatory Scenario with Maximum Contaminant Levels at the UCMR 5 MRLs, Category 1 and 2 PWS Service Areas

			Ra	ce and Ethnici	ty		Inco	ome	
PFAS	American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	People of Color ^a	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served
Large Systems	s								
PFOS	0.27	0.25	0.25	0.33	0.28	0.18	0.26	0.21	0.22
PFHxS	0.25	0.16	0.18	0.20	0.19	0.13	0.18	0.14	0.16
PFHpA	0.04	0.03	0.06	0.07	0.06	0.04	0.06	0.05	0.05
PFOA	0.16	0.22	0.19	0.25	0.22	0.16	0.19	0.18	0.19
Small Systems	S								
PFOS	0.03	0.06	0.13	0.05	0.07	0.12	0.09	0.11	0.10
PFHxS	0.02	0.02	0.01	0.03	0.02	0.04	0.03	0.04	0.04
PFHpA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PFOA	0.00	0.05	0.00	0.02	0.01	0.04	0.01	0.04	0.03

Abbreviations: PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid. Note:

^aThe demographic group people of color includes individuals who identify as Hispanic and/or a race other than White. It is calculated from EJScreen's percent minority indicator and is non-duplicative across race and ethnicity categories.

8.3.2.3.4 Hypothetical Regulatory Scenario #2: 10.0 ppt

Table 8-19 summarizes results for populations served by large category 1 and 2 PWS service areas with PFAS occurrence above 10.0 ppt. Table 8-20 summarizes results for populations served by small category 1 and 2 PWS service areas with PFAS occurrence above 10.0 ppt. Table 8-21 characterizes population-weighted average reductions in PFAS exposures anticipated to occur for large and small PWSs in a hypothetical regulatory scenario where system-level means are reduced to 10.0 ppt. The first set of rows in Table 8-19 and Table 8-20 summarizes populations served by large and small category 1 and 2 PWSs with modeled PFAS occurrence above the 10.0 ppt, respectively. The second set of rows provides these estimates as a percentage of the total population served by these PWS service areas.

In Table 8-19 and Table 8-20, percentages are bolded and italicized when the percent of the population in a specific demographic group with PFAS occurrence above 10.0 ppt is greater than the percentage of the total population across all demographic groups with PFAS occurrence above 10.0 ppt. Table 8-21, highlighted cells represent whether the average reduction for a given demographic group is higher than the reductions for the total population served across all demographic groups in large and small PWSs (right-hand column). The percentages that are bolded, italicized, or highlighted indicate more PFAS exposure above 10.0 ppt for a given demographic group; EPA anticipates relatively higher reductions in PFAS exposure will accrue to these demographic groups under this hypothetical regulatory scenario compared to the percentage of the population across all demographic groups.

For large systems, American Indian or Alaska Native, Asian and Pacific Islander, Black, and Hispanic populations as well as populations with income below twice the poverty level have elevated exposure above 10.0 ppt for particular PFAS analytes compared to the population served across all demographic groups.

For small systems, Asian and Pacific Islander, Black, and non-Hispanic White populations have elevated exposure above 10.0 ppt for particular PFAS analytes compared to the population served across all demographic groups. The average reductions by demographic group, shown in Table 8-21, largely confirm the findings of Table 8-19 and Table 8-20, with greater average reductions generally accruing to populations with a higher percentage of potentially exposed individuals for large and small PWSs.

As previously noted, the sample size of small PWS service areas included in categories 1 and 2 is limited, with population served capturing roughly 1 percent of the total U.S. population. Additionally, the population served by the subset of small systems in categories 1 and 2 is disproportionately White and non-Hispanic compared to the overall U.S. population, as previously discussed. Further evaluation is needed to demonstrate whether the sample population served by small category 1 and 2 PWS service areas is representative of the demographic breakdown of all small systems nationwide.

Table 8-19: Hypothetical Regulatory Scenario #2: Demographic Breakdown of Population Served by Category 1 and 2 PWS Service Areas Above 10.0 ppt and as a Percent of Total Population Served, Large Systems

			Ra	ce and Ethnici	ty		Inco	ome		
		American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served	System Count
Population	PFOS	18,161	189,206	427,433	602,112	1,258,751	925,193	1,609,362	2,534,555	42
Served	PFHxS	14,774	70,599	133,793	174,106	556,601	355,138	614,293	969,431	25
Above 10.0	PFHpA	2,534	10,830	82,127	52,010	220,399	131,069	244,365	375,434	7
ppt	PFOA	7,491	138,790	230,052	213,388	787,930	436,150	964,752	1,400,902	34
Population	PFOS	1.24%	1.18%	1.25%	1.30%	0.94%	1.22%	1.00%	1.07%	_
Served	PFHxS	1.01%	0.44%	0.39%	0.38%	0.41%	0.47%	0.38%	0.41%	_
Above 10.0	PFHpA	0.17%	0.07%	0.24%	0.11%	0.16%	0.17%	0.15%	0.16%	-
ppt as a Percentage of Total Population Served	PFOA	0.51%	0.87%	0.67%	0.46%	0.59%	0.58%	0.60%	0.59%	-
Total Populat Served in Sar Population		1,460,058	16,019,564	34,265,272	46,196,824	134,300,144	75,618,752	160,696,528	236,315,280	-

Abbreviations: PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid; ppt – parts per trillion.

Table 8-20: Hypothetical Regulatory Scenario #2: Demographic Breakdown of Population Served by Category 1 and 2 PWS Service Areas Above 10.0 ppt and as a Percent of Total Population Served, Small Systems

			Race a	and Ethnicity			Incom	ie	Total	G 4
		American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	Non-Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Population Served	System Count
Population	PFOS	134	65	4,043	192	16,673	6,219	14,307	20,526	4
Served	PFHxS	123	39	74	136	7,513	2,058	5,955	8,013	2
Above 10.0 ppt	PFHpA	1	7	11	48	155	81	149	230	1
PPt	PFOA	11	256	116	282	8,084	889	7,996	8,885	2
Population	PFOS	0.23%	0.10%	1.27%	0.05%	0.70%	0.57%	0.67%	0.63%	-
Served	PFHxS	0.21%	0.06%	0.02%	0.04%	0.32%	0.19%	0.28%	0.25%	-
Above 10.0 ppt as a Percentage	PFHpA	0.00%	0.01%	0.00%	0.01%	0.01%	0.01%	0.01%	0.01%	-
of Total Population Served	PFOA	0.02%	0.38%	0.04%	0.07%	0.34%	0.08%	0.37%	0.27%	-
Total Populat Served in Sar Population		58,311	68,007	317,990	376,431	2,372,983	1,098,134	2,144,171	3,242,305	-

 $Abbreviations: PFHpA-perfluoroheptanoic\ acid; PFHxS-perfluorohexane sulfonic\ acid; PFOA-perfluorooctanoic\ acid; PFOS-perfluorooctane sulfonic\ acid; ppt-parts\ perfluoron.$

Table 8-21: Reductions in Average PFAS Concentrations (ppt) by Demographic Group in a Hypothetical Regulatory Scenario with Maximum Contaminant Levels at 10.0 ppt, Category 1 and 2 PWS Service Areas

			Ra	ice and Ethnici	ty		Inco	ome	
PFAS	American Indian or Alaska Native	Asian and Pacific Islander	Black	Hispanic	People of Color ^a	Non- Hispanic White	Below Twice the Poverty Level	Above Twice the Poverty Level	Total Population Served
Large Systems	S								
PFOS	0.10	0.11	0.11	0.12	0.11	0.08	0.12	0.08	0.09
PFHxS	0.07	0.07	0.08	0.07	0.07	0.05	0.08	0.05	0.06
PFHpA	0.00	0.00	0.01	0.00	0.00	0.01	0.01	0.00	0.00
PFOA	0.04	0.04	0.06	0.04	0.05	0.05	0.05	0.04	0.05
Small Systems	;								
PFOS	0.01	0.03	0.05	0.03	0.04	0.06	0.05	0.05	0.05
PFHxS	0.01	0.02	0.01	0.02	0.02	0.02	0.02	0.02	0.02
PFHpA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
PFOA	0.00	0.01	0.00	0.00	0.00	0.00	0.00	0.01	0.00

Abbreviations: PFHpA – perfluoroheptanoic acid; PFHxS – perfluorohexanesulfonic acid; PFOA – perfluorooctanoic acid; PFOS – perfluorooctanesulfonic acid. Note:

^aThe demographic group people of color includes individuals who identify as Hispanic and/or a race other than White. It is calculated from EJScreen's percent minority indicator and is non-duplicative across race and ethnicity categories.

8.4 SafeWater EJ Analysis of Proposed Regulatory Option and Alternatives

8.4.1 Methodology

In addition to analyzing EJ exposure using the EJSCREENbatch R package, EPA also conducted an EJ analysis of the proposed regulatory option and regulatory alternatives using the SafeWater Multi-Contaminant Benefit-Cost Model (MCBC). EPA's proposed option sets MCLs of 4.0 ppt for PFOA and PFOS and an HI of 1.0 for PFNA, HFPO-DA, PFHxS, and PFBS. Options 1a, 1b, and 1c set MCL values for PFOA and PFOS at 4.0 ppt, 5.0 ppt, and 10.0 ppt, respectively.

SafeWater MCBC was used to analyze the distribution of anticipated health benefits and household costs associated with the proposed PFAS NPDWR across race/ethnicity groups. For more information on SafeWater MCMC and its application in EPA's analysis of national quantified benefits and costs associated with the proposed PFAS NPDWR, see Section 5.2.

Using SafeWater MCBC, EPA estimated the quantified health benefits and household costs expected to accrue to specific race/ethnicity groups for category 1 and 2 PWS service areas. As previously described in Section 8.3.1, category 1 and 2 PWS service areas include systems that have sampled PFAS occurrence data from UCMR 3 and have predelineated service area boundaries or those estimated using zip code served information (n=4,723). The subset of category 1 and 2 PWSs captured in the analysis represents roughly 3 percent of active PWSs. ¹⁰¹

Results are presented across four race/ethnicity groups, consistent with the subpopulation definitions used to estimate the national quantified benefits for the proposed PFAS NPDWR (see Section 8.1). These race/ethnicity groups include: non-Hispanic Black, Hispanic, non-Hispanic White, and Other. Race/ethnicity categories examined in EPA's analysis using SafeWater MCBC differ from the demographic groups presented in the exposure analysis discussed previously in this chapter due to the availability of demographic information utilized in EPA's quantified benefits analysis. For more information on the selection of data inputs to EPA's benefit analysis, see Chapter 6.

The total sample population captured by EPA's analysis using SafeWater MCBC is roughly 196 million people, with a breakdown by race/ethnicity group as follows:

• Non-Hispanic Black: 25.1 million (~13%)

• Hispanic: 32.6 million (~17%)

• Other: 12.2 million (~6%)

• Non-Hispanic White: 125.9 million (~64%)

When compared to the breakdown of the total U.S. population by these same race/ethnicity groups, the makeup of the sample population in EPA's analysis is generally representative of the

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¹⁰¹ The number of active PWSs was retrieved from SDWIS/Fed fourth quarter 2021.

 $^{^{102}}$ The "Other" race/ethnicity category includes any race/ethnicity populations that are *not* non-Hispanic Black, Hispanic, or non-Hispanic White.

overall U.S. population. Non-Hispanic Black, Hispanic, and Other race/ethnicity groups (making up ~13 percent, ~19 percent, and ~8 percent of the U.S. population, respectively) are slightly underrepresented, while the non-Hispanic White race/ethnicity group (making up ~60% of the U.S. population) is slightly overrepresented in EPA's analysis (U.S. Census Bureau, 2020a).

Because demographic proportion information utilized in EPA's benefits analysis was available at the county level, EPA utilized the following step-by-step approach to identify the number of people in each race/ethnicity group within a given PWS service area. Specifically, in this order, EPA utilized the following stepwise approach:

- 1. Overlayed census block groups with PWS service area boundaries;
- 2. Calculated the area of each census block group and PWS service area boundary;
- 3. Calculated the percent of each census block group overlapping each PWS service area boundary;
- 4. Multiplied the population of the census block group by the percent of each census block overlapping each PWS service area boundary;
- 5. Summed across census block groups to calculate the population in each PWS service area boundary that lives in each county;
- 6. Calculated the percent of the population in each county (PWS_county_weight) for each PWS; and
- 7. Estimated the number of people served by a PWS for each subpopulation as follows:

Equation 24:

$$SubPop = \sum_{c} PWS_county_weight_c \ x \ PWS_Pop \ x \ Subpop_share_c$$

Where:

SubPop = number of people in each subpopulation served by a PWS

PWS_County_weight_c = the percentage of the PWS population in each county (c)

PWS_Pop = Number of people served by PWS from SDWIS/Fed inventory

Subpop_share $_c$ = The share of county (c) population consisting of the subpopulation from the U.S. Census

As part of its national analysis of quantified benefits and costs using SafeWater MCBC, EPA accounted for states that have enacted enforceable MCLs for PFAS contaminants. For these states, EPA assumed that the state MCL is the maximum baseline PFAS occurrence value for all entry points in the state. For more information on this assumption and on state-enacted MCLs, see Section 4. EPA has applied this assumption as part of its EJ analysis conducted in SafeWater MCBC.

8.4.2 SafeWater EJ Analysis Results 8.4.2.1 Health Benefits

To determine if there are disproportionate health impacts borne by any race/ethnicity subpopulation under the proposed regulatory option or regulatory alternatives, EPA estimated the annual avoided cases of mortality and morbidity per 100,000 people, as shown in Table 8-22 through Table 8-25.

For the analysis conducted in SafeWater MCBC, EPA reports the estimated avoided cases of mortality and morbidity by race/ethnicity group for the following health endpoints:

- Cardiovascular disease (CVD): Non-fatal myocardial infarction (MI), non-fatal ischemic stroke (IS), CVD deaths
- Renal cell carcinoma (RCC): Non-fatal RCC cases avoided, fatal RCC cases avoided
- Birth weight: Birth weight gain (total grams), birth weight-related deaths avoided

Baseline incidence associated with these health endpoints varies by race/ethnicity, and disparities in underlying incidence by race/ethnicity likely influence the distribution of quantified health benefits expected under the proposed PFAS NPDWR. For example, non-fatal MI incidence is generally most prevalent among non-Hispanic White males, while non-fatal IS incidence is generally most prevalent among non-Hispanic Black males. The demographic distribution of quantified health benefits presented here incorporates differing prevalence in baseline health outcomes by race/ethnicity. As such, the demographic distribution of quantified health benefits that EPA reports here have not been adjusted for underlying disparities in death or disease incidence by race/ethnicity and therefore provides a comprehensive evaluation of quantified benefits across race/ethnicity groups. For a detailed breakdown of incidence associated with the effects of reduced birth weight on infant mortality, CVD events, and RCC by race/ethnicity, see Appendices E, G, and J, respectively.

EPA did not analyze the demographic breakdown of bladder cancer cases avoided that are expected to result from the co-removal of PFAS and DBP precursors (discussed in Section 6.7). EPA models bladder cancer impacts based on a national-level distribution of finished water TOC levels; because specific TOC levels at actual PWSs are not available, EPA did not include these impacts in the portion of its EJ analysis conducted in SafeWater MCBC.

Table 8-22 summarizes the number of avoided cases of morbidity and mortality per 100,000 people per year for all health endpoints evaluated under EPA's proposed regulatory option. Table 8-23 through Table 8-25 summarize the number of avoided cases of morbidity and mortality per 100,000 people per year for all health endpoints evaluated under EPA's regulatory alternatives.

Across the proposed option and all regulatory alternatives, benefits are anticipated to be realized across all health endpoints and race/ethnicity groups evaluated. A summary of benefits anticipated for each health endpoint is included below. In general, when comparing benefits under the proposed option to those across regulatory alternatives, the distribution of quantified health benefits for a given race/ethnicity group is relatively similar. Variation exists between the proposed option and regulatory alternatives with respect to the total amount of health benefits anticipated. Additionally, across all health endpoints evaluated and across all race/ethnicity groups, the greatest benefits are anticipated under the proposed option.

Below is a summary of quantified health benefits categorized by endpoint, with results presented across the proposed option and regulatory alternatives and across race/ethnicity groups.

Cardiovascular Disease

Non-Fatal MI Cases Avoided — Under the proposed option and all alternatives and across all race/ethnicity groups, values range from 0.84 to 3.59 cases avoided per 100,000 people per year. Under the proposed option and all alternatives, EPA anticipates the greatest benefit to accrue to Other race/ethnicity groups and the lowest benefit to accrue to the non-Hispanic Black race/ethnicity group.

Non-Fatal IS Cases Avoided – Under the proposed option and all alternatives and across all race/ethnicity groups, values range from 1.73 to 5.97 cases avoided per 100,000 people per year. Under the proposed option and all alternatives, EPA anticipates the greatest benefit to accrue to the non-Hispanic Black race/ethnicity group and the lowest benefit to accrue to the non-Hispanic White race/ethnicity group. ¹⁰³

CVD Deaths Avoided – Under the proposed option and all alternatives and across all race/ethnicity groups, values range from 0.51 to 3.10 deaths avoided per 100,000 people per year. Under the proposed option and all alternatives, EPA anticipates the greatest benefit to accrue to the non-Hispanic Black race/ethnicity group and the lowest benefit to accrue to the Hispanic race/ethnicity group.

Renal Cell Carcinoma

Non-Fatal RCC Cases Avoided – Under the proposed option and all alternatives and across all race/ethnicity groups, values range from 1.01 to 3.16 cases avoided per 100,000 people per year. Under the proposed option and all alternatives, EPA anticipates the greatest benefit to accrue to Other race/ethnicity groups and the lowest benefit to accrue to the non-Hispanic Black race/ethnicity group.

Fatal RCC Cases Avoided – Under the proposed option and all alternatives and across all race/ethnicity groups, values range from 0.27 to 0.97 deaths avoided per 100,000 people per year. Under the proposed option and all alternatives, EPA expects the greatest benefit to accrue to the Hispanic race/ethnicity group and the lowest benefit to accrue to the non-Hispanic White race/ethnicity group.

Birth Weight

Birth Weight Gain (total grams) – Under the proposed option and all alternatives and across all race/ethnicity groups, values range from 34,024 grams to 115,689 grams of birth weight gain per 100,000 people per year. Under the proposed option and all alternatives, EPA expects the largest benefit to accrue to the Hispanic race/ethnicity group and the lowest benefit to accrue to the non-Hispanic White race/ethnicity group.

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¹⁰³ The non-Hispanic White race/ethnicity group is anticipated to experience the lowest benefit related to non-fatal IS cases avoided, except under Option 1c where both non-Hispanic White and Hispanic race/ethnicity groups are anticipated to experience the lowest benefit (i.e., 1.73 cases avoided per 100,000 people).

Birth Weight-Related Deaths Avoided – Under the proposed option and all alternatives and across all race/ethnicity groups, values range from 0.19 to 0.75 birth weight-related deaths avoided per 100,000 people per year. Under the proposed option and all alternatives, EPA anticipates the greatest benefit to accrue to the non-Hispanic Black race/ethnicity group and the lowest benefit to accrue to the non-Hispanic White race/ethnicity group.

Table 8-22: Annualized Cases Avoided per 100,000 People by Race/Ethnicity Group, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0)

Health Endpoint	Non- Hispanic Black	Hispanic	Other	Non- Hispanic White
Non-Fatal MI Cases Avoided	1.86	2.60	3.59	2.78
Non-Fatal IS Cases Avoided	5.97	3.67	3.95	3.62
CVD Deaths Avoided	3.10	1.08	1.32	1.21
Non-Fatal RCC Cases Avoided	2.61	2.78	3.16	2.72
Fatal RCC Cases Avoided	0.76	0.97	0.85	0.70
Birth Weight Gain (total grams)	92,441	115,689	105,872	67,668
Birth Weight-Related Deaths Avoided	0.75	0.64	0.47	0.38

 $Abbreviations: CVD-cardiovascular\ disease;\ MI-myocardial\ infarction;\ IS-ischemic\ stroke;\ RCC-renal\ cell\ carcinoma.$

Table 8-23: Annualized Cases Avoided per 100,000 People by Race/Ethnicity Group, Option 1a (PFOA and PFOS MCLs of 4.0 ppt)

Health Endpoint	Non- Hispanic Black	Hispanic	Other	Non- Hispanic White
Non-Fatal MI Cases Avoided	1.83	2.56	3.54	2.74
Non-Fatal IS Cases Avoided	5.86	3.61	3.89	3.56
CVD Deaths Avoided	3.05	1.06	1.30	1.19
Non-Fatal RCC Cases Avoided	2.56	2.73	3.10	2.67
Fatal RCC Cases Avoided	0.75	0.95	0.84	0.68
Birth Weight Gain (total grams)	90,753	113,827	104,297	66,562
Birth Weight-Related Deaths Avoided	0.74	0.63	0.46	0.38

 $Abbreviations: CVD-cardiovascular\ disease;\ MI-myocardial\ infarction;\ IS-ischemic\ stroke;\ RCC-renal\ cell\ carcinoma.$

Table 8-24: Annualized Cases Avoided per 100,000 People by Race/Ethnicity Group, Option 1b (PFOA and PFOS MCLs of 5.0 ppt)

Health Endpoint	Non- Hispanic Black	Hispanic	Other	Non- Hispanic White
Non-Fatal MI Cases Avoided	1.58	2.22	3.08	2.37
Non-Fatal IS Cases Avoided	5.05	3.13	3.39	3.08
CVD Deaths Avoided	2.62	0.92	1.13	1.03
Non-Fatal RCC Cases Avoided	2.14	2.30	2.63	2.22
Fatal RCC Cases Avoided	0.62	0.80	0.71	0.57
Birth Weight Gain (total grams)	78,860	99,954	91,914	58,186
Birth Weight-Related Deaths Avoided	0.64	0.55	0.40	0.33

 $Abbreviations: CVD-cardiovascular\ disease;\ MI-myocardial\ infarction;\ IS-ischemic\ stroke;\ RCC-renal\ cell\ carcinoma.$

Table 8-25: Annualized Cases Avoided per 100,000 People by Race/Ethnicity Group, Option 1c (PFOA and PFOS MCLs of 10.0 ppt)

Health Endpoint	Non- Hispanic Black	Hispanic	Other	Non- Hispanic White
Non-Fatal MI Cases Avoided	0.84	1.23	1.70	1.33
Non-Fatal IS Cases Avoided	2.70	1.73	1.87	1.73
CVD Deaths Avoided	1.40	0.51	0.62	0.58
Non-Fatal RCC Cases Avoided	1.01	1.15	1.35	1.05
Fatal RCC Cases Avoided	0.29	0.40	0.37	0.27
Birth Weight Gain (total grams)	44,270	58,434	53,923	34,024
Birth Weight-Related Deaths Avoided	0.36	0.32	0.24	0.19

 $Abbreviations: CVD-cardiovascular\ disease;\ MI-myocardial\ infarction;\ IS-ischemic\ stroke;\ RCC-renal\ cell\ carcinoma.$

8.4.2.2 Household Costs

For category 1 and 2 PWS service areas, EPA used SafeWater MCBC to estimate the distribution of average annual incremental household costs across race/ethnicity groups. The results are provided by system size category in Table 8-26 and Table 8-27. In addition to presenting average incremental household costs for each race/ethnicity group, EPA also presents household costs across "All" race/ethnicity groups to provide a basis for comparison.

In estimating annualized incremental household costs of the proposed PFAS NPDWR, SafeWater MCBC first divided each PWS's total compliance costs by the PWS's average daily flow to determine the cost of compliance per 1,000 gallons of daily flow. Next, this cost was multiplied by the average household consumption from the Community Water System Survey (CWSS) to calculate the average household cost of compliance for the PWS. To calculate the average household cost for each race/ethnicity group by PWS system size strata, for each PWS included in the subset of systems in EPA's EJ analysis, EPA calculated a weighted average household cost by using the number of people in each race/ethnicity group served by each PWS as the weight. In addition to estimating the demographic breakdown of annualized incremental household costs of the proposed PFAS NPDWR for all systems included in EPA's EJ analysis, EPA also estimated the demographic breakdown of annualized incremental household costs for just the subset of PWSs that are anticipated to install treatment to comply with the rule. 104

Below is a summary of the demographic distribution of incremental household costs, categorized by system size, for the proposed option and regulatory alternatives. Results are presented both for the entire subset of PWSs included in EPA's EJ analysis and just those anticipated to install treatment under the rule. Note that an analysis of household costs served by systems serving fewer than 3,300 people could not be completed due to limited sample size. Except in one case, the proposed option is anticipated to have the largest associated costs, and Option 1c is anticipated to have the lowest associated costs.

8.4.2.2.1 Incremental Household Costs for All PWSs

System size 3,300 to 10,000 – Average incremental household costs range from \$5.20 to \$17.79 per year across the proposed option and regulatory alternatives and across race/ethnicity groups. When comparing household costs borne by particular race/ethnicity groups to those borne by the overall population served by systems in this size category, the non-Hispanic Black race/ethnicity group bears minimal elevated household costs under the proposed option and all regulatory alternatives. Additionally, the Hispanic and Other race/ethnicity groups bear minimal elevated household costs under the proposed option and Options 1a and 1b. The magnitude of household cost differences between each of these race/ethnicity groups and the overall population is small, ranging from \$0.39 to \$2.53 per year across race/ethnicity groups and across the proposed option and regulatory alternatives. The non-Hispanic Black race/ethnicity group bears the highest household cost, while the Hispanic race/ethnicity group bears the lowest household cost.

System size 10,000 to 50,000 – Average incremental household costs range from \$2.71 to \$9.11 per year across the proposed option and regulatory alternatives and across race/ethnicity groups. When comparing household costs borne by particular race/ethnicity groups to those borne by the

¹⁰⁴ For additional detail on treatment technology selection among systems anticipated to install treatment under the proposed rule, see Section 5.3.1.1.

overall population served by systems in this size category, the Other race/ethnicity group bears minimal elevated household costs under the proposed option and all regulatory alternatives. The magnitude of these household cost differences is very small, ranging from \$0.02 to \$0.90 per year across race/ethnicity groups and across the proposed option and regulatory alternatives. The Other race/ethnicity group bears the highest household cost, while the non-Hispanic Black race/ethnicity group bears the lowest household cost.

System size 50,000 to 100,000 – Average incremental household costs range from \$1.51 to \$5.97 per year across the proposed option and regulatory alternatives and across race/ethnicity groups. When comparing household costs borne by particular race/ethnicity groups to those borne by the overall population served by systems in this size category, the Hispanic and Other race/ethnicity groups bear minimal elevated household costs under the proposed option and all regulatory alternatives. The magnitude of these household cost differences is very small, ranging from \$0.21 to \$0.74 per year across race/ethnicity groups and across the proposed option and regulatory alternatives. The Other race/ethnicity group bears the highest household cost, while the non-Hispanic Black race/ethnicity group bears the lowest household cost.

System size 100,000 to 1,000,000 – Average incremental household costs range from \$2.53 to \$10.04 per year across the proposed option and regulatory alternatives and across race/ethnicity groups. When comparing household costs borne by particular race/ethnicity groups to those borne by the overall population served by systems in this size category, the Hispanic and Other race/ethnicity groups bear minimal elevated household costs under the proposed option and all regulatory alternatives. As in other system size categories, the magnitude of these household cost differences is small, ranging from \$0.53 to \$1.87 per year across race/ethnicity groups and across the proposed option and regulatory alternatives. The Hispanic race/ethnicity group bears the highest household cost, while the non-Hispanic Black race/ethnicity group bears the lowest household cost.

EPA's comparison of incremental household costs across system size categories reveals that, in general, as system size increases, average incremental household costs decrease under the proposed option and all regulatory alternatives and across all race/ethnicity groups. One exception to this trend is among systems serving 100,000 to 1,000,000 people, where costs are marginally higher than for systems serving 50,000 to 100,000 people.

The highest average incremental household costs under the proposed option and all regulatory alternatives are realized for the smallest systems (i.e., systems serving 3,300 to 10,000 people). The range of household costs within this system size category is \$5.20 to \$17.79 per year, and EPA anticipates the highest cost (\$17.79 per year) under the proposed option for the non-Hispanic Black race/ethnicity group. The lowest average incremental household costs under the proposed option and all regulatory alternatives are realized for systems serving 50,000 to 100,000 people. The range of household costs within this system size category is \$1.51 to \$6.48, with the non-Hispanic Black race/ethnicity group having the lowest cost of \$1.51 under Option 1c.

Comparing the magnitude of household costs anticipated across system size categories illustrates the role that system size plays in household costs anticipated under the proposed PFAS rule. This is an expected result due to economies of scale and the impact that a smaller customer and tax base has on costs per household for funding and financing capital and operational infrastructure

investments. Further, this analysis includes the estimated household costs for all systems impacted by the rule, not just the systems expected to install and operate treatment after exceeding the proposed MCLs. Households served by water systems triggered into treatment are expected to face greater cost increases than those presented here. EPA presents the demographic breakdown of estimated household costs for those systems anticipated to install treatment under the proposed rule in Section 8.4.2.2.2. Additionally, EPA assesses the impact of treatment technology costs specifically on small system households in the small system affordability analysis. For more information, see EPA's assessment of small system affordability in Section 9.12.

Table 8-26: Annualized Population Weighted Household Cost by PWS Size Category and Race/Ethnicity Group (\$2021)

System Size ^a	Race/Ethnicity Group	Proposed Option ^b	Option 1a ^c	Option 1b ^d	Option 1ce
3,300 to 10,000	All	\$15.25	\$15.08	\$11.93	\$5.34
3,300 to 10,000	Non-Hispanic Black	\$17.79	\$17.61	\$14.14	\$6.40
3,300 to 10,000	Hispanic Black	\$16.00	\$15.83	\$12.48	\$5.20
3,300 to 10,000	Other	\$15.88	\$15.63	\$12.32	\$5.29
3,300 to 10,000	Non-Hispanic White	\$14.75	\$14.58	\$11.51	\$5.21
10,000 to 50,000	All	\$8.20	\$8.03	\$6.38	\$2.80
10,000 to 50,000	Non-Hispanic Black	\$8.06	\$7.90	\$6.25	\$2.71
10,000 to 50,000	Hispanic	\$8.22	\$8.03	\$6.35	\$2.77
10,000 to 50,000	Other	\$9.11	\$8.91	\$7.15	\$3.23
10,000 to 50,000	Non-Hispanic White	\$8.16	\$7.99	\$6.35	\$2.79
50,000 to 100,000	All	\$5.74	\$5.59	\$4.31	\$1.71
50,000 to 100,000	Non-Hispanic Black	\$5.22	\$5.10	\$3.92	\$1.51
50,000 to 100,000	Hispanic	\$5.97	\$5.80	\$4.54	\$1.99
50,000 to 100,000	Other	\$6.48	\$6.27	\$4.93	\$2.12
50,000 to 100,000	Non-Hispanic White	\$5.69	\$5.54	\$4.25	\$1.62
100,000 to 1,000,000	All	\$8.25	\$7.96	\$6.41	\$2.86
100,000 to 1,000,000	Non-Hispanic Black	\$7.70	\$7.42	\$5.93	\$2.53
100,000 to 1,000,000	Hispanic	\$9.31	\$8.96	\$7.28	\$3.39
100,000 to 1,000,000	Other	\$10.04	\$9.71	\$8.08	\$3.99
100,000 to 1,000,000	Non-Hispanic White	\$7.84	\$7.58	\$6.07	\$2.64

Notes:

^aThe number of systems serving fewer than 3,300 people represented in the UMCR 3 occurrence data is too limited to accurately estimate average population-weighted household costs by subpopulation. Therefore, results for these small systems are omitted. Also, household costs in this exhibit are population-weighted and will not match average household costs by size category shown in other exhibits in the economic analysis document that are not population-weighted.

^bThe proposed option sets PFOA and PFOS MCLs of 4.0 ppt and an HI of 1.0.

^cOption 1a sets PFOA and PFOS MCLs of 4.0 ppt.

dOption 1b sets PFOA and PFOS MCLs of 5.0 ppt.

eOption 1c sets PFOA and PFOS MCLs of 10.0 ppt.

8.4.2.2.2 Incremental Household Costs for Treating PWSs

System size 3,300 to 10,000 – Average incremental household costs for systems anticipated to install treatment range from \$91.40 to \$122.25 per year across the proposed option and regulatory alternatives and across race/ethnicity groups. When comparing household costs borne by particular race/ethnicity groups to those borne by the overall population served by systems in this size category, the non-Hispanic Black race/ethnicity group bears minimal elevated household costs under the proposed option and all regulatory alternatives. Additionally, the Hispanic race/ethnicity group bears minimal elevated household costs under the proposed option and Option 1a, and the non-Hispanic White race/ethnicity group bears minimal elevated household costs under Options 1b and 1c. The magnitude of household cost differences between each of these race/ethnicity groups and the overall population ranges from \$0.17 to \$9.47 per year across race/ethnicity groups and across the proposed option and regulatory alternatives. The non-Hispanic Black race/ethnicity group bears the highest household cost, while the Hispanic race/ethnicity group bears the lowest household cost.

System size 10,000 to 50,000 – Average incremental household costs for systems anticipated to install treatment range from \$24.58 to \$33.31 per year across the proposed option and regulatory alternatives and across race/ethnicity groups. When comparing household costs borne by particular race/ethnicity groups to those borne by the overall population served by systems in this size category, the non-Hispanic White race/ethnicity group bears minimal elevated household costs under the proposed option and all regulatory alternatives. Additionally, the Other race/ethnicity group bears minimal elevated household costs under the proposed option, and Options 1a and 1b and the non-Hispanic Black race/ethnicity group bears minimal elevated costs under all regulatory alternatives (Options 1a-1c). The magnitude of household cost differences between each race/ethnicity groups and the overall population is extremely small, ranging from \$0.01 to \$0.43 per year across race/ethnicity groups and across the proposed option and regulatory alternatives. The non-Hispanic White race/ethnicity group bears the highest household cost, while the Hispanic race/ethnicity group bears the lowest household cost.

System size 50,000 to 100,000 – Average incremental household costs for systems anticipated to install treatment range from \$17.63 to \$23.90 per year across the proposed option and regulatory alternatives and across race/ethnicity groups. When comparing household costs borne by particular race/ethnicity groups to those borne by the overall population served by systems in this size category, the Other and non-Hispanic White race/ethnicity groups bear minimal elevated costs under the proposed option and all regulatory alternatives. The magnitude of household cost differences between each of these race/ethnicity groups and the overall population is very small, ranging from \$0.03 to \$0.87 per year across race/ethnicity groups and across the proposed option and regulatory alternatives. The Other race/ethnicity group bears the highest household cost, while the Hispanic race/ethnicity group bears the lowest household cost.

System 100,000 to 1,000,000 – Average incremental household costs for systems anticipated to install treatment range from \$17.24 to \$27.89 per year across the proposed option and regulatory alternatives and across race/ethnicity groups. When comparing household costs borne by particular race/ethnicity groups to those borne by the overall population served by systems in this size category, the Other race/ethnicity group bears minimal elevated costs under the proposed option and all regulatory alternatives. Additionally, the Hispanic race/ethnicity group bears minimal elevated costs under the proposed option and Options 1a and 1b. The magnitude of

household cost differences between each of these race/ethnicity groups and the overall population is small, ranging from \$0.16 to \$2.58 per year across race/ethnicity groups and across the proposed option and regulatory alternatives. The Other race/ethnicity group bears the highest household cost, while the non-Hispanic Black race/ethnicity group bears the lowest household cost.

Consistent with EPA's findings for incremental household costs across all systems, EPA's comparison of incremental household costs across system size categories for just treating systems reveals that, in general, as system size increases, average incremental household costs decrease under the proposed option and all regulatory alternatives and across all race/ethnicity groups. One exception to this trend is among systems serving 100,000 to 1,000,000 people where, in many cases, costs are marginally higher than for systems serving 50,000 to 100,000 people.

The highest average incremental household costs for treating systems under the proposed option and all regulatory alternatives are realized for the smallest systems, with the range of incremental household costs for systems serving 3,300 to 10,000 people ranging from \$91.40 to \$122.25 per year. EPA anticipates the highest cost (\$122.25 per year) would be for Option 1c for the non-Hispanic Black race/ethnicity group. Systems serving 10,000 to 50,000 people bear the lowest average incremental household costs for treating systems under the proposed option and Options 1a and 1b, while systems serving 10,000 to 50,000 or 50,000 to 1,000,000 people, depending on the race/ethnicity group, bear the lowest costs for treating systems under Options 1c.

This analysis provides an opportunity to understand the demographic breakdown of incremental household costs anticipated to be incurred due to treatment installation needed to comply with the proposed PFAS NPDWR. Average incremental household costs for systems required to install treatment are higher for all size categories and across all race/ethnicity groups compared to average incremental household costs across all systems. These differences are expected, as treatment installation costs are higher than other compliance costs (i.e., monitoring and reporting). In some cases, such as for the smallest communities (i.e., systems serving 3,300 to 10,000 people), the annual average incremental household costs isolated among only systems anticipated to install treatment are up to \$100 higher than annual incremental household costs averaged across all systems.

Table 8-27: Annualized Population-Weighted Household Cost for Treating PWSs by Size Category and Race/Ethnicity Group

	<u> </u>				
System Size ^a	Race/Ethnicity Group	Proposed Option ^b	Option 1a ^c	Option 1b ^d	Option 1c ^e
3,300 to 10,000	All	\$118.50	\$117.90	\$117.18	\$112.78
3,300 to 10,000	Non-Hispanic Black	\$118.74	\$118.06	\$117.36	\$122.25
3,300 to 10,000	Hispanic	\$119.67	\$118.84	\$116.15	\$91.43
3,300 to 10,000	Other	\$116.35	\$116.22	\$113.09	\$99.40
3,300 to 10,000	Non-Hispanic White	\$118.39	\$117.80	\$117.50	\$115.28
10,000 to 50,000	All	\$32.88	\$32.24	\$30.83	\$26.83
10,000 to 50,000	Non-Hispanic Black	\$32.84	\$32.25	\$30.85	\$27.23
10,000 to 50,000	Hispanic	\$30.78	\$30.15	\$28.67	\$24.58
10,000 to 50,000	Other	\$33.07	\$32.41	\$30.99	\$26.71

Table 8-27: Annualized Population-Weighted Household Cost for Treating PWSs by Size Category and Race/Ethnicity Group

System Size ^a	Race/Ethnicity Group	Proposed Option ^b	Option 1a ^c	Option 1b ^d	Option 1c ^e
10,000 to 50,000	Non-Hispanic White	\$33.31	\$32.67	\$31.26	\$27.26
50,000 to 100,000	All	\$23.03	\$22.46	\$21.43	\$17.83
50,000 to 100,000	Non-Hispanic Black	\$22.45	\$21.96	\$21.11	\$17.65
50,000 to 100,000	Hispanic	\$22.25	\$21.65	\$20.63	\$17.63
50,000 to 100,000	Other	\$23.90	\$23.16	\$22.07	\$18.35
50,000 to 100,000	Non-Hispanic White	\$23.26	\$22.70	\$21.65	\$17.86
100,000 to 1,000,000	All	\$25.45	\$24.64	\$23.02	\$17.79
100,000 to 1,000,000	Non-Hispanic Black	\$24.74	\$23.89	\$22.27	\$17.24
100,000 to 1,000,000	Hispanic	\$25.83	\$24.94	\$23.18	\$17.38
100,000 to 1,000,000	Other	\$27.89	\$27.01	\$25.60	\$19.99
100,000 to 1,000,000	Non-Hispanic White	\$25.16	\$24.39	\$22.79	\$17.74

Notes:

8.5 Conclusions

This section provides a summary of the EJ analyses for estimating baseline PFAS exposure and exposure over several thresholds as well as the cost and benefits of the proposed PFAS NPDWR.

8.5.1 EJ PFAS Exposure Analysis

EPA's baseline analysis of demographic groups with PFAS exposure over baseline thresholds based on Method 537.1 detection limits demonstrates that certain communities of color experience elevated baseline PFAS drinking water exposures compared to the entire sample population. For example, the percentage of Asian and Pacific Islander and Hispanic populations with PFAS drinking water exposure above baseline thresholds is greater than the percentage of the total population served across all demographic groups with PFAS drinking water exposure above these levels. When these results are further filtered by system size, for large systems, Asian and Pacific Islander and Hispanic populations have higher baseline PFAS drinking water exposure compared to the percentage of the total population served across all demographic groups. For small systems, Black populations served have higher baseline PFAS drinking water exposure compared to the percentage of the total population served across all demographic groups facing PFAS drinking water exposure over these thresholds.

Across all hypothetical regulatory thresholds, elevated exposure—and thus anticipated reductions in exposure under the hypothetical regulatory scenarios—is anticipated to occur in

^aThe number of systems serving fewer than 3,300 people represented in the UMCR 3 occurrence data is too limited to accurately estimate average population-weighted household costs by subpopulation. Therefore, results for these small systems are omitted. Also, household costs in this exhibit are population-weighted and will not match average household costs by size category shown in other exhibits in the economic analysis document that are not population-weighted.

^bThe proposed option sets PFOA and PFOS MCLs of 4.0 ppt and an HI of 1.0.

^cOption 1a sets PFOA and PFOS MCLs of 4.0 ppt.

^dOption 1b sets PFOA and PFOS MCLs of 5.0 ppt.

^eOption 1c sets PFOA and PFOS MCLs of 10.0 ppt.

communities of color and/or low-income populations. EPA estimates the most notable differences in anticipated reductions in exposure are for Hispanic populations, specifically when using UCMR 5 MRL values as hypothetical regulatory thresholds in the analysis. The results from EPA's analysis indicate that Hispanic populations are estimated to face nearly twice the rate of exposure for PFOA and PFOS. Hispanic populations are therefore also anticipated to have greater reductions in exposure compared to the entire sample population.

These findings are supported by literature that indicates that communities of lower socioeconomic status are more likely to live near environmentally hazardous facilities and face disproportionate impacts of exposure to toxic chemicals than are communities of relatively higher socioeconomic status (Brown, 1995; Brulle et al., 2006; Banzhaf et al., 2019; U.S. EPA, 1994). The literature also indicates that people of color and low-income populations are more likely to be served by water systems with higher PFAS occurrence or reside in proximity to a PFAS contamination site, thereby increasing baseline exposure (Black et al., 2021; Lee, Kang, et al., 2021; Desikan et al., 2019).

8.5.2 SafeWater EJ Analysis of Regulatory Options

EPA's analysis of the demographic distribution of health benefits and household costs anticipated to result from the proposed PFAS NPDWR demonstrate that for all race/ethnicity groups, EPA's proposed option offers the greatest quantified benefits. Additionally, in all but one instance, EPA's proposed option will result in the highest household costs.

Under the proposed option, quantified health benefits are highest in every evaluated race/ethnicity group and health endpoint compared to the other regulatory alternatives. Additionally, across all health endpoints, communities of color (i.e., Hispanic, non-Hispanic Black, and/or Other race/ethnicity groups) are anticipated to experience the greatest quantified benefits associated with the proposed option. This finding could be driven by disparities in baseline exposure to PFAS and underlying disparities in death and/or disease incidence by race/ethnicity. This potential explanation is supported by literature demonstrating that vulnerable communities continue to experience elevated rates of morbidity and mortality (Uche et al., 2021; Driscoll et al., 2021; Fryar et al., 2017). Additionally, evidence in the literature indicates that people of color and low-income populations are more likely to be served by water systems with higher PFAS occurrence or reside in close proximity to a PFAS contamination site, which also supports this finding (Black et al., 2021; Lee, Kang, et al., 2021; Desikan et al., 2019).

While some race/ethnicity groups (i.e., non-Hispanic Black, Hispanic, and Other) are anticipated to bear elevated costs compared to incremental household costs for the overall population across race/ethnicity groups, relative differences in these household costs are small. The minimal differences in household costs anticipated to result from the proposed PFAS NPDWR can likely be attributed to disparities in baseline PFAS exposure among different race/ethnicity groups.

Additionally, incremental household costs to all race/ethnicity groups generally decrease as system size increases, which is expected due to economies of scale. Due to the overlap in vulnerabilities demonstrated by slightly elevated household costs anticipated for particular race/ethnicity groups and consistently elevated household costs for households served by small systems, communities of color served by small systems are anticipated to face compounding burdens. This is especially true if systems serving these communities are required to install treatment to comply with the PFAS NPDWR.

8.5.3 Overall Environmental Justice Conclusion

EPA conducted the EJ analyses presented in this chapter on populations served by a subset of PWSs to assess the demographic distribution of exposure to PFAS and the EJ impacts that are anticipated to result from the proposed PFAS NPDWR. EPA conducted two separate analyses to address the following questions:

- (1) Are population groups of concern (i.e., people of color and low-income populations) disproportionately exposed to PFAS compounds in drinking water delivered by PWSs?
- (2) Are population groups of concern disproportionately affected by the proposed rule?
- (3) If any disproportionate impacts are identified, do they create or mitigate baseline EJ concerns?

When examined collectively, results from these analyses identify communities of color and low-income communities as being disproportionately exposed to PFAS in drinking water under current baseline conditions. In one hypothetical regulatory scenario, communities of color are currently exposed to twice the rate of PFAS exposure in drinking water compared to exposure faced by the entire sample population. When quantifying the race/ethnicity distribution of quantified health benefits anticipated to result from the proposed PFAS NPDWR, EPA found that of the race/ethnicity groups evaluated, communities of color are anticipated to experience the greatest health benefits under the proposed option and all regulatory alternatives. For instance, for the non-Hispanic Black race/ethnicity group, under the proposed option, it is anticipated that 3.10 deaths from CVD will be avoided per 100,000 people per year.

When comparing benefits across the proposed option and regulatory alternatives, quantified health benefits were the highest for communities of color under the proposed option. This finding could be influenced by the fact that elevated baseline exposure rates for these populations translate to higher benefits associated with the proposed option, as greater reductions in exposure are anticipated to occur as a result of implementing the proposed PFAS NPDWR.

To alleviate potential cost disparities identified by EPA's analysis, there may be an opportunity for some communities to utilize BIL (P.L. 117-58) funding to provide financial assistance for addressing emerging contaminants. BIL funding has specific allocations for both disadvantaged and/or small communities and emerging contaminants, including PFAS.

9 Statutory and Administrative Requirements

As part of the rulemaking process, EPA is required to address the burden that the proposed rule may place on certain types of governments, businesses, and populations. This chapter presents analyses performed by EPA in accordance with the following federal mandates and statutory requirements:

- 1. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563 (2011): Improving Regulation and Regulatory Review.
- 2. Paperwork Reduction Act (PRA) (U.S. EPA, 2010b).
- 3. The Regulatory Flexibility Act (RFA) of 1980, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.
- 4. Unfunded Mandates Reform Act (UMRA) of 1995.
- 5. Executive Order 13132: Federalism
- 6. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments.
- 7. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks.
- 8. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use.
- 9. National Technology Transfer and Advancement Act of 1995 (NTTAA).
- 10. Executive Order 12898: Federal Action to Address Environmental Justice in Minority Populations and Low-Income Populations.
- 11. Consultations with the Science Advisory Board (SAB), National Drinking Water Advisory Council (NDWAC), and the Department of Health and Human Services.
- 12. SDWA Section 1412(b)(4)(E) National Small System Affordability Determination.

Many of the statutory requirements and executive orders listed above call for an explanation of why the proposed requirements are necessary, the statutory authority for the proposed requirements, and the primary objectives that the proposed requirements are intended to achieve (see Chapter 3 for additional information regarding the need for the proposed rule). Others are designed to assess the financial and health effects of the proposed regulatory requirements on sensitive, low-income, and tribal populations as well as on small systems and governments.

9.1 Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Executive Order 12866, 1993 (58 FR 51735, October 4, 1993) gives OMB the authority to review regulatory actions that are categorized as "significant" under section 3(f) of Executive Order 12866. The Order defines "significant regulatory action" as one that is likely to result in a rule that may:

1. Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities.

- 2. Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency.
- 3. Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof.
- 4. Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

This action is an economically significant regulatory action that was submitted to the OMB for review. Any changes made in response to OMB recommendations have been documented in the docket. The analysis in Chapter 7 compares the annual estimated incremental costs and the annual incremental benefits of the proposed rule. In addition to the monetized costs and benefits of the proposed regulation, a number of non-monetized impacts exist. See Sections 5.7, 6.2.2, and 6.2.3 of this EA for greater detail on the non-monetized impacts of the proposed regulation.

9.2 Paperwork Reduction Act

The information collection requirements for the proposed rule will be submitted for approval to OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq. The ICR supporting statement prepared by the EPA has been assigned the EPA ICR number 2732.01 and is available in the docket at https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114.

The PRA requires the EPA to estimate the burden, as defined in 5 CFR 1320.3(b), on PWSs and Primacy Agencies of complying with the rule. The information collected as a result of the proposed rule should allow Primacy Agencies and EPA to determine appropriate requirements for specific systems and evaluate compliance with the proposed rule. Burden is defined at 5 CFR 1320.3(b) and means the total time, effort, and financial resources required to generate, maintain, retain, disclose, or provide information to or for a federal agency. The burden includes the time needed to conduct Primacy Agency and system activities during the first three years after promulgation, as described below.

9.2.1 Primacy Agency Activities

EPA anticipates Primacy Agencies will be involved in the following activities for the first three years after publication of the final rule:

- Startup activities read and understand the rule, adopt regulatory change, and provide internal and system staff with training and technical assistance;
- Review the initial monitoring event results, including confirmation sample results for MCL exceedances; and
- Review the results of quarterly monitoring from systems.

9.2.2 Public Water System Activities

EPA anticipates systems will be involved in the following activities for the first three years after publication of the final rule:

- Startup activities read and understand the rule and attend initial training from the primacy agency;
- Conduct initial monitoring including confirmation sampling for MCL exceedances; and

• Conduct quarterly monitoring, as needed; EPA assumed that sampling for triennial monitoring would not occur until after the three-year ICR period.

For the first three years after publication of the rule in the Federal Register, information requirements apply to an average of 38,089 respondents annually, including 38,033 PWSs and 56 Primacy Agencies. The burden associated with the proposed rule over the three years covered by the ICR is 3.8 million hours, for an average of 1.3 million hours per year. The total costs over the three-year period is \$142.6 million, for an average of \$47.5 million per year (simple average over three years). The average burden per response (i.e., the amount of time needed for each activity that requires a collection of information) is 6.6 hours for PWSs and 1.1 hours for primacy agencies; the average cost per response is \$234.41 for PWSs and \$60.89 for primacy agencies. The collection requirements are mandatory under SDWA (42 U.S.C. 300g-7). Details on the calculation of the proposed rule information collection burden and costs can be found in the ICR for the proposed rule and Chapter 5 of this EA. A summary of the average annual burden and costs of the collection is presented in Table 9-1. The burdens and costs reflect labor and laboratory analysis costs.

Table 9-1: Average Annual Burden, Costs, and Responses for the Proposed Rule Information Collection Request

Item	Burden (hours in thousands) ^a	Costs (Million \$2021) ^a	Responses
Systems	1,189	\$42.3	180,630
Primacy agencies	91	\$5.2	85,225
Total ^b	1,281	\$47.5	265,855
Average per response – systems (hours or dollars)	6.6	\$234	Not applicable
Average per response – primacy agencies (hours or dollars)	1.1	\$61	Not applicable

Notes:

The estimates of total responses, burden, and cost for system and primacy agency startup activities are provided in Table 9-2.

^aDifferent units indicated for the estimates of burden and cost average per response.

^bDetail may not add to totals because of independent rounding.

Source: ICR Supporting Statement, available in the docket at https://www.regulations.gov/docket/EPA-HO-OW-2022-0114.

Table 9-2: Total Burden, Costs, and Responses for Each Required Activity

Item	Burden (thousand hours)	Costs (Million \$2021)	Responses
System startup activities	1,485	\$52.8	133,060
Systems collect initial samples	1,127	\$39.0	218,557
Systems collect quarterly samples	956	\$35.2	190,274
System subtotal	3,568	\$127.0	541,891
Primacy agency startup activities	154	\$8.7	168
Primacy agency review initial monitoring data	73	\$4.1	160,370
Primacy agency review quarterly samples	48	\$2.7	95,137
Primacy agency subtotal ^a	274	15.6	255,675
Combined systems and primacy agency ^a	3,842	142.6	797,566

Note:

Source: ICR Supporting Statement, available in the docket at https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

As part of the *Federal Register* notice on the proposed rule, EPA will solicit comments on this information collection and the estimates in this ICR. EPA will solicit comments on specific aspects of the proposed information collection, as described below:

- 1. EPA's need for this information.
- 2. The accuracy of the provided burden estimates.
- 3. Any suggested methods for minimizing respondent burden.

Comments should be directed to Docket ID Number EPA-HQ-OW-2022-0114.

In compliance with the PRA (44 USC 3501 et seq.), EPA will submit the ICR for the proposed rule to OMB for review. EPA will summarize any comments received from OMB on the ICR at that time.

9.3 The Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (RFA) of 1980, amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, requires regulators to assess the effects of regulations on small entities including businesses, nonprofit organizations, and governments. RFA/SBREFA generally requires an agency to prepare an initial regulatory flexibility analysis (IRFA) of any rule subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities (SISNOSE). Small entities include small businesses, small organizations, and small governmental jurisdictions. Under the RFA, the IRFA must include a description of the reasons why action by the agency is being considered, a succinct statement of the objectives and legal basis for the

^aDetail may not add to totals because of independent rounding.

proposed rule. It must also include a description of and, where feasible, an estimate of the number of small entities that will be affected and it must describe the projected reporting, recordkeeping, and other compliance requirements of the proposed rule and must identify any relevant federal rules that may duplicate, overlap, or conflict with the proposed rule. Finally, the IRFA must describe any significant regulatory alternatives to the rule that would accomplish the stated objectives of the applicable statutes and would minimize any significant economic impacts of the rule on small entities.

The RFA provides default definitions for each type of small entity. Small entities are defined as: (1) a small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any "not-for-profit enterprise which is independently owned and operated and is not dominant in its field." The RFA also authorizes an agency to use alternative definitions for each category of small entity, "which are appropriate to the activities of the agency" after proposing the alternative definition(s) in the *Federal Register* and taking comment (5 USC 601(3)-(5)). In addition, to establish an alternative small business definition, agencies must consult with SBA's Chief Counsel for Advocacy.

For purposes of assessing the impacts of the proposed rule on small entities, EPA considered small entities to be systems serving 10,000 people or fewer. This is the threshold specified by Congress in the SDWA 1996 Amendments for small system flexibility provisions. As required by the RFA, EPA proposed using this alternative definition in the *Federal Register* (FR) (63 FR 7620, February 13, 1998), requested public comment, consulted with the SBA, and finalized the alternative definition in the Agency's Consumer Confidence Reports regulation (U.S. EPA, 1998c, 63 FR 44524, August 19, 1998). As stated in that Final Rule, the alternative definition would be applied for all future drinking water regulations.

EPA notes that the Infrastructure Investment and Jobs Act (also known as the Bipartisan Infrastructure Law (BIL), P.L. 117-58) invests over \$11.7 billion in the Drinking Water State Revolving Fund (SRF) General Supplemental fund; \$4 billion in the Drinking Water SRF Emerging Contaminants fund; and \$5 billion in the Emerging Contaminants in Small or Disadvantaged Communities grant program. Together, these funds will reduce people's exposure to perfluoroalkyl and polyfluoroalkyl substances (PFAS) and other emerging contaminants through their drinking water. The BIL funding will prioritize investment in local communities that are on the frontlines of PFAS contamination and that have few options to finance solutions through traditional programs and, help them meet their obligations under this proposed regulation.

9.3.1 Need for, Objectives, and Legal Basis of the Rule

The need for the rule, the objectives of the rulemaking, the stakeholder outreach conducted, and the statutory authority EPA is utilizing to finalize the rule are described in detail in Chapter 3. See Section 3.1 for detailed information on the need for the rule, Section 9 for information on stakeholder outreach during the rulemaking process, and Section 3.2 for additional detail on the statutory authority for the promulgation of the PFAS regulation. In summary, SDWA authorizes EPA to establish NPDWRs for contaminants that may have an adverse public health effect, that are known to occur or that present a substantial likelihood of occurring in PWSs at a frequency

and level of public health concern, and that present a meaningful opportunity for health risk reduction for persons served by PWSs. As a result, EPA is proposing an NPDWR for six PFAS including PFOA, PFOS, PFNA, PFHxS, HFPO-DA, and PFBS. Additionally, under the SDWA, the EPA Administrator is authorized to establish monitoring, recordkeeping, and reporting regulations that the Administrator can use to establish regulations under the SDWA, determine compliance with SDWA, and advise the public of the risks of unregulated contaminants.

EPA is also addressing PFAS through several of its statutory authorities other than SDWA, including the CERCLA, RCRA, Toxic Substances Control Act (TSCA), Clean Water Act, Clean Air Act, and Emergency Planning and Community Right-to-Know Act. For example, as part of the EPA PFAS Strategic Roadmap, in 2022, EPA anticipates proposing to designate certain PFAS as CERCLA hazardous substances to require reporting of PFOA and PFOS releases, enhance the availability of data, and ensure agencies can recover cleanup costs. EPA recognizes that future actions under some of these statutes may have direct or indirect impacts for drinking water treatment facilities and could impact the compliance requirements related to disposal of PFAS treatment residuals that are generated by water systems. EPA has also committed to restrict PFAS discharges from industrial sources through a multi-faceted Effluent Limitations Guidelines program to proactively establish national technology-based regulatory limits. Additionally, EPA is seeking to proactively use National Pollutant Discharge Elimination System (NPDES) authorities to reduce discharges of PFAS at the source and obtain more comprehensive information through monitoring on the sources of PFAS discharges and quantity of PFAS discharged by these sources. EPA notes that these actions may prevent or reduce PFAS entering into sources of drinking water in the future. More information on these statutory authorities and PFAS-related EPA activities can be found in the Roadmap.

9.3.2 Identification of Relevant Federal Rules

The proposed rule is not anticipated to duplicate, overlap, or conflict with any other federal rules. There are NPDWRs for over 90 contaminants and when developing drinking water regulations, the agency factors in the water quality impacts of compliance with a new regulation on the system's compliance with existing drinking water regulations (e.g., Lead and Copper Rule, Interim Enhanced Surface Water Treatment Rule, Stage 1 and Stage 2 Disinfectants and Disinfection Byproducts Rules). EPA will continue to consider and evaluate how water systems will need to manage simultaneous compliance with the proposed PFAS NPDWR requirements and these other EPA drinking water regulations. Further, while the proposed PFAS NPDWR is not anticipated to duplicate, overlap, or conflict with any other federal rules, EPA notes that monitoring under the UCMR 5 may also support monitoring requirements associated with the proposed PFAS NPDWR.

9.3.3 Summary of the SBAR Comments and Recommendations

A Small Business Advocacy Review Panel (SBAR Panel or Panel) was convened to review the planned proposed rulemaking on the Proposed PFAS NPDWR. In addition to EPA's Small Business Advocacy Chairperson, the Panel consists of the Director of the Standards and Risk Management Division of the EPA Office of Ground Water and Drinking Water, the Administrator of the Office of Information and Regulatory Affairs within the Office of Management and Budget, and the Chief Counsel for Advocacy of the Small Business Administration. The panel consulted with and reported on the comments of small entity

representatives (SERs) and made findings on issues related to elements of an IRFA under section 603 of the RFA. The SERs were presented with information related to PFAS background (such as health and occurrence, the SDWA regulatory development process and EPA's actions to address PFAS in drinking water potential monitoring and reporting rule compliance considerations, treatment and feasibility considerations, potential public notification and education rule compliance considerations, and preliminary economic impacts to small systems. EPA also provided to SERS that the agency's final regulatory determination for PFOA and PFOS outlined avenues that the agency considered to further evaluate additional PFAS chemicals, other than PFOA and PFOS, and consider groups of PFAS as supported by use of the best available science. Additionally, as part of EPA's PFAS Strategic Roadmap, EPA reaffirmed its commitment to evaluate additional PFAS and consider regulatory actions to address additional PFAS or groups of PFAS as it develops the NDPWR. Further, EPA provided to SERs that as EPA considers whether to include additional PFAS as part of this proposed regulation, the agency would consider several factors, including whether the same treatment approaches coremove certain PFAS contaminants and how different PFAS are anticipated to be removed as part of the treatment process, the likelihood that the PFAS co-occur, the similarity of health effects and chemical structures, the environmental persistence characteristics, and the availability of accepted and approved analytical methods or indicators with comparable costs to those currently identified by EPA to evaluate PFAS removal from drinking water, among other considerations.

In light of the SERs' comments, the Panel considered the regulatory flexibility issues and elements of the IRFA specified by RFA/SBREFA and developed the findings and discussion summarized in the SBAR report. For example, the SBAR Panel recommended several flexibilities in monitoring requirements for small systems, including the use of existing monitoring data (such as the UCMR 5) for initial monitoring purposes; as well as reduced compliance monitoring requirements specifically for small ground water systems. Regarding public comment requests, the Panel recommended that EPA request this for a few areas, such as laboratory capacity for monitoring, additional treatment technologies other than those identified in the proposed rule that have been shown to reduce levels of PFAS to the proposed regulatory standards, additional monitoring flexibilities, and PFAS disposal considerations. Moreover, specific to PFAS disposal, the Panel recommended that EPA continue to evaluate the potential impacts related to the disposal of PFAS treatment residuals and potential implications from other EPA statutory authorities. This recommendation included presenting the costs of both nonhazardous and hazardous waste disposal of treatment residuals as a part of the proposed rule. As a general matter, EPA notes that such wastes are not currently regulated under federal law as a hazardous waste. To address stakeholder concerns, including those raised during the SBREFA process, EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. As part of this analysis, EPA generated a second full set of unit cost curves that are identical to the curves used for the national cost analysis with the exception that spent GAC and spent IX resin are considered hazardous. EPA acknowledges that if federal authorities later determine that PFAS-contaminated wastes require handling as hazardous wastes, the residuals management costs are expected to be higher. EPA incorporated all of these Panel recommendations, as well as others, in the proposed rule.

The Panel also recommended EPA to consider rule implementation delays for potential laboratory capacity-related challenges if those challenges potentially impact the ability of water

systems to monitor for PFAS and reasonably comply with the NPDWR. As described in the preamble (section XII.D.), in accordance with SDWA 1412(b)(10), a state or EPA may grant an extension of up to two additional years to comply with an NPDWR's MCL if the state or EPA determines a system needs additional time for capital improvements. At this time, EPA does not intend to provide a two-year extension nationwide. However, under SDWA 1412(b)(10) or 1416 States may provide such as extension on an individual system basis which may address compliance issues associated with treatment, laboratory, and disposal capacity. Additionally, EPA notes that in the preamble (section IX.F.) the agency is seeking public comment on the proposed initial monitoring timeframe, particularly for NTNCWS or all systems serving 3,300 or fewer.

The report includes a number of other observations and recommendations to meet the statutory obligations for achieving small-system compliance through flexible regulatory compliance options. The report was finalized on August 1, 2022 and transmitted to EPA Administrator for consideration. Detailed information on the overall panel process, including the comprehensive comments of the SERs and full description of Panel recommendations, can be found in the panel report titled, *Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation* and can be found in the rulemaking docket at: https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114.

9.3.4 Number and Description of Small Entities Affected

EPA used SDWIS/Fed data from the fourth quarter of 2021 to identify 62,048 small PWSs that may be impacted by the proposed PFAS regulation. A small PWS serves between 25 and 10,000 people. These water systems include 44,753 CWSs that serve year-round residents and 17,295 NTNCWSs that serve the same persons over six months per year (e.g., a PWS that is an office park or church). EPA does not anticipate that the proposed NPDWR will affect TNCWSs as those systems will likely not be subject to the rule requirements. Additional information on the characteristics of these small drinking water systems along with a discussion of uncertainty in the dataset used to derive the estimated number of small systems impacted by the proposed PFAS regulation can be found in 4.2.1.

Table 9-3 and Table 9-4 show the number of affected small CWSS and NTNCWs respectively.

Table 9-3: Inventory of Small CWSs

System Size (Population	Ground Water	Surface Water	Total
Served)	A	В	C = A + B
≤ 100	10,654	739	11,393
101–500	13,037	2,042	15,079
501-1,000	4,132	1,179	5,311
1,001–3,300	5,503	2,460	7,963
3,301–10,000	2,784	2,223	5,007
TOTAL	36,110	6,601	44,753

Abbreviations: CWS – community water systems.

Note:

^aIncludes 23 CWSs serving 10,000 or fewer people for which no primary source water type was reported to SDWIS/Fed. EPA assigned these systems to the source type of Ground Water.

Source: SDWIS/Fed fourth quarter 2021 "frozen" dataset that contains information reported through January 14, 2022. Includes all active CWSs.

Table 9-4: Inventory of Small NTNCWSs

		NTNCWSs ^a	
System Size (Population Served)	Ground Water	SW	Total
	A	В	C=A+B
≤ 100	8,084	252	8,336
101–500	6,111	257	6,368
501-1,000	1,476	91	1,567
1,001-3,300	743	121	864
3,301–10,000	97	63	160
TOTAL	16,551	784	17,295

 $Abbreviations: \ NTNCWS-non-transient\ non-community\ water\ systems.$

Note:

Sources: SDWIS/Fed fourth quarter 2021 "frozen" dataset that contains information reported through January 14, 2022. Includes all active NTNCWSs.

9.3.5 Description of Compliance Requirements of the Proposed Rule

For a detailed description of the regulatory requirements under the proposed PFAS regulation see Section 2.1. Under the proposed rule requirements, PWSs subject to the rule are required to conduct initial monitoring or demonstrate that recent, previously collected monitoring data can be used to determine the level of PFAS in their water system. The proposed NPDWR includes a provision, made available to PWSs of all sizes, including CWSs and NTNCWs serving 10,000 or fewer people, to use qualified previously collected monitoring data. EPA assessed the extent to which this significant alternative minimizes the economic impact on small PWSs specifically in Section 9.3.7.1 below.

^aIncludes 11 NTNCWSs serving 3,300 or fewer people for which no primary source type was reported to SDWIS/Fed. EPA assigned these systems to the source water type of Ground Water.

Based on initial monitoring results, systems will be required to conduct ongoing monitoring at least every three years or as often as four times per year. Details on the monitoring frequency requirements of the proposed NPDWR can be found in Section IX of the Federal Register Notice for the proposed rule. EPA has included a provision in the proposed NPDWR where ground water systems serving a population of 10,000 or fewer may collect two quarterly samples over a one-year period for the purpose of initial monitoring, rather than collecting four quarterly samples. EPA assessed the extent to which this regulatory flexibility minimizes the economic impact on small PWSs in Section 9.3.7.2 below.

PWSs that exceed the drinking water standard are required to choose between treatment and non-treatment compliance options. EPA identified the following Small System Compliance Technologies (SSCTs) GAC, Anion Exchange (AIX), and High-pressure membranes (Reverse Osmosis [RO] and Nanofiltration [NF]. POU RO is not currently listed as a compliance option because the regulatory options under consideration require treatment to concentrations below the current NSF International/American National Standards Institute (NSF/ANSI) certification standard for POU device removal of PFAS. However, POU treatment is reasonably anticipated to become a compliance option for small systems in the future if NSF/ANSI or other independent third-party certification organizations develop a new certification standard that mirrors EPA's proposed regulatory standard. Details on SSCTs and costs can be found in Section 5.3.1 and *Best Available Technologies and Small System Compliance Technologies for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* (U.S. EPA, 2023f).

9.3.6 Analysis of Impact of Regulatory Options on Small System Costs

EPA limited the quantitative cost impact analysis to small CWSs because small NTNCWSs operate in numerous industries and EPA does not have information on NTNCWSs' revenues. EPA's decision to limit its cost impact analysis to CWSs is supported by EPA's Assessment of the Vulnerability of Noncommunity Water Systems to SDWA Cost Increases (2008). In this study, EPA examined the burden of SDWA rule costs in comparison to the average revenues of various categories of NTNCWSs. All the NTNCWS categories reviewed were less vulnerable to SDWA-related increases than a typical CWS. The report notes that in some categories of businesses, costs are more easily passed on to the customer base than in others. In each NTNCWS category, however, total expenditures on water were found to be a relatively small percentage of total revenues. Water expenditures (including expenditures for sewer service and miscellaneous other utilities) totaled less than one percent of total revenues in nearly all cases and were not more than 1.3 percent of total revenues for any category. The implication is that an increase in water costs would similarly be less than one percent of revenue. This report included several caveats such as one that considered the potential for underestimating the impact to golf courses, which were grouped in with other recreational entities whose use of water was less significant to the core business than the golf courses. EPA notes, however, that irrigation water for golf courses would not need to meet the proposed rule; only water used for human consumption would need to be treated. Despite the significant caveats listed, the report strongly suggests that NTNCWSs should not be considered particularly vulnerable to operating cost increases resulting from SDWA rulemakings.

To indicate the potential economic impact on small CWSs, EPA divided annual costs by annual revenues and converted the decimal values to percentages and identified the number and percent of CWSs for which the impact percentages exceeded thresholds of one percent and three percent. For each system, EPA estimated annual revenue using each system's average daily flow and the average revenue per thousand gallons delivered from the CWSS (U.S. EPA, 2009). For annual costs, EPA estimated annual average monitoring costs based on system size and baseline PFAS occurrence. Annual costs also included annual treatment costs when baseline PFAS concentrations exceeded the PFAS limits of the proposed rule or options. Annual treatment costs are the sum of annual operating and maintenance costs and annualized capital costs, which vary for 3 percent and 7 percent discount rate assumptions.

Table 9-5 shows the number and proportion of CWSs incurring annual costs that exceed 1 percent and 3 percent of annual revenue at the commercial rate of capital for the proposed option. Under the proposed option, 17,726 small CWSs (39 percent of small CWSs) could incur annual costs greater than 1 percent of annual revenue and 9,233 small CWSs (21 percent of small CWSs) could incur annual costs greater than 3 percent of revenue. These potential impacts are high enough to preclude a finding of no SISNOSE. For systems that install treatment to reduce PFAS, annual costs can range from approximately \$8,000 to \$315,000. Details on treatment costs curves can be found in Section 5.3.1 and *Best Available Technologies and Small System Compliance Technologies for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* (U.S. EPA, 2023f). For EPA's estimates of treatment costs by system size, see Appendix C.1. For information on federal financial assistance available to small systems for the installation of PFAS treatment technology, see Section 9.12.2.2.

Table 9-5: Cost-Revenue Ratio for Small CWSs, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0; Commercial Cost of Capital)

Ownership	Source Water	Population Served Size Category	Number of CWSs	Number of CWSs with Cost Revenue Ratio > 1%	Number of CWSs with Cost Revenue Ratio > 3%	Percent of CWS with Cost Revenue Ratio > 1%	Percent of CWS with Cost Revenue Ratio > 3%
Private	Ground	Less than 100	9,250	9,250	4,800	100%	52%
Private	Ground	100 to 500	8,223	2,758	1,468	34%	18%
Private	Ground	500 to 1,000	1,313	250	108	19%	8%
Private	Ground	1,000 to 3,300	1,046	154	72	15%	7%
Private	Ground	3,300 to 10,000	347	30	24	9%	7%
Private	Surface	Less than 100	399	398	196	100%	49%
Private	Surface	100 to 500	769	207	129	27%	17%
Private	Surface	500 to 1,000	244	44	16	18%	7%
Private	Surface	1,000 to 3,300	278	27	15	10%	6%
Private	Surface	3,300 to 10,000	184	14	12	7%	6%
Public	Ground	Less than 100	1,308	697	250	53%	19%
Public	Ground	100 to 500	4,684	1,142	806	24%	17%
Public	Ground	500 to 1,000	2,767	521	255	19%	9%

Table 9-5: Cost-Revenue Ratio for Small CWSs, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0; Commercial Cost of Capital)

Ownership	Source Water	Population Served Size Category	Number of CWSs	Number of CWSs with Cost Revenue Ratio > 1%	Number of CWSs with Cost Revenue Ratio > 3%	Percent of CWS with Cost Revenue Ratio > 1%	Percent of CWS with Cost Revenue Ratio > 3%
Public	Ground	1,000 to 3,300	4,385	681	315	16%	7%
Public	Ground	3,300 to 10,000	2,401	239	186	10%	8%
Public	Surface	Less than 100	330	170	71	51%	21%
Public	Surface	100 to 500	1,241	277	194	22%	16%
Public	Surface	500 to 1,000	925	164	65	18%	7%
Public	Surface	1,000 to 3,300	2,160	257	123	12%	6%
Public	Surface	3,300 to 10,000	2,026	146	128	7%	6%
Total			44,280	17,426	9,233	39%	21%

Abbreviations: CWS - community water system

9.3.7 Analysis of Significant Alternatives to the Proposed Rule

Significant alternatives presented by the SBAR panel report are described below. EPA evaluated the minimized economic impact for small systems for each of these alternatives.

9.3.7.1 Use of Previously Collected PFAS Monitoring Data

EPA has included a provision in the proposed NPDWR where PWSs of all sizes may use previously collected monitoring data if it meets stated criteria in lieu of initial monitoring. This significant alternative is expected to offer a substantial costs savings to small PWSs, particularly those serving between 3,301 and 10,000 that participate in UCMR 5. For the national cost analysis, EPA assumes that systems with either UCMR 5 data or monitoring data in the State PFAS Database (U.S. EPA, 2023g) will not need to conduct the initial year of monitoring. As a simplifying assumption for the cost analysis, EPA assumes all systems serving a population of greater than 3,300 have UCMR 5 data and those serving 3,300 or less do not. EPA notes that this assumption is conservative and will likely overestimate costs for systems less than 3,300 as many state monitoring programs and other efforts will have collected monitoring data that can be used as initial monitoring data for these systems, thus offsetting those costs. Under these assumptions, EPA estimates that this provision will reduce the economic burden on small systems nationally by \$39 million dollars.

9.3.7.2 Reduced Monitoring for Small Ground Water Systems

EPA has included a provision in the proposed NPDWR where ground water systems serving a population of 10,000 or fewer may collect two quarterly samples over a one-year period for the purpose of initial monitoring, rather than collecting four quarterly samples. EPA estimates that this provision will reduce the economic burden on small systems nationally by \$3 million per year.

9.3.7.3 Point of Use (POU) Technologies as Small System Compliance Technologies (SSCTs)

In the Best Available Technologies and Small System Compliance Technologies for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water (U.S. EPA, 2023f), EPA discusses POUs and notes that the current certification standard is 70 ppt, which would not ensure these devices are able to meet the MCLs of the proposed rule. EPA notes that based on the technologies used in many POU devices (e.g., RO), the Agency anticipates devices are or will be capable of meeting the MCLs in this proposed rulemaking. If POU certifications are updated and do meet the SSCT criteria in the final NPDWR, this could minimize the economic impact of the final regulation on small PWSs, particularly on water systems in the smallest size category (e.g., those serving between 25 and 500 people). In particular, NTNCWS that control all of their potable taps (e.g., schools, gas stations, churches) may find use of POUs to be a particularly attractive option. POUs tend to be most cost effective for the smallest water systems. Costs for POUs may range between \$317 to \$326 per year per system. These costs are lower than the costs for implementing centralized treatment options such as GAC or IX in the smallest system size category, which can range from \$376 to \$698 per year per system (U.S. EPA, 2023f). See Table 9-9 for more information costs by system size and treatment technology. EPA has not estimated the potential national economic impact reduction because the current certification prevents POUs from meeting the SSCT criteria for the proposed NPDWR. However, EPA notes there is a potential for significant burden reduction particularly for very small water systems if POU certifications are updated and POUs meet the SSCT criteria for the final NPDWR.

9.4 Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act (UMRA) (1995) seeks to protect state, local, and tribal governments from the imposition of unfunded federal mandates. In addition, the Act seeks to strengthen the partnership among the federal government and state, local, and tribal governments.

Title II of UMRA establishes requirements for federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. Under Section 202 of UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and Final Rules with "federal mandates" that may result in expenditures by state, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year, adjusted for inflation. EPA has calculated the cost of the rule in 2021 dollars, therefore, the UMRA requirements are triggered if expenditures exceed \$168 million in one year (escalation based on GDP deflator).

Section 205 of UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome option that achieves the objectives of the rule. The provisions of Section 205 do not apply when they are inconsistent with applicable law. Moreover, Section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the rule an explanation of why that alternative was not adopted.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under Section 203 of

UMRA a small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements. Options being considered for the proposed rule also met the consultation requirements of Federalism, therefore EPA elected to engage the UMRA and Federalism stakeholders in the same consultation as there are overlapping interests, and a discussion of potential options for the development of the proposed rule was more effectively communicated simultaneously. For more information on the consultation, refer to the Summary Report on Federalism and Unfunded Mandates Reform Act Consultation for the Development of the Proposed PFAS NPDWR in the public docket at https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114.

The proposed rule does contain a federal mandate that may result in expenditures to state, local, and tribal governments, in the aggregate, or to the private sector, of \$168 million or more in any one year. For the proposed rule, the highest annual incremental cost over the analysis period occurs in the 4th year after rule promulgation. In this year publicly owned PWSs are expected to have undiscounted incremental costs of \$8.0 billion, privately owned PWSs are expected to have undiscounted incremental costs of \$1.8 billion, and Primacy Agencies will have undiscounted incremental costs of \$18 million. Therefore, the proposed rule has costs in a single year of \$9.8 billion and, therefore, is subject to the requirements of Sections 202 and 205 of UMRA.

The annualized incremental costs of the proposed rule, that are borne by public, private, and tribal PWSs are provided in Table 9-6. As the exhibit shows, public entities bear most of the costs. As discussed in Chapter 5, in addition to these PWS costs primacy agencies will incur annualized incremental administrative costs of \$8 million (3 percent discount rate) or \$9 million (7 percent discount rate) under the proposed rule.

Table 9-6: Annual Incremental Costs by PWS Size and Ownership, Proposed Option (PFOA and PFOS MCLs of 4.0 ppt and HI of 1.0; Million \$2021, Commercial Cost of Capital)

	Public Water Systems Serving < 10,000 People	All Public Water Systems
Publicly-Owned Public Water Systems	\$127	\$712
Privately-Owned Public Water Systems	\$71	\$183
Tribal-Owned Public Water Systems	\$3	\$5

9.5 Executive Order 13132: Federalism

Executive Order 13132 (1999), entitled "Federalism" (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure "meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" are defined in the Executive Order to include regulations that have "substantial direct effects on the states, on the relationship between the national government

and the states, or on the distribution of power and responsibilities among the various levels of government."

This action has federalism implications due to the substantial direct compliance costs on state or local governments. The net change in Primacy Agency related cost for state, local, and tribal governments in the aggregate is estimated to be \$8 million (3 percent discount rate) or \$9 million (7 percent discount rate).

To fulfill requirements of Executive Order 13132 section 6, EPA held a Federalism consultation with state and local government officials as well as their representative associations to solicit input on key areas to inform the development of the proposed rule. Options being considered for the proposed rule also met the consultation requirements of UMRA, therefore EPA elected to engage the UMRA stakeholders in the same consultation because there are overlapping interests, and a discussion of potential options for the development of the proposed rule was more effectively communicated simultaneously. For more information on the consultation, refer to the Summary Report on Federalism and Unfunded Mandates Reform Act Consultation for the Development of the Proposed PFAS NPDWR in the public docket at https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114.

9.6 Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

Executive Order 13175 (2000), entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000), requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." The Executive Order defines "policies that have tribal implications to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the federal government and the Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes."

Under Executive Order 13175, EPA may not issue a regulation that has tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the federal government provides the funds necessary to pay the direct compliance costs incurred by tribal governments, or EPA consults with tribal officials early in the process of developing the proposed regulation and develops a tribal summary impact statement.

EPA has identified 998 public water systems serving tribal communities, 84 of which are federally owned. EPA estimates that tribal governments will incur public water system compliance costs of \$5 million per year attributable to monitoring, treatment or non-treatment actions to reduce PFAS in drinking water, and administrative costs, and that these estimated impacts will not fall evenly across all tribal systems. The proposed PFAS NPDWR does offer regulatory relief by providing flexibilities for all water systems to potentially utilize pre-existing monitoring data in lieu of initial monitoring requirements and for ground water CWSs and NTNCWSs serving 10,000 or fewer to reduce initial monitoring from quarterly monitoring during a consecutive 12-month period to only monitoring twice during a consecutive 12-month period. These flexibilities may result in implementation cost savings for many tribal systems since 98 percent of tribal CWSs and 94 percent of NTNCWs serve 10,000 or fewer people.

EPA has concluded that this proposed rule has Tribal implications, because it will impose direct compliance costs on Tribal governments, and the federal government will not provide funds necessary to pay those direct compliance costs. However, EPA notes that the federal government will provide a potential source of funds necessary to offset some of those direct compliance costs. The Infrastructure Investment and Jobs Act (also known as the Bipartisan Infrastructure Law (BIL), P.L. 117-58) invests over \$11.7 billion in the Drinking Water State Revolving Fund (SRF) General Supplemental fund; \$4 billion in the Drinking Water SRF Emerging Contaminants fund; and \$5 billion in the Emerging Contaminants in Small or Disadvantaged Communities grant program. Together, these funds will reduce people's exposure to perfluoroalkyl and polyfluoroalkyl substances (PFAS) and other emerging contaminants through their drinking water.

Consistent with the EPA's Policy on Consultation and Coordination with Indian Tribes (May 4, 2011), EPA consulted with tribal officials early in the process of developing this proposed regulation to gain an understanding of tribal views on key areas of the proposed PFAS NPDWR and provide tribal officials an opportunity to have meaningful and timely input on its development. For more information on the consultation with tribes, refer to the Summary Report on Tribal Consultation: Development of the Proposed PFAS NPDWR in the public docket at https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114.

9.7 Executive Order 13045: Protection of Children from Environmental Health and Safety Risks

Executive Order 13045 (1997), entitled "Protection of Children from Environmental Health and Safety Risks" (62 FR 19885; April 23, 1997) applies to any rule initiated after April 21, 1998, that (1) is determined to be "economically significant" as defined under Executive Order 12866; and (2) concerns an environmental, health, or safety risk that the EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental, health, or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible options considered by EPA.

The proposed rule is subject to Executive Order 13045 because it is economically significant as defined in Executive Order 12866. This action's health and risk assessments are contained in Section 6.2.2 of the EA, and the associated appendices. EPA expects that the proposed rule would provide additional protection to both children and adults who consume drinking water supplied by the affected systems. EPA also expects that the benefits of the proposed rule, including reduced health risk, will provide significant benefits to infants and children. As detailed in *Toxicity Assessments and Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water* (U.S. EPA, 2023d; U.S. EPA, 2023e), there is evidence for adverse effects of PFOA and PFOS for several developmental and reproductive endpoints, as well as evidence for adverse cardiovascular, endocrine, immune, and metabolic effects in infants or children. EPA discusses the qualitative benefits from avoided adverse health effects of PFOA, PFOS, and other PFAS, including effects on infants and children in Section 6.2.2.2 of the EA. In Section 6.2.2.1.1 of the EA, EPA quantifies the avoided morbidity and mortality associated with reductions in infant birth weight from reduced maternal PFOA and PFOS exposure in drinking

water. EPA also assesses the potential benefits of reduced PFNA on infant birth weight in a sensitivity analysis found in Appendix K.

Additionally, for chemicals exhibiting a threshold for toxic effects, EPA establishes the MCLGs based on an oral reference dose (RfD). The chronic RfD discussed in the *Toxicity Assessments* and *Proposed Maximum Contaminant Level Goals for PFOA and PFOS in Drinking Water* (U.S. EPA, 2023d; U.S. EPA, 2023e) provides an estimate of a daily oral exposure to the human population (including sensitive subpopulations) that is likely to be without an appreciable risk of deleterious non-cancer effects during a lifetime.

9.8 Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211 (2001), "Actions Concerning Regulations That Significantly Affect Energy Supply Distribution, or Use," provides that agencies shall prepare and submit to the Administrator of the Office of Information and Regulatory Affairs, OMB, a Statement of Energy Effects for certain actions identified as "significant energy actions." Section 4(b) of Executive Order 13211 defines "significant energy actions" as "any action by an agency (normally published in the *Federal Register*) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking: (1)(i) that is a significant regulatory action under Executive Order 12866 or any successor order, and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (2) that is designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action."

The proposed rule is not a "significant energy action" as defined in Executive Order 13211. This rule is a significant regulatory action under Executive Order 12866; however, it is not likely to have a significant adverse effect on the supply, distribution, or use of energy, for the reasons described as follows.

9.8.1 Energy Supply

The proposed rule does not regulate power generation, either directly or indirectly, and public and private systems subject to the proposed rule does not, as a general rule, generate power. Further, the energy cost increases borne by customers of systems as a result of the proposed rule is a low percentage of the total cost of water. Therefore, power generation utilities that purchase water as part of their operations are unlikely to face any significant effects as a result of the proposed rule.

9.8.2 Energy Distribution

The proposed rule does not regulate any aspect of energy distribution and systems that are regulated by the proposed rule already have electrical service. The rule is not expected to increase peak electricity demand at systems. Therefore, EPA assumes that the existing connections are adequate and that the proposed rule has no discernible adverse effect on energy distribution.

9.8.3 Energy Use

EPA has determined that the incremental energy used to implement water treatment at drinking water systems in response to the proposed regulatory requirements is minimal. Therefore, EPA does not expect any noticeable effect on the national levels of power generation in terms of average and peak loads.

9.9 National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when EPA decides not to use available and applicable voluntary consensus standards.

EPA's approved monitoring and sampling protocols generally include voluntary consensus standards developed by agencies such as the American National Standards Institute (ANSI) and other such bodies wherever EPA deems these methodologies appropriate for compliance monitoring.

9.10 Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, Executive Order 14008: Tackling the Climate Crisis at Home and Abroad

Executive Order 12898 (1994), "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission. Agencies must do this by identifying and addressing as appropriate any disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the U.S. For information on EPA's Environmental Justice Analysis, see Chapter 8.

On March 2, 2022 and April 5, 2022, EPA held public stakeholder meetings related to EJ and the development of the proposed NPDWR. The meetings provided an opportunity for EPA to share information and for communities to offer input on EJ considerations related to the development of the proposed rule. EPA received public comment on topics including establishing an MCL for PFAS and regulating PFAS as a class, affordability of PFAS abatement options and responsibility for remediation, limiting industrial discharge of PFAS, and EPA's relationship with community groups. For more information on the EJ stakeholder meetings, refer to the EJ Considerations for the Development of the Proposed PFAS Drinking Water Regulation Public Meeting Summaries in the public docket at https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114.

9.11 Consultations with the Science Advisory Board, National Drinking Water Council, and the Secretary of Health and Human Services

9.11.1 Science Advisory Board

As required by Section 1412(e) of the SDWA, in 2021-2022, EPA asked SAB to evaluate the current scientific data on the following: EPA's *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for PFOA and PFOS in Drinking Water* (U.S. EPA, 2021f; U.S. EPA, 2021g); a draft framework for estimated noncancer health risks associated with mixtures of PFAS; and EPA's methodology for evaluating reduced cardiovascular disease risks. EPA sought SAB comment on whether the analyses provided in these documents are scientifically supported, clearly described, and informative toward supporting EPA's proposed National Primary Drinking Water Rulemaking effort. The SAB PFAS Review Panel deliberated and sought input from public meetings held in December 2021, January 2022, and May 2022. The SAB Chartered Body conducted a quality review of the draft panel report July 2022. The SAB's final report, titled "EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS" was transmitted to the EPA Administrator on August 22, 2022. For information on EPA responses to SAB's review, see U.S. EPA (2022k).

9.11.2 National Drinking Water Advisory Council

In accordance with Section 1412 (d) of the SDWA, EPA consulted with NDWAC, on the proposed rule. EPA consulted with NDWAC in a public meeting on April 19, 2022, on key areas of the proposed rule including monitoring, treatment, public notification, and PFAS mixtures. For more information on the consultation with the NDWAC, refer to the NDWAC Virtual Public Meeting Summary in the public docket at https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114.

9.11.3 Secretary of Health and Human Services

In accordance with Section 1412 (d) of the SDWA, on September 28, 2022, EPA consulted with the Department of Health and Human Services (HHS). EPA provided information to HHS officials on the draft proposed NPDWR and considered HHS input as part of the interagency review. A summary of this meeting is available in the docket at EPA-HQ-OW-2022-0114 at www.regulations.gov.

9.12 Affordability Analyses

The SDWA, as amended in 1996, requires that EPA list technologies for small systems [Section 1412(b)(4)(E)(ii)]:

The Administrator shall include in the list any technology, treatment technique, or other means that is affordable, as determined by the Administrator in consultation with the States, for small public water systems serving -

(I) a population of 10,000 or fewer but more than 3,300;

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¹⁰⁵ For specific charge questions, visit the SAB website at https://sab.epa.gov/ords/sab/f?p=100:19:7661444876021:::19:P19_ID:963#charge.

(II) a population of 3,300 or fewer but more than 500; and

(III) a population of 500 or fewer but more than 25; and that achieves compliance with the maximum contaminant level (MCL) or treatment technique, including packaged or modular systems and point-of-entry or point-of-use treatment units (POU).

EPA's long-standing methodology for determining whether there are affordable compliance technologies for a new drinking water standard for small systems compares the cumulative cost of providing drinking water that complies with the new standard to an affordability threshold equal to 2.5 percent of median household income (63 FR 42032). Should EPA determine there are no affordable SSCTs, the SDWA Section 1412(b)(15)(B) requires EPA to identify variance technologies that may not achieve compliance with the drinking water standard but achieve the maximum reduction or inactivation efficiency that is affordable considering the size of the system and the quality of the source water.

In addition to the required analysis for small system affordability, EPA is exploring the use of alternative expenditure margins and other potential changes to the national level affordability methodology to better understand the cost impacts of new standards on low income and disadvantaged households served by small drinking water systems. As part of this analysis, EPA is utilizing a number of recommendations from the SAB, NDWAC, and other stakeholders such as the American Water Works Association (AWWA). The Agency conducted supplemental affordability analyses using alternative metrics suggested to EPA by these advisory bodies and stakeholders to demonstrate the potential affordability implications of the proposed NPDWR on the determination of affordable technologies for small systems at the national level of analysis. EPA is seeking public comment on the national level analysis of affordability of small system compliance technologies and specifically on the potential methodologies presented.

EPA's national small system affordability determination can be found in Section 9.12.1. EPA's supplementary affordability analyses can be found in Section 9.12.2.

9.12.1 National Small System Affordability Determination

EPA determined that there are several affordable treatment technologies for small systems. The determination, documented in *Best Available Technologies and Small System Compliance Technologies for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* (U.S. EPA, 2023f), compared the estimated incremental treatment costs per household with a baseline expenditure margin that equals 2.5 percent of median household income minus baseline drinking water utility cost per household. Table 9-7 shows which technologies satisfy the affordability criterion for three small system size categories. For systems serving between 25-500 and 501-3,300 people, GAC, ion exchange and point-of-use reverse osmosis are affordable technologies, but centralized reverse osmosis is not. For systems serving 3,301-10,000 people GAC, ion exchange and centralized RO are affordable technologies, and POU RO is not applicable to systems of that size category. ¹⁰⁶

¹⁰⁶ Note, the results shown in Table 9-7 and discussed in this section are dependent on the estimated annual household technology costs reported in Table 9-9 which assumes costs associated with standard waste management of spent GAC and spent IX resin using current typical management practices (reactivation for GAC and incineration for resin). Future changes to regulations

A technology must be both effective and affordable to be designated as an SSCT. Technologies that meet the effectiveness criterion include those designated as BATs for the proposed rule: GAC, PFAS-selective IX, and RO. This section also presents preliminary affordability results for

Table 9-7: SSCT Affordability Analysis Results – Technologies that Meet Effectiveness

System Size (Population Served)	GAC	Ion Exchange	RO	POU RO ^a
25 to 500	Yes	Yes	No	Yes
501 to 3,300	Yes	Yes	No^b	Yes
3,301 to 10,000	Yes	Yes	Yes	Not applicable ^c

Abbreviations: GAC – granular activated carbon; POU RO – Point-of-use reverse osmosis; RO – reverse osmosis; SSCT – small system compliance technology.

Notes:

^aPOU RO is not currently a compliance option because the regulatory options under consideration require treatment to concentrations below 70 ppt total of PFOA and PFOS, the current certification standard for POU devices. However, POU treatment is anticipated to become a compliance option for small systems in the future should NSF/ANSI or another accredited third-party certification entity develop a new certification standard that mirrors (or is demonstrated to treat to concentrations lower than) EPA's proposed regulatory standard. The affordability conclusions presented here should be considered preliminary because they reflect the costs of devices certified under the current standard, not a future standard.

^bUpper bound estimated annual household treatment costs exceed expenditure margin. Lower bound estimated annual household treatment costs do not exceed the expenditure margin.

^cEPA's WBS model for POU treatment does not cover systems serving more than 3,300 people (greater than 1 MGD design flow), because implementing and maintaining a large-scale POU program is likely to be impractical.

POU RO. POU RO is not currently evaluated as a compliance option because the regulatory options under consideration require treatment to concentrations below 70 ppt total of PFOA and PFOS, the current certification standard for POU devices. However, POU treatment is anticipated to become a compliance option for small systems in the future should NSF/ANSI or another accredited third-party certification entity develop a new certification standard that mirrors EPA's proposed regulatory standard. NSF has an update in progress today, and has noted it will consider future updates as needed and appropriate. EPA does not anticipate additional costs for water systems associated with the certification updating process. To evaluate affordability, EPA compared incremental costs per household for each technology against an expenditure margin. Table 9-8 shows the expenditure margins for each system size category. It also shows how EPA derived the expenditure margins, beginning with estimates of MHI, which vary by system size category. The annual affordability threshold for household expenditures on drinking water is 2.5 percent of MHI. EPA deducted estimates of baseline or current water bills from the affordability threshold to obtain the expenditure margin estimates.

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might result in classification of spent GAC or spent IX resin as hazardous waste. EPA estimated annual cost per household if systems are required to dispose of these residuals as hazardous waste and conducted the same national level affordability analysis using the higher hazardous waste handling treatment costs. The Agency found the increased treatment costs for both GAC and IX did not change the affordability conclusions. See Table 9-10 for annualized cost per household assuming hazardous waste disposal and U.S. EPA (2023f) for the complete analysis.

 Table 9-8: Expenditure Margins for SSCT Affordability Analysis

System Size (Population	Median Household Income ^a	Affordability Threshold ^b	Baseline Water Cost ^c	Expenditure Margin
Served)	A	B = 2.5% x A	C	$\mathbf{D} = \mathbf{B} - \mathbf{C}$
25 to 500	\$55,377	\$1,384	\$507	\$877
501 to 3,300	\$53,596	\$1,340	\$587	\$753
3,301 to 10,000	\$58,717	\$1,468	\$613	\$855

Abbreviations: SSCT – small system compliance technology.

Notes

Table 9-9 provides ranges of per-household costs for each technology and system size category. The ranges indicate minimum and maximum costs, for further information on SSCT costs, see U.S. EPA (2023f).

Table 9-9: Total Annual Cost per Household for Candidate Technologies

System Size (Population Served)	GAC	IX	RO	POU ROa
25 to 500	\$395 to \$727	\$376 to \$645	\$3,711 to \$4,676	\$317 to \$326
501 to 3,300	\$139 to \$332	\$133 to \$235	\$608 to \$1,169	\$299 to \$300
3,301 to 10,000	\$136 to \$329	\$121 to \$218	\$326 to \$462	Not applicable ^b

Abbreviations: GAC – granular activated carbon; IX – ion exchange; POU RO – point-of-use reverse osmosis; RO – reverse osmosis; SSCT – small system compliance technology.

Notes:

^aPOU RO is not currently a compliance option because the regulatory options under consideration require treatment to concentrations below 70 ppt total of PFOA and PFOS, the current certification standard for POU devices. However, POU treatment is anticipated to become a compliance option for small systems in the future should NSF/ANSI or another accredited third-party certification entity develop a new certification standard that mirrors (or is demonstrated to treat to concentrations lower than) EPA's proposed regulatory standard. Costs presented here should be considered preliminary estimates because they reflect the costs of devices certified under the current testing standard, not a future standard.

^bEPA's WBS model for POU treatment does not cover systems serving more than 3,300 people (greater than 1 MGD design flow), because implementing and maintaining a large-scale POU program is likely to be impractical.

The results discussed above assume management of spent GAC and spent IX resin using current typical management practices (reactivation for GAC and incineration for resin). EPA is in the process of proposing some PFAS be designated as hazardous substances under CERCLA and listed as hazardous substances constituents under the RCRA. If finalized, neither of these actions would result in new requirements as to how PFAS containing waste, including spent GAC or resin, is required to be managed. However, waste management facilities may, at their own discretion, refuse to accept PFAS-containing materials or drinking water treatment operations may choose to send spent GAC and resin containing PFAS to facilities permitted to treat and/or

^aMHI based on U.S. Census Bureau's American Community Survey five-year estimates (U.S. Census Bureau, 2010) stated in 2010 dollars, adjusted to 2020 dollars using the CPI (for all items) for areas under 2.5 million persons.

^bAffordability threshold equals 2.5 percent of MHI.

^cHousehold water costs derived from 2006 Community Water System Survey (U.S. EPA, 2009), based on residential revenue per connection within each size category, adjusted to 2020 dollars based on the Consumer Price Index for All Urban Consumers: Water and Sewer and Trash Collection Services in U.S. City Average.

dispose of hazardous wastes. To consider the implications of this possibility, EPA has developed an assessment of the current unit costs for disposing spent treatment materials and the costs associated with their disposal as hazardous waste. Table 9-10 shows the resulting cost per household if systems dispose of these residuals as hazardous waste. Although costs increase in this scenario, the increases are not significant enough to change the conclusions about affordability.

Table 9-10: Total Annual Cost per Household Assuming Hazardous Waste Disposal

System Size (Population Served)	GAC	IX
25 to 500	\$417 to \$827	\$397 to \$678
501 to 3,300	\$149 to \$368	\$138 to \$243
3,301 to 10,000	\$146 to \$360	\$124 to \$222

Abbreviations: GAC – granular activated carbon; IX – ion exchange.

9.12.2 Supplemental Affordability Analyses

In 2002, Congress required EPA to re-evaluate small system variance policy because of the concern with the high cost of arsenic treatment in small communities. In response, in 2003, EPA consulted with NDWAC and SAB. The SAB and NDWAC made a number of recommendations regarding the method by which EPA evaluates the affordability of compliance with drinking water standards.

Some key recommendations made by both the SAB and the NDWAC include:

- EPA should consider the household cost of each new regulation on an incremental basis rather than a total cost of all water treatment regulations, and
- EPA should consider reducing the current affordability threshold, and
- financial assistance should be incorporated in the affordability calculations if the financial support is generally available to all systems (nationwide).

In addition to the SAB and NDWAC recommendations, several additional reports by stakeholders have offered recommendations on the improvement of EPA's affordability methodology, including:

- The National Academy of Public Administration (NAPA) report, Developing a New Framework for Community Affordability of Clean Water Services (NAPA, 2017),
- The National Association of Clean Water Agencies, American Water Works Association, and Water Environment Federation report, Developing a New Framework for Household Affordability and Financial Capability Assessment in the Water Sector (Raucher et al., 2019), and
- The American Water Works Association expert panel report, Improving the Evaluation of Household-Level Affordability in SDWA Rulemaking: New Approaches (AWWA, 2021)

In large part, the recommendations in these reports point to the need to further assess the impacts of new regulatory costs across income groups with a particular focus on low income and disadvantaged communities and individuals within water systems. In particular, the American Water Works Association (2021) expert panel report stressed that the Agency also assess the affordability impacts to low-income households by setting the per household expenditure margin based on the lowest quintile (20th percentile) of the income distribution.

EPA is considering the development of additional metrics to assess the impact of new regulations on communities served by small drinking water systems and is requesting comment of the methods which should be employed for this type of analysis. To provide commenters additional information the Agency has estimated the impact of some potential changes to National Level Affordability Criteria and analysis based on suggested changed from the SAB, NDWAC, and AWWA's expert panel. In the following sub-sections, EPA estimated small system affordability based on; (1) an incremental approach with expenditure margins of 1.0 percent of annual MHI and 2.5 percent of the lowest quintile of annual household income, and no additional adjustment for total current annual water expenditures, and (2) taking into account nationally available financial assistance when assessing affordability.

9.12.2.1 Small System Affordability Analysis with Potential Additional Expenditure Margins

As part of EPA's consideration of potential additional annual expenditure margins to improve the assessment of affordability impacts to low income and disadvantaged communities this subsection provides PFAS example analyses to inform public comment. Specifically, two incremental cost analyses are conducted utilizing alternative potential expenditure margins. Given the recommendations from the NDWAC, the first expenditure margin threshold is based on 1.0 percent of annual MHI. The second expenditure margin threshold is set equal to 2.5 percent of the lowest quintile of annual household income and is based on the American Water Works Association (2021) expert panel report. These expenditure margins are estimated for each of the small system size categories: 25 to 500, 501 to 3,300, and 3,301 to 10,000 people served. As this is an incremental analysis no additional adjustments are made to the values to account for current annual drinking water cost. Table 9-11 shows the calculated annual expenditure margins by system size.

Table 9-11: Potential Annual Expenditure Margins for SSCT Affordability Analysis

System Size (Population Served)	1.0% of Median Household Income ^a	2.5% of Lowest Quintile Income ^b	
	A	В	
25 to 500	\$554	\$643	
501 to 3,300	\$536	\$628	
3,301 to 10,000	\$587	\$681	

Abbreviations: SSCT – small system compliance technology.

Notes:

Given these alternative annual expenditure margins the remainder of the assessment process is the same as EPA's current small system affordability methodology. The estimated total annual household costs for each of the deemed efficient treatment technologies presented in Table 9-9 are compared against the estimated annual expenditure margin thresholds from Table 9-11 for each system size category. Table 9-12 presents the affordability results using the 1.0 percent of annual MHI expenditure margin and Table 9-13 provides the information when the 2.5 percent of the lowest quintile of annual household income is used as the threshold.

Table 9-12: Affordability Analysis Results Using a 1.0% of Annual Median Household Income Expenditure Margin

System Size (Population Served)	GAC	Ion Exchange	RO	POU ROa
25 to 500	No^b	No^b	No	Yes
501 to 3,300	Yes	Yes	No	Yes
3,301 to 10,000	Yes	Yes	Yes	Not applicable ^c

 $Abbreviations: GAC-granular\ activated\ carbon;\ POU\ RO-point-of-use\ reverse\ osmosis;\ and\ RO-reverse\ osmosis.$ Notes:

^aPOU RO is not currently a compliance option because the regulatory options under consideration require treatment to concentrations below 70 ppt total of PFOA and PFOS, the current certification standard for POU devices. However, POU treatment is anticipated to become a compliance option for small systems in the future should NSF/ANSI or another accredited third-party certification entity develop a new certification standard that mirrors (or is demonstrated to treat to concentrations lower than) EPA's proposed regulatory standard. The affordability conclusions presented here should be considered preliminary because they reflect the costs of devices certified under the current standard, not a future standard.

^bUpper bound estimated annual household treatment costs exceed expenditure margin. Lower bound estimated annual

^bUpper bound estimated annual household treatment costs exceed expenditure margin. Lower bound estimated annual household treatment costs do not exceed the expenditure margin.

^cEPA's WBS model for POU treatment does not cover systems serving more than 3,300 people (greater than 1 MGD design flow), because implementing and maintaining a large-scale POU program is likely to be impractical.

^aMHI based on U.S. Census Bureau's American Community Survey five-year estimates (U.S. Census Bureau, 2010) stated in 2010 dollars, adjusted to 2020 dollars using the CPI (for all items) for areas under 2.5 million persons.

^bLowest quintile (20th percentile) household income based on U.S. Census 2010 American Community Survey 5-year estimates (U.S. Census Bureau, 2010) stated in 2010 dollars, adjusted to 2020 dollars using the CPI (for all items) for areas under 2.5 million persons.

Table 9-13: Affordability Analysis Results Using a 2.5% of Lowest Quintile of Annual Household Income Expenditure Margin

System Size (Population Served)	GAC	Ion Exchange	RO	POU ROa
25 to 500	No ^b	No ^b	No	Yes
501 to 3,300	Yes	Yes	No^b	Yes
3,301 to 10,000	Yes	Yes	Yes	Not applicable ^c

Abbreviations: GAC – granular activated carbon; POU RO – point-of-use reverse osmosis; and RO – reverse osmosis. Notes:

^aPOU RO is not currently a compliance option because the regulatory options under consideration require treatment to concentrations below 70 ppt total of PFOA and PFOS, the current certification standard for POU devices. However, POU treatment is anticipated to become a compliance option for small systems in the future should NSF/ANSI or another accredited third-party certification entity develop a new certification standard that mirrors (or is demonstrated to treat to concentrations lower than) EPA's proposed regulatory standard. The affordability conclusions presented here should be considered preliminary because they reflect the costs of devices certified under the current standard, not a future standard.

The results in both Table 9-12 and Table 9-13, which utilize the potential additional expenditure margins, of 1.0 percent of annual MHI and 2.5 percent of the lowest quintile of annual household income, and the results of EPA's national level affordability analysis in Table 9-3, which utilizes a household expenditure margin estimated by adjusting 2.5 percent of median household income minus baseline median annual drinking water costs, differ in the case of GAC and IX for systems serving 25 to 500 people. As indicated by the "Nob" reported in Table 9-12 and Table 9-13 for GAC and IX the upper bound annual household treatment cost for both these technologies exceed both the 1.0 percent of annual MHI and 2.5 percent of the lowest quintile of annual household income expenditure margins, however, the estimated lower bound annual household treatment costs do not exceed the expenditure margins. The alternative expenditure margins also changed the affordability results for RO in the 501–3,300 system size category. In the national affordability analysis using the 2.5 percent of MHI with baseline adjustment upper bound RO annual household cost estimates exceed the expenditure margin but the lower bound costs do not. When using both the 1.0 percent of annual MHI and 2.5 percent of the lowest quintile of annual household income potential criteria both the high and low bound estimated annual household treatment costs exceed the expenditure margins. 107

9.12.2.2 Small System Affordability Analysis When Accounting for Financial Assistance

The SAB and NDWAC recommended to EPA that the national level affordability analysis should include the impact of financial assistance if the financial support is generally available to all systems (nationwide). EPA is considering including this recommendation in the national affordability calculations. The recommendations themselves indicate a two-step process; (1)

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¹⁰⁷ Note, the results shown in Table 9-12 and Table 9-13 and discussed in this section are dependent on the estimated annual household technology costs reported in Table 9-9 which assumes costs associated with standard waste management of spent GAC and spent IX resin using current typical management practices (reactivation for GAC and incineration for resin). Future changes to regulations might result in classification of spent GAC or spent IX resin as hazardous waste. EPA estimated annual cost per household if systems are required to dispose of these residuals as hazardous waste and conducted the same national level affordability analyses with the 1.0 percent of MHI and 2.5 percent of the lowest quintile of annual household income expenditure margins and using the higher hazardous waste handling treatment costs. The Agency found the increased treatment costs for both GAC and IX did not change the affordability conclusions.

determine if and how much financial assistance is available to small systems on a national level for compliance with a specific rule, in this case the DW PFAS rule, and (2) calculate the potential impact of the financial assistance on the estimated per household treatment costs for each of the small system size categories.

On the national level, significant financial assistance is available to small systems for the installation of PFAS treatment technology. One critical and long-established source of this assistance is available through EPA's Drinking Water State Revolving Fund (DWSRF) Program that was authorized by Congress as part of the 1996 Amendments to the Safe Drinking Water Act. The DWSRF's purpose is to provide a source of financial assistance to water systems and states to help them achieve the public health protection objectives of SDWA. A unique feature of the DWSRF Program is that it is state based. EPA awards capitalization grants to states who provide a 20 percent match, creating a dedicated fund from which loans are made to water systems and into which the loan repayments (and interest) are deposited so they can be loaned out again. Within some broad statutory constraints contained in SDWA, the states have considerable flexibility to tailor the DWSRF Program to their own unique needs and circumstances.

The SDWA established three criteria at the core of the process used by states in ranking projects in priority order to receive funding. States are required, to the maximum extent practicable, to give priority for the use of DWSRF funds to projects that:

- 1. Address the most serious risk to human health;
- 2. Are necessary to ensure compliance with SDWA requirements; and
- 3. Assist systems most in need on a per household basis according to state affordability criteria.

Thus, system level affordability, according to state affordability criteria, is a central consideration in ranking projects eligible to receive DWSRF assistance. Each state has developed, and EPA has approved, a project priority ranking procedure. The specific weight given to affordability considerations vis-à-vis public health and SDWA compliance considerations varies from state to state. States are required to include their project priority ranking system as part of the Intended Use Plan they are required to develop in support of their application for each capitalization grant. The Intended Use Plan must contain both the project priority ranking system and the priority list of projects eligible for DWSRF assistance. The state must provide notice and opportunity for public comment on the priority list of projects.

Under the core DWSRF Program, the state may establish an interest rate between zero percent and the market rate. The lower the interest rate, the greater the subsidy provided to the borrower. SDWA requires states to establish a Disadvantaged Communities Program within their DWSRF under which communities considered disadvantaged according to state developed affordability criteria could receive additional subsidies beyond a zero percent loan. These additional subsidies often take the form of principal forgiveness (i.e., loan forgiveness) or grants. There is no limit to the amount of additional subsidy that can be provided to a particular project except for an overall limit on the total amount of additional subsidy of 35 percent of the state's annual capitalization grant.

This additional subsidization could be directed entirely to a few projects, essentially making the assistance those projects receive equivalent to a 100 percent grant; or the additional subsidization

could be distributed among a larger number of projects and combined with zero or low-interest loans. States may also offer communities they consider disadvantaged ¹⁰⁸ a loan term of 40 years rather than the base period of 20 to 30 years. Notably, the loan term cannot extend beyond the design life of the capital improvement constructed via the DWSRF loan.

The SDWA provided EPA with the authority to publish information to assist states in establishing affordability criteria for purposes of a disadvantaged community program. The Agency worked with a group of expert stakeholders and published "Information for States on Developing Affordability Criteria for Drinking Water" (document number 816-R-98-002) in February 1998 (U.S. EPA, 1998b). The Agency provided additional information to assist states' affordability criteria development in the "Implementation of the Clean Water and Drinking Water State Revolving Fund Provisions of the Bipartisan Infrastructure Law" memorandum in March 2022 (U.S. EPA, 2022d).

PFAS drinking water treatment loans and grants have been and will continue to be available to systems of all sizes under the traditional DWSRF program funding and allocation structure. In addition to these funding sources, on November 15, 2021, the Bipartisan Infrastructure Law (BIL) (P.L. 117-58), also known as the "Infrastructure Investment and Jobs Act of 2021" (IIJA) appropriated \$4 billion over 5 years (\$800,000,000 per year) for projects that are DWSRF eligible whose primary purpose must be to address emerging contaminants, with a focus on PFAS. EPA expects to establish a NPDWR for PFOA and PFOS. The Agency is also evaluating additional PFAS and groups of PFAS. Given stated Congressional intent of this appropriation, PFAS-focused projects will be eligible for funding under this appropriation regardless of whether EPA has established a NPDWR for that particular PFAS or group of PFAS. These BIL funds must be distributed to communities entirely as forgivable loans or grants, and states are not required to provide matching funds as with most DWSRF projects. 25 percent of this BIL funding is targeted toward disadvantaged communities and/or communities fewer than or equal to 25,000 people.

In addition to the DWSRF BIL funds, as part of a government-wide effort to confront PFAS pollution, the BIL authorizes \$5 billion as part of the Emerging Contaminants in Small or Disadvantaged Communities grant program that can be used to reduce PFAS in drinking water in communities facing disproportionate impacts. The goal of the Emerging Contaminants in Small or Disadvantaged Communities grant program is for states to provide grants to public water systems in small or disadvantaged communities to address emerging contaminants, including PFAS. Funding will be provided to participating states and territories to benefit small or disadvantaged communities in scoping, planning, testing and remediating emerging contaminants in drinking and source water.

These funds can be used in small or disadvantaged communities to address emerging contaminants like PFAS in drinking water through actions such as technical assistance, water quality testing, contractor training, and installation of centralized treatment technologies and systems. On June 15, 2022, EPA announced that it is making \$1 billion available in FY2022 of a total of \$5 billion for fiscal years 2022–2026.

¹⁰⁸ Disadvantaged community is defined as the service area of a public water system that meets affordability criteria established after public review and comment by the State in which the public water system is located.

Given the BIL emerging contaminant funding being made available through the DWSRF and the Emerging Contaminants in Small or Disadvantaged Communities grant program, EPA expects that most small systems will have access to financial assistance for PFAS related capital expenditures. EPA estimates that the total amount of capital treatment technology expenditures for small systems nationally ranges between approximately \$1.1 and \$2.5 billion. EPA expects funding from BIL to be more than sufficient to cover the capital costs for small systems. Hence, it seems reasonable to consider these funds for the purposes of illustrating the potential impact of including financial assistance in the calculation of the national level affordability assessment for small system compliance technologies. Because BIL funds are limited to providing grants and loan forgiveness associated with PFAS drinking water treatment capital expenditures, EPA in this example zeroed out only the capital cost of the candidate effective technologies. The annual per household treatment cost ranges presented in Table 9-9 represent operations and maintenance costs for the technologies by small system size category. Comparing the cost ranges in Table 9-14 with unadjusted cost ranges in Table 9-9 demonstrates the potential large decrease in technology cost when financial assistance is considered. The decreases across technologies and system size categories range from 28 percent to 76 percent.

Table 9-14: Annual Cost per Household for Candidate Technologies Assuming 100% Financial Assistance for Technology Capital Costs

System Size (Population Served)	GAC	Ion Exchange	RO	POU ROª
25 to 500	\$125 to \$198	\$133 to \$153	\$1,081 to \$1,153	\$225 to \$234
501 to 3,300	\$51 to \$122	\$57 to \$76	\$252 to \$309	\$209 to \$210
3,301 to 10,000	\$57 to \$129	\$58 to \$84	\$167 to \$193	Not applicable ^b

Abbreviations: GAC – granular activated carbon; POU RO – point-of-use reverse osmosis; and RO – reverse osmosis. Notes:

^aPOU RO is not currently a compliance option because the regulatory options under consideration require treatment to concentrations below 70 ppt total of PFOA and PFOS, the current certification standard for POU devices. However, POU treatment is anticipated to become a compliance option for small systems in the future should NSF/ANSI or another accredited third-party certification entity develop a new certification standard that mirrors (or is demonstrated to treat to concentrations lower than) EPA's proposed regulatory standard. The affordability conclusions presented here should be considered preliminary because they reflect the costs of devices certified under the current standard, not a future standard.

^bEPA's WBS model for POU treatment does not cover systems serving more than 3,300 people (greater than 1 MGD design flow), because implementing and maintaining a large-scale POU program is likely to be impractical.

Table 9-15, Table 9-16, and Table 9-17 below show the affordability results utilizing the 2.5 percent of annual MHI minus the baseline median annual drinking water cost, the incremental 1.0 percent of annual MHI, and using the 2.5 percent of the lowest quintile of annual household income expenditure margins, respectively. Given the significant reduction in estimated per household annual treatment costs for GAC and ion exchange, the technologies were found to satisfy the national level affordability criterion for the three statutorily mandated small system size categories. ¹⁰⁹ Centralized RO with high per household operations and maintenance costs, of

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¹⁰⁹ Note, the results shown in Table 9-15, Table 9-16 and Table 9-17 and discussed in this section are dependent on the estimated annual household technology costs reported in Table 9-14 which assumes operations and maintenance costs associated with standard waste management of spent GAC and spent IX resin using current typical management practices (reactivation for GAC and incineration for resin). Future changes to regulations might result in classification of spent GAC or spent IX resin as

\$1,081 to \$1,153, in the system size category of 25–500 people served was found to be unaffordable in that system size category across all alternative expenditure margins, but economies of scale reduce per household costs in systems serving between 501 and 10,000 people sufficiently to approve the technology as affordable under the three alternative expenditure margins. POU RO was also found to be affordable at the national level of analysis for systems serving 25 to 500 and 501 to 3,300 people across the three presented expenditure margins. POU RO is not applicable to systems serving more than 3,300 people given the increasing complexity of managing POU programs at such large scales.

Table 9-15: Affordability Analysis Results Using a 2.5% of Annual Median Household Income Minus the Baseline Median Annual Drinking Water Cost Expenditure Margin and assuming 100% Financial Assistance for Technology Capital Costs

System Size (Population Served)	GAC	Ion Exchange	RO	POU RO ^a
25 to 500	Yes	Yes	No	Yes
501 to 3,300	Yes	Yes	Yes	Yes
3,301 to 10,000	Yes	Yes	Yes	Not applicable ^b

 $Abbreviations: GAC-granular\ activated\ carbon; POU\ RO-point-of-use\ reverse\ osmosis; and\ RO-reverse\ osmosis.$ Notes:

^aPOU RO is not currently a compliance option because the regulatory options under consideration require treatment to concentrations below 70 ppt total of PFOA and PFOS, the current certification standard for POU devices. However, POU treatment is anticipated to become a compliance option for small systems in the future should NSF/ANSI or another accredited third-party certification entity develop a new certification standard that mirrors (or is demonstrated to treat to concentrations lower than) EPA's proposed regulatory standard. The affordability conclusions presented here should be considered preliminary because they reflect the costs of devices certified under the current standard, not a future standard.

^bEPA's WBS model for POU treatment does not cover systems serving more than 3,300 people (greater than 1 MGD design flow), because implementing and maintaining a large-scale POU program is likely to be impractical.

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hazardous waste. EPA estimated annual operations and maintenance cost per household if systems are required to dispose of these residuals as hazardous waste and conducted the same national level affordability analyses using the three alternative expenditure margins using the higher hazardous waste handling treatment costs. The Agency found the increased treatment costs for both GAC and IX did not change the affordability conclusions.

Table 9-16: Affordability Analysis Results Using a 1.0% of Annual Median Household Income Expenditure Margin and assuming 100% Financial Assistance for Technology Capital Costs

System Size (Population Served)	GAC	Ion Exchange	RO	POU RO ^a
25 to 500	Yes	Yes	No	Yes
501 to 3,300	Yes	Yes	Yes	Yes
3,301 to 10,000	Yes	Yes	Yes	Not applicable ^b

Abbreviations: GAC – granular activated carbon; POU RO – point-of-use reverse osmosis; and RO – reverse osmosis. Notes:

^aPOU RO is not currently a compliance option because the regulatory options under consideration require treatment to concentrations below 70 ppt total of PFOA and PFOS, the current certification standard for POU devices. However, POU treatment is anticipated to become a compliance option for small systems in the future should NSF/ANSI or another accredited third-party certification entity develop a new certification standard that mirrors (or is demonstrated to treat to concentrations lower than) EPA's proposed regulatory standard. The affordability conclusions presented here should be considered preliminary because they reflect the costs of devices certified under the current standard, not a future standard.

^bEPA's WBS model for POU treatment does not cover systems serving more than 3,300 people (greater than 1 MGD design flow), because implementing and maintaining a large-scale POU program is likely to be impractical.

Table 9-17: Affordability Analysis Results Using a 2.5% of Lowest Quintile of Annual Household Income Expenditure Margin and assuming 100% Financial Assistance for Technology Capital Costs

System Size (Population Served)	GAC	Ion Exchange	RO	POU RO ^a
25 to 500	Yes	Yes	No	Yes
501 to 3,300	Yes	Yes	Yes	Yes
3,301 to 10,000	Yes	Yes	Yes	Not applicable ^b

Abbreviations: GAC – granular activated carbon; POU RO – point-of-use reverse osmosis; and RO – reverse osmosis.

Notes:

^aPOU RO is not currently a compliance option because the regulatory options under consideration require treatment to concentrations below 70 ppt total of PFOA and PFOS, the current certification standard for POU devices. However, POU treatment is anticipated to become a compliance option for small systems in the future should NSF/ANSI or another accredited third-party certification entity develop a new certification standard that mirrors (or is demonstrated to treat to concentrations lower than) EPA's proposed regulatory standard. The affordability conclusions presented here should be considered preliminary because they reflect the costs of devices certified under the current standard, not a future standard.

^bEPA's WBS model for POU treatment does not cover systems serving more than 3,300 people (greater than 1 MGD design flow), because implementing and maintaining a large-scale POU program is likely to be impractical.

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