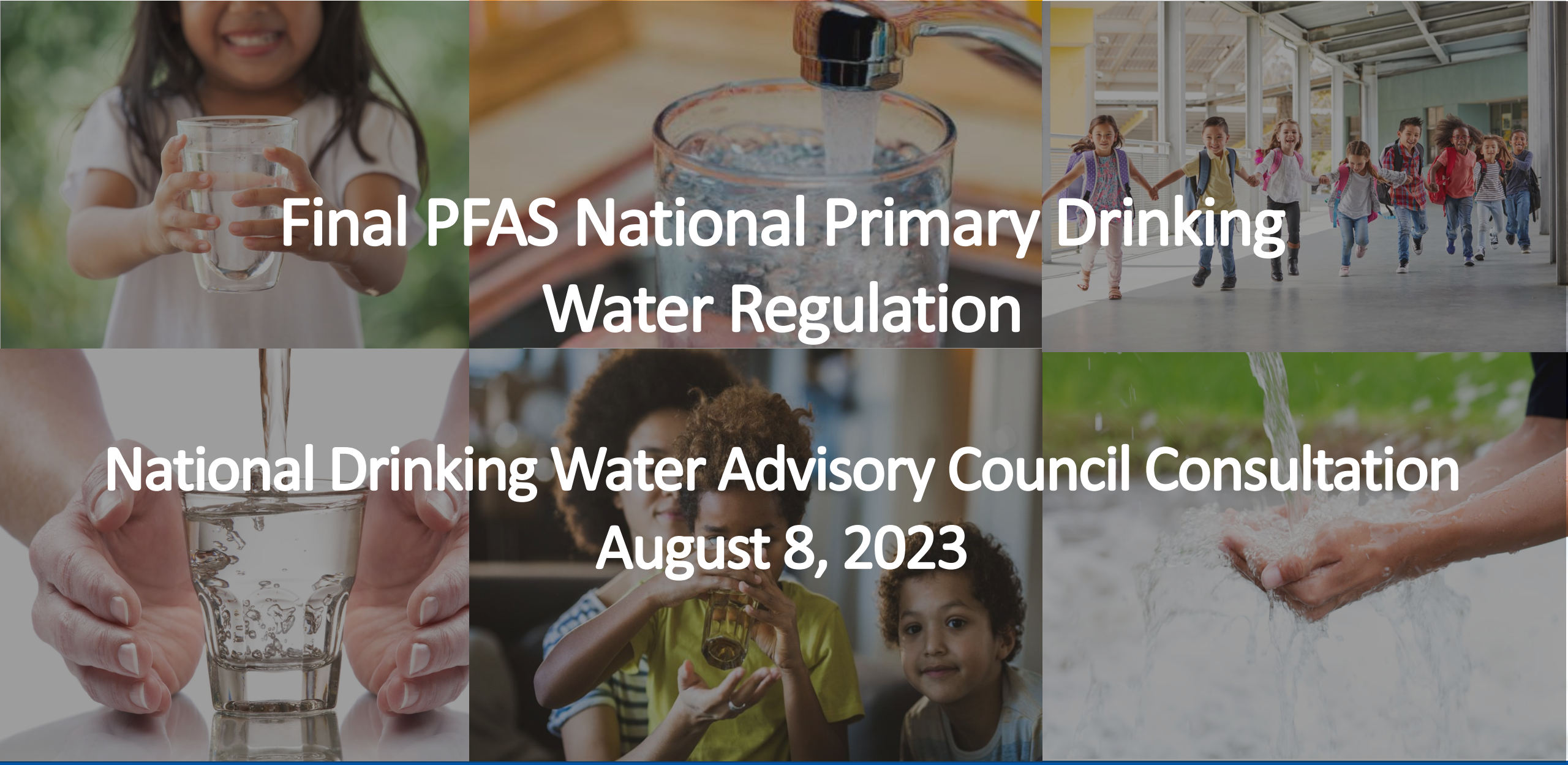


Final PFAS National Primary Drinking Water Regulation

National Drinking Water Advisory Council Consultation
August 8, 2023

EPA United States Environmental Protection Agency

Office of Water

Purpose

- To provide the National Drinking Water Advisory Council (NDWAC) with information on the proposed per-and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation (NPDWR)
- To consult with the NDWAC prior to promulgating the final PFAS NPDWR

Overview

- PFAS and Safe Drinking Water Act (SDWA) Background
- Proposed PFAS NPDWR Requirements
- Summary of NDWAC Member Perspectives on the Development of Key Areas of the Proposed Rule
- Questions and Discussion

PFAS Background

- PFAS are a category of manufactured chemicals that have been used in industry and consumer products since the 1940s.
- PFAS have characteristics that make them useful in a variety of products, including nonstick cookware, waterproof clothing, and firefighting foam, as well as in certain manufacturing processes.
- PFAS tend to break down extremely slowly in the environment and can build up in people, animals, and the environment over time.
- Even though some specific PFAS have been largely phased out due to health and environmental concerns, they may still be found in the environment and in drinking water.

PFAS Background

- We now know that over a long time PFAS may:
  - Lead to negative health effects on pregnant people and in developing babies
  - Weaken a body's ability to fight disease
  - An increased risk for some cancers, liver damage
  - Elevated cholesterol levels (which can increase the risk for heart attack or stroke)
- PFAS can enter drinking water in many ways, including discharges to rivers and lakes from manufacturing and processing facilities, as well as during industrial and commercial use. Areas can also be exposed due to proximity to industrial sites, airports, military installations, and other sites where PFAS have been produced or used.
- Drinking water is one of several ways people may be exposed to PFAS.
- Different PFAS are often found together and in combinations (or mixtures) in drinking water and the environment.
- EPA is acting to protect people's drinking water and reducing our exposure to PFAS, can lower our risk for these health effects.

Regulating PFAS in Drinking Water

- Under SDWA, EPA issued final regulatory determinations for PFOA and PFOS in March 2021. As a part of that action, EPA stated it would continue to evaluate additional PFAS to consider regulatory actions for other PFAS as supported by the best available science.
- In March 2023, EPA issued preliminary regulatory determinations to regulate four PFAS including PFHxS, PFNA, PFBS, HFPO-DA (commonly referred to as GenX Chemicals)
- Concurrent with these preliminary regulatory determinations, EPA proposed an NPDWR for these four PFAS as well as for PFOA and PFOS.
- This action is not final and does not require any actions until after EPA considers the public input and finalizes the regulation. Under SDWA, NPDWRs require compliance three years following rule promulgation.
- EPA anticipates that if fully implemented the rule will prevent tens of thousands of serious PFAS-attributable illnesses or deaths.

Overview of NPDWR Development Process

What are the best available, peer-reviewed science and supporting studies?

What is the level at which no known or anticipated adverse effects on the health of persons occur and which allows for an adequate margin of safety?

Develop a health risk reduction and cost analysis and determine what are the impacts of policy alternatives?

What is the regulatory standard that may be achieved with the use of best available technologies taking cost into consideration?

Are the benefits justified by the costs?

Stakeholder Input Informing the Proposed PFAS NPDWR

- To inform the proposed NPDWR, EPA gathered input from several stakeholder groups and public meetings including:
  - Local, state, and tribal governments and officials
  - Public drinking water systems,
    - Small system representatives to the Small Business Advocacy Review Panel
  - Science Advisory Board
  - National Drinking Water Advisory Council
  - Public meetings on environmental justice considerations

NDWAC Consultation on the Proposed PFAS NPDWR

- In April 2022, EPA conducted a consultation with the NDWAC prior to rule proposal. EPA provided information related to informing considerations for key areas of the proposed rule including:
  - PFAS mixtures
  - Monitoring
  - Public notification
  - Treatment

EPA's Proposed Action for the PFAS NPDWR

- EPA proposed health-based, non-enforceable Maximum Contaminant Level Goals (MCLGs) for six PFAS.
  - PFOA and PFOS as individual contaminants, and
  - PFHxS, PFNA, GenX Chemicals, and PFBS as a PFAS mixture
  - MCLGs are the maximum level of a contaminant in drinking water where there are no known or anticipated negative health effects allowing for a margin of safety.
- EPA proposed an NPDWR to establish legally enforceable MCLs for these six PFAS in drinking water.

Proposed PFOA and PFOS MCLGs Considerations

- To establish the MCLGs for PFOA and PFOS, EPA assessed the peer reviewed science examining cancer and noncancer health effects associated with oral exposure.
- Consistent with SDWA statutory definition of an MCLG, EPA establishes MCLGs of zero for carcinogens classified as *Carcinogenic to Humans* or *Likely to be Carcinogenic to Humans* where there is insufficient information to determine that a carcinogen has a threshold dose below which no carcinogenic effects have been observed.
- Under the EPA Guidelines for Carcinogen Risk Assessment, EPA reviewed the weight of the evidence and determined that PFOA and PFOS are *Likely to Be Carcinogenic to Humans*.
  - For PFOA, this determination is based on the statistically significant evidence of kidney cancer in humans and Leydig cell tumors, pancreatic acinar cell tumors, and hepatocellular adenomas in rats.
  - For PFOS, this determination is based on the statistically significant evidence of potentially human relevant tumors, including hepatocellular tumors in male and female rats and pancreatic islet cell carcinomas in male rats.

EPA's Proposed Action for the PFAS NPDWR

Compound	Proposed MCLG	Proposed MCL (enforceable levels)
PFOA	0 ppt*	4.0 ppt*
PFOS	0 ppt*	4.0 ppt*
PFNA	1.0 (unitless) Hazard Index	1.0 (unitless) Hazard Index
PFHxS		
PFBS		
HFPO-DA (commonly referred to as GenX Chemicals)		

The Hazard Index is a tool used to evaluate potential health risks from exposure to chemical mixtures.

*ppt = parts per trillion (also expressed as ng/L)

Proposed MCLs Considerations

- EPA proposed MCLs as close as feasible to the MCLGs.
- For the feasibility determination, EPA considered factors including:
  - Availability of analytical methods: There are multiple methods available (EPA Methods 533 and 537.1) to reliably measure and quantify the six PFAS at or below their proposed MCLs.
  - Identification of treatment technologies: There are several treatment technologies available and currently in use to treat and remove the six PFAS to levels at or below their proposed MCLs.

What is a Hazard Index?

- The HI is a tool used to evaluate potential health risks from exposure to chemical mixtures, based on an assumption of dose additivity.
- EPA is proposing that water systems use this approach to limit any mixture containing one or more of PFHxS, PFNA, PFBS, and GenX Chemicals. The HI does not include PFOA and PFOS which are proposed for regulation as individual contaminants due to their likely carcinogenicity.
- To determine the HI, water systems would monitor and compare the amount of each of the four PFAS in drinking water to its associated HBWC, which is the level below which no health effects are expected for that PFAS. The proposed HBWCs are:

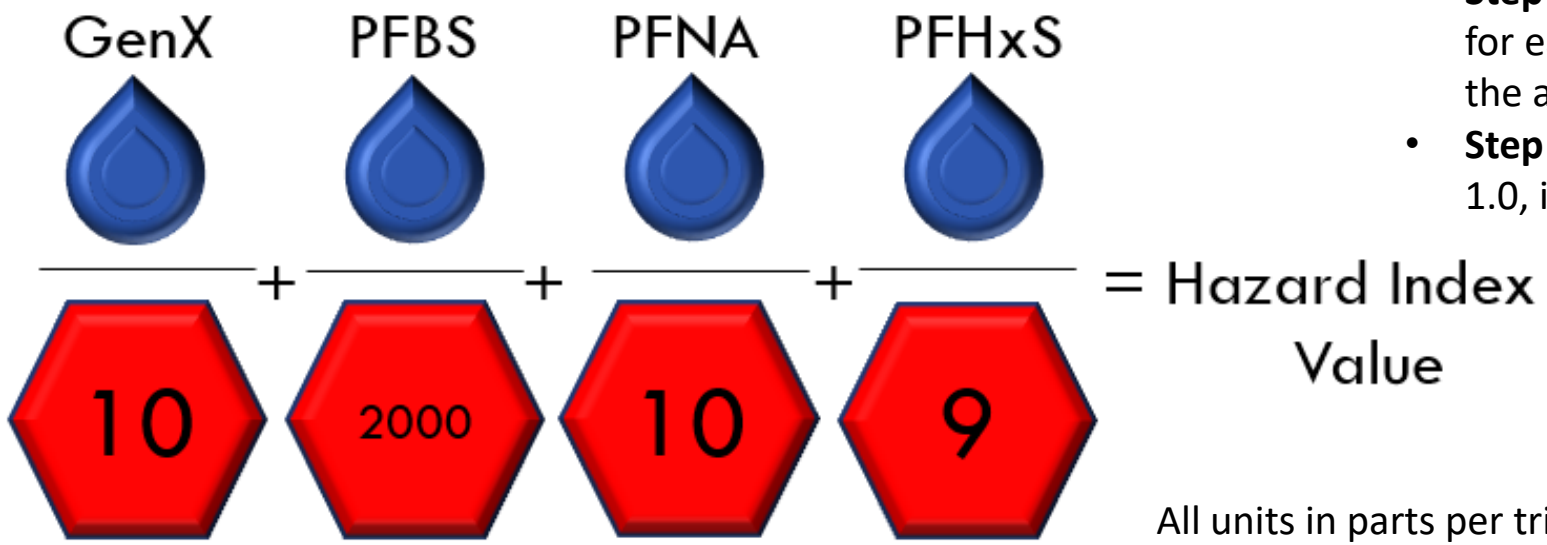
Compound	Proposed HBWC (ppt)
PFHxS	**9.0**
PFNA	**10**
PFBS	**2000**
HFPO-DA (commonly referred to as GenX Chemicals)	**10**

How do I calculate the Hazard Index?

The HI is used to understand health risks. For the PFAS NPDWR proposal, the HI considers the combined toxicity of PFNA, GenX Chemicals, PFHxS, and PFBS in drinking water.

What is a Hazard Index?

The HI is made up of a sum of fractions. Each fraction compares the level of each PFAS measured in the water to the level determined not to cause health effects (i.e., HBWC).



Steps:

- **Step 1:** Divide the measured concentration of **GenX** by the health-based value of **10 ppt***
- **Step 2:** Divide the measured concentration of **PFBS** by the health-based value of **2000 ppt**
- **Step 3:** Divide the measured concentration of **PFNA** by the health-based value of **10 ppt**
- **Step 4:** Divide the measured concentration of **PFHxS** by the health-based value of **9.0 ppt**
- **Step 5:** Add the ratios from steps 1, 2, 3, and 4 together
- **Step 6:** To determine HI compliance, repeat steps 1-5 for each sample collected in the past year and calculate the average HI for all the samples taken in the past year
- **Step 7:** If the running annual average HI greater than 1.0, it is a violation of the proposed HI MCL

All units in parts per trillion (ppt)

Hazard Index MCL Calculation Examples

GenX Chemicals	PFBS	PFNA	PFHxS	HI

- **Example 1** – Exceedance of proposed Hazard Index MCL

$$\left(\frac{[5\ \text{ppt}]}{[10\ \text{ppt}]}\right) + \left(\frac{[200\ \text{ppt}]}{[2000\ \text{ppt}]}\right) + \left(\frac{[5\ \text{ppt}]}{[10\ \text{ppt}]}\right) + \left(\frac{[9\ \text{ppt}]}{[9.0\ \text{ppt}]}\right) = \mathbf{2.1}$$

- **Example 2** – Exceedance of proposed Hazard Index MCL

$$\left(\frac{[0\ \text{ppt}]}{[10\ \text{ppt}]}\right) + \left(\frac{[200\ \text{ppt}]}{[2000\ \text{ppt}]}\right) + \left(\frac{[2\ \text{ppt}]}{[10\ \text{ppt}]}\right) + \left(\frac{[7\ \text{ppt}]}{[9.0\ \text{ppt}]}\right) = \mathbf{1.1}$$

- **Example 3** – Exceedance of proposed Hazard Index MCL

$$\left(\frac{[12\ \text{ppt}]}{[10\ \text{ppt}]}\right) + \left(\frac{[0\ \text{ppt}]}{[2000\ \text{ppt}]}\right) + \left(\frac{[0\ \text{ppt}]}{[10\ \text{ppt}]}\right) + \left(\frac{[0\ \text{ppt}]}{[9.0\ \text{ppt}]}\right) = \mathbf{1.2}$$

- **Example 4** – Meets proposed Hazard Index MCL

$$\left(\frac{[0\ \text{ppt}]}{[10\ \text{ppt}]}\right) + \left(\frac{[100\ \text{ppt}]}{[2000\ \text{ppt}]}\right) + \left(\frac{[4\ \text{ppt}]}{[10\ \text{ppt}]}\right) + \left(\frac{[3\ \text{ppt}]}{[9.0\ \text{ppt}]}\right) = \mathbf{0.8}$$

NDWAC Member Perspectives in the Pre-Proposal Consultation: PFAS Mixtures

How should EPA consider or address potential mixtures of PFAS in the proposed drinking water standard?

- EPA should consider mixtures of PFAS, and to the extent possible, addressing multiple contaminants at once is important.
- EPA could evaluate PFAS in groups similar to what is done for total trihalomethanes and haloacetic acids regulations.
- There could be challenges in regulating groups of PFAS where not enough similarities in health effects.

Questions and Discussion

EPA's Proposed Action for the PFAS NPDWR

- The proposed rule would require public water systems to:
  - Monitor for these PFAS;
  - Notify the public of the levels of these PFAS; and
  - Reduce the levels of these PFAS in drinking water if they exceed the proposed standards.

Proposed NPDWR Monitoring Requirements

- EPA's proposed requirements are based on EPA's Standardized Monitoring Framework for both initial and ongoing compliance monitoring of regulated PFAS to ensure that drinking water is not above MCLs.
- Initial monitoring must be completed in the three years between the rule promulgation date (anticipated end of 2023) and the rule effective date (anticipated end of 2026). Proposed initial monitoring requirements to establish baseline PFAS levels include any combination of:
  - Two or four samples collected at public water systems over one year, dependent on system population size and system type
  - Use of recent, previously acquired PFAS drinking water data from the fifth Unregulated Contaminant Monitoring Rule (UCMR 5), state-level drinking water occurrence monitoring, or other appropriate data collection program
- Initial monitoring results will determine the ongoing compliance monitoring requirements. Proposed ongoing compliance monitoring requirements include:
  - Quarterly monitoring as the normal frequency for all sampling locations
  - Reduced monitoring flexibility to once or twice every three years for sampling locations where the result is below 1/3 of the MCLs (i.e., rule trigger level)
- A system is in violation if monitoring results exceed one of the MCLs. Compliance calculations are based on running annual average, where if the measured value is below the PFAS practical quantitation level (PQL), zero is used for the calculation (e.g., a value of 2.0 for PFOA would default to zero).

Proposed NPDWR Monitoring Requirements

- EPA used PQLs for the six PFAS proposed for regulation in determining the proposed MCLs. PQLs are the lowest concentration of a contaminant that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions.
- The proposed rule trigger levels are set at levels that are useful in determining whether the contaminant is present in a sample rather than to determine its specific concentration.
- EPA requested comment on establishing the proposed rule trigger levels at 1/3 of the proposed MCLs and on alternative trigger levels such as 1/2 of the proposed MCLs.

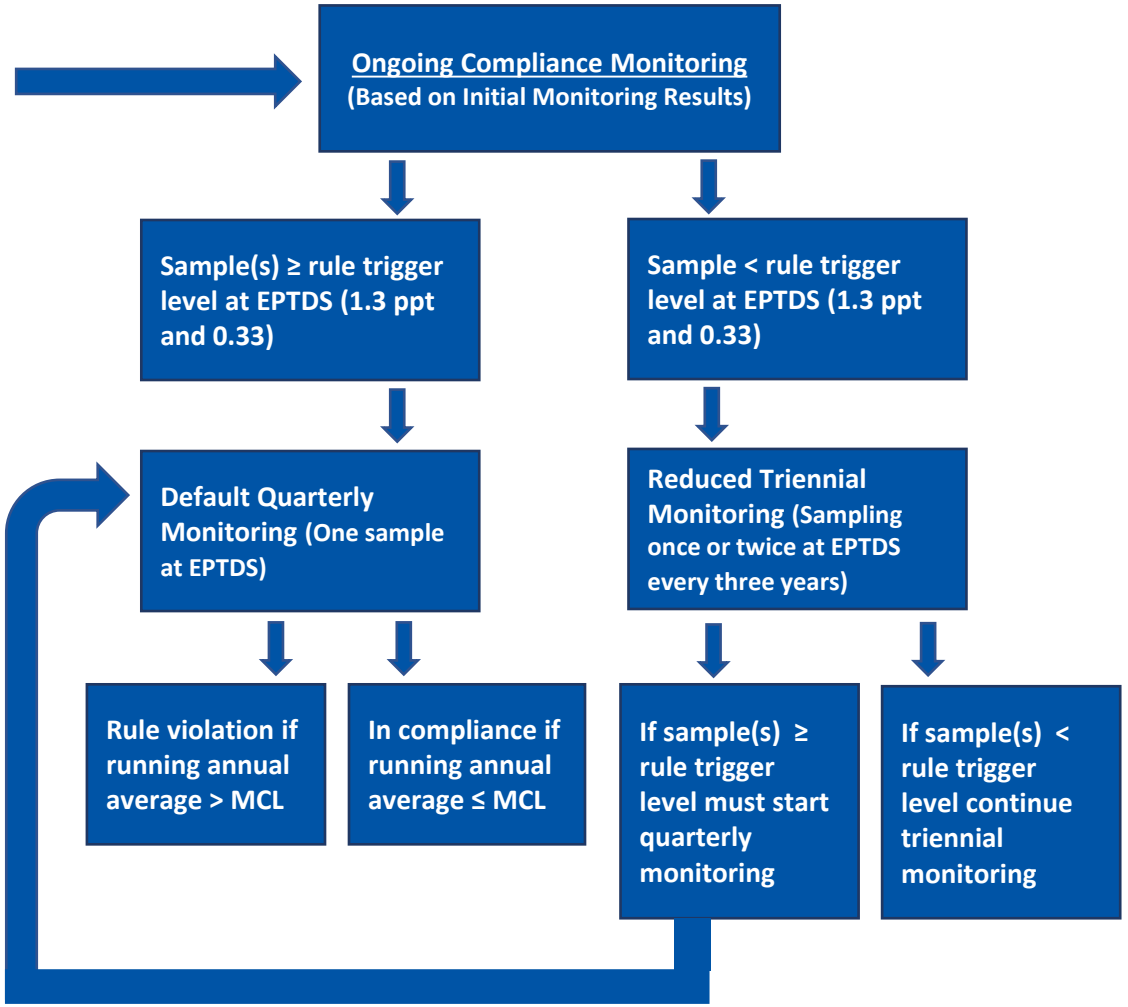
Proposed NPDWR Monitoring Requirements

Initial Monitoring

- Four quarterly samples within a 12-month period for ground water systems serving greater than 10,000 and all surface water systems
- Two semi-annual samples within a 12-month period for ground water systems serving 10,000 or fewer

AND/OR

- Use of recent, existing PFAS drinking water occurrence data



Rule Trigger Levels (1/3 Proposed MCLs)

- **PFOA and PFOS = 1.3 ppt**
- **Hazard Index PFAS = 0.33**

*** EPTDS = Entry point to the distribution system**

NDWAC Member Perspectives in the Pre-Proposal Consultation: Monitoring

How should available monitoring data be considered for initial monitoring requirements and should the Standardized Monitoring Framework for SOCs be incorporated?

- EPA should utilize a Standardized Monitoring Framework for monitoring.
- It is unlikely that monitoring waivers could be issued given how ubiquitous PFAS are in the environment. If waivers are allowed, it should be based on sampling results, though for other systems it could be based on their source water if it known to show little variation.
- Recent data collected under UCMR 5 or other monitoring efforts using EPA approved analytical methods could be used.
- EPA could offer a phased scheduled for monitoring to address any laboratory capacity issues.

Questions and Discussion

Proposed NPDWR Public Notification Requirements

- EPA proposed that public water systems be required to issue public notification to customers if the levels of regulated PFAS exceed the proposed PFAS NPDWR.
- Under the Public Notification Rule, EPA proposed the PFAS NPDWR as a "Tier 2" notification.
  - This would require notice as soon as possible, but within 30 days of the violation.
- EPA is proposing that community water systems be required to include PFAS information in the Consumer Confidence Report distribution to customers including:
  - The level of the regulated PFAS that is measured in their drinking water.
  - The potential health effects of the regulated PFAS detected in violation of the PFAS NPDWR.

NDWAC Member Perspectives in the Pre-Proposal Consultation: Public Notification

How quickly should water systems be required to notify the public following a violation of the PFAS standard and information that should be included in Consumer Confidence Reports regarding PFAS in drinking water?

- Members provided various comments on the public notification tier with some suggesting a Tier 2 or Tier 3 public notification is most appropriate, while other comments suggested a public notification tier between Tier 1 and Tier 2 and that EPA should identify a level above the MCL which would require an immediate notice.
- CCRs should include violations, however they should not include all detections. Other comment provided that all detections should be provided to the public as soon as possible, particularly for certain sensitive populations.
- Clear health effects language is critical, as well as explanation of how people can reduce their exposure beyond drinking water risks.

Questions and Discussion

PFAS Drinking Water Treatment Technologies

- Water systems with regulated PFAS above their proposed MCLs will be required to install treatment or take other action to reduce regulated PFAS levels in their drinking water and meet MCLs.
- As proposed, the rule would allow water systems the flexibility to determine the best actions and approaches to their specific situation.
- EPA evaluated technologies and has studies that demonstrate effective removal of all regulated PFAS. EPA has identified the following as best available technologies (BATs):
  - Granular activated carbon(GAC)
  - Anion Exchange (AIX)
  - Nanofiltration (NF) and Reverse Osmosis (RO)
- Some water systems may be able to reduce PFAS levels without installing treatment by using an alternative source of water that does not have PFAS contamination.

PFAS Drinking Water Treatment Technologies

- EPA conducted an extensive review of available PFAS removal treatment literature in EPA's Drinking Water Treatability Database and detailed in EPA's proposed rule support documents. The available data includes hundreds of studies conducted in the laboratory, in the field at pilot scale, and in full-scale application.
- Based on the best available science, EPA found that all of the best available technologies (GAC, AIX, RO, and NF) can exceed treatment removal efficiencies > 99% and can achieve concentrations below analytical detection limits.
- These technologies can also co-remove PFAS. For example, PFHxS is removed approximately as well as PFOA.

PFAS Treatment Residuals and Disposal

- EPA evaluated actions that public water systems must take to dispose of treatment residuals that contain PFAS.
- EPA has developed interim guidance for the destruction and disposal of PFAS and PFAS-containing materials from some products, including spent drinking water treatment media.
- EPA is aware that actions resulting from other environmental statutes (e.g., Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)) may impact future drinking water treatment and disposal options.
  - As part of the proposed PFAS NPDWR, EPA has considered the costs of various disposal options for drinking water treatment residuals that contain PFAS.
- EPA is prioritizing research on PFAS disposal options in different environmental media and best management practices.

NDWAC Member Perspectives in the Pre-Proposal Consultation: Treatment

Are there other treatment technologies EPA should consider or other non-treatment options? How should EPA consider the disposal of PFAS treatment residuals?

- When considering point of use treatment, EPA should evaluate who owns and operates them and where the responsibility lies.
- Treatment residual disposal should be considered in EPA's evaluation of drinking water treatment.
- More research is needed for the ultimate destruction and disposal of PFAS.
- EPA should consider requiring systems to identify new sources of water before applying treatment to address PFAS.
- EPA should allow treatment technologies that have not currently been identified under the rule to be implemented later and meet rule requirements.
- The burden to remove PFAS should not solely fall on public water systems and manufacturers and producers of PFAS should be responsible for limiting the formation and discharges of PFAS.

Questions and Discussion

Economic Analysis for the Proposed Rule

- Benefits are assessed as avoided cases of illness and deaths associated with exposure to the six PFAS in the NPDWR. EPA's benefits analysis considered the strength of evidence for each effect and the availability of data to quantify the associated morbidity and mortality impacts.
- Costs are assessed as the expenses incurred by public water systems to monitor for the six PFAS included in the NPDWR, install and operate treatment technologies, inform consumers, and perform record-keeping and reporting responsibilities. State (or primacy agency) costs are assessed as expenses incurred to administer and implement the rule.
- EPA used the best available science and peer reviewed models to complete the economic analysis for the proposed rule. **The Administrator determined that the benefits of this proposed regulation justify the costs.**

National Benefits Summary

- EPA quantified some of the reduced adverse health effects expected from the proposed rule including kidney cancers, heart attacks, strokes, and developmental (birth weight) effects. EPA relied on the assessment of adverse health effects of PFOA and PFOS in the MCLG documents to inform the benefits analysis.
- EPA anticipates significant additional benefits beyond those that EPA has quantified associated with the following adverse health effects:
  - Immune
  - Developmental
  - Cardiovascular
  - Hepatic
  - Carcinogenic
  - Endocrine
  - Metabolic
  - Reproductive
  - Musculoskeletal

Annualized Quantified Rule Benefits (i.e., per year)	3% Discount Rate	7% Discount Rate
	$1.23 billion	**$908 million**

National Costs Summary

- EPA expects roughly 66,000 water systems to be subject to the rule, with approximately 3,400-6,300 systems anticipated to exceed one or more MCL.
- EPA has estimated the costs of the proposed rule to public water systems associated with administration, monitoring, and treatment and costs to primacy agencies associated with rule implementation and administration.
- Public water system treatment cost estimates include capital, and yearly operation and maintenance costs over the period of analysis and are derived using peer-reviewed work breakdown structure models.

Annualized Quantified Rule Costs (i.e., per year)	3% Discount Rate	7% Discount Rate
	$772 million	**$1.20 billion**

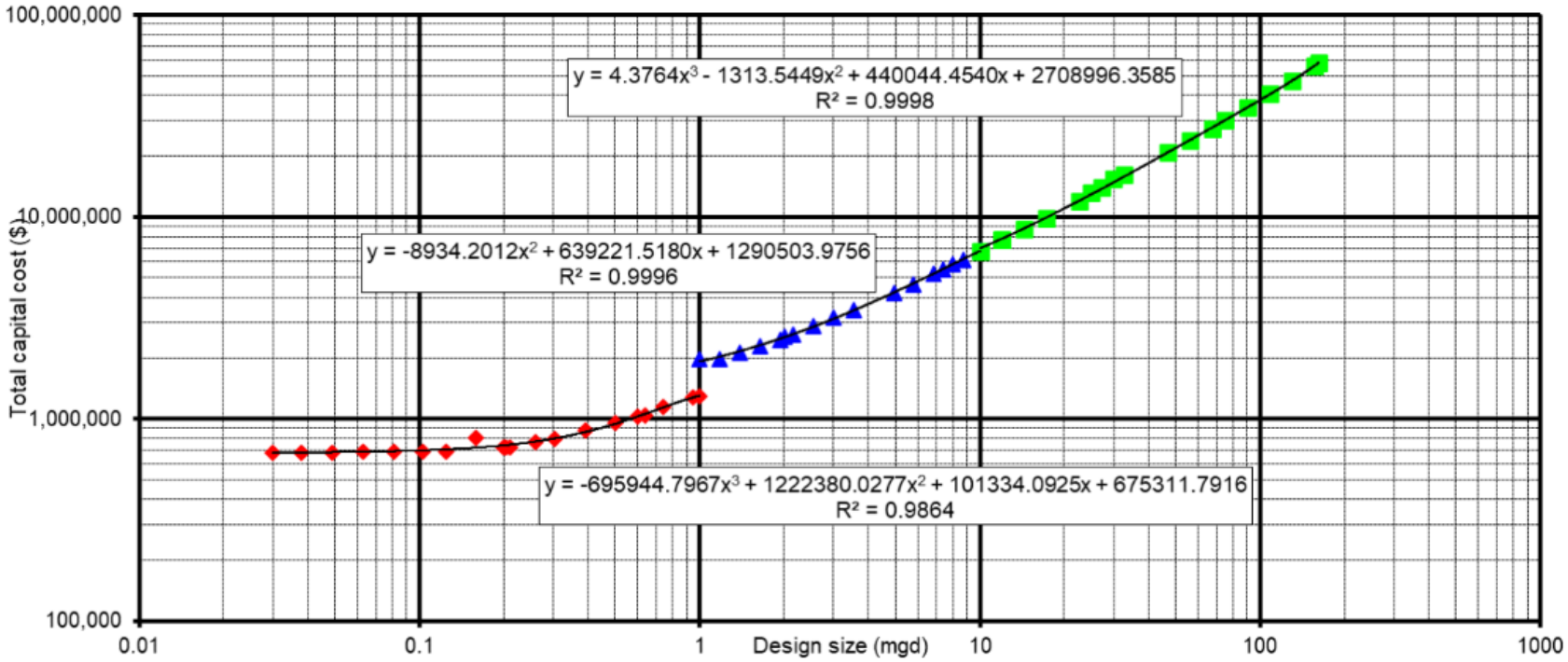
- EPA also prepared a supplemental cost analysis that estimates the annual costs would increase by $30-$61 million per year if water systems are required to dispose of PFAS treatment as hazardous waste.

Water System Treatment Costs

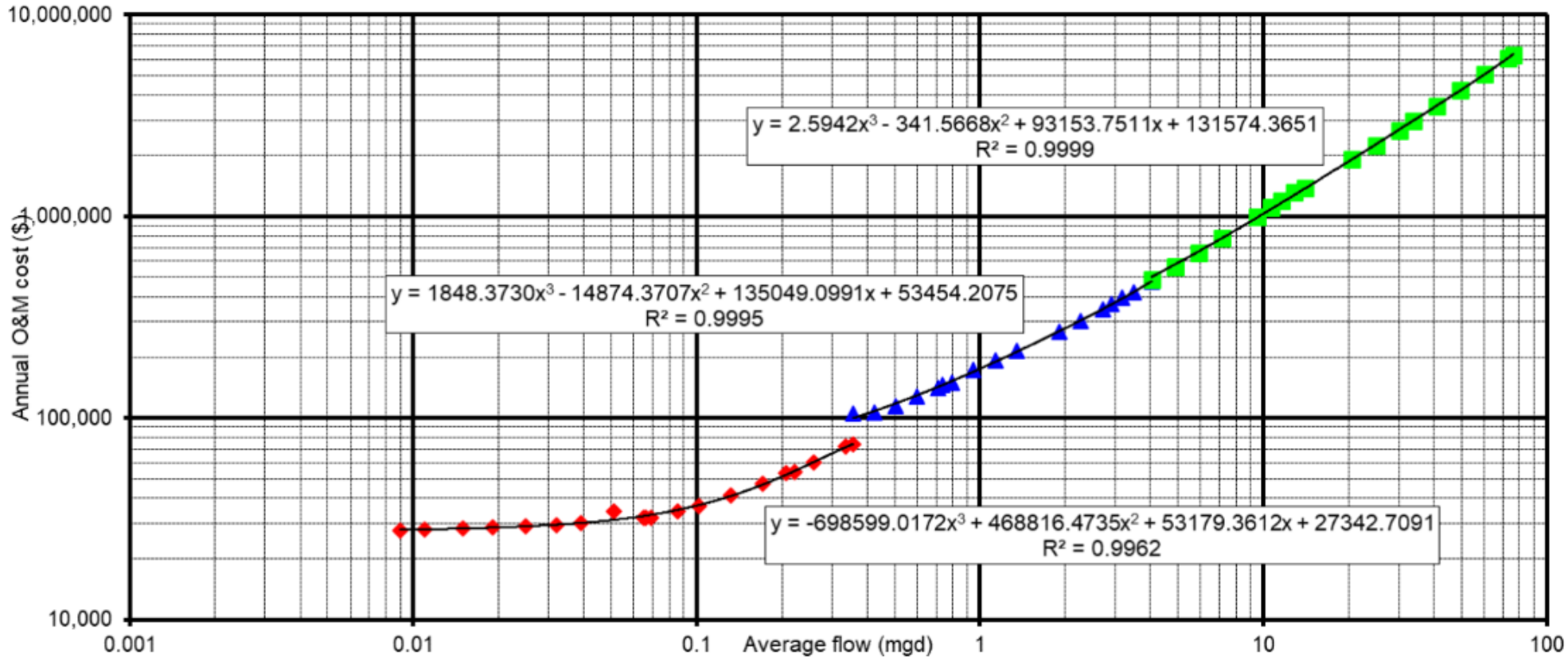
- EPA estimated annualized costs per year for water systems that treat or change water source.
  - Costs of system capital, operation, and maintenance are annualized.
- Quantified costs are estimated over a human lifetime (82 years) to be comparable to quantified benefits estimates.
- Costs factor in repairs and replacement of capital infrastructure at the end of its lifespan (variable, based on materials used; for example, useful life range of approximately 20-35 years for GAC capital).
- Costs differ based on treatment technology used.
- For more information, see USEPA (2023) Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances. EPA-822-P-23-001.

Capital Cost Estimates

- EPA developed dozens of Work Breakdown Structure cost equations for treatment at surface and ground water systems across the range of bed life (5,000 to 150,000 BVs) and residuals management scenarios (hazardous and non-hazardous), including high, mid, and low-cost levels.
- The mid-level capital cost curve (right) estimates costs of removal of PFAS from surface water using GAC.
- These curves are used to inform the SafeWater model, which estimates national level treatment costs.



Operation and Maintenance Cost Estimates



Mid-level Cost Results for Removal of PFAS from Surface Water Using Gravity GAC ($2020)

Bipartisan Infrastructure Law Funding for PFAS

- The Bipartisan Infrastructure Law provides $9 billion to invest in drinking water systems specifically impacted by PFAS and other emerging contaminants.
  - $4 billion through the Drinking Water State Revolving Fund (DWSRF)
  - $5 billion through EPA's Emerging Contaminants in Small or Disadvantaged Communities Grant Program
- States and communities can also leverage an additional nearly $12 billion in BIL DWSRF funds dedicated to making drinking water safer.

Proposed Rule Public Comment Period

- Following the proposed rule publishing, the public were invited to review the proposal and supporting information and provide their written input to EPA through the public docket.
  - The public docket can be accessed at: www.regulations.gov under Docket ID: EPA-HQ-OW-2022-0114.
- During the public comment period, EPA also held a public hearing to listen to the public's views about the proposal.
- EPA received approximately 122,000 public comments submitted to the docket and during the public hearing.
- EPA is currently evaluating and considering all the public comments to inform the final PFAS NPDWR.

PFAS NPDWR Key Milestones and Path Forward

- Final Regulatory Determinations for PFOA and PFOS: March 2021
- Preliminary Regulatory Determinations for PFHxS, PFNA, PFBS, GenX Chemicals, and their mixtures: March 2023
- Proposed PFAS NPDWR for PFOA, PFOS, PFHxS, PFNA, PFBS, and GenX Chemicals: March 2023
- Public Comment Period on Proposed PFAS NPDWR: March 29 – May 30, 2023
- Public Hearing on Proposed PFAS NPDWR: May 4, 2023
- Final PFAS NPDWR Promulgated: Anticipated December 2023
- PFAS NPDWR Effective Date: Anticipated December 2026 (three years following final rule promulgation)

Questions and Discussion

EPA's PFAS NPDWR website:

https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas