IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN WATER WORKS
ASSOCIATION, and ASSOCIATION
OF METROPOLITAN WATER
AGENCIES,

Petitioners,

v.

UNITED STATES
ENVIRONMENTAL PROTECTION
AGENCY, and MICHAEL S. REGAN,
in his official capacity as
Administrator, United States
Environmental Protection Agency,

Respondents.

Case No. 24-1188

PETITION FOR REVIEW

Pursuant to Federal Rule of Appellate Procedure 15, this Court's Rule 15, and section 1448(a)(1) of the Safe Drinking Water Act, 42 U.S.C. § 300j-7(a)(1), American Water Works Association and Association of Metropolitan Water Agencies hereby petition this Court for review of the final rule of respondent United States Environmental Protection Agency ("EPA") under the Safe Drinking Water Act published on April 26, 2024, at 89 Fed. Reg. 32,532, entitled "PFAS National

Primary Drinking Water Regulation." A copy of the final rule is attached as Exhibit A.

This Court has jurisdiction and is a proper venue for this action pursuant to 42 U.S.C. § 300j-7(a)(1). This petition for review is timely filed under the Safe Drinking Water Act. It has been filed with this Court within 45 days of April 26, 2024, the date on which the final rule was promulgated.

Petitioners strongly support the protection of public health and the use of a sound scientific process in the development of regulations. EPA did not rely on the best available science and the most recent occurrence data, and used novel approaches as the basis for certain portions of the rule. EPA finalized this rule without following the process mandated by Congress, without allowing the public an adequate opportunity to provide comment, and without addressing the concerns raised by those who work to deliver safe and affordable drinking water to their communities. Petitioners are seriously concerned about the impact of this rule on water affordability, particularly for households that struggle to pay for essential needs. EPA has significantly underestimated the costs of this rule and the adverse impact that it will have on individual water users.

The Court should grant this petition because, among its other defects, the rule is arbitrary and capricious or otherwise contrary to law, in excess of statutory authority, unreasonable, not feasible, and not supported by the best available health effects and occurrence data and science.

Dated: June 7, 2024

Respectfully submitted,

/s/ Corinne V. Snow

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RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Circuit Rule 26.1, Petitioners American Water Works Association and Association of Metropolitan Water Agencies hereby file the following corporate disclosure statement:

The American Water Works Association is a non-governmental corporation with no parent corporation and no publicly held company holding 10% or more of its stock. The American Water Works Association is a corporation organized and existing under the laws of the State of Illinois. The American Water Works Association is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes more than 4,000 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our 50,000-plus total membership represents the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. The American Water Works Association unites the diverse water community to advance public health, safety, the economy, and the environment.

Association of Metropolitan Water Agencies is a non-governmental corporation with no parent corporation and no publicly held company holding 10% or more of its stock. The Association of Metropolitan Water Agencies is a corporation organized under the laws of the District of Columbia. The Association of Metropolitan Water Agencies is a non-profit tax-exempt trade association representing approximately 180 of the largest publicly owned drinking water systems in the United States. The Association of Metropolitan Water Agencies' members provide more than 160 million people across the country with safe drinking water. The Association of Metropolitan Water Agencies' members include municipal agencies and special purpose districts and commissions serving customers on either a local or regional basis. Some are wholesalers providing water to other utilities, some serve end-use customers directly, and some do both. The Association's members are responsible for constructing and operating water treatment systems necessary to ensure compliance with National Primary Drinking Water Regulations promulgated pursuant to the Safe Drinking Water Act.

Dated: June 7, 2024

/s/ Corinne V. Snow

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CERTIFICATE OF SERVICE

Pursuant to Rules 15(c) and 25(d) of the Federal Rules of Appellate Procedure and Circuit Rule 15(a), I hereby certify that on June 7, 2024, I caused one copy of the foregoing Petition for Review and Rule 26.1 Disclosure Statement to be served on each of the following by certified U.S. Mail, return receipt requested:

The Honorable Michael S. Regan
Administrator
Office of the Administrator (1101A)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Mail Code 1101A
Washington, D.C. 20460

The Honorable Merrick B. Garland
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue NW
Washington, D.C. 20530-0001

Correspondence Control Unit
Office of General Counsel (2311)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

Dated: June 7, 2024

Respectfully submitted,

/s/ Corinne V. Snow
Corinne V. Snow

Counsel for Petitioners American Water Works Association and Association of Metropolitan Water Agencies

Exhibit A

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 141 and 142

[EPA–HQ–OW–2022–0114; FRL 8543–02–OW]

RIN 2040–AG18

PFAS National Primary Drinking Water Regulation

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: In March 2023, the U.S. Environmental Protection Agency (EPA) proposed and requested comment on the National Primary Drinking Water Regulation (NPDWR) and health-based Maximum Contaminant Level Goals (MCLGs) for six per- and polyfluoroalkyl substances (PFAS): perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO–DA, commonly known as GenX Chemicals), and perfluorobutane sulfonic acid (PFBS). After consideration of public comment and consistent with the provisions set forth under the Safe Drinking Water Act (SDWA), the EPA is finalizing NPDWRs for these six PFAS. Through this action, the EPA is finalizing MCLGs for PFOA and PFOS at zero. Considering feasibility, the EPA is promulgating individual Maximum Contaminant Levels (MCLs) for PFOA and PFOS at 4.0 nanograms per liter (ng/L) or parts per trillion (ppt). The EPA is also finalizing individual MCLGs and is promulgating individual MCLs for PFHxS, PFNA, and HFPO–DA at 10 ng/L. In addition to the individual MCLs for PFHxS, PFNA, and HFPO–DA, in consideration of the known toxic effects, dose additive health concerns and occurrence and likely co-occurrence in drinking water of these three PFAS, as well as PFBS, the EPA is finalizing a Hazard Index (HI) of 1 (unitless) as the MCLG and MCL for any mixture containing two or more of PFHxS, PFNA, HFPO–DA, and PFBS. Once fully implemented, the EPA estimates that the rule will prevent thousands of deaths and reduce tens of thousands of serious PFAS-attributable illnesses.

DATES: This final rule is effective on June 25, 2024. The incorporation by reference of certain publications listed in the rule is approved by the Director of the **Federal Register** as of June 25, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–HQ–OW–2022–0114. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Alexis Lan, Office of Ground Water and Drinking Water, Standards and Risk Management Division (Mail Code 4607M), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number 202–564–0841; email address: *PFASNPDWR@epa.gov*.

SUPPLEMENTARY INFORMATION:

Executive Summary

The Environmental Protection Agency (EPA) is issuing an adaptive and flexible National Primary Drinking Water Regulation (NPDWR) under the Safe Drinking Water Act (SDWA) to manage risks of per- and polyfluoroalkyl substances (PFAS) in drinking water. The EPA is establishing drinking water standards for six PFAS in this NPDWR to provide health protection against these individual and co-occurring PFAS in public water systems. The EPA's final rule represents data-driven drinking water standards that are based on the best available science and meet the requirements of SDWA. For the six PFAS, the EPA considered PFAS health effects information, evidence supporting dose-additive health concerns from co-occurring PFAS, as well as national and state data for the levels of multiple PFAS in finished drinking water. SDWA provides a framework for the EPA to regulate emerging contaminants of concern in drinking water. Under the statute, the EPA must act based on the ''best available'' science and information. Thus, the statute recognizes that the EPA may act in the face of imperfect information. It also provides a mechanism for the EPA to update standards as more science becomes available. For the PFAS covered by this rule, the EPA concluded that the state of the science and information has sufficiently advanced to the point to satisfy the statutory requirements and fulfill SDWA's purpose to protect public health by addressing contaminants in the nation's public water systems.

PFAS are a large class of thousands of organic chemicals that have unique physical and chemical properties. These compounds are designed to be stable and non-reactive because of the applications in which they are used: certain industrial and manufacturing processes; stain and water repellants in clothing, carpets, and other consumer products, as well as certain types of fire-fighting foams. PFAS tend to break down slowly and persist in the environment, and consequently, they can accumulate in the environment and the human body over time. Current scientific research and available evidence have shown the potential for harmful human health effects after being exposed to some PFAS. Although some PFAS have been phased out of use in the United States, they are still found in the environment and in humans based on biomonitoring data.

Drinking water is one of several ways people can be exposed to PFAS. The EPA's examination of drinking water data shows that different PFAS can often be found together and in varying combinations as mixtures. Additionally, decades of research demonstrates that exposure to mixtures of different chemicals can elicit dose-additive health effects: even if the individual chemicals are each present at levels considered ''safe,'' the mixture may cause significant adverse health effects. The high likelihood for different PFAS to co-occur in drinking water; the additive health concerns when present in mixtures; the diversity and sheer number of PFAS; and their general presence and persistence in the environment and the human body are reflective of the environmental and public health challenges the American public faces with PFAS, which poses a particular threat for overburdened communities that experience disproportionate environmental impacts. The final NPDWR includes:

1. Individual Maximum Contaminant Levels (MCLs)
    a. Perfluorooctanoic acid (PFOA) MCL = 4.0 nanograms per liter or parts per trillion (ng/L or ppt)
    b. Perfluorooctane sulfonic acid (PFOS) MCL = 4.0 ng/L
    c. Perfluorohexane sulfonic acid (PFHxS) MCL = 10 ng/L
    d. Perfluorononanoic acid (PFNA) MCL = 10 ng/L
    e. Hexafluoropropylene oxide dimer acid (HFPO–DA) MCL = 10 ng/L

2. A Hazard Index MCL to account for dose-additive health effects for mixtures that could include two or more of four

PFAS (PFHxS, PFNA, HFPO–DA, and perfluorobutane sulfonic acid (PFBS)). The Hazard Index MCL defines when the combined levels of two or more of these four PFAS requires action. A PFAS mixture Hazard Index less than or equal to 1 (unitless) indicates a level at which no known or anticipated adverse effects on the health of persons occur and allows for an adequate margin of safety with respect to health risk associated with a mixture of PFAS in finished drinking water. A PFAS mixture Hazard Index greater than 1 (unitless) indicates an exceedance of the health protective level. To calculate the Hazard Index, a ratio is developed for each PFAS by dividing the measured level of the PFAS in drinking water by the level (in ng/L or ppt) below which adverse health effects are not likely to occur (*i.e.,* the Health Based Water Concentration or HBWC). The HBWCs for each PFAS in the Hazard Index are:

a. PFHxS = 10 ng/L or ppt
b. PFNA = 10 ng/L
c. HFPO–DA = 10 ng/L
d. PFBS = 2,000 ng/L

The individual PFAS ratios are then summed across the mixture to yield the Hazard Index MCL as follows:

$$HI\ MCL = \left(\frac{[HFPO\text{–}DA_{water}\, ng/L]}{[10\ ng/L]}\right) + \left(\frac{[PFBS_{water}\, ng/L]}{[2000\ ng/L]}\right) + \left(\frac{[PFNA_{water}\, ng/L]}{[10\ ng/L]}\right) + \left(\frac{[PFHxS_{water}\, ng/L]}{[10\ ng/L]}\right) = 1$$

Based on the administrative record for the final PFAS NPDWR and as discussed above, certain PFAS (including PFHxS, PFNA, HFPO–DA, and PFBS) have been shown to be toxicologically similar; *i.e.,* elicit the same or similar profile of adverse effects in several biological organs and systems (see USEPA, 2000a; USEPA, 2007; USEPA, 2024a; USEPA, USEPA, 2024c; and section IV.B of this preamble). Studies with PFAS and other classes of chemicals support the health-protective conclusion that chemicals that have similar observed adverse effects following individual exposure should be assumed to act in a dose-additive manner when in a mixture unless data demonstrate otherwise (USEPA, 2024a). Additionally, the record further supports that there is a substantial likelihood that PFBS, PFHxS, PFNA, and HFPO–DA co-occur as mixtures in drinking water at levels of public health concern (see USEPA, 2024b and sections VI.C and D of this preamble). Though the EPA is not promulgating an individual MCL or Maximum Contaminant Level Goal (MCLG) for PFBS at this time as it is for PFHxS, PFNA, and HFPO–DA (see section III.A of this preamble for specific discussion), based on these evaluations, the agency is establishing a Hazard Index MCL that addresses PFBS as part of mixtures where its co-occurrence with other PFAS (PFHxS, HFPO–DA, and/or PFNA) can affect health endpoints when present in these mixtures.

The individual and Hazard Index MCLs are independently applicable for compliance purposes.

Additionally, the EPA is finalizing important public ‘‘right to know’’ provisions of the EPA's SDWA regulations, specifically, public notification (PN) and Consumer Confidence Report (CCR) requirements. The changes under this rule will strengthen risk communication and education for the public when elevated levels of these PFAS are found. Finally, the EPA is finalizing monitoring and reporting requirements that enable public water systems (PWSs) and primacy agencies to implement and comply with the NPDWR.

Consistent with the timelines set out under SDWA, PWSs are required to conduct their initial monitoring by April 26, 2027, and to conduct PN and include PFAS information in the CCR. After carefully considering public comment, the EPA is extending the compliance deadline for all systems nationwide to meet the MCL to allow additional time for capital improvements. As such, PWSs are required to make any necessary capital improvements and comply with the PFAS MCLs by April 26, 2029.

As part of its *Health Risk Reduction and Cost Analysis* (HRRCA), the EPA evaluated quantifiable and nonquantifiable health risk reduction benefits and costs associated with the final NPDWR. At a two percent discount rate, the EPA estimates the quantifiable annual benefits of the final rule will be $1,549.40 million per year and the quantifiable costs of the rule will be $1,548.64 million per year. The EPA's quantified benefits are based on the agency's estimates that that there will be 29,858 fewer illnesses and 9,614 fewer deaths in the communities in the decades following actions to reduce PFAS levels in drinking water. While the modeled quantified net benefits are nearly at parity, under SDWA, the EPA must consider whether the costs of the rule are justified by the benefits based on all statutorily prescribed costs and benefits, not just the quantified costs and benefits (see SDWA 1412(b)(3)(c)(i)).

The EPA expects that the final rule will result in additional nonquantifiable costs, including costs with generally greater uncertainty, which the EPA has examined in quantified sensitivity analyses in the Economic Analysis for the final rule. First, the EPA had insufficient nationally representative data to precisely characterize occurrence of HFPO–DA, PFNA, and PFBS. In an effort to better consider and understand the costs associated with treatment of these regulated compounds at systems both with and without PFOA, PFOS and PFHxS occurrence in exceedance of the MCLs, the EPA performed a quantitative sensitivity analysis of the costs associated with Hazard Index and/or MCL exceedances resulting from HFPO–DA, PFNA, and PFBS. The EPA expects that the quantified national costs, which do not include HFPO–DA, PFNA, and PFBS treatment costs are marginally underestimated (on the order of 5 percent). Second, stakeholders have expressed concern to the 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. The EPA has conducted a sensitivity analysis and found that should all water systems use hazardous waste disposal options national costs would increase by 7 percent.

The EPA anticipates significant additional benefits that cannot be quantified, will result from avoided negative developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects as a result of reductions in the levels of the regulated PFAS and other co-removed contaminants. For example, elevated concentrations of both PFOA and PFOS negatively impact the immune and endocrine systems, impacts which the agency is unable to quantify at this time. As another example, the EPA assessed the developmental benefits associated with PFNA exposure reductions semi-quantitively in sensitivity analysis, and the analysis demonstrates significant additional benefits associated with reductions in PFNA. There are other nonquantifiable benefits for other PFNA health endpoints, and numerous endpoints for PFHxS, HFPO–DA, PFBS, and other PFAS that are anticipated to be removed as a result of the final NPDWR. Additionally, as a result of the ability for available treatment technologies to remove co-occurring contaminants, there are benefits not quantified for removal of co-occurring contaminants for this regulation (*e.g.,* certain pesticides, volatile organic compounds). Considering both quantifiable and nonquantifiable costs and benefits of the rule, the EPA is reaffirming the Administrator's determination at the time of proposal, that the quantifiable and nonquantifiable benefits of the final rule justify the quantifiable and nonquantifiable costs.

To help communities on the frontlines of PFAS contamination, the passage of the Infrastructure Investment and Jobs Act (IIJA), also referred to as the Bipartisan Infrastructure Law (BIL), invests billions of dollars over a 5-year period. BIL appropriates over $11.7 billion in the Drinking Water State Revolving Fund (DWSRF) General Supplemental; $4 billion to the DWSRF for Emerging Contaminants; and $5 billion in grants to the Emerging Contaminants in Small or Disadvantaged Communities. These funds will assist many disadvantaged communities, small systems, and others with the costs of installation of treatment when it might otherwise be cost-challenging.

Table of Contents

I. General Information

A. What are the EPA's final rule requirements?

The Safe Drinking Water Act (SDWA) provides a framework for the Environmental Protection Agency (EPA) to regulate emerging contaminants of concern in drinking water. Under the statute, the EPA may act based on the ''best available'' science and information. Thus, the statute recognizes that the EPA may act in the face of imperfect information and provides a mechanism for the EPA to update standards as more science becomes available. For the per- and polyfluoroalkyl substances (PFAS) covered by this rule, the EPA concluded that the state of the science and information has sufficiently advanced to the point to satisfy the statutory requirements and fulfill SDWA's purpose to protect public health by addressing contaminants in the nation's public water systems. In this final action, the EPA is finalizing the PFAS National Primary Drinking Water Regulation (NPDWR) that is based upon the best available peer-reviewed science. The final NPDWR for PFAS establishes Maximum Contaminant Level Goals (MCLGs) and enforceable Maximum Contaminant Levels (MCLs) for six PFAS compounds: perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO–DA, commonly known as GenX Chemicals), and perfluorobutane sulfonic acid (PFBS). The final rule requirements and references to where additional discussion can be found on these topics are summarized here:

The EPA is finalizing MCLGs for PFOA and PFOS at zero (0) and enforceable MCLs for PFOA and PFOS at 4.0 ng/L (ng/L or ppt). Please see section IV of this preamble on the MCLG derivation for PFOA and PFOS. Additionally, please see section V of this preamble for discussion on the MCL for PFOA and PFOS.

The EPA is finalizing individual regulatory determinations to regulate PFHxS, PFNA, and HFPO–DA (commonly known as ''GenX Chemicals''). The EPA is deferring the individual regulatory determination to regulate PFBS in drinking water. Concurrent with the final determinations, the EPA is promulgating individual MCLGs and MCLs for PFHxS, PFNA, and HFPO–DA at 10 ng/L each.

Additionally, the EPA is finalizing a regulatory determination for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS due to their substantial likelihood for co-occurrence and dose-additive health concerns when present as a mixture in drinking water. Concurrent with this final determination, the EPA is finalizing a Hazard Index (HI) of 1 as the MCLG and enforceable MCL to address mixtures of PFHxS, PFNA, HFPO–DA, and PFBS where they co-occur in drinking water. Please see section III of this preamble for discussion on the EPA's final regulatory determinations; section IV of this preamble for discussion on the MCLG derivation for these additional compounds; and section V of this preamble for a discussion on the final MCLs.

This action also lists feasible technologies for public water systems (PWSs) that can be used to comply with the MCLs. The EPA notes that systems are not required to use the listed technologies to meet the MCL; rather, the MCL is a numeric regulatory limit systems must meet that is developed while considering treatment feasibility and cost. Please see section X for additional discussion on feasible treatment technologies.

The EPA is finalizing SDWA Right-to-Know requirements for the final rule, including Consumer Confidence Report (CCR) and Public Notification (PN) requirements. Community water systems (CWSs) must prepare and deliver to its customers an annual CCR in accordance with 40 CFR part 141, subpart O. Under this rule, CWSs will be required to report detected PFAS in their CCRs and provide health effects language in the case of MCL violations. Additionally, under the final rule, MCL violations require Tier 2 public notification, or notification provided as soon as practicable but no later than 30 days after a system learns of the violation, as per 40 CFR 141.203. Additionally, monitoring and testing procedure violations require Tier 3 notification, or notice no later than one year after the system learns of the violation. Please see section IX of this preamble for additional discussion on SDWA Right-to-Know requirements.

Additionally, the EPA is finalizing monitoring and reporting requirements for PWSs to comply with the NPDWR. PWSs are required to sample each EP using a monitoring regime generally based on the EPA's Standard Monitoring Framework (SMF) for Synthetic Organic Contaminants (SOCs). As a part of these requirements, to establish baseline levels of regulated PFAS, water systems must complete initial monitoring within three years following rule promulgation and/or use results of recent, previously acquired monitoring to satisfy the initial monitoring requirements. Following initial monitoring, beginning three years following rule promulgation, to demonstrate that finished drinking water does not exceed the MCLs for regulated PFAS, PWSs will be required to conduct compliance monitoring for all regulated PFAS at a frequency specifically based on sample results. Compliance with the NPDWRs will be based on analytical results obtained at each sampling point. PWSs are required to report to primacy agencies the results of all initial and compliance monitoring to ensure compliance with the NPDWRs. Please see section VIII of this preamble for additional discussion on these requirements.

Finally, the EPA is exercising its authority under SDWA section 1412(b)(10) to implement a nationwide capital improvement extension to comply with the MCL. All systems must comply with the MCLs by April 26, 2029. All systems must comply with all other requirements of the NPDWR, including initial monitoring, by April 26, 2027. For additional discussion on extensions and exemptions, please see section XI.

B. Does this action apply to me?

Entities regulated by this action are CWSs and non-transient non-community water systems (NTNCWSs). A PWS, as defined in 40 CFR 141.2, provides water to the public for human consumption through pipes or ''other constructed conveyances, if such system has at least fifteen service connections or regularly serves an average of at least twenty-five individuals daily at least 60 days out of the year.'' A PWS is either a CWS or a non-community water system (NCWS). A CWS, as defined in § 141.2, is ''a public water system which serves at least fifteen service connections used by year-round residents or regularly serves at least twenty-five year-round residents.'' The definition in § 141.2 for a NTNCWS is ''a public water system that is not a [CWS] and that regularly serves at least 25 of the same persons over 6 months per year.'' The following table provides examples of the regulated entities under this rule:

Category	Examples of potentially affected entities
Public water systems	CWSs; NTNCWSs.
State and Tribal agencies	Agencies responsible for drinking water regulatory development and enforcement.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be regulated by this action. This table includes the types of entities that the EPA is now aware could potentially be regulated by this action. To determine whether your entity is regulated by this action, this final rule should be carefully examined. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

All new systems that begin operation after, or systems that use a new source of water after, April 26, 2024, must demonstrate compliance with the MCLs within a period of time specified by the Primacy Agency. The EPA has defined in 40 CFR chapter I, subchapter D, part 141, § 141.2, a wholesale system as a PWS that supplies finished PWSs and a consecutive system as a PWS that buys or otherwise receives some or all its finished water from a wholesale system. In this action, the EPA reiterates that all CWS and NTNCWS must comply with this regulation. This includes consecutive CWS and NTNCWS systems; however, the requirements these consecutive systems must implement to comply with the regulation may be, and often are, much less extensive. For finished water that is provided through a system interconnection, the wholesale systems will be responsible for conducting the monitoring requirements at the entry point (EP) to the distribution system. The final regulation does not require that any monitoring be conducted at a system interconnection point. Where a violation does occur, the wholesale system must notify any consecutive systems of this violation and it is the responsibility of the consecutive system to provide PN to their customers pursuant to § 141.201(c)(1). In addition, wholesale systems must also provide information in Subpart O to consecutive systems for developing CCRs (§ 141.201(c)(1)). Consecutive systems are responsible for providing their customers with the reports (§ 141.153(a)).

II. Background

A. What are PFAS?

Per- and polyfluoroalkyl substances (PFAS) are a large class of thousands of synthetic chemicals that have been in use in the United States and around the world since the 1940s (USEPA, 2018a). The ability for PFAS to withstand heat and repel water and stains makes them useful in a wide variety of consumer, commercial, and industrial products, and in the manufacturing of other products and chemicals. This rule applies directly to six specific PFAS: perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO–DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS). Due to their widespread use, physicochemical properties, and prolonged persistence, many PFAS co-occur in air, water, ice, and soil, and in organisms, such as humans and wildlife. Exposure to some PFAS can lead to bioaccumulation in tissues and blood of aquatic as well as terrestrial organisms, including humans (Domingo and Nadal, 2019; Fromme et al., 2009). Pregnant and lactating women, as well as infants and children, may be more sensitive to the harmful effects of certain PFAS, such as PFOA, PFOS, PFNA, and PFBS. For example, studies indicate that PFOA and PFOS exposure above certain levels may result in adverse health effects, including developmental effects to fetuses during pregnancy or to breast- or formula-fed infants, increased risk for certain cancers, and negative immunological effects, among others (USEPA, 2024c; USEPA, 2024d). It has been documented that exposure to other PFAS are associated with a range of adverse health effects (USEPA, 2021a; USEPA, 2021b; ATSDR, 2021; NASEM, 2022).

The Environmental Protection Agency (EPA) is aware that PFAS still enter the environment and there are viable pathways for human exposure. Most United States production of PFOA, PFOS, and PFNA, along with other long-chain PFAS, was phased out and then generally replaced by production of PFHxS, HFPO–DA, PFBS, and other PFAS. The EPA is also aware of ongoing use of PFOA, PFOS, PFNA, and other long-chain PFAS (USEPA, 2000b; ATSDR, 2021). Long-chain PFAS are typically defined as including perfluoroalkyl sulfonic acids containing ≥ 6 carbons, and perfluoroalkyl carboxylic acids with ≥ 7 carbons. While domestic production and import of PFOA has been phased out in the United States by the companies participating in the 2010/2015 PFOA Stewardship Program, small quantities of PFOA may be produced, imported, and used by companies not participating in the PFOA Stewardship Program (USEPA, 2021c). The EPA is also aware of ongoing use of PFAS available from existing stocks or newly introduced via imports (see USEPA, 2022a). Additionally, the environmental persistence of these chemicals and formation as degradation products from other compounds may contribute to their ongoing release in the environment (ATSDR, 2021).

The six PFAS in this rule and their relevant Chemical Abstract Service registry numbers (CASRNs) are:

- PFOA ($C_8F_{15}O_2^-$; CASRN: 45285–51–6)
- PFOS ($C_8F_{17}SO_3^-$; CASRN: 45298–90–6)
- PFHxS ($C_6F_{13}SO_3^-$; CASRN: 108427–53–8)
- PFNA ($C_9F_{17}O_2^-$; CASRN: 72007–68–2)
- HFPO–DA ($C_6F_{11}O_3^-$; CASRN: 122499–17–6)
- PFBS ($C_4F_9SO_3^-$; CASRN: 45187–15–3)

These PFAS may exist in multiple forms, such as isomers or associated salts, and each form may have a separate CAS registry number or no CASRN at all. Additionally, these compounds have various names under different classification systems. However, at environmentally relevant pHs, these PFAS are expected to dissociate in water to their anionic (negatively charged) forms. For instance, International Union of Pure and Applied Chemistry substance 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoate (CASRN: 122499–17–6), also known as HFPO–DA, is an anionic molecule which has an ammonium salt (CASRN: 62037–80–3), a conjugate acid (CASRN: 13252–13–6), a potassium salt (CASRN: 67118–55–2), and an acyl fluoride precursor (CASRN: 2062–98–8), among other variations. At environmentally relevant pHs these all dissociate into the propanoate/anion form (CASRN: 122499–17–6). Each PFAS listed has multiple variants with differing chemical connectivity, but the same molecular composition (known as isomers). Commonly, the isomeric composition of PFAS is categorized as 'linear,' consisting of an unbranched alkyl chain, or 'branched,' encompassing a potentially diverse group of molecules including at least one, but potentially more, offshoots from the linear molecule. While broadly similar, isomeric molecules may have differences in chemical properties. This rule covers all salts, isomers and derivatives of the chemicals listed, including derivatives other than the anionic form which might be created or identified.

B. Human Health Effects

The publicly available landscape of human epidemiological and experimental animal-based exposure-effect data from repeat-dose studies across PFAS derive primarily from carboxylic and sulfonic acid species such as PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS (ATSDR, 2021; USEPA, 2021a; USEPA, 2021b; USEPA, 2024c; USEPA, 2024d). Many other PFAS have some human health effects data available (Mahoney et al., 2022) and some PFAS, such as PFBS, HFPO–DA, PFNA, and PFHxS, have sufficient data that has allowed Federal agencies to publish toxicity assessments (USEPA, 2021a; USEPA, 2021b; USEPA, 2024c; USEPA, 2024d; ATSDR, 2021) and derive toxicity values (*e.g.,* a reference dose), which is an estimate of daily exposure to the human population (including sensitive populations) that is likely to be without an appreciable risk of deleterious effects during a lifetime). The adverse health effects associated with exposure to such PFAS include (but are not limited to): effects on the liver (*e.g.,* liver cell death), growth and development (*e.g.,* low birth weight), hormone levels, kidney, the immune system (reduced response to vaccines), lipid levels (*e.g.,* high cholesterol), the nervous system, and reproduction, as well as increased risk of certain types of cancer.

Exposure to PFAS may have disproportionate health effects on children. Adverse health effects relevant to children associated with exposure to some PFAS include developmental effects to fetuses during pregnancy or to breast-fed infants, cardiovascular effects, immune effects, endocrine effects, and reproductive effects. Additionally, PFAS are known to be transmitted to the fetus via the placenta and to the newborn, infant, and child via breast milk (USEPA, 2021a; USEPA, 2021b; USEPA, 2024c; USEPA, 2024d; ATSDR, 2021).

Please see sections III.B and IV of this rule for additional discussion on health considerations for the six PFAS the EPA is regulating in this document.

C. Statutory Authority

Section 1412(b)(1)(A) of SDWA requires the EPA to establish National Primary Drinking Water Regulations (NPDWRs) for a contaminant where the Administrator determines that the contaminant: (1) may have an adverse effect on the health of persons; (2) is known to occur or there is a substantial likelihood that the contaminant will occur in PWSs (public water systems) with a frequency and at levels of public health concern; and (3) in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by PWSs.

D. Statutory Framework and PFAS Regulatory History

Section 1412(b)(1)(B)(i) of the Safe Drinking Water Act (SDWA) requires the EPA to publish a Contaminant Candidate List (CCL) every five years. The CCL is a list of contaminants that are known or anticipated to occur in PWSs, are not currently subject to any proposed or promulgated NPDWRs and may require regulation under the drinking water program. In some cases, developing the CCL may be the first step in evaluating drinking water contaminants. The EPA uses the CCL to identify priority contaminants for regulatory decision-making (*i.e.,* regulatory determinations), and for data collection. Publishing a CCL does not impose any requirements on PWSs. The EPA included PFOA and PFOS on the third and fourth CCLs published in 2009 (USEPA, 2009a) and 2016 (USEPA, 2016a). The EPA then included PFAS as a chemical group in its most recent list, the fifth CCL (CCL 5) (USEPA, 2022b). This group is inclusive of the PFAS the EPA is regulating through this action; however, the fifth CCL did not include PFOA and PFOS as they had already had final positive regulatory determinations completed for them in March 2021 (USEPA, 2021d).

The EPA collects data on the CCL contaminants to better understand their potential health effects and to determine the levels at which they occur in PWSs. SDWA 1412(b)(1)(B)(ii) requires that, every five years and after considering public comments on a ''preliminary'' regulatory determination, the EPA issues a determination to regulate or not regulate at least five contaminants on each CCL. In addition, section 1412(b)(1)(B)(ii)(III) authorizes the EPA to make a determination to regulate a contaminant not listed on the CCL at any time so long as the contaminant meets the three statutory criteria based on available public health information. SDWA 1412(b)(1)(B)(iii) requires that ''each document setting forth the determination for a contaminant under clause (ii) shall be available for public comment at such time as the determination is published.'' To implement these requirements, the EPA issues preliminary regulatory determinations subject to public comment and then issues a final regulatory determination after consideration of public comment. Section 1412(b)(1)(E) requires that the EPA propose an NPDWR no later than 24 months after a final determination to regulate. The statute also authorizes the EPA to issue a proposed rule concurrent with a preliminary determination to regulate. The EPA must then promulgate a final regulation within 18 months of the proposal (which may be extended by 9 additional months).

The EPA also implements a monitoring program for unregulated contaminants under SDWA 1445(a)(2) that requires the EPA to issue a list once every five years of priority 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 (CWSs) and non-transient community water systems (NTNCWSs) to better improve the EPA's understanding of the frequency of unregulated contaminants of concern occurring in the nation's drinking water systems and at what levels. The first four UCMRs collected data from a census of large water systems (serving more than 10,000 people) and from a statistically representative sample of small water systems (serving 10,000 or fewer people).

Between 2013–2015, water systems collected monitoring data for six PFAS (PFOA, PFOS, PFHxS, PFNA, PFBS, and perfluoroheptanoic acid (PFHpA)) as part of the third UCMR (UCMR 3) monitoring program. The fifth UCMR (UCMR 5), published December 2021, requires sample collection and analysis for 29 PFAS, including PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS, to occur between January 2023 and December 2025 using drinking water analytical methods developed by the EPA. Section 2021 of America's Water Infrastructure Act of 2018 (AWIA) (Pub. L. 115–270) amended SDWA and specifies that, subject to the availability of the EPA appropriations for such purpose and sufficient laboratory capacity, the EPA must require all public water systems (PWSs) serving between 3,300 and 10,000 people to monitor and ensure that a nationally representative sample of systems serving fewer than 3,300 people monitor for the contaminants in UCMR 5 and future UCMR cycles. All large water systems continue to be required to participate in the UCMR program. Section VI of this preamble provides additional discussion on PFAS occurrence. While the complete UCMR 5 dataset was not available to inform this rule and thus not a basis for informing the agency's decisions for the final rule, the EPA acknowledges that the small subset of data released (7 percent of the total results that the EPA expects to receive) as of July 2023 confirms the EPA's conclusions supported by the extensive amount of data utilized in its UCMR 3, state data, and modelling analyses. This final rule allows utilities and primacy agencies to use the UCMR 5 data to support implementation of monitoring requirements. Sections VI and VIII of this preamble further discusses these occurrence analyses as well as monitoring and compliance requirements, respectively.

After careful consideration of public comments, the EPA issued final regulatory determinations for contaminants on the fourth CCL (CCL 4) in March of 2021 (USEPA, 2021d) which included determinations to regulate two contaminants, PFOA and PFOS, in drinking water. The EPA found that PFOA and PFOS may have an adverse effect on the health of persons; that these contaminants are known to occur, or that there is a substantial likelihood that they will occur, in PWSs with a frequency and at levels that present a public health concern; and that regulation of PFOA and PFOS presents a meaningful opportunity for health risk reduction for persons served by PWSs. As discussed in the final Regulatory Determinations 4 Notice for CCL 4 contaminants (USEPA, 2021d) and the EPA's *PFAS Strategic Roadmap* (USEPA, 2022c), the agency has also evaluated additional PFAS chemicals for regulatory consideration as supported by the best available science. The agency finds that additional PFAS compounds also meet SDWA criteria for regulation. The EPA's regulatory determination for these additional PFAS is discussed in section III of this preamble.

Section 1412(b)(1)(E) provides that the Administrator ''may publish such proposed regulation concurrent with the determination to regulate.'' The EPA interprets this provision as allowing concurrent processing of a preliminary determination with a proposed rule, not a final determination (as urged by some commenters—see responses in section III of this preamble). Under this interpretation, section 1412(b)(1)(E) authorizes the EPA to issue a preliminary determination to regulate a contaminant and a proposed NPDWR addressing that contaminant concurrently and request public comment at the same time. This represents the only interpretation that accounts for the statutory language in context and is the only one that fulfills Congress's purpose of permitting the agency to adjust its stepwise processes where appropriate to avoid any unnecessary delay in regulating contaminants that meet the statutory criteria. To the extent the statute is ambiguous, the EPA's interpretation is the best interpretation of this provision for these same reasons. As a result, this rule contains both a final determination to regulate four PFAS contaminants (individually and/or as part of a PFAS mixture), and regulations for those contaminants as well as the two PFAS contaminants (PFOA and PFOS) for which the EPA had already issued a final Regulatory Determination. The EPA developed an MCLG and an NPDWR for six PFAS compounds pursuant to the requirements under section 1412(b)(1)(B) of SDWA. The final Maximum Contaminant Level Goals (MCLGs) and NPDWR are discussed in more detail in the following section.

E. Bipartisan Infrastructure Law

The passage of the Infrastructure Investment and Jobs Act (IIJA), often referred to as the Bipartisan Infrastructure Law or BIL, invests over $50 billion to improve drinking water, wastewater, and stormwater infrastructure—the single largest investment in water by the Federal Government. This historic investment specific to safe drinking water includes $11.7 billion in the Drinking Water State Revolving Fund (DWSRF) General Supplemental (referred to as BIL DWSRF General Supplemental); $4 billion to the Drinking Water SRF for Emerging Contaminants (referred to as BIL DWSRF EC); and $5 billion in grants for Emerging Contaminants in Small or Disadvantaged Communities (referred to as EC–SDC) from Federal fiscal years 2022 through 2026 (USEPA, 2023a). For the BIL DWSRF General Supplemental and BIL DWSRF EC, states must provide 49% and 100%, respectively, as additional subsidization in the form of principal forgiveness and/or grants. The EC–SDC grant has no cost-share requirement. Together, these funds will assist many disadvantaged communities, small systems, and others with the costs of addressing emerging contaminants, like PFAS, when it might otherwise be cost-challenging. This financial assistance can be used to address emerging contaminants in drinking water through actions such as technical assistance, certain water quality testing, operator and contractor training and equipment, and treatment upgrades and expansion. Investments in these areas which will allow communities additional funding to meet their obligations under this regulation and help ensure protection from PFAS contamination of drinking water. The Drinking Water SRF can be used by water systems to reduce the public health concerns around PFAS in their drinking water and is already being successfully utilized. Additionally, to support BIL implementation, the EPA is offering water technical assistance (WaterTA) to help communities identify water challenges and solutions, build capacity, and develop application materials to access water infrastructure funding (USEPA, 2023b). The EPA collaborates with states, Tribes, territories, community partners, and other stakeholders with the goal of more communities with applications for Federal funding, quality water infrastructure, and reliable water services.

F. EPA PFAS Strategic Roadmap

In October 2021, the EPA published the *PFAS Strategic Roadmap* (or *Roadmap*) that outlined the whole-of-agency approach to ''further the science and research, to restrict these dangerous chemicals from getting into the environment, and to immediately move to remediate the problem in communities across the country'' (USEPA, 2022c). The *Roadmap* offers timelines by which the EPA acts on key commitments the agency made toward addressing these contaminants in the environment, while continuing to safeguard public health. These include the EPA proposing to designate certain PFAS as Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) hazardous substances; issuing advance notice of proposed rulemakings on various PFAS under CERCLA; and issuing updated guidance on destroying and disposing of certain PFAS and PFAS-containing materials. Additionally, the EPA is issued a memorandum to states in December 2022 that provides direction on how to use the National Pollutant Discharge Elimination System (NPDES) program to protect against PFAS (USEPA, 2022d; USEPA, 2022e). The EPA also announced revisions to several Effluent Limitation Guidelines (ELGs) including, Organic Chemical, Plastic, Synthetic Fibers manufacturing, Metal Finishing & Electroplating, and Landfills to address PFAS discharge from these point source categories. These ELGs collectively will, if finalized, restrict and reduce PFAS discharges to waterways used as sources for drinking water. The EPA is taking numerous other actions to advance our ability to understand and effectively protect people from PFAS, such as the October 11, 2023, rule finalized under the Toxic Substances Control Act (TSCA) that will provide the EPA, its partners, and the public with a dataset of PFAS manufactured and used in the United States. The rule requires all manufacturers (including importers) of PFAS and PFAS-containing articles in any year since 2011 to report information to the extent known or reasonably ascertainable: chemical identity, uses, volumes made and processed, byproducts, environmental and health effects, worker exposure, and disposal to the EPA. With this final NPDWR, the EPA is delivering on another key goal in the *Roadmap* to ''establish a National Primary Drinking Water Regulation'' for PFAS. This rule will protect the American people directly from everyday PFAS exposures that might otherwise occur from PFAS-contaminated drinking water, complementing the many other actions in the *Roadmap* to protect public health and the environment from PFAS.

III. Final Regulatory Determinations for Additional PFAS

A. Agency Findings

As noted earlier, in 2021, the EPA made a determination to regulate two per- and polyfluoroalkyl substances—perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS)—in drinking water under the Safe Drinking Water Act. This section describes the EPA's regulatory determination findings with respect to three additional PFAS and mixtures of four PFAS.

Pursuant to sections 1412(b)(1)(A) and 1412(b)(1)(B)(ii)(II) of SDWA, the EPA is making a final determination to individually regulate as contaminants PFHxS, PFNA, and HFPO–DA and is publishing Maximum Contaminant Level Goals (MCLGs) and promulgating National Primary Drinking Water Regulations (NPDWRs) for these compounds individually. Under this authority, the EPA is also making a final determination to regulate as a contaminant a mixture of two or more of the following: perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO–DA, commonly known as GenX Chemicals), perfluorohexane sulfonic acid (PFHxS), and perfluorobutane sulfonic acid (PFBS), and is publishing an MCLG and promulgating an NPDWR for mixtures of these compounds. The agency has determined that PFHxS, PFNA, and HFPO–DA may have individual adverse health effects, and any mixture of these three PFAS and PFBS may also have dose-additive adverse effects on the health of persons; that there is a substantial likelihood that PFHxS, PFNA, and HFPO–DA occur individually with a frequency and at levels of public health concern and that mixtures of these three PFAS and PFBS occur and co-occur in public water systems (PWSs) with a frequency and at levels of public health concern; and that, in the sole judgment of the Administrator, individual regulation of PFHxS, PFNA, and HFPO–DA, and regulation of mixtures of these three PFAS and PFBS, presents a meaningful opportunity for health risk reduction for persons served by PWSs. The EPA refers to ''mixtures'' in its regulatory determinations to make clear that its determinations cover all the combinations of PFHxS, PFNA, HFPO–DA, and PFBS that could co-occur in a mixture but that each regulated mixture is itself a contaminant.

While the final determination includes mixtures of PFBS in combinations with PFHxS, HFPO–DA, and PFNA, the EPA is deferring the final individual regulatory determination for PFBS to further evaluate it individually under the three SDWA regulatory determination criteria; consequently, the agency is not promulgating an individual MCLG or NPDWR for PFBS in this action. The EPA is deferring its final individual regulatory determination because after considering the public comments, the EPA has decided to further consider whether occurrence information supports a finding that there is a substantial likelihood that PFBS will individually occur in public water systems and at levels of health concern. However, as stated previously, when evaluating PFBS in mixtures combinations with PFHxS, PFNA, and/or HFPO–DA, the EPA has determined that based on the best available information it does meet all three statutory criteria for regulation when a part of these mixtures, including that it is anticipated to have dose-additive adverse health effects (see sections III.B and IV.B.1), there is a substantial likelihood of its co-occurrence in combinations with PFHxS, PFNA, and/or HFPO–DA with a frequency and at levels of public health concern (see sections III.C, VI.C, VI.D, and USEPA 2024b), and there is a meaningful opportunity for health risk reduction by regulating mixture combinations of these four PFAS (see section III.D of this preamble). Hence, although the agency is deferring the individual final regulatory determination for PFBS, it is included in the final determination to regulate mixture combinations containing two or more of PFHxS, PFNA, HFPO–DA, and PFBS.

This section describes the best available science and public health information used by the agency to support the regulatory determinations. The MCLGs and NPDWR, including the MCLs, are discussed further in sections IV and V of this preamble.

1. Proposal

The agency proposed preliminary determinations to regulate PFHxS, PFNA, HFPO–DA, and PFBS individually, and to regulate mixtures of these four PFAS contaminants, in drinking water. In the proposal, the agency concluded that PFHxS, PFNA, HFPO–DA, and PFBS, and mixtures of these PFAS, may cause adverse effects on the health of persons; there is a substantial likelihood that they will occur and co-occur in PWSs with a frequency and at levels of public health concern, particularly when considering them in a mixture; and in the sole judgment of the Administrator, regulation of PFHxS, PFNA, HFPO–DA, PFBS, and mixtures of these PFAS, presents a meaningful opportunity for health risk reductions for people served by PWSs.

Within the proposal, the agency described section 1412(b)(1)(E) which provides that the Administrator may publish a proposed drinking water regulation concurrent ''with the determination to regulate.'' This provision authorizes a more expedited process by allowing the EPA to make concurrent the regulatory determination and rulemaking processes. As a result, for the proposal, the EPA interpreted the relevant reference to ''determination to regulate'' in section 1412(b)(1)(E) as referring to the regulatory process in 1412(b)(1)(B)(ii) that begins with a preliminary determination. Under this interpretation, section 1412(b)(1)(E) authorizes the EPA to issue a preliminary determination to regulate a contaminant and a proposed NPDWR addressing that contaminant concurrently and request public comment at the same time. This allows the EPA to act expeditiously where appropriate to issue a final determination to regulate concurrently with a final NPDWR to avoid delays to address contaminants that meet the statutory criteria.

Additionally, as part of the proposal, the EPA explained why mixtures of PFAS qualify as a ''contaminant'' for purposes of section 1412. SDWA section 1401(6) defines the term ''contaminant'' to mean ''*any* physical, chemical or biological or radiological substance or matter in water.'' A mixture of two or more of the regulated PFAS qualifies as a ''contaminant'' because the mixture itself is ''*any* physical, chemical or biological or radiological substance or matter in water'' (emphasis added). Therefore, pursuant to the provisions outlined in section 1412(b)(1)(A) and 1412(b)(1)(B) of SDWA, the agency made a preliminary determination to regulate PFHxS, PFNA, HFPO–DA, PFBS, and any mixtures of these PFAS as a contaminant in drinking water. In the past and in this instance, the EPA's approach to regulating contaminant groups or mixtures under SDWA considers several factors, including health effects, similarities in physical and chemical properties, contaminant co-occurrence, ability for treatment technology co-removal, or where such a regulatory structure presents a meaningful opportunity to improve public health protection.

2. Summary of Major Public Comments and EPA Responses

The EPA requested comments on its preliminary regulatory determinations for PFHxS, PFNA, HFPO–DA, and PFBS, and mixtures of these PFAS, including the agency's evaluation of the statutory criteria and any additional data or studies the EPA should consider that inform the preliminary regulatory determinations for these contaminants and their mixtures. The EPA also requested comment on its preliminary determination that regulation of PFHxS, PFNA, HFPO–DA, PFBS, and their mixtures, in addition to regulation of PFOA and PFOS, will also provide protection from PFAS (*e.g.,* PFDA, PFDoA, PfHpA, PFHxA, PFHpS, PFPeS) that will not be regulated because the treatment technologies that would be used to ensure compliance for these PFAS are also effective in reducing concentrations of other unregulated PFAS.

Many commenters expressed support for the EPA's preliminary regulatory determinations, including that the EPA has appropriately determined that the three statutory criteria for regulation have been met for all four contaminants and their mixtures using the best available information. Many other commenters did not agree that the agency presented sufficient information to make a preliminary determination to regulate PFHxS, PFNA, HFPO–DA, PFBS, and their mixtures, with some commenters recommending that that the agency withdraw the portion of the proposed rule associated with these four PFAS because in their view there is insufficient health effects and/or occurrence data at this time to support the EPA's action. For some of the four contaminants and their mixtures, a few commenters stated that the EPA had not met the statutory criteria for regulation or that data suggests a determination not to regulate is more appropriate. The EPA disagrees with these commenters because there is information to support individual regulation of PFHxS, PFNA, and HFPO–DA, as well as mixtures of these three PFAS and PFBS, based on the three statutory criteria (these findings are discussed in this section).

As discussed earlier in this section, after consideration of all the public comments on this issue, the agency is deferring the determination to individually regulate PFBS for further evaluation under the statutory criteria. This determination is informed by public comment suggesting that the three statutory criteria for individual regulation of PFBS, particularly related to the occurrence criterion have not been met. The EPA will continue to consider other available occurrence information, including from UCMR 5, to determine whether the information supports a finding that there is a substantial likelihood that PFBS will individually occur in PWSs and at a level of public health concern. The record demonstrates that exposure to a mixture with PFBS may cause adverse health effects; that there is a substantial likelihood that PFBS co-occurs in mixtures with PFHxS, PFNA, and/or HFPO–DA in PWSs with a frequency and at levels of public health concern; and that, in the sole judgment of the Administrator, regulation of PFBS in mixtures with PFHxS, PFNA, and/or HFPO–DA presents a meaningful opportunity for health risk reduction for persons served by PWSs.

Furthermore, the EPA is making a final determination to regulate PFHxS, PFNA, and HFPO–DA individually. While the EPA recognizes there will be additional health, occurrence, or other relevant information for these PFAS and others in the future, the EPA has determined that there is sufficient information to make a positive regulatory determination and the agency concludes that these three PFAS currently meet all of the statutory criteria for individual regulatory determination. Therefore, the agency is proceeding with making final determinations to regulate these contaminants both individually and as part of mixtures with PFBS and is concurrently promulgating individual MCLs for PFHxS, PFNA, and HFPO–DA (see section V of this preamble). For detailed information on the EPA's evaluation of the three regulatory determination statutory criteria for PFHxS, PFNA, and HFPO–DA individually and mixtures of these three PFAS and PFBS, as well as more specific comments and the EPA responses related to each of the three statutory criteria, see subsections III.B, C, and D.

Several commenters requested that the EPA evaluate additional occurrence data to further inform its analysis for the regulatory determinations. In response to public comments on the proposal, the EPA evaluated updated and new occurrence data and the updates are presented within subsection III.C. and section VI of this preamble. These additional occurrence data further confirm that the SDWA criteria for regulation have been met for PFHxS, PFNA, and HFPO–DA as individual contaminants and for mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS.

A couple of commenters questioned the EPA's rationale for selecting PFHxS, PFNA, HFPO–DA, and PFBS for regulation. The agency's process is allowable under SDWA and, as described within this section of the preamble, there is available health, occurrence, and other meaningful opportunity information for three PFAS (PFHxS, PFNA, and HFPO–DA) to meet the SDWA statutory criteria for regulation individually and four PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) as a mixture. The EPA disagrees with commenters who suggested that the agency should not develop national regulations that differ from state-led actions. While states may establish drinking water standards for systems in their jurisdiction prior to regulation under SDWA, once an NPDWR is in place, SDWA 1413(a)(1) requires that states or Tribes adopt standards that are no less stringent than the NPDWR to maintain primacy. Moreover, the agency further notes that all four PFAS the EPA is regulating individually or as a mixture are currently regulated by multiple states as shown in table 4–17 of USEPA, 2024e.

The EPA received several comments related to the EPA's interpretation in the proposal that the agency may, as it did here, issue a preliminary regulatory determination concurrent with a proposed NPDWR. Many stated that the EPA is authorized under SDWA to process these actions concurrently and agreed with the EPA's interpretation of the statute, noting that the EPA has followed all requirements under SDWA including notice and opportunity for public comment on both the preliminary regulatory determination and proposed NPDWR, and that simultaneous public comment periods are not precluded by SDWA. Several other commenters expressed disagreement with the EPA's interpretation. These dissenting commenters contend that the statute only allows the EPA to ''publish such proposed regulation concurrent with the determination to regulate'' (*i.e.,* in their view, the final determination), not the ''preliminary determination to regulate.'' Moreover, some of these commenters further indicated that they believe the EPA's final determination to regulate must precede the EPA's proposed regulation. The EPA disagrees with commenters who stated that the EPA cannot issue a preliminary determination concurrent with a proposed NPDWR. Section 1412(b)(1)(e) states that ''[t]he Administrator shall propose the maximum contaminant level goals and national primary drinking water regulation for a contaminant *not later than 24 months* *after the determination to regulate under subparagraph (B),* and may publish such proposed regulation *concurrent with the determination to regulate*'' (emphasis added). The EPA maintains its interpretation that ''determination to regulate'' in the second phrase of 1412(b)(1)(E) allows for concurrent processing of a preliminary determination and proposed rule, not a final determination and proposed rule.

The first clause of the provision provides an enforceable 24-month deadline for the EPA to issue a proposed rule once it has decided to regulate. Contrary to the suggestion of some commenters, the statutory language providing that the EPA ''shall'' propose an NPDWR ''not later than 24 months *after* the determination to regulate'' states when the 24 months to issue a proposed rule begins, *i.e.,* the deadline is 24 months *after* making a final determination to issue a proposed regulation. The phrase ''after the determination to regulate'' here simply identifies when SDWA's deadline begins to run; there is no textual or other indication in the language that Congress meant it to constitute the beginning of an exclusive 24-month window in which the EPA is permitted to propose an NPDWR. Further, though the EPA's reading is clear on the face of the provision, it is also supported by language elsewhere in SDWA illustrating that when Congress intends to provide a window for action (as opposed to a deadline for action) it knows how to do so clearly. In fact, Congress did so in this very provision when it required the EPA to ''publish a maximum contaminant level goal and promulgate a national primary drinking water regulation *within* 18 months after the proposal thereof.'' See also, 42 U.S.C. 1448 (providing, among other things, that petitions for review of the EPA regulations under SDWA ''shall be filed *within* the 45-day period *beginning on* the date of the promulgation of the regulation . . .'') (emphasis added). In addition, the phrase ''not later than,'' expressly acknowledges that the EPA may issue a proposed rule concurrent with a final determination. And because this language only provides a deadline without a beginning trigger, the language in the first clause of this provision would also not preclude the EPA from issuing a proposed rule at any time prior to the expiration of the 24 months after a final regulatory determination, including issuing the proposed rule on the same day as the preliminary regulatory determination.

The second clause, which states that the Administrator ''may publish such proposed regulation concurrent with the determination to regulate'' should not be read to limit when the EPA can issue a proposed rule *prior* to a final determination. First, Congress's use of the phrase ''determination to regulate'' elsewhere in SDWA is not consistent, requiring the agency to discern its meaning based on statutory context. Second, reading ''determination to regulate'' to refer to a final determination would, without good reason, hinder Congress' goal in enacting this provision, to accelerate the EPA action under SDWA. Finally, the EPA's interpretation to allow for concurrent processes is fully consistent with, and indeed enhances, the deliberative stepwise process provided in the statute for regulating new contaminants.

Language throughout the statute demonstrates that Congress did not use the term ''determination to regulate'' consistently. In fact, ''preliminary determination'' only appears once in the entire provision, ''final determination'' is never used, and the remainder of the references simply refer to ''determination.'' Specifically, section 1412(b)(1)(B)(ii)(I) expressly requires public comment on a ''preliminary'' regulatory determination made as part of the contaminant candidate listing process. The rest of section 1412(b)(1)(B)(ii) and (iii) as well as the title of the provision only refer to a ''determination to regulate'' or ''determination.'' For example, 1412(b)(1)(B)(iii) states that ''[e]ach document setting forth the determination for a contaminant under clause (ii) shall be available for public comment at such time as the determination is published.''[1] Although this provision only refers to a ''determination for a contaminant under clause (ii),'' this language clearly refers to public comment on a preliminary determination and not a final determination to regulate. The EPA has interpretated ''determination'' in this paragraph to refer to ''preliminary determination'' because that is the best interpretation to effectuate Congressional intent to provide public comment prior to issuing a final determination. The EPA has done the same with section 1412(b)(1)(E) here, as only a reading that allows for, in appropriate cases, concurrent processing of a preliminary determination to regulate and proposed NPDWR allows for rulemaking acceleration by the EPA as Congress envisioned. To the extent there is ambiguity, the EPA's reading of section 1412(b)(1)(E) is the best one to effectuate these purposes.

The EPA could issue a proposed rule concurrent with a final determination; there is nothing in the statute or the APA that requires the EPA to wait. The SDWA gives the EPA 24 months to act after a final determination but does not require the agency to wait 24 months. The ''no later than'' language in the first clause of section 1412(b)(1)(E), expressly acknowledges that the EPA may issue a proposed rule concurrent with a final determination. Therefore, construing the second phrase of section 1412(b)(1)(E) simply to authorize the EPA to issue a proposed rule concurrent with a final determination renders that provision of the statute authorizing the EPA to publish such proposed regulation concurrent with the determination to regulate a nullity. The well-known tools of statutory construction direct the agencies and courts not to construe statutes so as to render Congress's language mere surplusage, yet that it is what commenters' interpretation would do. The EPA's construction is the one which gives meaning to that language.

Moreover, the EPA's interpretation of ''determination to regulate'' in the phrase ''may publish such proposed regulation concurrent with the determination to regulation'' in section 1412(b)(1)(E) to be a preliminary determination best effectuates Congress' goal in enacting this provision, to accelerate the EPA action under SDWA when the EPA determines such a step is necessary and the EPA has, as it does here, a sufficient record to proceed with both regulatory determination and regulation actions concurrently. In addition to authorizing concurrent processes, Congress' intent to expedite regulatory determinations when necessary is evidenced more generally by the text and structure of section 1412(b)(1)(B)(ii). The statute contemplates regulatory determinations could be made as part of the 5-year cycle for the contaminant candidate list under section 1412(b)(1)(B)(ii)(I) but may also be made at any time under section 1412(b)(1)(B)(ii)(III). The fact that Congress provided the EPA with express authority to make a regulatory determination at any time is a recognition that the EPA may need to act expeditiously to address public

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[1] Even the first clause of section 1412(b)(1)(E) setting the 24-month deadlines use ''regulatory determination'' without further clarifying whether it is preliminary or final. Again, it is clear when viewed in context that the term refers to a final determination, as triggering a deadline to propose regulations on a preliminary decision to regulate would not be reasonable, as the agency may change its mind after reviewing publicv comment, obviating the need for a proposed NPDWR.

health concerns between the statutory periodic 5-year cycle. The EPA's interpretation of the relevant language in section 1412(b)(1)(E) best effectuates all provisions of the statute because simultaneous public processes for off-cycle regulatory determinations and NPDWRs allow for administrative efficiency that may be needed to address pressing public health concerns.

Finally, the EPA's interpretation of the statute allowing for concurrent processes is fully consistent with the stepwise process for issuing an NPDWR set out by the statute. Here, the EPA provided for public comment on an extensive record for both the regulatory determinations and the proposed regulatory levels and it is not clear what further benefit would be provided by two separate public comment periods. This is especially true given the D.C. Circuit's ruling in *NRDC* v. *Regan,* 67 F.4th 397 (D.C. Cir 2023), which held that the EPA cannot withdraw a final determination to regulate a contaminant. Thus, even if the EPA were to provide two separate comment periods, the information provided on a proposed rule cannot be used to undo a final regulatory determination. Indeed, although not required by the statute, the EPA in proposing actions concurrently provides commenters with much more information to evaluate the preliminary regulatory determinations. This is because the EPA has provided not just the information to support the preliminary determinations to regulate but also the full rulemaking record and supporting risk, cost, occurrence, and benefit analysis that supports the proposed Maximum Contaminant Levels (MCLs). Further, the EPA has a much more comprehensive record for the regulatory determinations to ensure that the final determination, which cannot be withdrawn, is based on the comprehensive record provided by the rulemaking and Health Risk Reduction and Cost Analysis (HRRCA) development processes.

The EPA received comments on its statutory authority to regulate mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS, specifically the agency's interpretation under section 1401(6) that a mixture of two or more contaminants also qualifies as the definition of a contaminant under SDWA since a mixture itself meets the same definition. A few commenters disagreed and contended that a mixture does not meet the definition of being a single contaminant under SDWA. The EPA disagrees with these commenters, as the SDWA definition of a contaminant does not specify that a contaminant is only a singular chemical. The SDWA definition is very broad, specifically stating that a contaminant is ''*any* physical, chemical or biological or radiological substance or matter'' (emphasis added), with no specific description or requirement for how it is formed. Matter for example, by definition, is comprised of either pure substances or mixtures of pure substances. A pure substance is either an element or compound, which would include any PFAS chemical. The statute encompasses ''matter'' which is a broad term that includes mixtures and therefore definitionally includes PFAS mixtures, comprised of a combination of PFAS (chemical substances), as itself qualifying as a ''contaminant'' under SDWA. Moreover, other provisions of the statute, would be restricted in a manner inconsistent with Congressional intent if the EPA were to adopt the cabined approach to ''contaminant'' suggested by some commenters. For example, section 1431 of SDWA provides important authority to the EPA to address imminent and substantial endangerment to drinking water supplies posed by ''a contaminant'' that is present in or threatened those supplies. Congress clearly intended this authority to be broad and remedial, but it would be significantly hampered if the EPA would be restricted to only addressing individual chemicals and not mixtures threatening a water supply. For these reasons, the EPA's interpretation of the definition of contaminant is the only reading that is consistent with the statutory definition and use of the term in context and at to the extent the definition of contaminant is ambiguous, the EPA's interpretation represents the best interpretation of that term. Finally, even if a mixture is considered a group, as some commenters suggest, Congress clearly contemplated that the EPA could regulate contaminants as groups. *See* H.R. Rep. No 93–1185 (1974), reprinted in 1974 U.S.C.C.A.N. 6454, 6463–64) (noting the tens of thousands of chemical compounds in use commercially, with many more added each year, of which many will end up in the nation's drinking water and finding that ''[i]t is, of course, impossible for EPA to regulate each of these contaminants which may be harmful to health on a contaminant-by-contaminant basis. Therefore, the Committee anticipates that the Administrator will establish primary drinking water regulations for some groups of contaminants, such as organic and asbestos.'') Thus, the EPA has the authority to regulate a mixture as a contaminant under SDWA.

The commenters also suggested that the EPA has not followed its *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000a), specifically that the agency did not use a ''sufficiently similar mixture'' where ''components and respective portions exist in approximately the same pattern'' and suggested that there has to be consistent co-occurrence of the mixture components. The EPA disagrees with these comments. It is not possible or necessary to use a whole-mixture approach for PFHxS, PFNA, HFPO–DA, and PFBS or a ''sufficiently similar mixture.'' Instead, the EPA is using a longstanding component-based mixture approach called the Hazard Index, which was endorsed in the context of assessing potential risk associated with PFAS mixtures by the Science Advisory Board (SAB) during its 2021 review of the EPA's *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)* (USEPA, 2021e) (see section IV of this preamble). The goal of this component-based approach is to approximate what the whole-mixture toxicity would be if the whole mixture could be tested and relies on toxicity information for each individual component in a mixture (USEPA, 2000a). A whole-mixture approach for regulating these four PFAS in drinking water is not possible because it would entail developing a single toxicity value (*e.g.,* a reference dose (RfD)) for one specific mixture of PFHxS, PFNA, HFPO–DA, and PFBS with defined proportions of each PFAS. Toxicity studies are typically conducted with only one test substance to isolate that particular substance's effects on the test organism, and whole-mixture data are exceedingly rare. There are no known whole-mixture studies for PFHxS, PFNA, HFPO–DA, and PFBS, and even if they were available, the corresponding toxicity value (*i.e.,* a single RfD for a specific mixture of these four PFAS) would only be directly applicable to that specific mixture. Thus, a more flexible approach that takes into account the four component PFAS in different combinations and at different concentrations (*i.e.,* the Hazard Index approach) is necessary. The Hazard Index indicates risk from exposure to a mixture and is useful in this situation to ensure a health-protective MCLG in cases where the mixture is spatially and/or temporally variable. For a more detailed discussion on whole-mixture and component-based approaches for PFAS health assessment, please see the EPA's *Framework for*

Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS) (USEPA, 2024a).

Many other commenters supported the EPA's interpretation of regulating a mixture as a ''contaminant'' that consists of a combination of certain PFAS, citing the EPA's broad authority under SDWA to set regulatory standards for groups of related contaminants and the EPA precedent for doing so under other NPDWRs including disinfection byproducts (DBPs; for total trihalomethanes [TTHMs] and the sum of five haloacetic acids [HAA5] (USEPA, 1979; USEPA, 2006a)), as well as radionuclides (USEPA, 2000c) and polychlorinated biphenyls (PCBs). The EPA also noted some of these examples within the proposed rule. One commenter disagreed that these previous EPA grouping approaches are applicable to the mixture of the four PFAS, noting that TTHMs and HAA5 are byproducts of the disinfection process and are the result of naturally occurring compounds reacting with the disinfectants used in drinking water treatment; thus, their formation cannot be controlled and is dependent on the presence and amount of disinfectant. As a result of these factors, measuring them as a class is required; however, the four PFAS are not byproducts, and the presence of one PFAS does not change the presence of the other PFAS. Moreover, the commenter provided that related to radionuclides, alpha particles are identical regardless of their origination and using this example for PFAS is not supported since the four PFAS are fundamentally different. The EPA disagrees with this commenter. As noted above, the SDWA definition of contaminant is very broad (''*any* physical, chemical or biological or radiological substance or matter'' (emphasis added)) with no limitations, specific description or requirement for how it is formed. The statute therefore easily encompasses a mixture, comprised of a combination of PFAS (chemical substances), as itself qualifying as a ''contaminant'' under SDWA. Moreover, as also noted above, to the extent the mixture is considered a ''group,'' Congress clearly anticipated that the EPA would regulate contaminants by group. As a result, even if the PFAS ''group'' is different than other SDWA regulatory groupings, such a regulation is clearly authorized under the statute. Furthermore, it makes sense to treat these mixtures as a ''contaminant'' because the four PFAS share similar characteristics: it is substantially likely that they co-occur; the same treatment technologies can be used for their removal; they are measured simultaneously using the same analytical methods; they have shared adverse health effects; and they have similar physical and chemical properties resulting in their environmental persistence.

3. The EPA's Final Determination

The EPA is making determinations to regulate PFHxS, PFNA, and HFPO–DA individually and to regulate mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS. A mixture of PFHxS, PFNA, HFPO–DA, and PFBS can contain any two or more of these PFAS. The EPA refers to ''mixtures'' in its final regulatory determinations to make clear that its determinations cover all of the combinations of PFHxS, PFNA, HFPO–DA, and PFBS that could co-occur in a mixture but that any combination itself qualifies as a contaminant.

In this preamble, as discussed earlier, the EPA is deferring the final determination to regulate PFBS individually to further evaluate the three criteria specified under SDWA 1412(b)(1)(A), particularly related to its individual known or likely occurrence, but is making a final determination to regulate PFBS as part of a mixture with PFHxS, PFNA, and/or HFPO–DA.

To support the agency's regulatory determinations, the EPA carefully considered the public comments and examined health effects information from available final peer-reviewed human health assessments and studies, as well as drinking water monitoring data collected as part of the UCMR 3 and state-led monitoring efforts. The EPA finds that oral exposure to PFHxS, PFNA, and HFPO–DA individually, and combinations of these three PFAS and PFBS in mixtures, may result in a variety of adverse health effects, including similar or shared adverse effects on several biological systems including the endocrine, cardiovascular, developmental, immune, and hepatic systems (USEPA, 2024f). Based on the shared toxicity types, exposure to PFHxS, PFNA, or HFPO–DA individually, or combinations of these three PFAS and PFBS in a mixture, is anticipated to affect common target organs, tissues, or systems to produce dose-additive effects from co-exposures. Additionally, based on the agency's evaluation of the best available science, including a review of updated data from state-led drinking water monitoring efforts discussed in subsection III.C of this preamble, the EPA finds that PFHxS, PFNA, and HFPO–DA each have a substantial likelihood to occur in finished drinking water and that these three PFAS and PFBS are also likely to co-occur in mixtures and result in increased total PFAS exposure above levels of public health concern. Therefore, as discussed further in this section, the agency is determining that:

- exposure to PFHxS, PFNA, or HFPO–DA individually, and any mixture of these three PFAS and PFBS, may have adverse effects on the health of persons;
- there is a substantial likelihood that PFHxS, PFNA, and HFPO–DA will occur and there is a substantial likelihood that combinations of these three PFAS plus PFBS will co-occur in mixtures in PWSs with a frequency and at levels of public health concern; and
- in the sole judgment of the Administrator, individual regulation of PFHxS, PFNA, and HFPO–DA, and mixtures of the three PFAS plus PFBS, presents a meaningful opportunity for health risk reductions for persons served by PWSs.

The EPA is making a final individual regulatory determination for PFHxS, HFPO–DA, and PFNA and promulgating individual MCLGs and NPDWRs for PFHxS, HFPO–DA, and PFNA. These NPDWRs ensure public health protection when one of these PFAS occurs in isolation above their MCLs and also support risk communication efforts for utilities (see section V of this preamble for more information). The EPA is also making a final mixture regulatory determination and promulgating a Hazard Index MCLG and NPDWR for mixtures containing two or more of PFHxS, PFNA, HFPO–DA, and PFBS. The Hazard Index is a risk indicator and has been shown to be useful in chemical mixtures decision contexts (USEPA, 2023c).[2] Individual NPDWRs do not address dose additive risks from co-occurring PFAS. However, the Hazard Index NPDWR accounts for PFAS co-occurring in mixtures where the individual concentrations of one or more PFAS may not exceed their individual levels of public health concern, but the combined levels of these co-occurring PFAS result in an overall exceedance of the health-protective level. In this way, the Hazard Index NPDWR protects against dose-additive effects. This approach also recognizes that exposure to the PFAS included in the Hazard Index is associated with adverse health effects at differing potencies (*e.g.,* the toxicity reference value for PFHxS is lower than

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[2] Some describe the Hazard Index as an indicator of potential hazard because it does not estimate the probability of an effect; others characterize the Hazard Index as an indicator of potential risk because the measure integrates both exposure and toxicity (USEPA 2000c; USEPA, 2023c).

the one for PFBS) and that, regardless of these potency differences, all co-occurring PFAS are included in the hazard calculation (*i.e.,* the health effects and presence of lower toxicity PFAS are neither ignored nor are they over-represented). Furthermore, the approach accounts for all the different potential combinations of these PFAS that represent a potential public health concern that would not be addressed if the EPA only finalized individual NPDWRs and considered individual PFAS in isolation.

B. Statutory Criterion 1—Adverse Health Effects

The agency finds that exposure to PFHxS, PFNA, and HFPO–DA individually, and any mixture of these three PFAS and PFBS, may have an adverse effect on the health of persons. Following is a discussion of health effects information for each of these four individual PFAS and the levels at which those health effects may be adverse. The agency developed health reference levels (HRLs) for PFHxS, PFNA, HFPO–DA, and PFBS as part of its effort to identify the adverse effects each contaminant may have on the health of persons. In this instance, the EPA identified the HRL as the level below which adverse health effects over a lifetime of exposure are not expected to occur, including for sensitive populations and life stages, and allows for an adequate margin of safety. The HRLs are also used as health-based water concentrations (HBWCs) in the calculation of the Hazard Index MCLG (see section IV).

1. PFHxS

Studies have reported adverse health effects, including on the liver, thyroid, and development, after oral exposure to PFHxS (ATSDR, 2021). For a detailed discussion on adverse effects associated with oral exposure to PFHxS, please see ATSDR (2021) and USEPA (2024f).

The EPA derived the individual HRL/HBWC for PFHxS using a chronic reference value of 0.000002 (2E–06) mg/kg/day based on adverse thyroid effects (follicular epithelial hypertrophy/hyperplasia), a sensitive noncancer effect determined to be adverse and relevant to humans, observed in male rats after oral PFHxS exposure during adulthood (ATSDR, 2021; USEPA, 2024f). The EPA applied a bodyweight-adjusted drinking water intake (DWI–BW) exposure factor for adults within the general population (0.034 L/kg/day; 90th percentile direct and indirect consumption of community water, consumer-only two-day average, adults 21 years and older) and a relative source contribution (RSC) of 0.20 to calculate the HRL/HBWC (USEPA, 2024f). The HRL/HBWC for PFHxS is 10 ng/L which was used to evaluate individual occurrence of PFHxS for the final regulatory determination as discussed in section III.C of this preamble.

2. PFNA

Studies have reported adverse health effects, including on development, reproduction, immune function, and the liver, after oral exposure to PFNA (ATSDR, 2021). For a detailed discussion of adverse effects associated with oral exposure to PFNA, please see ATSDR (2021) and USEPA (2024f).

The EPA derived the HRL/HBWC for PFNA using a chronic reference value of 0.000003 (3E–06) mg/kg/day based on decreased body weight gain and impaired development (*i.e.,* delayed eye opening, delayed sexual maturation) in mice born to mothers that were orally exposed to PFNA during gestation (with presumed continued indirect exposure of offspring via lactation) (ATSDR, 2021; USEPA, 2024f). These sensitive noncancer effects were determined to be adverse and relevant to humans (ATSDR, 2021; USEPA, 2024f). The EPA applied a DWI–BW exposure factor for lactating women (0.0469 L/kg/day; 90th percentile direct and indirect consumption of community water, consumer-only two-day average) and an RSC of 0.20 to calculate the HRL/HBWC (USEPA, 2024f). The HRL/HBWC for PFNA is 10 ng/L which was used to evaluate individual occurrence of PFNA for the final regulatory determination as discussed in section III.C of this preamble.

3. HFPO–DA

Animal toxicity studies have reported adverse health effects after oral HFPO–DA exposure, including liver and kidney toxicity and immune, hematological, reproductive, and developmental effects (USEPA, 2021b). The EPA determined that there is Suggestive Evidence of Carcinogenic Potential after oral exposure to HFPO–DA in humans, but the available data are insufficient to derive a cancer risk concentration for oral exposure to HFPO–DA. For a detailed discussion of adverse effects of oral exposure to HFPO–DA, please see USEPA (2021b).

The most sensitive noncancer effects observed among the available data were the adverse effects on liver (*e.g.,* increased relative liver weight, hepatocellular hypertrophy, apoptosis, and single-cell/focal necrosis), which were observed in both male and female mice and rats across a range of exposure durations and dose levels, including the lowest tested dose levels and shortest exposure durations. The EPA derived the HRL/HBWC for HFPO–DA from a chronic oral RfD of 0.000003 (3E–06) mg/kg/day that is based on adverse liver effects, specifically a constellation of liver lesions including cytoplasmic alteration, single-cell and focal necrosis, and apoptosis, observed in parental female mice following oral exposure to HFPO–DA from pre-mating through day 20 of lactation (USEPA, 2021b). The EPA applied a DWI–BW exposure factor for lactating women (0.0469 L/kg/day; 90th percentile direct and indirect consumption of community water, consumer-only two-day average) and an RSC of 0.20 to calculate the HRL/HBWC (USEPA, 2024f). The HRL/HBWC for HFPO–DA is 10 ng/L which was used to evaluate individual occurrence of HFPO–DA for the final regulatory determination as discussed in section III.C of this preamble.

4. PFBS

Toxicity studies of oral PFBS exposure in animals have reported adverse health effects on development, as well as on the thyroid and kidneys (USEPA, 2021a). Human and animal studies evaluated other health effects following PFBS exposure including effects on the immune, reproductive, and hepatic systems and lipid and lipoprotein homeostasis, but the evidence was determined to be equivocal (USEPA, 2021a). No studies evaluating the carcinogenicity of PFBS in humans or animals were identified. The EPA concluded that there is Inadequate Information to Assess Carcinogenic Potential for PFBS and its potassium salt (K + PFBS) by any route of exposure based on the EPA's *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a). For a detailed discussion on adverse effects after oral exposure to PFBS, please see USEPA (2021a).

As noted previously, the agency is deferring the final individual regulatory determination for PFBS. For the purposes of evaluating PFBS in mixture combinations with PFHxS, PFNA, and HFPO–DA (see section III.B.5 of this preamble), the EPA derived the HRL/HBWC for PFBS from a chronic RfD of 0.0003 (3E–04) mg/kg/day that is based on adverse thyroid effects (decreased serum total thyroxine) observed in newborn mice following gestational exposure to the potassium salt of PFBS (USEPA, 2021a). The EPA applied a DWI–BW exposure factor for women of child-bearing age (0.0354 L/kg/day; 90th percentile direct and indirect consumption of community water, consumer-only two-day average) and an

RSC (relative score contribution) of 0.20 to calculate the HRL/HBWC (USEPA, 2024f). The HRL/HBWC for PFBS is 2000 ng/L.

5. Mixtures of PFHxS, PFNA, HFPO–DA, and PFBS

Exposure to per- and polyfluoroalkyl acids (PFAAs), a subclass of PFAS that includes PFHxS, PFNA, HFPO–DA, and PFBS, can disrupt signaling of multiple biological pathways, resulting in a shared set of adverse effects, including effects on thyroid hormone levels, lipid synthesis and metabolism, development, and immune and liver function (ATSDR, 2021; EFSA et al., 2018; EFSA et al., 2020; USEPA, 2021a; USEPA, 2021b; USEPA, 2024f; see further discussion in section III.B.6.e of this preamble).

Studies with PFAS and other classes of chemicals support the health-protective conclusion that chemicals that have similar observed adverse effects following individual exposure should be assumed to act in a dose-additive manner when in a mixture unless data demonstrate otherwise (USEPA, 2024a). Dose additivity means that the combined effect of the component chemicals in the mixture (in this case, PFHxS, PFNA, HFPO–DA, and/or PFBS) is equal to the sum of their individual doses or concentrations scaled for potency (USEPA, 2000a). In other words, exposure to these PFAS, at doses that individually would not likely result in adverse health effects, when combined in a mixture may result in adverse health effects. See additional discussion of PFAS dose additivity in section IV of this preamble.

The EPA used a Hazard Index (HI) HRL of 1 (unitless) to evaluate co-occurrence of combinations PFHxS, PFNA, HFPO–DA, and PFBS in mixtures for the final regulatory determination as discussed in section III.C of this preamble. For technical details on the Hazard Index approach, please see section IV of this preamble, USEPA (2024a), and USEPA (2024f).

6. Summary of Major Public Comments and EPA Responses

Commenters referred to the HRLs and HBWCs interchangeably, so comments related to those topics are addressed in this section. (Other comments related to the MCLGs are addressed in section IV of this preamble.)

Many commenters expressed support for the EPA's derivation of HRLs/HBWCs and use of best available peer-reviewed science, specifically the use of the final, most recently published Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels for PFHxS and PFNA as chronic reference values. Other commenters criticized the EPA for using ATSDR minimal risk levels and stated that they are inappropriate for SDWA rulemaking.

The EPA finds that the ATSDR minimal risk levels for PFHxS and PFNA currently represent the best available, peer-reviewed science for these chemicals. SDWA specifies that agency actions must rely on ''the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices.'' At this time, the 2021 ATSDR *Toxicological Profile for Perfluoroalkyls,* which covers 10 PFAS including PFHxS and PFNA, represents the best available peer-reviewed scientific information on the human health effects of PFHxS and PFNA. ATSDR minimal risk levels for PFHxS and PFNA are appropriate for use under SDWA because ATSDR uses scientifically credible approaches, its work is internally and externally peer-reviewed and undergoes public comment, and its work represents the current best available science for these two chemicals. The 2021 ATSDR *Toxicological Profile for Perfluoroalkyls* underwent intra- and interagency review and subsequent external peer review by seven experts with knowledge of toxicology, chemistry, and/or health effects.

The agency acknowledges that ATSDR minimal risk levels and EPA RfDs are not identical. The two agencies sometimes develop toxicity values for different exposure durations (*e.g.,* intermediate, chronic) and/or apply different uncertainty/modifying factors to reflect data limitations. Additionally, ATSDR minimal risk levels and EPA RfDs are developed for different purposes: ATSDR minimal risk levels are intended to serve as screening levels and are used to identify contaminants and potential health effects that may be of concern at contaminated sites, whereas EPA RfDs are used to support regulatory and nonregulatory actions, limits, and recommendations in various environmental media. However, from a practical standpoint, an oral minimal risk level and an oral RfD both represent the level of daily oral human exposure to a hazardous substance for a specified duration of exposure below which adverse health effects are not anticipated to occur. The EPA has routinely used and continues to use ATSDR minimal risk levels in human health assessments when they represent the best available science—for example, in the context of Clean Air Act section 112(f)(2) risk assessments in support of setting national emission standards for Hazardous Air Pollutants (HAPs), developing Clean Water Act ambient water quality criteria, evaluating contaminants for the CCL, and site evaluations under the Resource Conservation and Recovery Act (RCRA) and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).

Some commenters questioned the EPA's external peer-review process for the four underlying final toxicity assessments used to calculate the HRLs/HBWCs. Some commenters noted that the EPA does not yet have completed Integrated Risk Information System (IRIS) assessments for PFHxS and PFNA, questioning the EPA's use of non-EPA assessments (see above). The EPA notes that all four toxicity assessments containing the toxicity values (RfD or minimal risk level) used to calculate the HRLs/HBWCs (*i.e.,* the EPA human health toxicity assessments for HFPO–DA and PFBS (USEPA, 2021a; USEPA, 2021b) and the ATSDR toxicity assessments of PFNA and PFHxS (ATSDR, 2021)) underwent rigorous, external peer review (ATSDR, 2021; USEPA, 2021a; USEPA, 2021b). The EPA is not required under SDWA to exclusively use EPA assessments to support an NPDWR, and in fact, SDWA's clear direction in section 1412(b)(3)(A)(i) is to use the best *available,* peer-reviewed science when developing NPDWRs (emphasis added). Final EPA assessments for PFHxS and PFNA are under development but are not currently available; final, peer reviewed ATSDR assessments are available.

Other commenters offered critical comments on the HRLs/HBWCs for PFHxS, PFNA, HFPO–DA, and PFBS and raised technical and process concerns with the underlying human health assessments. Some commenters asserted that the human health toxicity values (EPA RfDs, ATSDR minimal risk levels) upon which the HRLs/HBWCs are based have too much uncertainty (*e.g.,* inappropriately apply a composite uncertainty factor (UF) of 3,000) and are therefore inadequate to support a SDWA regulatory determination. The EPA disagrees with these comments. The HRLs/HBWCs are data-driven values that incorporate UFs based on the EPA guidance and guidelines thus, represent the levels below which adverse health effects are not expected to occur over a lifetime. According to the EPA guidelines and longstanding practices (USEPA, 2002a; USEPA, 2022f), UFs reflect the limitations of the data across the five areas used in the current EPA human health risk assessment development: (1) human interindividual variability (UF_H); (2) extrapolation from animal to human (UF_A); (3) subchronic-to-chronic duration extrapolation (UF_S); (4) lowest-observed-adverse-effect level-to-no-observed-adverse-effect level (LOAEL-to-NOAEL) extrapolation (UF_L); and (5) database uncertainty (UF_D). In minimal risk level development, ATSDR also applies uncertainty factors as appropriate to address areas of uncertainty, with the exception of subchronic-to-chronic duration extrapolation (ATSDR, 2021). For the ATSDR minimal risk levels on which the HRLs/HBWCs for PFNA and PFHxS are based, ATSDR utilized UF_Hs, UF_As, and what ATSDR calls a modifying factor to address database deficiencies (equivalent to the EPA's UF_D) (ATSDR, 2021). The EPA carefully reviewed ATSDR's application of uncertainty and modifying factors for PFNA and PFHxS and applied additional uncertainty factors as warranted. Specifically, the EPA applied an additional UF (UF_S) for PFHxS to extrapolate from subchronic to chronic duration per agency guidelines (USEPA, 2002a) and standard practice because the critical effect was not observed during a developmental lifestage (*i.e.,* the effect was in parental male rats). A chronic toxicity value (*i.e.,* RfD, MRL) represents the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime; the EPA is using a chronic toxicity value to derive the MCLG to ensure that it is set at a level at or below which no known or anticipated adverse effects on human health occur and allowing an adequate margin of safety. The EPA guidelines indicate that the composite (total) UF may be equal to or below 3,000; composite UFs greater than that represent ''excessive uncertainty'' (USEPA, 2002a; USEPA, 2022f). In the case of this final NPDWR, a composite UF of 3,000 was appropriately applied to derive toxicity values used to develop HRLs/HBWCs for two of the four PFAS (HFPO–DA and PFHxS) following peer-reviewed agency guidance and longstanding practice (see USEPA (2024f) for complete discussion of UF application for all four PFAS). The EPA has previously developed an MCLG for a chemical that had a composite UF of 3,000 applied to derive a toxicity value (*e.g.,* thallium [USEPA, 1992]). Further, a composite uncertainty factor of 3,000 has been applied in the derivation of oral RfDs for several chemicals that have been evaluated within the EPA's IRIS (Integrated Risk Information System) program (*e.g.,* fluorene, cis- and trans-1,2-dichloroethylene, 2,4-dimethylphenol; please see the EPA's IRIS program website [*https://www.epa.gov/iris*] for further information).

Some commenters opposed the EPA's application of a 20 percent RSC (relative source contribution) in the HRL/HBWC calculations and stated that it was a ''conservative default'' approach not supported by available information and that adequate exposure data exist to justify an RSC other than 20 percent (although commenters did not offer a suggested alternative RSC). The EPA disagrees with these comments. The EPA applies an RSC to account for potential aggregate risk from exposure routes and exposure pathways other than oral ingestion of drinking water to ensure that an individual's total exposure to a contaminant does not exceed the daily exposure associated with toxicity (*i.e.,* threshold level or reference dose). Application of the RSC in this context is consistent with EPA methods (USEPA, 2000d) and long-standing EPA practice for establishing drinking water MCLGs and NPDWRs (*e.g.,* see USEPA, 1989; USEPA, 2004; USEPA, 2010). The RSC represents the proportion of an individual's total exposure to a contaminant that is attributed to drinking water ingestion (directly or indirectly in beverages like coffee, tea, or soup, as well as from dietary items prepared with drinking water) relative to other exposure pathways. The remainder of the exposure equal to the RfD (or minimal risk level) is allocated to other potential exposure sources (USEPA, 2000d). The purpose of the RSC is to ensure that the level of a contaminant (*e.g.,* MCLG) in drinking water, when combined with other identified potential sources of exposure for the population of concern, will not result in total exposures that exceed the RfD (or minimal risk level) (USEPA, 2000d). This ensures that the MCLG under SDWA meets the statutory requirement that it be a level of a contaminant in drinking water at or below which no known or anticipated adverse effects on human health occur and allowing an adequate margin of safety.

To determine the RSCs for the four HRLs/HBWCs, the agency assessed the available scientific literature on potential sources of human exposure other than drinking water. The EPA conducted literature searches and reviews for each of the four HRLs/HBWCs to identify potential sources of exposure and physicochemical properties that may influence occurrence in environmental media (Deluca et al., 2022; USEPA, 2024f). Considering this exposure information, the EPA followed its longstanding, peer-reviewed Exposure Decision Tree Approach in the EPA's *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health* (USEPA, 2000d) to determine the RSC for each PFAS. As discussed by the EPA in the Hazard Index MCLG document (USEPA, 2024f), the EPA carefully evaluated studies that included information on potential exposure to these four PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) via sources other than drinking water, such as food, soil, sediment, and air. For each of the four PFAS, the findings indicated that there are significant known or potential uses/sources of exposure beyond drinking water ingestion (*e.g.,* food, indoor dust) (Box 6 in the EPA Exposure Tree; USEPA, 2000d), but that data are insufficient to allow for quantitative characterization of the different exposure sources (Box 8A in USEPA, 2000d). The EPA's Exposure Decision Tree approach states that when there are insufficient environmental and/or exposure data to permit quantitative derivation of the RSC, the recommended RSC for the general population is 20 percent (Box 8B in USEPA, 2000d). This means that 20 percent of the exposure equal to the RfD is allocated to drinking water, and the remaining 80 percent is attributed to all other potential exposure sources.

Some commenters disagreed with the bodyweight-adjusted drinking water intake (DWI–BWs) that the EPA used to calculate the HRLs/HBWCs and thought the selected DWI–BWs were too high (overly health protective). One commenter stated that the DWI–BW used in the calculation of the HRL/HBWC for HFPO–DA is inappropriate and that the EPA should have used a DWI–BW for general population adults instead of for lactating women. The EPA disagrees with this comment. To select an appropriate DWI–BW for use in derivation of the HRL/HBWC for HFPO–DA, the EPA considered the HFPO–DA exposure interval used in the oral reproductive/developmental toxicity study in mice that served as the basis for chronic RfD derivation (the critical study). In this study, parental female mice were dosed from pre-mating through lactation, corresponding to three potentially sensitive human adult life stages that may represent critical windows of HFPO–DA exposure: women of childbearing age, pregnant women, and lactating women (Table 3–63 in USEPA, 2019a). Of these three, the highest DWI–BW, for lactating women (0.0469 L/kg/day), is anticipated to be protective of the other two sensitive life stages and was used to calculate the HRL/HBWC for HFPO–DA (USEPA, 2024f).

Other commenters urged the EPA to consider infants as a sensitive life stage for PFHxS, PFNA, and PFBS and use the DWI–BW for infants to calculate the HRLs/HBWCs. The EPA disagrees with this comment. The EPA's approach to DWI–BW selection includes a step to identify the sensitive population(s) or life stage(s) (*i.e.,* those that may be more susceptible or sensitive to a chemical exposure) by considering the available data for the contaminant, including the adverse health effects observed in the toxicity study on which the RfD/minimal risk level was based (known as the critical effect within the critical or principal study). Although data gaps can complicate identification of the most sensitive population (*e.g.,* not all windows or life stages of exposure and/or health outcomes may have been assessed in available studies), the critical effect and point of departure (POD) that form the basis for the RfD (or minimal risk level) can provide some information about sensitive populations because the critical effect is typically observed at the lowest tested dose among the available data. Evaluation of the critical study, including the exposure window, may identify a sensitive population or life stage (*e.g.,* pregnant women, formula-fed infants, lactating women). In such cases, the EPA can select the corresponding DWI–BW for that sensitive population or life stage from the *Exposure Factors Handbook* (USEPA, 2019a). DWI–BWs in the *Exposure Factors Handbook* are based on information from publicly available, peer-reviewed studies, and were updated in 2019. In the absence of information indicating a sensitive population or life stage, the DWI–BW corresponding to the general population may be selected. Following this approach, the EPA selected appropriate DWI–BWs for each of the four PFAS included in the Hazard Index MCLG (see USEPA, 2024f). The EPA did consider infants as a sensitive life stage for all four PFAS; however, the agency did not select the infant DWI–BW because the exposure intervals of the critical studies supporting the chronic toxicity values did not correspond to infants. Instead, the exposure intervals were relevant to other sensitive target populations (*i.e.,* lactating women or women of childbearing age) or the general population. (See also comments related to DWI–BW selection under PFBS section III.B.6.d. of this preamble).

a. PFHxS

Some commenters noted a typographical error in the HRL/HBWC calculation for PFHxS which was reported as 9.0 ng/L in the proposal. The agency has corrected the value in this NPDWR and within the requirements under 40 CFR part 141, subpart Z. The correct HRL/HBWC for PFHxS is 10 ng/L.

Two commenters questioned the human relevance of thyroid effects (*i.e.,* changes in tissue structure (*e.g.,* enlarged cells; increased numbers of cells) in the thyroids of adult male rats) observed in the critical study used to derive the ATSDR minimal risk level and the EPA's PFHxS HRL/HBWC because, as noted in the ATSDR *Toxicological Profile for Perfluoroalkyls,* this observed effect may have been secondary to liver toxicity and, therefore, the commenters state that its significance is unclear. The EPA disagrees with this comment. SDWA requires that the EPA use ''the best available, peer reviewed science'' to inform decision making on drinking water regulations. Although there is some uncertainty regarding the selection of thyroid alterations as the critical effect (as the ATSDR toxicological profile notes), at this time, the 2021 ATSDR toxicological profile represents the best available peer reviewed scientific information regarding the human health effects of PFHxS. As the most sensitive known effect as supported by the weight of the evidence, the thyroid effect was appropriately selected by ATSDR as the critical effect. Additionally, published studies in rats have shown that PFHxS exposure results in other thyroid effects, including decreases in thyroid hormone (primarily T4) levels in serum (NTP, 2018a; Ramhøj et al., 2018). Similarly, peer-reviewed final EPA assessments of other PFAS, including PFBS (USEPA, 2021a) and perfluorobutanoic acid (PFBA) (USEPA, 2022g), have concluded that these changes in rodents are adverse and human-relevant, and appropriate for RfD derivation. Furthermore, it is appropriate to use other health protective (toxicity) values developed by other authoritative governmental agencies, including ATSDR minimal risk levels, if available, as these agencies use scientifically credible approaches and their work is peer-reviewed (the ATSDR toxicological profile underwent intra- and interagency review and external peer review by seven experts with knowledge of toxicology, chemistry, and/or health effects). The ATSDR minimal risk levels reflect the best available, peer-reviewed science.

Furthermore, the EPA's draft *IRIS Toxicological Review of Perfluorohexanesulfonic Acid (PFHxS) and Related Salts (Public Comment and External Review Draft)* (USEPA, 2023d), which is in the public domain, preliminarily provides confirmatory evidence that PFHxS significantly affects human development (emphasis added): ''Overall, the available evidence indicates that *PFHxS exposure is likely to cause thyroid and developmental immune effects in humans,* given sufficient exposure conditions. For thyroid effects, the primary supporting evidence for this hazard conclusion included evidence of decreased thyroid hormone levels, abnormal histopathology results, and changes in organ weight in experimental animals. For immune effects, the primary supporting evidence included decreased antibody responses to vaccination against tetanus or diphtheria in children.'' Although the EPA did not rely on this draft IRIS toxicological review for PFHxS in this rule, the draft is available to the public and offers confirmation that PFHxS elicits developmental effects in humans.

b. PFNA

Some commenters questioned the human relevance of developmental effects observed in PFNA animal studies (*i.e.,* decreased body weight gain, delayed eye opening, delayed sexual maturation) used to derive the ATSDR minimal risk level and the EPA's PFNA HRL/HBWC. The EPA disagrees with this comment. At this time, the 2021 ATSDR *Toxicological Profile for Perfluoroalkyls* represents the best available peer-reviewed scientific information regarding the human health effects of PFNA. In addition, according to the March 2023 *Interagency PFAS Report to Congress,* PFNA is documented to affect the developmental health domain (United States OSTP, 2023), and a recently published meta-analysis (Wright et al., 2023) specifically supports decreases in birth weight as an effect of PFNA exposure in humans. Published studies have shown that PFNA exposure results in statistically significant, dose-responsive developmental effects, including reduced fetal/pup bodyweight, reduced fetal/pup survival, changes in fetal/pup liver gene expression, increased fetal/pup liver weight, and delayed onset of puberty. Also, the EPA's 1991 *Guidelines for Developmental Toxicity Risk Assessment* (USEPA, 1991a; pp. vii-ix and pp. 1–2) cites evidence that, in the absence of clear evidence to the contrary, developmental effects observed in experimental animals are interpreted as relevant to humans.

c. HFPO–DA

A few commenters submitted critical comments related to the adverse health effects associated with exposure to HFPO–DA and how these health effects are quantified to derive the RfD in the human health toxicity assessment for HFPO–DA (USEPA, 2021b). Commenters claimed that the RfD for HFPO–DA is not scientifically sound, and cited one or more of the following reasons why: (1) the selected critical effect from the study (constellation of liver lesions) includes different liver effects that were not consistently observed across male and female mice and were not necessarily all adverse; (2) the hepatic effects in mice (the selected critical effect) are mediated by a rodent specific MOA, peroxisome proliferator-activated receptor alpha (PPARα), and therefore not relevant to humans; (3) the EPA incorporated results of a pathology working group which misapplied diagnostic criteria classifying apoptotic and necrotic lesions; and (4) the EPA misapplied uncertainty factors (UFs) (*i.e.,* the subchronic to chronic UF and database UF) according to agency guidance resulting in the maximum possible UF of 3,000 (USEPA, 2002a; USEPA, 2022f). Another commenter thought that the interspecies UF should be further increased. Also, some commenters stated that the EPA did not properly consider all available epidemiological data. These comments are addressed in this preamble.

Overall, the EPA disagrees with the commenters and maintains that the final published peer-reviewed human health toxicity assessment that derived the RfD for HFPO–DA is appropriate and sound, reflects the best available peer-reviewed science, and is consistent with agency guidance, guidelines, and best practices for human health risk assessment. Notably, the EPA sought external peer review of the toxicity assessment *twice* (USEPA, 2018b; USEPA, 2021f), released the draft toxicity assessment for public comment and provided responses to public comment (USEPA, 2021g), and engaged a seven-member pathology working group at the National Institutes of Health—an entirely separate and independent organization—to re-analyze pathology slides from two critical studies (USEPA, 2021b, appendix D), all of which supported the EPA's conclusions in the toxicity assessment, including the RfD derivation.

Regarding critical effect selection: the EPA's approach to critical effect selection for the RfD derivation considers a range of factors, including dose at which effects are observed, biological variability (which can produce differences in effects observed between sexes), and relevance of the effect(s) seen in animals to human health. The EPA maintains that selection of the constellation of liver lesions as the critical effect for HFPO–DA RfD derivation is appropriate and scientifically justified, and that the constellation of liver lesions represents an adverse effect. The EPA engaged a pathology working group within the National Toxicology Program (NTP) at the National Institutes of Health to perform an independent analysis of the liver tissue slides. The pathology working group determined that the tissue slides demonstrated a range of adverse effects and that the constellation of liver effects caused by HFPO–DA exposure, which included cytoplasmic alteration, apoptosis, single cell necrosis, and focal necrosis, constitutes an adverse liver effect in these studies (USEPA, 2021b, appendix D). The EPA evaluated the results of the pathology working group and determined that the effects were relevant to humans according to the best available science (*e.g.,* Hall et al., 2012). Additionally, the EPA convened a second independent peer-review panel of human health risk assessment experts to review the EPA's work on HFPO–DA, including critical effect selection. The panel unanimously agreed with the selection of the constellation of liver lesions as the critical effect, the adversity of this effect and its relevance to humans (USEPA, 2021f).

The commenters' assertion that the hepatic effects observed in mice are not relevant to humans because they are PPARα-mediated is unsupported. The commenter claims that one specific effect—apoptosis—can be PPARα-mediated in rodents (a pathway that some data suggest may be of limited or no relevance to humans). However, in supporting studies cited by commenters, a decrease in apoptosis is associated with a PPARα MOA, with Corton et al. (2018) stating, ''[t]he data indicate that a physiological function of PPARα activation is to increase hepatocyte growth through an increase in hepatocyte proliferation or a decrease in apoptosis or a combination of both effects'' while HFPO–DA is associated with increased apoptosis (USEPA, 2021b). Therefore, the commenter's claim that apoptosis is associated with the known PPARα MOA is unsupported. the critical study selected by the EPA, and indeed other studies as well, reported not only apoptosis but also other liver effects such as necrosis that are not associated with a PPARα MOA and therefore are relevant for human health (Hall et al., 2012). Further, according to the available criteria, effects such as cytoplasmic alteration in the presence of liver cell necrosis are considered relevant to humans (Hall et al., 2012). Additionally, commenters asserted that a 2020 study by Chappell et al. reported evidence demonstrating that the rodent liver effects are not relevant to humans, and that the EPA failed to consider this study. It is important to note that while Chappell et al. (2020) was published after the assessment's literature search cut-off date (USEPA, 2021b, appendix A; USEPA, 2022h), the EPA considered this paper initially through the Request for Correction process (USEPA, 2022h) and noted that this study specifically assessed evidence for PPARα-driven apoptosis and did not investigate other potential modes of action or types of cell death, specifically necrosis. The authors state that they could ''not eliminate the possibility that necrotic cells were also present.'' The EPA again considered Chappell et al., (2020), in addition to other studies submitted through public comment (Heintz et al., 2022; Heintz et al., 2023; Thompson et al., 2023), and determined that these studies do not fully explore a necrotic/cytotoxic MOA with Thompson et al., 2023 stating that ''there are no gene sets for assessing necrosis in transcriptomic databases.'' Critically, the commenter and these cited studies fail to recognize that increased apoptosis is a key criterion to establish a cytotoxic MOA. As outlined in the toxicity assessment (USEPA, 2021b), Felter et al., (2018) ''identified criteria for establishing a cytotoxicity MOA, which includes: . . . (2) clear evidence of cytotoxicity by histopathology, such as presence of necrosis and/or increased apoptosis.'' Overall, the EPA has determined that these studies support the mechanistic conclusions of the toxicity assessment ''that multiple MOAs could be involved in the liver effects observed after GenX chemical exposure'' including PPARα and cytotoxicity (USEPA, 2021b).

With respect to claims that the EPA misapplied diagnostic criteria classifying apoptotic and necrotic lesions: as mentioned above, the EPA engaged a pathology working group within the NTP at the National Institutes of Health to perform an independent analysis of the liver tissue slides. Seven pathologists—headed by Dr. Elmore, who was the lead author of the pathology criteria that the commenter cites (Elmore et al., 2016)—concluded that exposure to HFPO–DA caused a ''constellation of liver effects'' that included cytoplasmic alteration, apoptosis, single cell necrosis, and focal necrosis, and that this full ''constellation of lesions'' should be considered the adverse liver effect within these studies. The EPA then used the established Hall criteria (Hall et al., 2012) to determine that since liver cell death was observed, all effects, including cytoplasmic alteration, were considered adverse and relevant to humans.

The EPA disagrees with the commenters' assertion about UF application. As noted above, agency guidance (USEPA, 2002a; USEPA, 2022f) have established the appropriateness of the use of UFs to address uncertainty and account for data limitations. UFs reflect the limitations of the data across the five areas used in the current EPA human health risk assessment development (referenced above); all individual UFs that are applied are multiplied together to yield the composite or total UF. The EPA guidance dictates that although a composite UF greater than 3,000 represents ''excessive uncertainty'' (USEPA, 2002a; USEPA, 2022f), a composite UF can be equal to 3,000. For HFPO–DA, a composite UF of 3,000 was appropriately applied to account for uncertainties, including variability in the human population, database uncertainties, and possible differences in the ways in which humans and rodents respond to HFPO–DA that reaches their tissues. Furthermore, the composite UF of 3,000 and specifically the database UF and subchronic-to-chronic UF used for HFPO–DA was peer-reviewed by a panel of human health risk assessment experts, and the panel supported the application of the database UF of 10 and the subchronic-to-chronic UF of 10 (USEPA, 2021f). Additionally, a UF_A of 3 was appropriately applied, consistent with peer-reviewed EPA methodology (USEPA, 2002a), to account for uncertainty in characterizing the toxicokinetic and toxicodynamic differences between rodents and humans. As noted in the toxicity assessment for HFPO–DA (USEPA, 2021b), in the absence of chemical-specific data to quantify residual uncertainty related to toxicokinetics and toxicodynamic processes, the EPA's guidelines recommend use of a UF_A of 3.

Finally, some commenters claimed that the EPA did not consider available epidemiological evidence showing no increased risk of cancers or liver disease attributable to exposure to HFPO–DA. The EPA disagrees with this comment because the agency considered all available scientific evidence, including epidemiological studies (USEPA, 2021b). The exhibit submitted by the commenter presents an observational analysis comparing cancer and liver disease rates in North Carolina to rates in other states. It does not present the results of a new epidemiological study that included HFPO–DA exposure measures, health outcome measures, or an assessment of association between exposure and health outcome. The exhibit submitted by the commenter consists of a secondary analysis of disease rate information that was collected from various sources and does not provide new, high-quality scientific information that can be used to assess the impact of exposure to concentrations of HFPO–DA on human health.

d. PFBS

A few commenters suggested that the EPA lower the HRL/HBWC for PFBS to account for thyroid hormone disruption during early development and cited the Washington State Action Level for PFBS, which is 345 ng/L. Washington State used the same RfD (3E–04 mg/kg-d) but a higher DWI–BW to develop their Action Level as compared to the EPA's HRL/HBWC (Washington State used the 95th percentile DWI–BW of 0.174 L/kg/day for infants, whereas the EPA selected the 90th percentile DWI–BW of 0.0354 L/kg/day for women of child-bearing age). The EPA disagrees that the infant DWI–BW is more appropriate for HRL/HBWC calculation. The EPA selected the thyroid hormone outcome (decreased serum total thyroxine in newborn mice seen in a developmental toxicity study) as the critical effect in its PFBS human health toxicity assessment (USEPA, 2021a). Notably, the RfD derived from this critical effect included application of a 10X UF to account for life-stage-specific susceptibility (UF_H). To select a DWI–BW for use in deriving the HRL/HBWC for PFBS, the EPA followed its established approach of considering the PFBS exposure interval used in the developmental toxicity study in mice that was the basis for chronic RfD derivation. In this study, pregnant mice were exposed throughout gestation, which is relevant to two human adult life stages: women of child-bearing age who may be or become pregnant, and pregnant women and their developing embryos or fetuses (Table 3–63 in USEPA, 2019a). To be clear, the critical study exposed mice to PFBS only during pregnancy and not during postnatal development; newborn mice in early postnatal development, which would correspond to the human infancy life stage, were not exposed to PFBS. Of the two relevant adult stages, the EPA selected the 90th percentile DWI–BW for women of child-bearing age (0.0354 L/kg/day) to derive the HRL/HBWC for PFBS because it is the higher of the two, and therefore more health-protective. Please see additional information related to DWI–BW selection above.

Other commenters stated that the EPA's human health toxicity assessment for PFBS is overly conservative, uncertain, and that the confidence in the chronic RfD is low. The EPA disagrees with these comments. Confidence in the critical study (Feng et al., 2017) and corresponding thyroid hormone critical effect in newborn mice was rated by the EPA as 'High;' this rating was a result of systematic study evaluation and risk of bias analysis by a team of EPA experts. The Feng et al. (2017) study, the critical effect of thyroid hormone disruption in offspring, dose-response assessment, and corresponding RfD were subjected to extensive internal EPA, interagency, and public/external peer review. While confidence in the critical study was rated 'High,' the 'Low' confidence rating for the PFBS chronic RfD was in part a result of the lack of a chronic exposure duration study in any mammalian species; this lack of a chronic duration study was one of the considerations that resulted in the EPA applying a UF of 10 to account for database limitations (UF_D). Based on the EPA's human health assessment practices, the lowest confidence rating across the areas of consideration (*e.g.,* existent hazard/dose-response database) is assigned to the corresponding derived reference value (*e.g.,* RfD). Thus, the EPA has high confidence in the critical study (Feng et al., 2017) and critical effect/thyroid endpoint, but the database is relatively limited. Although the PFBS RfD was based on best available peer-reviewed science, there is uncertainty as to the hazard profile associated with PFBS after prolonged (*e.g.,* lifetime) oral exposure. In the toxicity assessment for PFBS (USEPA, 2021a), the EPA noted data gaps in specific health effects domains, as is standard practice. Toxicity assessments for most chemicals identify data gaps; the issue of uncertainty due to toxicological study data gaps is not unique to PFBS. Data gaps are considered when selecting the UF_D because they indicate the potential for exposure to lead to adverse health effects at doses lower than the POD derived from the assessment's critical study. There is a potential that effects with greater dose-response sensitivity (*i.e.,* occurring at lower daily oral exposures) might be discovered from a chronic duration exposure study. Due to this uncertainty, the EPA applied a UF_D of 10.

One commenter questioned the EPA's approach to estimating the human equivalent dose (HED) from the animal data using toxicokinetic (TK) data rather than using default body-weight scaling and suggested that the default allometric approach is more appropriate for estimating an HED. The EPA disagrees with this comment. In human health risk assessment practice, the EPA considers a hierarchical approach to cross-species dosimetric scaling consistent with technical guidance to calculate HEDs (USEPA, 2011; see pp. X–XI of the Executive Summary in '*Recommended Use of Body Weight*$^{3/4}$ *as the Default Method in Derivation of the Oral Reference Dose'*). The preferred approach is physiologically based toxicokinetic (PBTK) modeling; however, there are rarely sufficient chemical-specific data to properly parameterize such a model. In the absence of a PBTK model, the EPA considers an intermediate approach in which chemical-specific data across species, such as clearance or plasma half-life, are used to calculate a dosimetric adjustment factor (DAF) (USEPA, 2011). If chemical-specific TK data are not available, only then is a default approach used wherein allometric scaling, based on body weight raised to the ¾ power, is used to calculate a DAF. The human health toxicity assessment for PFBS invoked the intermediate approach, consistent with guidance, as TK data were available for humans and rodents.

e. Mixtures of PFHxS, PFNA, HFPO–DA, and PFBS

Comments on the EPA's preliminary regulatory determination on the mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS were varied. Many commenters supported the EPA's proposal to regulate a mixture of these PFAS and agreed with the EPA's scientific conclusions about PFAS dose additivity. Many commenters urged the EPA to consider making a determination to regulate for additional PFAS (in a mixture) or all PFAS as a class. As described throughout section III of this preamble, the agency is required to demonstrate a contaminant meets the SDWA statutory criteria to make a regulatory determination. In this preamble, in addition to PFOA and PFOS which the EPA has already made a final determination to regulate, the agency is making final determinations for all PFAS with sufficiently available information to meet these statutory criteria either individually and/or as part of mixture combinations. As information becomes available, the agency will continue to evaluate other PFAS for potential future preliminary regulatory determinations.

Many commenters opposed the EPA's conclusion about PFAS dose additivity and use of the Hazard Index approach to regulate co-occurring PFAS. A few commenters agreed with the EPA's decision to regulate mixtures of certain PFAS and the EPA's conclusion about dose additivity but questioned the EPA's use of the general Hazard Index, and instead, suggested alternative approaches. Please see section IV of this preamble for a summary of comments and the EPA responses on the Hazard Index MCLG and related topics.

There is substantial evidence that PFHxS, PFNA, HFPO–DA, and PFBS act in a dose additive manner, that these four PFAS elicit similar health effects, and that exposure to mixtures of these PFAS may have adverse health effects. Following is a discussion of dose additivity and similarity of adverse effects of PFHxS, PFNA, HFPO–DA, and PFBS.

As noted in this section, the available data indicate that PFHxS, PFNA, HFPO–DA, and PFBS, while not necessarily toxicologically identical, elicit many of the same or similar adverse health effects across different levels of biological organization, tissues/organs, lifestages, and species (ATSDR, 2021; EFSA et al., 2018; EFSA et al., 2020; USEPA, 2021d; USEPA, 2021f; USEPA, 2024f). Each of these PFAS disrupts signaling of multiple biological pathways, resulting in a shared set of adverse effects including effects on thyroid hormone levels, lipid synthesis and metabolism, development, and immune and liver function (ATSDR, 2021; EFSA et al., 2018; EFSA et al., 2020; USEPA, 2021d; USEPA, 2021f; USEPA, 2024f). Please also see USEPA (2024a) for an overview of recent studies that provide supportive evidence of similar effects of PFAS.

Available health effects studies indicate that PFAS mixtures act in a dose-additive manner when the individual components share some health endpoints/outcomes. Individual PFAS, each at doses that are not anticipated to result in adverse health effects, when combined in a mixture may result in adverse health effects. Dose additivity means that when two or more of the component chemicals (in this case, PFHxS, PFNA, HFPO–DA, and/or PFBS) exist in one mixture, the risk of adverse health effects following exposure to the mixture is equal to the sum of the individual doses or concentrations scaled for potency (USEPA, 2000a). Thus, exposure to these PFAS, at doses that individually would not likely result in adverse health effects, when combined in a mixture may pose health risks.

Many commenters supported the EPA's scientific conclusions about PFAS dose additivity and agreed that considering dose-additive effects is a health-protective approach. Many other commenters disagreed with the EPA's scientific conclusions regarding PFAS dose additivity and a few commenters questioned the agency's external peer-review process and whether the agency sufficiently responded to SAB (Science Advisory Board) comments. For example, these commenters stated that the evidence base of PFAS mixture studies is too limited to support dose additivity for these four PFAS and recommended that the EPA re-evaluate its conclusion about dose additivity as new data become available. A few commenters stated that the EPA failed to adequately follow the SAB recommendation that ''discussion of studies of toxicological interactions in PFAS mixtures in the EPA mixtures document be expanded to also include studies that do not indicate dose additivity and/or a common MOA [mode of action] for PFAS.'' The EPA's responses to these comments are summarized in this section.

The EPA continues to support its conclusion that PFAS that elicit similar adverse health effects following individual exposure should be assumed to act in a dose-additive manner when in a mixture unless data demonstrate otherwise. Numerous published studies across multiple chemical classes, biological effects, and study designs support a dose-additive mixture assessment approach for PFAS because they demonstrate that experimentally observed responses to exposure to PFAS and other chemical mixtures are consistent with modeled predictions of dose additivity (see the EPA's *Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)* (USEPA, 2024a)). Since the EPA's draft PFAS Mixtures Framework underwent SAB review in 2021, new studies from the EPA and others have published robust evidence of combined toxicity of PFAS in mixtures, corroborating and confirming earlier findings (*e.g.,* Conley et al., 2022a; Conley et al., 2022b; USEPA, 2023c; see USEPA, 2024a for additional examples). Additionally, the National Academies of

Sciences, Engineering, and Medicine (NASEM, 2022) recently recommended that clinicians apply an additive approach for evaluating patient levels of PFAS currently measured in the National Health and Nutrition Examination Survey (NHANES) in order to protect human health from additive effects from PFAS co-exposure.

The EPA directly asked the SAB for feedback on PFAS dose additivity in the charge for the 2021 review of the EPA's draft PFAS Mixtures Framework. Specifically, the EPA asked the SAB to, ''[p]lease comment on the appropriateness of this approach for a component-based mixture evaluation of PFAS under an assumption of dose additivity'' (USEPA, 2022i). The SAB strongly supported the scientific soundness of this approach when evaluating PFAS and concurred that it was a health protective conclusion. For example, the SAB said:

> . . . The information included in the draft framework supports the conclusion that toxicological interactions of chemical mixtures are frequently additive or close to additive. It also supports the conclusion that dose additivity is a public health protective assumption that typically does not underestimate the toxicity of a mixture . . . (USEPA, 2022i)
>
> The SAB Panel agrees with use of the default assumption of dose additivity when evaluating PFAS mixtures that have similar effects and concludes that this assumption is health protective. (USEPA, 2022i)

Regarding the commenters' assertion that the agency did not adequately follow the SAB recommendation to expand its discussion of PFAS mixtures study results that did not show evidence of dose additivity and/or a common MOA, the EPA disagrees. The EPA reviewed all studies provided by the SAB and in response, included a discussion of relevant additional studies in its public review draft PFAS Mixtures Framework (see section 3 in USEPA, 2023w). Since then, the EPA has included additional published studies and those findings further confirm dose additive health concerns associated with PFAS mixtures (see section 3 in USEPA, 2024a). Data from *in vivo* studies that rigorously tested accuracy of Dose Additivity (DA), Integrated Addition (IA), and Response Additivity (RA) model predictions of mixtures with components that disrupted common pathways demonstrated that DA models provided predictions that were better than or equal to IA and RA predictions of the observed mixture effects (section 3.2 in USEPA, 2024a). The National Academy of Sciences (NAS) conclusions on phthalates (and related chemicals) (NRC, 2008) and systematic reviews of the published literature (Boobis et al., 2011 and Martin et al., 2021; see also section 3.2 in USEPA, 2024a) support DA as the default model for estimating mixture effects in some circumstances, even when the mixtures included chemicals with diverse MOAs (but common target organs/effects) (Boobis et al., 2011; Martin et al., 2021; USEPA, 2024a). Recent efforts to investigate *in vitro* and *in vivo* PFAS mixture effects have provided robust evidence that PFAS behave in a dose-additive manner (see section 3 in USEPA, 2024a).

As supported by the best available science, the SAB, the agency's chemical mixtures guidance (USEPA, 1991b; USEPA, 2000a), and the EPA Risk Assessment Forum's *Advances in Dose Addition for Chemical Mixtures: A White Paper* (USEPA, 2023c), the EPA proposed a Hazard Index MCLG for a mixture of up to four PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) based on dose additivity because published studies show that exposure to each of these individual four PFAS elicits some of the same or similar adverse health effects/outcomes. As noted above, many commenters, as well as the SAB (USEPA, 2022i), supported this conclusion of dose additivity based on similarity of adverse effects.

While the SAB also noted that there remain some questions about PFAS interaction in mixtures (USEPA, 2022i), the available data justify an approach that accounts for PFAS dose additivity. Studies that have assessed PFAS mixture-based effects do not offer evidence for synergistic/antagonistic effects (USEPA, 2024a). For example, Martin et al. (2021), following a review of more than 1,200 mixture studies (selected from > 10,000 reports), concluded that there was little evidence for synergy or antagonism among chemicals in mixtures and that dose additivity should be considered as the default. Experimental data demonstrate that PFAS disrupt signaling in multiple biological pathways resulting in common adverse effects on several of the same biological systems and functions including thyroid hormone signaling, lipid synthesis and metabolism, developmental toxicity, and immune and liver function (USEPA 2024a). Additionally, several EPA Office of Research and Development (ORD) studies provide robust evidence that PFAS behave in a dose-additive manner (Conley et al., 2022a; Conley et al., 2022b; Conley et al., 2023; Gray et al., 2023).

Several commenters opposed the conclusion of dose additivity based on similarity of adverse effects and stated that the EPA failed to establish that the four PFAS included in the Hazard Index (PFHxS, PFNA, HFPO–DA, and PFBS) elicit similar adverse health effects. The EPA disagrees with these comments because the available epidemiology and animal toxicology studies demonstrate that these four PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) have multiple health endpoints and outcomes in common (USEPA, 2024f). Further, these four PFAS are well-studied PFAS for which the EPA or ATSDR have developed human health assessments and toxicity values (*i.e.,* RfDs, minimal risk levels). As shown in Table 1, available animal toxicological data and/or epidemiological studies demonstrate that PFHxS, PFNA, HFPO–DA, and PFBS are documented to affect at least five (5) of the same health outcomes for this evaluation: lipids, developmental, immune, endocrine, and hematologic (USEPA, 2024g). Similarly, according to the 2023 Interagency PFAS Report to Congress (United States OSTP, 2023), available animal toxicological data show that PFHxS, PFNA, HFPO–DA, and PFBS are documented to significantly affect at least eight (8) of the same major health effect domains: body weight, respiratory, hepatic, renal, endocrine, immunological, reproductive, and developmental. In short, multiple evaluation efforts have clearly demonstrated that each of the PFAS regulated by this NPDWR impact numerous of the same or similar health outcomes or domains.

Table 1: Affected health outcomes in animal toxicity and/or epidemiological studies for the four PFAS included in the Hazard Index MCLG (adapted from Table 6-7 in USEPA, 2024g)

Health Outcome	PFNA	PFHxS	PFBS	HFPO-DA
Lipids	X	X	X	X
Developmental	X	X	X	X
Hepatic	X	X	-	X
Immune	X	X	X	X
Endocrine	X	X	X	X
Renal	-	-	X	X
Hematologic	X	X	X	X

Notes: (X) Health outcome examined, evidence of association; (-) health outcome examined, no evidence of association.

In summary, there is substantial evidence that mixtures of PFHxS, PFNA, HFPO–DA, and PFBS act in a dose-additive manner and elicit multiple similar toxicological effects. Studies by the EPA and others provide evidence that corroborates the dose-additive toxicity of PFAS mixtures, and data on different chemical classes and research also provide support for dose additivity. Additionally, numerous *in vivo* and *in vitro* studies demonstrate that these four PFAS share many common health effects across diverse health outcome categories (*e.g.,* developmental, immunological, and endocrine effects), and that they induce some of the same effects at the molecular level along biological pathways (USEPA, 2024f).

C. Statutory Criterion 2—Occurrence

The EPA has determined that there is a substantial likelihood that PFHxS, PFNA, and HFPO–DA will individually occur and combinations of these three PFAS and PFBS will co-occur in mixtures in PWSs with a frequency and at levels of public health concern based on the EPA's evaluation of the best available occurrence information. In this preamble, while the EPA is making a final determination to regulate PFBS in mixtures with PFHxS, PFNA, and/or HFPO–DA, the agency is deferring the final individual regulatory determination for PFBS so that the agency can continue to evaluate this contaminant relative to the SDWA criteria for regulation, particularly related to its individual known or likely occurrence. For the other three PFAS, the EPA is making a final determination to regulate them individually in this preamble (*i.e.,* PFHxS, PFNA, and HFPO–DA). The EPA recognizes there will be additional occurrence or other relevant information for these and other PFAS in the future. The EPA has, however, determined that there is more than sufficient occurrence information to satisfy the statutory criterion to regulate PFNA, PFHxS, and HFPO–DA.

The EPA's evaluation of the second statutory criterion for regulation of PFHxS, PFNA, and HFPO–DA individually and regulation of combinations of these PFAS and PFBS in mixtures follows a similar process to previous rounds of regulatory determinations including the written Protocol developed under Regulatory Determination 3 (USEPA, 2014a) and also described in detail in the Preliminary Regulatory Determination 4 (USEPA, 2020a). Using the Protocol, and as conducted for the regulatory determinations in this action, the agency compares available occurrence data relative to the contaminant HRL, a health-based concentration against which the agency evaluates occurrence data when making regulatory determinations, as a preliminary factor in informing the level of public health concern. For both this regulatory determination and previous regulatory determinations, this is the first screening factor in informing if there is a substantial likelihood the contaminant will occur at a frequency and level of public health concern. Consistent with the Protocol and similar to all past regulatory determinations, these regulatory determinations are also based on other factors, not just the direct comparison to the HRL. As described clearly in the proposal, the EPA has not been able to determine a simple threshold of public health concern for all contaminants the agency considers for regulation under SDWA; rather, it is a contaminant-specific decision which ''involves consideration of a number of factors, some of which include the level at which the contaminant is found in drinking water, the frequency at which the contaminant is found and at which it co-occurs with other contaminants, whether there is an sustained upward trend that these contaminant will occur at a frequency and at levels of public health concern, the geographic distribution (national, regional, or local occurrence), the impacted population, health effect(s), the potency of the contaminant, other possible sources of exposure, and potential impacts on sensitive populations or lifestages.'' (USEPA, 2023f). It also includes consideration of production and use trends and environmental fate and transport parameters which may indicate that the contaminant would persist and/or be mobile in water. Appropriately, the EPA has considered these relevant factors in its evaluation that there is a substantial likelihood that PFHxS, PFNA, and HFPO–DA will individually occur and combinations of these three PFAS and PFBS will co-occur in mixtures in PWSs with a frequency and at levels of public health concern.

The EPA's evaluation of the second statutory criterion is based on the best available health information, which includes UCMR 3 data and more recent PFAS drinking water data collected by several states. Based on suggestions in public comments to update state occurrence data, the EPA supplemented the data used to inform the rule proposal with new data from states included in the original proposal and additional states that have made monitoring data publicly available since the rule proposal (USEPA, 2024b). Consistent with section 1412(b)(1)(B)(II), this information combined represents best available occurrence data. It includes results from tens of thousands of samples and the assembled data represent one of the most robust occurrence datasets ever used to inform development of a drinking water regulation of a previously unregulated contaminant. The state data were primarily gathered after the UCMR 3 using improved analytical methods that could measure more PFAS at lower concentrations. These additional data demonstrate greater occurrence and co-occurrence of the PFAS monitored under UCMR 3 (PFHxS, PFNA, and PFBS) at significantly greater frequencies than UCMR 3 and the data initially included in the analysis. Furthermore, the state data show the co-occurrence of PFAS at levels of public health concern, as well as the demonstrated occurrence and co-occurrence of HFPO–DA which was not included within UCMR 3. As discussed subsequently, these data demonstrate that there is a substantial likelihood PFHxS, PFNA, and HFPO–DA will occur and combinations of PFHxS, PFNA, HFPO–DA, and PFBS will co-occur in mixtures with a frequency and at levels of public health concern. When determining that there is a substantial likelihood PFHxS, PFNA, and HFPO–DA will occur and PFHxS, PFNA, HFPO–DA, and/or PFBS will co-occur at levels of public health concern, the EPA considered both the occurrence concentration levels for PFHxS, PFNA, and HFPO–DA individually, as well as their collective co-occurrence and corresponding dose additive health concerns from co-exposures with PFBS for purposes of considering a regulatory determination for mixtures of these four PFAS. The EPA also considered other factors in evaluating the second criterion and informing level of public health concern for PFHxS, PFNA, and HFPO–DA individually and combinations of these three PFAS and PFBS in mixtures, including the frequency at which the contaminant is found, the geographic representation of the contaminant's occurrence, and the environmental fate and transport characteristics of the contaminant. As the EPA noted previously, while the agency is not making an individual regulatory determination for PFBS at this time, PFBS is an important component in mixtures with PFHxS, PFNA, and HFPO–DA and the EPA presents occurrence information for PFBS as part of section III.C.5 and its co-occurrence analyses in sections VI.C and D of this preamble.

The EPA focused the evaluation of the state data on the non-targeted or non-site specific (*i.e.,* monitoring not conducted specifically in areas of known or potential contamination) monitoring efforts from 19 states. Non-targeted or non-site-specific monitoring is likely to be more representative of general occurrence because its framework and monitoring results will be less likely to potentially over-represent concentrations at locations of known or suspected contamination. Sixteen (16) of 19 states reported detections of at least three of PFHxS, PFNA, HFPO–DA, or PFBS.

The EPA considered the targeted state monitoring data separately since a higher rate of detections may occur as a result of specifically looking in areas of suspected or known contamination. For the targeted state data nearly all these states also reported detections at systems serving millions of additional people, as well as at levels of public health concern, both individually for PFHxS, PFNA, and HFPO–DA, and as mixtures of these three PFAS and PFBS. State data detection frequency and concentration results vary for PFHxS, PFNA, HFPO–DA, and PFBS, both between these four different PFAS and across different states, with some states showing much higher reported detections and concentrations of these PFAS than others. The overall results demonstrate the substantial likelihood that individually PFHxS, PFNA, and HFPO–DA and mixtures of these three PFAS with PFBS will occur and co-occur at frequencies and levels of public health concern. Tables 2 and 3 show the percent of samples with state reported detections of PFHxS, PFNA, HFPO–DA, and PFBS, and the percentage of monitored systems with detections of PFHxS, PFNA, HFPO–DA, and PFBS, respectively, across the non-targeted state finished water monitoring data. The EPA notes that Alabama is not included in Tables 2 and 3 as only detections were reported and there was no information on the total number of samples collected to determine percent detection.

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Table 2. Non-Targeted State PFAS Finished Water Data – Summary of Samples with State Reported Detections[1] of PFHxS, PFNA, HFPO-DA, and PFBS

State	PFHxS	PFNA	PFBS	HFPO-DA
Colorado	10.8%	0.9%	11.0%	0.2%
Illinois	13.4%	0.6%	17.6%	0.0%
Indiana	1.5%	0.2%	5.6%	0.0%
Kentucky	8.6%	2.5%	12.3%	13.6%
Maine	3.0%	3.5%	10.1%	N/A[2]
Maryland	18.2%	2.3%	19.3%	0.0%
Massachusetts	23.6%	2.9%	39.8%	0.1%
Michigan	4.3%	0.6%	7.5%	0.1%
Missouri	3.3%	0.0%	6.1%	0.0%
New Hampshire	16.8%	3.3%	32.1%	3.8%
New Jersey	26.2%	7.7%	28.1%	N/A[2]
New York	21.6%	8.6%	28.8%	0.7%
North Dakota	5.3%	0.0%	8.8%	0.0%
Ohio	6.6%	0.3%	5.0%	0.1%
South Carolina	8.1%	0.1%	13.7%	1.3%
Tennessee	0.0%	0.0%	0.0%	N/A[2]
Vermont	4.2%	2.5%	7.1%	0.2%
Wisconsin	27.2%	2.2%	28.0%	0.0%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] N/A indicates the analyte was not sampled as part of the state monitoring.

Table 3: Non-Targeted State PFAS Finished Water Data – Summary of Monitored Systems with State Reported[1] Detections of PFHxS, PFNA, HFPO-DA, and PFBS

State	PFHxS	PFNA	PFBS	HFPO-DA
Colorado	13.4%	1.0%	13.4%	0.3%
Illinois	4.6%	0.5%	8.0%	0.0%
Indiana	1.3%	0.3%	6.5%	0.0%
Kentucky	9.5%	2.7%	13.5%	12.2%
Maine	2.8%	3.9%	10.3%	N/A[2]
Maryland	12.7%	3.2%	12.7%	0.0%
Massachusetts	18.1%	4.4%	27.8%	0.3%
Michigan	4.1%	0.6%	7.9%	0.3%
Missouri	2.7%	0.0%	6.2%	0.0%
New Hampshire	22.5%	5.5%	38.1%	5.1%
New Jersey	32.9%	16.5%	35.2%	N/A[2]
New York	25.0%	9.7%	36.7%	1.1%
North Dakota	5.4%	0.0%	9.0%	0.0%
Ohio	2.2%	0.3%	2.4%	0.1%
South Carolina	13.7%	0.3%	22.1%	2.0%
Tennessee	0.0%	0.0%	0.0%	N/A[2]
Vermont	2.7%	0.9%	6.0%	0.5%
Wisconsin	31.8%	3.9%	33.9%	0.0%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] N/A indicates the analyte was not sampled as part of the state monitoring.

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As shown in Tables 2 and 3, all states except three report sample and system detections for at least three of the four PFAS. For those states that reported detections, the percentage of samples and systems where these PFAS were found ranged from 1 to 39.8 percent and 0.1 to 38.1 percent, respectively. While these percentages show occurrence variability across states, several of these states demonstrate that a significant number of samples (*e.g.,* detections of PFHxS in 26.2 percent of New Jersey samples) and systems (*e.g.,* detections of HFPO–DA in 12.2 percent of monitored systems in Kentucky) contain some or all four PFAS. This occurrence information, as well as the specific discussion related to individual occurrence for PFHxS, PFNA, and HFPO–DA and co-occurrence of these three PFAS and PFBS, supports the agency's determination that there is a substantial likelihood that PFHxS, PFNA, HFPO–DA occur and PFHxS, PFNA, HFPO–DA, and PFBS co-occur in combinations of mixtures with a frequency of public health concern. Additionally, the agency emphasizes that occurrence and co-occurrence of these PFAS is not only at a regional or local level, rather it covers many states throughout the country; therefore, a national level regulation is necessary to ensure all Americans served by PWSs are equally protected.

1. PFHxS

The occurrence data presented above, throughout section VI of this preamble and discussed in the USEPA (2024b) support the agency's final determination that there is a substantial likelihood PFHxS occurs with a frequency and at levels of public health concern in drinking water systems across the United States. PFHxS was found under UCMR 3 in approximately 1.1 percent of systems, serving 5.7 million people across 25 states, Tribes, and U.S. territories. However, under UCMR 3, the minimum reporting level for PFHxS was 30 ng/L. As this reporting level is three times greater than the health-based HRL for PFHxS (10 ng/L), it is extremely likely there is significantly greater occurrence and associated population exposed in the range between the HRL of 10 ng/L and the UCMR 3 minimum reporting level of 30 ng/L (as demonstrated by both the more recent state data and the EPA's occurrence model discussed in this section and in section VI of this preamble showing many results in this concentration range). Through analysis of available state data, which consisted of approximately 48,000 samples within 12,600 systems, 18 out of the 19 states that conducted non-targeted monitoring had reported detections of PFHxS in 1.3 to 32.9 percent of their systems (Tables 2 and 3). These same systems reported concentrations ranging from 0.2 to 856 ng/L with median sample concentrations ranging from 1.17 to 12.1 ng/L, demonstrating concentrations above the HRL of 10 ng/L.

Targeted state monitoring data of PFHxS show similar results. For example, in its targeted monitoring efforts, California reported 38.5 percent of monitored systems found PFHxS, where concentrations ranged from 1.1 to 160 ng/L, also demonstrating concentrations above the HRL. In total, considering both the non-targeted and targeted state data, PFHxS was found above the HRL in at least 184 PWSs in 21 states serving a population of approximately 4.3 million people.

The EPA also evaluated PFHxS in a national occurrence model that has been developed and utilized to estimate national-scale PFAS occurrence for four PFAS that were included in UCMR 3 (Cadwallader et al., 2022). The model has been peer reviewed and is described extensively in Cadwallader et al. (2022). The model and results are described in section VI.E of this preamble; briefly, both the UCMR 3 and some state data were incorporated into a Bayesian hierarchical model which supported exposure estimates for select PFAS at lower levels than were measured under UCMR 3. Hundreds of systems serving millions of people were estimated to have mean concentrations exceeding the PFHxS HRL (10 ng/L). Therefore, the UCMR 3 results, the national occurrence model results, and the substantial state data demonstrate the substantial likelihood PFHxS occurs at a frequency and level of public health concern. Finally, UCMR 5 data are being reported to the EPA while this final rule is being prepared. See section VI of this preamble for more information on the preliminary results. While these UCMR 5 PFHxS data are too preliminary to provide the basis for the regulatory determination, these preliminary UCMR 5 results appear to confirm state data and model results.

Further supporting this final determination, PFHxS is very stable and persistent in the environment. While PFHxS was phased out in the U.S. in the early 2000's there are still detections as previously demonstrated. In addition, legacy stocks may also still be used, production continues in other countries, and products containing PFHxS may be imported into the U.S. (USEPA, 2000b). Since PFHxS is environmentally persistent and products containing PFHxS are still in use and may be imported into the United States, the EPA anticipates environmental contamination to sources of drinking water will continue. To illustrate this point further, PFOA and PFOS, two of the most extensively sampled PFAS, are also very environmentally persistent and have similarly been phased out in the U.S. for many years, though these two contaminants continue to often be found at levels of public health concern as discussed in section VI of this preamble. Currently, this also appears to be a similar trend for PFHxS occurrence, where the drinking water sample data demonstrates it continues to occur at levels of public health concern. Therefore, in consideration of factors relating to the environmental persistence of PFHxS, its presence in consumer products and possible continued use, and the observed occurrence trend of PFOA and PFOS, the EPA finds that there is a substantial likelihood PFHxS occurs or will occur at a frequency and level of public health concern.

2. PFNA

The occurrence data presented above, throughout section VI of this preamble, and discussed in USEPA (2024b) support the agency's final determination that there is a substantial likelihood PFNA occurs with a frequency and at levels of public health concern in drinking water systems across the U.S.

PFNA was found under UCMR 3 in approximately 0.28 percent of systems, serving 526,000 people in 7 states, Tribes, and U.S. territories, using a minimum reporting level of 20 ng/L. As this reporting level is two times greater than the health-based HRL of 10 ng/L, the EPA expects there is even greater occurrence and exposed population in the range between 10 and 20 ng/L. Additionally, through analysis of the extensive amount of available state data, which consisted of approximately 57,000 samples within approximately 12,400 systems, 16 of 19 non-targeted monitoring states reported detections of PFNA within 0.3 to 16.5 percent of their systems (Tables 2 and 3). These same states reported sample results ranging from 0.23 to 330 ng/L, demonstrating levels above the HRL of 10 ng/L, with median sample results ranging from 0.35 to 7.5 ng/L.

Targeted state monitoring data of PFNA are also consistent with non-targeted state data; for example, Pennsylvania reported 5.8 percent of monitored systems found PFNA, where concentrations ranged from 1.8 to 18.1 ng/L, also showing concentrations above the HRL. When considering all available state data, there are at least 480 systems in 19 states serving more than 8.4 million people that reported any concentration of PFNA, and at least 52 systems in 12 states within different geographic regions serving a population of 177,000 people with reported concentrations above the HRL of 10 ng/L. Furthermore, when evaluating only a subset of the available state data representing non-targeted monitoring, PFNA was reported in approximately 3.6 percent of monitored systems; if these results were extrapolated to the nation and those system subject to the final rule requirements, the agency estimates that PFNA would be detectable in over 2,300 PWSs serving 24.9 million people. If those results were further compared to the HRL for PFNA (10 ng/L), PFNA would be detected above the HRL in 228 systems with 830,000 people exposed. Thus, in addition to the UCMR 3 results, these extensive state data also reflect there is a substantial likelihood PFNA occurs at a frequency and level of public health concern because it is observed or likely to be observed within numerous water systems above levels of public health concern across a range of geographic locations. Finally, UCMR 5 data are being reported to the EPA while this final rule is being prepared. See section VI of this preamble for more information on the preliminary results. While these PFNA UCMR 5 data are too preliminary to provide the basis for the regulatory determination, these preliminary UCMR 5 results appear to confirm state data discussed above.

Further supporting this final determination, PFNA is very stable and persistent in the environment. While it has generally been phased out in the U.S. there are still detections as demonstrated previously. Additionally, legacy stocks may still be used and products containing PFNA may still be produced internationally and imported to the U.S. (ATSDR, 2021). Since PFNA is environmentally persistent and products containing PFNA are still in use and may be imported into the U.S., there is a substantial likelihood that environmental contamination of sources of drinking water will continue. To illustrate this point further, PFOA and PFOS, two of the most extensively sampled PFAS, are also very environmentally persistent and have similarly been phased out in the U.S. for many years, though these two contaminants continue to often be found at levels of public health concern as discussed in section VI of this preamble. Currently, this also appears to be a similar trend for PFNA occurrence, where the drinking water sample data demonstrates it continues to occur at levels of public health concern. Therefore, in consideration of factors relating to the environmental persistence of PFNA, its presence in consumer products and possible continued use, and the observed occurrence trend of PFOA and PFOS, the EPA finds that there is a substantial likelihood PFNA occurs or will co-occur at a frequency and level of public health concern.

3. HFPO–DA

The occurrence data presented above, throughout section VI of this preamble, and discussed in the USEPA (2024b) support the agency's final determination that there is a substantial likelihood HFPO–DA occur with a frequency and at levels of public health concern in drinking water systems across the U.S. HFPO–DA was not included as a part of the UCMR 3; however, through analysis of available state data, which consisted of approximately 36,000 samples within approximately 10,100 systems, 10 of the 16 states that conducted non-targeted monitoring had state reported detections of HFPO–DA within 0.1 to 12.2 percent of their systems (Tables 2 and 3). These same states reported sample results ranging from 0.7 to 100 ng/L and median sample results ranging from 1.7 to 29.6 ng/L, demonstrating concentrations above the HRL of 10 ng/L.

Additionally, targeted state monitoring in North Carolina included sampling across six finished drinking water sites and 438 samples with HFPO–DA. Concentrations ranged from 9.52 to 1100 ng/L, a median concentration of 40 ng/L, and 433 (99 percent) samples exceeding the HRL (10 ng/L). When considering all available state data, there are at least 75 systems in 13 states serving more than 2.5 million people that reported any concentration of HFPO–DA, and at least 13 systems in 5 states within different geographic regions of the country serving a population of 227,000 people with reported concentrations above the HRL of 10 ng/L. Additionally, when evaluating only a subset of the available state data representing non-targeted monitoring to ensure that the data were not potentially over-represented by sampling completed in areas of known or suspected contamination, HFPO–DA was reported in approximately 0.48 percent of monitored systems; if these results were extrapolated to the nation and those system subject to the final rule requirements, the agency estimates that HFPO–DA would be detectable in over 320 PWSs serving 9.9 million people. If those results were further compared to the HRL for HFPO–DA (10 ng/L), HFPO–DA would be detected above the HRL in 42 systems with at least 495,000 people exposed. Finally, UCMR 5 data are being reported to the EPA while this final rule is being prepared. See section VI of this preamble for more information on the preliminary results. While these HFPO–DA UCMR 5 data are too preliminary to provide the basis for the regulatory determination, these preliminary UCMR 5 results appear to confirm the state data discussed above.

Further supporting this final determination, HFPO–DA is very stable and persistent in the environment. Additionally, unlike PFOA, PFOS, PFHxS, and PFNA which have been phased out in the U.S, HFPO–DA continues to be actively produced and used within the country and is generally considered to have replaced the production of PFOA. Since HFPO–DA is environmentally persistent and products containing HFPO–DA are still being actively produced and used, the EPA anticipates that contamination will continue, if not increase, due to disposal and breakdown in the environment. To illustrate this point further, PFOA and PFOS, two of the most extensively sampled PFAS, are also very environmentally persistent and have been phased out in the United States for many years, though these two PFAS continue to often be found at levels of public health concern as discussed in section VI of this preamble. Therefore, in consideration of factors relating to the environmental persistence of HFPO–DA, its continued and possibly increasing presence in consumer products and use, and the observed occurrence trend of PFOA and PFOS, the EPA anticipates that occurrence levels of HFPO–DA will similarly continue to be found at least to the levels described in this preamble demonstrating that there is a substantial likelihood HFPO–DA will occur at a frequency and level of public health concern.

As discussed, HFPO–DA continues to be actively produced and used throughout the U.S., it currently occurs at levels above its HRL, and it occurs within geographically diverse areas of the country demonstrating it is not a local or regional issue only. While the current individual occurrence profile of HFPO–DA is not as pervasive and is found at somewhat lower frequency as the currently observed levels of PFOA, PFOS, or PFHxS, based upon the available substantial amount of state occurrence data and given factors previously described, the EPA has determined that there is a substantial likelihood HFPO–DA occurs or will occur at a frequency and level of public health concern.

4. PFBS

The agency is deferring the final individual regulatory determination for PFBS to further consider whether occurrence information supports a finding that there is substantial likelihood that PFBS will individually occur in PWSs and at a level of public health concern. While current information demonstrates that PFBS frequently occurs, it has not been observed to exceed its HRL of 2,000 ng/L in isolation. However, when considered in mixture combinations with other PFAS, including PFHxS, PFNA, and HFPO–DA, PFBS is anticipated to have dose-additive adverse health effects (based on available data on PFAS and dose additivity) and there is a substantial likelihood of its co-occurrence in combinations of mixtures with PFHxS, PFNA, and HFPO–DA with a frequency and at levels of public health concern. This is described further in sections III.C.5 and VI.C. and VI.D of this preamble.

5. Mixtures of PFHxS, PFNA, HFPO–DA, and PFBS

Through the information presented within this section and in USEPA (2024b), along with the co-occurrence information presented in sections VI.C and VI.D of this preamble, the EPA's evaluation of all available UCMR 3 and state occurrence data demonstrates that there is a substantial likelihood that combinations of PFHxS, PFNA, HFPO–DA, and PFBS (collectively referred to as ''Hazard Index PFAS'') co-occur or will co-occur in mixtures at a frequency and level of public health concern.

As discussed throughout section III.C of this preamble, the EPA has determined that PFHxS, PFNA, and HFPO–DA each meet the second statutory criterion for individual regulation. Additionally, as demonstrated in sections VI.C. and D. of this preamble, the EPA has determined that these three PFAS also meet the second statutory criterion when present in mixture combinations. PFBS has not been observed to exceed its HRL of 2,000 ng/L in isolation; therefore, the EPA is deferring the individual regulatory determination for this PFAS to further consider future occurrence information. However, the agency has determined that PFBS frequently occurs (as shown in Table 2 and Table 3), and that when considering dose additivity there is a substantial likelihood of its co-occurrence in mixtures of PFHxS, PFNA, and/or HFPO–DA with a frequency and at a level of public health concern. Therefore, the agency has determined that PFBS also meets the criterion when present in mixture combinations with PFHxS, PFNA, and/or HFPO–DA.

In sections VI.C and D of this preamble, the EPA has presented its evaluation and findings related to the likelihood and frequency of co-occurrence of the four Hazard Index PFAS, including both through groupwise and pairwise analyses for the Hazard Index PFAS, in non-targeted state monitoring datasets. The groupwise co-occurrence analysis established the broad occurrence frequency of Hazard Index PFAS through a linkage to the presence of PFOA and PFOS. Because not as many states have monitored for the Hazard Index PFAS as compared to PFOA and PFOS, their occurrence information is less extensive than the occurrence information for PFOA and PFOS. Therefore, though the agency has previously made a final regulatory determination for PFOA and PFOS, establishing co-occurrence of Hazard Index PFAS with PFOA and PFOS is important to better understand the likelihood of Hazard Index PFAS occurrence. In this analysis, the six PFAS were separated into two groups—one consisted of PFOS and PFOA and the other group included the four Hazard Index PFAS. The analysis broke down the systems and samples according to whether chemicals from the two respective groups were detected. Given that the groupwise co-occurrence analysis established that there is a substantial likelihood that the Hazard Index PFAS frequently occur, particularly alongside PFOA or PFOS, the pairwise co-occurrence was relevant for understanding how the Hazard Index PFAS co-occur with each other instead of occurring independently. Pairwise co-occurrence analysis explored the odds ratios for each unique pair of PFAS included in the regulation. For every pair of PFAS chemicals included in the final regulation, the odds ratio, a statistic that, in this context, quantifies the strength of association between two PFAS being present, was found to be statistically significantly greater than 1. This means there was a statistically significant increase in the odds of reporting a chemical as present after knowing that the other chemical was detected. In most instances the odds appeared to increase in excess of a factor of ten. Thus, based on the large amount of available data, the chemicals are clearly demonstrated to frequently co-occur rather than occur independently of one another, supporting the agency's determination for mixtures of the four PFAS.

For the groupwise analysis, results generally indicated that when PFOA and PFOS were found, Hazard Index PFAS were considerably more likely to also be present. Additionally, for systems that only measured PFOA and/or PFOS and did not measure the Hazard Index PFAS, it can be assumed that the Hazard Index PFAS are more likely to be present in those systems, and that Hazard Index occurrence may be underestimated. Moreover, while PFOA and PFOS are not included within the Hazard Index PFAS or the determination to regulate mixtures of these PFAS, the pervasive occurrence of PFOA and PFOS shown in section VI of this preamble is a strong indicator that these other Hazard Index PFAS are also more likely to be found than what has been reported in state monitoring data to date. In this analysis, comparisons were also made between the number of Hazard Index PFAS analyzed and the number of Hazard Index PFAS reported present. As more Hazard Index PFAS were analyzed, more Hazard Index PFAS were reported present. Systems and samples where Hazard Index PFAS were found were more likely to find multiple Hazard Index PFAS than a single Hazard Index PFAS (when monitoring for three or four Hazard Index PFAS), demonstrating an increased likelihood of their co-occurrence. Additionally, for both system-level and sample-level analyses where PFOA and/or PFOS were reported present and all four Hazard Index PFAS were monitored, two or more Hazard Index PFAS were reported present more than half of the time, exhibiting they are more likely to occur together than in isolation. Furthermore, the EPA notes that when evaluating only a subset of the available state data representing non-targeted monitoring where either three or four Hazard Index PFAS were monitored, regardless of whether PFOA or PFOS were reported present, two or more of the Hazard Index PFAS were reported in approximately 12.1 percent of monitored systems; if these results were extrapolated to the nation, two or more of these four PFAS would co-occur in about 8,000 PWSs (see section VI.C.1 of this preamble for additional information).

The EPA uses a Hazard Index of 1 as the HRL to further evaluate the substantial likelihood of the Hazard Index PFAS co-occurring at a frequency and level of public health concern. As discussed in greater detail in section VI.D, of this preamble based on available state data the EPA finds that across 21 states there are at least 211 PWSs serving approximately 4.7 million people with results above a Hazard Index of 1 for mixtures including two or more of the Hazard Index PFAS. Specifically evaluating the presence of PFBS, in these same 211 systems where the Hazard Index was found to be greater than 1, PFBS was observed at or above its PQL in mixtures with one or more of the other three Hazard Index PFAS in at least 72 percent (152) of these systems serving approximately 4.5 million people. Additionally, as described previously in sections III.C.1–3, PFHxS, PFNA, HFPO–DA, and PFBS are all very stable and persistent in the environment. All are either still being actively used or legacy stocks may be used and imported into the U.S. Consequently, there is a substantial likelihood that environmental contamination of sources of drinking water from these PFAS will continue to co-occur to at least the levels described in this preamble.

Therefore, in consideration of the environmental persistence of these PFAS, their presence in consumer products and continued use, the findings of both the pairwise and groupwise co-occurrence analyses, and demonstration of combinations of Hazard Index PFAS mixtures exceeding the Hazard Index of 1, the EPA has determined there is sufficient occurrence information available to support the second criterion that there is a substantial likelihood that combinations of the four Hazard Index PFAS in mixtures co-occur at frequencies and levels of public health concern.

6. Summary of Major Public Comments and EPA Responses

The EPA requested comment on its preliminary regulatory determination for all four PFAS and their mixtures and its evaluation of the statutory criteria that supports the finding. The EPA also requested comment on additional occurrence data the agency should consider regarding its decision that PFHxS, PFNA, HFPO–DA, and PFBS and their mixtures occur or are substantially likely to occur in PWSs with a frequency and at levels of public health concern. The EPA received many comments on the agency's evaluation of the second statutory criterion under section 1412(b)(1)(A) of SDWA. Many commenters supported the EPA's preliminary determination that PFHxS, PFNA, HFPO–DA, and PFBS and mixtures of these four contaminants meet the second statutory occurrence criterion under SDWA.

A couple of commenters claimed that the EPA does not have a robust understanding of available occurrence data that supports any of the regulatory determinations for the four PFAS in this rule. Additionally, some commenters suggested that the preliminary determinations were ''rushed'' and ''non-scientific,'' and that the agency should wait until some or all of the UCMR 5 data is available and considered. The EPA disagrees. Sufficient occurrence data are available to establish a substantial likelihood of occurrence at frequencies and levels of health concern. Per the intent of the statute, the agency used the best available data in an expeditious manner, which, as the agency described earlier, was also a very large dataset consisting of tens of thousands of samples and representing one of the most robust occurrence datasets ever used to inform development of a drinking water regulation of a previously unregulated contaminant. The agency also disagrees that the occurrence analyses undertaken and available in the preamble as well as the technical support document for occurrence were non-scientific. Based on publicly available information within the state data, the EPA verified that the very large majority of samples (at least 97 percent) were collected using EPA-approved methods; the slight percentage the agency was unable to verify would not result in different agency conclusions. Additionally, the EPA notes that the aggregated data were assessed using precedented statistical metrics and analyses. In addition, the Cadwallader et al. (2022) model uses a robust, widely accepted Bayesian statistical approach for modeling contaminant occurrence. Based on these analyses, the EPA has a clear understanding of the occurrence of the modeled contaminants. As discussed in section III.C of this preamble and USEPA, 2024b, the EPA also has sufficient state data which consist of a greater number of total systems and samples than that included within the monitoring under UCMR 3, to confidently establish that there is a substantial likelihood of occurrence at frequencies and levels of public health concern.

As discussed above, the agency believes that the best currently available occurrence data demonstrate substantial likelihood of occurrence for the chemicals included in the final rule as they are demonstrated at frequencies and levels of public health concern. UCMR 5 data are being reported to the EPA while this final rule is being prepared. See section VI of this preamble for more information on the EPA's evaluation of the preliminary results. While these data are too preliminary to provide the basis for a regulatory determination, these preliminary UCMR 5 results appear to support the data discussed previously.

Several commenters disagreed that the available occurrence information supports a preliminary determination for HFPO–DA, with a few citing a lack of nationally representative data and suggesting a delay until UCMR 5 data is collected. The EPA disagrees with these comments, as the state monitoring data for the proposed rule demonstrates HFPO–DA occurrence in 13 geographically diverse states, including at 75 systems serving at least 2.5 million people. Moreover, non-national datasets may serve to demonstrate occurrence of a contaminant to warrant a positive determination and subsequent development of an NPDWR. For example, the best available HFPO–DA state data consists of approximately 36,000 samples within 10,000 systems and is representative of multiple geographic locations.

One commenter stated that a regulatory determination for PFNA was unnecessary as they do not believe it occurred with frequency under UCMR 3 monitoring, and a couple of other commenters suggested that a negative determination was appropriate for PFNA citing occurrence levels. The EPA disagrees that a negative determination is appropriate for PFNA as it has been demonstrated to occur at levels of public health concern in at least 52 water systems across 12 states. Furthermore, as described previously, when evaluating only a subset of the available state data representing non-targeted monitoring, PFNA was reported in approximately 3.6 percent of monitored systems and if those results were extrapolated across the country, PFNA would be detectable at any concentration in over 2,300 PWSs serving 21.2 million people and detectable above 10 ng/L in 227 systems serving 711,000 people. Additionally, PFNA frequently co-occurs with other PFAS, and as previously discussed in this section, presents dose additive health concerns with other PFAS demonstrating it is also an important component of the determination to regulate it in mixtures with PFHxS, HFPO–DA, and/or PFBS.

Commenters both agreed and disagreed with the EPA's individual preliminary determination for PFBS. With respect to commenters who suggested that the EPA has not met the occurrence criterion, while PFBS occurs at significant frequency, the agency is deferring the individual determination to regulate PFBS when it occurs individually until it conducts further evaluation under the statutory criteria. The EPA further finds that PFBS exposure may cause dose additive adverse health effects in mixtures with PFHxS, PFNA, and/or HFPO–DA; that there is a substantial likelihood that PFBS co-occurs in mixtures with PFHxS, PFNA, and/or HFPO–DA in PWSs with a frequency and at levels of public health concern; and that, in the sole judgment of the Administrator, regulation of PFBS in mixtures with PFHxS, PFNA, and/or HFPO–DA presents a meaningful opportunity for health risk reduction for persons served by PWSs. Therefore, PFBS will be regulated as part of a mixture with PFHxS, PFNA, and HFPO–DA.

A few commenters provided feedback on occurrence thresholds the agency should consider when evaluating the second statutory criterion for regulatory determinations. Particularly, these commenters recommended that the EPA should define a threshold for frequency and level of public health concern that warrants a specific regulatory determination. A few commenters cited other previous regulatory determinations where the agency made a determination not to regulate contaminants with similar or lower levels of occurrence suggesting that this should be the same for some or all of these four PFAS. Furthermore, some of these commenters stated that it would be arbitrary and capricious and conflict with the SDWA if the EPA did not use the level of adverse health effect (*i.e.,* the HRL) to represent the level at which a contaminant is considered a public health concern.

The EPA disagrees with these commenters and as demonstrated in the proposal and noted earlier in section III of this preamble, for this regulatory determination, as well as past determinations, the agency did compare available occurrence data relative to the contaminant HRL as a factor in informing the occurrence level of public health concern. However, the level of public health concern for purposes of the second criterion is a contaminant-specific analysis that include consideration of the HRL, as well as other factors and not solely based on the direct comparison to the HRL. There is not just one simple threshold used for public health concern for all contaminants. In the case of PFAS, this is particularly relevant given the dose-additivity of mixtures.

The EPA also disagrees with these commenters as SDWA does not define the occurrence level of public health concern for contaminants, nor does it prescribe the level of adverse health effects that must be used for a regulatory determination. Ultimately, the overall decision to regulate a contaminant considers all three statutory criteria, including the comprehensive assessment of meaningful opportunity which is in the Administrator's sole discretion. In previous EPA regulatory determinations, the agency has considered the occurrence criteria unique to the contaminant it is evaluating and has made decisions not to regulate contaminants both where there was substantial likelihood of occurrence at frequency and/or at levels of public health concern and where there was limited or no substantial likelihood of occurrence at frequency and/or at levels of public health concern. Consistent with this past regulatory history and the Administrator's authority under the terms of the statute, the decision considers all three criteria and cannot be determined in the exact same manner for different contaminants. While the EPA may have made negative determinations for other contaminants demonstrating occurrence at different frequencies and levels of public health concern, the basis for those decisions was specific to those contaminants and does not apply to these PFAS or any other future contaminants for which the EPA would make regulatory determinations. Therefore, the statute does not require, and the EPA does not use a minimum or one-size-fits-all occurrence thresholds (for either frequency or precise level) for regulatory determinations.

As described in section VI of this preamble, many commenters supported the EPA's proposal to regulate mixtures of PFAS. Specific to occurrence, some of these commenters particularly expressed support for the EPA's preliminary determination that mixtures of these four PFAS meet the second statutory occurrence criterion under SDWA, citing that the agency has used the best available information to determine that there is a substantial likelihood that combinations of these PFAS will co-occur in mixtures at a frequency and level of public health concern. One commenter stated that the additional occurrence data presented by the EPA in the proposal for the Hazard Index PFAS supports the EPA's proposed determination that these PFAS should be regulated under the SDWA. Conversely, several other commenters stated that there was not supporting evidence for the co-occurrence of the four Hazard Index PFAS. The EPA disagrees; the extent to which Hazard Index PFAS chemicals co-occur in the non-targeted state dataset is discussed extensively in the record for this rule and made evident through the system level analysis in section VI.C. of this preamble. As also discussed elsewhere in the record for this rule, in both system level and sample level analyses where PFOA and/or PFOS were reported present and all four Hazard Index PFAS were monitored, two or more Hazard Index PFAS were reported present more than half of the time. Further, the odds ratios tables in Exhibit 11 provide a statistical examination of pairwise co-occurrence. The odds ratio is a statistic that quantifies the strength of association between two events. In the context described here, an ''event'' is the reported presence of a specific PFAS contaminant. The odds ratio between PFOA and PFHxS, for example, reflects the strength of association between PFHxS being reported present and PFOA being reported present. If an odds ratio is greater than 1, the two events are associated. The higher the odds ratio, the stronger the association. For every pair of PFAS chemicals included in the proposed regulation, the odds ratio was found to be statistically significantly greater than 1. This means there was a statistically significant increase in the odds of a PFAS being present if the other PFAS compound was detected (*e.g.,* if PFOA is detected, PFHxS is more likely to also be found). In most instances the odds appeared to increase in excess of a factor of ten. Thus, based on the large amount of available data, the chemicals are clearly demonstrated to co-occur rather than occur independently of one another, further supporting the agency's determination for combinations of mixtures of the four PFAS.

After considering the public comments and additional occurrence data evaluated as requested by public commenters, the EPA finds that PFHxS, PFNA, and HFPO–DA individually and mixtures of these three PFAS and PFBS, meet the second statutory criterion for regulatory determinations under section 1412(b)(1)(A) of SDWA that the contaminant is known to occur or co-occur or there is a substantial likelihood that the contaminant will occur or co-occur in PWSs with a frequency and at levels of public health concern (USEPA, 2024b).

D. Statutory Criterion 3—Meaningful Opportunity

The agency has determined that individual regulation of PFHxS, PFNA, and HFPO–DA and regulation of combinations of PFHxS, PFNA, HFPO–DA, and PFBS in mixtures presents a meaningful opportunity for health risk reduction for persons served by PWSs. As discussed in section III.C. of this preamble, the EPA evaluated this third statutory criterion similarly to previous regulatory determinations using the Protocol developed under Regulatory Determination 3 (USEPA, 2014b) and also used in the Regulatory Determination 4. This evaluation includes a comprehensive assessment of meaningful opportunity for each unique contaminant including the nature of the health effects, sensitive populations affected, including infants, children and pregnant and nursing women, number of systems potentially affected, and populations exposed at levels of public health concern, geographic distribution of occurrence, technologies to treat and measure the contaminant, among other factors. The agency further reiterates that, per the statute, this determination of meaningful opportunity is in the Administrator's sole discretion.

Accordingly, the EPA is making this determination of meaningful opportunity after evaluating health, occurrence, treatment, and other related information and factors including consideration of the following:

- PFHxS, PFNA, and HFPO–DA and combinations of these three PFAS and PFBS in mixtures may cause multiple adverse human health effects, often at very low concentrations, on several biological systems including the endocrine, cardiovascular, developmental, renal, hematological, reproductive, immune, and hepatic systems as well as are likely to produce dose-additive effects from co-exposures.
- The substantial likelihood that PFHxS, PFNA, and HFPO–DA individually occur or will occur and that mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS co-occur or will co-occur together at frequencies and levels of public health concern in PWSs as discussed in section III of this preamble above and in section VI of this preamble, and the corresponding significant populations served by these water systems which potentially include sensitive populations and lifestages, such as pregnant and lactating women, as well as children.
- PFHxS, PFNA, HFPO–DA and combinations of these three PFAS and PFBS in mixtures are expected to be persistent in the environment, with some (*e.g.,* PFHxS, PFNA) also demonstrated to be very persistent in the human body.
- Validated EPA-approved measurement methods are available to measure PFHxS, PFNA, HFPO–DA, and

PFBS. See section VII of this preamble for further discussion.

- Treatment technologies are available to remove PFHxS, PFNA, and HFPO–DA and combinations of these three PFAS and PFBS from drinking water. See section X of this preamble for further discussion.
- Even though PFBS is very likely to be below its corresponding individual HRL when it occurs in a mixture, the record indicates that there is a substantial likelihood that it co-occurs with the regulated PFAS throughout public water systems nationwide. See sections III.C.5 and VI.C. of this preamble for further discussion. According to the 2023 Interagency PFAS Report to Congress (United States OSTP, 2023), PFBS has been shown to affect the following health endpoints: body weight, respiratory, cardiovascular, gastrointestinal, hematological, musculoskeletal, hepatic, renal, ocular, endocrine, immunological, neurological, reproductive, and developmental. Thus, including PFBS as a mixture component represents a meaningful opportunity to reduce PFBS' contributions to the overall hazard of the mixture and resulting dose additive health concerns. This is particularly relevant where the exposures of the other three PFAS in the mixture are also below their respective HRLs but when the hazard contributions of each mixture component are summed, the total exceeds the mixture HRL. In this scenario, the inclusion of PFBS allows for a more accurate picture of the overall hazard of the mixture so that PFBS can be reduced along with associated dose additive health concerns. In short, hazard would be underestimated if PFBS was not included in the regulated mixture. The EPA also considered the situation where PFHxS, PFNA, or HFPO–DA exceed one or more of their corresponding HRLs and co-occur with PFBS below its corresponding HRL. Although the exceedance of the mixture HRL is driven by a PFAS other than PFBS, PFBS is contributing to the overall hazard of the mixture and resulting dose additive health concerns. Including PFBS in the regulated mixture offers a meaningful opportunity to reduce dose additive health concerns because, when PFBS and other Hazard Index PFAS are present, public water systems will be able to better design and optimize their treatment systems to remove PFBS and any other co-occurring Hazard Index PFAS. This optimization will be even more effective knowing both that PFBS is present in source waters and its measured concentrations.
- Regulating PFHxS, PFNA, and HFPO–DA and combinations of these three PFAS and PFBS in mixtures is anticipated to reduce the overall public health risk from other PFAS, including PFOA and PFOS, that co-occur and are co-removed. Their regulation is anticipated to provide public health protection at the majority of known PWSs with PFAS-impacted drinking water.
- There are achievable steps to manage drinking water that can be taken to reduce risk.

As described in sections III.C, VI.C, VI.D, and USEPA (2024b), data from both the UCMR 3 and state monitoring efforts demonstrates the substantial likelihood of individual occurrence of PFHxS, PFNA, and HFPO–DA and co-occurrence of mixture combinations of PFHxS, PFNA, HFPO–DA, and PFBS at frequencies and levels of public health concern. Under UCMR 3, 5.7 million and 526,000 people had reported detections (greater than or equal to their minimum reporting levels which were two to three times their HRLs of 10 ng/L), of PFHxS and PFNA, respectively. Additionally, based on the more recent available state monitoring data presented earlier in this section, a range of geographically diverse states monitored systems that reported individual detections of PFHxS, PFNA, and HFPO–DA and serve approximate populations of 26.5 million, 2.5 million, and 8.4 million, respectively. Of these same systems, detections above the EPA's HRLs for PFHxS, PFNA, and HFPO–DA were seen in systems that serve approximate populations of 4.3 million, 227,000, and 177,000 people, respectively. As discussed previously, if these monitored systems were extrapolated to the nation, the EPA estimates that thousands of additional systems serving millions of people could have detectable levels of these three PFAS and hundreds of these systems may show values above the EPA's HRLs. Lastly, in evaluating the available state data, the EPA has found that mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS occur with a Hazard Index greater than 1 in systems serving approximately 4.7 million people. The agency further notes that while it has demonstrated through sufficient data that these four PFAS co-occur in mixtures at a frequency and level of public health concern in PWSs, throughout the nation it is extremely likely that additional systems and associated populations served would also demonstrate a Hazard Index greater than 1 if data for all PWSs were evaluated.

Analytical methods are available to measure PFHxS, PFNA, HFPO–DA, and PFBS in drinking water. The EPA has published two multi-laboratory validated drinking water methods for individually measuring PFHxS, PFNA, HFPO–DA, and PFBS. Additional discussion on analytical methods can be found in section VII of this preamble.

The EPA's analysis, summarized in section X of this preamble, found there are available treatment technologies capable of reducing PFHxS, PFNA, HFPO–DA, and PFBS. These technologies include granular activated carbon (GAC), anion exchange (AIX) resins, reverse osmosis (RO), and nanofiltration (NF). These treatment technologies remove PFHxS, PFNA, HFPO–DA, and PFBS and their mixtures. They also have been documented to co-remove other PFAS (Sörengård et al., 2020; McCleaf et al., 2017; Mastropietro et al., 2021). Furthermore, as described in section VI of this preamble, PFHxS, PFNA, HFPO–DA, and PFBS also co-occur with PFAS for which the agency is not currently making a regulatory determination. Many of these other emergent co-occurring PFAS are likely to also pose hazards to public health and the environment (Mahoney et al., 2022). Therefore, based on the EPA's findings that PFHxS, PFNA, HFPO–DA, and PFBS have a substantial likelihood to co-occur in drinking water with other PFAS and treating for PFHxS, PFNA, HFPO–DA, and PFBS is anticipated to result in removing these and other PFAS, individual regulation of PFHxS, PFNA, and HFPO–DA and regulation of mixtures of these three PFAS and PFBS also presents a meaningful opportunity to reduce the overall public health risk from all other PFAS that co-occur and are co-removed with PFHxS, PFNA, HFPO–DA, and PFBS.

With the ability to monitor for PFAS, identify contaminated drinking water sources and contaminated finished drinking water, and reduce PFAS exposure through management of drinking water, the EPA has identified meaningful and achievable actions that can be taken to reduce the human health risk of PFAS.

1. Proposal

The EPA made a preliminary determination that regulation of PFHxS, PFNA, HFPO–DA, and PFBS, both individually and in a mixture, presents a meaningful opportunity for health risk reduction for persons served by PWSs. The EPA made this preliminary determination after evaluating health, occurrence, treatment, and other related information against the three SDWA statutory criteria including consideration of the factors previously described in section III.D of this preamble above.

2. Summary of Major Public Comments and EPA Responses

The EPA received many comments on the agency's evaluation of the third statutory criterion under section 1412(b)(1)(A) of SDWA. Most commenters supported the EPA's evaluation under the preliminary determination that regulation of PFHxS, PFNA, HFPO–DA, PFBS and mixtures of these four contaminants presents a meaningful opportunity for health risk reduction and that the EPA had sufficiently justified this statutory criterion as well as the health and occurrence criterion. This included comments highlighting the extensive amount of work done by several states developing regulatory and non-regulatory levels for several PFAS compounds, including the PFAS for which the EPA is making regulatory determinations either individually or as a mixture. These commenters also noted the need for a consistent national standard for use in states where a state-specific standard has not yet been developed. Several commenters have also noted that although some states have developed or are in the process of developing their own state-level PFAS drinking water standards, regulatory standards currently vary across states. These commenters expressed concern that absence of a national drinking water standard has resulted in risk communication challenges with the public and disparities with PFAS exposure. Some commenters noted there are populations particularly sensitive or vulnerable to the health effects of these PFAS, including newborns, infants, and children. The EPA agrees with commenters that there is a need for a national PFAS drinking water regulation and that moving forward with a national-level regulation for PFHxS, PFNA, HFPO–DA, mixtures of these three PFAS and PFBS, as well as PFOA and PFOS, will provide improved national consistency in protecting public health and may reduce regulatory uncertainty for stakeholders across the country.

A few commenters expressed support for the EPA's evaluation of meaningful opportunity based on the treatment technologies which can remove the six PFAS for which the EPA is finalizing regulation. Furthermore, these commenters noted the meaningful opportunity to not only provide protection from the six regulated PFAS, but also other PFAS that will not be regulated as a part of this action.

Several commenters did not support the EPA's evaluation of the third statutory criterion, offering that in their opinion the EPA failed to justify that there is a meaningful opportunity for health risk reduction for the PFAS both individually and for their mixtures and stating that the EPA should consider other factors such as costs. A few of these commenters wrote that the EPA provided limited rationale and factors for its meaningful opportunity determination. The EPA disagrees with these commenters that the agency failed to justify that there is meaningful opportunity for health risk reduction or that the EPA provided limited rationale and factors in its meaningful opportunity evaluation for these contaminants individually and as mixtures. As described in the EPA's March 2023 proposal (USEPA, 2023f) and summarized previously, the EPA fully considered many factors both individually and within mixtures including individual contaminant and dose additive toxicity and health concerns, individual contaminant occurrence and co-occurrence of mixtures at frequencies and levels of public health concern, availability of similar treatment technologies to remove these four PFAS and analytical methods to measure them, and their individual and collective chemical and physical properties leading to their environmental persistence. Additionally, the EPA notes in this preamble, and as demonstrated through representative occurrence data, for the three contaminants individually and mixtures of the four, occurrence and co-occurrence is not only at a regional or local level, rather it covers multiple states throughout the country; therefore, a national level regulation is necessary to ensure all Americans served by PWSs are equally protected.

Some comments indicate that the health and occurrence information do not support that establishing drinking water standards presents a meaningful opportunity for health risk reduction. The agency disagrees with the commenters' assertion that the health and occurrence information are insufficient to justify a drinking water standard as supported in sections III.B. and III.C. of this preamble, and the agency finds that there is a meaningful opportunity for health risk reduction potential based upon multiple considerations including the population exposed to PFHxS, PFNA, HFPO–DA, and mixtures of these three PFAS and PFBS including sensitive populations and lifestages, such as newborns, infants and children.

Other comments assert that the EPA must evaluate the potential implementation challenges and cost considerations of regulation as part of the meaningful opportunity evaluation. The EPA disagrees with these commenters. The SDWA states that that the meaningful opportunity for overall health risk reduction for persons served by PWSs is in the sole judgement of the Administrator and does not require that the EPA consider costs for a regulatory determination. The SDWA does require that costs and benefits are presented and considered in the proposed rule's Health Risk Reduction Cost Analysis which the EPA did for the proposal and has updated as a part of the final rule within section XII.

A few other commenters provided that due to all of the additional human health exposure pathways other than drinking water for these PFAS, that regulation of drinking water would not represent a meaningful opportunity for overall health risk reduction. While the EPA recognizes that drinking water is one of several exposure routes, the EPA disagrees with these commenters. Removing the PFAS that have been found to occur or are substantially likely to occur from drinking water systems will result in a significant improvement in public health protection. The EPA also notes that through its *PFAS Strategic Roadmap* and associated actions, the agency is working expeditiously to address PFAS contamination in the environment and reduce human health PFAS exposure through all pathways. While beyond the scope of this rule, the EPA is making progress implementing many of the commitments in the Roadmap, including those that may significantly reduce PFAS source water concentrations.

E. The EPA's Final Determination Summary

The SDWA provides the EPA significant discretion when making a regulatory determination under section 1412(b)(1)(A). This decision to make a regulatory determination to individually regulate PFHxS, PFNA, and HFPO–DA and to regulate combinations of these three PFAS and PFBS in mixtures is based on consideration of the evidence supporting the factors individually and collectively.

The EPA's determination that PFHxS, PFNA, and HFPO–DA individually and mixtures of these three PFAS and PFBS ''may have an adverse effect on the health of persons'' is strongly supported by numerous studies. These studies demonstrate several adverse health effects, such as immune, thyroid, liver, kidney and developmental effects, and increased cholesterol levels, may occur following exposure to individual PFAS, and dose-additive health effects can occur following exposure to multiple PFAS at doses that likely would not individually result in these adverse health effects, but may pose health risks when combined in mixtures. Importantly, the best available peer reviewed science documents that these PFAS may have multiple adverse human health effects even at relatively low levels individually and when combined in mixtures (see section III.B.6.e f of this preamble or further information on studies supporting the conclusion of dose additivity).

The EPA's determination there is a substantial likelihood that the contaminant will occur in PWS with a frequency and at levels of public health concern is supported by evidence documenting the measured occurrence of PFHxS, PFNA, and HFPO–DA, and co-occurrence of these three PFAS and PFBS above the HRL, the stability and persistence of the contaminant in humans and/or the environment, and the current or legacy production and use in commerce.

Finally, the EPA's determination that individual regulation of PFHxS, PFNA, and HFPO–DA and regulation of these three PFAS and PFBS in mixtures presents a meaningful opportunity for health risks reductions is strongly supported by numerous factors, including the potential adverse human health effects at low levels and potential for exposure and co-exposure of these PFAS on sensitive populations and lifestages such as lactating and pregnant women and children, their persistence, and the availability of both analytical methods and treatment technologies to remove these contaminants in drinking water.

After considering these factors individually and together, the EPA has determined that PFHxS, PFNA, and HFPO–DA individually and mixtures of these three PFAS and PFBS meet the statutory criteria for regulation under SDWA. The EPA has an extensive record of information to make this determination now and recognizes the public health burden of these PFAS as well as PFOA and PFOS. The EPA notes the public urgency to reduce PFAS concentrations in drinking water described in the public comments. A PFAS NPDWR provides a mechanism to reduce these PFAS expeditiously for these impacted communities. In addition to making this final regulatory determination, the EPA is exercising its discretion to concurrently finalize MCLGs and NPDWRs for these PFAS as individual contaminants and for the specified PFAS mixtures in part to allow utilities to consider these PFAS specifically as they design systems to remove PFAS and to ensure that they are reducing these PFAS in their drinking water to the extent feasible and as quickly as practicable.

IV. MCLG Derivation

Section 1412(a)(3) of the Safe Drinking Water Act (SDWA) requires the Administrator of the Environmental Protection Agency (EPA) to publish a final MCLG simultaneously with the NPDWR. The MCLG is set, as defined in section 1412(b)(4)(A), at ''the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.'' Consistent with SDWA section 1412(b)(3)(C)(i)(V), in developing the MCLG, the EPA considers ''the effects of the contaminant on the general population and on groups within the general population such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population.'' Other factors considered in determining MCLGs can include health effects data on drinking water contaminants and potential sources of exposure other than drinking water. MCLGs are not regulatory levels and are not enforceable. The statute does not dictate that the MCLG take a particular form; however, it must represent a ''level'' that meets the MCLG statutory definition. Given that the MCL must be ''as close as feasible'' to the MCLG, and that the MCL is defined as the ''maximum permissible level of a contaminant in water which is delivered to any user of a public water system,'' the MCLG can take any form so long as it is a maximum level of a contaminant in water.

Due to their widespread use and persistence, many PFAS are known to co-occur in drinking water and the environment—meaning that these contaminants are often together and in different combinations as mixtures (see sections III.C and VI of this preamble for additional discussion on occurrence). PFAS exposure can disrupt signaling of multiple biological pathways resulting in common adverse effects on several biological systems and functions, including thyroid hormone levels, lipid synthesis and metabolism, development, immune function, and liver function. Additionally, the EPA's examination of health effects information found that exposure through drinking water to a mixture of PFAS can act in a dose-additive manner (see sections III.B and IV.B of this preamble for additional discussion on mixture toxicity). Dose additivity means that exposure to multiple PFAS, at doses that individually would not be anticipated to result in adverse health effects, may pose health risks when combined in a mixture.

A. MCLG Derivation for PFOA and PFOS

To establish an MCLG for individual contaminants, the EPA assesses the peer-reviewed science examining cancer and noncancer health effects associated with oral exposure to the contaminant. For known or likely linear carcinogenic contaminants, where there is a proportional relationship between dose and carcinogenicity at low concentrations or where there is insufficient information to determine that a carcinogen has a threshold dose below which no carcinogenic effects have been observed, the EPA has a long-standing practice of establishing the MCLG at zero (see USEPA, 1998a; USEPA, 2000c; USEPA, 2001; *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3). For nonlinear carcinogenic contaminants, contaminants that are designated as *Suggestive Human Carcinogens* (USEPA, 2005a), and non-carcinogenic contaminants, the EPA typically establishes the MCLG based on a noncancer RfD. An RfD is an estimate of a daily oral exposure to the human population (including sensitive populations) that is likely to be without an appreciable risk of deleterious effects during a lifetime. A nonlinear carcinogen is a chemical agent for which the associated cancer response does not increase in direct proportion to the exposure level and for which there is scientific evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk.

1. Proposal

To support the proposed rule, the EPA published PFOA and PFOS draft toxicity assessments and the proposed MCLGs for public comment (USEPA, 2023g; USEPA, 2023h). Prior to conducting the systematic review for the PFOA and PFOS draft toxicity assessments, the EPA established the internal protocols for the systematic review steps of literature search, Population, Exposure, Comparator, and Outcomes (PECO) development, literature screen, and study quality evaluation. The EPA incorporated detailed, transparent, and complete protocols for all steps of the systematic review process (USEPA, 2023g; USEPA, 2023h; USEPA, 2023i; USEPA, 2023j). Additionally, the EPA updated and expanded the protocols and methods based on SAB recommendations to improve the transparency of the process the EPA used to derive the MCLGs for PFOA and PFOS and to improve consistency with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f). The EPA followed this transparent systematic review process to evaluate the best available peer-reviewed science and to determine the weight of evidence for carcinogenicity and the cancer classifications for PFOA and PFOS according to agency guidance (USEPA, 2005a).

Based on the EPA's analysis of the best available data and following agency guidance, the EPA determined that both PFOA and PFOS are *Likely to be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals (USEPA, 2005a; USEPA, 2023g; USEPA, 2023h). The EPA also determined that a linear default extrapolation approach is appropriate for PFOA and PFOS as there is no evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk for either compound (USEPA, 2005a). Therefore, the EPA concluded that there is no known threshold for carcinogenicity. Based upon a consideration of the best available peer-reviewed science and the statute's directive that the MCLG be ''set at the level at which no known or anticipated adverse effects on the health of persons occur and which allow an adequate margin of safety,'' the EPA proposed MCLGs of zero for both PFOA and PFOS in drinking water. Setting the MCLG at zero under these conditions is also supported by long standing practice at the EPA's Office of Water for *Likely* or *Known Human Carcinogens* (see USEPA, 1998a; USEPA, 2000c; USEPA, 2001; USEPA, 2016b; *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3).

2. Summary of Major Public Comments and EPA Responses

The EPA requested comment on both the toxicity assessment conclusions and the proposed MCLG derivation for PFOA and PFOS. In this section the EPA focuses the summary of public comments and responses on comments related to the cancer classification determinations for PFOA and PFOS because that was the basis for the proposed MCLG derivations (USEPA, 2023g; USEPA, 2023h). The noncancer health effects that the EPA identified as hazards in the draft toxicity assessments (*i.e.,* decreased immune response in children, increased alanine aminotransferase (ALT), decreased birth weight and increased cholesterol) were not the basis for the proposed MCLG derivation. Importantly, an MCLG of zero is also protective of noncancer endpoints which were evaluated in the EPA's HRRCA (Health Risk Reduction and Cost Analysis). Comments related to the benefits the EPA quantified that are associated with noncancer health effects are described in section XII.

A few commenters agreed with the systematic review protocol the EPA used to evaluate the studies that supported the PFOA and PFOS cancer classification determinations in the draft toxicity assessments (USEPA, 2023g; USEPA, 2023h; USEPA, 2023i; USEPA, 2023j), with one commenter stating that the approach was ''thorough and well-reasoned.'' Commenters stated that the systematic review protocol was clear because the EPA had addressed all concerns highlighted during the peer review process.

One commenter stated that the EPA did not conduct a systematic review of the literature and did not follow the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) to develop the toxicity assessments for PFOA and PFOS. This commenter stated the EPA lacked ''a predefined protocol'' and that the ''systematic review methods lack[ed] transparency and consistency.'' The commenter took particular issue with the EPA's protocols for study quality evaluations, stating that they were inconsistent and not aligned with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f). The EPA disagrees with this commenter's claims. The EPA adopted the overall approach and steps in the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) and the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021h) to develop PFOA- and PFOS-specific protocols that then formed the basis for performing study quality evaluations, evidence integration, and critical study selection (see appendix A in USEPA, 2023g; USEPA, 2023h; USEPA, 2023i; USEPA, 2023j). This predefined protocol was made available for public comment as appendix A of the toxicity assessments (USEPA, 2023i; USEPA, 2023j). Importantly, the EPA's Office of Water collaborated with the EPA's Office of Research and Development in conducting study quality evaluations, evidence integration, and selection of critical studies to ensure consistency with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) and the *Systematic Review Protocol for the PFAS IRIS Assessments* (USEPA, 2021h).

A few commenters claimed that the EPA did not use the best available science when developing the toxicity assessments for PFOA and PFOS, asserting that the EPA did not follow its own guidance or data quality standards and that the EPA's systematic review process was flawed (see discussion above). The EPA disagrees with these commenters' claims. The EPA has followed statutory requirements to use the best available peer-reviewed science in two respects: by (1) considering relevant peer-reviewed literature identified by performing systematic searches of the scientific literature or identified through public comment and (2) relying on peer-reviewed, published EPA human health risk assessment methodology as well as systematic review best practices (USEPA, 2021h; USEPA, 2022f). The risk assessment guidance and best practices serve as the basis for the PFOA and PFOS health effects systematic review methods used to identify, evaluate, and quantify the available data. Not only did the EPA incorporate literature identified in previous assessments, as recommended by the SAB (USEPA, 2022i), but the EPA also conducted several updated systematic literature searches, the most recent of which was completed in February 2023. This approach ensured that the literature under review encompassed studies included in the 2016 *Health Effects Support Documents* (HESDs) (USEPA, 2016c; USEPA, 2016d) and recently available studies. The results of the most recent literature search provide further support for the conclusions made in the draft toxicity assessments for PFOA and PFOS (USEPA, 2023g; USEPA, 2023h) and are described in appendix A of the final toxicity assessments (USEPA, 2024h; USEPA, 2024i).

As described above, the PFOA and PFOS systematic review protocol is consistent with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) and also considers PFOA- and PFOS-specific protocol updates outlined in the *Systematic Review Protocol for the PFBA, PFHxA, PFHxS, PFNA, and PFDA (anionic and acid forms) IRIS Assessments* (USEPA, 2021h). The EPA additionally followed human health risk assessment methods for developing toxicity values (*e.g.,* USEPA, 2002a), conducting benchmark dose (BMD) modeling (USEPA, 2012), and other analyses. In the PFOA and PFOS toxicity assessments and the appendices, the EPA clearly describes the methods used and how those methods and decisions are consistent with the EPA practices and recommendations (*i.e.,* through quotes and citations) described in various guidance documents.

One commenter stated that the EPA did not use the best available peer-reviewed science because the assessments did not follow methodological or statistical guidance. Specifically, this commenter stated the EPA did not follow *A Review of the Reference Dose and Reference Concentration Processes* (USEPA, 2002a) when selecting uncertainty factors and claimed the EPA did not follow guidance on data quality (USEPA, 2003; USEPA, 2006b; USEPA, 2014b). The commenter stated they believed the assessments contained flaws including exclusion of covariates in modeling, reliance on peer-reviewed studies published by non-EPA employees, and an inability to replicate results. The EPA disagrees with these comments. Regarding data quality control, data quality objectives are an integral part of the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) and many of the concepts outlined in data quality guidance recommended by the commenter (USEPA, 2003; USEPA, 2006b; USEPA, 2014b) are addressed through the EPA's use of the *ORD Handbook* (USEPA, 2022f). Furthermore, this work was conducted under a programmatic quality assurance project plan (QAPP) which ensures that all EPA data quality guidance is followed, including those cited by the commenter. Additionally, by developing and implementing a systematic review protocol consistent with the *ORD Handbook* (USEPA, 2022f), the EPA reduced potential confirmation bias, a concern raised by another commenter, by conducting multiple independent evaluations of studies, relying on a data-driven, weight of evidence approach, and by incorporating expertise from across the agency.

In many cases the commenters have misinterpreted the methods and decisions the EPA used to analyze the data or misinterpreted the guidance itself. For example, one commenter mistakenly suggested that the EPA did not consider covariates in its analyses of epidemiological studies; the EPA described which covariates were considered in each analysis in several sections of the draft toxicity assessments and appendices (USEPA, 2023g; USEPA, 2023h; USEPA, 2023i; USEPA, 2023j), including in descriptions of the studies in section 3 and modeling of the studies in appendix E. The EPA also notes that the primary studies that provide the data describe covariate adjustments in their published analyses.

A couple of commenters suggested that the toxicity assessments for PFOA and PFOS were not adequately peer-reviewed because changes were made post peer review (*i.e.,* after publication of the final report by the SAB PFAS Review Panel (USEPA, 2022i)), the most significant of which was the updated cancer classification for PFOS, but also included the addition of figures and mechanistic syntheses. The EPA disagrees with this assertion. The toxicity assessments, including the conclusions that are material to the derivation of the MCLGs, were peer-reviewed by the SAB PFAS review panel (USEPA, 2022i). Notably, this panel ''agreed with many of the conclusions presented in the assessments, framework and analysis'' (USEPA, 2022i). The only assessment conclusion that changed and impacted MCLG derivation between SAB review and rule proposal was that the cancer classification for PFOS of *Suggestive Evidence of Carcinogenicity* was updated to *Likely to be Carcinogenic to Humans* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a). This conclusion for PFOS was based on a reevaluation of the available data in response to multiple comments from the SAB PFAS review panel stating that ''[s]everal new studies have been published that warrant further evaluation to determine whether the 'likely' designation is appropriate'' for PFOS and that the EPA's ''interpretation of the hepatocellular carcinoma data from the Butenhoff et al. (2012) study in the 2016 HESD is overly conservative in dismissing the appearance of a dose-response relationship for this endpoint, particularly in females'' (USEPA, 2022i). In responding to the SAB's recommendation that the EPA provide an ''explicit description of why the available data for PFOS do not meet the EPA *Guidelines for Carcinogen Risk Assessment* (2005) criterion for the higher designation as 'likely carcinogenic,' '' and taking into consideration recently published peer-reviewed epidemiological studies demonstrating concordance in humans identified through the final updated literature search recommended by the SAB, the EPA determined that PFOS meets the criterion for the higher designation of *Likely to Be Carcinogenic to Humans* (USEPA, 2005a). This decision was described in sections 3.5.5 and 6.4 of the draft assessment (USEPA, 2023h). Additional discussion regarding the PFOS cancer descriptor decision is provided here.

One commenter stated that the EPA addressed the SAB's concerns regarding the systematic review protocol in the documents supporting the proposed rulemaking. A few commenters reiterated the importance of the SAB's recommendations, including to more thoroughly describe systematic review methods used in the assessment (*e.g.,* study inclusion and exclusion criteria), incorporate additional epidemiological studies, provide rationale for critical study selection, and derive candidate toxicity values from both human and animal data. In contrast, a few commenters claimed that the EPA did not adequately consider several recommendations made by the SAB PFAS Review Panel in their final report (USEPA, 2022i), including that the EPA did not incorporate studies from the 2016 HESDs (USEPA, 2016c; USEPA, 2016d) or develop multiple cancer slope factors (CSFs). One commenter requested clarification on whether the EPA had implemented the feedback from the SAB.

The EPA disagrees with the comments that the agency did not ''meaningfully implement'' SAB feedback. The EPA agrees with commenters that highlighted the importance of the SAB's suggestions, and notes that the EPA addressed the SAB's recommendations to more thoroughly explain the systematic review protocol and expand the systematic review protocol beyond study quality evaluation and data extraction in the draft toxicity assessments published at the time of rule proposal (USEPA, 2023g; USEPA, 2023h; USEPA, 2023i; USEPA, 2023j). As outlined in the *EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation* (USEPA, 2023k), the EPA considered all of the comments and recommendations from the SAB and made substantial improvements to address the reported concerns prior to publishing the public comment draft assessments (USEPA, 2023g; USEPA, 2023h). The EPA published a response to SAB comments document that detailed how the agency considered and responded to the SAB PFAS Review Panel's comments at the time of rule proposal (USEPA, 2023k). The resulting draft toxicity assessments and protocol released for public comment along with the proposed rule reflect improvements including thorough and detailed descriptions of the methods used during assessment development, inclusion of epidemiological studies from the 2016 HESDs for PFOA and PFOS in the systematic review (USEPA, 2016c; USEPA, 2016d), updates to the literature, implementation of an evidence integration framework, expansion of rationale for critical study and model selections, development of toxicity values from both animal toxicological and epidemiological data, when warranted, and many other actions. The EPA appreciated the SAB's engagement, extensive review, and comments on the *Proposed Approaches* documents (USEPA, 2021i; USEPA, 2021j). Furthermore, the EPA provided its consideration of every recommendation the SAB provided when updating and finalizing the assessments for PFOA and PFOS at the time of rule proposal (USEPA, 2023k).

Many commenters agreed that that available data indicate that exposure to either PFOA or PFOS is associated with cancer in humans and supported the EPA's determination that PFOA and PFOS are *Likely to be Carcinogenic to Humans* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a). Multiple commenters agreed that studies published since the 2016 HESDs (USEPA, 2016c; USEPA, 2016d) have strengthened this conclusion. In particular, one commenter supported the EPA's conclusions regarding the human relevance of hepatic and pancreatic tumors observed in rats administered PFOS, citing their own independent health assessment conclusion that ''several lines of evidence do not support a conclusion that liver effects due to PFOS exposure are PPARα-dependent'' and therefore, may be relevant to humans (NJDWQI, 2018).

Several commenters disagreed with the EPA's determinations that PFOA and PFOS are each *Likely to be Carcinogenic to Humans.* Two commenters claimed that the tumor types observed in rats (*e.g.,* hepatic tumors) after PFOA or PFOS administration are not relevant to humans. Some commenters also stated that the human data do not support an association between PFOS exposure and cancer. One commenter specifically claimed that Shearer et al. (2021) does not provide sufficient evidence for changing PFOS's cancer classification from *Suggestive Evidence of Carcinogenicity* to *Likely to be Carcinogenic to Humans* because it did not report associations between PFOS exposure and risk of renal cell carcinoma (RCC). Two commenters stated that the EPA's discussion using structural similarities between PFOA and PFOS to support evidence of the carcinogenicity of PFOS was inconsistent with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a). A few commenters additionally questioned or disagreed with the determination that PFOA is *Likely to be Carcinogenic to Humans* because of uncertainties in the epidemiological database and a lack of evidence indicating that PFOA is genotoxic.

The EPA disagrees with these comments. With respect to the human relevance of the animal tumors observed in rats after chronic oral exposure to either PFOA or PFOS, the EPA considered all hypothesized modes of action (MOAs) and underlying carcinogenic mechanisms in its cancer assessments, including those that some commenters have argued are irrelevant to humans (*e.g.,* peroxisome proliferator-activated receptor α (PPARα) activation), the discussion for which is available in section 3.5.4.2 of the toxicity assessments for PFOA and PFOS (USEPA, 2024c; USEPA, 2024d). After review of the available mechanistic literature for PFOA and PFOS, the EPA concluded that there are multiple plausible mechanisms, including some that are independent of PPARα, that may contribute to the observed carcinogenicity of either PFOA or PFOS in rats. Further confirmatory support for the EPA's conclusions regarding multiple plausible mechanisms of carcinogenicity comes from literature reviews published by state and global health agencies which concluded that the liver tumors associated with PFOA and/or PFOS exposure may not entirely depend on PPARα activation and therefore may be relevant to humans (CalEPA, 2021; IARC, 2016; NJDWQI, 2017; NJDWQI, 2018).

Additionally, the EPA did not rely on results reported by Shearer et al. (2021) as a rationale for updating the cancer classification for PFOS to *Likely to be Carcinogenic to Humans* (USEPA, 2005a) and acknowledges uncertainties in the results from this study, including that the effect in the third PFOS exposure quartile was null, the effects were attenuated (*i.e.,* reduced in magnitude) when adjusted for exposure to other PFAS, and there was no association when exposure to PFOS was considered as a continuous variable, rather than when PFOS exposure levels were stratified by quartiles (USEPA, 2023h). As described in sections 3.5.5 and 6.4 of the draft PFOS toxicity assessment, the available information exceeds the characteristics for the classification of *Suggestive Evidence of Carcinogenic Potential* (USEPA, 2005a) because there is statistically significant evidence of multi-sex and multi-site tumorigenesis from a *high* confidence animal toxicological study, as well as mixed but plausible evidence of carcinogenicity in humans and mechanistic data showing potential human relevance of the observed tumor data in animals (USEPA, 2023h). The EPA notes that the recently published studies reporting associations between PFOS exposure and hepatocellular carcinoma in humans (Goodrich et al., 2022; Cao et al., 2022) further strengthen the epidemiological database and support the cancer classification of *Likely to be Carcinogenic to Humans* for PFOS.

Regarding commenters' claims that the EPA used the structural similarities between PFOA and PFOS as supporting evidence of the carcinogenic potential of PFOS, the EPA did not rely on structural similarities to draw conclusions about the cancer classification (see rationale listed above) but instead used this information as supplemental support for the *Likely* classification. The EPA originally included this supplemental line of evidence because the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a) explicitly states that ''[a]nalogue effects are instructive in investigating carcinogenic potential of an agent as well as in identifying potential target organs, exposures associated with effects, and potential functional class effects or modes of action.'' PFOA and PFOS differ in their chemical structure by a single functional group; nevertheless, since a full structure-activity relationship analysis was not conducted, the EPA removed discussion on this supplemental line of evidence from the final toxicity assessment for PFOS (USEPA, 2024d).

Further, the EPA disagrees with comments stating that the epidemiological database for PFOA is too uncertain to support a classification of *Likely to be Carcinogenic to Humans* (USEPA, 2005a). As described in both the draft (USEPA, 2023g) and final toxicity assessments for PFOA (USEPA, 2024c), as well as the *Maximum Contaminant Level Goals for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS)* document (USEPA, 2024j) the available data support an increased risk of both kidney and testicular cancers associated with PFOA exposure. There is also evidence that PFOA exposure may be associated with an increased breast cancer risk, based on studies in populations with specific polymorphisms and for specific types of breast tumors. Taken together, these results provide consistent and plausible evidence of PFOA carcinogenicity in humans. Additionally, the EPA notes that while genotoxicity is one potential MOA leading to carcinogenicity, there is no requirement that a chemical be genotoxic for the EPA to classify it as either *Carcinogenic to Humans, Likely to be Carcinogenic to Humans,* or *Suggestive Evidence of Carcinogenic Potential* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a). Importantly, the SAB PFAS Review Panel supported the *Likely to be Carcinogenic to Humans* designation for PFOA in its final report (USEPA, 2022i).

Many commenters supported the EPA's proposed MCLGs of zero for both PFOA and PFOS, citing well-documented health effects, including cancer, resulting from exposure to either PFOA or PFOS as rationale for their support of the proposed rulemaking. Several commenters also agreed with the EPA's long-standing practice of establishing the MCLG at zero (see USEPA, 1998a; USEPA, 2000c; USEPA, 2001; *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3) for known or likely linear carcinogenic contaminants, with one commenter stating that it is ''appropriate based on the weight of evidence for carcinogenicity and other adverse health impacts of PFOA and PFOS at very low exposures.''

Two commenters disagreed with MCLGs of zero for PFOA and PFOS, with one commenter claiming that the EPA's determinations were ''not consistent with the evidence the EPA presents nor with its own guidance'' (*i.e.,* the EPA's cancer assessment was not consistent with assessment approaches recommended in the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a)). The EPA disagrees with these commenters' assertions because there is sufficient weight of evidence for carcinogenic risk of both PFOA and PFOS exposures supporting a classification of *Likely to be Carcinogenic to Humans* according to the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a) from the available epidemiological and animal toxicological studies. Consistent with the guidelines, the EPA provided a narrative to ''explain the case for choosing one descriptor and discuss the arguments for considering but not choosing another'' (USEPA, 2005a) in the draft and final toxicity assessments (USEPA, 2024c; USEPA, 2024d; USEPA, 2023g; USEPA, 2023h).

3. Final Rule

Based on the best available peer-reviewed science and consistent with agency guidance (USEPA, 2005a), the EPA has determined that both PFOA and PFOS are *Likely to be Carcinogenic to Humans.* Therefore, following established agency practice regarding contaminants with this classification and consistent with the statutory directive to set an MCLG ''at 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,'' the EPA set individual MCLGs for both PFOA and PFOS at zero. As described above, the EPA used the best available peer-reviewed science, followed agency guidance and current human health risk assessment methodology, including the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f) and the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a), and adequately peer-reviewed (USEPA, 2022i) the science underlying the MCLG derivation for both PFOA and PFOS (USEPA, 2024c; USEPA, 2024d; USEPA, 2024j).

Consistent with the *Guidelines for Carcinogen Risk Assessment* (USEPA, 2005a), the EPA reviewed the weight of evidence and determined that PFOA and PFOS are each designated as *Likely to Be Carcinogenic to Humans,* because ''the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor Carcinogenic to Humans.'' For PFOA, this determination was based on the evidence of kidney and testicular cancer in humans and Leydig cell tumors, pancreatic acinar cell tumors, and hepatocellular tumors in rats as described in USEPA (2024c). For PFOS, this determination was based on the evidence of hepatocellular tumors in male and female rats, which is further supported by recent evidence of hepatocellular carcinoma in humans (Goodrich et al., 2022; Cao et al., 2022), pancreatic islet cell carcinomas in male rats, and mixed but plausible evidence of bladder, prostate, kidney, and breast cancers in humans (USEPA, 2024d). The EPA has updated and finalized the toxicity assessment for PFOS to reflect the new epidemiological evidence (USEPA, 2024d; USEPA, 2024i).

Consistent with the statutory definition of MCLG, the EPA establishes MCLGs of zero for carcinogens classified as either *Carcinogenic to Humans* or *Likely to be Carcinogenic to Humans* where there is a proportional relationship between dose and carcinogenicity at low concentrations or where there is insufficient information to determine that a carcinogen has a threshold dose below which no carcinogenic effects have been observed. In these situations, the EPA takes the health protective approach of assuming that carcinogenic effects should therefore be extrapolated linearly to zero. This is called the linear default extrapolation approach. This approach ensures that the MCLG is set at a level where there are no known or anticipated adverse health effects, allowing for an adequate margin of safety. Here, the EPA has determined that PFOA and PFOS are *Likely to be Carcinogenic to Humans* based on sufficient evidence of carcinogenicity in humans and animals (USEPA, 2024c; USEPA, 2024d). The EPA has also determined that a linear default extrapolation approach is appropriate as there is no evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk (USEPA, 2005a). Based on this lack of evidence, the EPA concluded that there is no known threshold for carcinogenicity. Based upon a consideration of the best available peer-reviewed science and statutory directive to set the MCLG ''at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety,'' the EPA has finalized MCLGs of zero for PFOA and PFOS in drinking water.

While not a basis for the EPA's MCLG, the EPA notes that its toxicity assessments indicate either PFOA or PFOS exposure are also associated with multiple non-cancer adverse health effects. The PFOA and PFOS candidate non-cancer RfDs based on human epidemiology studies for various health outcomes (*i.e.,* developmental, cardiovascular, immune, and hepatic) range from 2×10^{-7} to 3×10^{-8} mg/kg/day (USEPA, 2024c; USEPA, 2024d; USEPA, 2024h; USEPA, 2024i).

B. MCLG Derivation for Additional PFAS

Section 1412(b)(4)(A) requires the EPA to set the MCLG at a ''level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.'' In this action, the EPA is setting MCLGs (and MCLs) for five individual PFAS (section IV.C of this preamble) as well as for mixtures of three of these PFAS plus PFBS. In the context of this NPDWR, the Hazard Index is a method which determines when a mixture of two or more of four PFAS—PFHxS, PFNA, HFPO–DA, and PFBS—exceeds the level of health concern with a margin of safety and thus the Hazard Index (equal to 1) is the MCLG for any mixture of those four PFAS. Based on the scientific record, each PFAS within the mixture has a HBWC, which is set at the level below which adverse effects are not likely to occur and allows for an adequate a margin of safety. See USEPA, 2024f and section IV.B. of this preamble. The scientific record also shows that PFHxS, PFNA, HFPO–DA, and PFBS elicit the same or similar profiles of adverse health effects in several biological organs and systems, but with differing potencies for effect(s) (see USEPA, 2022i and 2024a; and section IV.B of this preamble). As a result, as discussed elsewhere in the preamble, PFAS that elicit similar observed adverse health effects following individual exposure should be assumed to act in a dose-additive manner when in a mixture unless data demonstrate otherwise (USEPA, 2024a). See USEPA, 2024a and section II and IV.B of this preamble. This means that where drinking water contains any combination of two or more of these PFAS, the hazard associated with each PFAS in the mixture must be added up to determine whether the mixture exceeds a level of public health concern.

The Hazard Index is the method for calculating this level (*i.e.,* the mixture MCLG) and reflects both the measured amount of each of the four PFAS in the mixture and the toxicity (represented by the HBWC) of each of the four PFAS. The PFAS mixture Hazard Index is an approach to determine whether any mixture of two or more of these four PFAS in drinking water exceeds a level of health concern by first calculating the ratio of the measured concentration of each of the four PFAS divided by its toxicity (the HBWC). This results in the ''hazard quotient'' (HQ) for each of the four PFAS. Because the health effects of these PFAS present dose additive concerns (USEPA, 2024a), the four HQs are added together, and if the result exceeds 1, then the hazard from the combined amounts of the four PFAS in drinking water exceeds a level of public health concern.

1. MCLG Derivation for a PFAS Mixture

a. Proposal

The EPA proposed a Hazard Index MCLG to protect public health from exposure to mixtures of any combination of PFHxS, PFNA, HFPO–DA, and/or PFBS, four PFAS that elicit a shared set of adverse effects and co-occur in drinking water. The Hazard Index is an approach based on dose additivity that has been validated and used by the EPA to assess chemical mixtures in several contexts (USEPA, 1986; USEPA, 2000a; USEPA, 2022i). The EPA's proposal was based on the agency's finding that the Hazard Index approach is the most practical approach for establishing an MCLG for PFAS mixtures that meets the statutory requirements outlined in section 1412(b)(1)(A) of SDWA. This is because the Hazard Index assesses the exposure level of each component PFAS relative to its HBWC, which is based on the most sensitive known adverse health effect (based on the weight of evidence) and considers sensitive population(s) and life stage(s) as well as potential exposure sources beyond drinking water. Furthermore, the Hazard Index accounts for dose additive health concerns by summing the hazard contribution from each mixture component to ensure that the mixture is not exceeding the level below which there are no known or anticipated adverse health effects and allows for an adequate margin of safety.

The proposal defined a mixture as containing one or more of the four PFAS and therefore covered each contaminant individually if only one of the four PFAS occurred. Thus, the Hazard Index as proposed ensures that the level of exposure to an individual PFAS remains below that which could impact human health because the exposure for that measured PFAS is divided by its corresponding HBWC. For example, if the mixture only included PFNA, then under the Hazard Index approach as proposed any measured concentrations over 10.0 ng/L divided over the 10.0 ng/L HBWC would be greater than the 1.0 Hazard Index MCLG. The proposed Hazard Index MCLG was 1.0 and the HBWCs of each mixture component were as follows: 9.0 ng/L[3] for PFHxS; 10.0 ng/L for HFPO–DA; 10.0 ng/L for PFNA; and 2000.0 ng/L for PFBS (USEPA, 2023e).

b. Summary of Major Public Comments and EPA Responses

Many commenters supported the EPA's proposal to regulate a mixture of PFAS and agreed with the EPA's scientific conclusions about PFAS dose additivity and the agency's use of the Hazard Index approach to develop an MCLG for a mixture of PFHxS, PFNA, HFPO–DA, and/or PFBS. Many commenters opposed the EPA's conclusion about dose additivity and the use of the Hazard Index approach to regulate co-occurring PFAS. A few commenters opposed the EPA's use of shared or similar health endpoints/outcomes rather than a shared MOA as a basis for assessing risks of PFAS mixtures. A few commenters agreed with the EPA's decision to regulate these PFAS as a mixture (that some commenters referred to as a ''group'') and supported the EPA's conclusion about dose additivity but questioned the EPA's use of the Hazard Index and suggested alternative approaches such as development of individual MCLGs or a target organ-specific Hazard Index (TOSHI). Some commenters claimed that the EPA did not appropriately seek review from the SAB, particularly on the application of the Hazard Index as an approach to regulate PFAS under SDWA. Comments on the number of significant digits applied in the HBWCs and the Hazard Index were varied. For a discussion of comments and the EPA responses on dose additivity and similarity of toxic effects, see section III.B of this preamble. Commenters referred to the HRLs and the HBWCs interchangeably; see section III of this preamble for comments on HBWCs and the EPA's responses. Responses to the other topics raised are discussed in the following paragraphs.

The EPA disagrees with commenters that the agency did not seek adequate consultation from the EPA SAB in the development of the NPDWR. SDWA section 1412(e) requires that the EPA ''request comments'' from the SAB ''prior to proposal'' of the MCLG and NPDWR. Consistent with this statutory provision, the EPA consulted with the SAB from 2021–2022. As discussed in the proposed rule, the SAB PFAS Review Panel met virtually via a video meeting platform on December 16, 2021, and then had three (3) subsequent meetings on January 4, 6 and 7, 2022 to deliberate on the agency's charge questions, which included a question specifically focused on the utility and scientific defensibility of the Hazard Index approach in the context of mixtures risk assessment in drinking water. Another virtual meeting was held on May 3, 2022, to discuss the SAB PFAS Review Panel's draft report. Oral and written public comments were considered throughout the advisory process. The SAB provided numerous recommendations to the EPA which can be found in the SAB's final report (USEPA, 2022i). The EPA addressed the SAB's recommendations and described the EPA's responses to SAB recommendations in its *EPA Response to Final Science Advisory Board Recommendations (August 2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation* (USEPA, 2023k) and also in the EPA's Response to Comments document in response to public comments on the proposed PFAS

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[3] Some commenters noted an error in the HBWC calculation for PFHxS which was reported as 9.0 ng/L in the proposal. The agency has corrected the value in this NPDWR and within the requirements under 40 CFR part 141 subpart Z. The correct HRL/HBWC for PFHxS is 10 ng/L.

NPDWR (USEPA, 2024k). Further discussion on the EPA consultations and stakeholder engagement activities can be found in section XIII of this preamble.

The agency also disagrees with commenters who contend that the EPA must seek advice from the SAB on all aspects of the NPDWR. The statute does not dictate on which scientific issues the EPA must request comment from the SAB. In this case, the EPA sought comments on four documents: *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water* (USEPA, 2021i); *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanesulfonic Acid (PFOS) in Drinking Water* (USEPA, 2021j); *Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water* (USEPA, 2021k); and *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* (USEPA, 2021e).

The approach of the EPA's *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* (USEPA, 2024a) and this rule is to evaluate risks from exposure to mixtures of PFAS that elicit the same or similar adverse health effects (but with differing potencies for effect(s)) rather than similarity in MOA. This is consistent with the EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000a) and expert opinion from the NAS National Research Council (NRC, 2008). MOA, which describes key changes in cellular or molecular events that may cause functional or structural changes that lead to adverse health effects, can be a useful metric by which risk can be assessed. It is considered a key determinant of chemical toxicity, and chemicals can often be classified by their type of toxicity pathway(s) or MOAs. However, because PFAS are an emerging chemical class, MOA data can be limited or entirely lacking for many PFAS. Therefore, the EPA's approach for assessing risks of PFAS mixtures is based on the conclusion that PFAS that share one or more adverse outcomes produce dose-additive effects from co-exposures. This evidence-based determination supports a health-protective approach that meets the statute's directive to set the MCLG at a level at which there are no known or anticipated adverse health effects and which allows for an adequate margin of safety (1412(b)(4)(A)). The EPA's evidence-based determination regarding dose additivity, based on similarity of adverse health effects rather than MOA, and use of the Hazard Index approach to assess risks of exposure to PFAS mixtures were supported by the SAB in its review of the *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* (USEPA, 2022i). For a detailed description of the evidence supporting dose additivity as the default approach for assessing mixtures of PFAS, see the final *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* (USEPA, 2024a).

A few commenters supported the EPA's approach to assessing risks of PFAS mixtures based on similarity of toxicity effect rather than similarity in MOA. A few commenters opposed the EPA's use of same or similar adverse health effects/outcomes rather than MOA as a basis for the approach to assessing risks of PFAS mixtures and suggested that the agency is not following its own chemical mixtures guidance (USEPA, 2000a). The EPA disagrees with these commenters' assertions. The EPA's approach, to evaluate health risks of exposure to mixtures of these four PFAS based on shared or similar adverse health effects of the mixture components rather than a common MOA, is consistent with the EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000a). Although a conclusion about dose additivity can be based on mixture components sharing a common MOA, dose additivity can also be based on ''toxicological similarity, but for specific conditions (endpoint, route, duration)'' (see the EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures,* USEPA, 2000a). The EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* indicates that although basing a conclusion about dose additivity on a common MOA across mixture components is optimal, there is flexibility in the level of biological organization at which similarity among mixture components can be determined.

The EPA directly asked the SAB for feedback on this issue during its 2021 review of the EPA's draft *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS.* Specifically, the EPA asked the SAB, ''If common toxicity endpoint/health effect is not considered an optimal similarity domain for those PFAS with limited or no available MOA-type data, please provide specific alternative methodologies for integrating such chemicals into a component-based mixture evaluation(s)'' (USEPA, 2022i). The SAB strongly supported the EPA's approach of using a similar toxicity endpoint/health effect instead of a common MOA as a default approach for evaluating mixtures of PFAS using dose additivity and did not offer an alternative methodology. For example, the SAB panel stated that:

> The Panel agreed with use of a similar toxicity endpoint/health effect instead of a common MOA as a default approach for evaluating mixtures of PFAS. This approach makes sense because multiple physiological systems and multiple MOAs can contribute to a common health outcome. Human function is based on an integrated system of systems and not on single molecular changes as the sole drivers of any health outcome. The Panel concluded that rather than the common MOA, as presented in the EPA draft mixtures document, common physiological outcomes should be the defining position (USEPA, 2022i).

The SAB panel also stated:

> Furthermore, many PFAS, including the four used in the examples in the draft EPA mixtures document and others, elicit effects on multiple biological pathways that have common adverse outcomes in several biological systems (*e.g.,* hepatic, thyroid, lipid synthesis and metabolism, developmental and immune toxicities) (USEPA, 2022i).

Some commenters expressed support for the EPA's proposed Hazard Index approach to regulating a mixture of one or more of the four PFAS in drinking water. The commenters also stated that occurrence and co-occurrence of these four PFAS in PWSs, as well as individual and dose-additive effects of these PFAS, justify the general Hazard Index approach. The EPA agrees that the general Hazard Index approach is the most scientifically sound and health-protective approach to deriving a PFAS mixtures MCLG which considers both their dose additive health concerns and co-occurrence in drinking water (see additional discussion in the following paragraphs).

Some commenters opposed the EPA's use of a general Hazard Index as opposed to a target organ-specific Hazard Index (TOSHI) and suggested the use of a TOSHI instead. As discussed in this section, the EPA disagrees with these comments because the use of the general Hazard Index approach to develop an MCLG for a mixture of PFHxS, PFNA, HFPO–DA, and/or PFBS is scientifically sound, supported by external peer review (SAB), and consistent with the EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 2000a).

The EPA considered the two main types of Hazard Index approaches: (1)

the general Hazard Index, which allows for component chemicals in the mixture to have different health effects or endpoints as the basis for their toxicity reference values (*e.g.,* RfDs, minimal risk levels), and (2) the TOSHI, which relies on toxicity reference values based on the same specific target organ or system effects (*e.g.,* effects on the liver or thyroid; effects on developmental or reproductive systems) (USEPA, 2000a). The general Hazard Index approach uses the most health-protective RfD (or minimal risk levels) available for each mixture component, irrespective of whether the RfDs for all mixture components are based on effects in the same target organs or systems. These ''overall'' RfDs (as they are sometimes called) are protective of all other adverse health effects because they are based on the most sensitive known endpoints as supported by the weight of the evidence. As a result, this approach is protective of all types of toxicity/adverse effects, and thus ensures that the MCLG is the level at and below which there are no known or anticipated adverse human health effects with an adequate margin of safety with respect to certain PFAS mixtures in drinking water. The TOSHI produces a less health protective indicator of risk than the general Hazard Index because the basis for the component chemical toxicity reference values has been limited to a specific target organ or system effect, which may occur at higher exposure levels than other effects (*i.e.,* be a less sensitive endpoint). Additionally, since a TOSHI relies on toxicity reference values aggregated for the same specific target organ or system endpoint/effect, an absence or lack of data on the specific target organ or system endpoint/effect for a mixture component may result in that component not being adequately accounted for in this approach (thus, underestimating health risk of the mixture). A TOSHI can only be derived for those PFAS for which the same target organ or system endpoint/effect-specific RfDs have been calculated. Many PFAS have data gaps in epidemiological or animal toxicological dose-response information for multiple types of health effects, thus limiting derivation of target organ-specific toxicity reference values; target organ-specific toxicity reference values are not currently available for PFHxS, PFNA, HFPO–DA, and PFBS. The EPA's *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures* recognizes the potential for organ- or system-specific data gaps and supports use of overall RfDs in a general Hazard Index approach, stating, ''The target organ toxicity dose (TTD) is not a commonly evaluated measure and currently there is no official EPA activity deriving these values, as there is for the RfD and RfC'' . . . ''Because of their much wider availability than TTDs, standardized development process including peer review, and official stature, the RfD and RfC are recommended for use in the default procedure for the HI'' (USEPA, 2000a). The EPA determined that the general Hazard Index approach is the most scientifically defensible and health protective approach for considering PFAS mixtures in this rule because it is protective of all adverse health effects rather than just those associated with a specific organ or system, consistent with the statutory definition of MCLG.

The EPA directly asked the SAB about the utility and scientific defensibility of the general Hazard Index approach (in addition to other methods, including TOSHI) during the 2021 review of the EPA's draft *Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS.* Specifically, the EPA asked the SAB to ''Please provide specific feedback on whether the HI approach is a reasonable methodology for indicating potential risk associated with mixtures of PFAS. If not, please provide an alternative;'' and ''Please provide specific feedback on whether the proposed HI methodologies in the framework are scientifically supported for PFAS mixture risk assessment'' (USEPA, 2022i). In its report (USEPA, 2022i), the SAB stated its support for the general Hazard Index approach:

> In general, the screening level Hazard Index (HI) approach, in which Reference Values (RfVs) for the mixture components are used regardless of the effect on which the RfVs are based, is appropriate for initial screening of whether exposure to a mixture of PFAS poses a potential risk that should be further evaluated. Toxicological studies to inform human health risk assessment are lacking for most members of the large class of PFAS, and mixtures of PFAS that commonly occur in environmental media, overall. For these reasons, the HI methodology is a reasonable approach for estimating the potential aggregate health hazards associated with the occurrence of chemical mixtures in environmental media. The HI is an approach based on dose additivity (DA) that has been validated and used by the EPA. The HI does not provide quantitative risk estimates (*i.e.,* probabilities) for mixtures, nor does it provide an estimate of the magnitude of a specific toxicity. This approach is mathematically straightforward and may readily identify mixtures of potential toxicological concern, as well as identify chemicals that drive the toxicity within a given mixture.

A few commenters stated that it is inappropriate to use the general Hazard Index in the context of a drinking water rule because it is a screening tool. The EPA guidance (*e.g., Risk Assessment Guidance for Superfund* [RAGS], USEPA, 1991b) and the SAB does characterize the general Hazard Index as appropriate for screening, but the SAB did not say that the methodology's use was limited to screening, nor that the agency would or should be prohibited from considering its use in any regulatory or nonregulatory application. The general Hazard Index is a well-established methodology that has been used for several decades in at least one other regulatory context to account for dose additivity in mixtures. The EPA routinely uses the Hazard Index approach to consider the risks from multiple contaminants of concern in the Remedial Investigations and Feasibility Studies for cleanup sites on the Superfund National Priorities List under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Noncarcinogenic effects are summed to provide a Hazard Index that is compared to an acceptable index, generally 1. This procedure assumes dose additivity in the absence of information on a specific mixture. These assessments of hazards from multiple chemical exposures are important factors to help inform the selection of remedies that are ultimately captured in the Superfund Records of Decision. Moreover, the EPA has determined that in the context of SDWA, the Hazard Index is also an appropriate methodology for determining the level at and below which there are no known or anticipated adverse human health effects with an adequate margin of safety with respect to certain PFAS mixtures in drinking water. The Hazard Index approach is the most practical approach for establishing an MCLG for PFAS mixtures that meets the statutory requirements outlined in section 1412(b)(1)(A) of SDWA. This is because the Hazard Index assesses the exposure level of each component PFAS relative to its HBWC, which is based on the most sensitive known adverse health effect (based on the weight of evidence) and considers sensitive population(s) and life stage(s) as well as potential exposure sources beyond drinking water. Furthermore, the Hazard Index accounts for dose additive health concerns by summing the hazard contribution from each mixture component to ensure that the mixture is not exceeding the level below which there are no known or anticipated adverse health effects and allows for an adequate margin of safety. In addition, given the temporal and spatial variability of PFAS occurrence in drinking water across the nation (USEPA, 2024b), this methodology allows the EPA to regulate these chemicals in drinking water by taking into account site-specific data at each PWS. Component PFAS HQs (hazard quotients) are expected to differ across time and space depending on the actual measured concentrations of each of the four PFAS at each PWS. This approach thus allows for flexibility beyond a one-size-fits-all approach and is tailored to address risk at each PWS. The EPA has made a final regulatory determination for mixtures of two or more of these PFAS. The EPA's application of the Hazard Index approach to regulate such mixtures accounts for the dose additivity that was the basis for the EPA's final determination to regulate such mixtures.

A Hazard Index greater than 1 is generally regarded as an indicator of adverse health risks associated with a specific level of exposure to the mixture; a Hazard Index less than or equal to 1 is generally regarded as not being associated with any appreciable risk (USEPA, 1986; USEPA,1991b; USEPA, 2000a). Thus, in the case of this drinking water rule, a Hazard Index greater than 1 indicates that occurrence of two or more of these four component PFAS in a mixture in drinking water exceeds the health protective level(s) (*i.e.,* HBWC(s)), indicating health risks.

The EPA proposed a Hazard Index MCLG of 1.0, expressed with two significant digits. The EPA's proposal expressed the HBWCs to the tenths place, as follows: 9.0 ng/L for PFHxS, 10.0 ng/L for HFPO–DA; 10.0 ng/L for PFNA; and 2000.0 ng/L for PFBS. The EPA's draft Hazard Index MCLG document expressed all of the HBWCs with one significant digit (9, 10, 10, 2000 ng/L, respectively) (USEPA, 2023e). A few commenters supported the use of two significant digits for the HBWCs, individual HQs, and the Hazard Index MCLG and stated that the use of two significant digits would not be expected to result in issues related to analytical methods precision. One commenter supported using all digits of precision in calculations but rounding to two significant digits for the final reported value of the Hazard Index, noting that the number of significant digits used only affects rounding during steps prior to the point at which a Hazard Index MCL is reached. Commenters noted the importance of clearly communicating the number of significant digits to be used in the documents, and that the choice of the number of significant digits could impact implementation of an MCL based on the Hazard Index. For example, a Hazard Index of 1 (*i.e.,* using one significant digit) would not be exceeded unless the value is calculated to be at 1.5 or above. Alternatively, a Hazard Index of 1.0 (reporting with more than one significant digit) would be exceeded when the Hazard Index is calculated to be 1.05 or above. For additional discussion on significant digit usage, please see sections V and VIII.

A few commenters did not support more than a single significant digit for the HBWCs and Hazard Index MCLG, with some stating that using two or more significant digits for the Hazard Index contradicts the EPA chemical mixtures guidance (USEPA, 2000a) and the RAGS (USEPA, 1991b). The EPA agrees that one (1) significant digit is appropriate for the HBWCs and the Hazard Index MCLG (*i.e.,* 1 rather than 1.0, as in the proposal) because although there is sufficient analytical precision for two significant digits at these concentrations, the RfVs (RfDs and minimal risk levels) used to derive the HBWCs have one significant digit. According to the EPA chemical mixtures guidance (USEPA, 2000a), ''Because the RfDs (and by inference the TTDs) are described as having precision no better than an order of magnitude, the HI should be rounded to no more than one significant digit.'' This approach of using a Hazard Index of 1 is consistent with agency chemical mixtures guidance (USEPA, 1986; USEPA, 2000a) and RAGS (USEPA, 1991b; USEPA, 2018c). The EPA's *Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual* states, ''For noncarcinogenic effects, a concentration is calculated that corresponds to an HI of 1, which is the level of exposure to a chemical from all significant exposure pathways in a given medium below which it is unlikely for even sensitive populations to experience adverse health effects,'' and ''The total risk for noncarcinogenic effects is set at an HI of 1 for each chemical in a particular medium'' (USEPA, 1991b). Finally, ''Cancer risk values and hazard index (HI) values may express more than one significant figure, but for decision-making purposes one significant figure should be used'' (USEPA, 2018c).

c. Final Rule

The EPA has made a final determination to regulate mixtures containing two or more of PFHxS, PFNA, HFPO–DA, and/or PFBS. For the final determination, the EPA's evaluation utilized an HRL as part of a general Hazard Index approach (for additional discussion on the EPA's *Final Regulatory Determinations,* please see section III of this preamble). The EPA's proposal included individual preliminary regulatory determinations for PFHxS, PFNA, HFPO–DA, and PFBS and a mixture regulatory determination for mixtures of those PFAS. The EPA's proposal addressed these regulatory determinations through the Hazard Index MCLG and MCL that would apply to a mixture containing one or more of PFHxS, PFNA, HFPO–DA, and PFBS. If two or more of these PFAS were present then the MCLG and MCL would account for dose additivity of all of the contaminants present, but if only one of the contaminants were present then the Hazard Index would operate as an individual MCLG and MCL. In this final rule, the EPA is promulgating individual MCLGs and MCLs to address the individual final regulatory determinations (PFHxS, PFNA, and HFPO–DA) and is promulgating a Hazard Index MCLG and MCL to address the final mixtures regulatory determination for two or more Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) present.

The EPA used the same general Hazard Index approach for the mixture MCLG. In the general Hazard Index approach, individual PFAS HQs are calculated by dividing the measured concentration of each component PFAS in water (*e.g.,* expressed as ng/L) by the corresponding HBWC for each component PFAS (*e.g.,* expressed as ng/L), as shown in the following equation (and described in USEPA, 2024f). For purposes of this NPDWR, the EPA is using the term ''health-based water concentration'' or ''HBWC'' given its role in calculating the Hazard Index (see the Executive Summary of this preamble). The EPA notes that the Hazard Index MCLG applies to the entire mixture but the EPA's technical justification for the HBWCs for the mixture components is the same as for the individual MCLGs provided in this rule. In this final rule, component PFAS HQs are summed across the PFAS mixture to yield the Hazard Index MCLG. The final PFAS mixture Hazard Index MCLG is set at 1 (one significant digit). A Hazard Index greater than 1 (rounded to one significant digit) indicates that exposure (*i.e.,* PFAS occurrence in drinking water) exceeds the health protective level (*i.e.,* HBWC) for two or more of the individual PFAS mixture components, and thus indicates health risks. The Hazard Index MCLG ensures that even when the individual components are below a level of concern, the components when added together in the mixture do not result in a mixture that itself exceeds a level of concern. A Hazard Index less than or equal to 1 indicates that occurrence of these four PFAS in drinking water does not exceed the health protective level and is therefore generally regarded as unlikely to result in any appreciable risk (USEPA, 1986; USEPA, 1991b; USEPA, 2000a). For more details, please see USEPA (2024a; USEPA, 2024f). The final Hazard Index MCLG for a mixture of PFHxS, PFNA, HFPO–DA, and/or PFBS is derived as follows:

$$HI\ MCLG = \left(\frac{[HFPO{-}DA_{water}]}{[HFPO{-}DA_{HBWC}]}\right) + \left(\frac{[PFBS_{water}]}{[PFBS_{HBWC}]}\right) + \left(\frac{[PFNA_{water}]}{[PFNA_{HBWC}]}\right) + \left(\frac{[PFHxS_{water}]}{[PFHxS_{HBWC}]}\right) = 1$$

$$HI\ MCLG = \left(\frac{[HFPO{-}DA_{ng/L}]}{[10\,ng/L]}\right) + \left(\frac{[PFBS_{ng/L}]}{[2000\,ng/L]}\right) + \left(\frac{[PFNA_{ng/L}]}{[10\,ng/L]}\right) + \left(\frac{[PFHxS_{ng/L}]}{[10\,ng/L]}\right) = 1$$

Where

$[PFAS_{water}]$ = the measured component PFAS concentration in water and

$[PFAS_{HBWC}]$ = the HBWC of a component PFAS.

2. MCLG Derivation for PFHxS, PFNA, and HFPO–DA

a. Proposal

As described in section IV.B.1.a of this preamble, in March 2023, the EPA proposed a Hazard Index MCLG to protect public health from exposure to mixtures of PFHxS, PFNA, HFPO–DA, and PFBS, four PFAS that affect many similar health endpoints/outcomes and that occur and co-occur in drinking water. At that time, the EPA also considered setting individual MCLGs for these PFAS either instead of or in addition to using a mixtures-based approach for PFHxS, PFNA, HFPO–DA, and PFBS. The EPA ultimately proposed the Hazard Index approach for establishing an MCLG for a mixture of these four PFAS.

b. Summary of Major Public Comments and EPA Responses

Several commenters favored finalization of individual MCLGs (and MCLs) for some or all of the PFAS included in the proposed Hazard Index, with or without a Hazard Index approach to address mixtures of these PFAS. Specifically, commenters supported establishing individual MCLGs for PFHxS, PFNA, HFPO–DA, and PFBS because they questioned the EPA's scientific conclusions regarding PFAS dose additivity and raised concerns about potential risk communication issues and confusion about the EPA's use of the Hazard Index to establish drinking water standards (for additional discussion on MCLs, please see section V of this preamble). The EPA agrees with commenters who favored finalization of individual MCLGs for some of the PFAS included in the Hazard Index, and to do so in addition to the Hazard Index MCLG being finalized for the mixture of the four PFAS. The EPA believes this provides clarity for purposes of implementation of the rule. The EPA is finalizing individual MCLGs for PFHxS, PFNA, and HFPO–DA (for additional discussion on the final regulatory determinations, please see section III of this preamble). Regarding risk communication and potential confusion about the use of the Hazard Index, the EPA acknowledges that effective risk communication is important, and the agency will develop communication materials to facilitate understanding of all aspects of this NPDWR, including the Hazard Index MCL (for additional discussion on MCLs, please see section V of this preamble). The EPA has provided language for consumer notifications as part of CCR (see section IX of this preamble).

One commenter stated that developing individual MCLGs (and MCLs) in addition to the Hazard Index mixture MCLG (and MCL) would have no practical impact, since an exceedance of an HBWC for an individual PFAS within a mixture would result in an exceedance of the Hazard Index even if none of the other PFAS included in the Hazard Index are detected. The EPA clarifies the final rule promulgates individual MCLs for PFHxS, PFNA and HFPO–DA as well as a mixture Hazard Index MCL for two or more of these PFAS and PFBS. There may be a practical impact of these individual MCLs (for PFHxS, PFNA and HFPO–DA) where one of these three PFAS occur in isolation (*i.e.,* without one of the other four Hazard Index PFAS present) above their individual MCLs. The EPA notes that this regulatory structure is consistent with the intended effect of the proposed regulation, where as proposed, a single PFAS above its HBWC would have caused an exceedance of the MCL. Based on public comment, the EPA has restructured the rule such that two or more of these regulated PFAS would be necessary to cause an exceedance of the Hazard Index and instead will regulate individual exceedances of PFNA, PFHxS, and HFPO–DA as individual MCLs to improve risk communication. Risk communication is an important focus for water systems and the EPA believes that finalizing individual MCLs for PFHxS, PFNA, and HFPO–DA can support risk communication as utilities and the public may be more familiar with this regulatory framework. Additionally, the final individual MCLs for PFHxS, PFNA and HFPO–DA will address and communicate health concerns for these compounds where they occur in isolation. At the same time, since those individual MCLs do not address additional risks from co-occurring PFAS, the EPA is finalizing a Hazard Index MCL that provides a framework to address and communicate dose additive health concerns associated with mixtures of PFHxS, PFNA, HFPO–DA, and PFBS that co-occur in drinking water. For the EPA's discussion on the practical impact of the establishment of stand-alone standards in lieu of or in addition to the Hazard Index MCL, please see sections V and IX.A of this preamble. The EPA's discussion on the practical impact of the establishment of stand-alone standards in lieu of or in addition to the Hazard Index MCL, please see sections V and IX.A of this preamble.

A few commenters questioned why the EPA is developing an NPDWR for contaminants that do not have EPA Drinking Water Health Advisories (PFHxS, PFNA), and stated that the EPA should wait to propose an NPDWR for PFHxS and PFNA until after Health Advisories are finalized for these PFAS. The EPA disagrees with this comment. Health Advisories are not a pre-requisite for an NPDWR under SDWA and there is nothing in the statute or the EPA's historical regulatory practice that suggests that the agency must or should delay regulation of a contaminant in order to develop a health advisory first.

c. Final Rule

As described in section III of this preamble, the EPA has made a final determination to individually regulate PFHxS, PFNA, and HFPO–DA.

The EPA is finalizing individual MCLGs for PFHxS, PFNA, and HFPO–DA as follows: PFHxS MCLG = 10 ng/L; HFPO–DA MCLG = 10 ng/L; and PFNA MCLG = 10 ng/L. The technical basis for why each of these levels satisfies the statutory definition for MCLG is described in section III of this preamble (and is the same technical basis the EPA used to explain the levels identified as the HBWCs). These MCLGs are expressed with one significant digit and are based on an analysis of each chemical's toxicity (*i.e.,* RfD/minimal risk level) and appropriate exposure factors (*i.e.,* DWI–BW, RSC) (USEPA, 2024f).

The EPA is deferring its individual regulatory determination for PFBS and not finalizing an individual MCLG for PFBS at this time (please see section III of this preamble, *Final Regulatory Determinations for Additional PFAS,* for further information).

V. Maximum Contaminant Levels

Under current law and as described in the proposed rule (USEPA, 2023f), the Environmental Protection Agency (EPA) establishes drinking water standards through a multi-step process. *See* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3. First, the agency establishes a non-enforceable Maximum Contaminant Level Goals (MCLG) for the contaminant in drinking water at a level which no known or anticipated adverse effects to the health of persons will occur and which allow for an adequate margin of safety. Second, the agency generally sets an enforceable Maximum Contaminant Level (MCL) as close to that public health goal as feasible, taking costs into consideration.

In this second step, consistent with the definition of ''feasible'' in section 1412(b)(4)(D), the EPA evaluates the availability and performance of Best Available Technologies (BATs) for treating water to minimize the presence of the contaminant consistent with the MCLG (see section X for additional discussion on BATs) as well as the costs of applying those BATs to large metropolitan water systems when treating to that level (1412(b)(4)(E) and (5)).[4] The definition of ''feasible'' means *feasible* with the use of the best technology . . . ''which includes consideration of the analytical limits of best available treatment and testing technology.'' *see* S. Rep. No. 169, 104th Cong., 1st Sess. (1995) at 3; *see also* section 1401(1)(C)(i) stating that a NPDWR includes an MCL only ''if, in the judgment of the Administrator, it is economically and technologically feasible to ascertain the level of such contaminant in water in public water systems.'' In addition, the MCL represents ''the maximum permissible level of a contaminant in water which is delivered to any user of a public water system,'' section 1401(3). Thus, in setting the MCL level, the EPA also identifies the level at which it is technologically feasible to measure the contaminant in the public water system. To identify this level, the EPA considers (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2) the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods (known as the practical quantitation levels (PQLs)). The ability of laboratories to measure the level of the contaminant with sufficient precision and accuracy using approved methods is essential to ensure that any public water system nationwide can monitor, determine compliance, and deliver water that does not exceed the maximum permissible level of a contaminant in water to any of its consumers. (See section VII of this preamble for additional discussion on analytical methods and PQLs for the per- and polyfluoroalkyl substances (PFAS) regulated in this rule.)

In practice this means that where the MCLG is zero, the EPA typically sets MCLs at the PQLs when treatment is otherwise feasible, based on cost and treatment availability, because the PQL is the limiting factor. Conversely, for contaminants where the MCLG is higher than the PQL, the EPA generally sets the MCL at the MCLG when treatment is otherwise feasible, based on costs and treatment availability, because the PQL is not a limiting factor.

The Safe Drinking Water Act (SDWA) defines an MCL as ''the maximum permissible level of a contaminant in water which is delivered to any user of a public water system.'' Like the MCLG, SDWA does not dictate that the MCL take a particular form; however, given this definition, an MCL establishes a ''maximum permissible level of a contaminant in water'' and as a practical matter the identified ''level'' must be capable of being validated so that it can be determined whether that public water systems are delivering water to any user meeting or exceeding that ''level.''

A. PFOA and PFOS

1. Proposal

In the March 2023 proposal, the EPA proposed individually enforceable MCLs for PFOA and PFOS at the PQL which is 4.0 ng/L (USEPA, 2023f). Section 1412(b)(4)(E) of SDWA requires that the agency ''list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting [the MCL],'' which are referred to as Best Available Technologies (BATs). The EPA found multiple treatment technologies to be effective and available to treat PFOA and PFOS to at or below the proposed standards (please see and section X (10) of this preamble and USEPA, 2024l for additional discussion on feasible treatment technologies including BAT/SSCT identification and evaluation). In addition, the EPA found that there are analytical methods available to reliably quantify PFOA and PFOS at the PQL. The EPA requested comment on regulatory alternatives for both compounds at 5.0 ng/L and 10.0 ng/L. The EPA also requested comment on whether setting the MCL at the PQL for PFOA and PFOS is implementable and feasible.

2. Summary of Major Public Comments and EPA Responses

The EPA received many comments that strongly support the proposed MCLs of 4.0 ng/L and the agency's determination that the standards are as close as feasible to the MCLG. These commenters request the agency to finalize the standards as expeditiously as possible. Consistent with these comments, through this action, the agency is establishing drinking water standards for PFOA and PFOS (and four other PFAS) to provide health protection against these contaminants found in drinking water.

Many commenters assert that implementation of the PFOA and PFOS standards would be challenging because the MCLs are set at the PQLs for each compound, and some commenters recommended alternative standards (*e.g.,* 5.0 ng/L or 10.0 ng/L). These commenters contend that by setting the

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[4] Based on legislative history, the EPA interprets ''taking cost into consideration'' in section 1412(b)(4)(D) to be limited to ''what may be reasonably be afforded by large metropolitan or regional public water systems.'' H.R. Rep. No 93–1185 (1974), *reprinted in* 1974 U.S.C.C.A.N. 6454, 6470–71.

MCLs at the PQLs, utilities would not be able to reliably measure when the concentration of contaminants in their drinking water is approaching the MCLs. Some of these commenters suggest that having a buffer between the PQLs and the MCLs may allow utilities to manage treatment technology performance more efficiently because utilities generally aim to achieve lower than the MCLs to avoid a violation and that this buffer would provide some level of operational certainty for systems treating for PFAS. The EPA disagrees that the PFOA and PFOS standards are not implementable because the MCLs are set at their respective PQLs.

As the agency noted in the proposed rule preamble, the EPA has promulgated, and both the EPA and water systems have successfully implemented, several NPDWRs with MCLs equal to the contaminant PQLs. As examples, in 1987, the EPA finalized the Phase I Volatile Organic Compounds (VOC) rule (USEPA, 1987), where the agency set the MCL at the PQL for benzene, carbon tetrachloride, trichloroethylene, vinyl chloride, and 1,2-dichloroethane (52 FR 25690). Other examples where MCLs were set at the PQL include benzo(a)pyrene, di(2-ethylhexyl) phthalate, dioxin, dichloromethane, hexachlorobenzene, and PCBs (see USEPA, 1991c and USEPA, 1992). Some commenters at the time stated they believed implementation would be challenging because the MCLs were set at the PQL in these examples; however, the EPA notes that those rules have been implemented successfully despite commenters initial concerns. The agency does not agree with commenters that operational flexibility (*i.e.,* the inclusion of a 'buffer' between the PQL and MCL) is relevant for purposes of setting an MCL. That is because the PQL is the lowest level that can be reliably achieved within specified limits of precision and accuracy and is therefore the metric by which the agency uses to evaluate the most feasible MCL pursuant to SDWA requirements. Considerations for operational flexibility may be relevant to other parts of the rule, such as determining monitoring and compliance with the rule. First, for purposes of determining compliance with the MCL, water systems must calculate the running annual average (RAA) of results, which could allow some results to exceed 4.0 ng/L for single measurements if the overall annual average is below the MCL. In other words, there is a buffer built into determining compliance with the MCL. Second, when calculating the RAA, zero will be used for results less than the PQL which provides an additional analytic buffer for utilities in their compliance calculations. This monitoring and compliance framework allows for temporal fluctuations in concentrations that may occur because of unexpected events such as premature PFOA and PFOS breakthrough or temporary elevated source water concentrations. Thus, periodic occurrences of PFOA or PFOS that are slightly above the PQLs do not necessarily result in a violation of the MCL if other quarterly samples are below the PQL. The agency notes that in general, PQLs are set above the limit of detection; for PFAS specifically, all the PQLs are well above their limits of detection. The PQL is also different than detection limits because the PQL is set considering a level of precision, accuracy, and quantitation. Systems may be able to use sample results below the PQL to understand whether PFOA and PFOS are present. While the EPA has determined that results below the PQL are insufficiently precise for determining compliance with the MCL, results below the PQL can be used to determine analyte presence or absence in managing a system's treatment operations and to determine monitoring frequency. See discussion in section VII of this preamble for further discussion of the PQL, results below the PQL, and how those results provide useful information.

Some commenters contend that the PQLs for PFOA and PFOS are not set at an appropriate level (*e.g.,* the PQLs are either too high or too low for laboratories to meet). Specifically, these commenters question whether enough laboratories have the ability to analyze samples at 4.0 ng/L and, as a result, contend it is not a ''reasonable quantitation level.'' The EPA disagrees with commenters who suggest the PQLs for PFOA and PFOS are not set at an appropriate level or that they should be either higher or lower levels than that proposed. As discussed above and in the March 2023 proposal, the EPA derives PQLs that reflect the level of contaminants that laboratories can reliably quantify within specific limits of precision and accuracy during routine laboratory operating conditions. The ability to reliably measure is an important consideration for feasibility to ensure that water systems nationwide can monitor and dependably comply with the MCLs and deliver drinking water that does not exceed the maximum permissible level. In the rule proposal (USEPA, 2023f), the EPA explained that the minimum reporting levels under UCMR 5 reflect ''a minimum quantitation level that, with 95 percent confidence, can be achieved by capable lab analysts at 75 percent or more of the laboratories using a specified analytical method'' (USEPA, 2022k). The PQLs for the regulated PFAS are based on the UCMR 5 minimum reporting levels. The EPA calculated the UCMR 5 minimum reporting levels using quantitation-limit data from multiple laboratories participating in multi-lab method validation studies conducted in the 2017–2019 timeframe, prior to the UCMR 5 Laboratory Approval Program (see appendix B of USEPA, 2020b). The calculations account for differences in the capability of laboratories across the country. Laboratories approved to analyze UCMR samples must demonstrate that they can consistently make precise measurements of PFOA and PFOS at or below the established minimum reporting levels. Therefore, the EPA finds that the UCMR 5 minimum reporting levels are appropriate for using as PQLs for this rule: the EPA estimates that laboratories across the nation can precisely and accurately measure PFOA and PFOS at this quantitation level. After reviewing data from laboratories that participated in the minimum reporting level setting study under UCMR 5 and in consideration of public comment, the EPA finds that the minimum reporting levels set in UCMR 5 of 4.0 ng/L for PFOA and PFOS, that are also the PQLs, are as close as feasible to the MCLG. While lower quantitation levels may be achievable for some laboratories, it has not been demonstrated that these lower quantitation levels can be achieved for ''at 75 percent or more of the laboratories using a specified analytical method'' across laboratories nationwide. Moreover, though the EPA is confident of sufficient laboratory capacity to implement this PFAS National Primary Drinking Water Regulation (NPDWR) as finalized, a lower PQL could potentially limit the number of laboratories available to support analytical monitoring that would be otherwise available to support analytical monitoring with PFOA and PFOS PQLs of 4.0 ng/L.

In the proposal, the EPA discussed how utilities may be able to use sample results below the PQL to determine analyte presence or absence in managing their treatment operations; however, a few commenters contend that this is not practical to determine compliance with the MCL as these values are less precise and violations may result in expensive capital improvements. Commenters are conflating two different issues. While commenters are referring to quantitation of a sampling result for compliance with the rule, the EPA's discussion on results below the PQL refers to determining simple presence or absence of a contaminant for other purposes. Sampling results below the PQL may not have the same precision as a sampling result at or above the PQL but they are useful for operational purposes such as understanding that PFOA and PFOS may be present, which can inform treatment decisions and monitoring frequency. For example, a utility may use sampling results below 4.0 ng/L as a warning that they are nearing the PFOA and PFOS MCLs of 4.0 ng/L prior to an exceedance. Then, the utility can make informed treatment decisions about managing their system (*e.g.,* replacing GAC). Additionally, the EPA evaluated data submitted as part of the UCMR 5 Laboratory Approval Program (LAP) and found that 47 of 53 laboratories (89 percent) that applied for UCMR 5 approval generated a minimum reporting level confirmation at 2 ng/L (one-half the proposed MCL) or less for Method 533 (USEPA, 2022j). This suggests that the majority of laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide useful screening measurement results below the PQL. Further, as discussed in section VII of this preamble, all labs are required per the approved methods to demonstrate whether laboratory reagent blank (LRB) quality control (QC) samples have background concentrations of less than one-third the minimum reporting level (*i.e.,* the minimum concentration that can be reported as a quantitated value for a method analyte in a sample following analysis). Therefore, for a laboratory to be compliant with the methods, they must be able to detect, not necessarily quantify, analytes at or above ⅓ the minimum reporting level.

The EPA agrees with commenters that it is inappropriate to make potentially costly compliance decisions based on measurements below the PQL because they do not have the same level of precision and accuracy as results at or above the PQL. As previously discussed, for MCL compliance purposes, results less than the PQL will be recorded as zero. For additional details on monitoring and compliance requirements, please see section VIII of this preamble.

Some commenters argue that the EPA did not sufficiently consider cost in the agency's feasibility analysis of the proposed MCLs and therefore disagreed with the EPA that the standards are feasible. In particular, these commenters suggest that the agency did not adequately consider costs associated with implementation (*e.g.,* costs for labor, materials, and construction of capital improvements) and compliance (*e.g.,* costs to monitor) with the proposed MCLs. Based on these factors, many of these commenters suggest either raising the MCLs or re-proposing the standard in its entirety. The EPA did consider these costs and therefore disagrees with commenters' assertions that the agency did not consider these issues in establishing the proposed MCLs for PFOA and PFOS (USEPA, 2024g; USEPA, 2024l; USEPA, 2024m). The EPA considers whether these costs are reasonable based on large metropolitan drinking water systems. H.R. Rep. No 93–1185 (1978), *reprinted in* 1974 U.S.C.C.A.N. 6454, 6470–71. The EPA considered costs of treatment technologies that have been demonstrated under field conditions to be effective at removing PFOA and PFOS and determined that the costs of complying with an MCL at the PQL of 4.0 are reasonable for large metropolitan water systems at a system and national level (USEPA, 2024e; USEPA, 2024g). To designate technologies as BATs, the EPA evaluated each technology against six BAT criteria, including whether there is a reasonable cost basis for large and medium water systems. The EPA evaluated whether the technologies are currently being used by systems, whether there were treatment studies available with sufficient information on design assumptions to allow cost modeling, and whether additional research was needed (USEPA, 2024l). In considering the results of this information, the EPA determined that these costs are reasonable to large metropolitan water systems.

Pursuant to SDWA section 1412(b)(4)(E)(ii), the agency also evaluated ''technolog[ies], treatment technique[s], or other means that is affordable'' for small public water systems. In this evaluation, the agency determined that the costs of small system compliance technologies (SSCTs) to reach 4.0 ng/L are affordable for households served by small drinking water systems. Additionally, the EPA notes that SDWA section 1412(b)(4)(D) states that ''granular activated carbon is feasible for the control of synthetic organic chemicals'' which the agency lists as a BAT for this rule (section X). All PFAS, including PFOA and PFOS, are SOCs, and therefore, GAC is BAT as defined by the statute. For additional discussion on BATs and SSCTs, please see section X of this preamble.

Some commenters disagreed with the EPA's determination that the rule is feasible under SDWA asserting that there is insufficient laboratory capacity and other analytic challenges to measure samples at these thresholds. As described above in the agency's approach toward evaluating feasibility, the EPA assesses (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2) the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods (*i.e.,* the PQLs). This framework inherently considers both the capacity and capability of labs available to meet the requirements of the NPDWR. Based on the EPA's analysis of these factors, the EPA disagrees with commenter assertions that there is insufficient laboratory capacity at this time to support implementation of the NPDWR. Currently, there are 53 laboratories for PFAS methods (Method 533 or 537.1) in the EPA's Unregulated Contaminant Monitoring Rule (UCMR) 5 Laboratory Approval Program, more than double the participation in UCMR 3 (21 laboratories), with several laboratory requests to participate after the lab approval closing date. At a minimum, these 53 labs alone have already demonstrated sufficient capacity for current UCMR 5 monitoring, which requires monitoring for all systems serving above 3,300 or more persons and 800 systems serving less than 3,300 persons over a three-year period. The 21 laboratories participating in UCMR 3 provided more than sufficient capacity for that monitoring effort, which required monitoring for all systems serving greater than 10,000 persons and 800 systems serving less than 10,000. Further, a recent review of state certification and third-party accreditation of laboratories for PFAS methods found an additional 25 laboratories outside the UCMR 5 LAP with a certification or accreditation for EPA Method 533 or 537.1. Additionally, as has happened with previous drinking water regulations, the EPA anticipates laboratory capacity to grow once the rule is finalized to include an even larger laboratory community, as the opportunity for increased revenue by laboratories would be realized by filling the analytical needs of the utilities (USEPA, 1987; USEPA, 1991c; USEPA, 1991d; USEPA, 1992; USEPA, 2001). Finally, with the use of a reduced monitoring schedule to once every three years for eligible systems, and the ability for systems that are reliably and consistently below the MCLs of 4.0 ng/L to only monitor once per year, the EPA anticipates that the vast majority of utilities may be able to take advantage of reduced or annual monitoring, and will not require a more frequent monitoring schedule, thus easing the burden of laboratory capacity as well.

The EPA also disagrees with commenter assertions that there is insufficient laboratory capability at this time. As discussed above and in the proposed rule preamble, the EPA proposed a PQL of 4.0 ng/L for both PFOA and PFOS based on current analytical capability and from the minimum reporting levels generated for the UCMR 5 program. The EPA evaluated data submitted as part of the UCMR 5 LAP and found that 47 of 53 laboratories (89 percent) that applied for UCMR 5 approval generated a minimum reporting level confirmation at 2 ng/L (one-half the proposed MCL) or less for Method 533. The MCLs for PFOA and PFOS were also set at 4.0 ng/L as a result of the analytical capability assessment under the minimum reporting level setting study for UCMR 5, as well as consideration of other factors (*e.g.,* treatment, costs) as required under SDWA. For UCMR 5, all UCMR-approved laboratories were able to meet or exceed the PFOS and PFOA UCMR minimum reporting levels, set at 4 ng/L, the proposed MCL for both. The UCMR 5 minimum reporting levels of 4 ng/L for PFOS and PFOA are based on a multi-laboratory minimum reporting level calculation using lowest concentration minimum reporting level (LCMRL) data. The LCMRL and minimum reporting level have a level of confidence associated with analytical results. More specifically, the LCMRL calculation is a statistical procedure for determining the lowest true concentration for which future analyte recovery is predicted with 99% confidence to fall between 50 and 150% recovery (Martin et al., 2007). The multi-laboratory minimum reporting level is a statistical calculation based on the incorporation of LCMRL data collected from multiple laboratories into a 95% one-sided confidence interval on the 75th percentile of the predicted distribution referred to as the 95–75 upper tolerance limit. This means that 75% of participating laboratories will be able to set a minimum reporting level with a 95% confidence interval. The quantitation level of 4 ng/L has been demonstrated to be achieved with precision and accuracy across laboratories nationwide, which is important to ensure that systems can dependably comply with the MCL and deliver drinking water that does not exceed the maximum permissible level. The agency anticipates that these quantitation levels for labs will continue to improve over time, as technology advances and as laboratories gain experience with the PFAS Methods. The EPA's expectation is supported by the record borne out by the significant improvements in analytical capabilities for measuring certain PFAS, including PFOA and PFOS, between UCMR 3 and UCMR 5. For example, the minimum reporting levels calculated for UCMR 3 (2012–2016) were 40 ng/L and 20 ng/L for PFOS and PFOA, respectively, the minimum reporting levels calculated for UCMR 5 (2022–2025) were 4 ng/L each for PFOA and PFOS.

Some commenters recommend a different regulatory framework than what the EPA proposed to alleviate perceived implementation concerns (*e.g.,* reduce the potential of inundating laboratories or providing more time to plan and identify opportunities for source water reduction). For example, a few commenters suggest a phased-in MCL, where systems demonstrating higher concentrations are addressed first in the NPDWR, or MCL approaches where interim targets are set for compliance. Upon consideration of information submitted by commenters, particularly issues related to supply chain complications that are directly or indirectly related to the COVID–19 pandemic residual challenges, the EPA has determined that a significant number of systems subject to the rule will require an additional 2 years to complete the capital improvements necessary to comply with the MCLs for PFAS regulated under this action. Thus, the EPA also disagrees with recommendations to create a phased schedule for rule implementation based on the concentrations of PFAS detected because the EPA has granted a two-year extension for MCL compliance to all systems. For additional discussion on this extension and the EPA responses to public comment on this issue, please see section XI.D.

Some commenters argue for a lower PFOA and PFOS MCL due to the underlying health effects of these contaminants. These commenters suggest the EPA establish MCLs lower than the agency's proposed standard of 4.0 ng/L due to the capability of some laboratories to quantitate lower concentrations. Some of these commenters also argue that since PFOA and PFOS are likely human carcinogens, the EPA should consider an MCL at zero. While the EPA agrees with the health concerns posed by PFAS that are the basis for the proposed health based MCLGs for these contaminants, the agency disagrees with commenters on these alternative MCL thresholds given the EPA's consideration of feasibility as required by SDWA. These commenters did not provide evidence demonstrating the feasibility of achieving lower MCL thresholds (including an MCL at zero) consistent with SDWA requirements in establishing an MCL. For example, commenters did not provide evidence to support a lower PQL that can be consistently achieved by laboratories across the country. They also did not provide arguments supporting why the EPA should accept less than 75% of participating laboratories will be able to set a minimum reporting level with a 95% confidence interval. Thus, the agency is finalizing the MCLs for PFOA and PFOS at 4.0 ng/L (at the PQL) as this is the closest level to the MCLG that is feasible due to the ability of labs using approved analytical methods to determine with sufficient precision and accuracy whether such a level is actually being achieved. The record supports the EPA's determination that the lowest feasible MCL for PFOA and PFOS at this time is 4.0 ng/L.

A few commenters suggest the EPA did not appropriately consider disposal concerns for spent treatment media as part of the agency's feasibility determination. These commenters state that they believe disposal options are currently limited for liquid brine, reject waters resulting from RO, or solid waste from GAC treatment and that disposal capacity will be further limited should the EPA designate PFAS waste as hazardous. These commenters contend that these limitations increase operating expenses for utilities and should be factored in the establishment of the PFOA and PFOS MCLs. The EPA disagrees with these commenters that the agency did not adequately consider disposal of spent treatment media in the rule. First, disposal options for PFAS are currently available. These destruction and disposal options include landfills, thermal treatment, and underground injection. Systems are currently disposing of spent media, such as activated carbon, through thermal treatment, to include reactivation, and at landfills. While precautions should be taken to minimize PFAS release to the environment from spent media, guidance exists that explains the many disposal options with relevant precautions. See section X for further discussion. Furthermore, the EPA has provided guidance for pretreatment and wastewater disposal to manage PFAS that enters the sanitary sewer system and must be managed by publicly owned treatment works (POTWs) (USEPA, 2022d; USEPA, 2022e). As discussed in the proposed rule (USEPA, 2023f), the EPA assessed the availability of studies of full-scale treatment of residuals that fully characterize residual waste streams and disposal options. Although the EPA anticipates that designating chemicals as hazardous substances under CERCLA generally should not result in limits on the disposal of PFAS drinking water treatment residuals, the EPA has estimated the treatment costs for systems both with the use of hazardous waste disposal and non-hazardous disposal options to assess the effects of potentially increased disposal costs. Specifically, the EPA assessed the potential impact on public water system (PWS) treatment costs associated with hazardous residual management requirements in a sensitivity analysis. The EPA's sensitivity analysis demonstrates that potential hazardous waste disposal requirements may increase PWS treatment costs marginally; however, the increase in PWS costs is not significant enough to change the agency's feasibility determination nor the determination made at proposal that benefits of the rulemaking justify the costs. These estimates are discussed in greater detail in the HRRCA section of this final rule and in appendix N of the *Economic Analysis* (EA) (USEPA, 2024e). For the discussion on management of treatment residuals and additional responses to stakeholder concerns on this topic, please see section X of this preamble. While beyond the scope of this rule, the EPA further notes that the agency is proposing to amend its regulations under the Resource Conservation and Recovery Act (RCRA) by adding nine specific per-and polyfluoroalkyl substances (PFAS), their salts, and their structural isomers, to the list of hazardous constituents at 40 CFR part 261, appendix VIII (89 FR 8606). The scope of the proposal is limited and does not contain any requirements that would impact disposal of spent drinking water treatment residuals. This is because listing these PFAS as RCRA hazardous constituents does not make them, or the wastes containing them, RCRA hazardous wastes. The principal impact of the proposed rule, if finalized, will be on the RCRA Corrective Action Program. Specifically, when corrective action requirements are imposed at a RCRA treatment, storage, and disposal facility (TSDF), these specific PFAS would be among the hazardous constituents expressly identified for consideration in RCRA facility assessments and, where necessary, further investigation and cleanup through the RCRA corrective action process.

Some commenters suggest that the EPA failed to consider the costs and impacts of the proposed MCLs in non-drinking water contexts, such as its potential uses as CERCLA clean-up standards. As required by SDWA, this rule and analyses supporting the rulemaking only includes costs that ''are likely to occur solely as a result of compliance with the [MCL].'' (SDWA section 1412(b)(3)(C)(i)(III)) Thus, the EPA's cost analyses focused on the compliance costs of meeting the MCL to public water systems that are directly subject to this regulation. The same provision expressly directs the EPA to exclude ''costs resulting from compliance with other proposed or promulgated regulations.'' Thus, the EPA cannot consider the costs of use of the MCLs under other EPA statutes (such as CERCLA) as part of its EA because SDWA specifically excludes such consideration (42 U.S.C. 300g–1(b)(3)(C)(i)(III)). See also *City of Waukesha* v. *EPA,* 320 F.3d 228, 243–244 (D.C. Cir. 2003) (finding that SDWA excludes consideration of the costs of, for example, CERCLA compliance, as part of the required cost/benefit analysis). In addition, whether and how MCLs might be used in any particular clean-up is very site-specific and as a practical matter cannot be evaluated in this rule.

Many commenters compared the proposed MCLs to existing state and international standards, regulations, and guidelines. In particular, these commenters acknowledge the fact that several states have conducted their own rulemakings to promulgate MCLs and suggest that the EPA's analysis in support of the proposed MCLs are inconsistent with these state approaches. Further, these commenters ask the EPA to explain why certain states' cost-benefit analyses supported their respective levels and why the EPA's analysis is different. Regarding state PFAS regulations, the EPA disagrees with commenters who suggested that the agency should develop regulations consistent with current state-led actions in setting a national standard in accordance with SDWA. While some states have promulgated drinking water standards for various PFAS prior to promulgation of this NPDWR, this rule provides a nationwide, health protective level for PFOA and PFOS (as well as four other PFAS) in drinking water and reflects regulatory development requirements under SDWA, including the EPA's analysis of the best available and most recent peer-reviewed science; available drinking water occurrence, treatment, and analytical feasibility information relevant to the PQL; and consideration of costs and benefits. After the NPDWR takes effect, SDWA requires primacy states to have a standard that is no less stringent than the NPDWR. Additionally, analyses conducted by the agency in support of an NPDWR undergo a significant public engagement and peer review process. The EPA notes that the EA for this rule accounts for existing state standards at the time of analysis. Specifically, to estimate the costs and benefits of the final rule, the EPA assumed that occurrence estimates exceeding state limits are equivalent to the state-enacted limit. For these states, the EPA assumed that the state MCL is the maximum baseline PFAS occurrence value for all EP in the state. Additionally, while states may establish drinking water regulations or guidance values absent Federal regulation as they deem appropriate, the presence of state regulations does not preclude the EPA from setting Federal regulations under the authority of SDWA that meets that statute's requirements. For additional information on the EPA's EA, please see section XII.

3. Final Rule

After considering public comments, the EPA is finalizing enforceable MCLs for PFOA and PFOS at 4.0 ng/L as the closest feasible level to the MCLG. First, the agency is establishing non-enforceable MCLGs at zero for contaminants where no known or anticipated adverse effects to the health of persons will occur, allowing for an adequate margin of safety. The EPA then examined the treatment capability of BATs and the accuracy of analytical techniques as reflected in the PQL in establishing the closest feasible level. In evaluating feasibility, the agency has determined that multiple treatment technologies (*e.g.,* GAC, AIX) ''examined for efficacy under field conditions and not solely under laboratory conditions'' are found to be both effective and available to treat PFOA and PFOS to the standards and below. The EPA also determined that there are available analytical methods to measure PFOA and PFOS in drinking water and that the PQLs for both compounds reflect a level that can be achieved with sufficient precision and accuracy across laboratories nationwide using such methods. Since limits of analytical measurement for PFOA and PFOS require the MCL to be set at some level greater than the MCLG, the agency has determined that 4.0 ng/L (the PQL for each contaminant) represents the closest feasible level to the MCLG and the level at which laboratories using these methods can ensure, with sufficient accuracy and precision, that water systems nationwide can monitor and determine compliance so that they are ultimately delivering water that does not exceed the maximum permissible level of PFOA and PFOS to any user of their public water system. The EPA evaluates the availability and performance of BATs for treating water to minimize the presence of the contaminant consistent with the MCLG as well as the costs of applying those BATs to large metropolitan water systems when treating to that level. In consideration of these factors, the EPA is therefore establishing the MCL of 4.0 ng/L for both PFOA and PFOS. The EPA further notes that the agency has determined that the costs of SSCTs to reach 4.0 ng/L are affordable for households served by small drinking water systems. For additional discussion on the EPA's EA, please see section XII of this preamble. For additional discussion on the PQLs for the PFAS regulated as part of this NPDWR, please see section VII of this preamble. The EPA notes that upon consideration of information submitted by commenters regarding the implementation timeline for the rule, the agency is also exercising its authority under SDWA section 1412(b)(10) to allow two additional years for systems to comply with the MCL. For additional discussion on this extension, please see section XI.

The EPA clarifies that the MCLs for PFOA and PFOS are set using two significant digits in this final rule. In the proposed rule, the EPA proposed MCLGs for PFOA and PFOS at zero (0) and an enforceable MCL for PFOA and PFOS in drinking water with two significant digits at 4.0 ng/L. As previously discussed in section IV of this preamble, the MCLG for PFOA and PFOS is zero because these two PFAS are likely human carcinogens. Because the MCLGs are zero, the number of significant digits in the MCLGs are not the appropriate driver for considering the number of significant digits in the MCLs. This approach is consistent with other MCLs the EPA has set with carcinogenic contaminants, including for arsenic and bromate.

By setting the MCLs at 4.0, the EPA is setting the MCLs as close as feasible to the MCLGs. The EPA guidance states that all MCLs should be expressed in the number of significant digits permitted by the precision and accuracy of the specified analytical procedure(s) and that data reported should contain the same number of significant digits as the MCL (USEPA, 2000h). The EPA determined that two significant digits were appropriate for PFOA and PFOS considering existing analytical feasibility and methods. The EPA drinking water methods typically use two or three significant digits to determine concentrations. The EPA methods 533 and 537.1, those authorized for use in determining compliance with the MCLs, state that ''[c]alculations must use all available digits of precision, but final reported concentrations should be rounded to an appropriate number of significant digits (one digit of uncertainty), typically two, and not more than three significant digits.'' The EPA has determined that both methods 533 and 537.1 provide sufficient analytical precision to allow for at least two significant digits.

B. PFAS Hazard Index: PFHxS, PFNA, HFPO–DA, and PFBS

1. Proposal

The EPA proposed an MCL for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS expressed as a Hazard Index to protect against additive health concerns when present in mixtures in drinking water. As discussed in the March 2023 proposal (USEPA, 2023f), a Hazard Index is the sum of hazard quotients (HQs) from multiple substances. An HQ is the ratio of exposure to a substance and the level at which adverse effects are not anticipated to occur. The EPA proposed the MCL for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS as the same as the MCLG: as proposed, the Hazard Index must be equal to or less than 1.0. This approach would set a permissible level for the contaminant mixture (*i.e.,* a resulting PFAS mixture Hazard Index greater than 1.0 is an exceedance of the health protective level and has potential human health risk for noncancer effects from the PFAS mixture in water). The proposal defined a mixture as containing one or more of the four PFAS and therefore covered each contaminant individually if only one of the four PFAS occurred. Thus, the Hazard Index as proposed ensures that the level of exposure to an individual PFAS remains below that which could impact human health because the exposure for that measured PFAS is divided by its corresponding HBWC. The EPA proposed HBWCs of 9.0 ng/L[5] for PFHxS; 10.0 ng/L for HFPO–DA; 10.0 ng/L for PFNA; and 2000.0 ng/L for PFBS (USEPA, 2023e).

The EPA requested comment on the feasibility of the proposed Hazard Index MCL, including analytical measurement and treatment capability, as well as reasonable costs, as defined by SDWA.

2. Summary of Major Public Comments and EPA Responses

The EPA received many comments supporting the use of the Hazard Index approach and regulation of additional PFAS. Consistent with these comments, through this action, the agency is establishing drinking water standards for PFHxS, PFNA, HFPO–DA, and PFBS (as well as PFOA and PFOS) to provide health protection against these contaminants found in drinking water. The EPA considered PFAS health effects information, evidence supporting dose additive health concerns from co-occurring PFAS, as well as national and state data for the levels of multiple PFAS in finished drinking water.

A few commenters disagreed with the EPA's feasibility evaluation in setting the MCL at the MCLG (*i.e.,* Hazard Index value of 1.0). Some of these commenters assert that technologies to remove the Hazard Index PFAS are not the same as those that effectively remove PFOA and PFOS. A couple of commenters were concerned that meeting the Hazard Index MCL may require more frequent media change-outs (*e.g.,* GAC), thereby increasing operating costs such that the Hazard Index MCL of 1.0 is not feasible. The agency disagrees with these commenters. As described above in part A of this section for PFOA and PFOS, the agency similarly considered feasibility as defined by SDWA for PFHxS, PFNA, HFPO–DA, and PFBS. First, the EPA established a Hazard Index MCLG as a Hazard Index of 1 for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS. As part of setting the Hazard Index MCLG, the agency defined an HBWC for PFHxS, PFNA, HFPO–DA, and PFBS used in the calculation (see discussion in section IV of this preamble for further information).[6]

In considering the feasibility of setting the MCLs as close as feasible to the MCLG, the EPA first evaluated the (1) the availability of analytical methods to reliably quantify levels of the contaminants in drinking water and (2)

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[5] Some commenters noted an error in the HBWC calculation for PFHxS which was reported as 9.0 ng/L in the proposal. The agency has corrected the value in this NPDWR and within the requirements under 40 CFR part 141 subpart Z. The correct HRL/HBWC for PFHxS is 10 ng/L.

[6] The EPA notes that the HBWC are akin to an MCLG in that they reflect a level below which there are no known or anticipated adverse effects over a lifetime of exposure, including for sensitive populations and life stages, and allows for an adequate margin of safety.

the lowest levels at which contaminants can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions using the approved methods (*i.e.,* the PQLs). The EPA determined that there are available analytical methods approved (*i.e.,* Methods 533 and 537.1, version 2.0) to quantify levels below these HBWC levels. In addition, the PQLs for PFHxS, PFNA, HFPO–DA, and PFBS (between 3.0 to 5.0 ng/L) are all lower than the respective HBWCs used in setting the Hazard Index MCLG for each of these PFAS (10 ng/L for PFHxS, PFNA, and PFHxS, and 2000 ng/L for PFBS). Thus, the PQLs are not a limiting factor in determining the MCL. Second, the EPA evaluated the availability and performance of Best Available Technologies (BATs) for treating water to minimize the presence of these contaminants consistent with the MCLGs (see section X for additional discussion on BATs) as well as the costs of applying those BATs to large metropolitan water systems when treating to that level. The EPA has found the same technologies identified for PFOA and PFOS are also both available and have reliably demonstrated PFAS removal efficiencies that may exceed >99 percent and can achieve concentrations less than the proposed Hazard Index MCL for PFHxS, PFNA, HFPO–DA, and PFBS, and that the cost of applying those technologies is reasonable for large metropolitan water systems. As discussed above, for contaminants where the MCLG is higher than the PQL, the EPA sets the MCL at the MCLG if treatment is otherwise feasible because the PQL is not a limiting factor. In consideration of the availability of feasible treatment technologies, approved analytical methods to reliably quantify levels of the contaminants in drinking water, the EPA's cost analysis, and the fact that the PQLs are below the HBWCs used in setting the Hazard Index MCLG, the agency determines that setting the MCL at the same level as the MCLG for mixtures of PFHxS, PFNA, HFPO–DA and PFBS is feasible. Thus, the EPA is setting the Hazard Index MCL of 1 for mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS. For additional discussion and considerations surrounding BATs, please see section X.A of this preamble. For more information about the EPA's cost estimates, please see section XII of this preamble.

Many commenters support excluding PFOA and PFOS from the Hazard Index MCL. The EPA agrees with these commenters as there are analytical limitations that would complicate including PFOA and PFOS in the Hazard Index. As discussed in section IV of this preamble of the Hazard Index approach, individual PFAS hazard quotients (HQs) are calculated by dividing the measured concentration of each component PFAS in water (*e.g.,* expressed as ng/L) by the corresponding health-based water concentration (HBWC) for each component PFAS (*e.g.,* expressed as ng/L). The HBWC is akin to an MCLG in that they reflect a level below which there are no known or anticipated adverse effects over a lifetime of exposure, including for sensitive populations and life stages, and allows for an adequate margin of safety. Since PFOA and PFOS are likely human carcinogens, the MCLG (and if included in the Hazard Index, the HBWC) for each contaminant is zero. The only feasible way to represent PFOA and PFOS in the Hazard Index approach would be to only consider values for PFOA and PFOS at or above the PQL of 4.0 ng/L, however the level at which no known or anticipated adverse effects on the health of persons would occur is well below the PQL. As a result, any measured concentration above 4.0 ng/L for PFOA and PFOS would result in an exceedance of the Hazard Index MCL. The Hazard Index is intended to capture the aggregate risks of the Hazard Index PFAS when the monitored concentration is above the PQL but below the HBWC. These risks are not relevant to PFOA and PFOS given their PQLs. Because of the PQL considerations discussed in the preceding section V.A of this preamble, the EPA is not including PFOA and PFOS in the final rule Hazard Index. Therefore, the EPA is finalizing individual MCLs for PFOA and PFOS but not including these contaminants in the Hazard Index.

A few commenters provided feedback on the EPA's request for comment regarding the usage of significant figures to express the MCLs. See discussion on this issue in section IV of this preamble above. In summary, after considering public comment, the EPA agrees that one (1) significant digit is appropriate for the individual PFAS for PFHxS, PFNA and HFPO–DA (*i.e.,* 10 ng/L rather than 10.0 ng/L), and Hazard Index MCL (*i.e.,* 1 rather than 1.0).

Some commenters asked about inclusion of other PFAS in the Hazard Index in future revisions. The agency believes the Hazard Index approach can be an adaptive and flexible framework for considering additional PFAS. The EPA is required to review NPDWRs every six years and determine which, if any, need to be revised (*i.e.,* the Six-Year Review Process). The purpose of the review is to evaluate current information for regulated contaminants and to determine if there is any new information on health effects, treatment technologies, analytical methods, occurrence and exposure, implementation and/or other factors that provides a health or technical basis to support a regulatory revision that will improve or strengthen public health protection. This process allows the agency to consider these and other information as appropriate in deciding whether existing NPDWRs should be identified as candidates for revision as required by SDWA.

Many commenters compared the proposed MCLs to existing state and international standards, regulations, and guidelines. In particular, these commenters acknowledge that several states have conducted their own rulemakings to promulgate MCLs and suggest that the EPA's analysis in support of the proposed MCLs is inconsistent with these state approaches. Further, these commenters ask the EPA to explain why certain states' cost-benefit analyses supported their respective levels and why the EPA's analysis is different. Regarding state PFAS regulations, the EPA disagrees with commenters who suggested that the agency should not develop regulations different from state-led actions. SDWA mandates Federal regulation where the EPA determines that a contaminant meets the criteria for regulation under the statute. Moreover, the EPA's rule sets a national standard in accordance with SDWA for certain PFAS in drinking water that provides important protections for all Americans served by PWSs. Please see discussion above in part A under this section for consideration for existing state and international standards.

A few commenters suggest a need for effective data management systems to implement the Hazard Index. These commenters indicated that it will be challenging to implement the Hazard Index as proposed due to the tracking of multiple contaminants and automating these data into existing data management systems. For discussion on rule implementation issues, including primacy agency record keeping and reporting requirements, please see section XI of this preamble.

Some commenters raised concerns that the EPA did not consider a sufficient range of regulatory alternatives. For example, a few commenters contend that the EPA violated 1412(b)(3)(C)(i) of SDWA and the Unfunded Mandates Reform Act (UMRA) because the agency did not identify and consider what they deem a reasonable number of regulatory alternatives for PFHxS, PFNA, HFPO–DA and its ammonium salts, and PFBS. Specifically, these commenters cite that the EPA only considered a single HBWC and did not consider any alternatives to the Hazard Index MCL of 1 itself. The EPA disagrees with these commenters.

SDWA does not require the agency to consider any certain number of alternative MCLs or a range of alternatives. SDWA 1412(b)(3)(C)(i)(IV) only requires that in developing the HRRCA, the agency must consider the ''incremental costs and benefits associated with each alternative maximum contaminant level considered.'' Thus, the agency must conduct a cost-benefit analysis with each alternative MCL that is considered, if any. The EPA maintains that the proposed rule and regulatory alternatives considered at proposal met all requirements to consider alternatives. In the proposed rule, the EPA did not separately present changes in quantified costs and benefits for these approaches because the agency described that including individual MCLs in addition to the Hazard Index approach will be not change costs and benefits relative to the proposal (*i.e.,* the same number of systems will incur identical costs to the proposed option and the same benefits will be realized). For the final rule, the EPA has also estimated the marginal costs for the individual PFHxS, PFNA, and HFPO–DA MCLs in the absence of the Hazard Index (See chapter 5.1.3 and appendix N.4 of the EA for details). The EPA notes that the costs for the individual PFHxS, PFNA, and HFPO–DA MCLs have been considered in this final rule. For further discussion of how the EPA considered the costs of the five individual MCLs and the HI MCL, see section XII.A.4 of this preamble.

The EPA identified and analyzed a reasonable number of regulatory alternatives to determine the MCL requirement in the proposed rule as required by UMRA. UMRA's requirement to identify and consider a reasonable number of regulatory alternatives builds on the assessment of feasible alternatives required in E.O. 12866.[7] Specifically, as described in the proposed rule, the EPA considered an alternative approach to the one proposed that only used the Hazard Index MCL. The proposal took comment on establishing individual MCLs instead of and in addition to using a mixture-based approach for PFHxS, PFNA, HFPO–DA, and/or PFBS in mixtures. In that proposal, the EPA described how a traditional approach may be warranted should the EPA not finalize a regulatory determination for mixtures of these PFAS. Under this alternative, ''the proposed MCLG and MCL for PFHxS would be 9.0 ng/L; for HFPO–DA the MCLG and MCL would be 10.0 ng/L; for PFNA the MCLG and MCL would be 10.0 ng/L; and for PFBS the MCLG and MCL would be 2000.0 ng/L.'' The agency requested comment on these alternatives for PFHxS, PFNA, HFPO–DA, and PFBS and whether these individual MCLs instead of or in addition to the Hazard Index approach would change public health protection, improve clarity of the rule, or change costs. Additionally, the EPA considered alternative mixture-based approaches such as a target organ-specific Hazard Index (TOSHI) or relative potency factor (RPF) approach. The agency requested comment on these approaches. Based on the EPA's technical expertise, the agency determined that the Hazard Index is the most cost-effective and least burdensome alternative for purposes of UMRA because this approach for mixtures that achieves the objectives of the rule because of the level of protection afforded for the evaluation of chemicals with diverse (but in many cases shared) health endpoints. The EPA followed agency chemical mixture guidance (USEPA, 1986; USEPA, 1991b; USEPA, 2000a, which explain that when the Hazard Index value is greater than one (1) then risk is indicated (because exposure exceeds toxicity). The agency did not propose alternative Hazard Index values (*i.e.,* higher Hazard Index values) because the EPA determined that a Hazard Index MCL of 1 is feasible: multiple treatment technologies are available and are found effective to treat to or below the MCL; the costs of applying these technologies to large metropolitan water systems are reasonable; and there are analytical methods available to reliably quantify the four PFAS captured in the Hazard Index MCL. In addition, these alternative Hazard Index or mixture-based approaches would not provide sufficient protection against dose-additive health concerns from co-occurring PFAS. For example, a higher Hazard Index value (*e.g.,* Hazard Index equal to 2) allows for exposure to be greater than the toxicity and will not result in a sufficient health-protective standard that is close as feasible to the MCLG, which is a level at which there are no known or anticipated adverse effects on human health and allows for an adequate margin of safety. The EPA notes that commenters have not provided support justifying an alternative MCL standard for the Hazard Index. For additional discussion on UMRA, please see chapter 9 of USEPA (2024g).

3. Final Rule

Through this action, the EPA is promulgating the Hazard Index MCL for mixtures of two or more of PFHxS, PFNA, HFPO–DA and PFBS. The following equation provides the calculation of the PFHxS, PFNA, HFPO–DA, and PFBS Hazard Index MCL as finalized:

$$HI\ MCL = \left(\frac{[HFPO - DA_{ng/L}]}{[10\ ng/L]}\right) + \left(\frac{[PFBS_{ng/L}]}{[2000\ ng/L]}\right) + \left(\frac{[PFNA_{ng/L}]}{[10\ ng/L]}\right) + \left(\frac{[PFHxS_{ng/L}]}{[10\ ng/L]}\right)$$

Where:

HFPO–DA$_{\text{water}}$ = monitored concentration of HFPO–DA in ng/L;

PFBS$_{\text{water}}$ = monitored concentration of PFBS;

PFNA$_{\text{water}}$ = monitored concentration of PFNA and

PFHxS$_{\text{water}}$ = monitored concentration of PFHxS

The presence of PFBS can only trigger an MCL violation if it is present as part of a mixture with at least one of the other three PFAS (PFHxS, PFNA and

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[7] See OMB Memorandum M–95–09, Guidance for Implementing Title II of S.1.

HFPO–DA). As such, elevated PFBS concentrations that would normally cause a Hazard Index exceedance in isolation will not cause a violation if none of the other three PFAS are present in the mixture. The EPA is promulgating individual MCLs for PFHxS, PFNA, and HFPO–DA as well the Hazard Index MCL for mixtures of PFHxS, PFNA, HFPO–DA and PFBS concurrent with final regulatory determinations for these contaminants (please see section III of this preamble for additional discussion on the EPA's regulatory determinations).

The EPA has determined that it is feasible to set the MCL at the same level as the MCLG for mixtures of PFHxS, PFNA, HFPO–DA and PFBS as current BATs can remove each contaminant to a level equal to or below their respective HBWC. In addition, there are analytical methods available for these contaminants and the PQL for each contaminant is below the level established by the MCLG. The EPA also considered costs and determined that establishing a Hazard Index MCL of 1 is reasonable based on consideration of the costs to large metropolitan water systems. These considerations support a determination that a Hazard Index MCL of 1 for mixtures of two or more of PFHxS, PFNA, HFPO–DA and PFBS is feasible and therefore the EPA is setting the MCL at the same level as the MCLG. The EPA's MCL of 1 establish a ''maximum permissible level of contaminant in water'' because it is a limit for a mixture with PFAS components that must be met before the water enters the distribution system. Public water systems use their monitoring results as inputs into the Hazard Index equation to determine whether they are delivering water to any user that meets the MCL. For additional discussion regarding the derivation of the individual HBWCs and MCLGs, please see discussion in section III and IV of this preamble above.

C. Individual MCLs: PFHxS, PFNA and HFPO–DA

1. Proposal

As described in section V.B of this preamble above, the EPA proposed an MCL for mixtures of PFHxS, PFNA, HFPO–DA and PFBS based on a Hazard Index. The EPA proposed to address its preliminary regulatory determinations for PFHxS, PFNA, HFPO–DA, and/or PFBS and mixtures of these PFAS together through the Hazard Index approach. The proposal defined a mixture as containing one or more of the four PFAS and therefore covered each contaminant individually if only one of the four PFAS occurred. The EPA considered and took comment on establishing individual MCLGs and MCLs in lieu of or in addition to the Hazard Index approach for mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS.

2. Summary of Major Public Comments and EPA Responses

Commenters were mixed on the EPA's request for public comment on the establishment of stand-alone MCLs in lieu of or in addition to the Hazard Index MCL. Many of the comments were related to risk communications and messaging to consumers. While several commenters favored stand-alone MCLs in lieu of the Hazard Index to improve communications to their customers, several other commenters recommended stand-alone MCLs in addition to the Hazard Index MCL to achieve this purpose. Several commenters opposed individual MCLs for some or all of the PFAS because they believe it may complicate risk communication. After consideration of public comments, the EPA is addressing the final individual regulatory determination for PFHxS, HFPO–DA, and PFNA by promulgating individual MCLGs and NPDWRs for PFHxS, HFPO–DA, and PFNA. The EPA is addressing the final mixture regulatory determination by promulgating a Hazard Index MCLG and NPDWR for mixtures containing two or more of PFHxS, PFNA, HFPO–DA, and PFBS. This approach avoids confusion caused by the EPA's proposal that covered all the preliminary regulatory determinations in one Hazard Index standard. The EPA agrees that proper risk communication is an important focus for water systems and believes that finalizing individual MCLs for PFHxS, PFNA and HFPO–DA may help support risk communication as utilities and the public may be more familiar with this regulatory framework. At the same time, since those individual MCLs do not address additional risks from co-occurring PFAS, the EPA is finalizing a Hazard Index MCL to address dose additive health concerns associated with mixtures of two or more of PFHxS, PFNA, HFPO–DA, and PFBS that co-occur in drinking water. For additional discussion on the Hazard Index approach and other mixture-based approaches (*e.g.,* TOSHI), please see section IV of this preamble above.

3. Final Rule

The EPA is promulgating individual MCLs for PFHxS, PFNA and HFPO–DA at the same level as their respective MCLGs (which are equivalent to the HBWCs). The EPA is finalizing individual MCLs as follows: HFPO–DA MCL = 10 ng/L; PFHxS MCL = 10 ng/L; and PFNA MCL = 10 ng/L. The EPA is promulgating individual MCLs for PFHxS, PFNA, and HFPO–DA as well the Hazard Index MCL for mixtures of PFHxS, PFNA, HFPO–DA and PFBS concurrent with final determinations for these contaminants (please see section III of this preamble for additional discussion on the EPA's regulatory determinations).

The agency considered feasibility as defined by SDWA and the EPA's feasibility justification for these individual PFHxS, PFNA and HFPO–DA MCLs are the same and based on the same information as the Hazard Index MCL discussed in V.B above. The EPA further notes that the Hazard Index MCLG applies to the entire mixture but the EPA's technical justification for the underlying values (*i.e.,* HBWCs) are the same as the individual MCLGs in this rule. In summary, the EPA has determined that it is feasible to set the individual MCLs at the MCLGs for PFHxS, PFNA and HFPO–DA because current BATs can remove each contaminant to a level equal to or below their respective MCLGs. In addition, there are analytical methods available for these contaminants and the practical quantitation level (PQL) for each contaminant is below the level established by the MCLG. The EPA also considered costs and determined that establishing individual MCLs of 10 ng/L for PFHxS, PFNA, and HFPO–DA is reasonable based on consideration of the costs to large metropolitan water systems. These considerations support a determination that individual MCLs of 10 ng/L for PFHxS, PFNA, and HFPO–DA are feasible and therefore the EPA is setting the MCL at the same level as the MCLG. For additional discussion regarding the derivation of the individual HBWCs and MCLGs, please see section III and IV of this preamble above.

VI. Occurrence

The EPA relied on multiple data sources, including Unregulated Contaminant Monitoring Rule (UCMR) 3 and state finished water data, to evaluate the occurrence of PFOA, PFOS, PFHxS, PFNA, and HFPO–DA and probability of co-occurrence of these PFAS and PFBS. The EPA also incorporated both the UCMR 3 and some state data into a Bayesian hierarchical model which supported exposure estimates for select PFAS at lower levels than were measured under UCMR 3. The EPA has utilized similar statistical approaches in past regulatory actions to inform its decision making, particularly where a contaminant's occurrence is at low concentrations

(USEPA, 2006c). The specific modeling framework used to inform this regulatory action is based on the peer-reviewed model published in Cadwallader et al. (2022). Collectively, these data and the occurrence model informed estimates of the number of water systems (and associated population) expected to be exposed to levels of the final and proposed alternative MCLs for PFOA and PFOS, the final MCLs for PFHxS, PFNA, and HFPO–DA, and the final Hazard Index MCL for PFHxS, PFNA, HFPO–DA, and PFBS.

The EPA notes that, as described in sections III and V of this preamble, the EPA is finalizing individual Maximum Contaminant Levels (MCLs) for three of the four Hazard Index PFAS (PFHxS, PFNA, and HFPO–DA) at 10 ng/L each. An analysis of occurrence relative to HRLs for PFHxS, PFNA, and HFPO–DA (which are the same as the final individual MCLs for these compounds at 10 ng/L) using UCMR 3 data and updated state datasets is presented in section III.C of this preamble and further described in the *Occurrence Technical Support Document* (USEPA, 2024b). The information in the following sections supports the agency's finding that PFHxS, PFNA, and HFPO–DA occur at a frequency and level of public health concern as discussed in section III.C of this preamble.

A. UCMR 3

1. Proposal

UCMR 3 monitoring occurred between 2013 and 2015 and is currently the best nationally representative finished water dataset for any PFAS, including PFOA, PFOS, PFHxS, PFNA, and PFBS. Under UCMR 3, 36,972 samples from 4,920 public water systems (PWSs) were analyzed for these five PFAS. PFOA was found above the UCMR 3 minimum reporting level (20 ng/L) in 379 samples at 117 systems serving a population of approximately 7.6 million people located in 28 states, Tribes, or U.S. territories. PFOS was found in 292 samples at 95 systems above the UCMR 3 minimum reporting level (40 ng/L). These systems serve a population of approximately 10.4 million people located in 28 states, Tribes, or U.S. territories. PFHxS was found above the UCMR 3 minimum reporting level (30 ng/L) in 207 samples at 55 systems that serve a population of approximately 5.7 million located in 25 states, Tribes, and U.S. territories. PFBS was found in 19 samples at 8 systems above the UCMR 3 minimum reporting level (90 ng/L). These systems serve a population of approximately 350,000 people located in 5 states, Tribes, and U.S. territories. Lastly, PFNA was found above the UCMR 3 minimum reporting level (20 ng/L) in 19 samples at 14 systems serving a population of approximately 526,000 people located in 7 states, Tribes, and U.S. territories.

2. Summary of Major Public Comments and EPA Responses

Some commenters supported the EPA's use of the best available public health information including data from UCMR 3 and state occurrence data. A few commenters criticized the use of UCMR 3 data, stating that the data suffer from limitations. These commenters expressed concern over the high minimum reporting levels, the exclusion of many small systems, and the lack of national monitoring of HFPO–DA. Some of these commenters assert that UCMR 3 does not represent best available occurrence data for this rule. The EPA disagrees with these commenters. While UCMR 3 does have higher reporting limits than those available through current analytical methods, the data still provides the best available nationwide occurrence data to inform the occurrence and co-occurrence profile for the regulated PFAS for which monitoring was conducted. These data are also a critical component of the EPA's model to estimate national level occurrence for certain PFAS and ensure it is nationally representative (see subsection E of this section). The EPA also disagrees that the UCMR 3 excludes small water systems as it included a statistically selected, nationally representative sample of 800 small drinking water systems. Regarding commenter concerns for lack of UCMR monitoring data on HFPO–DA, the agency notes that the EPA examined recent data collected by states who have made their data publicly available. A discussion of these data and public comments on this information is presented in sections III.C and VI.B of this preamble.

3. Final Rule

After considering public comment, the EPA maintains that UCMR 3 data are the best available, complete nationally representative dataset and they play an important role in supporting the EPA's national occurrence analyses, demonstrating occurrence and co-occurrence of the monitored PFAS in drinking water systems across the country that serve millions of people.

B. State Drinking Water Data

1. Proposal

The agency has supplemented the UCMR 3 data with more recent data collected by states who have made their data publicly available. In general, the large majority of these more recent state data were collected using newer EPA-approved analytical methods and state results reflect lower reporting limits than those in the UCMR 3. State results show continued occurrence of PFOA, PFOS, PFHxS, PFNA, and PFBS in multiple geographic locations. These data also show these PFAS occur at lower concentrations and significantly greater frequencies than were measured under the UCMR 3 (likely because the more recent monitoring was able to rely on more sensitive analytical methods). Furthermore, these state data include results for more PFAS than were included in the UCMR 3, including HFPO–DA.

At the time of proposal, the EPA evaluated publicly available state monitoring data from 23 states, representing sampling conducted on or before May 2021. The EPA acknowledged that the available data were collected under varying circumstances; for example, targeted vs. non-targeted monitoring (*i.e.,* monitoring not conducted specifically in areas of known or potential contamination). Due to the variability in data quality, the EPA further refined this dataset based on representativeness and reporting limitations, resulting in detailed technical analyses using a subset of the available state data. A comprehensive discussion of all the available state PFAS drinking water occurrence data was included in the *Occurrence Technical Support Document* (USEPA, 2023l).

2. Summary of Major Public Comments and EPA Responses

Commenters generally supported the use of state datasets. A few commenters discussed their own PFAS occurrence data, some of which were provided to the EPA, relative to the EPA's proposed regulatory levels and/or provided summaries of other monitoring efforts. Where possible, the EPA presents this information within its occurrence analysis—see the *Other Data* sections of USEPA (2024b). A few commenters recommended that the EPA expand the datasets used for the final rule to include additional and updated state sampling information. The EPA agrees with these suggestions to rely on additional and updated sampling information in order to evaluate PFAS occurrence in drinking water. Therefore, the agency has included updated information in its occurrence analyses as described in section VI.B.3 of this preamble. The EPA notes that this information is consistent with the analyses contained in the proposal for this action.

A few commenters criticized the use of state datasets in occurrence analyses. These commenters claimed that the state datasets were insufficient for national extrapolation and not dependable due to being collected under variable circumstances. These commenters expressed the need for enhanced quality control (QC) by the EPA to exclude data below reasonable reporting thresholds. The agency disagrees with commenters who contend that state datasets are insufficient for national extrapolation. For both the rule proposal and this final action, the EPA took QC measures to ensure the EPA used the best available data for national extrapolation. For example, the EPA acknowledged in the proposal that states used various reporting thresholds when presenting their data, and for some states there were no clearly defined reporting limits. The EPA identified state reporting thresholds where possible and, when appropriate, incorporated individual state-specific thresholds when conducting data analyses. For other states, the EPA presented the data as provided by the state. Due to the reporting limitations of some of the available state data (*e.g.,* reporting combined analyte results rather than individual analyte results), the EPA did not utilize all of these data in the subsequent occurrence analyses/co-occurrence analyses. Specific data analysis criteria (*e.g.,* separation of non-targeted and targeted monitoring results) were also applied. Additionally, the agency also verified that the vast majority of the data were collected using EPA-approved methods. Further, the EPA reviewed all available data thoroughly to ensure that only finished drinking water data were presented. A description of the scope and representativeness of the state data was provided in the proposal of this action in the *PFAS Occurrence and Contaminant Background Support Document* (USEPA, 2023l). These include describing the states the EPA found to have publicly available data, identifying the reporting thresholds where possible, and distinguishing whether monitoring was non-targeted or targeted (*i.e.,* monitoring in areas of known or potential PFAS contamination). These QC measures ensured that the EPA utilized the best available data for national extrapolation.

3. Final Rule

In the proposed rule preamble, the EPA discussed how states may have updated data available and that additional states have or intend to conduct monitoring of finished drinking water and that the agency would consider these additional data to inform this final regulatory action. After consideration of all the public comments on this issue, the EPA has updated its analysis of state monitoring data by including results that were available as of May 2023. This updated state dataset includes publicly available data from 32 states: Alabama, Arizona, California, Colorado, Delaware, Georgia, Idaho, Illinois, Indiana, Iowa, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, Pennsylvania, South Carolina, Tennessee, Vermont, Virginia, West Virginia, and Wisconsin. The dataset includes data from 9 states that were not available at the time of proposal.

Tables 4 and 5 in this section demonstrate the number and percent of samples with PFOA and PFOS based on state-reported detections, and the number and percent of systems with PFOA and PFOS based on state-reported detections, respectively, for the non-targeted state finished water monitoring data. Section III.B. of this preamble describes the state reported finished water occurrence data for PFHxS, PFNA, HFPO–DA, and PFBS data.

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Table 4. Non-Targeted State PFOS and PFOA Finished Water Data – Summary of Samples with State Reported Detections[1]

State	PFOS state reported sample detections	PFOS state reported sample detection (percent)	PFOA state reported sample detections	PFOA state reported sample detections (percent)
Alabama[2]	249	N/A	176	N/A
Colorado	60	10.3%	54	9.3%
Illinois	306	14.3%	298	14.0%
Indiana	8	1.7%	8	1.7%
Kentucky	33	40.7%	24	29.6%
Maine	101	14.3%	142	20.1%
Maryland	17	19.3%	20	22.7%
Massachusetts	4432	47.4%	5363	57.4%
Michigan	489	4.6%	557	5.2%
Missouri	22	9.2%	17	7.1%
New Hampshire	495	27.3%	1010	55.7%
New Jersey	6502	40.9%	8063	50.7%
New York	1576	22.3%	1751	24.8%
North Dakota	3	2.6%	2	1.7%
Ohio	113	5.8%	116	6.0%
South Carolina	135	17.6%	141	18.3%
Tennessee	0	0.0%	0	0.0%
Vermont	192	12.3%	225	14.4%
Wisconsin	187	23.9%	167	21.2%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] State only reported detections (i.e., there was no information on total number of samples collected)

Table 5: Non-Targeted State PFOS and PFOA Finished Water Data – Summary of Monitored Systems with State Reported Detections[1]

State	PFOS Monitored Systems with State Reported Detections	PFOS Monitored Systems with State Reported Detections (Percent)	PFOA Monitored Systems with State Reported Detections	PFOA Monitored Systems with State Reported Detections (Percent)
Alabama[2]	88	N/A	65	N/A
Colorado	50	12.6%	45	11.3%
Illinois	73	7.3%	67	6.7%
Indiana	7	1.9%	8	2.2%
Kentucky	30	40.5%	22	29.7%
Maine	94	14.6%	132	20.4%
Maryland	9	14.3%	10	15.9%
Massachusetts	417	31.4%	520	39.1%
Michigan	105	4.2%	135	5.4%
Minnesota	55	9.5%	69	12.0%
Missouri	11	8.8%	7	5.6%
New Hampshire	189	33.8%	310	55.4%
New Jersey	541	48.2%	625	55.7%
New York	496	26.3%	558	29.6%
North Dakota	6	5.4%	7	6.3%
Ohio	29	2.0%	33	2.2%
South Carolina	80	26.7%	85	28.3%
Tennessee	0	0.0%	0	0.0%
Vermont	38	6.7%	49	8.7%
Wisconsin	70	29.3%	66	27.6%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] State only reported detections (i.e., there was no information on total number of samples collected)

As illustrated in Tables 4 and 5, there is a wide range in PFOA and PFOS results between states. Nonetheless, more than one-third of states that conducted non-targeted monitoring observed PFOA and/or PFOS at more than 25 percent of systems. Among the detections, PFOA concentrations ranged from 0.21 to 650 ng/L with a range of median concentrations from 1.27 to 5.61 ng/L, and PFOS concentrations ranged from 0.24 to 650 ng/L with a range of median concentrations from 1.21 to 12.1 ng/L.

Monitoring data for PFOA and PFOS from states that conducted targeted monitoring efforts, including 15 states, demonstrate results consistent with the non-targeted state monitoring. For example, in Pennsylvania, 26.3 and 24.9 percent of monitored systems found PFOA and PFOS, respectively, with reported concentrations of PFOA ranging from 1.7 to 59.6 ng/L and PFOS ranging from 1.8 to 94 ng/L. California reported 35.8 and 39.0 percent of monitored systems found PFOA and PFOS, respectively, including reported concentrations of PFOA ranging from 0.9 to 190 ng/L and reported concentrations of PFOS from 0.4 to 250 ng/L. In Maryland, PFOA and PFOS were found in 57.6 and 39.4 percent of systems monitored, respectively, with reported concentrations of PFOA ranging from 1.02 to 23.98 ng/L and reported concentrations of PFOS ranging from 2.05 to 235 ng/L. In Iowa, PFOA and PFOS were found in 11.2 and 12.1 percent of systems monitored, respectively, with reported concentrations of PFOA ranging from 2 to 32 ng/L and reported concentrations of PFOS ranging from 2 to 59 ng/L.

As discussed above in section V of this preamble, the EPA is finalizing individual MCLs of 4.0 ng/L for PFOA and PFOS, individual MCLs for PFHxS, PFNA, and HFPO–DA, and a Hazard Index level of 1 for PFHxS, PFNA, HFPO–DA, and PFBS. The EPA also evaluated occurrence for the regulatory alternatives discussed in section V of this preamble, including alternative MCLs for PFOA and PFOS of 5.0 ng/L and 10.0 ng/L. Table 6, Table 7, and Table 8 demonstrate, based on available state data, the total reported number and percentages of monitored systems that exceed these proposed and alternative MCL values across the non-targeted state finished water monitoring data.

Table 6: Non-Targeted State PFOS and PFOA Finished Water Data – Summary of Monitored Systems with State Reported Detections[1] ≥ 4.0 ng/L

State	PFOS Monitored Systems with State Reported Detections	PFOS Monitored Systems with State Reported Detections (Percent)	PFOA Monitored Systems with State Reported Detections	PFOA Monitored Systems with State Reported Detections (Percent)
Alabama[2]	64	N/A	36	N/A
Colorado	22	5.5%	18	4.5%
Illinois	30	3.0%	22	2.2%
Indiana	1	0.3%	1	0.3%
Kentucky	4	5.4%	9	12.2%
Maine	48	7.4%	76	11.8%
Maryland	9	14.3%	8	12.7%
Massachusetts	261	19.6%	335	25.2%
Michigan	40	1.6%	47	1.9%
Minnesota	8	1.4%	15	2.6%
Missouri	3	2.4%	3	2.4%
New Hampshire	107	19.1%	210	37.5%
New Jersey	356	31.7%	457	40.7%
New York	201	10.7%	217	11.5%
North Dakota	0	0.0%	0	0.0%
Ohio	29	2.0%	33	2.2%
South Carolina	45	15.0%	52	17.3%
Tennessee	0	0.0%	0	0.0%
Vermont	20	3.5%	27	4.8%
Wisconsin	12	5.0%	11	4.6%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] State only reported detections (i.e., there was no information on total number of samples collected)

Table 7: Non-Targeted State PFOS and PFOA Finished Water Data – Summary of Monitored Systems with State Reported Detections[1] ≥ 5.0 ng/L

State	PFOS Monitored Systems with State Reported Detections	PFOS Monitored Systems with State Reported Detections (Percent)	PFOA Monitored Systems with State Reported Detections	PFOA Monitored Systems with State Reported Detections (Percent)
Alabama[2]	53	N/A	30	N/A
Colorado	16	4.0%	14	3.5%
Illinois	23	2.3%	13	1.3%
Indiana	1	0.3%	1	0.3%
Kentucky	3	4.1%	4	5.4%
Maine	38	5.9%	67	10.4%
Maryland	5	7.9%	8	12.7%
Massachusetts	220	16.5%	280	21.0%
Michigan	36	1.4%	35	1.4%
Minnesota	7	1.2%	12	2.1%
Missouri	2	1.6%	3	2.4%
New Hampshire	86	15.4%	186	33.2%
New Jersey	306	27.2%	409	36.4%
New York	154	8.2%	183	9.7%
North Dakota	0	0.0%	0	0.0%
Ohio	29	2.0%	33	2.2%
South Carolina	36	12.0%	38	12.7%
Tennessee	0	0.0%	0	0.0%
Vermont	16	2.8%	23	4.1%
Wisconsin	10	4.2%	5	2.1%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] State only reported detections (i.e., there was no information on total number of samples collected)

Table 8: Non-Targeted State PFOS and PFOA Finished Water Data – Summary of Monitored Systems with State Reported Detections[1] ≥ 10.0 ng/L

State	PFOS Monitored Systems with State Reported Detections	PFOS Monitored Systems with State Reported Detections (Percent)	PFOA Monitored Systems with State Reported Detections	PFOA Monitored Systems with State Reported Detections (Percent)
Alabama[2]	34	N/A	18	N/A
Colorado	3	0.8%	2	0.5%
Illinois	5	0.5%	7	0.7%
Indiana	0	0.0%	0	0.0%
Kentucky	1	1.4%	1	1.4%
Maine	10	1.5%	32	5.0%
Maryland	5	7.9%	7	11.1%
Massachusetts	112	8.4%	123	9.2%
Michigan	16	0.6%	17	0.7%
Minnesota	2	0.3%	4	0.7%
Missouri	0	0.0%	1	0.8%
New Hampshire	39	7.0%	83	14.8%
New Jersey	159	14.2%	223	19.9%
New York	57	3.0%	64	3.4%
North Dakota	0	0.0%	0	0.0%
Ohio	21	1.4%	15	1.0%
South Carolina	12	4.0%	8	2.7%
Tennessee	0	0.0%	0	0.0%
Vermont	7	1.2%	7	1.2%
Wisconsin	8	3.3%	0	0.0%

Notes:

[1] Detections determined by individual state reported limits which are not defined consistently across all states.

[2] State only reported detections (i.e., there was no information on total number of samples collected)

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Based on the available state data presented in Table 6, Table 7, and Table 8, within 20 states that conducted non-targeted monitoring there are 1,260 systems with results above the PFOS MCL of 4.0 ng/L and 1,577 systems with results above the PFOA MCL of 4.0 ng/L. These systems serve populations of 12.5 and 14.4 million people, respectively. As expected, the number of systems exceeding either of the proposed alternative MCLs decreases as the values are higher; however, even at the highest alternative PFOS and PFOA MCL values of 10.0 ng/L, there are still 491 and 612 systems with exceedances, serving populations of approximately 5.3 and 6.0 million people, respectively.

Monitoring data for PFOA and PFOS from states that conducted targeted sampling efforts shows additional systems that would exceed the final and alternative MCLs. For example, in California, Maine, Maryland, and Pennsylvania, 30.9 percent (38 PWSs), 27.8 percent (5 PWSs), 25 percent (18 PWSs), and 19.3 percent (66 PWSs) of monitored systems reported results above the proposed PFOS MCL of 4.0 ng/L, respectively, and 29.3 percent (36 PWSs), 27.8 percent (5 PWSs), 25 percent (18 PWSs), and 21.1 percent (72 PWSs) of monitored systems reported results above the proposed PFOA MCL of 4.0 ng/L, respectively. While these frequencies may be anticipated given the sampling locations, within only these four states that conducted limited, targeted monitoring, the monitored systems with results above the proposed PFOS MCL and proposed PFOA MCL serve significant populations of approximately 5.7 million people and approximately 5.6 million people, respectively.

C. PFAS Co-Occurrence

While the discussions in sections III.B, VI.A. and VI.B of this preamble describe how PFOA, PFOS, PFHxS, PFNA, and HFPO–DA occur individually, numerous studies and analyses have documented that PFAS co-occur in finished drinking water (Adamson et al., 2017; Cadwallader et al., 2022; Guelfo and Adamson, 2018). As discussed in section V of this preamble, the EPA is finalizing regulation of mixtures that include at least two of PFHxS, PFNA, HFPO–DA, and PFBS (collectively referred to as ''Hazard Index PFAS'') as part of a Hazard Index approach.

1. Proposal

In the March 2023 proposal preamble, the EPA presented occurrence data that illustrated the extent to which PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS co-occur in drinking water. Co-occurrence analyses primarily utilized available non-targeted state PFAS finished drinking water data, though UCMR 3 data analysis is presented in the *PFAS Occurrence and Contaminant Background Support Document* (USEPA, 2024b). The EPA also conducted two separate analyses using state datasets to determine the extent to which these six PFAS co-occur: a groupwise analysis and a pairwise analysis.

When analyzing PFAS co-occurrence, groupwise analysis is important for determining whether the presence of PFOA and PFOS provides insight regarding the likelihood of Hazard Index PFAS being present as well, which has broad implications for public health. This is because occurrence information for the Hazard Index PFAS is less extensive than the occurrence information for PFOA and PFOS due to fewer states monitoring the Hazard Index PFAS; therefore, establishing co-occurrence with PFOA and PFOS helps with understanding the extent of general Hazard Index PFAS occurrence. For the groupwise analysis, the six PFAS were separated into two groups—one consisted of PFOS and PFOA and the other group included the four Hazard Index PFAS. The analysis broke down the systems and samples according to whether chemicals from the respective groups were detected. Results were also shown separated by state. Results generally indicated that when PFOA or PFOS were found, Hazard Index PFAS were considerably more likely to also be found. This implies that, for systems that only measured PFOA and/or PFOS, detected those PFAS, and did not measure the Hazard Index PFAS, the Hazard Index PFAS are more likely to also be present than if PFOA and/or PFOS were not detected. At a national level, since many systems monitored for PFOA and PFOS only and detected these PFAS, this means that estimates of Hazard Index PFAS occurrence based on state Hazard Index PFAS data alone are likely to be underestimated. Given that the state datasets varied in the specific PFAS that were monitored, the analysis also compared the number of Hazard Index PFAS analyzed with the number of Hazard Index PFAS reported present. As more Hazard Index PFAS were analyzed, more Hazard Index PFAS were found. Further, systems and samples where Hazard Index PFAS were found were more likely to find multiple Hazard Index PFAS than a single Hazard Index PFAS (when monitoring for 3 or 4 Hazard Index PFAS).

Given that the groupwise co-occurrence analysis established that the Hazard Index PFAS, as a group, occur with a substantial level of frequency, particularly alongside PFOA or PFOS, the pairwise co-occurrence is relevant for understanding how the individual PFAS included in the rule co-occur with each other. The pairwise co-occurrence analysis explored the odds ratios for each unique pair of PFAS included in the regulation. Pairwise co-occurrence through odds ratios showed statistically significant relationships between nearly all unique pairs of PFAS included in the proposed rule. Odds ratios reflect the change in the odds of finding one chemical (*e.g.,* Chemical A) given that the second chemical (*e.g.,* Chemical B) is known to be present compared to the odds of finding it if the second chemical is not present. For example, an odds ratio of 2 would indicate that the presence of the second chemical would be expected to double the odds of the first chemical being reported present. An odds ratio of 1 indicates that there is no association between the two chemicals. At the system level, point odds ratios estimates ranged from 1.7–142.7, indicating that in some instances the odds of finding one PFAS increased by more than two orders of magnitude if the other PFAS was reported present (in other words, for some PFAS combinations, if one PFAS is present, there is more than 100 times the odds of certain other PFAS being present). HFPO–DA and PFHxS was the only pair of PFAS chemicals included in the proposed regulation that did not have a statistically significant relationship; 1 fell within the 95 percent confidence interval, indicating that the odds ratio was not determined to be statistically significantly different from 1.

In the proposed rule, the agency determined that, both as a group and as individual chemicals, the Hazard Index PFAS had a higher likelihood of being reported if PFOS or PFOA were present, First, the groupwise analysis established that the Hazard Index PFAS, in addition to PFOA and PFOS, occur at a significant frequency in drinking water. Then, the pairwise analysis demonstrated that PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS (the individual PFAS) generally co-occur with each other, as opposed to occurring independently. These data further support the EPA's finding that these PFAS are likely to occur, and that there is a substantial likelihood that combinations of PFHxS, PFNA, HFPO–DA, and PFBS co-occur in mixtures with a frequency of public health concern in drinking water systems.

2. Summary of Major Public Comments and EPA Responses

Some commenters agreed with the agency's conclusion in the March 2023 proposal that the PFAS included in the regulation appeared to meaningfully co-occur. However, some other commenters stated that they believed the data used to assess PFAS co-occurrence were too limited to make substantive conclusions. The EPA disagrees that the data were too limited or that the co-occurrence analysis was inconclusive. Based on the non-targeted state monitoring data used in the co-occurrence analysis (from 11 states), findings of the pairwise and groupwise analyses established a strong likelihood that these chemicals meaningfully co-occur in drinking water. This was observed through odds ratios statistically significantly greater than 1 in the pairwise analysis as well as frequency at which multiple chemicals were detected in the groupwise analysis. Based on public comment, the agency has updated its analysis to include more recent non-targeted state data that became publicly available after the proposal analyses were finalized. This ensures that findings are up to date; as discussed further in the following subsection, the more recent data confirms the proposal analysis.

3. Final Rule

After considering public comment and updating analyses, the EPA concluded that the co-occurrence analyses continue to support the premise in the proposed rule that PFAS are likely to co-occur and support the EPA's final rule approach. Following is a discussion and presentation of information related to the EPA's co-occurrence analysis for this final rule effort. These data include all data from the rule proposal, in addition to the updated data the EPA incorporated based on public comment. As discussed elsewhere in this preamble, the newer data confirm the EPA's conclusions from proposal.

a. Groupwise Chemical Co-Occurrence

Table 9 shows the distribution of systems and samples according to whether states reported detections for any Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS) and whether they also reported detections of PFOS or PFOA. USEPA (2024b) provides additional information for this analysis.

Table 9: Non-Targeted State PFAS Finished Water Data – Samples and Systems Binned According to Whether PFOS or PFOA were Reported by States and Whether Additional Hazard Index PFAS were Reported

Type	No PFOS or PFOA Reported		PFOS or PFOA Reported		Total Count
	No HI PFAS Reported	At Least One HI PFAS Reported	No HI PFAS Reported	At Least One HI PFAS Reported	
Samples	28,249 (57.8%)	1,321 (2.7%)	7,365 (15.1%)	11,954 (24.5%)	48,889
Systems	8,576 (70.6%)	401 (3.3%)	1,079 (8.9%)	2,089 (17.2%)	12,145

Considering eligible samples and systems within the aggregated state dataset, states reported either PFOA, PFOS, or one or more Hazard Index PFAS in 42.2 percent (20,640 of 48,889) of samples and 29.4 percent (3,569 of 12,145) of systems. When any PFAS (among PFOA, PFOS, and the Hazard Index PFAS) were reported, at least one Hazard Index PFAS was also reported in 64.3 percent (13,275 of 20,640) of samples and at 69.8 percent (2,490 of 3,569) of systems. Further, among samples and systems that reported PFOS or PFOA, at least one Hazard Index PFAS was reported in 61.9 percent (11,954 of 19,319) of samples and at 65.9 percent (2,089 of 3,168) of systems. This demonstrated strong co-occurrence of Hazard Index PFAS with PFOA and PFOS and a substantial likelihood (over 60 percent) of at least one Hazard Index PFAS being present at systems reporting the presence of PFOS or PFOA. Overall, one or more Hazard Index PFAS were reported at about 20.5 percent (2,490 of 12,145) of systems included in the aggregated state dataset of non-targeted monitoring. If this percentage were extrapolated to the nation, one or more Hazard Index PFAS would be found in over 13,000 systems. Table 10 shows the distribution of systems in a similar manner but provides a breakdown by state and includes only systems that monitored for either three or four of the Hazard Index PFAS.

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Table 10: Non-Targeted State PFAS Finished Water Data – Systems that Sampled for 3 or 4 Hazard Index PFAS Binned According to Whether PFOS or PFOA were Reported and Whether Any Additional Hazard Index PFAS were Reported by State

State	**No PFOA/S Reported**		**PFOA/S Reported**		**Total System Count**
	No HI Reported	**HI Reported**	**No HI Reported**	**HI Reported**	
CO	270 (68.0%)	26 (6.5%)	11 (2.8%)	90 (22.7%)	397
IL	880 (88.4%)	28 (2.8%)	25 (2.5%)	63 (6.3%)	996
IN	339 (91.4%)	19 (5.1%)	6 (1.6%)	7 (1.9%)	371
KY	38 (51.4%)	3 (4.1%)	17 (23.0%)	16 (21.6%)	74
MA	479 (36.5%)	33 (2.5%)	146 (11.1%)	655 (49.9%)	1,313
MD	51 (81.0%)	0 (0.0%)	3 (4.8%)	9 (14.3%)	63
ME	469 (73.2%)	12 (1.9%)	84 (13.1%)	76 (11.9%)	641
MI	2,205 (87.9%)	130 (5.2%)	66 (2.6%)	107 (4.3%)	2,508
MO	102 (90.3%)	2 (1.8%)	4 (3.5%)	5 (4.4%)	113
ND	99 (89.2%)	9 (8.1%)	0 (0.0%)	3 (2.7%)	111
NH	64 (27.0%)	13 (5.5%)	68 (28.7%)	92 (38.8%)	237
NJ	227 (34.1%)	7 (1.1%)	142 (21.4%)	289 (43.5%)	665
NY	275 (40.1%)	15 (2.2%)	132 (19.2%)	264 (38.5%)	686
OH	1,397 (94.5%)	31 (2.1%)	25 (1.7%)	26 (1.8%)	1,479
SC	187 (62.8%)	11 (3.7%)	28 (9.4%)	72 (24.2%)	298
TN	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1
VT	492 (87.2%)	14 (2.5%)	26 (4.6%	32 (5.7%)	564
WI	140 (60.1%)	24 (10.3%)	10 (4.3%)	59 (25.3%)	233

Tennessee only had data from one system which did not report the presence of any of the six PFAS. Otherwise, the percentage of systems included in Table 10 that reported any Hazard Index PFAS ranged from 3.9 to 52.4 percent of systems when broken down by state, with eight states exceeding 20 percent of systems. The percentage of systems that reported any PFAS ranged from 5.5 to 73.0 percent. Many systems and/or samples that were included in the aggregated state dataset did not monitor for all four Hazard Index PFAS. It is possible that more systems would have reported the presence of Hazard Index PFAS if they had monitored for all four Hazard Index PFAS. Additionally, as demonstrated in Table 10, when PFOA and/or PFOS were reported, at least one of the Hazard Index PFAS chemicals were also frequently reported. For systems that did not measure Hazard Index PFAS but measured and detected PFOA and/or PFOS, the groupwise analysis demonstrates that the Hazard Index PFAS were more likely to have been present in those systems as well. Table 11 presents system counts for systems where PFOS or PFOA were reported according to a) how many Hazard Index PFAS were monitored and b) how many Hazard Index PFAS were reported present.

Table 11: Non-Targeted State PFAS Finished Water Data – System Counts According to Hazard Index PFAS Analyzed and Reported Present for Systems Where PFOS and PFOA were Reported

HI Analyzed	HI Reported Present					Total
	0	1	2	3	4	
1	148 (65.5%)	78 (34.5%)	-	-	-	226
2	138 (48.6%)	85 (29.9%)	61 (21.5%)	-	-	284
3	282 (36.5%)	183 (25.0%)	183 (25.0%	84 (11.5%)	-	732
4	511 (26.5%)	449 (23.3%)	668 (34.7%)	278 (14.4%)	20 (1.0%)	1,926
Total	1,079	795	912	362	20	

Among systems that reported the presence of PFOS and/or PFOA, the fraction of systems that also reported any Hazard Index PFAS tended to increase as systems monitored for more of the Hazard Index PFAS. At systems monitoring for a single Hazard Index PFAS, 34.5 percent reported a positive result at some point during sampling. This increased to 73.5 percent of systems reporting the presence of at least one Hazard Index PFAS when monitoring for all four Hazard Index PFAS. Not only did the fraction of systems reporting the presence of any Hazard Index PFAS increase as the number of Hazard Index PFAS monitored increased, so did the number of Hazard Index PFAS that were reported as present. When four Hazard Index PFAS were monitored, nearly 50 percent of systems reported the presence of two to three of the Hazard Index PFAS. Thus, if PFOS or PFOA are reported, there is a reasonable likelihood that multiple Hazard Index PFAS would be present as well.

b. Pairwise Chemical Co-Occurrence

In addition to considering the co-occurrence of six PFAS as two groups, the EPA conducted a pairwise analysis to further explore co-occurrence relationships. Table 12 shows the calculated system-level odds ratios for every unique pair of PFAS chemicals evaluated. The equation for calculating odds ratios is symmetrical. Because of this, in a given row it does not matter which chemical is ''Chemical A'' and which is ''Chemical B.'' Additional information on odds ratios may be found in USEPA (2024b) and a brief explanation is described following Table 12 as well as in section III.C of this preamble.

Table 12: Non-Targeted State PFAS Finished Water Data – System-level Counts of Pairwise Chemical Occurrence and Odds Ratios Calculated from Aggregated State Dataset PFAS Samples for PFOA, PFOS, and HI PFAS

Chem A	**Chem B**	**Chems A and B Reported**	**Only Chem B Reported**	**Only Chem A Reported**	**Neither Chem Reported**	**Odds Ratio [95% CI]**
HFPO-DA	PFBS	33	1,532	21	7,614	7.8 [4.5-13.5]
HFPO-DA	PFHxS	23	1,137	31	8,007	5.2 [3.1-8.9]
HFPO-DA	PFNA	20	327	34	8,818	15.9 [9.1-27.7]
HFPO-DA	PFOA	39	1,665	16	7,480	11.0 [6.2-19.5]
HFPO-DA	PFOS	37	1,530	18	7,613	10.2 [5.9-17.9]
PFBS	PFHxS	1,282	245	721	9,093	66.0 [56.4-77.2]
PFBS	PFNA	423	85	1,510	8,735	28.8 [22.7-36.6]
PFBS	PFOA	1,605	852	401	8,485	39.9 [35.0-45.4]
PFBS	PFOS	1,497	692	509	8,645	36.7 [32.4-41.7]
PFHxS	PFNA	415	108	1,115	9,455	32.6 [26.1-40.7]
PFHxS	PFOA	1,374	1,259	230	8,820	41.9 [35.9-48.7]
PFHxS	PFOS	1,369	939	235	9,140	56.7 [48.6-66.2]
PFNA	PFOA	575	2,190	23	8,764	100.1 [65.9-151.8]
PFNA	PFOS	555	1,864	43	9,089	62.9 [46.0-86.1]
PFOA	PFOS	2,304	341	729	9,972	92.4 [80.6-106.0]

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Odds ratios reflect the change in the odds of finding one chemical (*e.g.,* Chemical A) given that the second chemical (*e.g.,* Chemical B) is known to be present compared to the odds of finding it if the second chemical is not present. For example, as shown in Table 12, the point estimate of 92.4 for the odds ratio between PFOA and PFOS indicates that the odds of finding PFOA after knowing that PFOS has been observed are 92.4 times what the odds would have been if PFOS was not observed, and vice versa. For every pair of chemicals, both the point estimate and 95 percent confidence interval (CI) were above 1, indicating significant increases in the likelihood of detecting one chemical if the other is present.

Both as a group and as individual chemicals, the Hazard Index PFAS had a higher likelihood of being reported if PFOS or PFOA were present. PFHxS, PFNA, HFPO–DA, and PFBS (the individual Hazard Index PFAS) are demonstrated to generally co-occur with each other, as well. These data support that there is a substantial likelihood that PFHxS, PFNA, HFPO–DA, and PFBS co-occur in mixtures with a frequency of public health concern in drinking water systems as discussed in section III.C of this preamble.

D. Occurrence Relative to the Hazard Index

1. Proposal

In the proposed rule, the EPA analyzed the available state data in comparison to the proposed Hazard Index MCL of 1.0 to evaluate the co-occurrence of PFHxS, PFNA, HFPO–DA, and PFBS. The EPA requested comment on the number of systems estimated to solely exceed the Hazard Index (but not the PFOA or PFOS MCLs) according to the approach outlined in USEPA (2024b).

2. Summary of Major Public Comments and EPA Responses

The EPA received comments on the analyses presented in the proposal of occurrence relative to the Hazard Index. Many commenters agreed that the Hazard Index PFAS co-occurred in mixtures at levels of health concern. Two of these comments came from states that conducted monitoring of Hazard Index PFAS post-UCMR 3 and stated that those occurrence data supported the EPA's findings. Several state agencies provided a summarized analysis of the number of systems expected to exceed the proposed Hazard Index of 1.0 in their state. The EPA notes that these estimates were based on the proposed Hazard Index, which included two significant figures. Since the EPA has determined to finalize the Hazard Index with one significant figure, these estimations are likely high. Nonetheless, these state data and the analyses provided by commenters provide illustrative confirmatory insight of the EPA's Hazard Index analyses (please see section IV of this preamble for additional discussion on the usage of significant figures).

One commenter suggested that a national dataset and model complete with all four Hazard Index PFAS are necessary to accurately estimate the number of systems that may exceed the Hazard Index. The EPA disagrees with the commenter; as described in section F, state data and model outputs were appropriately combined to estimate exceedance of the Hazard Index on a national level. Several commenters stated that there was a limited amount of available data to determine the prevalence of co-exposure of the Hazard Index compounds, and that further review would be needed prior to establishing the Hazard Index. The EPA disagrees with these commenters and believes that sufficient data were available to reasonably assess the occurrence of Hazard Index PFAS. An analysis of co-occurrence of Hazard Index compounds using a substantial amount of data encompassing tens of thousands of samples across over 10,000 systems is provided in section VI.C. of this preamble above and demonstrates that the four Hazard Index PFAS co-occur with each other as well as with PFOA and PFOS. One commenter suggested that more systems may exceed the Hazard Index than the PFOA and PFOS MCLs, since current treatment technologies have been optimized for PFOA and PFOS and not for other PFAS. The EPA's analysis of state datasets clearly contradicts this claim; using the best available data and scientifically robust analytical approaches, the EPA estimates more systems will exceed the PFOA and PFOS MCLs than the Hazard Index MCL. The use of a single significant figure for the Hazard Index MCL in this final rule will further increase the likelihood of this being the case.

3. Final Rule

The EPA used its updated state dataset to update analyses related to Hazard Index occurrence and found the analyses generally consistent with the proposal analyses. In the final rule, the EPA is reducing the number of significant figures used to determine Hazard Index exceedance following all calculations and rounding from two to one; this change had the effect of reducing system counts expected to exceed the Hazard Index. For purposes of the final analyses, only systems with an unrounded Hazard Index of 1.5 or greater were counted as an exceedance. Table 13 presents the total number and percentage of monitored systems with results above the proposed Hazard Index MCL based on state reported Hazard Index PFAS data for the states that conducted non-targeted monitoring and that sampled all four Hazard Index PFAS as a part of their overall monitoring efforts. The EPA notes that for equivalent comparison purposes Table 13 only accounts for samples that included reported values (including non-detects) of all four Hazard Index PFAS. As shown within the table, the majority of states evaluated had monitored systems with results above the proposed Hazard Index MCL, ranging from 0.35 to 3.17 percent of total monitored systems. For additional discussion on the usage of significant figures in this rule, please see section IV of this preamble.

Table 13: Non-Targeted State PFAS Finished Water Data – Summary of Total Number and Percent of Monitored Systems Exceeding the Hazard Index with Samples Containing Reported Values of All Four Hazard Index PFAS

State	**Total Monitored Systems > Final HI of 1**	**Percent Systems > Final HI of 1**
Colorado	2	0.50%
Illinois	7	0.70%
Indiana	0	0.00%
Kentucky	2	2.70%
Maryland	2	3.17%
Massachusetts	23	1.76%
Michigan	17	0.68%
Missouri	1	0.91%
New York	7	1.28%
New Hampshire	3	2.17%
North Dakota	0	0.00%
Ohio	16	1.08%
South Carolina	2	0.68%
Vermont	2	0.35%
Wisconsin	7	3.03%

Further evaluating the available state data related to the proposed Hazard Index MCL of 1, Table 14 presents the total number of systems that exceed the final Hazard Index of 1 based on state reported Hazard Index PFAS results for the same states shown in Table 13. However, in this case, the EPA also analyzed the same non-targeted state data, including additional samples even if those samples did not contain reported values (including non-detects) for all four Hazard Index PFAS (*i.e.,* exceeding the Hazard Index based on two or three Hazard Index PFAS with reported values included within a sample). Moreover, while these states did monitor for all four Hazard Index PFAS as a part of their overall monitoring, in a subset of those states some samples did not include reported data on all four Hazard Index PFAS (*i.e.,* values of one or more of the Hazard Index PFAS were not reported as non-detect, rather no value was reported). This analysis, presented in Table 14, shows an increase in the number of monitored systems exceeding the proposed Hazard Index of 1 and demonstrates prevalence of these PFAS at levels of concern, even when all four PFAS may not be included within a sample.

Table 14: Non-Targeted State PFAS Finished Water Data – Summary of Total Monitored Systems Exceeding the Hazard Index with Samples Containing Reported Values of 2 or More Hazard Index PFAS

State	Total Monitored Systems > Final HI of 1	Percent Systems > Final HI of 1
Colorado	2	0.50%
Illinois	7	0.70%
Indiana	0	0.00%
Kentucky	2	2.70%
Maine	4	0.62%
Maryland	7	5.19%
Massachusetts	31	2.34%
Michigan	17	0.68%
Missouri	1	0.87%
New Jersey	27	4.06%
New York	18	2.67%
New Hampshire	17	3.04%
North Dakota	0	0.00%
Ohio	16	1.08%
South Carolina	2	0.67%
Vermont	2	0.35%
Wisconsin	7	2.95%

Combining the non-targeted monitoring results shown previously with targeted state monitoring conducted for all four Hazard Index PFAS showed at least 864 samples from 211 PWSs in 21 states had results above the final Hazard Index of 1. These systems serve approximately 4.7 million people. More information on occurrence in state monitoring is available in section III.C of this preamble and in USEPA (2024b).

In summary, the finished water data collected under both non-targeted and targeted state monitoring efforts from 32 states showed there are at least 1,772 PWSs serving a total population of approximately 24.3 million people that have at least one result exceeding the final PFOA MCL of 4.0 ng/L. In those same 32 states, there are also at least 1,432 PWSs serving a total population of approximately 21.0 million people that have at least one result exceeding the final PFOS MCL of 4.0 ng/L. Finished water data showed that there are at least 187 systems in 23 states serving a total population of approximately 4.4 million people with at least one result exceeding the final PFHxS MCL of 10 ng/L. Finished water data from 12 states showed there are at least 52 systems serving a total population of approximately 176,000 people that have at least one result exceeding the final PFNA MCL of 10 ng/L. Finished water data showed 13 systems from 5 states serving over 226,000 people have at least one result exceeding the final HFPO–DA MCL of 10 ng/L. Related to the Hazard Index, finished water data collected under both non-targeted and targeted state monitoring efforts in 21 states showed there are at least 211 systems serving a total population of approximately 4.7 million people with results above the final Hazard Index value of 1 for PFHxS, PFNA, HFPO–DA, and PFBS. Samples that only had monitoring results for one Hazard Index PFAS were not included. USEPA (2024b) presents a detailed discussion on state PFAS monitoring information.

E. Occurrence Model

A Bayesian hierarchical occurrence model was developed to characterize national occurrence of the four PFAS that were most frequently detected in the UCMR 3: PFOA, PFOS, PFHxS, and PFHpA.[8] This model was used to generate the baseline national occurrence estimates for PFOA, PFOS, and PFHxS, which were used in the subsequent economic analysis in USEPA (2024g). Bayesian hierarchical models are a widely used statistical approach in which subsets of data may be recognized as more related than others (such as samples from the same PWS are more related than samples between different PWSs) to capture complex relationships between levels of data and can aid in understanding the factors that influence outcomes. The objective of this model was to use both UCMR 3 data and supplemental state data to develop national estimates of

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[8] PFHpA was included in the model because of its UCMR 3 occurrence data availability.

PFAS occurrence that inform occurrence distributions both within and across PWSs. Supplemental state data were incorporated to improve the model's ability to estimate PFAS occurrence at levels below the UCMR 3 minimum reporting levels (20 ng/L for PFOA, 40 ng/L for PFOS, and 30 ng/L for PFHxS). The state data incorporated to supplement the model came from publicly available datasets. In order to maintain the statistically robust UCMR 3 sampling framework, thereby enabling the agency to make conclusions about national representativeness of the model results, incorporation of state data into the model was limited only to data from systems that took part in the UCMR 3. The model does not include PFNA and PFBS due to data limitations; PFNA and PFBS lacked sufficient reported values above the UCMR 3 minimum reporting levels to be incorporated into the model. The model has been peer reviewed and is described extensively in Cadwallader et al. (2022).

The model uses Markov chain Monte Carlo (MCMC) simulation and the assumption of lognormality in PFAS chemical occurrence. Markov chain Monte Carlo is a powerful statistical tool used to understand uncertainty and making informed decisions when analyzing data. The EPA has used similar hierarchical models to inform regulatory decision making in the past, such as for development of the NPDWR for Arsenic and *Cryptosporidium parvum* (USEPA, 2006c; USEPA, 2000e).

After log-transformation of data informing the model, system-level means (where each system has a mean concentration for each chemical) were assumed to be distributed multivariate normally. Further, within-system occurrence was assumed to be distributed normally for each chemical. Since system-level means were modeled multivariate normally, correlation between estimated system-level means across chemicals could also be assessed. The assumption of lognormality as well as the incorporation of state data with lower reporting limits allowed the model to generate reasonable estimates for PFAS occurrence at levels below the UCMR 3 minimum reporting levels.

After the model was fit with available data from PWSs that were included in the UCMR 3, it was used to simulate occurrence at an inventory of active community water systems (CWS) and non-transient non-community water systems (NTNCWS) extracted from the Safe Drinking Water Information System (SDWIS). System-level means for non-UCMR 3 systems were simulated by sampling from the multivariate normal distribution of system-level means that was produced during the model fitting process. For systems that were included in the UCMR 3, the fitted system-level mean was used directly. This approach allowed national occurrence distributions to be estimated alongside the associated populations when combined with population data from SDWIS.

1. Proposal

In the March 2023 proposal preamble, model estimates of contaminant occurrence were presented. For the analysis presented in the proposal, UCMR 3 data were supplemented with 23,130 analytical results from 771 systems across 17 states that were available from public state websites through August 2021. Key model results that were presented directly included correlation coefficients across pairs of chemicals included in the model, extrapolated estimates of the number of system level means anticipated to exceed various threshold, and the estimated population associated with systems that had mean concentrations exceeding the various thresholds. The results indicated that system-level mean concentrations were moderately to strongly correlated across the modeled PFAS and that thousands of systems were estimated to have mean PFAS concentrations in the range of single digit ng/L.

2. Summary of Major Public Comments and EPA Responses

A few commenters stated that they believed the model was an overly complicated approach to characterizing chemical occurrence and found it difficult to understand. Further, a few commenters stated that they believed the model was not transparent. The EPA disagrees; the occurrence approach used by the agency in this rule is based on a widely utilized and accepted statistical approach which is used in a variety of fields from education to health care and from business to the environment. These models allow exploration of the relationships among groups of data and the EPA used this model to better inform the agency's understanding of probable PFAS occurrence. For more information about Bayesian statistics and the wide variety of potential applications, see, for example, Hoff (2009); van de Schoot et al. (2021); Aguilera et al. (2011); and Messner et al. (2001). While the model uses an advanced statistical method and requires some statistical background to fully understand, Bayesian hierarchical models have previously been employed to assess occurrence for drinking water contaminants, as was discussed in the March 2023 proposal preamble as well as Cadwallader et al. (2022). Cadwallader et al. (2022) describes the model structure while the annotated model code and inputs were provided directly as supporting information alongside the manuscript. This information was incorporated into the docket for this rule's proposal. Sufficient information to replicate the model run was provided. Thus, the agency disagrees with the assertion that the model was not transparent.

Regarding the model complexity, the core structure of this specific model is comparatively simple among Bayesian hierarchical models. The model uses a multivariate normal distribution of system-level means (of log transformed data) for the four modeled PFAS. It also includes a parameter for small systems to assess whether they appear to have systematically different (higher or lower) concentrations than large systems. As stated in Cadwallader et al. (2022), the model extrapolates to the nation by sampling from the multivariate normal distribution and accounting for whether the system being simulated was small. The multivariate normal distribution and the parameter to distinguish small systems from large systems are two simple but important pieces of the model structure.

Many commenters stated that the model relied on insufficient data and produced substantial underestimates of the number of systems that would fail to meet MCL requirements. The agency disagrees both that the approach taken would systematically underestimate PFAS occurrence and that the data were insufficient inform the model. The Bayesian approach used here makes a precedented assumption about drinking water contaminant occurrence distributions (lognormality) and uses the available data to generate iterative estimates of distribution parameters that capture uncertainty through MCMC simulation. Across these iterations, the density of the posterior distribution for model parameters is proportionate to the likelihood that a given value would have produced the observed data. The subsequent national extrapolations also reflect this uncertainty.

For the results presented in the March 2023 proposal preamble, the model was fit using 171,017 analytical results across the 4,920 UCMR 3 systems. This was a nationally representative set of systems. 147,887 of the analytical results were collected as part of UCMR 3 while 23,130 were aggregated from 17 subsequently collected state datasets. The model was designed to utilize both results reported as observed concentrations (8,209 results) and results reported as less than a reporting limit (162,808 results). While the UCMR 3 used higher reporting limits than are currently available, both reported concentrations and values reported as below the minimum reporting level cumulatively make substantial contributions to informing the model's estimates of the PFAS occurrence distribution because of this statistically robust framework. Due to this efficient use of data, and the steps taken to maintain a nationally representative set of systems, the agency believes that the over 170,000 analytical results were sufficient to generate reasonable estimates of occurrence for the modeled contaminants.

Several commenters expressed concern with model bias resulting from the supplemental state data that was incorporated when fitting the model. The hierarchical structure of the model minimizes the bias impact of introducing additional state data for only some UCMR 3 systems (those with additional data available) because the data are explicitly linked to their parent systems rather than being pooled with all other data informing the model. The primary impact that these data have is on the model's estimate of specific system means for those systems that had additional data and informing the within-system variability parameters in the model. Refinement of a single system's mean estimate has a much smaller impact on the high-level distribution of system-level means and such shifts are proportionate to the added evidence derived from the supplemental data.

The addition of data from systems not included in the UCMR 3 would pose a much greater concern for bias, since not all states have publicly available data. States with additional data would become disproportionately represented in the fit of the high-level distribution, since each system acts as a data point in fitting the distribution. The resulting high-level distribution would shift to resemble the states more closely with higher system representation in the source dataset. This would also be reflected in the subsequent national extrapolation. This same bias concern applies to national extrapolation approaches where some fraction of systems in a subset are identified as exceeding a given threshold and the national inventory of systems is multiplied by that fraction to generate a national estimate of systems that would exceed the threshold. If certain states have a disproportionate number of systems included in the subset compared to in the nation as a whole, the national estimate will be biased towards the tendencies of those states. In addition to this bias, the simple example approach discussed above would not naturally reflect uncertainty. Thus, for the purpose of national extrapolation, a nationally representative set of systems is more appropriate, even if data from other systems are available.

While the EPA believes the model design and data selected for the analysis presented in the March 2023 proposal remain appropriate given the data availability at the time, the EPA has also continued to collect newly available data from publicly available state datasets, as the agency committed to in the proposed rulemaking (USEPA, 2023f). The Bayesian hierarchical model has been refit using the updated dataset with the same methods and criteria for data selection that were used for the analysis presented in the March 2023 proposal.

3. Final Rule

After considering public comment, the agency has used the Bayesian statistical model described in Cadwallader et al. (2022) to support the economic analysis for this final regulation by combining the available occurrence information from UCMR 3 and state data subsequently collected at UCMR 3 systems to maintain the nationally representative nature of the set of drinking water systems informing the model, utilizing those data to compute estimates of national occurrence for PFAS contaminants, and providing estimates on the number of systems impacted by this final rule. These estimates directly informed the economic analysis in USEPA (2024g). For the final rule, the model was updated with additional state data collected through May 2023. In total, based on public comment, the EPA supplemented the state dataset with 65,537 analytical results from 1,156 systems across 28 states. Of these supplemental data, 24,950 analytical results were observed concentrations while 40,587 results were reported as below some reporting limit. The previously presented results have been updated and are presented in Table 15. The EPA notes that results from the updated dataset and model were confirmatory of its proposal analyses and did not result in changes to the EPA's final decisions. Median estimates and 90 percent credible intervals are shown for counts of systems with system-level means at or above various PFAS concentrations in Table 15 and the population served by those systems in Table 16.

Table 15: National Occurrence Model Estimate – Estimated Number of Systems

With System-level Means at or Above Various Concentrations

Concentration (ng/L)	PFHxS [90% CI]	PFOA [90% CI]	PFOS [90% CI]
4.0	1,828 [1,226-2,689]	3,260 [2,416-4,349]	3,368 [2,461-4,566]
5.0	1,252 [823-1,888]	2,194 [1,588-2,994]	2,447 [1,757-3,386]
10.0	340 [209-555]	523 [354-771]	793 [537-1,166]

Table 16: National Occurrence Model Estimate – Estimated Population Served by Systems with System-level Means at or Above Various Concentrations

Concentration (ng/L)	PFHxS [90% CI]	PFOA [90% CI]	PFOS [90% CI]
4.0	20,386,000 [17,436,000-24,351,000]	34,343,000 [30,897,000-40,600,000]	34,313,000 [30,703,000-41,110,000]
5.0	15,436,000 [12,524,000-18,458,000]	24,287,000 [21,551,000-28,222,000]	26,594,000 [23,793,000-31,240,000]
10.0	4,645,000 [3,557,000-7,205,000]	7,132,000 [4,871,000-8,987,000]	10,205,000 [7,552,000-12,232,000]

For PFOA, PFOS, and PFHxS, thousands of systems were estimated to have mean concentrations over the lowest thresholds (*i.e.,* 4.0 and 5.0 ng/L) presented in Tables 15 and 16 with the total population served estimated to be in the tens of millions. The populations shown here represent the entire populations served by systems estimated to have system-level means over the various thresholds. It is likely that different subpopulations would be exposed to different mean PFAS concentrations if multiple source waters are used.

In addition to the estimates of individual chemical occurrence, the multivariate normal distribution of system-level means allowed the model to provide insight on estimated co-occurrence. The model results support the co-occurrence of PFOA, PFOS and Hazard Index PFAS. The model evaluated whether untransformed (*i.e.,* expressed in the original units of measurement) estimates of system-level means were correlated across each unique pair of the four modeled chemicals included in the model. Estimates of the Pearson correlation coefficient are shown in Table 17. The Pearson correlation coefficient serves as an indicator of the strength of the linear relationship between two variables and may range from −1 to 1. Positive values indicate a positive relationship (*i.e.,* as one variable increases, so does the other). shown in Table 17. The Pearson correlation coefficient serves as an indicator of the strength of the linear relationship between two variables and may range from −1 to 1. Positive values indicate a positive relationship (*i.e.,* as one variable increases, so does the other).

Table 17: National Occurrence Model Estimate – Median Estimated Pearson Correlation Coefficient and 90% Credible Interval Among System-level Means

Chemical Pair	Pearson Correlation Coefficient [90% CI]
PFOS-PFOA	0.73 [0.63-0.80]
PFOS-PFHpA	0.67 [0.56-0.75]
PFOS-PFHxS	0.82 [0.72-0.89]
PFOA-PFHpA	0.83 [0.79-0.87]
PFOA-PFHxS	0.51 [0.39-0.60]
PFHpA-PFHxS	0.58 [0.44-0.67]

The EPA considered a moderate strength correlation as greater than 0.5 and a strong correlation as greater than 0.7. Each point estimate of correlation coefficients between two chemicals was above the threshold for a moderate strength correlation. The carboxylic acids (PFOA–PFHpA) and sulfonic acids (PFOS–PFHxS) had the highest estimated correlation strengths, with both the point estimate and the 90 percent credible interval above the threshold for a strong correlation. PFOS–PFOA and PFOS–PFHpA had similar point estimates and 90 percent credible interval ranges, spanning the moderate-to-strong correlation range. Both PFOA–PFHxS and PFHpA–PFHxS had the bulk of their posterior distributions fall in the range of a moderate strength correlation. Thus, the model predicted significant positive relationships among system-level means of all four chemicals that were included. These results support the co-occurrence discussion presented in section VI.C of this preamble that indicated extensive co-occurrence of PFOA, PFOS, and the Hazard Index PFAS observed in state datasets from both groupwise and pairwise chemical perspectives.

F. Combining State Data With Model Output To Estimate National Exceedance of Either MCLs or Hazard Index

In order to broadly estimate the number of systems that would be impacted by the regulation, including MCLs of 4.0 ng/L for PFOA and PFOS alongside a Hazard Index of 1 for PFHxS, PFNA, HFPO–DA, and PFBS, findings from non-targeted monitoring in state datasets were combined with model estimates. Specific details on the methodology can be found in USEPA (2024b). Briefly, information collected from non-targeted state datasets included the fractions of systems that reported a measurement at or above the UCMR 5 minimum reporting level for a given analyte and an empirical cumulative distribution function (eCDF) consisting of system-level maximum observed concentrations of that chemical at these systems. The UCMR 5 minimum reporting levels for PFNA, HFPO–DA, and PFBS are equivalent to 4 ng/L, 5 ng/L, and 3 ng/L, respectively (USEPA, 2022j). This applies the assumption that the fraction of systems that observed PFNA, HFPO–DA, and PFBS at or above UCMR 5 minimum reporting levels and the maximum concentrations observed at those systems are reasonably representative of the nation.

1. Proposal

The model was used to simulate EP-level concentrations of the four modeled PFAS (PFOA, PFOS, PFHpA, and PFHxS) under the assumption that within-system concentrations are lognormally distributed (a common assumption for drinking water contaminants, see (Cadwallader et al. (2022)) and that variability in concentrations is entirely across EP (thus a given EP is assumed to have a constant concentration). For each system, the maximum estimated EP PFOA or PFOS concentration was selected to determine whether the system exceeded either of the proposed MCLs of 4.0 ng/L. The EP with the maximum concentration is the point that determines whether a system has an EP that is above an MCL. Estimates of the system-level maximum for PFHxS were also selected for the Hazard Index calculation. The maximum value of the sum of the four modeled PFAS at each system was selected and used as a basis for determining which systems would receive superimposed concentrations of the three remaining Hazard Index chemicals (PFNA, HFPO–DA, and PFBS). This approach was selected due to the extensive observed co-occurrence of PFAS in the UCMR 3, state data, and modeled estimates.

Multiple methods of system selection were used that reflected different degrees of co-occurrence. The chemical concentration that was applied to selected systems were randomly sampled from the eCDF for each chemical. Based on the model output, this assumes that system-level maximums for PFNA, HFPO–DA, and PFBS would occur at the same location within a system. Given the substantial co-occurrence among PFAS observed and estimated across various analyses, combination of system-level maximums independently pulled from chemical eCDFs is a reasonable simplifying assumption. This is particularly true since systems selected for each chemical are not necessarily the same and in most cases were probability weighted. Estimates of the range of systems impacted were developed by taking Q5 and Q95 estimates for each method. The low end of the range was taken as the lowest Q5 estimate across methods, rounded down, while the high end of the range was taken as the highest Q95 estimate across methods, rounded up. This was also done for the total population served by these systems.

The analysis to support the March 2023 proposal estimated that 100–500 systems that were not already exceeding an MCL for PFOA or PFOS would exceed the Hazard Index. This resulted in a total of 3,400–6,300 systems estimated to be exceeding either the Hazard Index, the MCL for PFOA, or the MCL for PFOS.

2. Summary of Major Public Comments and EPA Responses

One commenter stated that they believed it is difficult to determine whether the estimated number of systems exceeding the Hazard Index is a reasonable estimate until a complete national dataset is available. The EPA disagrees with this commenter. The agency believes that it has taken steps to produce reasonable estimates using a robust set of available data, and that the data and analyses are sufficient to inform the EPA's regulatory decisions. Namely, this includes the use of non-targeted state datasets and multiple scenarios reflecting varying degrees of co-occurrence as described in USEPA (2024b). Among other important uses for these data, the EPA considered them to inform the regulatory determination for the mixture of the Hazard Index PFAS and the EA. The EPA has used these data to clearly demonstrate that there is a substantial likelihood that combinations of the Hazard Index PFAS co-occur as mixtures in public water systems with a frequency and at levels of public health concern. See section III of this preamble for additional discussion. Additionally, these data support the EPA's EA, and considerations of costs and benefits consistent with SDWA's requirements. See section XII of this preamble for further discussion.

3. Final Rule

The method to combine state data for non-modeled Hazard Index PFAS with model estimates has largely remained the same for this final rule as it was for the March 2023 proposal. One key change, based on public comments, was to use an updated set of non-targeted state data to inform Hazard Index contaminant prevalence above UCMR 5 minimum reporting levels and eCDFs. Another key alteration, also based on public comments, was accounting for significant figures when counting systems exceeding the MCL for PFOA, the MCL for PFOS or the Hazard Index. For a system to be exceeding the Hazard Index, it must be greater than or equal to 2 (*i.e.,* greater than 1) after rounding (for additional discussion on significant figure usage in the final rule, please see section IV of this preamble). To exceed the MCLs for PFOA or PFOS, the concentration must be greater than or equal to 4.1 ng/L after rounding. Finally, model estimates of PFHxS were converted to zero for the purposes of calculating the Hazard Index if they fell below the PQL of 3 ng/L.

The total number of systems estimated to be exceeding one or more MCLs in the rule was 4,100–6,700 (compared to 3,400–6,300 in the proposal) serving a total population of 83–105 million people. Among these systems, 100–300 are estimated to be exceeding the Hazard Index without exceeding the PFOA or PFOS MCLs. The EPA used these modeled estimates to inform the costs and benefits determination as described in section XII of this preamble. Additional details regarding the approach used here can be found in USEPA (2024b).

G. UCMR 5 Partial Dataset Analysis

1. Summary of Major Public Comments and EPA Responses

UCMR 5 occurrence data were not available to inform the proposal, but the agency discussed that additional nationwide monitoring data would be available for systems participating in the monitoring program. Some commenters called for the EPA to delay issuance of the final PFAS rule until the complete UCMR 5 occurrence dataset can be analyzed, and some commenters stated that rule promulgation should be delayed until at least a portion of the UCMR 5 data is obtained. The EPA disagrees with these commenters. The EPA is not required under the statute to wait for another round of UCMR data to be collected before proposing or finalizing a regulation; in this case, the completion of UCMR 5 data reporting is expected at the end of 2025, with the final dataset not being available until 2026. Rather, SDWA section 1412(b)(1)(B)(ii)(II) expressly provides that the EPA must use the ''best *available* public health information'' in making a regulatory determination (emphasis added). The EPA has sufficiently robust occurrence information to make regulatory determinations and promulgate a regulation for the six PFAS in this regulation. In addition to serving as a significant way for helping many utilities reduce initial monitoring costs, the final full UCMR 5 dataset will also be valuable for informing future regulatory decisions for the 23 PFAS included in UCMR 5 that are not directly addressed by this rulemaking. The agency believes that the best currently available occurrence data demonstrate sufficient occurrence or substantial likelihood of occurrence for the contaminants included in the final rule.

2. Final Rule

While the EPA is under no legal obligation to consider the preliminary, partial UCMR 5 dataset prior to rule promulgation, based on public comment and interest, the agency examined UCMR 5 data released as of February 2024 (USEPA, 2024n). While these data were not available for this rule's proposal, are not complete, and are not a basis for informing the agency's decisions for the final rule, the EPA notes that they generally confirm the extensive occurrence analyses the agency has conducted: namely, that all six regulated PFAS occur in finished drinking water and that the six regulated PFAS co-occur with one another. The EPA notes some important caveats when considering these data. First, as of February 2024, the partial UCMR 5 dataset is a subset of data that will be collected, representing approximately 24 percent of the total data that might be collected under that effort. Additionally, under UCMR 5, systems must collect either 2 or 4 samples, depending on their source water characteristics. In this preliminary dataset, systems have varying degrees of completeness in their sample collection and results may shift at the system level as additional samples are collected. Analyses included examination of sample-level results as well as EP mean-level results.

The UCMR 5 data publicly available as of February 2024 included a combined total of 100,629 analytical results for PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS ranging from 16,766 to 16,778 analytical results for each chemical. 16,743 complete sample sets where an analytical result was reported for each chemical were available. 9,528 EPs and 3,719 PWS had at least one analytical result for each of the six PFAS and one sample for which the Hazard Index could be calculated. As mentioned previously, this partial dataset is estimated to contain approximately 24 percent of the data that will be available once the dataset is completed and finalized.

The preliminary dataset was assessed for sample-level threshold exceedances of PFOA (4.0 ng/L), PFOS (4.0 ng/L), PFHxS (10 ng/L), PFNA (10 ng/L), HFPO–DA (10 ng/L), and the Hazard Index (1). Note that for PFOA and PFOS, two significant figures were considered (*i.e.,* analytical results had to meet or exceed 4.05 to be considered exceedances) while for PFHxS, PFNA, HFPO–DA, and the Hazard Index one significant figure was considered (*i.e.,* an analytical result had to meet or exceed 15 to be considered an exceedance for PFHxS, PFNA, and HFPO–DA and 1.5 to be considered an exceedance for the Hazard Index). Sample-level analysis only included complete sample sets while EP and system-level analysis included only systems that provided sufficient data to determine maximum PFOA, PFOS, PFHxS, PFNA, and HFPO–DA, and Hazard Index (which required at least one sample set where the Hazard Index could be calculated). The EPA notes that this analysis does not represent an estimate for the number of systems that will be in compliance with the MCL; as discussed in section V of this preamble, MCL compliance is determined based on an RAA. Additionally, samples below the PQL would be treated as zero in the compliance calculation. In the preliminary UCMR 5 dataset, PFOA exceeded 4.0 ng/L in 6.1 percent of samples (1,024 samples), at 7.5 percent of EPs (719 EPs), and at 11.2 percent of systems (415 systems). PFOS exceeded 4.0 ng/L in 6.6 percent of samples (1,100 samples), at 8.0 percent of EPs (766 EPs), and at 12.4 percent of systems (462 systems). PFHxS exceeded 10 ng/L in 0.4 percent of samples (66 samples), at 0.6 percent of EPs (53 EPs), and at 1.1 percent of systems (42 systems). PFNA exceeded 10 ng/L in <0.1 percent of samples (5 samples), at <0.1 percent of EPs (5 EPs), and at 0.1 percent of systems (5 systems). HFPO–DA exceeded 10 ng/L in <0.1 percent of samples (2 samples), at <0.1 percent of EPs (1 EP), and at <0.1 percent of systems (1 system). The Hazard Index exceeded 1 in 0.5 percent of samples (76 samples), at 0.6 percent of EPs (60 EPs), and at 1.3 percent of systems (48 systems). When the thresholds were considered simultaneously, 9.0 percent of samples (1,504 samples), 10.9 percent of EPs (1,043 EPs), and 15.8 percent of systems (589 systems) exceeded a threshold. Note that single sample exceedances of thresholds do not necessarily reflect the averages that might be observed in the completed dataset. Specifically, the EPA notes that it is likely that many of the 15.8 percent of systems with an exceedance would not exceed the MCLs because additional samples used to determine an RAA may produce lower results.

To further illustrate this point, though there is insufficient data to fully evaluate RAAs,[9] EP-level means and systems with EP-level means exceeding an MCL threshold were also assessed with the preliminary dataset. For this analysis, only complete sample sets and EPs with multiple complete sample sets were included. 5,269 EPs and 2,498 systems had data that met these criteria. When calculating EP means, results reported as less than the minimum reporting limit were treated as zero. Note that for PFOA and PFOS, two significant figures were considered (*i.e.,* calculated means had to meet or exceed 4.05 to be considered exceedances) while for PFHxS, PFNA, HFPO–DA, and the Hazard Index one significant figure was considered (*i.e.,* calculated mean had to meet or exceed 15 to be considered an exceedance for PFHxS, PFNA, and HFPO–DA and 1.5 to be considered an exceedance for the Hazard Index). Mean PFOA concentration exceeded 4.0 ng/L at 4.8

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[9] An RAA is calculated using results for samples taken at a particular monitoring location during the previous four consecutive quarters (see section XIII.B for more information).

percent of EPs (253 EPs) and at 6.0 percent of systems (149 systems). Mean PFOS concentration exceeded 4.0 ng/L at 5.3 percent of EPs (278 EPs) and at 7.2 percent of systems (179 systems). Mean PFHxS concentration exceeded 10 ng/L at 0.3 percent of EPs (15 EPs) and at 0.4 percent of systems (11 systems). Mean PFNA concentration exceeded 10 ng/L at <0.1 percent of EPs (1 EP) and at <0.1 percent of systems (1 system). Mean HFPO–DA concentration exceeded 10 ng/L at <0.1 percent of EPs (1 EP) and at <0.1 percent of systems (1 system). Mean Hazard Index exceeded 1 at 0.3% of EPs (18 EPs) and at 0.6% of systems (14 systems). Considered simultaneously, an MCL was exceeded at 7.2 percent of EPs (381 EPs) and 9.4 percent of systems (235 systems). While the EP means described above include multiple sample sets, observed mean concentrations are likely to change as systems complete UCMR 5 sampling.

Among 16,743 completed sample sets and 9,529 EPs and 3,719 systems which had at least one result for each analyte, 13.9 percent of samples (2,335 samples), 16.5 percent of EPs, and 22.6 percent of systems (842 systems) had an observed concentration at or above the minimum reporting level for at least one of the 6 PFAS. Table 18 shows counts of samples, EPs, and systems according to how many of the 6 PFAS included in this final rule were present at or above the minimum reporting level. As shown in Table 18, about 7.5 percent of samples, 9.4 percent of EPs, and 14.2 percent of systems observed multiple PFAS at or above the minimum reporting level.

Table 18: Preliminary UCMR 5 Dataset[1] – Samples, EPs, and Systems Binned According to Number of PFAS Among PFOA, PFOS, PFHxS, PFNA, HFPO-DA and PFBS That Were Reported at or Above the Minimum Reporting Level

PFAS Observed	Samples	EPs	Systems
0	14,408 (86.1%)	7,954 (83.5%)	2,877 (77.4%)
1	1,077 (6.4%)	676 (7.1%)	313 (8.4%)
2	541 (3.2%)	379 (4.0%)	191 (5.1%)
3	393 (2.3%)	289 (3.0%)	172 (4.6%)
4	303 (1.8%)	215 (2.3%)	148 (4.0%)
5	21 (0.1%)	16 (0.2%)	18 (0.5%)
6	0 (0.0%)	0 (0.0%)	0 (0.0%)

Notes:

1 The preliminary UCMR 5 dataset contains approximately 24 percent of the samples anticipated to be available once the dataset is complete.

Groupwise co-occurrence was also examined in the preliminary UCMR 5 dataset. Table 19 provides the counts and percentages of systems, EPs, and samples where PFOA and/or PFOS were reported as well as whether any of the Hazard Index PFAS were reported. Sample-level results only included completed sample sets while system-level results only included systems which provided one analytical result for each of the 6 PFAS.

Table 19: Preliminary UCMR 5 Dataset[1] – Samples, EPs, and Systems Binned According to Whether PFOS or PFOA were Reported by States and Whether Additional Hazard Index PFAS were Reported

Type	No PFOS or PFOA Reported		PFOS or PFOA Reported		Total Count
	No HI PFAS Reported	At Least One HI PFAS Reported	No HI PFAS Reported	At Least One HI PFAS Reported	
Samples	14,408 (86.1%)	786 (4.7%)	498 (3.0%)	1,051 (6.3%)	16,743
EPs	7,954 (83.5%)	508 (5.3%)	317 (3.3%)	750 (7.9%)	9,529
Systems	2,877 (77.4%)	242 (6.5%)	145 (3.9%)	455 (12.2%)	3,719

Notes:

[1] The preliminary UCMR 5 dataset contains approximately 24 percent of the samples anticipated to be available once the dataset is complete.

In samples, at EPs, and at systems where PFOA and/or PFOS were reported present, one or more Hazard Index contaminant was reported at or above the minimum reporting level about 68, 70, and 76 percent of the time, respectively. As UCMR 5 monitoring continues, it is possible that additional systems from this subset will report the presence of PFOA, PFOS or a Hazard Index PFAS. The percentage of systems detecting neither PFOA, PFOS, nor a Hazard Index PFAS would then decrease. Table 20 shows the number of Hazard Index PFAS that were observed in samples, at EPs, and at systems where PFOA and/or PFOS were reported.

Table 20: Preliminary UCMR 5 Dataset[1] – Sample, EP, and System Counts According Number of Hazard Index PFAS Reported Present for Systems Where PFOS and/or PFOA were Reported

HI Observed	Samples	EPs	Systems
0	498 (32.1%)	317 (29.7%)	145 (24.2%)
1	573 (37.0%)	403 (37.8%)	223 (37.2%)
2	453 (29.2%)	329 (30.8%)	214 (35.7%)
3	25 (1.6%)	18 (1.7%)	18 (3.0%)
4	0 (0.0%)	0 (0.0%)	0 (0.0%)
Total	1,549	1,067	600

Notes:

[1] The preliminary UCMR 5 dataset contains approximately 24 percent of the samples anticipated to be available once the dataset is complete.

At systems where Hazard Index PFAS were reported in addition to PFOA/PFOS, about 51.0 percent of systems reported multiple Hazard Index PFAS. As described above, it is possible that systems may detect additional PFAS as sample collection continues under UCMR 5. System-level pairwise odds ratios based on the first release of UCMR 5 data are shown in Table 21.

Table 21: Preliminary UCMR 5 Dataset[1] – System-level Counts of Pairwise Chemical Occurrence and Odds Ratios Calculated from Aggregated State Dataset PFAS Samples for PFOA, PFOS, and Hazard Index PFAS

Chem A	Chem B	Chems A and B Reported	Only Chem B Reported	Only Chem A Reported	Neither Chem Reported	Odds Ratio [95% CI]
HFPO-DA	PFBS	10	560	7	3,143	8.0 [3.1-20.5]
HFPO-DA	PFHxS	3	371	14	3,333	1.9 [0.6-6.3]
HFPO-DA	PFNA	0	26	17	3,679	0.0 [0.0-32.6]
HFPO-DA	PFOA	12	417	5	3,286	18.9 [6.9-51.8]
HFPO-DA	PFOS	13	464	4	3,239	22.7 [7.7-66.4]
PFBS	PFHxS	259	115	311	3,034	22.0 [17.1-28.2]
PFBS	PFNA	19	7	551	3,143	15.5 [6.6-36.1]
PFBS	PFOA	290	139	280	3,011	22.4 [17.7-28.4]
PFBS	PFOS	327	150	243	2,999	26.9 [21.3-34.0]
PFHxS	PFNA	17	9	357	3,338	17.7 [8.0-39.2]
PFHxS	PFOA	204	225	170	3,120	16.6 [13.0-21.2]
PFHxS	PFOS	273	204	101	3,142	41.6 [31.8-54.5]
PFNA	PFOA	22	407	4	3,287	44.4 [15.9-123.9]
PFNA	PFOS	20	457	6	3,237	23.6 [9.7-57.4]
PFOA	PFOS	306	171	123	3,119	45.4 [35.0-58.9]

Notes:

[1] The preliminary UCMR 5 dataset contains approximately 24 percent of the samples anticipated to be available once the dataset is complete.

Except for two chemical pairings with HFPO–DA, each pairwise odds ratio estimate between PFAS is statistically significantly greater than one. As previously described, this indicates an increased likelihood of reporting one chemical given that the other chemical is known to be present. HFPO–DA odds ratios with PFBS, PFOS, and PFOA were also statistically significantly above 1. Given that the UCMR 5 dataset is not complete, it is important to note that, for chemical pairs where very few systems have fallen into one or more of the categories of chemical pairings, subsequent sampling may result in substantial shifts in the odds ratio estimate and the associated CI. For example, if one more system reported both HFPO–DA and PFHxS, the odds ratio estimate would increase by 33 percent. On the other hand, if one more system detected both PFOA and PFOS, the odds ratio estimate would shift by less than 1 percent. As the count of systems in each category increases, the odds ratio estimate becomes more stable with subsequent sampling. This may be particularly relevant for relationships with HFPO–DA and other Hazard Index PFAS, given the relatively low number of systems (17 systems) that reported HFPO–DA at or above the minimum reporting level in the preliminary UCMR 5 dataset as of February 2024.

After the release of approximately 24 percent of the data that will be available in the full UCMR 5 dataset, there appears to be considerable PFAS occurrence and co-occurrence demonstrated (USEPA, 2024n). Over 15 percent of systems with appropriate data described above have observed a sample-level exceedance of any of the MCLs while over 9 percent of systems have had an EP with a mean concentration exceeding an MCL. Approximately 75 percent of systems that reported the presence of PFOA or PFOS also observed at least one Hazard Index contaminant. Over half of these systems reported the presence of multiple Hazard Index contaminants. The national PFAS occurrence model estimated between about 6.2 percent and 10.1 percent of all CWS and NTNCWS would have an exceedance of an MCL. The 9.4 percent of UCMR 5 systems that had an EP mean concentration over an MCL is not a direct comparison to this because not all EPs have sampled a year worth of quarterly data and because large systems make up a larger fraction of UCMR systems than systems in the national inventory (the model estimated generally higher concentrations at larger systems). However, separating these UCMR 5 results by system size and weighting according to system counts in the national inventory of systems would result in an estimation of 7.8 percent of all systems having an EP with a mean concentration exceeding an MCL threshold. These estimates are likely to shift as UCMR 5 sampling continues and system sampling regimes are completed.

VII. Analytical Methods

A. Analytical Methods and Practical Quantitation Levels (PQLs) for Regulated PFAS

1. Proposal

The agency proposed two EPA methods to support the monitoring requirements of this regulation. The EPA developed the two liquid chromatography/tandem mass spectrometry (LC/MS/MS) analytical methods to quantitatively monitor drinking water for targeted PFAS: EPA Method 533 (USEPA, 2019b) and EPA Method 537.1, Version 2.0 (USEPA, 2020c). The agency found that all six PFAS proposed for regulation can be measured by both EPA Methods 533 and 537.1, ver. 2.0 and both methods are acceptable for meeting the monitoring requirements of this regulation.

Additionally, the EPA proposed PQLs for the six PFAS proposed for regulation, as outlined in Table 22.

Table 22: PQLs for Regulated PFAS

Contaminant	PQL (ng/L)
PFOA	4.0
PFOS	4.0
HFPO-DA	5.0
PFHxS	3.0
PFNA	4.0
PFBS	3.0

In the proposed rule preamble (USEPA, 2023f), the EPA discussed laboratory performance in the EPA's Unregulated Contaminant Monitoring Rule (UCMR) 5 Laboratory Approval Program (LAP) and found that the UCMR 5 minimum reporting levels are appropriate as the basis for the practical quantitation level (PQL) in this rule. These quantitation levels account for the measurement precision and accuracy that the EPA estimates can be achieved across laboratories nationwide.

2. Summary of Major Public Comments and EPA Responses

Several commenters note analytical differences between EPA Methods 533 and 537.1 such as differences in the quality control (QC) acceptance levels between the methods, sample preservation and holding times, as well as variability in sample and spike duplicates. In some instances, these commenters request specific modification to the methods, revisions to the EPA laboratory certification manual, or for the agency to develop guidance that laboratories and state accreditation/certification bodies could use. These commenters note that while both methods are valid under the proposed rule, variability between the two may lead to differences in sampling results and may impact a water system's compliance status. The EPA agrees that Methods 533 and 537.1 have some differences that allow for analysis of varying chain lengths and molecular structures of PFAS. Method 533 generally captures ''short chain'' PFAS (*i.e.,* those with carbon chain lengths of 4 to 12) and fluorotelomer sulfonic acids. Method 537.1 includes some overlap with Method 533's analyte list while including some longer-chain PFAS. However, the agency notes that all six PFAS proposed for regulation can be analyzed by either Method 533 or 537.1 and neither method has inherent QC issues that lead to significant variation in sampling results when followed. While there are differences between the methods and how they measure their respective target analytes, both EPA Methods 533 and 537.1 perform comparably. The methods are clear and outline specific instructions regarding requirements that are needed for compliance monitoring measurements.

Some public commenters suggested that the EPA allow alternate analytical procedures or modifications to the two published EPA methods for meeting the monitoring requirements in the final rule. The EPA continues to specify the use of Methods 533 and 537.1 because consistent, reliable compliance data are necessary for implementation of the regulation at the maximum contaminant level (MCL) However, the EPA recognizes that improvements in analytical technology and methodology occur. The EPA's Drinking Water Alternate Test Procedure (ATP) Program provides a mechanism for submission and review of alternative methods to measure a contaminant for nationwide use under 40 CFR 141.27. A method developer may apply for the EPA review of a method modification or a new method through the ATP Program. In the meantime, the agency has concluded that Methods 533 and 537.1 are reliable for use in compliance monitoring with respect to accuracy and recovery (lack of bias) and precision (good reproducibility) at the MCL levels.

Several commenters requested that all laboratories be required to identify their quantitation limits (*i.e.,* the smallest detectable concentration of an analyte greater than the detection limit where the accuracy (precision and bias) achieves the objectives of the intended purpose) and/or method detection limits (*i.e.,* the minimum result which can be reliably discriminated from a blank). Specifically, some commenters note if labs have to demonstrate they can get below the PQL, the EPA should establish reporting or detection limits demonstrating they can get to these levels. The EPA is finalizing rule trigger levels below the PQL to support the monitoring provisions discussed in section VIII of this preamble. The EPA disagrees with these commenters that such reporting is needed to support compliance monitoring for the rule and that such reporting would be a cost burden on laboratories. All labs are required per the approved methods to demonstrate whether laboratory reagent blank (LRB) QC samples have background concentrations of less than one-third the minimum reporting level (*i.e.,* the minimum concentration that can be reported as a quantitated value for a method analyte in a sample following analysis). Therefore, for a laboratory to be compliant with the methods, they must be able to detect, not necessarily quantify, analytes at or above ⅓ the minimum reporting level.

Some commenters sought clarity on which methods are approved for use in compliance monitoring for the final PFAS National Primary Drinking Water Regulation (NPDWR). Some of these commenters requested that only Method 533 be approved for monitoring under the final NPDWR, noting that it may be more suitable should additional PFAS analytes within its scope be targeted for regulation at the future date. Others requested that they be permitted to use Method 537, version 1.1. The EPA disagrees and reaffirms that Methods 537.1, version 2.0 and Method 533 are both applicable and suitable for use in compliance monitoring in the final rule. The EPA notes that HFPO–DA is one of the PFAS regulated under this action and only Method 537.1, version 1.0 and version 2.0, and Method 533 support the collection of data for HFPO–DA. The agency notes that the primary difference between Method 537.1, version 1.0 and Method 537.1, version 2.0 is the field reagent blank (FRB) preparation: version 2.0 exposes the FRB to the preservative (Trizma) at the time of field sample collection. Version 1.0 combines the lab reagent water and the preservative together in the FRB prior to field sampling. Version 2.0 was created to more-closely mimic the FRB process used in Method 533. Additionally, Version 2.0 explicitly states that the solid phase extraction (SPE) cartridge sorbents may not be modified with monomers other than styrene divinylbenzene (SDVB).

A few commenters critiqued how the proposed PQLs were established for the rule. Some of these commenters provided feedback on the feasibility of the proposed PQL and suggested that it may be too low, resulting in recurring QC failures that will necessitate repeat sample analysis, increased cost, and reduced laboratory capacity. Other commenters suggest that lower PQLs can be attainable by larger labs with advanced analytical instruments. The agency disagrees that PQLs should be established at either a higher or lower level than that proposed. As discussed in the proposed rule preamble, the PQLs are based on a multi-laboratory assessment of analytical capacity. The EPA derives PQLs which reflect the level that can be reliably quantified within specific limits of precision and accuracy during routine laboratory operating conditions. Based on the multi-laboratory data acquired for the UCMR 5 rule, the EPA has defined the PQL for the PFAS regulated in this rule (Table 22). This quantitation level considers the precision and accuracy that the EPA estimates can be achieved across laboratories nationwide. The EPA anticipates that over time, as technology advances and as laboratories gain experience with the PFAS Methods, laboratories will generally improve their capability to measure at lower levels.

3. Final Rule

The EPA is establishing the following approved methods for use in compliance monitoring in the final PFAS NPDWR: EPA Method 533 (USEPA, 2019b) and EPA Method 537.1, Version 2.0 (USEPA, 2009b; USEPA, 2020c). The PFAS addressed by this regulation can be measured by both EPA Methods 533 and 537.1 and either method is acceptable for meeting the monitoring requirements of this regulation. Table 1 to paragraph (f)(1)(iv) of § 141.903 of subpart Z lists the PQLs for the PFAS regulated under this action.

VIII. Monitoring and Compliance Requirements

A. What are the Monitoring Requirements?

1. Proposal

The EPA proposed requirements for community water systems (CWS) and non-transient non-community water systems (NTNCWSs) to monitor for six PFAS. The agency proposed to amend 40 CFR part 141 by adding a new subpart to incorporate the regulated PFAS discussed in this preamble. Under this new subpart, public water systems (PWSs) would be required to sample EP using a monitoring regime based on the EPA's Standard Monitoring Framework (SMF) for Synthetic Organic Contaminants (SOCs).

The EPA proposed the following requirements for initial monitoring, which systems would be required to complete by the date three years after the date of rule promulgation (see section VIII.F of this preamble for more information). The EPA proposed that, consistent with the SMF for SOCs, groundwater systems serving greater than 10,000 persons and all surface water systems would be initially required to monitor quarterly within a 12-month period for regulated PFAS. To provide additional flexibilities for small groundwater systems, the EPA proposed to modify the SMF for SOCs such that groundwater systems serving 10,000 or fewer persons would be initially required to monitor only twice for regulated PFAS within a 12-month period, each sample at least 90 days apart. In the proposal, all systems would be allowed to use previously acquired monitoring data to satisfy the initial monitoring requirements (see section VIII.C of this preamble for additional details about using previously acquired monitoring data to satisfy initial monitoring requirements). Based on the SMF, the EPA also proposed that primacy agencies be able to use initial monitoring results to reduce compliance monitoring frequency for a system to once or twice every three years (depending on system size) if the monitoring results are below the proposed rule trigger level (defined in the following paragraphs).

The EPA proposed that, after initial monitoring, water systems would conduct compliance monitoring to demonstrate that finished drinking water does not exceed the maximum contaminant levels (MCLs) for regulated PFAS. The EPA proposed that systems with multiple EP may establish different compliance monitoring schedules for those EP depending on their monitoring results.

The EPA proposed to base compliance monitoring requirements on initial monitoring results and on system size. Then subsequent monitoring requirements would be based on results from compliance monitoring and, for systems on triennial monitoring, also on system size. To determine compliance monitoring frequency only, the EPA proposed a rule trigger level of one-third the MCLs (1.3 ng/L for PFOA and PFOS and 0.33 for Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS)). If results for an EP are below the trigger level, systems would be eligible for reduced monitoring. To implement this provision, the EPA proposed to include the ‘‘trigger level’’ concept in the new subpart.

As proposed, each water system would be eligible for reduced compliance monitoring at each EP for which all PFAS results are below the rule trigger level, according to the following schedule:

- A water system that serves 3,300 or fewer customers would be required to analyze one sample for all regulated PFAS per three-year compliance period at each EP where the water system does not have results for any regulated PFAS at or above the rule trigger level (1.3 ng/L for PFOA and PFOS and 0.33 for the Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS)),
- A water system that serves more than 3,300 persons would be required to analyze two samples for all regulated PFAS at least 90 days apart in one calendar year per three-year compliance period at each EP where the water system does not have results for any regulated PFAS at or above the rule trigger level (1.3 ng/L for PFOA and PFOS and 0.33 for the Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS).

In the proposal, if any result for an EP is at or above the rule trigger level for regulated PFAS, the water system would be required to monitor at that EP for all regulated PFAS quarterly. For compliance monitoring collection schedules, the EPA did not specify the required number of days between sampling events and only required collection during a quarter. Systems monitoring an EP less frequently than quarterly whose sample result is at or above the rule trigger level would also be required to begin quarterly sampling at the EP where regulated PFAS were observed at or above the trigger level. In either case, the primacy agency would be able to allow a system to move an individual EP to a reduced monitoring frequency when the primacy agency determines that the EP is below the rule trigger level and reliably and consistently below the MCL. However, primacy agencies would not be permitted to determine that the EP is below the rule trigger level and reliably and consistently below the MCL until at least four consecutive quarters of quarterly compliance monitoring have occurred with all sample results below the rule trigger level.

Additionally, related to laboratory capacity considerations, the EPA described in the proposal that it anticipates that laboratories will be able to adjust to demand and that the demand will be distributed across the three-year implementation period.

2. Summary of Major Public Comments and EPA Responses

The following discussion details numerous comments the EPA received on the proposed monitoring requirements, both for initial monitoring and long-term compliance monitoring.

The majority of comments the EPA received on the initial monitoring requirements related to the number of initial samples systems would be required to collect and the intervals between required samples. Most commenters were generally supportive of the EPA's proposed initial monitoring requirements, including the flexibilities to use previously acquired monitoring data to satisfy some or all the initial monitoring requirements and, for those groundwater systems serving 10,000 or fewer that do not have this data, that they be required to only collect two samples at each EP to satisfy initial monitoring requirements. For a discussion of comments and final rule requirements specific to the use of previously acquired monitoring data to satisfy the initial monitoring requirements see section VIII.C of this preamble.

While most commenters were supportive of the number of initial monitoring samples the EPA proposed, a few commenters indicated they thought the EPA should not allow the flexibility for groundwater systems serving 10,000 or fewer to collect only two samples and instead require quarterly samples be collected by all systems to meet initial monitoring requirements, which would be fully consistent with the SMF framework for other SOCs. A couple of these commenters suggested that there are no data demonstrating that smaller systems are less likely to have elevated levels of PFAS than large systems or that groundwater systems are less likely to have elevated levels of PFAS than surface water systems. Additionally, other commenters generally suggested that two samples may not generate enough data to accurately capture the level of PFAS in drinking water and any potential seasonal variability. Related to potential seasonal changes in measured PFAS concentrations, some commenters from state agencies indicated that they have not observed seasonal variations in concentrations of PFAS measured by groundwater systems, whereas other commenters suggested the opposite and that they have seen changes seasonally based on their state's monitoring data.

The EPA disagrees with commenters that suggest two samples for small groundwater systems would not accurately capture the baseline level of regulated PFAS in drinking water. The EPA determined the initial monitoring requirements based on both source water type and system size considerations. First, from a national-level perspective, the EPA's model for estimating national PFAS drinking water occurrence (see section VI.E of this preamble) indicates that, regardless of source water type, small systems generally have lower mean PFAS concentrations and lower within-system variability than large systems. Further accounting for source water type, as compared to all groundwater systems, all surface water systems potentially have a larger number of sources of contamination and greater hydrology variability so more monitoring data is necessary to ensure an appropriately protective monitoring schedule. Both the differences in the occurrence estimations for large and small sized systems as well as the general source water characteristics of groundwater systems were collectively considered as part of establishing the proposed initial monitoring requirements for small groundwater systems. Consequently, the agency expects that small groundwater systems would be less likely to experience variations throughout a year and, where there may be seasonal variations, requiring the samples to be collected in different parts of a year would provide sufficient information to determine the appropriate compliance monitoring schedule. Furthermore, given the different experiences cited by commenters, possible seasonal variation is likely based on the specific geographic location and other localized factors. If there are regional factors that suggest more frequent sampling is warranted, the rule provides that primacy agencies may increase the required monitoring frequency, where necessary, to detect variations within the system (*e.g.,* fluctuations in concentrations due to seasonal use or changes in water source).

In response to comments about the alignment of Unregulated Contaminant Monitoring Rule (UCMR) 5 sampling with initial monitoring requirements, a couple of commenters indicated that requiring larger groundwater systems to collect four samples would translate into these systems needing to collect two additional samples beyond those collected for the UCMR 5 monitoring effort. The EPA acknowledges that while the initial monitoring requirements generally align with the UCMR 5 sampling requirements, groundwater systems serving greater than 10,000 would need to collect two additional samples and notes that they have the three years following rule promulgation to complete this monitoring. As described previously, the model for estimating national PFAS drinking water occurrence indicates that larger systems have greater within-system variability than smaller systems, therefore it is appropriate that these larger groundwater systems collect four initial monitoring samples; this is consistent with initial monitoring requirements for groundwater systems under existing SOC National Primary Drinking Water Regulations (NPDWRs).

In addition, a couple of commenters recommended that the number of required samples for initial monitoring be based on the results of the first two samples, with subsequent monitoring only required if regulated PFAS are detected in those earlier samples. The EPA recognizes there is some logic to this approach; however, there would be challenges implementing it. Specifically, it could be challenging for primacy agencies to track and implement the proposed approach, particularly for groundwater systems serving 10,000 or fewer which would require the additional samples to occur in quarters not represented by the first two samples. Furthermore, tracking this varying monitoring would result in additional administrative burden and oversight challenges for primacy agencies, rather than having a consistently defined schedule for monitoring requirements as is used for other SOCs.

The EPA also received several comments from state agencies about the required intervals associated with initial quarterly and semiannual sample collection. In its proposal, the EPA specified that samples be collected at least 90 days apart, whether the samples were required of a system monitoring on a quarterly basis or a system monitoring semi-annually. A couple of commenters noted that they believed that semiannual samples should be separated by more than 90 days to better capture seasonal variations (*e.g.,* seasonal changes in the percent contributions of water blended from different sources, other fluctuations in concentrations). One commenter suggested semiannual samples should be collected at least 180 days apart, which would also be in better alignment with the required schedule for UCMR 5 semiannual sampling. The EPA agrees with these comments. In the final rule, the EPA is requiring that the samples be collected 5 to 7 months apart for semiannual initial monitoring (see table 2 to paragraph (a)(4)(i)(B) of the regulations governing the UCMR program in 40 CFR 141.40).

With respect to the sample collection timing requirements for quarterly initial monitoring (for all surface water systems and groundwater systems serving greater than 10,000), a few commenters indicated that they were opposed to the proposed requirement for samples to be spaced at least 90 days apart. These commenters indicated that such a requirement was unnecessarily prescriptive and would make sample collection logistically challenging for public water systems. These commenters suggested the EPA change the required spacing in a way that still satisfies the EPA's intent to not have samples collected only a few days apart, but in different quarters, so that quarterly samples are more representative of fluctuations in concentrations over time. The EPA agrees with these comments and sees the value of systems being able to use four existing samples collected in separate quarters but also allow flexibility that they are not all spaced at least 90 days apart. In the final rule, the EPA is modifying the required spacing of quarterly initial monitoring samples to be 2 to 4 months apart if samples are collected in a 12-month period. For systems that would need to supplement previously acquired data to satisfy all the initial monitoring requirements, the final rule requires that they must also be 2 to 4 months apart from the months of available pre-existing data. This will also better parallel the language outlining the required spacing of quarterly samples collected for the UCMR 5 monitoring effort.

Some commenters asked the EPA to clarify which systems would be subject to the initial monitoring requirements for surface water systems and which systems would be subject to the requirements for groundwater systems, in some cases presenting examples of specific scenarios. One example is when a system relies on surface water at some EP and groundwater at other EP. The EPA has modified the language of the final rule in § 141.902(b)(1)(ii) to clarify that initial monitoring requirements are to be determined based on the type(s) of water serving as the source for a given EP; thus, one system may have different initial monitoring requirements that apply to different EP. In response to questions, the EPA is clarifying in § 141.902(b)(1)(iv) that, if an EP uses water blended from multiple sources (some groundwater and some surface water), or if it uses different types of sources throughout the year, the system must follow the monitoring frequency for a surface water system (since water from surface water sources is used at least in part, for at least a portion of the year). This approach is more protective of public health because, as described earlier, generally surface water systems have more variable hydrology and potentially more sources of contamination so more monitoring data is necessary to ensure an appropriately protective monitoring schedule.

A couple of commenters asked for clarification about whether EP supplying groundwater under the direct influence of surface water (GWUDI) would qualify for semiannual initial monitoring. As noted in § 141.902(b)(1)(iii), GWUDI systems follow the requirements for surface water systems. GWUDI systems may be as susceptible to contamination as surface water systems; thus, these systems must use the sampling requirements for surface water during the initial sampling phase to establish baseline levels of regulated PFAS.

Regarding the requirements for longer-term compliance monitoring, the comments the EPA received related primarily to the frequency with which sampling would occur under different circumstances, whether each EP would be allowed to be on a different compliance monitoring schedule, and the trigger levels that would support decisions about reduced triennial monitoring. Regarding the latter point, commenters also addressed laboratory capabilities to measure levels below practical quantitation levels (PQLs).

The EPA's proposal would allow systems eligible for reduced monitoring, and serving 3,300 or fewer, to collect one sample triennially and would allow eligible larger systems to collect two samples during a three-year compliance period. The EPA specifically requested comment on whether all water systems, regardless of system size, should be allowed to collect and analyze one sample per three-year compliance period if the system does not measure any regulated PFAS in their system at or above the rule trigger level. A few commenters stated that they did not agree with a different number of triennial samples eligible systems must collect based on the size of the population a system serves. These commenters indicated that they believe that one sample collected every three years is sufficient for systems of any size on reduced monitoring. The EPA agrees with these commenters that systems eligible for triennial monitoring should be allowed to collect one sample every three years, regardless of system size, especially considering other changes to the compliance monitoring framework, as described subsequently.

Several commenters recommended that an annual sampling frequency tier be added to the required monitoring framework for various reasons including the mobility and persistence of PFAS in the environment, to ensure that systems that have demonstrated elevated levels of regulated PFAS are not allowed to move directly from quarterly to triennial monitoring, and based on their concerns that some laboratories may not be able to produce results at or below the rule trigger levels (resulting in some systems remaining on quarterly monitoring indefinitely even if they can consistently demonstrate they are below the MCLs). A few commenters supported offering three possible monitoring frequencies: quarterly, annually, and triennially, whereas many other commenters recommended against allowing triennial sampling at all and recommended that sampling be required no less than annually, to best protect public health. Those commenters supportive of allowing both annual and triennial monitoring, depending on prior sample results, suggested that annual monitoring should be an option for systems with regulated PFAS concentrations that are reliably and consistently below the MCLs. This modification would parallel the three tiers of monitoring allowed for other organic chemicals under the SMF.

The EPA does not agree with the comments suggesting that no systems should be allowed to sample triennially and that the longest sampling interval at any location should be one year. Based on the EPA's national occurrence estimates, most water systems subject to the rule's requirements will not have results for regulated PFAS that exceed the MCLs, and many will not identify PFAS at or above the triggers for reduced monitoring. These systems, after demonstrating results below the trigger level and therefore no or very little presence of regulated PFAS during the initial monitoring period or through ongoing compliance monitoring, should be able to reduce their monitoring burden and conduct triennial sampling. These monitoring requirements will sufficiently maintain public health protection. If a system monitoring triennially did have a sample result with elevated levels of a regulated PFAS (at or above the trigger level), it would be required to immediately initiate quarterly monitoring. Additionally, the rule specifically provides that primacy agencies may increase the required monitoring frequency for compliance sampling for a variety of reasons, including to detect variations within specific systems (*e.g.,* fluctuations in concentrations due to seasonal use patterns or changes in water sources).

For any system that has regulated PFAS concentrations at or above the trigger level, but reliably and consistently below the applicable MCL, the EPA is introducing in the final rule an annual monitoring frequency within the compliance monitoring framework, consistent with the SMF for SOCs. A demonstration of reliably and consistently below the MCL would include consideration of at least four quarterly samples below the MCL. Annual samples would be collected during the quarter with the highest concentration measured during the prior round of quarterly sampling. The EPA expects this modification in the final rule to reduce the number of systems that are required to be on quarterly monitoring for extended periods of time, compared to the EPA's proposal.

In adopting a three-tiered monitoring framework, the EPA is modifying the required sampling frequency from triennial to annual for systems determined by states to be reliably and consistently below the MCL and changing the threshold for this determination from the trigger level to the MCL. To further reduce monitoring, any system that transitions into annual sampling will be required to collect three years of annual samples each of which show concentrations of regulated PFAS below trigger levels (*i.e.,* not an average of the three annual sample results) before then being eligible for triennial monitoring. Moreover, no system required to collect quarterly samples during compliance monitoring would be allowed to transition to triennial monitoring without first conducting three years of annual monitoring, with all results below the trigger level. If eligible for triennial monitoring, the sample collected triennially would need to be collected in the same quarter during which prior results were highest.

This additional tier is intended to create a gradual step-down schedule for affected EP to confirm levels of regulated PFAS are remaining consistently low or decreasing. The modifications to the requirements for a reliable and consistent determination and the creation of the new annual sampling tier in the final rule make the requirements for regulated PFAS more consistent with the NPDWR requirements for SOCs. They also represent flexibilities that address concerns about laboratory capability concerns. The EPA believes this three-tier approach, including the eligibility criteria for each outlined above, provides the best approach to protect public health and moderate the total cost of sampling borne by a system.

The EPA also received a few comments about the practice by systems that have installed treatment for PFAS to regularly sample finished water to ensure the efficacy of their treatment media (*e.g.,* filters), above and beyond what they would do for compliance monitoring. A few commenters suggested systems that have installed treatment would conduct this additional sampling voluntarily, typically for process control purposes. A few state agency commenters suggested that any system that is treating its water for PFAS should be required to sample more frequently than triennially (*e.g.,* annually) no matter the levels of previous PFAS detections, since the effectiveness of treatment media may decline over time, if not replaced. The EPA disagrees with the commenters recommending a greater sampling frequency for systems that treat their water for PFAS and does not see a compelling reason to depart from the three-tier compliance monitoring program for a system that has installed treatment. In the final rule, the EPA is adding an annual tier of sampling for any system with concentrations reliably and consistently below the MCL but not consistently below the trigger level. The EPA believes this tier will likely apply to most systems treating their water for regulated PFAS, at least for the first three years of treatment, as the EPA estimates as part of its rule costs that systems needing to install treatment will assume a treatment target of 80 percent of the MCLs. The majority of systems with elevated levels of regulated PFAS contamination are likely to sample quarterly, at least initially (unless they have treatment for PFAS in place prior to the collection of initial monitoring samples). In practice, the result is that most systems with PFAS contamination will likely not be eligible for triennial sampling unless their PFAS treatment is consistently optimized and maintained. However, the rule provides that primacy agencies may increase the required monitoring frequency, where necessary to detect variations within the system, and this approach could be applied to those systems that have installed treatment. In addition, the EPA notes that, when systems are treating for other regulated chemicals pursuant to NPDWRs, no distinctions are made between the monitoring frequency required of a system that is treating for a chemical and a system that has not installed treatment. Thus, not establishing a different monitoring frequency specifically for systems that are treating their water for PFAS is consistent with existing NPDWRs.

The EPA requested comment on the proposed allowance of a water system to potentially have each EP on a different compliance monitoring schedule based on specific EP sampling results (*i.e.,* some EP being sampled quarterly and other EP sampled only once or twice during each three-year compliance period), or if compliance monitoring frequency should be consistent across all of a system's sampling points. A few commenters recommended that all EP used by a system monitor at the same frequency, or that doing so be optional, to reduce the complexity of monitoring requirements or the potential for mistakes to be made with respect to sampling windows. However, the overwhelming majority of those who commented on this topic indicated they supported allowing different sampling frequencies for different EP. The EPA agrees that it would be beneficial to allow different sampling frequencies for different EP because it would allow utilities to realize cost savings if only the EP with elevated levels of PFAS are required to sample most frequently. In addition, the EPA notes it allows systems to use different sampling frequencies for different EP for compliance with other NPDWRs.

The EPA requested comment on monitoring-related flexibilities that should be considered to further reduce burden while also maintaining public health protection, including setting a rule trigger level at different values than the proposed values of 1.3 ng/L for PFOA and PFOS and 0.33 for the Hazard Index PFAS (PFHxS, PFNA, HFPO–DA, and PFBS). Alternative values of 2.0 ng/L for PFOA and PFOS and 0.50 for the Hazard Index PFAS were identified as possibilities. The EPA received numerous comments on the proposed rule trigger levels. Comments addressed the proposed values, specifically for PFOA and PFOS, and their intended purpose for determination of compliance monitoring frequency. Several commenters suggested that the proposed values (*i.e.,* 1.3 ng/L for PFOA and PFOS and 0.33 for the Hazard Index) are too high and the EPA should instead set lower trigger level to ensure greater public health protection. Many other commenters suggested the opposite, stating that the proposed levels are too low, that laboratories will not be able to achieve these levels, and that it may exacerbate any laboratory capacity issues. Consequently, some of these commenters were concerned that water systems would be ineligible for reduced monitoring based on their laboratory's analytical limitations. Several commenters suggested that the proposed values are inconsistent with the SMF for SOCs.

Many who commented on the subject were fully supportive of the EPA's proposed alternative trigger level values of 2.0 ng/L for PFOA and PFOS and 0.50 for the Hazard Index, while others expressed support for the inclusion of trigger levels only if these higher levels were incorporated. Some noted that these higher trigger levels would better align with current laboratory capabilities and allow greater use of previously collected drinking water data (to demonstrate systems are eligible for reduced triennial monitoring under the rule's initial monitoring requirements). A few commenters recommended alternative values of 70–80 percent of the MCLs be used as the trigger levels.

The EPA agrees with commenters that the trigger levels should be finalized as one-half of the MCLs (*i.e.,* PFOA and PFOS at 2.0 ng/L each, PFHxS, PFNA, and HFPO–DA at 5 ng/L each, and Hazard Index at 0.5). Using data submitted as part of the UCMR 5 LAP as a reference point, the EPA notes that 47 of 53 laboratories (89 percent) that applied for UCMR 5 approval generated a minimum reporting level confirmation at 2 ng/L (one-half the proposed MCL) or less for Method 533. This suggests that most laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide screening measurement results at the revised trigger level of one-half of the MCL. This corresponds with other comments described in section VIII.C of this preamble that provided their experience that laboratories are capable of reliably quantifying values below the PQLs, particularly to 2.0 ng/L for PFOA and PFOS.

Additionally, based on the EPA's evaluation of state drinking water data, updating the final rule trigger levels (to one-half of the MCL) will result in a considerable number of additional water systems significantly reducing their ongoing monitoring frequency from quarterly or annual monitoring to triennial monitoring. Although this modification from one-third of the MCL to one-half of the MCLs may provide slightly less information on a water system's measured PFAS levels as a result of their less frequent monitoring, the trigger levels for the final rule (*i.e.,* one-half of the MCLs) will ensure sufficient public health protection while reducing burden for water systems.

Many other commenters stated that either trigger levels should be removed from the rule entirely or that trigger levels should not be set to any levels below PQLs since these represent the level that can be reliably measured with a high degree of precision and accuracy across all laboratories. Several of these commenters suggested that data below the PQL are unreliable, would result in higher costs, and should not be used as the basis for any regulatory decisions. Thus, they suggested that if trigger levels are incorporated, they should be the same as the PQLs. These commenters also cited laboratory challenges in achieving measurement below the PQLs and suggested that water systems would not be eligible for reduced triennial monitoring as a result of these limitations. Additionally, some of these commenters suggested that decision making based on any values below the PQLs may exacerbate laboratory capacity issues, claiming that such trigger levels would result in errors, such as false positives, which would lead to increased monitoring where samples need to be re-tested.

The EPA emphasizes that the use of trigger levels set at values below the MCLs is consistent with other SOCs under the SMF and not novel for drinking water regulations (as described in the subsequent paragraph). Their use allows water systems the opportunity to reduce their monitoring schedule and burden where it can be demonstrated through sampling results that they are at low risk of PFAS contamination. In the absence of trigger levels, or some other threshold, all water systems would be deprived of the opportunity for reduced monitoring. At a national level, were the EPA to eliminate reduced monitoring options, this would result in a significant increase in costs to utilities. Consequently, the EPA is choosing to incorporate these levels to allow flexibility and reduce burden for water systems while maintaining health protection.

For commenters that suggest the trigger levels should be identical to the PQLs, particularly for PFOA and PFOS, the EPA disagrees as the agency must have greater assurance that the levels are below the regulatory standard, the systems are actually lower risk, and a reduced monitoring schedule is appropriate. Specifically, in the case of PFOA and PFOS, the EPA believes it would represent an unacceptable public health risk to set trigger levels at the PQLs because the EPA is setting the MCL at the PQL which means that it represents the ''maximum permissible level.'' Moreover, the approach of considering measured levels lower than PQLs for determining monitoring frequency is not novel but has been part of the drinking water standards for many years. Many drinking water standards even use a method detection limit, which by definition is lower than the PQL. Under the SMF for SOCs, for example, results both at or below detection limits and between detection limits and the MCL are utilized for monitoring frequency determination. Additionally, 40 CFR 141.24(h)(7) prescribes the monitoring frequency for organic contaminants based on sample results relative to detection limits (as defined in in paragraph (h)(18) of the same section). In each of these cases, detection limits are below their PQLs (often by a factor of 10). The approach in this rule—using levels lower than the PQL to determine monitoring frequency—is consistent with the EPA's approach for other NPDWRs (see section V of this preamble).

As described earlier, some commenters raised concerns about potential laboratory analytical and capacity issues. Some suggested that laboratories cannot achieve levels below the PQLs, which would result in water systems not being eligible for reduced monitoring based on not demonstrating results below trigger levels. The EPA recognizes that some laboratories may not be able to produce results at these lower levels with the same degree of accuracy and precision as results at or above the PQLs, and notes that there is not a requirement that they do so for these purposes. The EPA uses the PQL to inform the MCL feasibility determination and the same level of precision and accuracy is not required to determine monitoring frequency. Along these lines, several commenters questioned if the sample results must be quantified to be used for the determination of monitoring frequency, given the proposed trigger level values were set below the PQLs, requesting further clarity from the EPA on how to interpret and utilize quantified and non-quantified data. Furthermore, some commenters suggested that if values below the PQLs are used, only quantified results should be used for determining monitoring frequency. Other commenters stated there should not be a numerical value associated with results below the PQL (*e.g.,* results between the trigger levels and the PQLs) and instead such results should only be reported on an absence/presence basis.

The EPA agrees that results below the PQL may not have the same precision and accuracy as higher-level measurements; however, results below the PQL can be sufficiently determined for these purposes. Data below the PQL will be critical to ensuring that systems are monitoring at the correct frequency and whether a contaminant is present within a certain range. Moreover, while results near the trigger level may be less definitive than results at or above the PQL, such results are appropriate for establishing monitoring frequency, as well as for reporting as part of the annual Consumer Confidence Report (CCR). CCR reporting is based on *detected* contaminants and for the purposes of the PFAS NPDWR, § 141.151(d) defines ''detections'' as results at or above the rule trigger levels (see section IX of this preamble for more information on CCR requirements).

Under this final rule, for monitoring frequency determination purposes, systems are required to use all compliance sample results, including those below the PQLs and not quantified with the same precision and accuracy as is associated with the MCL compliance calculation determination. Additionally, the determination of monitoring frequency is not based on a running annual average result, but each individual sampling result. As an illustration of the approach, if a water system has quarterly sampling results at an EP from initial monitoring for PFOA that are 2.0, 1.5, 5.0, and 1.5 ng/L, there are two results (*i.e.,* 2.0 and 5.0 ng/L) at or above the EPA's final trigger level for PFOA (*i.e.,* 2.0 ng/L). Thus, the water system would not be eligible for triennial monitoring at this EP for all regulated PFAS when compliance monitoring begins. Providing a different example, if a water system that is currently required to conduct quarterly compliance monitoring has quarterly sampling results at an EP for PFOA that are 2.0, 3.5, 2.5, and 1.5 ng/L, all results are below the MCL for PFOA (*i.e.,* 4.0 ng/L), however three results are above the PFOA trigger level. In this case, because four quarters of data have been collected and assuming all other regulated PFAS sampling results are below their MCLs as well, the water system could be deemed reliability and consistently below the MCL by the primacy agency and be eligible to monitor annually at this EP. For all frequencies of ongoing compliance monitoring, including quarterly, annual and triennial, this determination would be done the same where all sample results are used, even those below the PQLs.

Many commenters requested that the EPA provide clarification on how laboratories and PWSs should report levels below the PQLs for monitoring frequency purposes. All results at or above the trigger level are to be reported as numeric values and used for determining monitoring frequency. Under the EPA approved analytical methods discussed in section XII, numeric values as low as the rule trigger levels will be available because of the need to meet ongoing QC requirements of the methods for blanks, demonstrating no background contamination. Within each analytical batch of samples, the laboratory must document passing blank QC criteria by attaining qualitative measurements of the regulated PFAS that are no higher than one-third of the laboratories reporting limit, which must be at or below the PQL. The EPA intends to provide guidance materials with details and examples on this to support successful implementation of the final rule.

Some commenters suggested the potential for confusion related to the differences in how results less than PQLs are used in monitoring frequency determination and the MCL compliance determination. Several commenters suggested that there should be a consistent approach. Most commenters suggested that the approach should follow that of the MCL compliance determination, where zero is used in the calculation of annual averages when measured values are below PQLs. The EPA reiterates that the trigger levels are used for establishing appropriate monitoring frequency. For certain regulated PFAS, they are set at a defined threshold that shows if these PFAS are present or absent. The PQLs, which are used for the MCL compliance determination, are set at specific concentrations that laboratories nationwide can measure with high certainty. To alleviate possible confusion, the EPA intends to provide communication materials on these monitoring requirements to support successful implementation of the final rule. Nevertheless, the difference in approach (between data used for compliance monitoring determinations and data used to determine monitoring frequency) reflects the most appropriate application of the data for each of the intended purposes and assures that adequate monitoring is occurring in systems where the regulated PFAS have been shown to be present at the trigger level or higher. The EPA's rationale is described in detail in section VIII.B of this preamble.

Several other issues related to monitoring flexibilities were raised in public comments. One commenter asked, if one EP has a result for a single regulated PFAS at a concentration above the trigger level, but other regulated PFAS are below trigger levels, must the system initiate quarterly sampling for all regulated PFAS at the EP or are they only required to initiate quarterly sampling for PFAS observed at or above the trigger level. As described in the rule proposal, if a regulated PFAS is detected at or above a trigger level, the system must monitor quarterly at that sampling point for all regulated PFAS. This is appropriate as the same analytical methods are used for the analysis of all regulated PFAS (no extra analyses need to be performed to measure the other PFAS) and the regulated PFAS have been shown to significantly co-occur.

In addition, commenters questioned whether quarterly sampling would be triggered when a result is equal to but does not exceed the trigger level for systems monitoring triennially. One commenter pointed out that the language proposed for inclusion in § 141.905(b)(2) stated that systems monitoring triennially whose sample result is at or exceeds the trigger level must begin quarterly sampling, whereas § 141.902(b)(2)(ii) stated the trigger level must be exceeded before quarterly monitoring is required. The EPA is clarifying this point in the final rule to reflect the EPA's intent that quarterly sampling would be triggered when a result is at or above the trigger level as prescribed in § 141.905(b)(2). This same approach has been used in other NPDWRs (*e.g.,* for SOC trigger levels).

3. Final Rule

This final rule establishes initial monitoring requirements and reflects minor modifications to the proposed approach. Groundwater CWS and NTNCWS serving 10,000 or fewer must collect two (semiannual) samples in a consecutive 12-month period and must collect the samples 5 to 7 months apart, to better capture seasonal variation. Groundwater CWS and NTNCWS serving greater than 10,000 and all surface water CWS and NTNCWS must collect four (quarterly) samples 2 to 4 months apart in a consecutive 12-month period. The EPA is maintaining the provision described in the proposed rule that allows PWSs to use previously collected data to satisfy initial monitoring requirements; see § 141.902(b)(1)(vi). Systems that need to collect additional quarterly samples to meet the initial monitoring requirements may sample outside of a 12-month period, if all quarters are represented with sample months 2 to 4 months apart. This 2-to-4-month interval also aligns with UCMR 5 sampling requirements for surface water systems subject to this rule and better captures possible seasonal variability establishing a well-informed baseline. In addition, the EPA is modifying the proposed initial monitoring requirements to now specify that if the water source for the EP is surface water, a blend of surface water and groundwater, or GWUDI, the initial monitoring requirements for surface water source (4 quarterly samples) apply. If the EP source is only groundwater, initial semiannual monitoring is required.

The EPA is modifying the number of samples required for some systems with sampling locations eligible for triennial monitoring. Regardless of the population served, all systems with sampling locations eligible for triennial sampling will collect one sample every three years. The sample is to be collected during the quarter with the highest prior concentration identified in the most recent year when samples were collected.

In the final rule the EPA is establishing a third tier for monitoring frequencies and updating the proposed requirements for each tier. The new monitoring frequency tier provides for annual monitoring at sampling locations that have collected at least four consecutive quarterly samples following initial monitoring if the primacy agency determines the results at that EP are reliably and consistently below the MCL. In establishing this tier, the EPA is removing the proposed rule requirement for a state to determine that the running annual average (RAA) concentration is below the trigger levels to reach this reliably and consistently below the MCL determination. Instead, in the final rule, reliably and consistently below the MCL means that each of the sample results for the regulated PFAS are below the applicable MCLs. In this new annual monitoring tier, if EP receive the reliably and consistently below the MCL determination and remain below the MCLs in subsequent sampling, even if above a trigger level, they may continue on an annual monitoring schedule.

The criteria eligibility for triennial monitoring have been changed accordingly. EP with all results below the trigger levels during initial monitoring are eligible for triennial monitoring, as described in the proposed rule. But, under the final rule, if an EP is required to conduct quarterly sampling during the compliance monitoring period, then triennial monitoring is only available after the EP has three consecutive annual samples that each contain concentrations below the trigger level. For EP that consistently have results between the trigger levels and the MCLs, as described previously most would remain on annual monitoring, rather than quarterly monitoring, which provides a sufficient indication of contaminant level while reducing the total sampling costs.

With respect to whether different EP for a particular water system may be sampled at different compliance monitoring frequencies, based on specific EP sampling results, the final NPDWR affirms this flexibility, as proposed. In addition, there is no change to the language in the final rule discussing the timing for taking quarterly samples during the long-term compliance monitoring period. The EPA does not specify a required interval between samples; the requirement is quarterly.

The EPA is finalizing rule trigger levels for compliance monitoring frequency purposes only at one-half of the MCLs for regulated PFAS (*i.e.,* 2.0 ng/L for PFOA and PFOS, 5 ng/L for PFHxS, PFNA, and HFPO–DA, and 0.5 for Hazard Index). If all PFAS results for an EP are below these levels, the EP would be eligible for triennial monitoring, with the following exception. If sampling location is under an annual monitoring schedule, it would be eligible for triennial monitoring following three consecutive annual samples with all sample results below the trigger levels.

The EPA's proposed rule included monitoring requirements specific to PFAS. To avoid possible confusion, the EPA is amending 40 CFR 141.24(h) to clarify that the applicable monitoring requirements for PFAS are in 40 CFR 141.902 and that the monitoring requirements for non-PFAS SOCs in 40 CFR 141.24(h) do not apply to PFAS.

B. How are PWS compliance and violations determined?

1. Proposal

Consistent with existing rules for determining compliance with NPDWRs, the EPA proposed that compliance would be determined based on the analytical results obtained at each sampling point. For systems monitoring quarterly, compliance with the proposed MCLs would be determined by calculating RAAs for each sampling point. As proposed, eligibility for reduced monitoring would be determined by the sample result(s) at the sampling point. If the sample result(s) are at or exceed the rule trigger level, the system would be required to revert to quarterly sampling, for all regulated PFAS, at each EP where a result is at or above the trigger level. In such case, the sample event that included a result(s) at or above the trigger level would be considered the first quarter of monitoring in calculating the RAA.

An RAA is calculated using results for samples taken at a particular monitoring location during the previous four consecutive quarters. As proposed, if a system takes more than one compliance sample during each quarter at a particular monitoring location, the system must average all samples taken in the quarter at that location to determine the quarterly average, which would then be used in calculating the RAAs. Conversely, if a system does not collect required samples for a quarter, the RAA would be based on the total number of samples collected for the quarters in which sampling was conducted. As proposed, MCL compliance determinations would not be made until a system has completed one year of quarterly sampling, except in the case where a quarterly sampling result is high enough that it will clearly cause the RAA to exceed an MCL (*i.e.,* the analytical result is greater than four times the MCL). In that case, the system would be in violation with the MCL immediately.

In the proposal, when calculating the RAAs, if a sample result is less than the PQL for the monitored PFAS, the EPA proposed to use zero to calculate the average for compliance purposes.

2. Summary of Major Public Comments and EPA Responses

The agency received a few different types of comments on how the compliance determination and violations were proposed to be assessed. Many commenters supported the EPA's approach to assess violations, including that violations are only assessed through an RAA for systems conducting quarterly monitoring. A couple of commenters suggested that in a scenario where a particular high quarterly sample (*i.e.,* result greater than four times the MCL) would cause the RAA to exceed an MCL, the system should not be deemed out of compliance until the end of the quarter (to allow utilities to conduct additional monitoring during that quarter and average the results from the multiple samples). The EPA disagrees with commenters that suggest additional voluntary sampling be used in calculating the quarterly average. The final rule requires that a compliance sample be taken during each quarter for those systems conducting quarterly monitoring. Further, as prescribed under 141.902(b)(2)(v), the state may require a confirmation sample for any sampling results and, if this sample is required, the result must be averaged with the first sampling results and used for the compliance determination. Therefore, any samples other than a state-required confirmation sample should not be averaged within the quarterly compliance result which will be assessed at the end of the quarter.

A couple of other commenters suggested changing the time periods for determining compliance (for both systems conducting quarterly monitoring and those conducting triennial monitoring). These recommendations included assessing compliance based on the results from eight consecutive quarterly samples (rather than four). For those systems conducting triennial monitoring, some commenters proposed that the compliance determination be based on one triennial sample result. For systems determining compliance through an RAA calculation, the EPA believes four consecutive quarterly samples is an adequate representation of the regulated PFAS levels while also assessing compliance in a timely manner. For systems conducting triennial monitoring, if a water system has a sample result at or above the EPA's trigger levels, the system will immediately be required to begin quarterly monitoring. This is consistent with other monitoring requirements for other SOCs and, given the change in measured concentration, will provide additional information over a consistent and longer period of time to better assess the average level of regulated PFAS within the water supply and ensure the water system is reliably and consistently below the MCL.

In the proposed rule, the EPA requested comment on whether the agency should consider an alternative to the approach of using zero when calculating the RAAs if a sample result is less than the PQL. Specifically, in the case where a regulated PFAS is detected but the result is below its proposed PQL, the proposed rule invited comment on whether the trigger level (proposed as one third of the PQL) should be used as the value in calculating the RAA for compliance purposes.

The EPA received numerous comments related to the proposed approach for calculating the RAA for compliance with the NPDWRs, particularly on the incorporation of sample results below the PQLs for the regulated PFAS (see sections V and VII for more information on PQLs.) Many commenters, including some states, supported the EPA's proposed approach to utilize zero for results below PQL to calculate the average for compliance purposes. These commenters cited the definition of the PQL as the lowest concentration of an analyte that can be reliably measured within specified limits of precision and accuracy during routine laboratory conditions and noted that this is a level that all laboratories should be able to achieve. Consequently, they suggested that values below these PQLs should not be used for the compliance calculation. Several of these commenters expressed concern that using estimated or other values with less precision in the compliance calculation could result in utilities needing to take actions to address levels of regulated PFAS that are not well-quantified and may not be representative of regulated PFAS levels. Many commenters suggested that since all laboratories cannot achieve values less than the PQLs, this would result in equity issues with respect to disparate laboratories capabilities. Some also suggested that the approach could exacerbate any potential laboratory capacity issues.

The EPA agrees with these commenters that values below the PQLs for the regulated PFAS should not be used in the compliance calculation. As cited previously by commenters and the EPA in sections V and VII, PQLs are the lowest concentration that can be reliably measured within specified limits of precision and accuracy during routine laboratory operations. As noted in the rule proposal, ''the agency must have a high degree of confidence in the quantified result as it may compel utilities to make potentially costly compliance decisions in order to comply with the MCL.'' Moreover, because compliance with the MCL is determined by analysis with approved analytical techniques, the ability to analyze consistently and accurately for a contaminant is important to enforce a regulatory standard. The EPA recognizes the potential for minor analytical variabilities within sampling procedures and laboratory analyses below the PQL and this approach offers operational certainty to utilities, provides assurances of precision and accuracy in the concentrations at or above the PQL that are achievable for all laboratories, ensures equitable access to all laboratories with comparable analytical capabilities for the purposes of compliance sample results, and reduces the potential for laboratory capacity issues.

Many other commenters did not support the EPA's proposed approach and offered that all sample results between method detection limits and PQLs, even if estimated, should be used. Alternatively, some suggested that any results that laboratories are able to quantify should be used in calculating the RAA for compliance. A subset of these commenters suggested that using zero (instead of an estimated or semi-quantitative value) biases the RAA compliance calculation, is even less precise and accurate than using the values below the PQLs, is contrary to the RAA compliance calculation for other SOC NPDWRs and demonstrates a reduction in public health protection. Some commenters also suggested that this could result in public communication challenges if laboratories are able to estimate or quantify values below the PQLs and zero is instead used in the calculation. Further, several commenters submitted that, in their experiences, some laboratories are capable of reliably and accurately reporting below the PQLs.

While the EPA recognizes that using zero for values below the PQL would result in a differing RAA compliance calculation result than if the values below the PQL were instead used, on a national scale, these values below the PQL do not consistently represent values with the precision, accuracy, and reliability the EPA believes are necessary for compliance determination purposes. Therefore, the EPA's national approach to achieve consistency (recognizing that laboratories have varying analytical capabilities) is to judge compliance based on results at or above the PQL. Using inconsistent values below the PQL may result in MCL compliance determination inequities across systems.

The EPA agrees that some laboratories are capable of reliably measuring the regulated PFAS below the EPA's PQLs. This is supported by a subset of state PFAS monitoring data that represents some sampling with quantified values below the EPA's PQLs. Further, in the March 2023 proposal, the EPA recognized that ''quantitation of the contaminants can be achieved between the method detection limit and the PQL'' though the EPA also noted in the proposal that this is ''not necessarily with the same precision and accuracy that is possible at and above the PQL.'' The EPA must set requirements evaluating the circumstances of all PWSs and laboratory capabilities throughout the country. The agency notes that states must establish requirements at least as stringent as the EPA to maintain primacy; however, under the Safe Drinking Water Act (SDWA), states with primacy may establish more stringent requirements. In instances where a laboratory can demonstrate it is capable of precisely and accurately quantifying values below the PQLs, some states may choose to establish their own requirements that are more stringent and use these values for the compliance calculation.

The agency also received a few comments on the possible alternative approach of using the proposed trigger level as the value in calculating the RAA for compliance purposes when the result is estimated as between the trigger level and PQL. Most commenters did not agree with using the trigger levels as an estimate instead of zero when values are below the PQL and noted that these values could result in inequitable implementation of the rule based on laboratory analytical capabilities.

After consideration of all these comments and for the reasons described previously, the EPA does not believe it is appropriate to use trigger level values or any other values above defined detection limits but below the PQL as part of the RAA compliance calculation based on the information available to the agency today. Trigger levels are appropriate to determine if the contaminant is present (*i.e.,* detected) and for the determination of reduced monitoring frequency, however the EPA concludes that values below the PQL would not consistently and reliably demonstrate the accuracy and reliability necessary for compliance determination purposes that can result in make potentially costly expenditures for PWSs.

3. Final Rule

For the final rule, the EPA is maintaining the proposed compliance calculation determination approach. For systems with sampling locations monitoring quarterly, compliance with the MCLs for regulated PFAS is determined by calculating RAAs using compliance results for particular sampling points. Based on final rule changes to the compliance monitoring requirements previously described in section VIII.A of this preamble above, systems with sampling locations monitoring less frequently than quarterly are required to revert to quarterly sampling for *all* regulated PFAS in the next quarter at each EP with the exceedance where either the sample result(s) are at or above the rule trigger level (for those on triennial monitoring) or the sample result(s) are at or exceed the MCL (for those on annual monitoring). In both cases, the triggered sample result is required to be used for the first quarter of monitoring in calculating the RAA. If a system takes more than one compliance sample during each quarter at a particular monitoring location, the system must average all samples taken in the quarter at that location to determine the quarterly average and this will be used in calculating the RAAs. Conversely, if a system does not collect the required compliance samples for a quarter, the RAA will be based on only those quarters where samples were collected during the past four quarters. A system will generally not be considered in violation of an MCL until it has completed one year of quarterly sampling (*i.e.,* a system on an annual or triennial monitoring schedule with an exceedance of the MCL is not in violation until it completes one year of quarterly sampling with the sample exceeding the MCL used as the sample result for the first quarter of the RAA). However, regardless of the result of subsequent monitoring, if a quarterly sample result will cause the RAA to exceed an MCL at any sampling point (*e.g.,* the first quarter sample result is greater than twice the MCL and the second quarter sample result is also greater than twice the MCL) or if an annual or triennial sample result causes the RAA to exceed an MCL at any sampling point (*i.e.,* the analytical result is greater than four times the MCL), then the system is out of compliance with the MCL immediately.

The EPA is also retaining the proposed approach for the MCL compliance calculation where, if a sample result is less than the PQL for the monitored PFAS, zero will be used to calculate the RAA (if monitoring quarterly). To clarify how to implement approach, the EPA is providing a few different examples related to calculating the RAA for the PFOA/PFOS MCLs, the individual MCLs for PFHxS, PFNA, and HFPO–DA, and the Hazard Index MCL for the mixtures of PFHxS, PFNA, HFPO–DA, and PFBS.

If a system conducting quarterly monitoring has sample results for PFOA that are 2.0, 1.5, 5.0, and 1.5 ng/L for their last four quarters at a sample location, the values used to calculate the RAA for that sample location would be 0, 0, 5.0, and 0 ng/L with a resulting PFOA RAA of 1.3 ng/L (*i.e.,* (0 + 0 + 5.0 + 0)/4 = 1.3 ng/L). For PFOA and PFOS, as described in section V of this preamble, the MCLs of 4.0 ng/L are promulgated with two significant figures and must be expressed as such in the calculation with any rounding not occurring until the end of the calculation. Data reported to the primacy agency must contain the same number of significant digits as the MCL. In calculating data for compliance purposes, the number must be rounded to two significant digits. The last significant digit should be increased by one unit if the digit dropped is 5, 6, 7, 8, or 9, and if the digit is 0, 1, 2, 3, or 4, the preceding number does not change (*e.g.,* 1.37 is reported as 1.4).

As described in section V of this preamble, the EPA is finalizing individual MCLs and Health Based Water Concentrations (HBWCs) for PFHxS (10 ng/L), HFPO–DA (10 ng/L), and PFNA (10 ng/L), the HBWC for PFBS (2000 ng/L), and the Hazard Index MCL (1 unitless) with one significant figure. Similar to PFOA and PFOS, if a sample result is less than the respective PQLs for these PFAS (*i.e.,* 3.0 ng/L for PFHxS, 5.0 ng/L for HFPO–DA, and 4.0 ng/L for PFNA), zero will be used to calculate compliance both for the PFHxS, PFNA, and HFPO–DA MCLs and the Hazard Index MCL for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS. As an example, for the HFPO–DA MCL compliance calculation (which would be the same for the PFHxS and PFNA MCLs using their respective PQLs), if a system conducting quarterly monitoring has HFPO–DA sample results that are 3.2, 6.1, 5.5, and 2.7 ng/L for the last four quarters at a sample location, the values used to calculate the RAA for that sample location would be 0, 6.1, 5.5, and 0 ng/L with a resulting HFPO–DA RAA of 3 ng/L after rounding to one significant figure at the end of the calculation (*i.e.,* (0 + 6.1 + 5.5 + 0)/4 = 2.9 ng/L). Therefore, this system has not violated the MCL for HFPO–DA. The EPA notes that for all MCL RAA calculations, water systems are required to retain the unrounded RAA value (2.9 ng/L in this example) for use in the next RAA calculation as no rounding should occur until the end of the overall compliance calculation (*i.e.,* 2.9 ng/L, not 3 ng/L, should be used).

To provide an example calculation for determining compliance with the Hazard Index MCL for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS, if the quarterly sample results at a sample location are 2.1 ng/L for PFHxS, 3.4 for HFPO–DA, 4.1 for PFNA, and 20.0 for PFBS, the water system would first determine the Hazard Index value for that quarter, which is 0.42 (*i.e.,* ((0/10) + (0/10) + (4.1/10) + (20.0/2000) = 0.42). To then calculate the RAA Hazard Index MCL, if the preceding three quarters had unrounded Hazard Index values of 0.76, 1.10, and 0.53 at the same sample location, the resulting RAA Hazard Index MCL would be 0.7 after rounding to one significant figure at the end of the calculation (*i.e.,* (0.76 + 1.10 + 0.53 + 0.42)/4 = 0.70). Consequently, this system has not violated the Hazard Index MCL.

C. Can systems use previously collected data to satisfy the initial monitoring requirement?

1. Proposal

The EPA proposed that systems be allowed to use previously collected monitoring data to satisfy the initial monitoring requirements. In general, a system with appropriate historical monitoring data for each EP, collected using EPA Methods 533 or 537.1 as part of UCMR 5 or a state-level or other appropriate monitoring campaign, could use that monitoring data to satisfy initial monitoring requirements. The EPA notes that for systems monitoring under UCMR 5, all surface water systems are required to collect four quarterly samples and all groundwater systems are required to collect two quarterly samples over a period of 12 months.

While the EPA expects most systems serving 3,300 or greater will have some UCMR 5 data, the EPA also proposed that systems with previously acquired monitoring data from outside UCMR 5, including state-led or other appropriate occurrence monitoring using EPA Methods 533 or 537.1 would also be permitted to use these other monitoring data in lieu of separate initial monitoring for regulated PFAS. The proposed approach may have allowed systems serving fewer than 3,300 (many of whom do not participate in UCMR 5) to otherwise satisfy the initial monitoring requirements. The EPA proposed that data collected after January 1, 2023, be accepted for EP samples, and data collected between January 1, 2019, and December 31, 2022, also be accepted if it is below the proposed rule trigger level of 1.3 ng/L for PFOA and PFOS and a Hazard Index of 0.33 for PFHxS, PFNA, HFPO–DA, and PFBS. Additionally, the EPA proposed that if systems have multiple years of data, the most recent data were to be used.

In the proposal, the EPA stated that if a system had conducted prior monitoring involving fewer than the number of samples required for initial monitoring under this PFAS NPDWR, then all surface water systems, GWUDI systems, and groundwater systems serving greater than 10,000 would be required to collect at least one sample in each quarter of a calendar year that was not acquired and groundwater systems serving 10,000 or fewer would be required to collect one sample in a different quarter of the calendar year than the one in which the previous sample was acquired.

2. Summary of Major Public Comments and EPA Responses

The EPA requested comment on the proposal to allow the use of previously acquired monitoring data to satisfy the initial monitoring requirements. This included a request for feedback on the data collection timeframe requirements and on whether particular QA requirements should be established for such data. Of commenters that provided input on the proposed allowance, nearly all supported the use of previously collected data to support the initial monitoring requirements. The EPA agrees with these commenters that appropriate, previously collected data should be allowed and notes that there will be significant data available from UCMR 5 monitoring and from the many states that have been proactively conducting PFAS drinking water monitoring. This will allow for a significant opportunity to reduce burden for numerous water systems, as well as decrease the potential for laboratory capacity issues. One commenter suggested that the use of this data may not be sufficiently representative of current PFAS concentrations in drinking water systems as the laboratory analyses previously used may not have been sufficiently sensitive to detect the analytes, relative to the proposed PFAS regulatory standards. The EPA disagrees with this commenter as the analytical methods proposed for PFAS analysis were available for the majority of the time period (*i.e.,* 2019 and after) in which data are allowed to be used to satisfy the initial monitoring requirements. Furthermore, the rule provides that a primacy agency may choose to not allow these data to satisfy initial monitoring requirements and may require more frequent monitoring on a system-specific basis. Additionally, the EPA clarifies that previous monitoring does not automatically qualify water systems for reduced compliance monitoring; rather it is the results from that monitoring that determine the eligibility for a reduced compliance monitoring schedule.

Many commenters suggested that the use of these data should be at the state's discretion and requested that the EPA provide additional flexibility to the primacy agencies in the determination of which data are allowed, including the number of samples and the QA requirements. Moreover, several commenters asked that the EPA clarify how much additional data would be needed to satisfy the initial monitoring requirements if a previous monitoring campaign included less sampling than required under the rule initial monitoring requirements. Specifically, a few commenters noted that, under the requirements of UCMR 5 monitoring, groundwater systems serving greater than 10,000 would have results from two sampling events, not the four needed to satisfy the initial monitoring requirements of this rule. Commenters requested that the EPA explain if these UCMR 5 systems would need to collect additional (supplemental) samples. A few commenters suggested UCMR 5 monitoring should sufficiently meet the requirements for all systems, even though the proposed rule requires quarterly sampling for all groundwater systems serving greater than 10,000.

Having considered the public comments, the EPA is establishing in the final rule that water systems that have collected fewer samples (under UCMR or other programs) than required in this rule for initial monitoring must conduct supplemental monitoring that allows them to meet the minimum requirements. Additional details on this requirement are in section VIII.C.3 of this preamble. In the case of UCMR 5, for example, groundwater systems serving greater than 10,000 will be required to collect two additional samples beyond the two collected for UCMR 5. For more information on the initial monitoring requirements, please see section VIII.A of this preamble.

Several commenters requested that the EPA clarify whether only samples collected under UCMR 5 would be allowed to fulfill initial monitoring requirements, or if data under other monitoring efforts, such as state monitoring, would also be acceptable. As provided in the proposal and final rule, a state may accept results from all appropriate monitoring efforts, as determined by the state, including, but not limited to, UCMR 5 and other state-led efforts.

Several commenters provided various comments related to QA requirements for previously collected data, including data analysis methods, minimum reporting levels, and data collection timeframe. A few commenters expressed that the EPA should allow the use of results from modified EPA methods and/or other state-developed analytical methods. The EPA disagrees with these commenters. While there are other methods that have been used for data collection and analysis, the EPA is requiring that any data used for this rule be collected and analyzed using Methods 533 and 537.1 to ensure consistency across analytical results, as well as to align with the final rule analytical method requirements described in § 141.901. A few commenters requested that the EPA provide additional information on reporting level requirements of the data, with one commenter suggesting that the EPA should not allow this data to be used for initial monitoring purposes if the reporting limits of the laboratory are higher than the EPA's proposed PQLs. The rule provides that the available data can be used regardless of reporting or detection limits to satisfy the initial monitoring requirements; however, given these factors, the results may not support determinations for reduced compliance monitoring. Regarding data collection timeframes, a few commenters questioned why data collected prior to 2023 would not be accepted where the results are higher than the proposed rule trigger levels. In response, the EPA has modified the rule to allow data from January 1, 2019, and later to satisfy initial monitoring requirements, even if it is not below the final rule trigger levels if it meets all other requirements (including being analyzed using Methods 533 and 537.1). Data collected prior to 2019 may not be representative of water quality conditions and likely would not have been analyzed using these methods (given when they were published). The EPA notes if the results exceed the final rule trigger levels the system will not be eligible for a reduced monitoring schedule at that EP.

3. Final Rule

The EPA is retaining the proposed allowance of using previously collected monitoring data to satisfy some or all of the initial monitoring requirements. The agency notes that while use of this data is allowed, water systems may choose to conduct additional monitoring to satisfy their initial monitoring requirement in lieu of using pre-existing data. As described previously in section VIII.A of this preamble, the final rule initial monitoring requirements specify that all system sizes with surface water or GWUDI sources and groundwater systems serving greater than 10,000 are required to collect four quarterly samples, and groundwater systems serving 10,000 or fewer are required to collect two samples. The EPA is clarifying that the number of samples required is based at the EP; therefore, if a system serving 10,000 or fewer has EP with different source water types, the required monitoring is based on the source water type of that EP (*i.e.,* a system serving 10,000 or fewer that has surface water, groundwater, and/or GWUDI sources during the initial monitoring period must collect two samples at the EP sourced by groundwater and four samples at the EP sourced by surface water or GWUDI). For systems serving 10,000 or fewer that change the source water type at EP throughout the initial monitoring period (*i.e.,* one part of the year is surface water, and the remaining part of the year is groundwater and/or GWUDI), the EP must follow the sampling requirements of surface water systems.

In the final rule under § 141.902(b)(1)(viii), the EPA is maintaining that if a system has some previously collected results, but fewer than the number required to satisfy the initial monitoring requirements, they must conduct additional monitoring such that it, coupled with the previous monitoring, meets the requirements of this rule. All surface water and GWUDI systems, and groundwater systems serving greater than 10,000, must collect the required additional samples 2–4 months apart from the months with available data, without regard to year, such that all quarters are represented (see section VIII.A of this preamble for more information).

In § 141.902(b)(1)(vi), the final rule maintains the requirement that the data must have been collected and analyzed using EPA Methods 533 or 537.1, and eliminates the requirement that data collected between January 1, 2019, and December 31, 2022, must reflect the laboratory's ability to measure at or below the rule trigger level to satisfy initial monitoring requirements. Data collected before January 1, 2019, cannot be used to satisfy these requirements. Additionally, any results above the final rule trigger levels of 2.0 ng/L each for PFOA and PFOS, 5 ng/L each for PFHxS, PFNA, and HFPO–DA, and a Hazard Index of 0.5 for PFHxS, PFNA, HFPO–DA, and PFBS would not allow the associated EP to be eligible for reduced monitoring.

D. Can systems composite samples?

1. Proposal

Subpart C of 40 CFR 141.24 describes instances where primacy agencies may reduce the samples a system must analyze by allowing samples to be composited. Composite sampling can potentially reduce analytical costs because the number of required analyses is reduced by combining multiple samples into one and analyzing the composited sample. However, in the proposal, the EPA noted that based on input the agency received from consulting with state regulators and small business entities (operators of small PWSs), PFAS are ubiquitous in the environment at low concentrations, which necessitates robust laboratory analytical precision at these low concentrations. Based on these potential implementation issues, the EPA proposed that compositing of samples would not be allowed.

2. Summary of Major Public Comments and EPA Responses

The EPA received comments related to composite sampling. The majority of these commenters agreed with the EPA's proposal to not allow samples to be composited due to analytical limitations and the increased potential for background contamination, along with the physical and chemical characteristics of PFAS. A few commenters suggested that they believed composite sampling could be implemented and would reduce the cost of analyses. Further, some of these commenters suggested that with proper guidelines and procedures for analyzing samples, possible contamination issues could be mitigated and asserted that issues with false negative and positive samples also impact discrete samples (*i.e.,* that they are not unique to composite sampling).

The EPA received other comments regarding the specifics of composite monitoring. One commenter noted grab samples as more appropriate and suggested that individual systems be permitted to request alternative sampling methodologies if needed. One other commenter suggested that compositing samples from varying EP should not be allowed. In addition, one commenter requested that the EPA provide information as to the increased risk of compositing samples, along with discussion of the proposed departure from the SMF for SOC ahead of rule finalization.

For commenters who offered that composite sampling could be implemented, the EPA agrees it would potentially decrease sampling analysis costs and that sampling errors can occur when handling and analyzing discrete samples. However, the compositing of samples necessarily involves additional handling, opening, and transfer steps than are required for the collection and analysis of individual samples. Therefore, the combining of samples that must be done for composite sample analysis represents an increased risk of sampling error, which could result in decreased public health protection and additional sampling costs. The agency also does not agree that alternative sampling methodologies should be permitted and requires the use of EPA Methods 533 and 537.1 for monitoring per the requirements of the rule. Please see section VII of this preamble for more information on methods.

As discussed previously, PFAS are pervasive in the environment and require robust laboratory analytical precision, particularly at low concentrations. Accordingly, the EPA agrees with commenters that do not support the allowance of composite sampling and maintains that discrete sampling is the most appropriate type of sampling for regulated PFAS.

3. Final Rule

Based on consideration of public comments (many of which supported the EPA's concerns about the ubiquitous nature of PFAS at low concentrations in the environment, the necessary robust laboratory analytical precision required, and potential implications for implementation), the final rule does not allow composite samples.

E. Can primacy agencies grant monitoring waivers?

1. Proposal

Subpart C of 40 CFR 141.24 describes instances where the primacy agency may grant waivers predicated on proximity of the system to contaminant sources (*i.e.,* susceptibility to contamination) and previous uses of the contaminant within the watershed (including transport, storage, or disposal). The EPA did not include a provision to allow primacy agencies to grant monitoring waivers as a regulatory flexibility in the proposed rule. The EPA did, however, request public comment on whether to allow systems to apply to the primacy agency for a monitoring waiver of up to nine years (one full compliance cycle) if, after at least one year of quarterly sampling, the results are below the rule trigger level, or for systems that may be approved for reduced monitoring, if at least two consecutive results are below the rule trigger level. The EPA also requested comment on allowing similar monitoring waivers to be granted based on previously acquired monitoring data as described in section VIII.C of the preamble for the proposed rulemaking. The EPA additionally sought comment on possible alternatives to traditional vulnerability assessments that should be considered in order to identify systems as low risk and potentially eligible for monitoring waivers.

2. Summary of Major Public Comments and EPA Responses

Several commenters suggested that monitoring waivers should not be allowed for this rule. Several additional commenters cited the persistence and mobility of PFAS in the environment and advised that reduced monitoring frequencies should be no less than every three years on the basis that drinking water consumers in unmonitored areas may unknowingly be exposed to these PFAS. Furthermore, many other commenters suggested that PFAS contamination can migrate significantly over a three-year period.

Many other commenters were supportive of monitoring waivers for this rule under certain circumstances. Several commenters indicated that waivers would be appropriate if they were based on monitoring results. A few commenters recommended that if monitoring waivers were to be allowed, that they should not be based solely on a traditional vulnerability assessment. A couple of commenters stated that waivers based on vulnerability alone should not be allowed during the initial monitoring period. One commenter recommended waiting until UCMR 5 monitoring is complete before allowing monitoring waivers to be granted through vulnerability assessments. A couple of commenters suggested that waivers be considered if they are based on a combination of vulnerability *and* monitoring results, while one other commenter suggested that assessing watershed characteristics to demonstrate eligibility for monitoring waivers would be protective of chronic health risks. One commenter noted that merely allowing waivers to be granted would not necessarily reduce public health protection under the rule, as primacy agencies will retain the ability to deny waiver applications.

After consideration of these comments, and due to the mobility and persistence characteristics of the regulated PFAS, the final rule does not allow monitoring waivers. These specific properties of the regulated PFAS and their observed ubiquity in both drinking water and within many other sources make waivers impractical and complicate the ability to maintain public health protection if such a provision were included as part of this rule. Moreover, the EPA is not confident that allowing monitoring any less frequently than every three years or conducting vulnerability assessments will accurately capture potential concentration variations over the long term or protect against risks from new contamination sources.

3. Final Rule

Consistent with the proposal, the final rule does not include a provision that would allow primacy agencies to issue monitoring waivers. These waivers would increase the potential for public health risks and the EPA does not consider them necessary to reduce burdens on primacy agencies, water systems and communities given the other flexibilities provided in the rule.

F. When must systems complete initial monitoring?

1. Proposal

Pursuant to section 1412(b)(10), the proposed rule required compliance with all aspects of the NPDWR three years after promulgation. This included satisfying initial monitoring requirements as described in sections VIII.A and VIII.C within the three years following rule promulgation.

2. Summary of Major Public Comments and EPA Responses

In the proposal, the EPA requested public comment on the proposed initial monitoring timeframe, particularly for NTNCWS or all systems serving 3,300 or fewer. Many commenters expressed support for the EPA requiring initial monitoring as soon as possible with a few commenters explicitly supporting the EPA's proposed initial monitoring timeframe noting it allows sufficient time for water systems to comply with the initial monitoring requirements. However, other commenters suggested that water systems would not be able to utilize the full three years following rule promulgation to perform initial monitoring and take actions to ensure compliance with the MCL if monitoring results showed elevated levels of PFAS. While the agency agrees that it may be difficult to conduct initial monitoring and take necessary remedial actions (*e.g.,* treatment installation) within three years, the EPA finds that it is practicable for all systems to complete their initial monitoring within three years. This is particularly the case since the large majority of systems serving greater than 3,300 will have sufficient monitoring data from UCMR 5 and many other systems will have at least some data to satisfy the rule's initial monitoring requirements. Moreover, as described in section XI.D. of this preamble, the EPA is exercising its authority under SDWA section 1412(b)(10) to implement a nationwide two-year capital improvement extension to comply with MCL. Consequently, water systems will have up to the full three years following rule promulgation to plan and conduct monitoring and still have two additional years to complete any actions needed to comply with the MCLs.

Several commenters suggested that the EPA consider a staggered initial monitoring timeframe by system size, such as those used in other previous NPDWRs, where, for example, larger sized systems conduct monitoring first followed by smaller systems. In the examples provided by commenters, this staggered monitoring could also allow systems to achieve compliance on a staggered schedule. A few commenters suggested that this is necessary to address potential laboratory capacity issues and to allow smaller systems additional time to plan and obtain resources to conduct the monitoring. The EPA disagrees that staggering the monitoring requirements to allow different compliance dates is necessary. SDWA 1412(b)(10) specifies that all systems must demonstrate compliance three years following rule promulgation except where a state or the EPA may grant an extension of up to two additional years to comply with MCL(s) if the EPA or the state (for an individual system) needs additional time for capital improvements. Therefore, the intent of the statute is to allow extensions to complete the capital improvements necessary to comply with the MCL. The EPA considers the three years sufficient for completing the rule's initial monitoring requirement. The EPA's allowance of previously collected monitoring data will also significantly reduce the potential for laboratory capacity challenges. As previously noted in section VIII.A of this preamble, the EPA has revised the required intervals between samples collected for initial monitoring under this rule to closely parallel the intervals required for UCMR 5, to promote the useability of existing data.

The EPA is not prescribing any staggering of monitoring (*e.g.,* based on system size) but encourages primacy agencies to work with the systems they oversee to ensure their initial monitoring occurs and adjust schedules (within the three years following rule promulgation) as appropriate.

3. Final Rule

The EPA is finalizing the requirement that initial monitoring, or demonstration of previously collected data to satisfy initial monitoring requirements, must be completed within the three years following rule promulgation (*i.e.,* April 26, 2027) to ensure that water systems have the information needed to inform decisions to meet the MCL compliance date. As described previously and in section XI.D, the EPA is providing a two-year capital improvement extension under SDWA 1412(b)(10), allowing additional time for those systems to comply with the MCL. Requiring water systems to conduct initial monitoring within the three years following rule promulgation will ensure public health protection as soon as practicable and allow these water systems to maximize utilization of the capital-improvement extension time. Additionally, the flexibility in the final rule for systems to use previously acquired monitoring data to satisfy some or all of their initial monitoring will reduce the potential for laboratory capacity challenges. The EPA encourages systems that may not have available data and/or choose to conduct additional monitoring to conduct their initial monitoring as soon as practicable following rule promulgation to allow for remedial actions that may needed, based on monitoring results, and to comply with the MCL by the compliance date.

G. What are the laboratory certification requirements?

1. Proposal

The EPA proposed that laboratories demonstrate their capability to meet the objectives of this regulation. The proposal would require laboratories to analyze performance evaluation (PE) samples every year for each method and contaminant in order to achieve and maintain certification from their primacy agency.

2. Summary of Major Public Comments and EPA Responses

A few commenters requested that the EPA develop guidance and training for drinking water laboratory certification programs to evaluate laboratories seeking certification. The EPA agrees that training for laboratory certification officers is appropriate. The EPA will develop training materials and guidance for drinking water certification programs to evaluate laboratories to ensure adherence to the requirements of EPA Methods 533 and 537.1 (USEPA, 2005b).

One commenter requested that the EPA establish reciprocity between laboratory certification programs to utilize all potential laboratory capacity available. As described in the EPA's *Manual for the Certification of Laboratories Analyzing Drinking Water,* laboratory certification programs may recognize drinking water laboratory certifications (or comparable ''accreditation'') from other laboratory certification programs, by reciprocity (USEPA, 2005b). Most laboratory certification programs do utilize the practice of reciprocal certification. Reciprocal certification can only be granted to laboratories utilizing EPA Methods 533 and 537.1.

3. Final Rule

Under the final rule, certified laboratories must demonstrate their capability to meet the objectives of this regulation. Laboratories are required to analyze PE samples every year for each method and contaminant in order to achieve and maintain certification from their primacy agency.

H. Laboratory Quality Assurance/ Quality Control

In the proposal, the EPA requested comment on other monitoring-related considerations including quality assurance/quality control (QA/QC) associated with drinking water sampling and analysis.

Many commenters suggested the potential for false positives to misrepresent actual levels of the regulated PFAS within the drinking water sample due to the ubiquity of PFAS and the possible background interference. The EPA is aware of the potential for background contamination due to the ubiquitous nature of PFAS in the environment. The EPA agrees that PFAS sampling is highly sensitive and there is potential for sample contamination. However, with proper training tools and communications, that potential can be mitigated, though not sufficiently enough to allow for composite sampling as discussed in section VIII.D of this preamble. For example, the UCMR program has released several sampling guidance documents and a small-systems sampling video to assist small and medium utilities with the PFAS sampling. These products have also been distributed to the UCMR laboratory community, which has been encouraged to share them with their PWS clients.

Also, Method 533 and Method 537.1 require the analysis of an LRB with each extraction batch. If method analytes are detected at or above ⅓ the minimum reporting level, suggestive of background contamination, all positive field sample results associated with that extraction batch are invalid for the impacted analytes. Both methods also require the analysis of an FRB (a blank that is prepared at the sampling location) when any PFAS are detected above the minimum reporting level in field samples. The use of laboratory and field blanks were incorporated into the methods as QC to reduce the potential for false positives due to background contamination.

IX. Safe Drinking Water Act (SDWA) Right To Know Requirements

A. What are the Consumer Confidence Report requirements?

1. Proposal

A community water system (CWS) must prepare and deliver to its customers an annual Consumer Confidence Report (CCR) in accordance with requirements in 40 CFR part 141, subpart O. A CCR provides customers with information about their local drinking water quality as well as information regarding the water system's compliance with drinking water regulations. The EPA proposed that CWSs be required to report detected PFAS in their CCRs, specifically, PFOA, PFOS, PFHxS, PFNA, HFPO–DA, and PFBS, and the Hazard Index for mixtures of PFHxS, PFNA, HFPO–DA, and PFBS. The EPA also proposed adding paragraph (g) to 40 CFR 141.154 that would require health effects language be provided when any regulated PFAS is measured above the maximum contaminant level (MCL), in addition to those with an MCL violation.

2. Summary of Major Public Comments and EPA Responses

A few commenters requested clarification of the health effects language included in the CCR. Specifically, a couple of commenters said the proposed standard health effects language included in the CCR for a Hazard Index MCL exceedance was not clear. Commenters found some of the language regarding the Hazard Index MCL to be confusing and offered suggestions for clarification. The EPA has considered this input and revised the health effects language associated with PFAS exposure, including the Hazard Index.

A few of commentors raised concerns about requiring reporting of results below the practical quantitation level (PQL) in the CCR as these data may not be quantified with what they deem is appropriate precision. One commentor requested that any detected PFAS, not just the six regulated contaminants, be reported in the CCR. The EPA disagrees with commenters who voice concern over reporting measurements below the PQLs for PFOA and PFOS as ''detected'' contaminants in the CCR. Reporting these measurements in the CCR will allow customers to understand that the contaminant was detected in the water supply. While measurements below the PQL will not be used to calculate compliance with MCLs for the final rule, measurements lower than the PQL are achievable by individual laboratories, and therefore these measurements can be used for screening, to determine compliance monitoring frequency, and to educate consumers about the existence of PFAS (for further discussion of PQLs for regulated PFAS, please see section VII of this preamble). As such, the EPA believes that measurements below the PQL can reasonably be reported as ''detected'' for purposes of the CCR. This requirement is consistent with the CCR Rule in 40 CFR 141.153(d) which requires CWSs to report information on detected contaminants for which monitoring was required by the EPA or the state. The CCR reporting requirement includes unregulated contaminants for which monitoring is required pursuant to the Unregulated Contaminant Monitoring Rule (UCMR) as well as regulated contaminants in accordance with SDWA (Safe Drinking Water Act) 1414(c)(4). If the system has performed additional monitoring, the EPA strongly encourages them to include the results in the CCR, consistent with 40 CFR 141.153(e)(3).

3. Final Rule

As part of this action, the EPA has modified the trigger level value for quarterly monitoring from one-third of the MCL to one-half of the MCL in response to concerns that laboratories would not have the capacity to consistently measure as low as the threshold of one-third of the MCL (for further discussion of the EPA's trigger levels for the final rule, please see section VIII of this preamble). To reflect this change in the trigger level, the EPA has modified 40 CFR 141.151(d), which identifies what is considered detected for purposes of reporting in CCRs consistent with SDWA 1414(c)(4). The EPA had also proposed adding a provision to require CWSs that detect any PFAS above the MCL to include health effects language for PFAS and stated in the preamble for the rule proposal that CWSs would be required to report detected PFAS as part of their CCRs. Because SDWA 1414(c)(4)(B) specifies that the Administrator may only require health effects language be reported in the CCR for situations other than an MCL violation for not more than three regulated contaminants, the EPA has removed the amendment to paragraph (g) of 40 CFR 141.154 included in the proposed rule from the final rule and has instead updated appendix O to part 141 for the final rule to only require CWSs that have violations of the PFAS MCLs to include health effects language for PFAS. Since systems must complete initial monitoring within three years of rule promulgation, systems will be required to report results and other required information in CCRs beginning with 2027 reports. As the MCL compliance date is set at five years following rule promulgation, systems will be required to report MCL violations in the CCR, accompanied by the required health effects language and information about violations, starting in 2029.

The EPA acknowledges the need to protect public health with clear and concise language that outlines the risks associated with exposures exceeding the MCLs and Hazard Index. The EPA's broad review of the most current research provides a comprehensive understanding of how exposure to PFAS may result in adverse impacts on the health of individuals. In response to commenter requests for plain language explanations of the Hazard Index, the EPA is adding the following definition of the *Hazard Index* in 40 CFR 141.153(c)(3)(v) of the CCR Rule to improve clarity and understandability for consumers (for more information on how the Hazard Index is calculated for this rule, please see table to paragraph (b) under 40 CFR 141.50):

Hazard Index or HI: The Hazard Index is an approach that determines the health concerns associated with mixtures of certain PFAS in finished drinking water. Low levels of multiple PFAS that individually would not likely result in adverse health effects may pose health concerns when combined in a mixture. The Hazard Index MCL represents the maximum level for mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS allowed in water delivered by a public water system. A Hazard Index greater than one (1) requires a system to take action.

Additionally, in response to commenters' request for clearer mandatory health effects language, the final rule includes revised mandatory health effects language required as part of CCRs, in cases when MCL violations have occurred.[10] Identical mandatory health effects language is also required for public notification (PN) under the final rule (PN requirements are described further in section IX.B of this preamble). The mandatory health effects language in the final rule reads as follows:

Health effects language for PFOA: Some people who drink water containing PFOA in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including kidney and testicular cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOA in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Health effects language for PFOS: Some people who drink water containing PFOS in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including liver cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOS in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Health effects language for PFHxS: Some people who drink water containing PFHxS in excess of the MCL over many years may have increased health risks such as immune, thyroid, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFHxS in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Health effects language for PFNA: Some people who drink water containing PFNA in excess of the MCL over many years may have increased health risks such as elevated cholesterol levels, immune effects, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFNA in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Health effects language for HFPO–DA: Some people who drink water containing HFPO–DA in excess of the MCL over many years may have increased health risks such as immune, liver, and kidney effects. There is also a potential concern for cancer associated with HFPO–DA exposure. In addition, there may be increased risks of developmental effects for people who drink water containing HFPO–DA in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Health effects language for Hazard Index PFAS: Per- and polyfluoroalkyl substances (PFAS) can persist in the human body and exposure may lead to increased risk of adverse health effects. Low levels of multiple PFAS that individually would not likely result in increased risk of adverse health effects may result in adverse health effects when combined in a mixture. Some people who consume drinking water containing mixtures of PFAS in excess of the Hazard Index (HI) MCL may have increased health risks such as liver, immune, and thyroid effects following exposure over many years and developmental and thyroid effects following repeated exposure during pregnancy and/or childhood.

B. What are the Public Notification (PN) requirements?

1. Proposal

As part of SDWA, the PN Rule ensures that consumers will know if there is a problem with their drinking water. Notices alert consumers if there is risk to public health. They also notify customers: if the water does not meet drinking water standards; if the water system fails to test its water; if the system has been granted a variance; or if the system has been granted an exemption (that is, more time to comply with a new regulation).

All public water systems (PWSs) must give the public notice for all violations of National Primary Drinking Water Regulations (NPDWRs) and for other situations. Under the EPA's PN Rule, the public notice requirements for each violation or situation are determined by the tier to which it is assigned. The EPA specifies three categories, or tiers, of PN requirements, to take into account the seriousness of the violation or situation and any potential adverse health effects that may occur (USEPA, 2000f). The

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[10] The EPA has developed the existing mandatory health effects language to communicate accurate, clear health information to a non-technical audience. Although the EPA believes additional detail is not necessary to include in the mandatory health effects language which is required only where MCL violations have occurred, the EPA also recognizes that, in general, a single exposure at a critical time in development may produce an adverse developmental effect (see USEPA, 1991a).

EPA proposed that violations of the three MCLs in the proposal be designated as Tier 2 and as such, PWSs would be required to comply with 40 CFR 141.203. Per 40 CFR 141.203(b)(1), notification of an MCL violation should be provided as soon as practicable but no later than 30 days after the system learns of the violation. The proposed rule also designated monitoring and testing procedure violations as Tier 3, which would require systems to provide notice no later than one year after the system learns of the violation. The system would then be required to repeat the notice annually for as long as the violation persists.

2. Summary of Major Public Comments and EPA Responses

Many commenters support the Tier 2 PN requirement for MCL violations. Commenters assert that Tier 2 notification is appropriate and consistent with other MCLs for chemicals with chronic effects. Conversely, many commenters suggest that the PN tiering be raised from Tier 2 to Tier 1 or that the EPA consider other PN approaches given concerns about health impacts resulting from exposure on timescales shorter than chronic exposure. Commenters assert that raising PN for MCL violations from Tier 2 to Tier 1 would ensure that consumers are informed of potential harm associated with elevated PFAS levels in a timelier manner so they can make informed risk management decisions. Additionally, a few commenters request the EPA re-categorize repeat MCL violations to Tier 3 due to the expected length of time needed for a PWS to design and construct treatment. Commenters argue that quarterly PN would not offer added value and could possibly result in confusion for consumers.

The EPA agrees with commenters that Tier 2 PN is appropriate for MCL violations based on analysis of a wide range of scientific studies that shows that long-term exposure may have adverse health effects. The EPA disagrees with commenters who recommend issuing Tier 1 notification for MCL violations. Tier 1 notices must ‘‘be distributed as soon as practicable, but no later than 24 hours, after the public water system learns of the violation’’ pursuant to section 1414(c)(2)(C)(i) of SDWA. The PN Rule preamble characterizes contaminants with violations routinely requiring a Tier 1 notice as those with ‘‘a significant potential for serious adverse health effects from short-term exposure’’, stating that other violations do not require Tier 1 notice because elevated levels of these contaminants are not ‘‘strongly or consistently linked to the occurrence of the possible acute health effects’’ (USEPA, 2000f). The EPA has not characterized health risks resulting from acute exposure (*i.e.,* < or = 24 hours) to PFAS and the EPA believes that issuing Tier 2 PN for MCL violations constitutes a health protective approach given that the MCLG values are based on health effects that occur after chronic exposure to PFAS (*i.e.,* cancer). Based on the available health effects information, the EPA has characterized developmental effects, including immune impacts, associated with developmental PFAS exposure in addition to health effects that occur after chronic exposure. The agency considers it reasonable to notify consumers within 30 days of a PWS learning of an MCL violation because it generally provides protection of the adverse health effects that may occur from exposure to PFAS during sensitive lifestages such as gestation. The EPA typically reserves Tier 1 notifications for acutely toxic contaminants. For example, nitrate, nitrite, or total nitrate and nitrite require Tier 1 notice because exceedances can result in immediate life-threatening health impacts for infants (*i.e.,* methemoglobinemia). Based on the currently available information, the developmental and chronic effects associated with exposure to these PFAS are not known to represent immediate acute health effects. For more information on the EPA's characterization of health effects resulting from PFAS exposure, please see (USEPA, 2024c; USEPA, 2024d). This approach is also consistent with the PN requirements for other synthetic organic contaminants regulated under SDWA. The EPA acknowledges that there may be instances in which it is appropriate to elevate the tiering of PN on a case-by-case basis. Under the existing PN Rule in 40 CFR 141.202(a), a violation that routinely requires a Tier 2 notice but poses elevated risk from short-term exposure may be elevated to Tier 1 at the discretion of the primacy agency (USEPA, 2000f). Additionally, the EPA will develop appropriate implementation guidance to assist in the understanding of PN requirements among other final rule requirements.

The EPA disagrees with commenters that recommended reclassifying ongoing MCL violations to Tier 3 for repeat notices. The EPA believes there is sufficient flexibility in the existing PN Rule 40 CFR 141.203(b)(2) that allows primacy agencies to allow a less frequent repeat notice on a case-by-case basis for unresolved violations, but no less than once per year, and the determination must be in writing. The EPA believes repeat notices are valuable to consumers that may not receive the initial notice and allow water systems to provide any updates to consumers, such as actions being taken to resolve the situation and estimated timelines.

A few commenters recommended that the EPA update the proposed PN health effects language. Commenters stated that the proposed health effects language was confusing and needed to be clarified as it did not sufficiently explain the health effects resulting from PFAS exposure. Additionally, commenters stated that further clarifying the health effects language would mitigate confusion from customers when receiving PN from their water system.

The EPA agrees with commenters that additional explanation of the health effects of PFAS exposure will more effectively communicate risk to consumers when they receive PN from their water system. The EPA has considered this input and has revised health effects language for the final rule to further clarify the health effects associated with PFAS exposure.

3. Final Rule

The final rule requires the PN of violations of all MCLs promulgated under this final rule to be designated as Tier 2 and as such, PWSs would be required to comply with 40 CFR 141.203. The final rule also designates monitoring and testing procedure violations as Tier 3, requiring systems to provide notice no later than one year after the system learns of the violation. Systems are also required to repeat the notice annually for as long as the violation persists. As systems must comply with initial monitoring requirements within three years of rule promulgation, systems will be required to provide Tier 3 notification for monitoring and testing procedure violations starting in 2027. As the MCL compliance date is set at five years following rule promulgation, systems will be required to provide Tier 2 notification for MCL violations starting in 2029. However, the EPA acknowledges that primacy agencies have the authority in the existing PN Rule (table 1 to § 141.201) to require systems to provide notices to consumers prior to the MCL compliance date. The EPA encourages primacy agencies to use this flexibility to require systems to provide notices to consumers for PFAS detections that precede the date that MCL compliance will take effect, as they deem appropriate. By encouraging systems to provide timely notification, it allows customers to take actions to protect their health, such as using a filter, while systems take necessary steps to apply treatment.

With respect to violations and reporting associated with the individual MCLs and Hazard Index MCL, the EPA recognizes that a utility may have two or more of these PFAS present that, over the course of four quarterly samples, may result in violation of multiple MCLs. For example, if, following four quarterly samples, a utility has PFHxS and HFPO–DA present and the RAA is above their respective MCLs and HBWCs of 10 ng/L, the system would be in violation of both the individual MCLs for PFHxS and HFPO–DA, as well as the Hazard Index MCL. Issuing multiple notifications (three in this example) for these violations may cause public confusion as the adverse health effects and exposure concern in this instance is not meaningfully different from either a Hazard Index or individual MCL perspective. To simplify implementation of PN in this scenario, the EPA is finalizing requirements in appendix A to subpart Q of part 141 such that utilities who violate the Hazard Index MCL and one or more individual MCLs because of the same compounds can issue one notification to satisfy the PN requirements for the multiple violations.

The EPA has also made edits to clarify the mandatory health effects language required in the PN of an MCL violation, as well as the CCR. The mandatory health effects language required for both PN and CCRs is summarized in section IX.A.3 of this preamble above.

X. Treatment Technologies

Section 1412(b)(4)(E) of the Safe Drinking Water Act (SDWA) requires that the agency ‘‘list the technology, treatment techniques, and other means which the Administrator finds to be feasible for purposes of meeting [the MCL],’’ which are referred to as best available technologies (BATs). The EPA generally uses the following criteria for identifying ‘‘feasible’’ BATs: (1) The capability of a high removal efficiency; (2) a history of full-scale operation; (3) general geographic applicability; (4) reasonable cost based on large metropolitan water systems; (5) reasonable service life; (6) compatibility with other water treatment processes; and (7) the ability to bring all the water in a system into compliance. Section 1412(b)(4)(E)(ii) of SDWA requires that the agency identify small system compliance technologies (SSCTs), which are affordable treatment technologies, or other means that can achieve compliance with the maximum contaminant level (MCL).

In the proposed rule, the EPA requested comments on: technologies designated as BATs, costs associated with nontreatment options; whether employing these treatment technologies are sound strategies to address PFAS as well as whether the BATs could feasibly treat to below the proposed MCLs; the type of assistance that would help public water systems (PWSs); potential benefits from co-removal; treatment residual disposal estimates; the capacity to address the increased demand for BATs as well as residuals disposal or reuse; impacts that PFAS residuals disposal may have in communities adjacent to the disposal facilities; the most appropriate disposal means for PFAS contaminated residuals and waste the systems may be generating; and SSCT selection as well as national affordability analysis, specifically on the methodologies.

A. What are the best available technologies?

1. Proposal

The agency proposed GAC, AIX, NF, and RO as BATs for the six PFAS under consideration in the proposed rule. The EPA also acknowledged that there are nontreatment options which may be used for compliance such as replacing a PFAS-contaminated drinking water source with a new uncontaminated source. The EPA also stated that conventional and most advanced water treatment methods are ineffective at removing PFAS.

2. Summary of Major Public Comments and EPA Responses

The vast majority of comments germane to the BAT designations support the EPA's designation of granular activated carbon (GAC), anion exchange resins (AIX), and high-pressure membranes (nanofiltration (NF) and reverse osmosis (RO)) as BATs that are technologically feasible for treating drinking water to the proposed standards or below. Many commenters shared practical experience with installed treatment including successes, costs, implementation considerations, challenges, and other areas. The EPA agrees that GAC, AIX, RO, and NF are BATs and consistent with the criteria outlined in the BAT/SSCT document for identifying ‘‘feasible’’ treatment for PFAS in this rule, and the comments providing information on practical full-scale experience with these technologies further support for this finding.

A few commenters suggested either that the designated BATs could not treat to or below the MCL or that not enough data was available to support the conclusion that the BATs could treat to at or below the proposed MCL. The EPA disagrees with these commenters based on the history of full-scale use as documented in the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document (USEPA, 2024l), the information in the rule preamble, and in the comments that provided full-scale data as well as case studies. For example, commenters highlighted more than 45 military installations that have treated PFAS, including those in this rule, successfully for more than 15 years, a major water treatment company provided information on over 150 successful installations they had performed, and comments supported that there are significant numbers of industrial users successfully treating PFAS, including those in this rule. One commenter noted the example of the Chemours Fayetteville facility which used GAC to eliminate PFAS, including those in this rule, as high as 345,000 ng/L and has reduced PFAS in effluent to non-detect levels for several PFAS. Finally, the Water Quality Association reviewed proprietary performance data from its accredited laboratory demonstrating that this standard is feasible for the BATs selected to effectively remove the PFAS regulated in this rule from drinking water.

Many commenters pointed out site-specific issues with particular BATs. The EPA acknowledges that not every BAT represents the best treatment option for an individual system and site-specific considerations can limit BAT selection. For instance, residuals management considerations can limit the choice of RO/NF; particularly in states with limited water resources. While many commenters agreed that high pressure membranes such as RO and NF can remove the six PFAS included in the proposal, many commenters also suggested that high pressure membranes may not be the most feasible treatment option for some systems because of residual management considerations, which are discussed in the residuals management section. There are, however, documented RO/NF facilities for treating PFAS in California, Illinois, North Carolina, and Alabama (USEPA, 2024l). In response to public comment and residual management concerns surrounding high pressure membrane technologies, the EPA has adjusted RO/NF's technology projection compliance forecast to 0% in the EA. While the EPA does not estimate any water systems will elect to install RO/NF to comply with the PFAS rule, it remains a BAT for water systems to consider. For additional details on the EPA's EA, please see section XII.

The EPA also acknowledges that due to technical site-specific considerations, some BATs may not be the best choice for particular water types. PFAS treatment option selection should consider conditions for a given utility including water quality, available space, disposal options, and currently installed unit operations. AIX may be the preferred technology for some utilities based on expected treatment needs, while others may select GAC or other technologies. However, as many commenters indicated, the BAT designations are appropriate for water systems across the country.

Several commenters pointed out that GAC may release arsenic at levels exceeding arsenic's MCL temporarily when installed and upon changing media, deleteriously impacting finished water quality. While the EPA has documented challenges surrounding GAC and arsenic (USEPA, 2024l), the EPA disagrees that the arsenic release poses an exposure concern so long as appropriate procedures are followed. Those procedures include discarding the initial bed volumes (BVs) after installation or replacement of media. A bed volume is the volume of liquid contained within a GAC contactor, it is the container volume minus the solids volume and void space. The quantity of treated water discarded can be significant (*e.g.,* as high as 350 BVs as one commenter noted). However, this amount of discarded water is low in comparison to the normal service life between GAC replacement, which is approximately 84,000 BVs or approximately about 0.5% of the total treated volume. The total water volume discarded is also low in comparison to water loss through leaks across the United States, which account for about 15% of treated water or what would be approximately 12,600 BV equivalents for this system. While conserving water is a significant issue, the water discarded due to GAC applications is relatively low. Systems can reduce water discard associated with BAT implementation by using acid washed and/or prerinsed GAC or using buffered/pre-flushed resins for AIX. Any treatment technology can create problems if improperly maintained and operated. Finally, GAC has been statutorily designated as ''feasible for the control of synthetic organic chemicals,'' such as PFAS, in SDWA section 1412(b)(5).

The EPA received many suggestions for additional BATs including powdered activated carbon (PAC), alternative sorbents, and new destructive technologies. However, these alternative BATs proposed, except for PAC, currently lack demonstrated full-scale removal of the six PFAS under consideration. The EPA notes that there are some reports of PAC use on a temporary basis and that it can reduce PFAS concentrations in drinking water. PAC may be an appropriate choice of technology in certain circumstances, however, its efficacy for trace removal tends to be variable due to factors such as carbon particle size, background organics, and plant efficiency. Therefore, PAC is not as effective as GAC overall, and the agency has not designated it as a BAT. The EPA periodically reevaluates treatment technologies and may add additional technologies based on updated information. It is important to note that water systems may use any technology or practice to meet the PFAS MCLs and are not limited to the BATs in this rule. Other technologies may be chosen in lieu of BAT because they may be more cost effective or better suited to the specific operating conditions of the particular site to meet the MCL. Electing not to use a BAT, however, means that a system will not be eligible for a variance under SDWA section 1415(a)(1)(A). For example, if a facility does not install GAC where it is the designated BAT, but uses PAC instead, and fails to meet the MCL, the facility would not be eligible for a variance under SDWA section 1415(a)(1)(A). On the other hand, the same facility may be eligible for an exemption under SDWA section 1416 if, for example, GAC could not be installed due to an inability to obtain financing and PAC was used instead, and the facility failed to meet the MCL.

Many commenters pointed out the need for increased research, technological innovation, and guidance in treating drinking water for PFAS. The available information is sufficient to finalize the BATs as proposed but the EPA agrees that more research may be beneficial (USEPA, 2022c). With respect to the EPA's request for public comment on additional guidance materials that would be helpful to support successful technical implementation of the rule, the EPA received many comments related to the need for technical materials to support rule implementation. The agency plans to collaborate with states, technical assistance providers, industry associations and interested stakeholders, including small systems, following the rule promulgation to provide technical materials that can assist water systems in complying with the regulations. The EPA is currently funding many technical assistance efforts associated with PFAS, including supporting treatment infrastructure projects through the Drinking Water State Revolving Fund (DWSRF) and the Emerging Contaminant grant program as designated and funded through the Bipartisan Infrastructure Law (BIL).

Many commenters supplied information related to capital as well as operations and maintenance costs. Many commenters expressed concerns over potential costs and capacity while some commenters expressed the opposite opinion. These issues are further addressed in the EPA cost analysis in section XII and within the EPA's *Response to Public Comments on the Proposed PFAS NPDWR* (USEPA, 2024k). For additional discussion regarding the feasibility of the final MCLs, please see section V of this preamble above.

Many comments pointed to potential supply chain issues in both material and technical capacity such as qualified personnel, including certified operators. While there may be some supply chain issues in the short-term, comments from BAT suppliers indicate excess capacity as well as investment in production. Furthermore, while there may be temporary difficulties in supply chain and technical capacity, the structural demand increase is expected to lead to supply increases as well as innovation such as proposed technologies which were not designated as BATs. This has been historically demonstrated multiple times in prior drinking water rules. For example, activated alumina was listed as one of the BATs and a SSCT for arsenic removal in the Arsenic Rule (USEPA, 2001), and acknowledgement was given to granular ferric hydroxide media as a developing technology. While the granular ferric hydroxide media was not selected as a BAT/SSCT at the time due to lack of full-scale demonstration, these media became the predominant approach to addressing arsenic: Rubel (2003) stated that new iron-based materials could be ''employed economically on a spent media basis without the incorporation of pH adjustment chemicals and equipment.'' McCullough et al. (2005) cited over a dozen demonstration sites across the US implementing granular iron media treatment technologies, providing further supporting evidence that new technologies evolved in the wake of the Arsenic rule to provide more efficient and economical treatment systems. Additionally, the present statutory standard for ''best available technology'' under 1412(b)(4)(D) represents a change from the provision prior to 1986, which required the EPA to judge feasibility on the basis of ''best technologies generally available'' (BTGA). The 1986 Amendments to the SDWA changed BTGA to BAT and added the requirement that BAT must be tested for efficacy under field conditions, not just under laboratory conditions. The legislative history explains that Congress removed the term ''generally'' to assure that MCLs ''reflect the full extent of current technology capability'' [S. Rep. No. 56, 99th Cong., 1st Sess. at 6 (1985)]. Read together with the legislative history, the EPA has concluded that the statutory term ''best available technology'' is a broader standard than ''best technology generally available,'' and that this standard allows the EPA to select a technology that is not necessarily in widespread use, as long as its performance has been validated in a reliable manner. Indeed, the 1991 Lead and Copper Rule stated, ''as long as it has been tested beyond the laboratory under full-scale conditions for other contaminants, and the performance of the technology for lead and copper may reasonably be projected based upon other available treatment data (*i.e.,* laboratory or pilot scale), the EPA believes the technology can be established as BAT.''

With respect to the challenges raised by commenters surrounding capital improvement, the EPA has provided compliance flexibility by providing a two-year capital improvements extension of the MCL compliance deadline allowed by section 1412(b)(10) of SDWA. Additionally, the EPA will continue its research as well as outreach efforts to help develop technical and operator capacities. For comments and additional information regarding the implementation timeframe for this rule, please see section XI.D.

Many commenters stated that permitting needs to be streamlined and that more assistance should be proffered to primacy agencies, utilities, and other interested stakeholders. While SDWA does not require permits, state and local authorities often require permits for the installation of treatment facilities at water systems. The EPA has developed supporting rule documents such as the *Best Available Technologies and Small System Compliance for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water* document (USEPA, 2024l) that can be used to help permitting authorities develop more familiarity with these technologies over time. After finalization of the PFAS National Primary Drinking Water Rule (NPDWR), the EPA also intends to work with stakeholders to provide support to utilities, primacy agencies, and other interested parties to ensure successful rule implementation.

3. Final Rule

In the final rule, the EPA is codifying GAC, AIX, NF, and RO as BATs. The record does not support including additional BATs at this time. A BAT designation is informational, and while installation of the BAT is a condition of a variance under section 1415(a)(1)(A), systems without a variance are not required to use a BAT for MCL compliance. The owner/operator of a PWS will need to consider site specific circumstances as well as technical, economic, and local regulatory considerations when choosing a compliance technology for this rule. To address the challenges raised by commenters surrounding capital improvement, the EPA has provided a two-year compliance extension for capital improvements which is discussed in greater detail in section XI (*Rule Implementation and Enforcement*) and will continue its research efforts. The two-year capital improvement extension should also provide time for development of technical capacities and qualified personnel including certified operators. In response to public comment and in acknowledgement of residuals management concerns surrounding high pressure membrane separation technologies, the EPA is lowering RO/NF's technology projection compliance forecast in the EA. For comments and additional information related to the EPA's cost analysis, please see section XII. For comments and additional information regarding the implementation timeframe for this rule, please see section XI.D.

B. PFAS Co-Removal

1. Proposal

The EPA stated that AIX and GAC are effective at removing PFAS and there is generally a linear relationship between PFAS chain length and removal efficiency shifted by functional group. The EPA also notes that perfluoroalkyl sulfonates (PFSA), such as PFOS, are removed with greater efficiency than the corresponding perfluoroalkyl carboxylic acid (PFCA), such as PFOA, of the same carbon backbone length. Additionally, the compounds with longer carbon chains display a smaller percentage decrease in average removal efficiency over time (McCleaf et al., 2017). These same technologies also remove other long-chain and higher carbon/higher molecular weight PFAS as well as total organic carbon (TOC, DBP precursors). RO and NF may also remove other contaminants including arsenic, TOC, and chromium-VI. In short, the EPA noted that this regulation, if finalized, would result in a reduction of the six PFAS proposed for regulation, other co-occurring PFAS, and other co-occurring contaminants.

2. Summary of Major Public Comments and EPA Responses

A significant majority of commenters supported the EPA's position that treatment technologies which remove PFAS provide ancillary benefits by removing other known or potential contaminants. One commenter disputed the ability of these technologies to provide ancillary benefits, and others suggested that the EPA's proposed regulation would provide only limited protection against the many PFAS not under consideration in the rule. The EPA disagrees with the commenters who state that the proposed regulation would not result in a reduction in co-occurring PFAS and other contaminants. Burkhardt et al. (2023) used a theoretical approach[11] to estimate that all but one of the PFAS that are quantified by EPA Methods 533 and 537.1 could be economically removed by GAC in typical water qualities and that of 428 PFAS evaluated, 76–87 percent could be cost-effectively treatable. The co-removal benefits are well documented in the scientific literature and in the evidence submitted by public comment. The *Best Available Technologies and Technologies and Cost* support documents summarize literature demonstrating the co-removal capabilities of treatment technologies.

Some commenters stated that treatment for one PFAS does not inherently imply removal of other PFAS. The EPA agrees, as discussed in the proposed rule preamble. In general, there is an inverse relationship between treatability and toxicity which is tied to the carbon backbone (Bellia et al., 2023). Generally, the longer the carbon backbone length, the more easily the PFAS is removed by a given treatment technology. For example, if PFOA (C8) is targeted for removal by the water system, perfluorodecanoic acid (PFDA, C10) would most likely be removed as well. However, the converse would not

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[11] While PFAS are often discussed as a group, the individual PFAS species can have a range of different removal efficacies using GAC. A theoretical approach for PFAS fills information gaps where analytical methods do not exist for all PFAS and testing is expensive and time consuming

be true (*i.e.,* a system targeting PFNA (C9) removal would reduce PFHxA (C6) to a lesser extent).

Some commenters suggested that co-removal would decrease the removal efficiency of GAC or AIX and that removal efficiency of non-target contaminants is lower than it could otherwise be. The EPA agrees that the removal of non-targeted contaminants by GAC or AIX can lower the PFAS removal efficiency; the agency has accounted for this uncertainty in appendix N of the EA (USEPA, 2024e). The EPA also agrees that targeting contaminants for removal will be more effective than relying on other non-targeted removal. For example, a GAC facility designed to remove PFAS will not be as effective at removing DBP precursors as a facility designed for that; however, there will still be co-removal of DBP precursors which may lead to a reduction in DBPs. Ultimately, treatment facilities operate best when tailored to specific contaminants or mixture of contaminants unique to that location. For additional information on the EPA's co-benefit analysis, please see section XII.

Some commenters expressed concern about co-removal taking beneficial ions from water, specifically fluoride ions, and suggested that would be an added cost to the rule. The EPA notes that fluoride has a legally enforceable MCL of 4.0 mg/L, and a non-enforceable secondary standard of 2.0 mg/L to prevent mild or moderate dental fluorosis. The EPA also notes that while some PFAS do contain organic fluorine bound to carbon, fluorine and fluoride are not the same. The BATs identified for the removal of PFAS for drinking water are not optimized for the removal of fluoride and do not necessarily provide effective removal of naturally occurring fluoride. For example, GAC is ineffective for fluoride removal at environmentally relevant pHs (USEPA, 2024o).

Some commenters suggested that co-removal may make it more difficult to dispose of materials left over from the drinking water treatment processes, known as treatment residuals. For example, GAC may remove and concentrate radon or other contaminants to such an extent that the spent media is considered hazardous. The EPA believes that removing hazardous constituents from drinking water is generally beneficial even though it could complicate residual management. More details on treatment residuals, are discussed in part C of this section.

Some commenters also suggest more research may be beneficial to understanding co-removal. The EPA agrees (USEPA, 2022c).

3. Final Rule

GAC, AIX, NF, and RO are codified in the final rule as BATs. As discussed elsewhere in the record for this final rule, because of PFAS co-occurrence and the ability for treatment technologies to co-remove co-occurring PFAS and other contaminants, the EPA anticipates the final rule will result in significant co-removal public health benefits in addition to those benefits from removing the six PFAS being directly regulated by this action.

C. Management of Treatment Residuals

1. Proposal

As part of the BAT evaluation, the EPA reviews full-scale studies that fully characterize residual waste streams and disposal options. The EPA found that the most likely management options for spent material containing PFAS is reactivation for GAC, incineration for spent IX resin, and for disposal of RO/NF retentate, treatment and discharge via a NPDES compliant facility to surface water or, sanitary sewer, or in limited circumstances, underground injection. Large volumes of spent GAC and AIX containing PFAS are periodically generated and must be removed which does not lend itself to on-site storage over time. The EPA stated that the disposal options identified in the 2020 *Interim PFAS Destruction and Disposal Guidance* (USEPA, 2020d) are landfill disposal, thermal treatment, and in limited circumstances, underground injection.

The EPA recognizes that future actions through statutory authorities other than SDWA may have direct or indirect implications for the residuals from drinking water treatment. Future hazardous waste listings for certain PFAS may limit disposal options for spent drinking water treatment residuals containing PFAS and/or potentially increase costs. A CERCLA designation as a hazardous substance does not restrict, change, or recommend any specific activity or type of waste (USEPA, 2022l). The EPA evaluated the potential impact on PWS treatment costs to PWSs associated with hazardous residual management should PFAS be listed as a hazardous waste in the future. For comments and additional information related to the EPA's cost analysis, please see section XII.

2. Summary of Major Public Comments and EPA Responses

While some commenters stated that more research can be beneficial to further our understanding of managing PFAS treatment residuals, others urged the EPA to proceed with this rulemaking as expeditiously as possible in the interest of public health. Others argued that the EPA should delay this action until the *PFAS Destruction and Disposal Guidance* is updated. The National Defense Authorization Act for Fiscal Year 2020, Public Law 116–92, section 7361, directs the EPA to revise the *PFAS Destruction and Disposal Guidance* triennially; the new destruction and disposal guidance is anticipated to be released approximately concurrently with this rule and further revisions may be expected before the effective dates for this rule. The EPA disagrees that the projected significant and direct public health protections for drinking water consumers in this rule should be delayed for the revision of guidance on management of PFAS waste streams.

Many commenters expressed concern that not enough was being done to manage spent drinking water treatment residuals containing PFAS at the end of their useful working life and that residual management amounted to media shifting (*i.e.,* taking PFAS from water via sorption media then landfilling that media does nothing to reduce the overall amount of PFAS). Many commenters stated that landfills and thermal treatment facilities can potentially be PFAS sources as the BATs in this rule are separative as opposed to destructive technologies.

The EPA notes that from a mass balance perspective, PFAS removal from drinking water is generally anticipated to result in lower concentrations of PFAS in the environment. With appropriate controls, landfills, and thermal treatment of PFAS contaminated media can minimize PFAS releases to the environment (USEPA, 2020d). Sorptive media can be incinerated or reactivated. There is also ongoing research into destructive and sequestration technologies that may help quantify the extent to which PFAS may be destroyed some of which is funded by the EPA (USEPA, 2022c).

Furthermore, it is also important to distinguish between a potential environmental release and a direct exposure. A PFAS release does not inherently imply human exposure and a release is not inherently risky to specific populations. From a risk management perspective, while the EPA acknowledges that while each destruction and disposal technology has limitations, a potential environmental release under point source management is anticipated to be a more health protective alternative than human exposure through drinking water.

Some commenters recommended the EPA consider additional destruction and disposal technologies. The EPA notes that disposal and destruction technologies are currently available to manage drinking water residuals. The EPA appreciates the example destructive technologies, and while beyond the scope of finalizing this NPDWR, the agency intends to consider additional destruction and disposal technologies in future destruction and disposal guidance.

Many commenters, including destruction and disposal trade associations, stated there would be difficulties managing spent residuals containing PFAS generated from drinking water treatment. In contrast, other commenters stated that there was existing national capacity and at least one company stated they were actively evaluating investment for additional capacity to handle residuals. The record demonstrates that there is existing national capacity to handle spent drinking water residuals containing PFAS in a manner that minimizes risk to human health. Destruction and disposal of PFAS-containing materials is currently not subject to certain hazardous waste regulation and therefore the materials may be managed in non-hazardous and hazardous waste treatment and disposal systems (USEPA, 2020d). Hazardous waste is regulated pursuant to RCRA authority 42 U.S.C. 6921–6939 (also known as RCRA ''Subtitle C''). The regulatory definition of hazardous waste is found in 40 CFR 261.3. PFAS are currently not a listed hazardous waste or characterized as a hazardous waste, but a PFAS-containing waste may meet the regulatory definition of hazardous waste if PFAS is mixed with a listed hazardous waste or if a PFAS-containing mixture exhibits a hazardous characteristic (*e.g.,* corrosivity or another characteristic stemming from the material that is mixed with PFAS). PFAS which are commingled with hazardous substances and/or hazardous wastes will be subject to the appropriate rules and regulations and may be included as Applicable or Relevant and Appropriate Requirements on a site-specific basis. Not all disposal sites may be appropriate for spent drinking water treatment residuals containing PFAS and the EPA strongly encourages owners and operators of treatment facilities to refer to appropriate and up-to-date guidance on treatment residual management such as the *2020 Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances* (USEPA, 2020d) and subsequent updates.

The EPA anticipates approximately 226,500 short tons of spent drinking water media such as activated carbon and AIX resin to be generated annually as a result of this rule; in calendar year 2018 alone, the U.S. generated about 290 million short tons of waste (USEPA, 2022m). The increase in total waste caused by this action is approximately 0.08% of the total U.S. waste produced. This is a minor change in aggregate waste produced; the same amount as a pound contributes to a ton. Even if PFAS were to be designated in the future as regulatory hazardous waste, there is existing capacity to handle these waste streams through existing hazardous waste facilities in every state. Some water systems may have to ship hazardous wastes significant distances; however, the main cost driver is disposal fees not transportation. The EPA rejects the assertion that it has not evaluated if sufficient capacity exists for disposal and storage of PFOA and PFOS contaminated materials. The EPA also acknowledges that CERCLA section 104(c)(9) does not allow the agency to initiate a remedial action, unless the state first enters into a state Superfund State Contract or Cooperative Agreement (CA) that assures the availability of adequate capacity to manage hazardous wastes generated in the state for 20 years following the date of the response agreement. The EPA's rulemaking designating PFOA and PFOS as CERCLA hazardous substances, if finalized, does not impose any capacity concerns that require further action under section 104(c)(9). In that action, the EPA is designating PFOA and PFOS as CERCLA hazardous substances. No PFAS are currently listed, or being proposed to be listed, as hazardous wastes under RCRA. The 2021 *Biennial Report Summary Results* indicate about 18 million tons of hazardous wastes are normally generated annually. Drinking water treatment materials then would constitute about a 1.26% increase in hazardous wastes generated annually. Since there is over twenty years' capacity, the relatively small magnitude of the increase indicates that waste management capacity is sufficient in the short term should PFAS be designated as regulatory hazardous wastes.

Many commenters conveyed concern over the cost of drinking water residuals management resulting from finalizing this rule. The EPA conducted an EA to help address these concerns. For comments and additional information related to the EPA's cost analysis, please see section XII.

While no PFAS are currently listed as regulatory hazardous wastes under RCRA, in response to stakeholder feedback, the EPA included a sensitivity analysis to determine the impact on water systems should they be required to handle and dispose of PFAS treatment materials as hazardous waste in the future. The results of this analysis can be found in the EA for this rule (USEPA, 2024g). Some commenters suggested that accounting for future potential regulations is uncommon, and trying to account for all potential future contingencies would make economic analyses impossible. The EPA strongly agrees and has not attempted to do so here; this analysis was limited to looking at a hypothetical future hazardous waste listing situation because that has been of particular concern in this rule. Some commenters stated that the EPA should account for the public health benefits of treating PFAS as hazardous wastes, not just additional costs incurred. The EPA agrees and has modified the analysis to include a qualitative statement about the public health benefits which could potentially arise from treating PFAS as hazardous wastes. Many commenters stated that the EPA hazardous waste cost would drive the total cost higher than the 3–5% estimated by the EPA. After considering public comment, the EPA has revised the final cost estimates in this rule. The EPA estimated increased cost would be approximately $99M at the 2% discount rate. The increased cost was driven by updating the dollar year of cost curves from 2021 to 2022 which increased waste management unit costs by approximately 12%; implementing a cap on media life even if not indicated; changing the technology compliance forecast by eliminating RO/NF while increasing GAC and AIX (thereby increasing spent media volume); and increasing occurrence estimates for the final rule compared to the proposed rule, triggering more systems into treatment. The increased costs were not driven by changes to unit cost estimates for hazardous waste management. The EPA believes its assessment is accurate; the total cost encompasses capital costs, maintenance, design, and operations, including waste management. Waste management costs are thus a subset of operational cost which in turn is a subset of total costs; generally, changes in the cost of one subcomponent would not significantly influence total costs, and the record does not reflect that a change in waste disposal costs would have a significant impact on total costs under this rule. These estimates are discussed in greater detail in the HRRCA section of this rule and in appendix N of the EA (USEPA, 2024e).

Many commenters suggested that regulations under other statutes, particularly a potential CERCLA hazardous substance designation, will increase disposal costs. The EPA disagrees that, if finalized, the CERCLA hazardous substance designation for PFOA and PFOS will increase disposal costs for water treatment facilities. The designation of PFOA and PFOS as CERCLA hazardous substances would not require waste (*e.g.,* biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any specific particular type of landfill. The designation also does not restrict, change, or recommend any specific activity or type of waste at landfills. Along with other release notification requirements, CERCLA designation would require that any person in charge of a vessel or facility report a release of PFOA and/or PFOS of one pound or more within a 24-hour period. The EPA does not expect spent drinking water treatment residuals containing PFAS to be released into the environment at or above the reportable quantity as a part of standard residuals management practices used by water systems. This is because the PFAS loading onto sorptive media is very small. The weight percent of PFAS onto GAC under normal treating scenarios will vary widely; however, a reasonable order of magnitude estimate is 1×10^{-5} grams PFAS per gram of sorbent in full-scale applications. High pressure membranes split water into a treated stream and concentrated waste stream. The concentrated waste stream will contain about 5–12 times more PFAS than the influent which is likely to still be in the ng/L scale. A drinking water facility which takes reasonable precautions is unlikely to release enough low concentration residuals to release one pound of PFOA and/or PFOS within a 24-hour period. At the concentrations discussed above, to exceed a one-pound threshold, a facility using sorptive techniques would have to release approximately 50 tons of sorbent, within a 24-hour period. A one-pound uncontrolled release from RO or NF facilities, assuming 500 ng/L of PFAS in the reject water, would require approximately 240 million gallons of high-pressure membrane concentrate to be released within 24 hours. Additionally, neither a release nor a report of a release automatically requires any response action under CERCLA. The EPA makes CERCLA response decisions based on site-specific information, which includes evaluating the nature, extent, and risk to human health and/or the environment from the release. Hazardous substance designations do not automatically result in CERCLA liability for any specific release. Whether an entity may be subject to litigation or held liable under CERCLA are site-specific and fact-dependent inquiries. Likewise, CERCLA affords the Federal Government broad discretion as to whether or how to respond to a release. For those reasons, the EPA cannot assess with reasonable certainty what litigation or liability outcomes may indirectly result from this designation since those outcomes are often linked to the EPA's discretionary decisions with respect to CERCLA response actions as well as site-specific and fact-dependent court rulings.

Many commenters suggested that high pressure membranes, which separate PFAS from one stream and concentrate it in another stream, may not be feasible as a BAT because utilities treating and discharging reject water from high pressure membranes typically require a NPDES permit. The EPA disagrees because there are currently full-scale facilities which use this technology to treat PFAS and high-pressure membranes may be the best viable option in a multi-contaminant setting. The brine may undergo further pre-treatment as part of a process train to enable discharge, such as GAC or AIX treatment. Some RO/NF applications discharge directly to surface water or through an interconnection to a wastewater treatment plant. The EPA, however, does agree that brine treatment or disposal may be challenging and in 2022, the EPA issued memorandum that recommended NPDES and POTW pretreatment program permitting conditions for PFAS discharges (USEPA, 2022d; USEPA, 2022e). In conclusion, in limited applications, high pressure membranes may still serve as a viable treatment strategy, such as for facilities with access to brine treatment or disposal.

Some commenters suggested that reactivation was not permissible under the *2020 Interim PFAS Destruction and Disposal Guidance* or that interim storage was required. Commenters are incorrect in their interpretation of the plain language in that guidance. The guidance does not state that reactivation or thermal treatment are prohibited. The guidance does acknowledge a need for further refinement and research and that interim storage may be an option if the immediate dispensation of PFAS-containing materials is not imperative. However, nowhere does that guidance mandate interim storage or prohibit other forms of PFAS destruction and disposal.

3. Final Rule

The final rule does not specifically require any specific destruction or disposal practices for spent media containing PFAS. The EPA has considered residual waste streams and disposal options and found that management options exist for treatment residuals containing PFAS.

D. What are Small System Compliance Technologies (SSCTs)?

1. Proposal

Section 1412(b)(4)(E)(ii) requires that the agency identify SSCTs, which are affordable treatment technologies, or other means that can achieve compliance with the MCL. The EPA identified SSCTs using the affordability criteria methodology developed for drinking water rules (USEPA, 1998b) and proposed the following table which shows which of the BATs listed above are also affordable for each small system size category listed in section 1412(b)(4)(E)(ii) of SDWA.

Table 23: Proposed SSCTs for PFAS Removal

System Size (Population Served)	GAC	IX	RO/NF	Point of Use (POU) RO/NF [1]
25-500	Yes	Yes	No	Yes
501-3,300	Yes	Yes	No	Yes
3,301-10,000	Yes	Yes	Yes	not applicable [2]

Notes:

[1] POU RO is not currently listed as a compliance option.

[2] Implementing and maintaining a large-scale POU program is likely to be impractical.

Point-of-use (POU) and point-of-entry (POE) were not listed as compliance options 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. As the EPA has determined that affordable SSCTs are available, the agency is not proposing any variance technologies.

2. Summary of Major Public Comments and EPA Responses

Many commenters stated that the POU/POE water treatment industry may already have multiple products that can reduce PFAS chemicals to below the proposed MCL. Additionally, some commenters stated that the influent used (*i.e.,* the challenge water) to test these POU/POE products often contains much higher concentrations of PFAS than would normally be found in most source waters. Commenters also pointed out that under NSF/ANSI, 53 and 58 certifications exist for total PFAS (PFOA, PFOS, PFHxS, PFHxA, and PFDA), as well as PFHpA, PFHxS, and PFNA individually. However, SDWA section 1412(b)(4)(E)(ii) requires that SSCTs achieve compliance with the MCL or treatment technique. While devices certified to the NSF/ANSI standards must be demonstrated to significantly reduce PFAS concentrations and, in many cases, can reasonably be expected to treat below this rule's MCLs, the current standards and certification procedures do not assure compliance with this rule. In particular, PFBS and HFPO–DA, have no certification standards at this time and the certification standards for PFOA, PFOS, and PFHxS are above this rule's MCL. The certification standards for PFOA, PFOS, and PFHxS are 20 ng/L, compared to the MCLs of 4.0 ng/L for PFOA and PFOS, as well as 10 ng/L for PFHxS; the total PFAS certification standard is 20 ng/L effluent comprised of PFOA, PFOS, PFHxS, PFHxA, and PFDA compared to a Hazard Index of 1 for mixtures of PFHxS, PFNA, HFPO–DA and PFBS. Since the NPDWR has standards that NSF/ANSI are currently unable to verify, POE/POU technologies could potentially not achieve compliance contrary to SDWA section 1412(b)(4)(E)(ii) which requires that SSCTs achieve compliance with the MCL. While POU/POE technologies may provide significant levels of protection, and the EPA anticipates they will eventually comply with the NPDWR, there is not yet a systematic verification process in place for the level of protection provided by these devices. As mentioned in the proposal, the EPA is aware that the NSF/ANSI Drinking Water Treatment Unit Joint Committee Task Group is in the process of updating their standards; should these future standards meet the NPDWR, the EPA could revise the SSCT list to include POE/POU.

Many commenters also correctly pointed out numerous challenges surrounding POU/POE as a compliance option for some PWSs such as resident cooperation, operation and maintenance, monitoring, and implementation of distributed treatment approaches. The EPA agrees implementation of POU/POE as a compliance option for any NPDWR can be challenging for some PWSs but also agrees with commenters who noted that POU/POE can provide flexibility and compliance options to very small water systems or certain NTNCWS such as schools, factories, office buildings, and hospitals that provide their own water.

The EPA received many comments that other POU devices other than RO/NF should be acceptable ways to meet the MCLs for small systems. For instance, commenters noted that a combination GAC/AIX device with filters could reduce PFAS concentrations to below the MCL values. The EPA agrees and has changed wording in the final rule preamble and related supporting documents that implied that only RO/NF POU devices would be able to meet a future certification standard. The EPA notes that for small systems, as long as the proposed POU/POE devices are certified by an appropriate third-party certifier (*e.g.,* ANSI/NSF) to meet the regulatory MCL, they would meet the requirements of this regulation. The EPA also received many requests to change the way data was displayed in tables 20 and 22 of the proposed rule which summarized proposed SSCTs for PFAS removal and total annual cost per household for candidate technologies. In the proposal, the EPA wrote that this data was ''Not Applicable'' because of the economies of scale for centralized treatment. While the EPA still believes that a POU program that large is likely to be impractical, the EPA has changed the way this is displayed by replacing the term ''Not Applicable'' with ''Data Unavailable.'' The EPA notes that neither of these changes imposes nor relieves any rule requirements and only serve to recharacterize the way the EPA reports available technologies.

The EPA asked for comment on the national level analysis of affordability of SSCTs and specifically on the potential methodologies presented in the EA for the proposed rule section 9.12. A couple of commenters recommended the EPA not use median household income (MHI) in the affordability analysis. The EPA decided to retain the MHI measure of income in its primary national level SSCT affordability methodology, and specifically use 2.5% of the MHI as the affordability threshold, given the value is easily understandable and available, providing a central tendency for income which is representative of a whole community's ability to pay and is not unduly influenced by outlier values. However, in this rule, the EPA recognizes the value in examining alternative measures of a community's ability to afford an SSCT, so the agency chose to include supplemental analyses that use alternative metrics, specifically 1% of MHI, 2.5% of lowest quintile income (LQI), and an analysis accounting for financial assistance. See chapter 9.13.2 of the EA for more details. These supplemental analyses help to characterize affordability when considering the marginal impact, disadvantaged community groups, and subsidization.

Some commenters stated that the data the EPA used to inform current water rates from the 2006 Community Water System Survey (CWSS) is outdated. While dated, the data from the 2006 CWSS remains the best available dataset for this national level analysis and affordability determination for the following reasons: (1) the CWSS survey used a stratified random sample design to ensure the sample was representative and (2) these responses can be extrapolated to national estimates since the survey has a known sampling framework; and the data can be organized by system size, source, and ownership (USEPA, 2020e).

Some commenters recommended the EPA extend the affordability analysis to medium and large systems. The EPA disagrees with this recommendation, as the purpose of this analysis is to determine if available SSCTs are affordable, per SDWA section 1412(b)(4)C(ii). Therefore, the EPA chose to continue to analyze small system technologies rather than include medium and large systems.

Some commenters specifically disagreed with one of the EPA's supplemental affordability analyses that examined the impact of the rule when accounting for the financial assistance through BIL and other sources that are generally available to small systems. These commenters stated that the EPA should not assume that this funding will be available or enough to cover the small system capital costs associated with the rule. The EPA conducted this supplemental analysis in response to the recommendations of the SAB, which stated, ''[i]f this funding is readily available to many or most systems facing affordability problems, it seems appropriate to take the availability of this funding into account in determining national level affordability.'' (USEPA, 2002b) The EPA disagrees with these commenters as this significant funding will be generally available, and the EPA continues its efforts to help PWSs access it. It is therefore reasonable to consider the burden reduction in the supplemental affordability analysis.

Some commenters disagreed with the EPA's affordability determination because they stated it was based on inaccurate treatment cost information. A couple of commenters presented their own estimates for small system household costs and compared these estimates to the EPA's affordability threshold and concluded the rule is unaffordable. The EPA disagrees with many of the underlying assumptions in the commenters' cost estimates which, on whole, result in overestimated household costs, see section XII.A. These commenters cited cost information that is not representative of the range of treatment costs nationally, and the EPA disagrees with the commenter's cost model that systematically overestimates capital operation and treatment costs. The EPA updated the affordability analysis for the national affordability determination using the updated treatment cost curves (discussed in section XII.D) and found for systems serving between 25 and 500 people, that the upper bound estimated annual household treatment costs for GAC exceed the expenditure margin. Lower bound estimated annual household treatment costs for GAC do not exceed the expenditure margin; for more information see section XII. These exceedances are primarily driven by capital costs and attributable to the use of high-cost materials (*e.g.,* stainless steel) in the upper bound estimates. Systems using low-cost materials, but with source water characteristics otherwise set to the upper bound (*e.g.,* influent PFAS at approximately 7,000 ng/L, influent TOC at 2 mg/L), would fall below the expenditure margin. Although costs increase in some scenarios, the increases are not significant enough to change the conclusions about affordability. The small system compliance technologies available to meet the requirements of the final rule are affordable for all small systems when the technologies do not use the high-end materials. Technologies that do not use high end materials may be less durable but nonetheless are available for small systems and can meet the requirements of the final rule. For more information on the EPA's response to comments on treatment costs see section XII. The EPA also disagrees that there are no affordable compliance technologies for small systems as the EPA has demonstrated that SCCTs are available below the affordability threshold using the best available peer reviewed information to support the agency's cost estimates.

3. Final Rule

The final rule includes sorptive devices as well as combination devices, should they meet third party verification standards and the MCL. In USEPA, 2024l, the EPA also changed the way data are presented by replacing the term ''Not Applicable'' with ''Data Unavailable'' in response to public comment. Finally, the final affordability analysis reflects updates made to the unit cost curves after considering public comments. The EPA has determined that affordable SSCTs are available that meet the requirements of the final rule (see table 6 to paragraph (e) of 40 CFR 141.61).

The EPA's affordability determination for the final rule, using long standing EPA methodology and supplemental affordability analyses can be found in the EA chapter 9.12.

The EPA notes that POU RO devices are not currently listed as a SSCT because the NPDWR requires treatment to concentrations below the current NSF International/American National Standards Institute (NSF/ANSI) certification standard for POU device removal of PFAS. However, POU treatments are reasonably anticipated to become a compliance option for small systems in the future if NSF/ANSI develop a new certification standard that mirrors or is more stringent than the final regulatory standards. Other third-party entities including NSF can independently certify drinking water treatment units (DWTUs) that meet these standards. NSF/ANSI is considering lowering its current standard to levels closer to final standards in this NPDWR. Based on efficacy of reverse osmosis technology, RO POU devices can reasonably be anticipated to remove the majority of PFAS when they are properly designed and maintained. Other POU devices (*e.g.,* activated carbon) may also meet future EPA PFAS regulatory limits. These devices would also need third-party testing and certified against the regulatory standards. Further, the EPA notes that water systems may use any technology or practice to meet the MCLs promulgated in this NPDWR and are not limited to the BATs nor SSCTs discussed in this section. Other technologies or nontreatment options may be chosen in lieu of a BAT or SSCT because they may be more cost effective or better suited to the specific operating conditions of the particular site to meet any MCL.

XI. Rule Implementation and Enforcement

A. What are the requirements for primacy?

1. Proposal

SDWA section 1413 establishes requirements that primacy agencies (states, Tribes and territories) must meet to have primary enforcement responsibility (primacy) for its PWSs. These include: (1) adopting drinking water regulations that are no less stringent than Federal NPDWRs in effect under sections 1412(a) and 1412(b) of SDWA; (2) adopting and implementing adequate procedures for enforcement; (3) keeping records and making reports available on activities that the EPA requires by regulation; (4) issuing variances and exemptions (if allowed by the state) under conditions no less stringent than allowed by SDWA sections 1415 and 1416; and (5) adopting and being capable of implementing an adequate plan for the provision of safe drinking water under emergency situations. The regulations in 40 CFR part 142 set out the specific program implementation requirements for states to obtain primacy for the Public Water System Supervision (PWSS) Program, as authorized under section 1413 of the Act.

Under 40 CFR 142.12(b), all primacy agencies are required to submit a revised program to the EPA for approval within two years of promulgation of any final PFAS NPDWR or request an extension of up to two years in certain circumstances. To be approved for a program revision, primacy agencies are required to adopt revisions at least as stringent as the revised PFAS-related provisions. To obtain primacy for this rule, primacy applications must address the general requirements specified in subpart B of part 142. The EPA proposed special primacy requirements for the PFAS NPDWR (§ 142.16(r)), to outline additional requirements for a primacy agency related to identifying its plan for implementing the initial monitoring requirements.

2. Summary of Major Public Comments and EPA Responses

The EPA received one comment that most of the initial monitoring may occur before primacy applications will be submitted, which are not due until two years after final rule promulgation. A couple of commenters assert that it is unclear why states are required to include an initial monitoring plan in their primacy application and that states will not be able to implement and demonstrate that this monitoring plan is enforceable under state law until state regulations have been promulgated. The EPA recognizes that some initial monitoring by water systems may occur prior to a state, territory, or Tribe receiving the EPA approval for primacy and agrees with the commentor that for states to develop a monitoring plan that addresses when systems will be scheduled to conduct initial monitoring is not a necessary requirement for a primacy application. However, where states are approved for primacy before the compliance date for the water systems, primacy agencies should have procedures for evaluating whether data that a CWS or NTNCWS submits to satisfy the initial monitoring requirements are acceptable. It is therefore appropriate to require primacy agencies to include in their primacy application a description of their procedures for reviewing water system's use of pre-existing data to meet initial monitoring requirements, including the criteria that will be used to determine if the data are acceptable and the primacy agency's procedures for ensuring water system compliance within the required timeframes. The compliance deadline for this initial monitoring by systems is three-years from promulgation, by which time primacy agencies should have primacy or interim primacy. To address the possibility that a state, Tribe, or territory may get an extension to apply for primacy, the final rule provides that these special primacy requirements are not applicable after the initial monitoring deadline (*i.e.,* three years after publication of the rule in the **Federal Register**). When a primacy agency does not yet have primacy for a new drinking water rule, an NPDWR is nonetheless applicable to water systems and may be enforced by the EPA following the compliance dates specified in § 141.900(b).

3. Final Rule

The EPA is revising the requirements for primacy as proposed in 40 CFR 142.16(r) by removing the requirements to develop an initial monitoring plan, although the EPA is finalizing the proposed requirement for primacy agency procedures for ensuring all systems complete the initial monitoring period requirements, including for determining whether pre-existing data are acceptable, but clarifying that these requirements would not apply after the deadline for initial monitoring has passed (*i.e.,* three years after publication of the rule in the **Federal Register**). The EPA also corrected two grammatical errors. In the final rule, the EPA requires that a PWS complete the initial monitoring by three years following date of promulgation (for additional discussion on monitoring and compliance requirements, please see section VIII of this preamble). It is the EPA's expectation that primacy agencies will have completed the requirements for primacy within the two years (*i.e.,* without an extension) and in that case, they will have the authority in place to ensure that systems comply with the initial monitoring requirements. If a primacy agency is applying for primacy after the deadline for initial monitoring has passed, then the requirement is no longer applicable. In that case, an NPDWR is nonetheless applicable to water systems and implementation would be overseen and enforced by the EPA consistent with any agreements with the state pursuant to the primacy application extension approval.

B. What are the record keeping requirements?

1. Proposal

The current regulations in 40 CFR 142.14 require primacy agencies to keep records of analytical results to determine compliance, system inventories, sanitary surveys, state approvals, vulnerability and waiver determinations, monitoring requirements, monitoring frequency decisions, enforcement actions, and the issuance of variances and exemptions. The primacy agency record keeping requirements remain unchanged and would apply to PFAS as with any other regulated contaminant.

2. Summary of Major Public Comments and EPA Responses

The EPA received a few comments about the record keeping that primacy agencies must maintain for compliance determinations and reporting, storing PWS facility data, tracking monitoring schedules, and keeping the public informed of the quality of their drinking water. As noted in the comments, most primacy agencies rely on SDWIS, developed by the EPA, to support this record keeping requirement. It was recommended that the EPA develop a data system, either SDWIS or a replacement, that is capable of fully managing the data associated with the proposed rule. Further, it was recommended that the EPA develop data management solutions such as a mechanism for migrating UCMR data into SDWIS State to reduce or eliminate the burden of ensuring compliance with the initial monitoring. The EPA agrees that appropriate data management solutions are needed to effectively comply with SDWA requirements; however, the agency does not believe these systems must be available at the time of rule promulgation. Additionally, while beyond the scope of this rulemaking itself, the EPA is actively working on PFAS data management solutions, including DW–SFTIES support and potentially updating the SDWIS suite of applications to manage data reported from this rule.

3. Final Rule

The primacy agency record keeping requirements in 40 CFR 142.14 remain unchanged and would apply to PFAS as with any other regulated contaminants. Water system recordkeeping requirements are referenced within subpart Z in § 141.904. In the final rule, the EPA updated this regulatory text to cross-reference the record retention provisions in § 141.33. The EPA is developing the Drinking Water State-Federal-Tribal Information Exchange System (DW–SFTIES) that will support all SDWA drinking water rules. The EPA plans to continue to provide support for necessary updates to SDWIS State, including for reporting requirements for new rules, until the DW–SFTIES is in production and in use by primacy agencies. SDWIS State support and updates will continue until the DW–SFTIES Board recommends a sunset date after DW–SFTIES is in production and in use by primacy agencies. The EPA will evaluate the migration of UCMR data into the suite of SDWIS applications.

C. What are the reporting requirements?

1. Proposal

Under 40 CFR 142.15, primacy agencies must report to the EPA information regarding violations, variances and exemptions, enforcement actions, and general operations of state PWS programs. The primacy agency reporting requirements remain unchanged and would apply to PFAS as with any other regulated contaminant. The water system reporting requirements are mentioned in § 141.904 and cross-reference the reporting timeframes and provisions in § 141.31.

2. Summary of Major Public Comments and EPA Responses

A few commenters recommended that the EPA provide Data Entry Instructions within six months of the promulgation of the rule to allow primacy agencies, particularly those that do not use SDWIS State, to implement their data systems for reporting to the EPA, prepare their PWS, and train staff. The EPA acknowledges this comment and will work to develop Data Entry Instructions as soon as possible. One commentor recommended that the EPA provide separate tracking of reporting and monitoring violations. The EPA acknowledges this comment and will consider this as data reporting tools are developed. A couple of commentors recommended that the reporting and recordkeeping requirements for compliance within the rule should provide an option for not requiring the RAA to be reported by the laboratories if the primacy agency performs the RAA calculations for the water system. In addition, one commenter requested that the primacy agency calculate the RAA, and another commentor inquired whether the EPA intended to allow the water systems not to perform the RAA calculations if the primacy agency performs the RAA calculations. The EPA disagrees with these comments. To ensure that the water system has immediate knowledge of their compliance status, the final rule requires that water systems calculate the RAA and report this to the primacy agency. Primacy agencies or laboratories may also calculate the RAA, to confirm the results of the water system, but it is not a required reporting element under this regulation. Lastly another commentor suggested that utilities be required to report the occurrence and concentration of other PFAS listed in the method (preferably 533) to facilitate data collection and to better inform water treatment objectives. The EPA notes that many water systems are currently collecting samples and reporting monitoring data for 29 PFAS that can be measured with EPA Methods 533 and 537.1 under UCMR 5 where EPA has the regulatory authority.

3. Final Rule

The reporting requirements for primacy agencies under 40 CFR 142.15 remain unchanged and apply to PFAS as with any other regulated contaminant. The EPA intends to develop and provide access to Data Entry Instructions within one year after rule publication. The EPA will follow the usual protocol of engaging with a State-EPA workgroup for drafting the Data Entry Instructions. In this process, the EPA will consider the use of separate monitoring and reporting violation codes, like is used for the Revised Total Coliform Rule (RTCR). In this final regulation, the cross-reference to the water system reporting timeframes and provisions in § 141.31 at the start of § 141.904 is retained, and, at 40 CFR 141.904(b), table 2, the EPA requires water systems to report PFAS RAAs to their primacy agency. As a general process, the laboratory will conduct the analysis of the sample and the system will use the result to calculate their RAA; the RAA calculation may subsequently be completed by the primacy agency as a compliance check. The EPA does recognize that state laboratories often directly report results to the state as allowed in 40 CFR 141.31(c) and that electronic reporting tools, such as the Compliance Monitoring Data Portal (CMDP), may be used by systems to comply with this reporting requirement.

D. Exemptions and Extensions

1. Proposal

Pursuant to SDWA section 1412(b)(10), the EPA proposed that all systems must comply with the NPDWR three years after rule promulgation. The EPA's proposal acknowledged that a primacy agency or the EPA may grant an extension of up to two additional years to comply with an NPDWR's MCL(s) if the primacy agency or the EPA determines an individual system needs additional time for capital improvements. The EPA stated that ''[a]t this time, the EPA does not intend to provide a two-year extension nationwide.'' 88 FR 18689. The proposal also discussed how a state which has primary enforcement responsibility may exempt any individual system facing compelling factors, such as economic factors, additional time to comply with any requirement respecting an MCL of any applicable NPDWR under SDWA section 1416 (USEPA, 2023f).

2. Summary of Major Public Comments and EPA Responses

SDWA section 1412(b)(10) requires that a ''NPDWR shall take effect ''3 years after the date on which the regulation is promulgated unless the administrator determines that an earlier date is practicable.'' Section 1412(b)(2) also authorizes ''the Administrator, or a State (in the case of an individual system), may allow up 2 additional years to *comply with a maximum contaminant level* . . . if the Administrator or the State . . . determines that additional time is necessary for capital improvements'' (emphasis added). Congress intended the extension under this provision to allow for a total of five years to comply with the MCL. Thus, if the EPA provides a two-year extension of the MCL compliance deadline for all systems based on the need for capital improvements, a state cannot provide an additional two-year extension under section 1412(b)(10) for capital improvements but may grant exemptions under section 1416 consistent with applicable requirements.

Many commenters, including utilities and state primacy agencies, expressed difficulty in meeting the three-year compliance deadline. Commenters expressed that it will be very challenging to both conduct initial monitoring and take actions (*e.g.,* installing treatment) to comply with the MCL within three years. Many of these commenters shared their on-the-ground experience in managing facilities that required capital improvements and provided evidence that additional time is needed to procure, design, pilot, permit, and ultimately construct treatment systems. Additionally, several commenters provided evidence of on-going labor and workforce challenges as well as recent experience with supply chain difficulties to obtain materials necessary to design and construct treatment facilities, which many attributed as a direct or indirect result of the COVID-pandemic residual impacts (AWWA, 2023).

The agency has evaluated the data and information shared by commenters regarding their experience with the time it takes to implement capital improvement projects. The EPA estimates that approximately 4,100–6,700 systems will be impacted by the MCLs in this final rule. Based on the EPA's initial compliance forecast, the agency anticipates that many of these systems will be installing advanced treatment technologies to meet the final PFAS standards (for additional discussion on the compliance forecast, please see section XII). The treatment technologies listed as BAT for the final rule include GAC, ion exchange resins, and centralized RO/NF (please see section X for more information). To ensure cost effective compliance with the PFAS MCLs, systems often need to evaluate their treatment technology options as a first step. Several commenters have noted that this planning step may include pilot studies with potential treatment systems, or it may be limited to an evaluation of the raw water characteristics. Further, some commenters have submitted data and project management plans for systems choosing to conduct pilot testing, indicating that it may take a year or more to contract with vendors and to perform pilot testing. Once the planning step is completed, systems must design and construct the treatment systems. Several commenters submitted information to the EPA indicating that the design and permitting of the treatment systems can take an additional year or longer, and construction of the treatment system can take another year or longer. Because systems will also need time to obtain funding, obtain local government approval of the project, or acquire the land necessary to construct these technologies, many commenters contend that systems will need additional time beyond the three-year effective date to comply with the MCLs.

While the EPA stated in the proposed rule that the agency did not intend to provide a two-year extension nationwide necessary for capital improvements, the EPA finds that the evidence submitted by commenters strongly supports that a significant number of systems covered by this rule will need two additional years to make capital improvements to meet the MCL. Specifically, the EPA reviewed data from applicants seeking DWSRF funding for capital improvement projects (*e.g.,* installation of advanced treatment technologies such as GAC or IX) and confirmed that these projects, on average, take about three or more years to complete (which excludes the time and activities that may occur to ensure these capital improvement projects are implemented successfully, such as the time it may take to secure funding or to conduct pilot testing). This evidence along with the breadth of practicable experience shared by utilities and primacy agencies demonstrate that additional time is necessary for a significant number of system sizes and types located throughout the country to make capital improvements. Additionally, the EPA notes that the number of systems estimated to be impacted by the MCLs are greater than what the agency anticipated in the proposal (*i.e.,* an increase from 3,400–6,300 systems to 4,100–6,700 systems nationally). This increase provides further evidence that a capital improvement extension is warranted as the agency expects that many of these systems will be installing advanced treatment technologies to meet the final PFAS standards. The agency also agrees with commenters that on-going labor and workforce challenges exist and can limit the ability to design, construct and operate treatment facilities. These workforce challenges facing water utilities and other sector organizations support the need for a capital improvement extension as a sufficient availability of qualified personnel is necessary to implement and sustain capital improvement projects. These issues may be attributed as a direct or indirect result of the recent COVID–19 pandemic and are clearly documented in data submitted to the agency as part of the public comment process (AWWA, 2023). Based upon these considerations, the EPA determined, in accordance with section 1412(b)(10) of SDWA, that the compliance date for the PFAS MCLs, regardless of system size, will be 5 years from the date of promulgation of the standard.

Some commenters recommend the EPA to follow a staggered implementation timeframe similar to what was done in some previous NPDWRs where compliance deadlines were staggered based on system size (USEPA, 2001; USEPA, 2006a). In these prior examples, larger systems typically conducted their monitoring and implemented the MCL first, followed by smaller systems. Upon consideration of information submitted by commenters, particularly issues related to supply chain complications that are directly or indirectly related to the COVID–19 pandemic residual challenges, the EPA has determined that a significant number of systems subject to the rule, including large systems, will require two additional years to complete the capital improvements necessary to comply with the MCLs for PFAS regulated under this action. For this reason, the EPA disagrees with commenters that staggered implementation based on system size is warranted for this rule. While large systems may have greater resources to implement capital improvements (*e.g.,* engineering and construction management staff to manage the projects), they still require time to design, pilot, permit, and construct treatment facilities.

Some commenters note that it will be challenging for systems to conduct their initial monitoring and install treatment within three years, particularly for those systems not conducting UCMR 5 monitoring that is ongoing until 2026. The EPA notes that the agency is finalizing a flexibility for systems to use previously acquired monitoring data from UCMR 5 or an equivalent state-led monitoring program for their initial monitoring which is intended to alleviate the burden placed on water systems in collecting additional data (see section VIII of this preamble for additional information on monitoring). While the agency agrees that systems need an additional two years to make capital improvements, the EPA finds that it is practicable for most systems to complete their initial monitoring within three years because all systems serving greater than 3,300 people will have appropriate monitoring data from UCMR 5. Many systems smaller than 3,300 people will also have appropriate monitoring data from state-led monitoring programs that may be eligible to meet the rule's initial monitoring requirements, and some will have UCMR 5 or other data. If systems find elevated levels of PFAS, these systems have an additional two years to comply with the MCL. If a system does not have eligible previously collected monitoring data and are concerned about insufficient time to install capital improvements, the EPA encourages these facilities to collect monitoring data as soon as possible after rule promulgation, allowing them the bulk of the five-year period to plan for and install any capital improvements if necessary.

Some commenters point to concerns regarding laboratory capability and capacity in supporting the proposed three-year compliance timeline. Additionally, a couple of commenters noted that if additional time were allowed, water systems that are close to the MCL may have time to identify and address sources of PFAS in their watersheds rather than investing resources on treatment initially. Finally, a couple of commenters recommend the EPA consider implementation flexibilities for small and rural water systems and suggest that these types of utilities may not have staff capacity nor expertise to compete for funding to implement the rule. The EPA notes that these issues are not directly related to capital improvements and thus were not the basis for the EPA's decision to extend the compliance date for the PFAS MCLs. Although the EPA disagrees with assertions about insufficient laboratory capacity and capability at this time to support implementation of the NPDWR, to the extent there are initial implementation issues just after promulgation, extending the compliance date will also provide ancillary benefits toward addressing any such laboratory capability and capacity issues and may provide opportunities for systems who are close to exceeding the MCLs to investigate sources of contamination. Additionally, the extended compliance deadline may give smaller and rural water utilities more time to apply for funding under BIL (please see section II of this preamble above for a discussion on BIL). Further, other assistance programs such as the Environmental Justice Thriving Communities Technical Assistance Centers may provide additional fundamental training and capacity building activities for underserved and overburdened communities toward navigating Federal grant applications and managing funding opportunities.

The EPA requested comment as to whether there are specific conditions, in addition to the statutory conditions, that should be mandated for systems to be eligible for exemptions from the PFAS NPDWR under SDWA section 1416. Several commenters requested the EPA provide additional guidance to primacy Agencies on when exemptions are appropriate under SDWA section 1416 similar to what was done for the final Arsenic NPDWR (USEPA, 2002c). The EPA is not issuing additional guidance around implementation of SDWA section 1416 at this time but may consider it in the future. The EPA notes primacy agencies who have adopted the 1998 *Variance and Exemptions Regulation* (USEPA, 1998c) may choose to grant exemptions consistent with the requirements under this regulation to encourage systems facing compelling circumstances to come into compliance with the MCLs in an appropriate period of time.

3. Final Rule

Pursuant to SDWA section 1412(b)(10), the final PFAS NPDWR is effective June 25, 2024. The compliance date for the PFAS NPDWR, other than the MCLs, is April 26, 2027. As discussed above and upon consideration of information submitted by commenters, the EPA is exercising its authority under SDWA section 1412(b)(10) to implement a nationwide capital improvement extension to comply with the MCLs. All systems must comply with the MCLs by April 26, 2029. All systems must comply with other requirements of the NPDWR, including initial monitoring, by April 26, 2027.

Systems must comply with initial monitoring requirements within three years of rule promulgation and will be required to summarize PFAS monitoring results and applicable information beginning with CCRs delivered in 2027. As the MCL compliance date is set at five years from rule promulgation, systems must report MCL violations in the CCR, accompanied by the required health effects language and information about violations, starting in 2029. Monitoring and testing procedure violations require Tier 3 notification: systems must provide notice no later than one year after the system learns of the violation. Systems must repeat the notice annually for as long as the violation persists. Systems must comply with initial monitoring requirements within three years of rule promulgation and systems must provide Tier 3 notification for monitoring and testing procedure violations starting in 2027. As the MCL compliance date is set at five years from rule promulgation, systems must provide Tier 2 notification for MCL violations, starting in 2029. For more information on SDWA Right-to-Know requirements, please see section IX of this preamble above.

The agency notes that SDWA section 1416(a) and (b)(2)(C) describe how the EPA or states may also grant an exemption for systems meeting specified criteria that provides an additional period for compliance. PWSs that meet the minimum criteria outlined in the SDWA may be eligible for an exemption from the MCLs for up to three years. For smaller water systems (≤3,300 population), exemptions can provide up to six additional years to achieve compliance with the MCLs. States exercising primacy enforcement responsibility must have adopted the 1998 *Variance and Exemption Regulation* (USEPA, 1998c) for water systems in those jurisdictions to be eligible for an exemption.

XII. Health Risk Reduction and Cost Analysis

This section summarizes the final rule Health Risk Reduction and Cost Analysis (HRRCA) supporting document (USEPA, 2024g) for the per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation (NPDWR), which is prepared in compliance with section 1412(b)(3)(C) of the Safe Drinking Water Act (SDWA) and under Executive Order (E.O.) 12866. Section 1412(b)(3)(C)(i) lists the analytical elements required in a HRRCA applicable to an NPDWR that includes a Maximum Contaminant Level (MCL). The prescribed HRRCA elements include:

(1) Quantifiable and nonquantifiable health risk reduction benefits;

(2) quantifiable and nonquantifiable health risk reduction benefits from reductions in co-occurring contaminants;

(3) quantifiable and nonquantifiable costs that are likely to occur solely as a result of compliance;

(4) incremental costs and benefits of each alternative MCL considered;

(5) effects of the contaminant on the general population and sensitive subpopulations including infants, children, pregnant women, the elderly, and individuals with a history of serious illness;

(6) any increased health risks that may occur as a result of compliance, including risks associated with co-occurring contaminants; and

(7) other relevant factors such as uncertainties in the analysis and factors with respect to the degree and nature of the risk.

Based on this analysis, the Administrator confirms the finding made at proposal under section 1412(b)(4)(C) of SDWA that the quantified and nonquantifiable benefits of the MCLs justify the costs. The complete HRRCA for the final NPDWR is commonly referred to as the ''Economic Analysis'' (or EA) in this final rule and can be found in the docket at USEPA (2024g).

Because this NPDWR is promulgated in 2024 and provides a 2-year nationwide extension of the date for MCL compliance, the EA assumes that capital improvements (*i.e.,* installation of treatment technologies) for systems taking action under the rule will be completed by five years from the date promulgated, or in 2029. All other requirements, including initial monitoring, are assumed to be completed within three years of rule promulgation, or by 2027. Based on an assumed mean human lifespan of 80 years, the Environmental Protection Agency (EPA) evaluates costs and benefits under the final rule through the year 2105.

The EPA selected this period of analysis to capture health effects from chronic illnesses that are typically experienced later in life (*i.e.,* cardiovascular disease [CVD] and cancer). Capital costs for installation of treatment technologies are spread over the useful life of the technologies. The EPA does not capture effects of compliance with the final rule after the end of the period of analysis. Costs and benefits discussed in this section are presented as annualized present values in 2022 dollars. The EPA determined the present value of these costs and benefits using a discount rate of 2 percent, which is the discount rate prescribed by the Office of Management and Budget (OMB; OMB, 2023). All future cost and benefit values are discounted back to the initial year of the analysis, 2024, providing the present value of the cost or benefit.

Estimates of PFAS occurrence used for cost-benefit modeling rely on a Bayesian hierarchical estimation model of national PFAS occurrence in drinking water (Cadwallader et al., 2022) discussed in section VI.E. of this preamble. The model was fitted using sample data from systems participating in PFAS sampling under the third Unregulated Contaminant Monitoring Rule (UCMR 3) and included all systems serving over 10,000 customers and a subset of 800 smaller systems. A best-fit model was selected using sample data to define occurrence and co-occurrence of perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), and perfluorohexane sulfonic acid (PFHxS[12]) in water systems stratified by system size and incorporating variations within and among systems. Sample data were derived from state-level datasets as well as from UCMR 3. For more information on the EPA's occurrence model, please see section VI.E. of this preamble.

In the EA, the EPA analyzes the costs and benefits of the final rule, which includes MCLs for PFOA and PFOS at 4.0 ng/L each and MCLs for PFHxS, perfluorononanoic acid (PFNA), and hexafluoropropylene oxide dimer acid (HFPO–DA) at 10 ng/L each and a unitless Hazard Index (HI) of 1 for any mixtures of PFHxS, PFNA, HFPO–DA, and PFBS. The EPA also analyzed the costs and benefits for several regulatory alternatives. The EPA analyzed the costs and benefits of setting individual MCLs for PFOA and PFOS at 4.0 ng/L, 5.0 ng/L, and 10.0 ng/L, referred to as regulatory alternative MCLs under option 1a, option 1b, and option 1c, respectively. The EPA assessed these regulatory alternative MCLs in the EA to understand the impact of less stringent PFOA and PFOS MCLs. Additionally, the EPA has separately estimated national level marginal costs associated with the individual MCL for PFHxS if this MCL were to be promulgated in the absence of the Hazard Index; see chapter 5.1.3 of the EA for details. The EPA has also estimated the marginal costs for the individual PFNA and HFPO–DA MCLs if there were no Hazard Index in the sensitivity analysis found in appendix N.4. The EPA notes that the costs for the individual PFHxS, PFNA, and HFPO–DA MCLs have been considered in this final rule.

Section A summarizes public comments received on the EA for the proposed rule and the EPA's responses to comments. Section B summarizes the entities which would be affected by the final rule and provides a list of key data sources used to develop the EPA's baseline water system characterization. Section C provides an overview of the cost-benefit model used to estimate the national costs and benefits of the final rule. Section D summarizes the methods the EPA used to estimate costs associated with the final rule. Section E summarizes the nonquantifiable costs of the final rule.[13] Section F summarizes the methods the EPA used to estimate quantified benefits associated with the final rule. Section G provides a summary of the nonquantifiable benefits associated with reductions in exposure to both PFOA and PFOS expected to result from the final rule. Section H provides a qualitative summary of benefits expected to result from the removal of PFAS included in the Hazard Index component of the final rule and additional co-removed PFAS contaminants. Section I of this preamble summarizes benefits expected to result from the co-removal of disinfection byproducts (DBPs). Section J provides a comparison of cost and benefit estimates. Section K summarizes and discusses key uncertainties in the cost and benefit analyses. Quantified costs and benefits for the final rule and regulatory alternative MCLs under options 1a-1c are summarized in section XII.J, specifically Tables 68–71. Tables 72–73 summarize the non-quantified costs and benefits and assess the potential impact of nonquantifiable costs and benefits on the overall cost and benefit estimates for the final rule.

A. Public Comment on the Economic Analysis for the Proposed Rule and EPA Response

1. Methods for Estimating Benefits

a. Methods for Estimating Benefits in the Proposed Rule

In the EA for the proposed rule, the EPA presented quantified and nonquantifiable health benefits expected from reductions in PFAS exposures. Quantified benefits are assessed as avoided cases of illness and deaths (or morbidity and mortality, respectively) associated with exposure to some of the regulated PFAS contaminants. The EPA provided a quantitative estimate of CVD, birth weight, and renal cell carcinoma (RCC) avoided morbidity and mortality associated with reductions in PFOA and PFOS consistent with the proposed rule. The EPA also developed a quantitative analysis for reductions in bladder cancer morbidity and mortality that stem from removal of DBP precursors as a function of PFAS treatment. Adverse human health outcomes associated with PFAS exposure that cannot be quantified and valued are assessed as nonquantifiable benefits.

The EPA qualitatively summarized potential health benefits associated with reduced exposure to PFAS other than PFOA and PFOS in drinking water. In the proposal, the EPA discussed non quantified benefits associated with health endpoints including developmental effects, cardiovascular effects, hepatic effects, immune effects,

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[12] The EPA notes that perfluoroheptanoic acid (PFHpA) is not included in the proposed or final PFAS NPDWR; however, it was included in the occurrence model because of its UCMR 3 occurrence data availability; please see *Cadwallader et al., 2022* for additional details.

[13] This section includes costs with generally greater uncertainty that the EPA assesses in quantified sensitivity analyses.

endocrine effects, metabolic effects, renal effects, reproductive effects, musculoskeletal effects, hematological effects, other non-cancer effects, and COVID–19.

b. Summary of Major Public Comments on Method for Estimating Benefits and EPA Responses

Overestimation of Quantified Benefits

The EPA received comments from industry groups and organizations representing water utilities about the EPA's methodology for estimating quantitative benefits associated with the NPDWR. While some commenters supported the EPA's analysis, a few commenters stated that the agency overestimated quantified benefits. These commenters asserted that the EPA overstated the benefits of the rule and that the HRRCA is flawed because the existing health evidence does not support the quantified benefits. The EPA disagrees with commenters that the existing evidence does not support the EPA's estimate of quantified benefits from avoided adverse health effects likely to occur as a result of treatment and that these benefits are overstated. Among other things, the EPA has used the best available science in three key respects: by (1) considering relevant peer-reviewed literature identified by performing systematic searches of the scientific literature or identified through public comment, (2) relying on peer-reviewed, published EPA human health risk assessment methodology (USEPA, 2022f), and (3) utilizing peer-reviewed methodologies to valuing and quantifying avoided adverse health outcomes. Specifically, the EPA identified the full range of expected human health outcomes, including quantified benefits associated with co-removal of co-occurring contaminants (*i.e.,* DBPs). This process was built upon multidisciplinary research, including hazard identification and dose-response analysis, exposure assessment, and economic valuation methods recommended by the EPA's *Guidelines for Preparing Economic Analyses* (USEPA, 2016e) and updated Circular A–4 Guidance (OMB, 2023) to enumerate all beneficial outcomes, identify beneficiaries, and determine human health endpoints that can be valued. The EPA notes that the benefits analysis contains uncertainties associated with the modeling inputs in each of the steps listed above. In accordance with OMB Circular A–4 guidance (OMB, 2023), the EPA characterizes sources of uncertainty in its quantitative benefits analysis and reports uncertainty bounds for benefits estimated for each health endpoint category modeled in the final rule. See Table 75 and also section 6.1 of the EA for the final rule (USEPA, 2024g) for the list of quantified sources of uncertainty in benefits estimates. The reported uncertainty bounds reflect the best available data on health effect-serum slope factors, baseline PFAS occurrence, population size and demographic composition, and the magnitude of PFAS concentration reductions. In addition, some model inputs did not have sufficient distributional data to be included in the quantitative uncertainty analysis, and there are also uncertainties that could not be assessed quantitatively. These sources of uncertainty are described in Table 62 and also in section 6.8 of the EA for the final rule (USEPA, 2024g). Although some imprecision in the estimated benefits may be expected due to the lack of perfect information, the EPA has demonstrated, using the best science and data available, that there is sufficient health evidence to support the estimation of quantified benefit values and that these values are not systematic overestimates of the welfare improvements derived from implementation of the NPDWR.

Another commenter claimed that ''for the large majority of health endpoints discussed, the EPA has not provided a factual basis by which to conclude that such benefits are likely to occur when the EPA decreases the levels of PFAS in drinking water.'' The EPA disagrees with the commenter's assertion that the agency has not provided a factual basis for the benefits that are likely to occur as a result of the rule, which is amply supported in the HRRCA by the best available peer-reviewed science, consistent with SDWA section 1412(b)(3). Moreover, the commenter did not provide any additional or contrary factual information for the EPA to consider.

One commenter stated that the EPA did not provide data to support the analysis of benefits predicted from the implementation of the Hazard Index MCL. The EPA disagrees with commenter that the EPA did not provide evidence to support Hazard Index MCL benefits. In section XII of the preamble and in section 6.2 of the EA (USEPA, 2024g), the EPA qualitatively summarized and considered the potential health benefits resulting from reduced exposure to PFAS other than PFOA and PFOS in drinking water. These qualitative potential health benefits are based on summaries of a significant body of peer reviewed science. As summarized in the EA, the qualitatively discussed health effects of the Hazard Index PFAS are considerable; reducing human exposure to the Hazard Index PFAS is expected to reduce the incidence of multiple adverse health impacts. The qualitative benefits discussion of the impacts of the four PFAS which are regulated through the Hazard Index, as well as their co-occurrence in source waters containing PFOA and/or PFOS and additive health concerns, supports the EPA's decision to regulate them through the Hazard Index in this rulemaking.

Additionally, the EPA evaluated the impacts of PFNA (one of the Hazard Index PFAS) on birthweight in quantitative sensitivity analyses (USEPA, 2024e). The EPA notes that new evidence since the release of the current, best available peer reviewed scientific assessment for PFNA (ATSDR, 2021) provides further justification for the EPA's analysis of potential economic benefits of PFNA exposure reduction and avoided birthweight effects. Specifically, this new evidence confirms that in instances where PFNA is present, the national quantified benefits may be underestimated; however, birth weight benefits are considered quantitatively as part of this EA in the sensitivity analysis and support the EPA's decision to regulate PFNA.

The EPA received a number of comments on the quantitative analysis for CVD risk reduction. These commenters disagree with the EPA's assessment that cardiovascular benefits are likely to occur as a result of PFOA and PFOS exposure reduction. One commenter stated that the associations with total cholesterol (TC) are not biologically significant and criticized the EPA's use of linear models in the CVD meta-analysis, stating that this approach biases the analysis by excluding higher-quality studies. The EPA disagrees with the commenter's statement that associations between PFOA/PFOS and TC are not biologically significant. Such serum lipid changes may or may not result in a concentration considered clinically elevated in a particular individual; however, given the distribution of individual concentrations within the population, small changes in average serum lipid concentrations can result in substantial adverse health effects at the population level (Gilbert and Weiss, 2006). The EPA disagrees with the commenter's suggestions that linear assumptions are inappropriate for use in this context. The EPA presents the exposure-response estimates evaluated considering all studies, studies with linear models only, and a variety of sensitivity analyses in appendix F of the

EA (Tables F–2 and F–3, USEPA, 2024e). Meta-analyses of studies reporting linear associations had statistically significant relationships. These relationships are supported by the EPA's review of epidemiological studies showing positive associations between PFOA/PFOS and TC. The EPA used data from peer-reviewed studies, and the assumption of linear exposure-response function to explain associations between PFAS and serum lipids such as TC which are supported by data from numerous studies, including those used in the meta-analysis. Other studies have explored log-linear or linear-log relationships between PFAS and serum lipids, while acknowledging only ''slight improvements'' in model fit, especially for serum lipids with least skewed distributions (Steenland et al., 2009).

A couple of commenters stated that the downward trend in decreasing total and low-density lipid cholesterol since the 1970s coupled with the decreasing PFOA and PFOS serum levels suggests that there is a substantial likelihood that the proposed MCLs for PFOA and PFOS are unlikely to result in benefits as great as those reported in the proposal. The EPA disagrees with these comments asserting that decreasing trends in cholesterol levels over time indicate that PFAS exposure is unlikely to contribute to a measurable increase in CVD risk. The EPA relied on recent National Health and Nutrition Examination Study (NHANES) data (2011–2016) to inform baseline cholesterol and blood pressure conditions in the population evaluated under the proposed rule. These data reflect the current population and do not reflect cholesterol conditions in the population between 1970 and 2010. Therefore, the CVD benefits analysis examines how the probability of the current population might benefit from reduced incidence of hard CVD events.[14]

The EPA received a comment stating that the benefits associated with high-density lipoprotein cholesterol (HDLC, often referred to as the 'good cholesterol') changes are not likely to accrue because the evidence of the relationship between PFAS and the health outcome is not conclusive, and that this endpoint should not have been quantified. The EPA disagrees; although the evidence of a relationship between PFAS exposure and HDLC is not conclusive, the SAB recommended that the EPA evaluate how the inclusion of HDLC effects would influence results. Thus, the EPA evaluated how benefits results are affected by the inclusion of HDLC effects in a sensitivity analysis presented in appendix K of the EA for the proposed (USEPA, 2023f) and final rule (USEPA, 2024e). Additionally, the same commenter and one other commenter challenged the EPA's quantification of PFOS and blood pressure, stating that the EPA's finding that PFOS might have ''the potential'' to affect blood pressure does not meet the SDWA standard for inclusion in a benefits analysis and that the ''rationale for including changes in BP in relation to PFOS is not clear.'' Another comment identified a study that utilized NHANES data and ''did not observe an association'' between PFOA and blood pressure. Finally, another commenter mentioned that ''neither the ATSDR nor the National Academy of Sciences (NAS) have found an association between PFOA/PFAS and increased blood pressure.'' While the EPA is aware of this previous work, in the EPA's own, more recent assessment, the strength of the evidence is determined both by the number but also the quality of studies investigating the relationship. One high confidence study conducted using U.S. general population data from NHANES showed a relationship between PFOS exposure and systolic blood pressure in humans (Liao et al., 2020). In addition, several *medium* and *low* confidence studies provided evidence for an association between PFOS and blood pressure and/or hypertension (Mitro et al., 2020; Bao et al., 2017; Mi et al., 2020; Liu et al., 2018). Because blood pressure is an important component of the Atherosclerotic Cardiovascular Disease (ASCVD) model used to estimate hard CVD event risk, and because epidemiology reports show consistent evidence of an association between PFOS and blood pressure in general adult populations (*i.e.,* the populations evaluated using the ASCVD model), the EPA included the relationship between PFOS exposure and blood pressure in the analysis. The EPA further notes that the Science Advisory Board recommended modeling the impacts of changes in all ASCVD model predictors (including blood pressure and HDLC) for which there is evidence of a likely causal relationship (USEPA, 2022i).

A few commenters questioned the evidence or stated that the evidence supporting an association between exposure to PFOA and PFOS and CVD is insufficient. The EPA disagrees with these comments. The agency's approach to estimating reductions in CVD risk was reviewed and supported by SAB panelists (USEPA, 2022i). Numerous studies have shown consistent associations between PFOA/PFOS exposure and changes in TC and blood pressure which are biomarkers for CVD risk. TC and blood pressure are well-established CVD risk biomarkers, are clearly associated with CVD events, and are important inputs to the ASCVD model that the EPA used to estimate CVD outcomes.

The EPA received public comments on the benefits analysis for developmental effects. A few commenters claimed that the studies used for developmental modeling did not provide sufficient evidence of an association between PFOA and PFOS exposure and stated that the studies which the EPA used to model the developmental effects relationship did not consider confounders including pregnancy hemodynamics and other chemical and non-chemical stressors, including other PFAS. One commenter stated that the EPA's findings are inconsistent with other regulatory agency findings that small decreases in birth weight are associated with maternal exposure to PFOA and PFOS but not increased risk of low birth weight. Other commenters stated that the EPA did not address these concerns and inappropriately used these studies to support quantitative analysis, and one commenter stated that because of the shortcomings of the studies used and the modeling uncertainties, peer review of the developmental effects modeling should be completed. Although there are some uncertainties in the developmental epidemiological effects data (*e.g.,* differences seen across biomarker sample timing), the EPA disagrees with these comments: the developmental benefits analysis is supported by a wide body of peer reviewed science (Verner et al., 2015; Negri et al., 2017; ATSDR, 2021; Waterfield et al., 2020; USEPA, 2016c; USEPA, 2016d; USEPA, 2024c; USEPA, 2024d). Specifically, birth weight was determined to be a critical effect based on findings in the EPA's health assessments (see USEPA, 2024c; USEPA, 2024d), and low birth weight 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.

Discussion regarding the selection of decreased birth weight as a critical effect, including the selection of specific studies for candidate RfD derivation and the evidence supporting associations between PFOA or PFOS and

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[14] Hard CVD events include fatal and non-fatal myocardial infarction (*i.e.,* heart attack), fatal and non-fatal stroke, and other coronary heart disease mortality.

developmental effects, is available in sections 3.4.4 and 4.1 of the final toxicity assessments for PFOA and PFOS (USEPA, 2024c; USEPA, 2024d). In estimating benefits of reducing PFOA and PFOS in drinking water, 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. The agency chose the results from these studies because they include the most recent meta-analyses on PFOA- and PFOS-birth weight relationships, and they included a large number of studies, including multiple studies with first trimester samples (seven studies in Steenland et al., 2018 and eight studies in Dzierlenga et al., 2020). To provide insights into the potential effects of sample timing and pregnancy hemodynamics, the EPA also performed a sensitivity analysis considering only first trimester estimates from Steenland et al (2018) for PFOA and Dzierlenga et al. (2020) for PFOS in section K.4 of the EA appendices (USEPA, 2024e). While reports prior to 2019 found ''plausible'' or ''suggestive'' (USEPA, 2016d; ATSDR, 2018) evidence of relationships between PFOA and PFOS and developmental outcomes, the EPA's assessment found clear evidence of an association for PFOA and PFOS in both toxicological and epidemiological studies (USEPA, 2024h; USEPA, 2024i). The agency further disagrees with the commenter's statement that further peer review is needed, as the EPA relies extensively on peer-reviewed studies in its developmental benefits model. Furthermore, the EPA characterizes the uncertainty in the PFOA and PFOS exposure-response functions as described in appendix L of the EA (USEPA, 2024e). In short, the benefits analysis for developmental effects relies on a wide body of the best available, peer-reviewed science, and the epidemiological evidence provides a reliable basis for quantifying the risks of low birth weight.

A different commenter claimed that the EPA relied on equivocal epidemiological evidence to estimate developmental benefits, stating that the RfDs calculated from animal studies in the EPA's health assessment documents for PFOA and PFOS are significantly higher than those based on human studies used for benefits analysis and that the animal studies represent a more appropriate estimate of the risk of PFOA and PFOS exposure. The EPA disagrees with the commenter that the analysis relies on equivocal epidemiological evidence to estimate benefits. The systematic literature review and assessment conducted by the EPA, the most comprehensive evaluation of the current literature to date, concluded that there is moderate evidence for developmental effects based on consistent adverse effects for fetal growth restriction including birthweight measures which are the most accurate endpoint (USEPA, 2024c; USEPA, 2024d). One commenter raised concerns about the EPA's reliance on the study (Steenland et al., 2018) that the EPA uses to model PFOA dose response for benefits analysis, stating that the EPA's benefits analysis for PFOA and developmental effects is not supported by the underlying publication. The same commenter questioned the EPA's reliance on the study that is used to model PFOS dose response for benefits analysis (Dzierlenga et al., 2020), stating that the study found that there was no evidence of a relationship at the beginning of pregnancy. The commenter contended that the meta-analysis was not peer reviewed and thus the validity of the EPA's methods should be questioned. The EPA disagrees with the commenter's criticism of the studies used to assess dose response in developmental benefits analysis. The selected meta-analyses on the relationship between PFOA/PFOS exposure and birth weight produced statistically significant results, are based on recent data, and include a large number of studies in each meta-analysis.

One commenter stated that given the discussion about changes over time in infant mortality, a dataset containing only two years of data is insufficient to build infant mortality regression models. The EPA disagrees that two years of data is insufficient to build regression models relating infant birth weight to infant mortality. The EPA's regression analysis improves upon earlier analyses relating birth weight to infant mortality (Almond et al., 2005; Ma and Finch, 2010) by evaluating two years of recent data. Sample sizes among the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics (NCHS) linked birth/infant death data per year are large (n = approximately 3.8 million infants) and contribute to the overall statistical significance of regression results. As described in appendix E of the EA (section E.2, USEPA, 2024e), there has been a notable decline in U.S. infant mortality rates since the analyses reported in Ma and Finch (2010) and Almond et al. (2005). Using recent data from two CDC NCHS linked birth/infant death data cohorts results is a more accurate and conservative characterization of recent infant mortality trends than if the EPA had included older CDC NCHS data.

The EPA received comments on the benefits analysis for RCC. Two commenters expressed concerns with the EPA's use of Shearer et al. (2021) to estimate RCC risk in benefits analysis and claimed flaws in the study related to outliers in the RCC group and inconsistent evidence of an association across epidemiological studies. One commenter stated that given what they perceive as SAB concerns and uncertainties in the modeling, further peer review is warranted. The EPA disagrees with the comments critical of the agency's use of information from the Shearer et al (2021) study for purposes of PFOA health assessment and benefits analysis. As noted in section 3.5.1 of the Final Toxicity Assessment for PFOA (USEPA, 2024c), the EPA determined that Shearer et al. (2021) is a *medium* confidence study after conducting study quality evaluation consistent with the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f). The biomonitoring measures of PFOA levels in Shearer et al. (2021) were reliable measures of PFOA exposure due to the chemical's well-established long half-life. The commenters failed to acknowledge multiple studies further supporting a positive association between PFOA exposure and RCC risk (Bartell and Vieira, 2021; Vieira et al., 2013; Steenland et al., 2022). Critically, the SAB PFAS Review Panel supported the *Likely to be Carcinogenic to Humans* designation for PFOA in its final report (USEPA, 2022i). Shearer et al (2021) has been sufficiently peer reviewed and it represents the best available science for purposes of health and benefits assessment in the PFAS NPDWR.

The EPA received comments on uncertainties associated with bladder cancer reductions. One commenter incorrectly stated that the ''EPA does not recognize the uncertainty that there is not always direct correlation between THM4 levels and TOC in all public water systems''. In response, the EPA notes that the THM concentrations in this co-removal analysis were not calculated based on TOC reduction. TOC was used to bin systems in the universe of PWSs using the fourth Six-Year Review (SYR4) database and PFAS occurrence model with the THM4 reduction calculated from the formation potential experiments before and after GAC treatment in the DBP Information Collection Rule Treatment Study Database. This dataset reflects the current best available data to determine THM4 reduction based on TOC removal using GAC treatment. Another commenter stated that the causal link of DBPs and bladder cancer has not been established. The EPA notes that an extensive body of 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. While research has not established a causal link between THM4 and bladder cancer, there is strong evidence that there is a correlation between THM4 and bladder cancer.

One commenter stated that the DBP co-removal benefit analysis did not meet the standards required by SDWA for estimating benefits since it was not reviewed by the SAB. The commenter is incorrect. SDWA 1412(e) directs the EPA to request comments from the SAB prior to proposing an MCLG and NPDWR. The EPA sought and received comment from the SAB prior to proposing this NPDWR (see USEPA, 2022i). The statute does not dictate the precise level of scientific questions for which the EPA must seek comments from the SAB. The EPA sought SAB comment on the four most significant areas that informed derivation of the MCLGs for all six PFAS regulated by this action and for other parts of the benefits analysis that informed the overall development of the NPDWR. The EPA did seek additional peer review of its DBP co-removal benefit analysis prior to its inclusion in the EA for which it received overwhelmingly favorable comments from reviewers (see USEPA, 2023m). Furthermore, this rule is based on the EPA's consideration of a wide body of existing peer-reviewed science on this subject (*e.g.,* Regli et al., 2015; Weisman et al., 2022). In short, the EPA has used peer reviewed science and sought further peer review to support its DBP co-removal analysis, and as part of the supporting material for the rule proposal, the EPA included the comments from the expert peer reviewers as well as how each comment was addressed or the rationale for why it was not changed. Please see *Response to Letter of Peer Review for DBP Co-benefits* (USEPA, 2023m) for discussion of that peer review and the EPA's responses to peer reviewed comments.

Another commenter claimed that the EPA improperly quantified benefits of co-removed substances rather than co-occurring substances. The EPA disagrees with these assertions since the analysis of DBP co-removal is focused on co-occurring contaminants. As demonstrated elsewhere in the record for this action, PFAS commonly co-occur with each other. Additionally, in waters where disinfection is required, TOC (*i.e.,* a DBP precursor) and PFAS may co-occur. The DBP co-removal benefits analysis relied on DBP formation potential experiments that highlighted the changes to TOC with and without GAC treatment. Furthermore, as discussed above, the methodology to estimate THM4 reductions was externally peer reviewed by three experts in GAC treatment for PFAS removal and DBP formation potential.

A few commenters stated that the EPA already had initiatives to reduce THMs in drinking water and suggested that reduction of bladder cancer cases is better addressed through existing DBP rules. While the EPA agrees that there are existing DBP regulations to reduce DBP exposure and risks, this rule will provide additional health risk reduction benefits associated with enhanced DBP reduction. The EPA has considered those co-removal benefits as part of the EA. The EPA notes that it is required under the SDWA 1412(b)(3)(C)(i)(II) to assess 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. DBP reductions presented in the EPA's HRRCA are those that are anticipated to result solely from compliance with the PFAS MCLs. As required under the SDWA, any quantifiable and nonquantifiable benefits from future actions concerning DBPs in drinking water will be addressed at the time of those actions and are independent from benefits stemming as a result of the PFAS rulemaking. A couple of commenters supported the EPA's analysis of DBP benefits but recommended that the EPA also consider other co-removed contaminants. The EPA agrees with the commenters that multiple co-occurring contaminants will be removed as a result of this rule. Furthermore, the EPA acknowledges in the EA that additional co-removal benefits would be realized due to treatment for PFAS. With the exception of DBPs co-removed, the EPA has not quantified other co-removal benefits at this time because of data limitations, the agency included discussion of nonquantifiable benefits for multiple other PFAS and for other contaminants.

Nonquantifiable Benefits of PFAS Exposure Reduction

One commenter expressed that the EPA's characterization of benefits is inadequate and not supported by science. The commenter specifically discussed hepatic effects, endocrine effects, and musculoskeletal effects and asserted that the EPA's characterization is based on mixed findings and inconsistent evidence regarding PFAS exposures and specific health outcomes. The EPA disagrees with this comment, as the EPA has evaluated the best available peer reviewed science, as required under SDWA. The EPA did not quantify or monetize benefits where there are inadequate data. For hepatic effects, the EPA's toxicity assessments determined that there is moderate evidence supporting the association between exposure to PFOA/PFOS and hepatic toxicity in humans. However, the EPA did not quantify benefits for hepatic effects because although there will be benefits delivered by reducing PFOA and PFOS in drinking water, there is a lack of adequate data available to accurately quantify those benefits. Further information on health effects related to PFAS exposures is provided in the health assessments within the MCLG documents (USEPA, 2024c; USEPA, 2024d).

Conversely, some commenters expressed support for the quantification that the EPA has already performed, stated that the benefits of the rule are underestimated, and urged the EPA to quantify and monetize additional health endpoints, particularly mammary gland and lactational effects, immunotoxicity, and liver disease. These commenters also provided additional resources and information with the intention of the EPA using that information to update analyses regarding lactational effects, expand analyses to include immune effects, and adjust analyses to characterize hepatotoxicity as a quantifiable benefit, as opposed to a non-quantifiable one. Commenters also urged the EPA to quantify some of the benefit categories, even if monetization is not possible, and to highlight the magnitude of some of the qualitatively discussed benefits. The EPA agrees with these commenters that the quantified benefits of the rule are underestimated. Where appropriate, the EPA used medical cost information provided by the commenters to supplement qualitative discussion of adverse effects. Additionally, and based on these comments, the EPA considered information in the record and added additional quantified benefits analysis in the sensitivity analysis evaluating the reductions in liver cancer cases expected by reducing concentrations of PFAS. This additional analysis was confirmatory of the EPA's previous analysis and did not result in changes to the NPDWR's requirements.

Some commenters also provided recommendations regarding the inclusion of additional costs and benefits beyond health endpoints. These included the opportunity cost of time, environmental benefits, and psychosocial benefits that are expected to result from the rule. The opportunity cost of time was suggested to be incorporated into morbidity estimates, while the other benefits were suggested to be encapsulated in a qualitative summary.

In the EA document, the EPA describes that the cost of illness (COI)-based approach does not account for the pain and suffering associated with non-fatal CVD events. Based on the above comments, for quantified cancer endpoints (*i.e.,* RCC and bladder cancers), the EPA has included a new sensitivity analysis using willingness to pay values for risk reductions which can inform the direction of benefits when opportunity cost is included. This additional analysis was confirmatory of the EPA's previous analysis and did not result in changes to the NPDWR's requirements.

c. Final Rule Analysis

For the final rule, the EPA retained the quantitative benefits analyses from the proposal for developmental, CVD, and cancer endpoints as well as the bladder cancer benefits from DBP exposure reduction as a result of the rule. In response to comments described above, the agency identified new information on willingness to pay values for non-fatal cancer risk reductions and added additional sensitivity analyses for RCC and bladder cancer in appendix K to the final rule EA (USEPA, 2024e). In light of new epidemiological studies on PFOS exposure and liver cancer that strengthened the weight of evidence and supported the toxicological information that was identified in the proposed rule, and comments received requesting that the EPA monetize additional health endpoints, the EPA developed a sensitivity analysis assessing the liver cancer impacts in appendix O of the final rule EA (USEPA, 2024e). The EPA estimates that PFOS liver cancer benefits would add $4.79 million annually to the national benefits estimates. The EPA retained discussion of nonquantifiable benefits associated with PFAS exposure reduction from the proposed rule for the final rule EA.

2. Treatment Costs

a. Treatment Cost Estimates in the Proposal

The EPA estimated costs associated with engineering, installing, operating, and maintaining PFAS removal treatment technologies, including treatment media replacement, and spent media destruction or disposal, as well as nontreatment actions that some PWSs may take in lieu of treatment, such as constructing new wells in an uncontaminated aquifer or interconnecting with and purchasing water from a neighboring PWS. To evaluate the treatment costs to comply with the proposed PFAS NPDWR, the EPA used the agency's Work Breakdown Structure (WBS) models, a spreadsheet-based engineering models for individual treatment technologies, linked to a central database of component unit costs. The WBS models are extensively peer-reviewed engineering models for individual treatment technologies and discussed in section XII.D of this preamble. The EPA used PFAS occurrence outputs from a Bayesian hierarchical estimation model of national PFAS occurrence in drinking water (Cadwallader et al., 2022), to estimate the number of water systems exceeding the proposed MCLs, and therefore triggered into action to comply with the proposed MCLs.

b. Summary of Major Public Comments on Treatment Costs and EPA Responses

Many commenters state that the EPA has underestimated the treatment costs required to comply with the proposed MCLs. One commenter suggested that the EPA has not complied ‘‘with its statutory requirements by conducting an analysis that fully captures these costs.’’ The EPA disagrees with the few commenters that suggested the EPA has not met its requirements under SDWA, and the EPA emphasizes the agency has used the best available peer reviewed science to inform it cost estimates, including treatment costs, of the MCLs. Specific aspects of comments related to treatment costs and the EPA's response are discussed further in this section.

Many commenters cited rising costs in the drinking water sector and discussed the effects of inflation and the COVID–19 pandemic on the costs of labor, construction, and capital, among other materials related to compliance with the MCLs. These commenters emphasized the significant impacts felt from supply chain and workforce issues. The EPA recognizes these impacts, and as recommended by commenters, adjusted the cost estimates by escalating unit costs using indices including the Bureau of Labor Statistics producer price indices (USBLS, 2010). The EPA updated each unit cost using the change in the relevant price index from year 2020 to 2022. For example, the EPA applied the percent increase of the price of metal tanks and vessels (50 percent increase from 2020 to 2022) to the price of metal tanks and vessels in the WBS cost models. The EPA also collected new vendor price quotes for cost driver equipment components (*e.g.,* pressure vessels, treatment media) and made several other adjustments to WBS model assumptions, described further in this section. Taken together, these adjustments increased the system level capital cost estimates in the EPA's cost assessment by a percentage that varied depending on the system size and treatment technology. For small systems using GAC and IX, the increase ranged from approximately 40 percent to 110 percent. For medium systems, the increase was approximately 20 to 60 percent; for large systems, 10 to 40 percent. Additionally, while revising the SafeWater model to incorporate new information from public comments, the EPA identified and corrected a coding error related to the discounting of future operation and maintenance costs resulting in increased estimated annualized treatment costs. The result of these changes are increased cost estimates for the final rule.

Some commenters state that while BIL funding is available, it is not enough to cover the compliance costs of the rule. For example, one commenter noted that, ‘‘[t]his amount of funding support, while crucial, will come nowhere near the cost to ratepayers that must be borne to implement necessary compliance actions for these MCLs.’’ The EPA disagrees with the commenter that BIL funding will be nowhere near the cost’’ necessary to implement compliance actions. The EPA estimates that the initial capital costs of the rule in undiscounted dollars is approximately $14.4 billion (see appendix P of the EA for more information). Given the BIL appropriations of $11.7 billion in DWSRF and an additional $5 billion for emerging contaminants, the EPA reasonably anticipates BIL funding is likely to be able support a substantial portion of the initial capital costs of the final rule. BIL funding appropriations began in the Federal Fiscal Year (FFY) 2022 and appropriations are anticipated to continue through FFY 2026.

Many commenters shared some information about the costs that they have incurred or estimated they would incur at a system level to install, operate, and maintain treatment to remove PFAS. Some system level cost information provided by commenters fell within the ranges of costs presented in the EPA's supporting documentation for the proposal and other information provided by commenters exceeded the EPA's system level cost ranges. The EPA does not dispute the commenters stated experience of costs to install, operate and maintain treatment to remove PFAS; however, many of these comments lacked supporting details. Many of the comments cited preliminary or conceptual estimates and did not specify the methods and assumptions used to develop the estimate. Furthermore, most comments did not include information to confirm that all of the reported or estimated costs were or would be directly associated with PFAS treatment, as opposed to other infrastructure improvements (*e.g.,* capacity expansion, administrative facilities, distribution system improvements) that happened to be completed as part of the same project. Most commenters also did not include information to confirm that key design and operating parameters (*e.g.,* empty bed contact time, media replacement frequency) would be similar to the typical values assumed in the EPA's estimates. To fully evaluate the commenters' reported or estimated costs in comparison to WBS model results, the EPA would need itemized line-item cost details and engineering design parameters. To inform the cost estimates of the proposed and final PFAS NPDWR, the EPA conducted an extensive review of the literature. The EPA has further validated the unit costs in the PFAS rule with equipment cost information from 2023 from a major supplier of treatment media. While the EPA recognizes there are likely site-specific instances where costs exceed the EPA's cost ranges, there are also likely site-specific instances where costs are less than the EPA's cost ranges, and this level of accuracy is appropriate for a national level analysis.

Other commenters compared state-level costs to the EPA's national level cost estimates, noting that the EPA's estimates appeared too low. Utilizing this permit data and project cost data submitted by water systems in applications to the DWSRF, one state estimated that total capital costs for installation of PFAS treatment to meet the EPA's proposed standards across the state could be as high as $1.065 billion. The EPA's EA analysis, however, presents national level cost estimates that are annualized over the period of analysis and are therefore not directly comparable to a single year estimate of capital costs.

A few commenters stated that the EPA incorrectly omitted the costs associated with performance monitoring, which commenters believe will be necessary because a water system needs to know how often it needs to replace its media. The EPA disagrees that large amounts of additional samples in performance monitoring will be required, and the commenter provided no data to support their assertion that this would be necessary. The EPA anticipates that many water systems will conduct a pilot test before implementing a full-scale treatment installation and that the operational results from the pilot test will be a sufficient indicator of performance; therefore, water systems should not have to collect large amounts of performance samples indefinitely during the full-scale operation of treatment technologies. The EPA includes the costs of pilot testing, and sampling during that time, in the treatment capital cost estimates. In response to public comments, the EPA increased the estimated length of the pilot study and the frequency of sampling during the pilot study. Additionally, the EPA added a full year of confirmation sampling after full-scale installation to the estimated pilot study costs. Taken together, these changes doubled to more than tripled the pilot study costs included in the EPA's estimates.

In response to public comments about residual management concerns for high pressure membrane technologies, the EPA has adjusted RO/NF's technology projection compliance forecast to zero percent in the EA for the final rule. Therefore, the EPA assumes that RO/NF will not generally be used solely for the purpose of complying with the final rule. For more information on public comments on residuals management and the EPA's response please see section X.

A few commenters stated that the EPA underestimated or insufficiently incorporated contingency in its cost estimates. For example, one commenter stated that the EPA's contingency assumptions in the proposal were ''. . . inconsistent with recommended best practices for cost estimators and [are] expected to be a major contributor to the EPA WBS' failure to accurately capture costs for PFAS treatment facility implementation.'' In response to these comments, the EPA changed its approach and incorporated contingency for all systems, not just high-cost systems. The EPA also increased the complexity factor applied to estimate contingency for systems using GAC. Taken together, these changes result in a contingency factor of 5 to 10 percent depending on total project cost at all cost levels for systems installing treatment. Additionally, the EPA includes a miscellaneous allowance of 10 percent. This allowance can be viewed as either as a form of contingency or a method to increase the level of project definition (thus reducing the amount of contingency required).

One commenter stated that the EPA underestimated the costs associated with interconnection.[15] This commenter stated that it was ''unrealistic to assume that booster pumps are unlikely to be necessary. Pressure loss associated with friction could be significant, especially for an interconnection that may span 10,000 feet or more,'' and recommended that the EPA include booster pumps in the cost estimate. Commenters also pointed out that ''. . . systems considering interconnections will need to thoroughly investigate this option and determine if it is both cost effective and appropriate given the water quality impacts.'' In response to these comments, the EPA made several changes to the assumptions used to estimate costs for interconnection in the WBS model for nontreatment options. The EPA agrees that booster pumps may be needed and added the costs of booster pumps designed to account for friction loss in interconnecting piping. The EPA also agreed that there are many considerations for water systems pursuing interconnections including elevated water age, nitrification, and DBPs, as pointed out by commenters, and therefore the EPA increased the complexity factor applied to estimate contingency for systems using nontreatment options. Taken together with the escalation to 2022 dollars, these changes increased the system level capital costs for interconnection by approximately 60 to 100 percent.

Many commenters cited and expressed agreement with the conclusions of a study conducted by Black & Veatch on behalf of the American Water Works Association (AWWA) (hereafter referred to as AWWA's B&V report) (AWWA, 2023). The EPA disagrees with many of the assumptions in AWWA's B&V report and the report's overall conclusions

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[15] Interconnection is when a system replaces their contaminated water source by purchasing water from another nearby system that is in compliance. Booster pumps can be needed when the pressure from the supplying system is lower than required at the purchasing system and also to overcome pressure losses due to friction in interconnecting piping.

about the estimated national costs of the PFAS NPDWR. Tables 24–26 detail some of the key assumptions related to (1) PWSs that exceed the MCL, (2) capital costs and (3) operation and maintenance costs that overestimate national treatment costs in AWWA's B&V report and the EPA's response to those assumptions and resulting estimates. In combination, all these factors result in an overestimate of treatment costs. For example, AWWA's B&V report Table 6–1 reports an average capital cost per EP for the smallest size category of $900,000. Using AWWA's B&V report's (overestimated) design flow calculations, the treatment system design flow at each EP would be approximately 0.062 million gallons per day (mgd). For comparison, Forrester (2019) reports capital equipment costs of approximately $300,000 for a 1 mgd GAC PFAS treatment system. Even after adding indirect capital and building costs, the $900,000 estimate appears substantially overestimated, given that it is for a treatment system designed for approximately 1/16th of the flow of the system in the Calgon Carbon estimate (Forrester, 2019). When AWWA's B&V report's EP level results are aggregated nationally to an overestimated number of systems treating for PFAS, the overestimates are compounded at the national level.

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Table 24. EPA Response to assumptions about PWSs exceeding the MCLs in AWWA's B&V Report

Analytical Component	**AWWA's B&V report**	**EPA response**
PFAS occurrence estimates	Used an occurrence dataset comprised of UCMR 3 and information from state regulatory agencies. Estimates the following number of water systems will exceed 4.0 ng/L PFOA and/or PFOS: Serving 10,000 or less: 7,056 PWS (8,808 EP) Serving more than 10,000: 393 PWS (1,214 EP) Total PWSs: 7,449 PWSs (10,022 EP)	The dataset used is not appropriate for national extrapolation, for example, 90 percent of non-UCMR systems used in the report come from just 6 states. As a result, AWWA's B&V report likely overestimates the number of water systems exceeding the MCLs, particularly small water systems. After incorporating updated state monitoring data into its occurrence model, the EPA estimates the following number of water systems will exceed 4.0 ng/L of PFOA and/or PFOS (**mean** (5th – 95th) from chapter 4.4 of the EA): Serving 10,000 or less: **3,870** (2,795-5,097) PWS **5,115** (3,666-6,858) EP Serving more than 10,000: **1,266** (1,203-1,328) PWS **3,878** (3,701-4,056) EP Total PWSs: **5,136** (4,018-6,441) PWSs **8,993** (7,497-10,711) EP AWWA's B&V report did not specify what measures, if any, were taken to ensure the data was nationally representative and this may be one cause of their overestimation of water systems exceeding the MCLs. The EPA used QC measures to ensure that the data represented finished drinking water and that the set of systems used to inform the model was nationally representative. Additional state data that were available at systems that were part of this nationally representative set of systems were used to fit the model. For more information see section VI of this preamble.

Number of EP installing treatment	Assumes every EP a system will require treatment regardless of whether a given EP exceeds the MCL.	This is an incorrect assumption and likely leads to a significant overestimate of national costs. A single water system often has EP that use different water sources, and therefore have different PFAS concentrations. The EPA conducted an EP-level cost analysis as compliance with the rule is determined at the EP-level and treatment is installed at the EP-level.
PWSs in states with existing PFAS regulations	Includes estimates of the costs to PWSs to comply with existing state PFAS regulations; and does not assume that PWSs are already in compliance with state standards.	This approach overestimates costs for water systems in states with existing state standards. The EPA adjusts the baseline by setting the maximum pre-regulation concentrations equal to the state MCL for systems in states with promulgated regulations. This allows the EPA to capture the incremental costs of the NPDWR MCLs more accurately.
Nontreatment options	Assumes all exceeding EP will install a treatment technology to comply with the MCLs.	This assumption overestimates costs, as the EPA is aware of a number of water systems that have elected to drill a new well to reduce PFAS concentrations in supplied water. Another commenter pointed out that Michigan expects up to 26 percent of water systems to interconnect with other systems to comply with their state standard. Other commenters pointed out the viability of interconnection and new wells as compliance options will vary regionally, and the EPA agrees. Nevertheless, the absence of these options entirely in AWWA's B&V report overestimates national costs.

Table 25. EPA Response to key capital cost assumptions in AWWA B&V Report

Analytical Component	AWWA B&V report	EPA response
Equipment lifespan	Assumes a fixed life cycle cost using a fixed 20-year lifespan for all capital equipment.	A 20-year lifespan may be reasonable for very small systems but based on the composite useful life of treatment systems derived from the useful lives of individual treatment system components and industry information, the EPA estimates that treatment system useful life can be 30 years or more for medium to larger systems using more durable materials of construction.
Contingency factors	Includes a contingency factor of 4 percent under contractor markup and an additional contingency factor of 30 percent under non-construction costs.	The inclusion of contingency twice is unusual and may not reflect actual realized contingency costs at project completion. A Construction Industry Institute (2001) study found that projects of $100 million or less incurred only 74 percent or less of the contingency initially budgeted. The EPA updated its approach to incorporate a contingency factor of 5 to 10 percent depending on total project cost at all cost levels for systems installing treatment. The EPA also included a miscellaneous allowance of 10 percent, which can be considered a form of contingency.
Building costs	Assumes a fixed unit cost of $200/square foot for buildings.	AWWA's fixed unit cost likely overestimates actual building costs, particularly for small systems that may not require complex or architecturally detailed buildings. The EPA estimates that building costs vary depending on building quality and square footage and range from $57/square foot to $204/square foot.
Pumping and backwash assumptions	Assumes that all GAC and IX treatment systems require a new influent pumping station, and all GAC and IX treatment systems require new backwash pumps. Except for the two smallest size categories, assumes all GAC and IX treatment systems require backwash recovery basins providing 20 feet of water depth.	AWWA's assumptions overestimate costs as many systems, including small groundwater systems, likely have sufficient existing influent pumping pressure to cover the additional head loss. Some systems using GAC (especially small systems) may not need a dedicated new backwash pump and may be able to accomplish backwash using existing influent or treated water pumps. In applications using PFAS-selective IX resins, periodic backwashing is not recommended (Berretta et al., 2021), so the need for these pumps is questionable and the assumption overestimates costs.

Capital equipment costs	The Association of Metropolitan Water Agencies (AMWA) and the AWWA surveyed its members to obtain recent cost data on installed PFAS treatment systems at drinking water treatment plants.	The EPA updated its equipment costs to 2022 dollars using current price indices. The EPA also collected new vendor price quotes for cost driver equipment components (e.g., pressure vessels, treatment media) and made several other adjustments to WBS model assumptions about pilot study costs and contingency costs that increased total capital costs. The B&V model, as presented in Figure 7-1 of AWWA's public comment letter, appears to overestimate costs for many of the case studies included in the B&V report. For example, it results in higher costs for 28 of the 32 case studies (88 percent) shown in Figure 7-1. The EPA assessed the WBS model results in comparison to the costs of GAC equipment packages from 2023 supplied by a nationally recognized vendor of GAC media and GAC treatment systems. Based on this assessment, the EPA concluded that the direct capital costs in the WBS model for comparable packages of equipment, excluding items the vendor does not supply, range from 23 percent lower to 19 percent higher than the vendor costs and with two exceptions, they are within 10 percent of the vendor costs.
Small system capital costs	Listed capital costs for small systems ranging from $900,000 to $5,300,000.	The EPA accounts for the use of package systems. AWWA appendix B, Table 3-1, indicates that their pressure GAC model accepts treatment capacity inputs from 1 to 12 mgd. It does not indicate how the model handles design flows less than 1 mgd. It is possible that the parametric estimates the model uses are not a good fit below this threshold and does not account for the use of package systems.
Average and design flow estimates	Service population data from SDWIS was used and the average flow for each PWS was assumed based on a per capita per day usage of 150 gallons. Peaking factors for different size systems from the EPA's *Cost and Technology Document for Final Groundwater Rule* were used.	Estimated design flow of a water system effects the size and cost of the capital equipment that will be installed on site. Average flow estimates are the driver for many operational costs. AWWA's approach to estimating design and average flow requirements overestimates the treatment system flow requirements, particularly for smaller systems. For the smallest systems, AWWA's approach overestimates flows by up to 30 percent. The EPA estimated the average daily flow and design flow for drinking water systems based on the empirical relationship between retail population served and flow. This relationship was derived using the data collected via the

		CWSS. It is reported in the EPA's *Geometries and Characteristics of Public Water Systems* report (USEPA, 2000g). As detailed in Table 4-34 of the EA for the final rule, water use efficiency has increased substantially since these relationships were developed, and therefore the trend of lower residential water use could result in lower flow per population and lower treatment costs as compared to predicted values in the EPA's analysis.

Table 26. EPA Response to key operation and maintenance cost assumptions in AWWA B&V Report

Analytical Component	AWWA B&V report	EPA response
Bed life	The BV values utilized for GAC were derived from data collected during a Black & Veatch GAC pilot study for Cape Fear Public Utility Authority (CFPUA). The values utilized for IX were derived partially from data collected during a Black & Veatch IX pilot study for CFPUA and partially from data collected during an IX pilot study for La Habra Height County Water District.	AWWA estimates bed life for all systems using parameters derived from one or two pilot studies. These site-specific pilot studies may not be representative of the range of water quality conditions experienced by systems across the country. For GAC in particular, using the parameters in AWWA's Table 5-9 results in estimated bed lives of less than 7,000 and 9,000 BVs for 90 percent removal of PFOA and PFOS, respectively. These short bed life estimates result in high annual operating costs and may be an artifact of the relatively high influent TOC in the CFPUA pilot study that is the basis of AWWA's estimates. Surface and groundwater systems with more moderate to low influent TOC would be expected to experience much longer GAC bed life and lower operating costs.
Disposal of treatment media	Assumed that spent GAC media would be incinerated "because of the unknown viability of GAC media reactivation under CERCLA." Replacement costs were therefore assumed to be virgin media.	The EPA has proposed PFOA and PFOS be designated as hazardous substances under CERCLA. If finalized, the designation of PFOA and PFOS as CERCLA hazardous substances would not require waste (e.g., biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any specific particular type of landfill. The designation also would not restrict, change, or recommend any specific activity or type of waste at landfills. This action should not result in limiting disposal options and how PFAS containing waste, including spent GAC or resin, is required to be managed. However, drinking water treatment operations may choose to send spent GAC and resin containing PFAS to facilities permitted to treat and/or dispose of hazardous wastes. Even where reactivation is not feasible, disposal in a RCRA permitted hazardous waste disposal facility is expected to be a more cost-effective option than incineration. Therefore, the assumption of incineration and replacement with virgin media overestimates the disposal costs in the B&V report.

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c. Treatment Costs in the Final Rule Analysis

The cost estimates in the EA for the final PFAS NPDWR reflects the adjustments made to the WBS curves and decision tree based on public comments discussed above as well as the additional occurrence information available since the publication of the proposed PFAS NPDWR. For detailed information on the EPA's occurrence analysis, see section VI of this preamble. For detailed information on the EPA's cost analysis and the EPA's estimates of the national annualized costs of the final MCLs, see section XII.D.

3. Primacy Agency Costs

a. Primacy Agency Cost Estimates in the Proposal

In the EA for the proposed rule, the EPA estimated the costs incurred by primacy agencies associated with the rule, including up front implementation costs as well as costs associated with system actions related to sampling and treatment.

b. Summary of Major Public Comments on Primacy Agency Costs and EPA Responses

Many commenters state that the EPA has underestimated the costs to primacy agencies required to comply with the rule. One commenter stated, ''EPA's analysis of primacy agency costs does not accurately capture all the activities that primacy agencies will undergo for PFAS implementation and underestimates the number of hours for the primacy tasks.'' Commenters recommend that the EPA use findings from ASDWA's PFAS Cost of State Transactions Study (PCoSTS) to reevaluate the primacy agency costs estimated in the EA. The EPA's response to specific recommendations is discussed here.

The EPA agrees with commenters on the burdens associated with regulatory start up; primacy package adoption; technical, managerial, and financial (TMF) assistance to water systems; and reviewing and approving treatment. Commenters pointed out activities not explicitly accounted for in the regulatory start up estimate in the EA for proposal including accreditation of laboratories for PFAS testing; SDWIS updates; monitoring schedule updates; time spent responding to questions from members of the public; inquiries from public officials; and media requests immediately following the final publication of the NPDWR. Commenters also pointed out that adopting primacy packages is a significant undertaking with ''specific and very detailed administrative procedures that must be adhered to in order to adopt water quality regulations'' and that ''some primacy agencies have requirements for robust public comment periods as a component of new rule adoption.'' As recommended by commenters, the EPA created a new cost item for primacy package adoption. Commenters stated the EPA's assumption in the proposal that the amount of time a primacy agency will need to review treatment plans directly correlates with the size of the water system was inaccurate. Commenters noted that ''. . . small systems often take the most time as they need significant assistance to navigate the process for the design and construction of new treatment and get into compliance.'' After considering these comments, the EPA agrees that reviewing and approving treatment for small systems is likely to take more time given the assistance needed for these systems. Because small systems often lack the technical, managerial, and financial capacity, it is likely that primacy agencies will spend more time assisting these systems in navigating compliance with the PFAS NPDWR. As such, the EPA adjusted burden estimates in the final rule to reflect the largest primacy agency burden per EP at the smallest systems and decreased burden hours with increasing system size, as commenters suggested.

Several commenters disagreed with the EPA's exclusion of additional costs to primacy agencies associated with reporting regarding violations, variances and exemptions, enforcement actions, and other compliance related primacy agency activities in the national cost analysis. One commenter estimated the PFAS NPDWR will likely result in hundreds of violations once in effect. The EPA recognizes that these activities do have an associated burden for primacy agencies but disagrees that these costs should be included in the EA. The EPA assumed 100 percent compliance for its national level analysis in the EA for the final rule because the EPA has determined that the final rule is feasible given known occurrence concentrations and efficacy of the technologies available. Further, this is consistent with the approach taken in EAs for other NPDWRs (USEPA, 2005c; USEPA, 2019c; USEPA, 2020f). Commenters recommended that the EPA include hours for additional annual reporting. The EPA disagrees and expects that adding PFAS results to already-required reports will have no discernable incremental burden for quarterly or annual reports to SDWIS Fed.

Commenters recommended that the EPA include the costs associated with various compliance activities. Given the EPA's assumption of 100 percent compliance for its national level analysis in the EA discussed above, the EPA disagrees and did not take commenters' recommendations to include the costs associated with assisting out of compliance systems and assisting systems to remain in compliance, pursuing enforcement actions, staff time checking in with system violations and reviewing system variances and exemptions. The EPA did include the costs associated with compliance activities for systems in compliance, including updating inspection SOPs and additional sanitary survey burden at water systems that have installed treatment to comply with the PFAS NPDWR.

c. Primacy Agency Costs in the Final Rule Analysis

After considering public comments on the burden hours associated with primacy agency activities, the EPA made the following changes. The EPA increased the estimate from 416 hours to ''read and understand the rule as well as adopt reg requirements'' to 4,000 hours per primacy agency to conduct a suite of regulatory start up activities. Per commenters' recommendation, the EPA included a new line item for primacy package adoption and estimated 300 hours per primacy agency. The EPA lowered the water system operator TMF training from 2,080 hours to 1,500 hours per primacy agency based on commenter recommendations. The EPA added a one-time burden estimate of 20 hours to inspection SOPs and an additional 2–5 burden hours for the primacy agency, by water system size, per sanitary survey per system installing treatment to comply with the rule. For more information see section XII.D.

4. Costs of the Hazard Index

a. Hazard Index Cost Estimates in the Proposal

In the EA for the proposed rule, the EPA estimated national costs associated with PFOA, PFOS, and PFHxS. Given available occurrence data for the other compounds in the proposed rule (PFNA, HFPO–DA, and PFBS) and the regulatory thresholds under consideration, the EPA did not use SafeWater to model national costs associated with potential Hazard Index (HI) exceedances as a direct result of these contaminants. To assess the potential impact of these compounds in the proposed rule, the EPA conducted an analysis of the additional, or incremental, system level impact that occurrence of these contaminants would have on treatment costs. The EPA estimated that the Hazard Index would increase costs by 0–77 percent at the system level, with costs varying due to PFAS occurrence scenario and treatment technology used.

b. Summary of Major Public Comments on Hazard Index Costs and EPA Responses

A few commenters recommended that the EPA further consider the costs associated with compliance with the Hazard Index (HI) MCL. Specifically, commenters stated that the EPA's analysis of system level costs associated with the Hazard Index does not adequately characterize the overall costs that will be incurred due to the Hazard Index standard. One commenter stated that ''EPA should not move forward with the Hazard Index until it has satisfied its statutory and policy obligation to conduct a cost-benefit analysis.'' Some commenters voiced concern regarding the EPA's assumption that costs associated with compliance with the Hazard Index MCL are insignificant and asserted that these costs must be reexamined, stating that this assessment ''requires more knowledge on the nationwide occurrence of these compounds'' and that the EPA ''cannot assume that addressing the costs of PFOA and PFOS is sufficient when the additional four PFAS will be driving treatment decisions at some PWSs.'' Conversely, one commenter asserted that available occurrence data demonstrate that few systems will be required to install treatment to comply with the Hazard Index MCL that would not already be treating to comply with the PFOA and PFOS MCLs.

The EPA disagrees with commenters who state that the agency did not meet its requirements under SDWA, which requires the agency to analyze ''quantifiable and nonquantifiable costs . . . that are likely to occur solely as a result of compliance with the maximum contaminant level.'' In the proposal, the EPA analyzed the quantifiable costs of the Hazard Index at the system level, using the best available information at the time of publication, and analyzed the nonquantifiable costs of the Hazard Index by including a qualitative discussion of the national level impacts and therefore met the statutory requirements under SDWA 1412(b)(3)(C). After considering recommendations from the public comments to further analyze the costs of the Hazard Index and the data available to support a quantitative analysis of the costs of the Hazard Index, the EPA decided to conduct a sensitivity analysis of the costs of the Hazard Index at the national level. The results of the sensitivity analysis supported the EPA's assumption in the proposal that quantified national costs are marginally underestimated as a result of this lack of sufficient nationally representative occurrence data. The EPA's consideration of Hazard Index costs in the final rule analysis are discussed in the following subsection.

c. Hazard Index and PFHxS, PFNA, and HFPO–DA MCL Costs in the Final Rule Analysis

To estimate quantified costs of the final rule presented in the national-level summary tables, the EPA first estimated baseline PFAS occurrence using a Bayesian hierarchical model fitted with sampling data collected from systems participating in UCMR 3. The model included three of the six PFAS compounds regulated through this NPDWR: PFOA, PFOS, and PFHxS (see section VI of this preamble). This permitted the agency to quantify costs at a national level with a higher degree of confidence and precision for these three PFAS than if simple extrapolations had been used. Since there are some limitations with nationally representative occurrence information for the other compounds that were either not included in UCMR 3 (HFPO–DA) or did not have a sufficient number of observed values above the UCMR 3 reporting limits (PFNA, PFBS), the EPA has a lesser degree of confidence and precision for its quantified estimates of these three PFAS, which are informed by a significant amount of available state-level data. Therefore, the EPA presented the cost estimates for PFNA, HFPO–DA, and PFBS in a sensitivity analysis in the EA (*i.e.,* national-level sensitivity analysis, see appendix N.3) instead of including these costs in the summary tables of quantified national level costs.[16]

In the EA for the proposed PFAS NPDWR, the EPA used a model system approach[17] to illustrate the potential incremental costs for removing PFAS not included in the national economic model (*i.e.,* PFNA, HFPO–DA, and PFBS). After considering public comments on the incremental cost analysis, many of which encouraged the EPA to further evaluate and consider quantified costs of the Hazard Index MCL where feasible, the EPA updated and combined existing analyses contained in the rule proposal to evaluate the incremental costs associated with the Hazard Index MCL and individual MCLs for PFNA and HFPO–DA with a quantified national level sensitivity analysis in the final rule. The updated analysis for the final rule builds on the proposal analysis by combining information that was presented separately at proposal. The analysis in appendix N of the final EA utilizes the system level treatment cost information presented at proposal (See appendix N of USEPA, 2023n, 2023o) with updates to the cost models for the final rule detailed in section XII.A.2. These treatment costs were applied to the number of systems expected to exceed the standards based on PFNA, PFBS, and HFPFO–DA occurrence using the approaches for estimating occurrence of these compounds presented at proposal (see section 10.3 of USEPA, 2023l). This modified analysis was primarily conducted to ensure that the EPA has not, as some commenters claim, substantially underestimated the potential magnitude of these costs. The EPA notes the approach presented in appendix N for the final rule and summarized here, by connecting analyses for proposed rule, allows the agency to consider and compare the relative degree of the potential overall costs of these otherwise nonquantifiable costs of the Hazard Index and PFNA and HFPO–DA MCLs relative to overall national rule costs. This analysis confirms the EPA's findings at proposal that the Hazard Index costs (and those costs for regulating PFNA and HFPO–DA individually) make up a small portion of

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[16] When available, nationally representative occurrence information is preferable for an economic analysis of national level costs and benefits. In the case of PFOA, PFOS, and PFHxS, the EPA has a sufficiently robust nationally representative dataset from UCMR 3. The EPA used additional state data that were available at systems that were part of this UCMR 3 set of systems to fit the national occurrence model that informed cost estimates for PFOA, PFOS, and PFHxS (see Cadwallader et al., 2022). In the case of PFNA, HFPO–DA, and PFBS, the EPA lacks the same level of precision as described above for PFOA, PFOS, and PFHxS. State-led data collection efforts provided valuable information about occurrence for PFNA, HFPO–DA, and PFBS, however they did not provide the nationally representative foundation provided by UCMR3 for PFOA, PFOS, and PFHxS to be incorporated into the MCMC national occurrence model.

[17] At proposal, the EPA used a 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 Hazard Index MCL exceedances not already captured in the national analysis. For further detail on the assumptions and findings of the EPA's analysis of incremental costs of other PFAS at rule proposal, please see appendix N.3 in the Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (USEPA, 2023n, 2023o).

the overall rule costs. Likewise, the EPA notes that while these costs are presented in appendix N because of the lesser degree of confidence and precision in the estimates, the EPA has considered these costs as part of this final regulation. It has done so by evaluating nonquantifiable costs and accounting for uncertainty, characterizing these otherwise nonquantifiable costs in appendix N to generate cost estimates that, while useful, are not as statistically robust as the national cost estimates presented in chapter 5 of the EA. Using this analysis, the agency has confirmed the Hazard Index and PFNA and HFPO–DA MCLs drive a relatively low percentage of the overall rule costs. The EPA has also considered these costs in the context that the Hazard Index and PFHxS, PFNA, and HFPO–DA MCLs are expected to deliver important nonquantifiable health benefits, including PFNA birth weight benefits [18] and other nonquantifiable benefits associated with the reduction of the Hazard Index PFAS (PFNA, PFHxS, HFPO–DA, and PFBS) [19] described in chapter 6.2 of the EA.

The proposed rule included a Hazard Index MCLG and MCL for any mixture of one or more of PFHxS, HFPO–DA, PFNA, and PFBS. The final rule includes a Hazard Index MCLG and MCL for any mixture of two or more of PFHxS, HFPO–DA, PFNA, and PFBS. The final rule also includes individual MCLGs and MCLs for PFHxS, PFNA, and HFPO–DA. The EPA's cost analysis at proposal considered the costs associated with the individual MCLs for PFHxS, PFNA, and HFPO–DA because the proposed Hazard Index MCL would function as individual MCLs when these contaminants occur in isolation. While the rule structure has changed in the final NPDWR, the costing framework used at proposal is still applicable in the final rule: what was considered a Hazard Index MCL exceedance at proposal would be an individual MCL exceedance under the final rule should those contaminants occur in isolation. Further, a Hazard Index exceedance in the final rule (defined as two or more of PFHxS, PFNA, HFPO–DA, and PFBS) is unchanged from a costing perspective to what the EPA proposed. Whether a system exceeds a Hazard Index MCL or individual MCL in the final rule, these costs are captured in the cost estimates the EPA considered and presented in appendix N.3 of the EA and summarized in this section. Specifically, if a system exceeds only one of the individual MCLs for PFHxS, PFNA, or HFPO–DA that exceedance is costed by estimating the removal needed to achieve compliance with a given individual MCL. If a system exceeds the Hazard Index MCL, that exceedance is costed by estimating the removal of the combination of contaminants needed to achieve compliance with the Hazard Index MCL. Therefore, the national level cost estimate for PFHxS is reflective of both the total national cost of the PFHxS individual MCL and instances of Hazard Index MCL exceedances where PFHxS is present above its HBWC while other Hazard Index PFAS are present.

To understand the totality of national-level cost impacts for the Hazard Index MCL, the EPA considered both the contribution of PFHxS (estimated as part of the national level cost analysis), as well as the costs for PFNA, HFPO–DA, and PFBS (estimated in the appendix N sensitivity analysis). Together, these provide information on the costs for the Hazard Index MCL and the individual MCLs for PFHxS, PFNA, and HFPO–DA, as a whole. Due to available data informing the Bayesian hierarchical occurrence model, the EPA was only able to quantify the portion of total costs for the Hazard Index MCL attributable to PFHxS [20] in the national level analysis. The EPA notes that this estimate also represents the national level quantified costs for the individual PFHxS MCL. The EPA acknowledges that this $11.6 million estimate is only a portion of the costs imposed by the Hazard Index MCL and also does not account for the costs imposed by the individual PFNA and HFPO–DA MCLs. The EPA accounted for those potential additional costs through the sensitivity analysis described in appendix N, in which the EPA found that costs of treating for PFNA, HFPO–DA, and PFBS to meet the Hazard Index MCL and individual MCLs for PFNA and HFPO–DA increased national costs by approximately 5 percent, from $1,549 million to $1,631 million. These costs represent the total costs of the final rule; in other words, this includes the costs associated with individual MCLs for PFOA, PFOS, PFHxS, HFPO–DA, and PFNA, as well as the Hazard Index MCL. Due to data limitations, the EPA has not separately estimated the costs of the Hazard Index in the absence of the individual MCLs. The sensitivity analysis demonstrates that the quantified national analysis cost estimate that includes only PFOA, PFOS, and PFHxS (where PFHxS represents only a portion of the Hazard Index costs) marginally underestimates total rule costs when also considering the potential cost impacts attributable to HFPO–DA, PFNA, and PFBS. The cost estimates stemming from both the quantified national estimate for PFOA, PFOS, and PFHxS, and from the sensitivity analysis conducted for PFNA, HFPO–DA, and PFBS together inform the impact of the Hazard Index MCL as required by the HRRCA under SDWA.

To fully weigh the costs and benefits of the action, the agency considered the totality of the monetized values, the potential impacts of the nonquantifiable uncertainties, the nonquantifiable costs and benefits, and public comments received by the agency related to the quantified and qualitative assessment of the costs and benefits. For the final rule, the EPA is reaffirming the Administrator's determination made at proposal that the quantified and nonquantifiable benefits of the rule justify its quantified and nonquantifiable costs.

In light of the individual MCLs, the EPA has separately presented national level marginal costs associated with the individual MCLs for PFHxS, PFNA and HFPO–DA in the absence of the Hazard Index MCL; see chapter 5.1.3 and appendix N.4 of the EA for details. Therefore, the costs for the individual PFHxS, PFNA, and HFPO–DA MCLs have been considered both in the

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[18] As discussed in appendix K.4, a 1 ppt reduction in both PFOA and PFOS for a system serving a population of 100,000 would result in $0.101 million in annualized birth weight benefits. If including a 1 ppt PFNA reduction, in addition to a 1 ppt reduction in both PFOA and PFOS, for a system serving a population of 100,000, the resulting annualized birth weight benefits would increase by $0.464 to $0.689 million, depending on the slope factor used for PFNA. The EPA estimates that 208 water systems may exceed the PFNA MCL.

[19] The EPA also anticipates additional substantial benefits to PWS customers associated with reduced exposure to Hazard Index compounds (PFHxS, HFPO–DA, PFNA, and PFBS) not included in the primary analysis. The nonquantifiable benefits impact categories include developmental, cardiovascular, immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects. See chapter 6.2 of the EA for more information.

[20] The EPA notes that there are anticipated to be circumstances where PFHxS exceeds its individual MCL and HBWC where PFNA, PFBS, and HFPO–DA do not co-occur. While resulting in an exceedance of the PFHxS MCL, if PFHxS exceeds its HBWC without other Hazard Index PFAS present, this would not result in an exceedance of the Hazard Index MCL. At rule proposal, a single exceedance of any of the four Hazard Index PFAS would have resulted in an exceedance of the Hazard Index MCL. However, to improve rule implementation and to support effective risk communication, the EPA has structured the final rule such that a Hazard Index exceedance only occurs when there are two or more of the Hazard Index PFAS present. Therefore, while for purposes of informing its quantified cost analysis the EPA is assuming that every PFHxS exceedance of the MCL also causes an exceedance of the Hazard Index MCL, this approach results in the EPA overestimating PFHxS-attributable Hazard Index costs in its national cost analysis.

proposed and final rule. For more information on the agency's methodology, findings, and limitations of the EPA's updated analysis of costs associated with compliance with the Hazard Index, please see appendix N.3 of the EA (USEPA, 2024e).

5. Benefit-Cost Determination

a. Benefit-Cost Determination in the Proposal

When proposing an NPDWR, the Administrator shall publish a determination as to whether the benefits of the MCL justify, or do not justify, the costs based on the analysis conducted under section 1412(b)(3)(C). For the proposed rule, the Administrator determined that the quantified and nonquantifiable benefits of the proposed PFAS NPDWR justified the costs.

b. Summary of Major Public Comments on Benefit-Cost Determination and EPA Responses

Many commenters agreed with the Administrator's determination that the benefits of the rule justify its costs. Specifically, commenters asserted that the EPA's estimation of the net benefits of enacting the MCLs is reasonable, stating that ''even if the costs are very substantial, the benefits associated with the anticipated drinking water improvements justify such expenditures.'' Commenters also stated that it is likely that ''the analysis understates the benefits'' of the rule, particularly given the ''significant unquantified risk reduction benefits and co-benefits'' that are anticipated to result from the rule.

In response to these comments, the EPA agrees that its quantified benefits likely significantly understate the benefits of the rule due to the large share of nonquantifiable benefits that are expected to be realized as avoided adverse health effects, in addition to the benefits that the EPA has quantified. The EPA anticipates additional benefits associated with developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects beyond those benefits associated with decreased PFOA and PFOS that the EPA has quantified. In response to commenters urging the EPA to quantify additional health endpoints associated with PFAS exposure, the EPA has developed a quantitative sensitivity analysis of PFOS effects and liver cancer, further strengthening the justification for this determination. Due to occurrence, health effects, and/or economic data limitations, the EPA is unable to quantitatively assess additional benefits of the rule.

Conversely, several commenters stated that the EPA has failed to demonstrate that the benefits of the rule justify its costs. Specifically, commenters disagreed with this determination because the EPA's analysis ''significantly underestimates the costs of the proposed MCLs. . .and overestimates its benefits.'' Commenters asserted that the EPA needs to update its EA to more accurately reflect the true costs of compliance of the rule to make the determination that the rule's costs are justified by its benefits. A few commenters urged the EPA to consider whether the benefits of finalizing the rule at regulatory alternative MCLs (*e.g.,* 5.0 or 10.0 ng/L) would better justify the costs of the rule.

After considering public comments, the EPA has made a number of adjustments to the cost model and collectively these changes have increased the agency's estimated annualized costs. The EPA has used the best available peer reviewed science to inform the cost estimates, including treatment costs, of the final PFAS NPDWR. For more information on the EPA's responses to comments on the rule costs, see sections XII.A.2–XII.A.4 of this preamble. The EPA disagrees with commenters that the EPA has overstated the benefits. As discussed in section XII.A.1, the EPA has used the best available peer reviewed science to quantify the benefits of the rule. The EPA also disagrees with commenters that suggested the benefits ''better justify'' the costs of PFOA and PFOS standards at 5.0 or 10.0 ng/L. These commenters pointed to the quantified net benefits of the regulatory alternatives and noted that net benefits are positive at 3 and 7 percent discount rates for a standard of 10.0 ng/L for PFOA and PFOS. The commenters' sole reliance on the quantified costs and benefits of the rule to support their argument is incorrect, as SDWA requires the agency to consider both the quantifiable and nonquantifiable impacts of the rule in the determination. Under SDWA 1412(b)(4)(B), the EPA is required to set an MCL as close as feasible to the MCLG, taking costs into consideration. In other words, SDWA does not mandate that the EPA establish MCLs at levels where the quantified benefits exceed the quantified costs. This was many commenters' justification for the recommendation to promulgate a standard of 10.0 ppt each for PFOA and PFOS in lieu of the proposed rule, and the EPA therefore disagrees that quantified costs and benefits can or should be the sole determinant of an MCL value. The Administrator's assessment that the benefits of the proposed rule justified its costs was based on the totality of the evidence, specifically the quantified and nonquantifiable benefits, which are anticipated to be substantial, as well as the quantified and nonquantifiable costs. Other commenters incorrectly stated that SDWA requires the EPA to set an MCL at a level '' . . . that maximizes health risk reduction benefits at a cost that is justified by the benefits.'' This test is found in section 1412(b)(6)(A) of SDWA and applies only when the Administrator determines based on the HRRCA that the benefits of a proposed MCL developed in accordance with paragraph (4) would not justify the costs of complying with the level. In the case of the proposed PFAS NPDWR, the Administrator determined that the benefits justify the costs for MCLs set as close as feasible to the MCLGs. For more information on the EPA's response to comments on the regulatory alternative MCLs considered in this rule, see section V of this preamble.

c. Benefit-Cost Determination in the Final Rule Analysis

For the final rule, considering both quantifiable and nonquantifiable costs and benefits of the rule as discussed in the EA and EA Appendices, the EPA is reaffirming the Administrator's determination made at proposal that the quantified and nonquantifiable benefits of the MCLs justify their costs.

B. Affected Entities and Major Data Sources Used To Develop the Baseline Water System Characterization

The entities potentially affected by the final rule are primacy agencies and PWSs. PWSs subject to final rule requirements are either CWSs or NTNCWSs. These water systems can be publicly or privately owned. PWSs subject to the rule would be required to meet the MCL and comply with monitoring and reporting requirements. Primacy agencies would be required to adopt and enforce the drinking water standard as well as the monitoring and reporting requirements.

Both PWSs and primacy agencies are expected to incur costs, including administrative costs, monitoring, and reporting costs, and in some cases, anticipated costs to reduce PFAS levels in drinking water to meet the final rule using treatment or nontreatment options. Section D of this preamble summarizes the method the EPA used to estimate these costs.

The systems that reduce PFAS concentrations will reduce associated health risks. The EPA developed methods to estimate the potential benefits of reduced PFAS exposure among the service populations of systems with PFAS levels exceeding the final drinking water standard. Section E summarizes the method used to estimate these benefits.

In its *Guidelines for Preparing Economic Analyses,* the EPA characterizes the ''baseline'' as a reference point that reflects the world without the final regulation (USEPA, 2016e). It is the starting point for estimating the potential benefits and costs of the final NPDWR. The EPA used a variety of data sources to develop the baseline drinking water system characterization for the regulatory analysis. Table 27 lists the major data sources and the baseline data derived from them. Additional detailed descriptions of these data sources and how they were used in the characterization of baseline conditions can be found in chapter 4 of USEPA (2024g).

Table 27: Data Sources Used to Develop Baseline Water System Characterization

Data Source	**Baseline Data Derived from the Source**
SDWIS Federal version fourth quarter 2021 Q4 "frozen" dataset [1]	*Water System Inventory:* PWS inventory, including system unique identifier, population served, number of service connections, source water type, and system type. *Population and Households Served:* PWS population served. *Treatment Plant Characterization:* Number of unique treatment plant facilities per system, which are used as a proxy for EP when UCMR 3 sampling site data are not available.
UCMR 3 (USEPA, 2017)	*Treatment Plant Characterization*: Number of unique EP sampling sites, which are used as a proxy for EP. *Treatment Plant Characterization:* PFAS concentration data collected as part of UCMR 3.
Independent state sampling programs	*Treatment Plant Characterization:* PFAS concentration data collected by states. These data supplemented the occurrence modeling for systems included in UCMR 3.
Six-Year Review 4 Information Collection Request (SYR4 ICR) Occurrence Dataset (2012-2019)	*Treatment Plant Characterization:* TOC.
Geometries and Characteristics of Public Water Systems (USEPA, 2000g)	*Treatment Plant Characterization:* Design and average daily flow per system.
2006 CWSS (USEPA, 2009c)	*Public Water System Labor Rates:* PWS labor rates.

Notes:

[1] Contains information extracted on January 14, 2022.

C. Overview of the Cost-Benefit Model

The EPA's existing SafeWater Cost Benefit Model (CBX) was designed to calculate the costs and benefits associated with setting a new or revised MCL. Since the final rule simultaneously regulates multiple PFAS contaminants, the EPA developed a new model version called the SafeWater Multi-Contaminant Benefit Cost Model (MCBC) to efficiently handle more than one contaminant. SafeWater MCBC allows for inputs that include differing mixtures of contaminants based on available occurrence data as well as multiple regulatory thresholds. The model structure allows for assignment of compliance technology or technologies that achieve all regulatory requirements and estimates costs and benefits associated with multiple PFAS contaminant reductions. SafeWater MCBC is designed to model co-occurrence, sampling, treatment, and administrative costs, and simultaneous contaminant reductions and resultant benefits. The modifications to the SafeWater model are consistent with the methodology that was developed in the single MCL SafeWater CBX Beta version that was peer reviewed. More detail on the modifications to the SafeWater model can be found in section 5.2 of the EPA's EA.

The costs incurred by a PWS depend on water system characteristics; SDWIS

Fed provides information on PWS characteristics that typically define PWS categories, or strata, for which the EPA developed cost estimates in rulemakings, including system type (CWS, NTNCWS), number of people served by the PWS, the PWS's primary raw water source (ground water or surface water), the PWS's ownership type (public or private), and the state in which the PWS is located.

Because the EPA does not have complete PWS-specific data across the approximately 49,000 CWSs and 17,000 NTNCWSs 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, the 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.

For a list of PWS characteristics that impact model PWS compliance costs, please see chapter 5 of USEPA (2024g). 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).

Once 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 final 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 system type (CWS and NTNCWS), primary water source (ground or surface), and size category. Note the 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). The detailed output across these strata can be found in the chapter 5 of USEPA (2024g).

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

D. Method for Estimating Costs

This section summarizes the cost elements and estimates total cost of compliance for the PFAS NPDWR discounted at 2 percent. The EPA estimated the costs associated with monitoring, administrative requirements, and both treatment and nontreatment compliance actions associated with the final rule (USEPA, 2024g).

1. Public Water System (PWS) Costs

a. PWS Treatment and Nontreatment Compliance Costs

The EPA estimated costs associated with engineering, installing, operating, and maintaining PFAS removal treatment technologies, including treatment media replacement and spent media destruction or disposal, as well as nontreatment actions that some PWSs may take in lieu of treatment, such as constructing new wells in an uncontaminated aquifer or interconnecting with and purchasing water from a neighboring PWS. The EPA used SafeWater MCBC to apply costs for one of the treatment technologies or nontreatment alternatives at each EP in a PWS estimated to be out of compliance with the final rule. For each affected EP, SafeWater MCBC selected from among the compliance alternatives using a decision tree procedure, described in more detail in USEPA (2024j). Next, the model estimated the cost of the chosen compliance alternative using outputs from the EPA's WBS cost estimating models. The WBS models are spreadsheet-based engineering models for individual treatment technologies, linked to a central database of component unit costs.

Specifically, the EPA used cost equations generated from the following models (USEPA, 2024m):

- the GAC WBS model (USEPA, 2024p);
- the PFAS-selective IX WBS model (USEPA, 2024q); and
- the nontreatment WBS model (USEPA, 2024r).

The *Technologies and Costs* (T&C) document (USEPA, 2024m) provides a comprehensive discussion of each of the treatment technologies, their effectiveness, and the WBS cost models as well as the equations used to calculate treatment costs. In total, there are more than 2,600 individual cost equations across the categories of capital and operation and maintenance (O&M) cost, water source, component level, flow, bed life (for GAC and IX), residuals management scenarios (for GAC and IX), and design type (for GAC). These models are available on the EPA's website at *https://www.epa.gov/sdwa/drinking-water-treatment-technology-unit-cost-models* as well as in the docket for this rule.

b. Decision Tree for Technology Selection

For EP at which baseline PFAS concentrations exceed regulatory thresholds, SafeWater MCBC selects a treatment technology or nontreatment alternative using a two-step process that both:

- Determines whether to include or exclude each alternative from consideration given the EP's characteristics and the regulatory option selected, and
- 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 SafeWater MCBC used in Step 1 include the following:

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

The EPA relied on information from the national PFAS occurrence model to inform influent PFAS concentrations. The EPA relied on *Geometries and Characteristics of Public Water Supplies* (USEPA, 2000g) and SDWIS inventory information to derive EP design flow. SafeWater MCBC selects influent TOC using the distribution shown in Table 28.

Table 28: 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

Source: The EPA's analysis of TOC concentrations in the SYR4 ICR database.

In Step 1, SafeWater MCBC uses these inputs to determine whether to include or exclude each treatment alternative from consideration in the compliance forecast. For the treatment technologies (GAC and IX), this determination is based on estimates of each technology's performance given available data about influent water quality and the regulatory option under consideration.

The EPA assumes a small number of PWSs may be able to take nontreatment actions in lieu of treatment. The viability of nontreatment actions is likely to depend on the quantity of water being replaced because the ability to purchase from another water system is limited by the seller water system's capacity and the ability to drill another well is limited by the ability to find an accessible, sufficiently large source. Therefore, SafeWater MCBC considers nontreatment only for EP with design flows less than or equal to 3.536 MGD. The EPA estimates approximately 2 percent of systems of this size will develop new wells and approximately 6–7 percent of systems will elect to interconnect with another system to achieve compliance.

In Step 2, SafeWater MCBC selects a compliance alternative for each EP from among the alternatives that remain in consideration after Step 1. Table 29 shows the initial compliance forecast that is the starting point for this step. The percentages in Table 29 consider data presented in the T&C document (USEPA, 2024m) on actions PWSs have taken in response to PFAS contamination.

To date, the majority of PWSs for which data are available have installed GAC (USEPA, 2024m). USEPA (2024m) includes data for 52 systems, 34 of which (65%) have installed GAC. The data in USEPA (2024m) also suggest that an increasing share of PWSs have selected IX in response to PFAS since the first full-scale system treated with PFAS-selective IX in 2017. Specifically, for systems installed prior to 2017, 78% used GAC. The EPA expects this trend to continue, so the initial percentages include adjustments to account for this expectation. In addition, the performance of GAC is affected by the presence of TOC, as further described in the cost chapter of the EA (USEPA, 2024g). Accordingly, the table includes adjusted distributions for systems with higher influent TOC. Finally, while central RO/NF remains a BAT for the final rule, the EPA does not anticipate water systems will select this technology to comply with the rule, largely due to the challenges presented by managing the treatment residuals from this process.

The list of compliance alternatives in Table 29 does not include POU devices for small systems. At this time, the EPA is not including POU devices in the national cost estimates because the final rule require treatment to concentrations below 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 independent third-party certification organizations, such as NSF or ANSI develop a new certification standard that mirrors the EPA's final regulatory standard. Therefore, the decision tree excludes POU devices from consideration.

Table 29: Initial Compliance Forecast

Compliance Alternative	**Design flow less than 1 MGD**		**Design flow 1 to less than 10 MGD**		**Design flow greater than or equal to 10 MGD**	
	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	79%	62%	81%	52%	89%	52%
PFAS-selective IX	12%	29%	11%	40%	11%	48%
Central RO/NF	0%	0%	0%	0%	0%	0%
Interconnection	7%	7%	6%	6%	0%	0%
New Wells	2%	2%	2%	2%	0%	0%

Source: The EPA's analysis of TOC concentrations in the SYR4 ICR database.

If all the compliance alternatives remain in consideration after Step 1, the decision tree uses the forecast shown in Table 29 above. If Step 1 eliminated one or more of the alternatives, SafeWater MCBC proportionally redistributes the percentages among the remaining alternatives and uses the redistributed percentages.

The EPA's approach to estimating GAC and IX performance for the final rule and all alternatives considered is discussed in detail within the cost chapter of the EA (USEPA, 2024g).

c. Work Breakdown Structure Models

The WBS models are spreadsheet-based engineering models for individual treatment technologies, linked to a central database of component unit costs. The EPA developed the WBS model approach as part of an effort to address recommendations made by the Technology Design Panel (TDP), which convened by the EPA in 1997 to review the agency's methods for estimating drinking water compliance costs (USEPA, 1997). The TDP consisted of nationally recognized drinking water experts from the 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, flexible, and transparent assessment of the capital and operating requirements for a treatment system.

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 the EPA's best estimates of complete compliance costs.

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, the EPA fit cost curves to the WBS estimates across a range of flow rates, which is described in chapter 5 of the EA (USEPA, 2024g).

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 polyvinyl chloride (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. The components used in each of the estimated component/cost levels provide the treatment efficacy needed to meet the regulatory requirements. Note that the level of component (*e.g.,* plastic versus resin or stainless-steel piping and vessels) may impact the capital replacement rate but does not interfere with treatment efficacy. The EPA estimates the three levels of cost because it has found that the choice of materials associated with the installation of new treatment equipment often varies across drinking water systems. These systems may, for example, choose to balance capital cost with staff familiarity with certain materials and existing treatment infrastructure. Given this experience, the EPA models the potential variability in treatment cost based on the three component/cost levels. To estimate costs for PFAS treatment, the 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). Cost equations for system automation are described in chapter 5 of the EA (USEPA, 2024g).

The WBS models generate cost estimates that include a consistent set of capital, add-on, indirect, and O&M costs. Table 30 identified these cost elements, which are common to all the WBS models and included in the cost estimates. As described and summarized in Tables 31–34 the WBS models also include technology-specific cost elements. The documentation for the WBS models provides more information on the methods and assumptions in the WBS models to estimate the costs for both the technology-specific and common cost elements (USEPA, 2024p; USEPA, 2024q; USEPA, 2024r). WBS model accuracy as well as limitations and uncertainty are described in chapter 5 of the EA (USEPA, 2024g).

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Table 30: 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 Costs	Mobilization and demobilization 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 Financing during construction Construction management
O&M Costs: Technology-specific	Operator labor for technology-specific tasks (e.g., managing backwash and media replacement) 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	Materials for maintenance of booster or influent pumps Materials for building maintenance
O&M Costs: Energy	Energy for operation of booster or influent pumps Energy for lighting, ventilation, cooling, and heating
O&M Costs: Residuals	Residuals management operator labor, materials, and energy Residuals disposal and discharge costs

The GAC 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 31 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 the Table 30 above.

Table 31: Technology-Specific Cost Elements Included in the GAC Model

Cost Category	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)
O&M Costs: Energy	Operating energy for backwash pumps
O&M Costs: Residuals	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)

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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. These assumptions are based on common vendor practice for these technologies, for example, see Khera et al. (2013) which says ''. . . small systems are often built as packaged, pre-engineered, or skid-mounted systems.'' 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. USEPA (2024p) provides complete details on the variant design assumptions used for package plants.

To generate the GAC cost equations, the 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; and
- Bed life varying over a range from 5,000 to 75,000 BV.

The 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 in a RCRA Subtitle C landfill and replacement with virgin GAC (*i.e.,* single use operation).

The T&C document (USEPA, 2024m) provides a comprehensive discussion of these and other key inputs and assumptions.

Table 32 shows the technology-specific capital equipment and O&M requirements included in the PFAS selective IX model. These items are in addition to the common WBS cost elements listed in the Table 30 above.

Table 32: Technology-Specific Cost Elements Included in the PFAS-Selective IX Model

Cost Category	Major Components Included
Direct Capital Costs	Booster pumps for influent water 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: Materials	Replacement cartridges for pre-treatment filters 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: Residuals	Disposal of spent cartridge filters Discharge fees for spent backwash/rinse Disposal of spent resin

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. USEPA (2024q) provides complete details on the variant design assumptions used for IX package plants.

To generate the IX cost equations, the 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 260,000 BV

The 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 (USEPA, 2024m) provides a comprehensive discussion of these and other key inputs and assumptions.

USEPA (2024r) provides a complete description of the engineering design process used by the WBS model for nontreatment actions. The model can estimate costs for two nontreatment alternatives: interconnection with another system and drilling new wells to replace a contaminated source. Table 33 shows the technology-specific capital equipment and O&M requirements included in the model for each alternative.

Table 33: Technology-Specific Cost Elements Included in the Nontreatment 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
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

To generate the cost equations, the EPA used the following key inputs in the nontreatment model for interconnection:

- An interconnection distance of 10,000 feet
- Includes booster pumps designed to account for friction loss in interconnecting piping
- An average cost of purchased water of $3.35 per thousand gallons in 2022 dollars.

For new wells, the 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 (USEPA, 2024m) provides a comprehensive discussion of these and other key inputs and assumptions.

d. Incremental Treatment Costs

The EPA has estimated the national level costs of the final rule associated with PFOA, PFOS, and PFHxS. As discussed in chapter 4 of the EA and detailed in the Technical Support Document for PFAS Occurrence and Contaminant Background chapter 10.1 and 10.3, there are limitations with nationally representative occurrence information for the other contaminants in the final rule (PFNA, HFPO–DA and PFBS). Specifically, HFPO–DA does not currently have a completed nationally representative dataset while PFNA and PFBS were not included in the national occurrence model because of limited results reported above the minimum reporting levels in UCMR 3. As described in the Technical Support Document for PFAS Occurrence and Contaminant Background chapter 10.3.2, non-targeted state monitoring datasets were used for extrapolation of PFNA, HFPO–DA, and PFBS in lieu of a nationally representative dataset. The EPA used conservative assumptions in this extrapolation to generate conservative cost estimates. As demonstrated in this analysis, the Hazard Index, PFNA, and HFPO–DA MCLs meaningfully increase public health protection at modest additional costs. Because of the increased uncertainty associated with PFNA, HFPO–DA and PFBS, the additional treatment cost from co-occurrence of PFNA, HFPO–DA, PFBS at systems already required to treat because of PFOA, PFOS, or PFHxS MCL and Hazard Index exceedances are not quantitatively assessed in the national cost estimates. These three PFAS' treatment costs are summarized here in this section and detailed in appendix N.3 of the EA (USEPA, 2024e). Likewise, treatment costs for systems that exceed the Hazard Index based on the combined occurrence of PFNA, HFPO–DA, PFBS, and PFHxS (where PFHxS itself does not exceed its HBWC of 10 ng/L) are not included in the national monetized cost estimates and are also summarized in this section and detailed in appendix N.3 of the EA (USEPA, 2024e).

In the EA for the proposed PFAS NPDWR, the EPA used a model system approach to illustrate the potential incremental costs for removing PFAS not included in the national economic model. After considering public comments on the incremental cost analysis, the EPA decided to further explore the incremental costs associated with the Hazard Index and MCLs with a national level sensitivity analysis for the final rule.

When the modeled occurrence data for PFNA, HFPO–DA, PFBS is incorporated into the SafeWater MCBC model, the estimated number of EP exceeding one or more MCLs, and therefore required to treat or use a different water source, increases to 9,471 from 9,043. This results in an increase in the expected national costs. Under the primary analyses, the expected total national cost is $1,549 million over the EPA's period of analysis (2024–2105) for the PFOA, PFOS, and PFHxS MCLs. When considering the additional incremental national cost impacts of the Hazard Index MCL for, PFNA, HFPO–DA, and PFBS (and individual MCLs for PFNA and HFPO–DA) the expected national costs of the final rule increase to $1,631 million at, or approximately a 5 percent national cost increase.

For further detail on the assumptions and findings of the EPA's analysis of incremental costs of other PFAS, see appendix N.3 and section XII.A of this preamble.

e. PWS Implementation Administration Costs

The EPA estimated PWS costs associated with one-time actions to begin implementation of the rule including reading and understanding the rule and attending training provided by primacy agencies. The average unit costs for PWSs are based on the following burden assumptions: (1) The EPA anticipates that the majority of water systems will likely not read the entirety of the rule preamble (as they are not required to do so) but focus their time and attention on understanding the regulatory requirements through the CFR regulatory text, relevant portions of the preamble, the EPA provided fact sheets and small system guidance documents, and state provided summaries documents; (2) Additionally, the EPA anticipates that system staff will attend primacy agency PFAS rule trainings to reenforce the systems' understanding of the final rule. The EPA assumes that systems will conduct these activities during years one through three of the analysis period. Table 34 lists the data elements and corresponding values associated with calculating the costs of these one-time implementation administration actions.

Table 34: Implementation Administration Startup Costs ($2022)

Data element description	Data element value
The labor rate per hour for systems	$36.43 (systems ≤3,300) $38.84 (systems 3,301-10,000) $41.00 (systems 10,001-50,000) $42.81 (systems 50,001-100,000) $50.03 (systems >100,000)
The average hours per system to read and adopt the rule	4 hours per system
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)

Estimated national annualized PWS implementation and administration startup costs for the final rule are $1.33 million. National annualized PWS cost estimates are further summarized in Table 39.

f. PWS Monitoring Costs

The final rule requires initial and long-term monitoring. As Table 35 shows, surface and ground water systems serving greater than 10,000 people will collect one sample each quarter, at each EP, 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 EP during the initial 12-month period. Ground water systems that serve 10,000 or fewer people will be required to sample once at each EP on a semi-annual basis for the first 12-month monitoring period.

Long-term monitoring schedules are based on specific EP sampling results (*i.e.,* water systems can have different EP within the system on different monitoring schedules). Long-term monitoring requirements differ based on whether a system can demonstrate during the initial monitoring period or once conducting long-term monitoring that an EP is below the trigger levels for regulated PFAS. The trigger levels are set as one-half the MCLs: 2.0 ng/L for PFOA and PFOS, 5 ng/L each for PFHxS, PFNA, and HFPO–DA, and 0.5 for the Hazard Index. EP below the trigger level values during the initial 12-month monitoring period and in future long-term monitoring periods may conduct triennial monitoring and collect one triennial sample at that EP. For EP with concentration values at or above a trigger level, a quarterly sample must be taken at that EP following initial monitoring. EP that demonstrate they are ''reliably and consistently'' [21] below the MCLs following four consecutive quarterly samples are eligible to conduct annual monitoring. After three annual samples at that EP showing no results at or above a trigger level, the location can further reduce to triennial monitoring.

For any samples that are above detection, the system will analyze the FRB samples collected at the same time as the monitoring sample. Systems that have an MCL exceedance will collect one additional sample from the relevant EP to confirm the results.

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[21] The definition of reliably and consistently below the MCL means that each of the samples contains regulated PFAS concentrations below the applicable MCLs. For the PFAS NPDWR, this demonstration of reliably and consistently below the MCL would include consideration of at least four quarterly samples at an EP below the MCL, but states will make their own determination as to whether the detected concentrations are reliably and consistently below the MCL.

Table 35: Modeled Initial and Long-Term Sampling Frequencies Per System EP

Initial Monitoring Period		**Long-Term Monitoring**[1]		
System Size Category	**Sample Number and Frequency**	**PFAS Detection ≥ MCLs**	**PFAS Detection ≥ trigger levels and < MCLs**[2]	**PFAS Detection < trigger levels**
≤ 10,000	Surface Water: 1 sample every quarter	1 sample every quarter	1 sample every year (following four consecutive quarterly samples reliably and consistently below the MCL)	1 triennial sample
	Ground Water: 1 sample every 6-month period			
>10,000	Surface Water and Ground Water: 1 sample every quarter	1 sample every quarter	1 sample every year (following four consecutive quarterly samples reliably and consistently below the MCL)	1 triennial sample

Notes:

[1] The EPA used the following thresholds to distinguish whether PFAS concentrations are reliably and consistently below the MCL: If after four consecutive quarterly samples, a system is below the MCLs (PFOA and PFOS – 4.0 ng/L, PFHxS, PFNA, HFPO-DA – 10 ng/L, Hazard Index – 1).

[2] Systems are not eligible for annual monitoring until after four consecutive quarterly samples are collected following initial monitoring.

For the national cost analysis, the EPA assumes that systems with either UCMR 5 data or monitoring data in the State PFAS Database (see section 3.1.4 in USEPA, 2024g) will not conduct the initial year of monitoring as allowed by the final rule. As a simplifying assumption for the cost analysis, the 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, the EPA relied on the PWSIDs stored in the database and exempted those systems from the first year of monitoring in the cost analysis. Note these simplifying assumptions may result in a small underestimate of initial monitoring costs. Under UCMR 5, individual water systems would be able to request the full release of data from the labs for use in determining their compliance monitoring frequency. PWSs may be able to use these lab analyses to demonstrate a ''below trigger level'' concentration using the UCMR 5 analyses by following up with the lab for a more detailed results report.

The EPA used system-level distributions of PFOA, PFOS, and PFHxS, as described in Cadwallader et al. (2022), to simulate EP concentrations and estimate PFAS occurrence relative to the final rule MCLs and trigger levels. Based on these occurrence distributions, the EPA estimates that the large majority of water systems subject to the rule (approx. 52,000–57,000) will have EP with concentrations below the trigger levels and would conduct reduced monitoring on a triennial basis. The EPA estimates that the remainder of water systems subject to the rule (approx. 9,000–15,000) will have at least one or more EP exceed the trigger level and therefore would be required to conduct quarterly monitoring.

The EPA assumes that systems with an MCL exceedance will implement actions to comply with the MCL by the compliance date. The EPA assumes a treatment target,[22] 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 MCLs. In the final rule, in order to reduce burden associated with monitoring, the EPA is adding an annual tier of sampling for any system with concentrations ''reliably and consistently'' [23] below the MCL but not consistently below the trigger level. The EPA believes this tier would likely

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[22] A treatment target is a contaminant concentration that a PWS has designed and operated their water system to meet. The EPA assumes all PWS will target 80% of the MCLs.

[23] The definition of reliably and consistently below the MCL means that each of the samples contains regulated PFAS concentrations below the applicable MCLs. For the PFAS NPDWR, this demonstration of reliably and consistently below the MCL would include consideration of at least four quarterly samples at an EP below the MCL, but states will make their own determination as to whether the detected concentrations are reliably and consistently below the MCL.

apply to most systems treating their water for regulated PFAS, at least for the first three years of treatment. Therefore, in the model, the EPA assumes EP that have installed treatment will take one year of quarterly samples, then continue to sample on an annual basis after that. The final rule allows EP showing no results at or above a trigger level after three annual samples to further reduce to triennial monitoring. In the national cost analysis, the EPA does not model this possibility nor does the EPA model instances where water systems are triggered back into quarterly monitoring after installing treatment.

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 36 presents the data elements and corresponding values associated with calculating sampling costs during the implementation monitoring period.

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Table 36: Sampling Costs ($2022)

Data Element Description	**Data Element Value**
The labor rate per hour for systems	$36.43 (systems ≤3,300) $38.84 (systems 3,301-10,000) $41.00 (systems 10,001-50,000) $42.81 (systems 50,001-100,000) $50.03 (systems >100,000)
The number of samples per EP per monitoring round for the initial monitoring in Year 1	2 samples (Ground Water systems ≤10,000) 4 samples (all systems) [1]
The number of samples per EP per long-term monitoring year for EPs that equal or exceed the MCLs	4 samples per year
The number of samples per EP per long-term monitoring year for EP < the MCLs and ≥ the trigger levels[2]	1 sample per year, following 4 quarterly samples reliably and consistently below the MCLs
The number of samples per EP per long-term monitoring round for EP < the trigger levels	1 sample every three years
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
The laboratory analysis cost per sample for EPA Method 537.1	$309
The laboratory analysis cost per sample for the FRB under EPA Method 537.1	$273 [3]

Notes:

[1] 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 discussed in USEPA, 2024g.

[2] The EPA used the following thresholds to distinguish whether PFAS concentrations are reliably and consistently below the MCL: If after four consecutive quarterly samples, a system is below the MCLs (PFOA and PFOS – 4.0 ng/L, PFHxS, PFNA, HFPO-DA – 10 ng/L, Hazard Index – 1).

[3] This incremental sample cost applies to all samples that exceed MDLs. The EPA used the Method 537.1 detection limits to apply this cost because Method 533 does not include detection limits.

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Estimated national annualized PWS sampling costs for the final rule have an expected value of $36.23 million. National annualized PWS cost estimates are further summarized in Table 39.

g. Treatment Administration Costs

Any system with an MCL exceedance adopts either a treatment or nontreatment alternative to comply with the rule. The majority of systems are anticipated to install treatment technologies while a subset of systems will choose alternative methods. The EPA assumes that systems will bear administrative costs associated with these treatment or nontreatment compliance actions (*i.e.,* permitting costs). The EPA assumes that systems will install treatment in the fifth year of the period of analysis. In addition, after installation of treatment, the EPA assumes that systems will spend an additional 2 hours per treating EP compiling data for and reviewing treatment efficacy with their primacy agency during their triennial sanitary survey. Table 37 presents the data elements and corresponding values associated with calculating treatment administration costs.

Table 37: Treatment Administration Costs ($2022)

Data element description	Data element value
The labor rate per hour for systems	\$36.43 (systems ≤3,300) \$38.84 (systems 3,301-10,000) \$41.00 (systems 10,001-50,000) \$42.82 (systems 50,001-100,000) \$50.03 (systems >100,000)
The hours per EP for a system to notify, consult, and submit a permit request for treatment installation [a]	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)
The additional hours per EP the system will spend every 3 years during a sanitary survey after PFAS related treatment is installed	2 hours, at EP that have installed treatment
The hours per EP for a system to notify, consult, and submit a permit request for source water change or alternative method[1]	6 hours

Notes:

[1] The EPA applied the cost per EP for this EA because the notification, consultation, and permitting process occurs for individual EP.

h. Public Notification (PN) Costs

The EPA's cost analysis assumes full compliance with the rule throughout the period of analysis and, as a result, the EPA does not estimate costs for the PN requirements in the final rule for systems with certain violations. The final rule designates MCL violations for PFAS as Tier 2, which requires systems to provide PN 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 final rule also designates monitoring and testing procedure violations as Tier 3, which requires systems to provide public notice no 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. CWSs may deliver Tier 3 PNs in their CCR if the timing, content, and delivery requirements are met according to 40 CFR 141.204(d). Using the CCR to deliver Tier 3 PNs can minimize the burden on systems by reducing delivery costs. For approximate estimates of the potential burden associated with Tier 2 and 3 PNs, please see USEPA (2024g).

i. Primacy Agency Costs

The EPA assumes that primacy agencies will have upfront implementation costs as well as costs associated with system actions related to sampling and treatment. The activities that primacy agencies are expected to carry out under the final rule include:

- Reading and understanding the rule, providing internal primacy agency officials training for the rule implementation, updating sanitary survey standard operating procedures,
- Primacy package application, including making regulatory changes to the Federal rule where applicable,
- Providing systems with training and technical assistance during the rule implementation,
- Reporting to the 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 PWS programs,
- Performing inspection of PFAS related treatment during sanitary surveys every three years

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

For the last three activities listed above, the primary agency burdens are incurred in response to action taken by PWSs; for instance, the cost to primacy agencies of reviewing sample results depends on the number of samples taken at each EP by each system under an agency's jurisdiction. Table 38 presents the data elements and corresponding values associated with calculating primacy agency costs.

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Table 38: Primacy Agency Costs ($2022)

Data element description	Data element value
The labor rate per hour for primacy agencies[1]	$59.69
The average hours per primacy agency to read and understand the rule, update sanitary survey standard operating procedures, and train internal staff.	4,020 hours per primacy agency
The average hours for a primacy agency to develop and adopt state-level regulations	300 hours per primacy agency
The average hours per primacy agency to provide initial training and technical assistance to systems	1,500 hours per primacy agency
The average hours per primacy agency to report annually to the EPA information under 40 CFR 142.15 regarding violations, variances and exemptions, enforcement actions and general operations of state PWS programs[2]	0
The hours per sample for a primacy agency to review sample results	1 hour
The hours per EP for a primacy agency to review and consult on installation of a treatment technology	80 hours (systems serving ≤3,300) 70 hours (systems serving 3,301 to 50,000) 50 hours (systems serving >50,000)
The additional hours per EP the primacy agency will spend every 3 years after PFAS-related treatment is installed during a sanitary survey	2 hours per EP that installs treatment every 3 years post installation
The hours per EP for a primacy agency to review and consult on a source water change	4 hours

Notes:

[1] In USBLS (2022), 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 Bureau of Labor Statistics (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.

[2] The EPA assumes that the final PFAS rule will have no discernable incremental burden for quarterly or annual reports to SDWIS Fed.

Estimated national annualized primacy agency costs for the final rule have an expected value of $4.65 million. National annualized cost estimates are further summarized in Table 39.

In addition to the costs described above, a primacy agency may also have to review the certification of any Tier 2 or 3 PNs sent out by systems. The EPA assumes full compliance with the final rule and therefore does not include this cost in national estimated cost totals but provides a brief discussion of the possible primacy agency burden associated with this component in USEPA (2024g).

In Table 39, the EPA summarizes the total annualized quantified cost of the final rule at a 2 percent discount rate expressed in millions of 2022 dollars. 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. The expected annualized PWS costs are $1,544 million. The uncertainty range for annualized PWS costs are $1,431 million to $1,667 million. Finally, annualized primacy agency implementation and administrative costs are added to the annualized PWS costs to calculate the total annualized cost of the final rule. The expected total annualized cost of the final rule is $1,549 million. The uncertainty range for the total annualized costs of the final rule is $1,436 million to $1,672 million. The EPA notes that treatment costs associated with the rule are the most significant contribution to overall rule costs for the final rule and the regulatory alternatives.

Table 39: National Annualized Costs, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L each, and Hazard Index of 1) (Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Annualized PWS Sampling Costs	$33.63	$36.23	$39.03
Annualized PWS Implementation and Administration Costs	$1.33	$1.33	$1.33
Annualized PWS Treatment Costs	$1,395.23	$1,506.44	$1,627.65
Total Annualized PWS Costs[2,3,4]	$1,431.00	$1,544.00	$1,667.10
Primacy Agency Rule Implementation and Administration Cost	$4.35	$4.65	$4.97
Total Annualized Rule Costs[2,3,4]	$1,435.70	$1,548.64	$1,672.10

Notes:

Detail may not add exactly to total due to independent rounding. 5th and 95th percentile values for total rule costs are not additive across cost categories as the categories are not completely correlated.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 74. This range does not include the uncertainty described in Table 43.

[2] The national level cost estimates for PFHxS are reflective of both the total national cost for PFHxS individual MCL exceedances, and Hazard Index MCL exceedances where PFHxS is present above its HBWC while one or more other Hazard Index PFAS is also present in that same mixture. Total quantified national cost values do not include the incremental treatment costs associated with the co-occurrence of PFNA, HFPO-DA, and PFBS. The EPA has considered the additional national costs of the Hazard Index and individual MCLs associated with HFPO-DA, PFBS, and PFNA occurrence in a quantified sensitivity analysis; see appendix N.3 of the EA (USEPA, 2024e) for the analysis and more information.

[3] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic 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, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N.2 of the EA (USEPA, 2024e) for additional detail.

[4] See Table 72 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.

In Tables 40, 41, and 42, the EPA summarizes the total annualized quantified cost of options 1a, 1b, and 1c, respectively.

Table 40: National Annualized Costs, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L; Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Annualized PWS Sampling Costs	$33.37	$35.98	$38.77
Annualized PWS Implementation and Administration Costs	$1.33	$1.33	$1.33
Annualized PWS Treatment Costs	$1,383.33	$1,495.14	$1,616.15
Total Annualized PWS Costs[2,3]	$1,419.20	$1,532.44	$1,654.80
Primacy Agency Rule Implementation and Administration Cost	$4.34	$4.63	$4.95
Total Annualized Rule Costs[2,3]	$1,423.60	$1,537.07	$1,660.30

Notes:

Detail may not add exactly to total due to independent rounding. 5th and 95th percentile values for total rule costs are not additive across cost categories as the categories are not completely correlated.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 74. This range does not include the uncertainty described in Table 43.

[2] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic 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, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N.2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 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.

Table 41: National Annualized Costs, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L; Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Annualized PWS Sampling Costs	$31.07	$33.29	$35.71
Annualized PWS Implementation and Administration Costs	$1.33	$1.33	$1.33
Annualized PWS Treatment Costs	$1,065.30	$1,153.31	$1,250.22
Total Annualized PWS Costs[2,3]	$1,098.40	$1,187.92	$1,286.50
Primacy Agency Rule Implementation and Administration Cost	$3.98	$4.21	$4.47
Total Annualized Rule Costs[2,3]	$1,102.60	$1,192.13	$1,291.40

Notes:

Detail may not add exactly to total due to independent rounding. 5th and 95th percentile values for total rule costs are not additive across cost categories as the categories are not completely correlated.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 74. This range does not include the uncertainty described in Table 4f3.

[2] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic 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, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N.2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 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.

Table 42: National Annualized Costs, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L; Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Annualized PWS Sampling Costs	$26.11	$27.48	$28.97
Annualized PWS Implementation and Administration Costs	$1.33	$1.33	$1.33
Annualized PWS Treatment Costs	$431.37	$467.12	$507.50
Total Annualized PWS Costs[2,3]	$459.50	$495.93	$537.21
Primacy Agency Rule Implementation and Administration Cost	$3.27	$3.37	$3.48
Total Annualized Rule Costs[2,3]	$462.87	$499.29	$540.68

Notes:

Detail may not add exactly to total due to independent rounding. 5th and 95th percentile values for total rule costs are not additive across cost categories as the categories are not completely correlated.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 74. This range does not include the uncertainty described in Table 43.

[2] PFAS- contaminated wastes are not considered RCRA regulatory or characteristic 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, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N.2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 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.

j. Data Limitations and Uncertainties in the Cost Analysis

Table 43 lists data limitations and characterizes the impact on the quantitative cost analysis. The 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. The 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 43: Limitations that Apply to the Cost Analysis for the Final 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. Chapter 5 of the EA (USEPA, 2024g) addressed the bed life assumption. The *Technologies and Costs* document (USEPA, 2024m) 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 final 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.
TOC 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 final rule can be higher or lower than the assigned values.
Insufficient UCMR 3 data for PFBS and PFNA and no UCMR 3 data for HFPO-DA were available to incorporate into the Bayesian hierarchical occurrence model	Underestimate	The final rule regulates PFNA, HFPO-DA, and PFBS in addition to the PFAS modeled in the primary analysis. In instances when concentrations of PFBS, PFNA, and/or HFPO-DA are high enough to cause or contribute to Hazard Index exceedances or PFNA and/or HFPO-DA are high enough to cause individual MCL exceedances, the modeled costs in the primary analysis 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 HBWC, then costs would be underestimated. Note that the EPA has conducted a sensitivity analysis of and considered the potential changes in treatment cost associated with the occurrence of PFNA, HFPO-DA, and PFBS using which is discussed in detail in appendix N.3 of the EA (USEPA, 2024e).

Uncertainty/ Assumption	**Effect on Quantitative Analysis**	**Notes**
POU not included in compliance forecast	Overestimate	If POU devices can be certified to meet concentrations that satisfy the final 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 RCRA regulatory or characteristic hazardous wastes. To address stakeholder concerns, including those raised during the SBREFA process, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. As part of this analysis, the 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. If in the future 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.2 of the EA (USEPA, 2024e) 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 the EPA OLEM's *Interim Guidance on the Destruction and Disposal of Perfluoroalkyl and Polyfluoroalkyl Substances and Materials Containing Perfluoroalkyl and Polyfluoroalkyl Substances* (USEPA, 2020d) and subsequent updates.
Population served held constant over time.	Uncertain	All PWS populations served were held constant over the period of analysis as not all locations have reliable information on population changes over time. If population served by affected PWSs increases (or decreases), then the estimated costs are likely underestimated (or overestimated).

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E. Nonquantifiable costs of the final rule

As described in section j. (*Data Limitations and Uncertainties in the Cost Analysis*) above, given the available occurrence data for the other compounds in the rule (PFNA, HFPO–DA, and PFBS) and the regulatory thresholds under consideration, the EPA considered national costs associated with potential Hazard Index exceedances as a direct result of these compounds in a sensitivity analysis; therefore, the additional treatment cost, from co-occurrence of PFNA, HFPO–DA, PFBS, at systems already required to treat because of PFOA, PFOS, or PFHxS MCL and Hazard Index exceedances are not presented in the national cost estimates above. Nor are treatment costs for systems that exceed the Hazard Index based on the combined occurrence of PFHxS (where PFHxS itself does not exceed 10 ng/L), PFNA, HFPO–DA, and PFBS presented in the national monetized cost estimates above. Treatment costs for the individual PFNA and HFPO–DA MCLs are also not considered above. For further discussion of how the EPA considered the costs of the five individual MCLs and the HI MCL, see section XII.A.4 of this preamble. These potential additional costs are described in greater detail in section 5.3.1.4 of USEPA (2024g) and appendix N.3 of USEPA (2024e). When considering the national cost impacts of the Hazard Index MCL for PFNA, HFPO–DA, and PFBS (and individual MCLs for PFNA and HFPO–DA) the expected national costs increase from $1,549 million to $1,631 million, or approximately a 5 percent national cost increase.

PFAS-contaminated wastes are not considered RCRA regulatory or characteristic 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, including those raised during the Small Business Regulatory Enforcement Fairness Act (SBREFA) process, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. As part of this analysis, the 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. If in the future PFAS-contaminated wastes require handling as hazardous wastes, the residuals management costs are expected to be higher. See appendix N.2 of the EA for a sensitivity analysis describing the potential increase in costs associated with hazardous waste disposal (USEPA, 2024e).

F. Method for Estimating Benefits

The EPA's quantification of health benefits resulting from reduced PFAS exposure in drinking water was driven by PFAS occurrence estimates, PK model availability, information on exposure-response relationships, and economic data to monetize the impacts. In the EA, the EPA either quantitatively assesses or qualitatively discusses health endpoints associated with exposure to PFAS. The EPA assesses potential benefits quantitatively if there is evidence of an association between PFAS exposure and health effects, if it is possible to link the outcome to risk of a health effect, and if there is no overlap in effect with another quantified endpoint in the same outcome group. Particularly, the most consistent epidemiological associations with PFOA and PFOS include decreased immune system response, decreased birthweight, increased serum lipids, and increased serum liver enzymes (particularly alanine transaminase, ALT). The available evidence indicates effects across immune, developmental, cardiovascular, and hepatic organ systems at the same or approximately the same level of exposure.

Table 44 presents an overview of the categories of health benefits expected to result from the implementation of treatment that reduces PFAS levels in drinking water. Of the PFAS compounds included in the final rule, the EPA quantifies some of the adverse health effects associated with PFOA and PFOS. These compounds have likely evidence linking exposure to a particular health endpoint and have reliable PK models connecting the compound to PFAS blood serum. PK models are tools for quantifying the relationship between external measures of exposure and internal measures of dose. Benefits from avoided adverse health effects of PFHxS, PFNA, HFPO–DA, and PFBS are discussed qualitatively in this section.

As Table 44 demonstrates, only a subset of the potential health effects of reduced PFAS in drinking water can be quantified and monetized. The monetized benefits evaluated in the EA for the final rule include changes in human health risks associated with CVD and infant birth weight from reduced exposure to PFOA and PFOS in drinking water and RCC from reduced exposure to PFOA. The 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 USEPA (2024g). The EPA quantified benefits associated with PFOS effects on liver cancer and PFNA effects on birth weight in sensitivity analyses.

The EPA was not able to quantify or monetize other benefits, including those related to other reported health effects including immune, liver, endocrine, metabolic, reproductive, musculoskeletal, or other cancers. The EPA discusses these benefits qualitatively in more detail in this section, as well as in section 6.2 of USEPA (2024g).

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Table 44: Overview of Health Benefits Categories Considered in the Analysis of Changes in PFAS Drinking Water Levels

Health Outcome		PFAS Compound[a,b,d]		Benefits Analysis	
Category	**Endpoint**	**PFOA**	**PFOS**	**Discussed Quantitatively**	**Discussed Qualitatively**
Lipids	Total cholesterol (TC)	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	
	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	
	Liver		X	X[e]	
	Testicular	X			X

Notes:

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

[b] Outcomes with indicative 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., LDLC overlaps with TC and SGA 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.

[c] Although evidence of associations between HDLC and PFOA and PFOS was mixed, certain individual studies reported robust associations in general adult populations. Based on comments and recommendations from the EPA SAB, the EPA assessed HDLC in a sensitivity analysis.

[d] Note that only PFOA and PFOS effects were modeled in the assessment of benefits under the final rule. For another PFAS in the rule, PFNA, the best available finalized analysis is based on studies published before 2018 (ATSDR, 2021). The EPA notes that new evidence since the release of the current, best available peer reviewed scientific assessment for PFNA (ATSDR, 2021) provides further justification for the EPA's analysis of potential economic benefits of PFNA exposure reduction and avoided birth weight effects. More recent epidemiological studies that evaluated PFNA and birth weight, including key studies modeled for PFOA and PFOS (Sagiv et al., 2018; Wikström et al., 2020), as well as a recently published meta-analysis of mean birth weight that indicates the birth weight results for PFNA are robust and consistent, even if associations in some studies may be small in magnitude (Wright et al., 2023). PFNA was modeled in a sensitivity analyses of birth weight benefits. This modeling relied on epidemiological studies published before 2018, representing the current, best available peer reviewed scientific assessment for PFNA (ATSDR, 2021) and the PFAS serum calculator developed by Lu and Bartell (2020) was used to estimate PFNA blood serum levels resulting from PFNA exposures in drinking water.

[e] Liver cancer benefits are not included in the national-level quantified benefits analysis. See appendix O of the EA for the liver cancer benefit analysis results.

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The EPA developed PK models to evaluate blood serum PFAS levels in adults resulting from exposure to PFAS via drinking water. To date, the EPA has developed PK models for PFOA and PFOS. The EPA used baseline and regulatory alternative PFOA/PFOS drinking water concentrations as inputs to its PK model to estimate blood serum PFOA/PFOS concentrations for adult males and females. For further detail on the PK model and its application in the EPA's benefits analysis, please see the EPA's *Final Human Health Toxicity Assessments for PFOA and PFOS* (USEPA, 2024c; USEPA, 2024d) and section 6.3 of USEPA (2024g).

1. Quantified Developmental Effects

Exposure to PFOA and PFOS is linked to developmental effects, including decreased infant birth weight (Steenland et al., 2018; Dzierlenga et al., 2020; Verner et al., 2015; USEPA, 2016c; USEPA, 2016d; USEPA, 2024c; USEPA, 2024d; Negri et al., 2017; ATSDR, 2021; Waterfield et al., 2020). The route through which infants are exposed prenatally to PFOA and PFOS is through maternal blood via the placenta. Most studies of the association between maternal serum PFOA/PFOS and birth weight report inverse relationships (Verner et al., 2015; Negri et al., 2017; Steenland et al., 2018; Dzierlenga et al., 2020). The EPA's PK model assumes that mothers were exposed to PFOA/PFOS from birth to the year in which pregnancy occurred.

The EPA quantified and valued changes in birth weight-related risks associated with reductions in exposure to PFOA and PFOS in drinking water. 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:

1. 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 baseline 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 a 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.

The EPA also considered the potential benefits from reduced exposure to PFNA that may be realized as a direct result of the final rule. The agency explored the birth weight impacts of PFNA in a sensitivity analysis based on epidemiological studies published before 2018 cited in the current, best available final human health analysis of PFNA (ATSDR, 2021), as well as a recently published meta-analysis of mean birth weight that indicates the birth weight results for PFNA are robust and consistent, even if associations in some studies may be small in magnitude (Wright et al., 2023). The EPA used a unit PFNA reduction scenario (*i.e.,* 1.0 ng/L change) and the PFAS serum calculator developed by Lu and Bartell (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, the 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, the EPA examined the effect of inclusion of PFNA-birth weight effects using estimates from two studies (Lenters et al., 2016; Valvi et al., 2017). The EPA found that inclusion of a 1.0 ng/L PFNA reduction increased annualized birth weight benefits by between a factor of 5.6 to 7.8, relative to the scenario that quantifies a 1.0 ng/L reduction in PFOA and a 1.0 ng/L 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). The 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. The EPA also notes that the PFNA slope factor estimates in this analysis are not precise, with 95 percent CIs covering wide ranges that include zero (*i.e.,* serum PFNA slope factor estimates are not statistically significant at 5 percent 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. The EPA did not include PFNA effects in the national benefits estimates for the final rule because there was insufficient data above the UCMR 3 MRL to reasonably fit model parameters for PFNA. For the EPA's PFNA sensitivity analysis, see appendix K of USEPA (2024g).

To estimate changes in birth weight resulting from reduced exposure to PFOA and PFOS under the regulatory alternatives, the 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. For more detail on the evaluation of the studies used in these meta-analyses, please see the EPA's *Final Human Health Toxicity Assessments for PFOA and PFOS* (USEPA, 2024c; USEPA, 2024d) and section 6.4 of USEPA (2024g).

Changes in serum PFOA and PFOS concentrations are calculated for each PWS EP during each year in the analysis period. The EPA assumes that, given the long half-lives of PFOS and PFOA (with median half-lives of 2.7 and 3.5 years, respectively (Li et al., 2018)), any one-time measurement during or near pregnancy is reflective of a critical exposure window and not subject to considerable error. In other words, blood serum concentrations in a single year are expected to correlate with past exposures and are reflective of maternal exposures regardless of the timing of pregnancy. 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 45, 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. Additional detail on the derivation of the exposure-response functions can be found in appendix D in USEPA (2024e). appendix K in USEPA (2024e) presents an analysis of birth weight risk reduction considering slope factors specific to the first trimester.

Table 45: Serum Exposure-Birth Weight Response Estimates

Compound	**g /ng/mL serum (95% CI)**
PFOA [a]	-10.5 (-16.7, -4.4)
PFOS [b]	-3.0 (-4.9, -1.1)

Notes:

[a] The serum-birth weight slope factor for PFOA is based on the main random effects estimate from Steenland et al. (2018).

[b] The serum-birth weight slope factor for PFOS is based on the EPA reanalysis of Dzierlenga et al. (2020).

The EPA places a cap on estimated birth weight changes in excess of 200 g, assuming that such changes in birth weight are unreasonable based on existing studies that found that changes to environmental exposures result in relatively modest birth weight changes (Windham and Fenster, 2008; Klein and Lynch, 2018; Kamai et al., 2019). 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.

Low birth weight 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 and Corman, 1991; Behrman and Butler, 2007; Behrman and Rosenzweig, 2004; Joyce et al., 2012; Kowlessar et al., 2013; Colaizy et al., 2016; Nicoletti et al., 2018; Klein and Lynch, 2018). Recent literature also linked low birth weight 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).

The 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 EA of birth weight effects from exposure to PFOA/PFOS in drinking water (ICF, 2021).

Two studies showed statistically significant relationships between incremental changes in birth weight and infant mortality: Almond et al. (2005) and Ma and Finch (2010). Ma and Finch (2010) used 2001 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 and Finch, 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 and Finch (2010) are likely to overestimate the benefits of birth weight changes.

Considering the discernible changes in infant mortality over the last 30 years, the EPA developed a regression analysis to estimate the relationship between birth weight and infant mortality using the *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; CDC, 2018). These data provide information on infants who are delivered alive and receive a birth certificate. The 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. The EPA included several variables used in Ma and Finch (2010) (maternal age, maternal education, marital status, and others) as well as additional variables to augment the set of covariates included in the analyses. In addition, the 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 and Finch (2010). Appendix E of USEPA (2024e) provides details on model development and regression results.

Table 46 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 gestational age categories vary across different race/ethnicity subpopulations. 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 low birth weight increases the probability of mortality within the first year more so among non-Hispanic Black infants than among non-Hispanic White and Hispanic infants.

The 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,[24] the 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 of USEPA (2024g).

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[24] 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).

Table 46: Race/Ethnicity and Gestational Age-Specific Birth Weight Marginal Effects and Odds Ratios from the Mortality Regression Models [1]

Race	Gestational Age Category [2]	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 (-0.03430, -0.03140)	0.9985 (0.99842, 0.99858)
	Moderately Preterm	-0.00677 (-0.00702, -0.00652)	0.99867 (0.99863, 0.99872)
	Term	-0.00228 (-0.00236, -0.00221)	0.99865 (0.99861, 0.99868)
Hispanic	Extremely Preterm	-0.15260 (-0.16770, -0.13750)	0.99835 (0.99817, 0.99853)
	Very Preterm	-0.03290 (-0.03510, -0.03070)	0.99846 (0.99835, 0.99858)
	Moderately Preterm	-0.00626 (-0.00659, -0.00592)	0.99856 (0.99849, 0.99862)
	Term	-0.00219 (-0.00229, -0.00208)	0.99849 (0.99844, 0.99855)

Notes:

[1] Data based on the *2016/17 and 2017/18 CDC Period Cohort Linked Birth-Infant Death Data Files* obtained from NCHS/National Vital Statistics System (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 percent level. Additional details are included in appendix E to the EA.

[2] 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).

The EPA weighted the race/ethnicity-specific odds ratios in Table 46 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 odds ratio estimate for each modeled race/ethnicity subpopulation and 100 g birth weight increment.

Based on reduced serum PFOA/PFOS exposures under the regulatory alternatives and the estimated relationship between birth weight and infant mortality, the 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. The EPA evaluated 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. Additional detail on the calculations the EPA used to estimate changes in birth weight, the affected population size, and infant deaths avoided, and the number of surviving infants is provided in chapter 6 of USEPA (2024g).

The EPA used the Value of a Statistical Life to estimate the benefits of reducing infant mortality and the cost of illness 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. The 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 and Lynch, 2018; ICF, 2021). The EPA selected the medical cost function from Klein and Lynch (2018) to monetize benefits associated with the estimated changes in infant birth weight resulting from reduced maternal exposure to PFOA/PFOS.[25]

Using the incremental cost changes from Klein and Lynch (2018), the 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, provided in Table 47.

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[25] The Klein and Lynch (2018) report was externally peer reviewed by three experts with qualifications in economics and public health sciences. The 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.

Table 47: Simulated Cost Changes for Birth Weight Increases ($2022) (Based on Klein and Lynch, 2018 Table 8)

Birth Weight[a,b]	**Simulated Cost Changes for Birth Weight Increases, Dollars per Gram ($2022)**[c]		
	+0.04 lb (+18 g)	**+0.11 lb (+50 g)**	**+0.22 lb (+100 g)**
2 lb (907 g)	-$131.66	-$117.44	-$113.82
2.5 lb (1,134 g)	-$98.72	-$88.07	-$85.35
3 lb (1,361 g)	-$74.03	-$66.04	-$64.00
3.3 lb (1,497 g)	-$62.29	-$55.56	-$53.85
4 lb (1,814 g)	-$41.63	-$37.13	-$35.99
4.5 lb (2,041 g)	-$31.21	-$27.84	-$26.98
5 lb (2,268 g)	-$23.41	-$20.88	-$20.23
5.5 lb (2,495 g)	-$0.97	-$0.88	-$0.87
6 lb (2,722 g)	-$0.95	-$0.86	-$0.86
7 lb (3,175 g)	-$0.92	-$0.83	-$0.83
8 lb (3,629 g)	-$0.89	-$0.81	-$0.80
9 lb (4,082 g)	$3.28	$2.99	$3.01
10 lb (4,536 g)	$3.69	$3.37	$3.39

Notes:

[a] Values for birth weight have been converted from lb to g.

[b] Note 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 high birth weight infants, there is a higher risk of birth trauma, metabolic issues, and other health problems (Klein and Lynch, 2018).

[c] Values scaled from $2010 to $2022 using the medical care Consumer Price Index (USBLS, 2022).

Tables 48 to 51 provide the health effects avoided and valuation associated with birth weight impacts. The EPA estimated that, over the evaluation period, the final rule will result in annualized benefits from avoided reductions in birth weight of $209 million.

Table 48: National Birth Weight Benefits, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L each, and Hazard Index of 1) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Increase in Birth Weight (Millions of Grams)	129.6	216.8	304.1
Number of Birth Weight-Related Deaths Avoided	781.9	1,301.7	1,823.6
Total Annualized Birth Weight Benefits (Million $2022) [2]	$124.85	$209.00	$292.78

Notes:

Detail may not add exactly to total due to independent rounding. Quantifiable benefits are increased under final rule table results relative to the other options presented because of modeled PFHxS occurrence, which results in additional quantified benefits from co-removed PFOA and PFOS.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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 49: National Birth Weight Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Increase in Birth Weight (Millions of Grams)	128.8	215.6	302.1
Number of Birth Weight-Related Deaths Avoided	777.4	1,294.4	1,812.9
Total Annualized Birth Weight Benefits (Million $2022) [2]	$124.82	$207.82	$291.00

Notes:

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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 50: National Birth Weight Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Increase in Birth Weight (Millions of Grams)	111.3	185.6	260.3
Number of Birth Weight-Related Deaths Avoided	668.9	1,114.7	1,561.2
Total Annualized Birth Weight Benefits (Million $2022) [2]	$107.34	$178.97	$250.00

Notes:

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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 51: National Birth Weight Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Increase in Birth Weight (Millions of Grams)	62.1	102.0	142.4
Number of Birth Weight-Related Deaths Avoided	375.8	616.6	859.1
Total Annualized Birth Weight Benefits (Million $2022) [2]	$60.24	$98.97	$137.75

Notes:

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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.

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2. Quantified Cardiovascular Effects

CVD is one of the leading causes of premature mortality in the United States (D'Agostino et al., 2008; Goff et al., 2014; Lloyd-Jones et al., 2017). As discussed in the EPA's *Final Human Health Toxicity Assessments for PFOA and PFOS,* exposure to PFOA and PFOS through drinking water contributes to increased serum PFOA and PFOS concentrations and elevated levels of TC, as well as suggestive evidence of changes in levels of HDLC and elevated levels of systolic blood pressure (USEPA, 2024c; USEPA, 2024d). Changes in TC and blood pressure are associated with changes in incidence of CVD events such as myocardial infarction (*i.e.,* heart attack), ischemic stroke, 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).

The EPA recognizes that the epidemiologic literature that provides strong support for an effect of PFOA and PFOS on cholesterol and blood pressure does not provide direct support for an effect of PFOA and PFOS on the risk of CVD. Therefore, the EPA uses the approach outlined here to link changes in CVD risk biomarkers (*i.e.,* cholesterol and blood pressure) to changes in CVD risk.

For each EP, evaluation of the changes in CVD risk involves the following key steps:

1. Estimation of annual changes in TC and blood pressure 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, fatal and non-fatal ischemic stroke or other coronary heart disease 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 blood pressure levels in all populations alive during or born after the start of the evaluation period; and
3. Estimation of the economic value of reducing CVD mortality and morbidity from baseline to regulatory alternative levels, using the Value of a Statistical Life and cost of illness measures, respectively.

Given the breadth of evidence linking PFOA and PFOS exposure to effects on TC and blood pressure in general adult populations, the EPA quantified public health impacts of changes in these well-established 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, the EPA assumed that PFOA/PFOS-related changes in TC and blood pressure had the same effect on the CVD risk as the changes unrelated to chemical exposure and used the Pooled Cohort ASCVD model (Goff et al., 2014) to evaluate their impacts on the incidence of myocardial infarction, ischemic stroke, and cardiovascular mortality occurring in populations without prior CVD event experience.

The ASCVD model includes TC as a predictor of first hard CVD events. The 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).

The EPA identified 14 studies from which to derive slope estimates for PFOA and PFOS associations with serum TC levels. Appendix F of USEPA (2024e) provides further detail on the studies selection criteria, meta-data development, meta-analysis results, and discussion of the uncertainty and limitations inherent in the EPA's exposure-response analysis.

The 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. When using studies reporting linear associations between TC and serum PFOA or PFOS, the EPA estimated a positive increase in TC of 1.57 (95 percent CI: 0.02, 3.13) mg/dL per ng/mL serum PFOA (p-value=0.048), and of 0.08 (95 percent CI: -0.01, 0.16) mg/dL per ng/mL serum PFOS (p-value=0.064). Based on the systematic review conducted by the EPA to develop the EPA's *Final Human Health Toxicity Assessments for PFOA and PFOS,* the available evidence supports a positive association between PFOS and TC in the general population. For more information on the systematic review and results, see USEPA (2024c) and USEPA (2024d).

PFOS exposure has been linked to other cardiovascular outcomes, such as systolic blood pressure and hypertension (Liao et al., 2020; USEPA, 2024d). Because systolic blood pressure is another predictor used by the ASCVD model, the EPA included the estimated changes in blood pressure from reduced exposure to PFOS in the CVD analysis. The 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. The evidence on the associations between PFOA and blood pressure is not as consistent as for PFOS. Therefore, the EPA is not including effect estimates for the serum PFOA-blood pressure associations in the CVD analysis.

The 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. 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.,* 2024), and age- and sex-specific time series of changes in TC and blood pressure levels obtained by combining serum PFOA/PFOS concentration time series with exposure-response information. Baseline and regulatory alternatives are evaluated separately, with regulatory alternative TC and blood pressure levels estimated using baseline information on these biomarkers from external statistical data sources and modeled changes in TC and blood pressure due to conditions under the regulatory alternatives.

The EPA estimated the incidence of first hard CVD events based on TC serum and blood pressure 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. The 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 blood pressure effects estimation, the EPA further restricts the modeled population to those not using antihypertensive medications for consistency with the exposure-response relationship. Modeled first hard CVD events include fatal and non-fatal myocardial infarction, fatal and non-fatal ischemic stroke, and other coronary heart disease mortality. The EPA has also estimated the incidence of post-acute CVD mortality among survivors of the first myocardial infarction or ischemic stroke within 6 years of the initial event.

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 of USEPA (2024e) provides detailed information on all CVD model components, computations, and sources of data used in modeling.

The EPA uses the Value of a 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. The EPA relies on cost of illness-based valuation that represents the medical costs of treating or mitigating non-fatal first hard CVD events (myocardial infarction, ischemic stroke) during the three years following an event among those without prior CVD history, adjusted for post-acute mortality.

The annual medical expenditure estimates for myocardial infarction and ischemic stroke are based on O'Sullivan et al. (2011). The estimated expenditures do not include long-term institutional and home health care. For non-fatal myocardial infarction, O'Sullivan et al. (2011) estimated medical expenditures are $53,246 ($2022) for the initial event and then $33,162, $14,635, $13,078 annually within 1, 2, and 3 years after the initial event, respectively. For non-fatal ischemic stroke, O'Sullivan et al. (2011) estimated medical expenditures are $16,503 ($2022) for the initial event and then $11,988, $788, $1,868 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 myocardial infarction and ischemic stroke events.

To estimate the present discounted value of medical expenditures within 3 years of the initial non-fatal myocardial infarction, the EPA combined O'Sullivan et al. (2011) myocardial infarction-specific estimates with post-acute survival probabilities based on Thom et al. (2001) (for myocardial infarction survivors aged 40–64) and Li et al. (2019) (for myocardial infarction survivors aged 65+). To estimate the present discounted value of medical expenditures within 3 years of the initial non-fatal ischemic stroke, the EPA combined O'Sullivan et al. (2011) ischemic stroke-specific estimates with post-acute survival probabilities based on Thom et al. (2001) (for ischemic stroke survivors aged 40–64, assuming post-acute myocardial infarction survival probabilities reasonably approximate post-acute ischemic stroke survival probabilities) and Li et al. (2019) (for ischemic stroke survivors aged 65+). The EPA did not identify post-acute ischemic stroke mortality information in this age group, but instead applied post-acute myocardial infarction mortality estimates for ischemic stroke valuation. Table 52 presents the resulting myocardial infarction and ischemic stroke unit values.

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Table 52: Cost of Illness of Non-Fatal First CVD Event Used in Modeling

Type of First Non-fatal Hard CVD Event	Age Group	Present Discounted Value of 3-Year Medical Expenditures ($2022, 2% discount rate)[a,b] Adjusted for Post-Acute Mortality[c]
MI	40-64 years	$110,040
	65+ years	$96,626
IS	40-64 years	$30,373
	65+ years	$27,954

Abbreviations: CVD – cardiovascular disease; MI – myocardial infarction (ICD9=410; ICD10=I21), IS – ischemic stroke (ICD9=433, 434; ICD10=I63).

Notes:

[a] Estimates of annual medical expenditures are from O'Sullivan et al. (2011).

[b] Original values from O'Sullivan et al. (2011) were inflated to $2022 using the medical care Consumer Price Index (USBLS, 2022).

[c] Post-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. The 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 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.

Tables 53 to 56 provide the health effects avoided and valuation associated with CVD. The EPA estimated that, over the evaluation period, the final rule will result in annualized benefits from avoided CVD cases and deaths of $606 million.

Table 53: National CVD Benefits, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L each, and Hazard Index of 1) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal MI Cases Avoided	1,407.7	6,333.1	11,189.0
Number of Non-Fatal IS Cases Avoided	2,074.8	9,247.6	16,279.0
Number of CVD Deaths Avoided	845.5	3,715.8	6,555.6
Total Annualized CVD Benefits (Million $2022) [2]	$140.66	$606.09	$1,069.40

Notes:

Detail may not add exactly to total due to independent rounding. Quantifiable benefits are increased under final rule table results relative to the other options presented because of modeled PFHxS occurrence, which results in additional quantified benefits from co-removed PFOA and PFOS.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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 54: National CVD Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L)

(Million $2022)

Benefits Category	**2% Discount Rate**		
	5th Percentile[1]	**Expected Benefits**	**95th Percentile**[1]
Number of Non-Fatal MI Cases Avoided	1,400.8	6,296.0	11,115.0
Number of Non-Fatal IS Cases Avoided	2,065.0	9,194.8	16,203.0
Number of CVD Deaths Avoided	839.9	3,695.1	6,484.4
Total Annualized CVD Benefits (Million $2022) [2]	$140.12	$602.72	$1,059.60

Notes:

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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 55: National CVD Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L)

(Million $2022)

Benefits Category	**2% Discount Rate**		
	5th Percentile[1]	**Expected Benefits**	**95th Percentile**[1]
Number of Non-Fatal MI Cases Avoided	1,209.2	5,352.0	9,417.5
Number of Non-Fatal IS Cases Avoided	1,778.3	7,826.9	13,778.0
Number of CVD Deaths Avoided	733.1	3,146.8	5,518.0
Total Annualized CVD Benefits (Million $2022) [2]	$119.18	$513.27	$900.13

Notes:

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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 56: National CVD Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L)

(Million $2022)

Benefits Category	**2% Discount Rate**		
	5th Percentile[1]	**Expected Benefits**	**95th Percentile[1]**
Number of Non-Fatal MI Cases Avoided	673.7	2,776.5	4,872.8
Number of Non-Fatal IS Cases Avoided	987.0	4,079.2	7,145.6
Number of CVD Deaths Avoided	411.6	1,640.9	2,878.1
Total Annualized CVD Benefits (Million $2022) [2]	$66.97	$267.56	$469.05

Notes:

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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.

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3. Quantified Kidney Cancer Effects

Data on the association between PFOA exposure and kidney cancer (*i.e.,* RCC), particularly from epidemiological studies, indicate 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; ATSDR, 2021; USEPA, 2016c; USEPA, 2024c, USEPA, 2024j). In the PFOA HESD (USEPA, 2016c), the EPA determined that PFOA is likely to be carcinogenic to humans (USEPA, 2005a) based in part on evidence of associations between PFOA exposure and kidney cancer in humans. A recent study of the relationship between PFOA and RCC in U.S. general populations found strong evidence of a positive association between exposure to PFOA and RCC in humans (Shearer et al., 2021). A meta-analysis of epidemiological literature also concluded that there was an increased risk of kidney cancer associated with increased PFOA serum concentrations (Bartell and Vieira, 2021). As such, the EPA selected RCC as a key outcome when assessing the health impacts of reduced PFOA exposures.

The EPA quantified and valued the changes in RCC risk associated with reductions in serum PFOA levels that are in turn associated with reductions in drinking water PFOA concentrations under the regulatory alternatives. 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 a Statistical Life and cost of illness measures, respectively.

To identify an exposure-response function, the EPA reviewed studies highlighted in the HESD for PFOA (USEPA, 2016c) 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 the EPA's *Final Human Health Toxicity Assessment for PFOA* (USEPA, 2024c; USEPA, 2024j). 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. 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 evidence that exposure to PFOA is associated with 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, the 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 $(ng/mL)^{-1}$. The analysis reported in 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) accounted for age, sex, race, ethnicity, study center, year of blood draw, smoking, and hypertension in modeling the association between PFOA and RCC. Results showed a strong and statistically significant association between PFOA and RCC. The EPA selected the exposure-response relationship from Shearer et al. (2021) because it included exposure levels typical in the general population and the study was found to have a low risk of bias when assessed in the EPA's *Final Human Health Toxicity Assessment for PFOA* (USEPA, 2024c; USEPA, 2024j).

The linear slope factor developed by the agency (see section 4.2 of USEPA, 2024c) based on Shearer et al. (2021) enables estimation of the changes in the lifetime RCC risk associated with reduced lifetime serum PFOA levels. Because baseline RCC incidence statistics are not readily available from the National Cancer Institute (NCI) public use data, the 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 (USEPA, 2024c; American Cancer Society, 2020). The 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 of USEPA (2024e).

Similar to the EPA's approach for estimating CVD risk reductions, the EPA relies on the life table approach to estimate RCC risk reductions. 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 excess RCC population mortality. For more detail on the EPA's application of the life table to cancer benefits analyses, please see appendix H of USEPA (2024e).

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 of USEPA (2024e), the EPA does not capture effects after the end of the period of analysis, 2105. 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 the EPA SDWIS, age-, sex-, and race/ethnicity-specific population estimates from the U.S. Census Bureau (2020), the Surveillance, Epidemiology, and End Results (SEER) program database (Surveillance Research Program—National Cancer Institute, 2020a; National Cancer Institute, 2020b), and the CDC NCHS. Appendix H of USEPA (2024e) provides additional detail on the data sources and information used in this analysis as well as baseline kidney cancer statistics. Appendix B of USEPA (2024e) describes estimation of the affected population.

The EPA uses the Value of a Statistical Life to estimate the benefits of reducing mortality associated with RCC in the population exposed to PFOA in drinking water. The EPA uses the cost of illness-based valuation to estimate the benefits of reducing morbidity associated with RCC.

The EPA used the medical cost information from a recent RCC cost-effectiveness study by Ambavane et al. (2020) to develop cost of illness 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 CheckMate 214 clinical trial and recent US-based healthcare cost information assembled from multiple sources (see supplementary information from Ambavane et al. (2020)).

The EPA received public comments on the EA for the proposed rule related to the EPA's use of cost of illness information for morbidity valuation. Specifically, some commenters recommended that the EPA use willingness to pay information (instead of cost of illness information) when valuing the costs associated with non-fatal illnesses, stating that willingness to pay information better accounts for lost opportunity costs (*e.g.,* lost productivity and pain and suffering) associated with non-fatal illnesses (USEPA, 2024k). To better account for these opportunity costs, the EPA used recently available willingness to pay values in a sensitivity analysis for morbidity associated with RCC. The sensitivity analysis results show that when willingness to pay values are used in RCC benefits analysis, morbidity benefits are increased by approximately 2 percent. See appendix O of the EA for full details and results on the willingness to pay sensitivity analyses.

Table 57 summarizes RCC morbidity cost of illness estimates derived by the 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 and 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. The EPA notes that the second line treatment costs are not reflected in the EPA's cost of illness 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, the EPA valued RCC morbidity at $261,175 ($2022) during year 1 of the diagnosis, $198,705 ($2022) during year 2 of the diagnosis, and $1,661 ($2022) starting from year 3 of the diagnosis. Additionally, the 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.

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Table 57: RCC Morbidity Valuation

Time Interval	First Line Medication ($2018)[a]	First Line Administration ($2018)[a]	First Line Adverse Effect Management	Disease Management ($2018)[a]	Total ($2018)	Total ($2022)[d]
Monthly cost, month 1-3 from diagnosis[a,e]	32,485	516	78	73	33,152	37,382
Monthly cost, month 4-24 from diagnosis[b,f]	13,887	647	78	73	14,685	16,559
Monthly cost, month 25+ from diagnosis[g]	-	-	-	123	123	139
Annual cost, year 1 from diagnosis	222,438	7,371	934	878	231,621	261,175
Annual cost, year 2 from diagnosis	166,644	7,764	934	878	176,220	198,705
Annual cost, year 3+ from diagnosis	-	-	-	1,473	1,473	1,661

Notes:

[a] Ambavane et al. (2020) Table 1.

[b] Ambavane et al. (2020) p. 41, a maximum treatment duration assumption of 2 years.

[c] The adverse effect management costs of $1,868 in Ambavane et al. (2020) Table 1 were reported for the treatment duration. The EPA used the treatment duration of 24 months (i.e., 2 years) to derive monthly costs of $77.83.

[d] To adjust for inflation, the EPA used U.S. Bureau of Labor Statistics Consumer Price Index for All Urban Consumers: Medical Care Services in U.S. (City Average).

[e] First line treatment induction.

[f] First line treatment maintenance.

[g] Treatment-free interval.

Tables 58 to 61 provide the health effects avoided and valuation associated with RCC. The EPA estimated that, over the evaluation period, the final rule will result in annualized benefits from avoided RCC cases and deaths of $354 million.

Table 58: National RCC Benefits, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L each, and Hazard Index of 1) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal RCC Cases Avoided	1,091.5	6,964.2	17,937.0
Number of RCC-Related Deaths Avoided	320.4	2,028.8	5,206.5
Total Annualized RCC Benefits (Million $2022) [2, 3]	$61.33	$353.90	$883.55

Notes:

Detail may not add exactly to total due to independent rounding. Quantifiable benefits are increased under final rule table results relative to the other options presented because of modeled PFHxS occurrence, which results in additional quantified benefits from co-removed PFOA and PFOS.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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.

[3] When using willingness-to-pay metrics to monetize morbidity benefits, total annualized RCC benefits are increased by $7.1 million.

Table 59: National RCC Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L)

(Million $2022)

Benefits Category	**2% Discount Rate**		
	5th Percentile[1]	**Expected Benefits**	**95th Percentile[1]**
Number of Non-Fatal RCC Cases Avoided	1,082.0	6,922.4	17,870.0
Number of RCC-Related Deaths Avoided	319.1	2,016.7	5,190.9
Total Annualized RCC Benefits (Million $2022) [2]	$60.90	$351.79	$877.47

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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 60: National RCC Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L)

(Million $2022)

Benefits Category	**2% Discount Rate**		
	5th Percentile[1]	**Expected Benefits**	**95th Percentile[1]**
Number of Non-Fatal RCC Cases Avoided	851.9	5,696.1	14,906.0
Number of RCC-Related Deaths Avoided	251.6	1,663.8	4,328.4
Total Annualized RCC Benefits (Million $2022) [2]	$48.41	$290.72	$730.99

Notes:

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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 61: National RCC Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L)

(Million $2022)

Benefits Category	**2% Discount Rate**		
	5th Percentile[1]	**Expected Benefits**	**95th Percentile**[1]
Number of Non-Fatal RCC Cases Avoided	372.1	2,648.1	6,967.4
Number of RCC-Related Deaths Avoided	111.5	782.8	2,057.3
Total Annualized RCC Benefits (Million $2022) [2]	$21.20	$137.30	$352.07

Notes:

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 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.

4. Key Limitations and Uncertainties in the Benefits Analysis

The following section discusses the uncertainty information incorporated in the quantitative benefits analysis. There are additional sources of uncertainty and limitations that could not be modeled quantitatively as part of the national benefits analysis. These sources of uncertainty are characterized in detail in section 6.8 of USEPA (2024g). This summary includes uncertainties that are specific to application of PK models for blood serum PFAS concentration estimation, developmental effects (*i.e.,* infant birth weight) modeling, CVD impacts modeling, RCC impacts modeling, and modeling of bladder cancer impacts from GAC treatment-related reductions in the sum of four trihalomethanes (THM4). Table 62 presents the key limitations and uncertainties that apply to the benefits analysis for the final rule. The 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 of the following tables, the 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 62: Key Limitations and Uncertainties that Apply to Benefits Analyses

Considered for the Final PFAS Rule

Uncertainty/ Assumption	**Effect on Benefits Estimate**	**Notes**
The EPA has quantified benefits for three health endpoints for PFOA (birth weight, CVD, and RCC) and two health endpoints for PFOS (birth weight and CVD)	Underestimate	For various reasons, the 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 F for more information about these nonquantifiable benefits.
The EPA has only quantified benefits for one co-removed contaminant group (THM4)	Underestimate	Treatment technologies that remove PFAS can also remove 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.
The EPA has not quantified national benefits for any health endpoint for the PFAS that make up the Hazard Index (PFHxS, PFNA, HFPO-DA, and PFBS)	Underestimate	PFHxS, PFNA, HFPO-DA, and PFBS each have substantial health impacts on multiple health endpoints. However, the effects of PFNA on birth weight are evaluated as part of a sensitivity analysis in appendix K. See discussion in section D for more information about these nonquantifiable benefits.
The analysis considers PFOA/PFOS concentrations from NTNCWSs	Overestimate	SDWIS population served estimates for NTNCWSs represent 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.
The EPA assumes that the effects of PFOA and	Uncertain	The exposure-response functions used in benefits analyses assume that the effects of serum PFOA/PFOS on the health outcomes considered

Uncertainty/ Assumption	**Effect on Benefits Estimate**	**Notes**
PFOS exposures are independent.		are independent and therefore additive. This assumption is consistent with the *Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)* (USEPA, 2024a). Due to limited evidence, the 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 the EPA's Final Human Health Toxicity Assessments indicate that the levels at which adverse health effects could occur are much lower than previously understood when the EPA issued the 2016 health advisories for PFOA and PFOS (70 ng/L) – 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 noncancer health endpoints.
Causality is assumed for all health effects for which exposure-response functions are used to estimate risk.	Overestimate	Analyses evaluating the evidence on the associations between PFAS exposure and health outcomes are ongoing and the EPA has not conclusively determined causality. As described in section 6.2 of the EA, the 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 the EPA's Stage 2 DBP 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	The 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 (see

Uncertainty/ Assumption	**Effect on Benefits Estimate**	**Notes**
		Tables G-3 through G-6 in appendix G of the EA; USEPA, 2024e).
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, which is expected to result in underestimated benefits. The EPA uses present-day information on life expectancy, disease, environmental exposure, and other factors, which are likely to change in the future.
For PWSs with multiple EP, the analysis assumes a uniform population distribution across the EP.	Uncertain	Data on the populations served by each EP are not available, and the EPA therefore uniformly distributes system population across EP. Effects of the regulatory alternative may be greater or smaller than estimated, depending on actual populations served by affected EP. For one large system serving more than one million customers the EPA has sufficient data on EP flow to proportionally assign effected populations.
The EPA does not characterize uncertainty associated with the Value of Statistical Life reference value or Value of Statistical Life elasticity	Uncertain	The 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 most of the overall benefits estimate, not considering uncertainty surrounding the Value of Statistical Life is a limitation.
Process wastes not classified as hazardous	Underestimate	The national EA reflects the assumption that PFAS-contaminated wastes are not considered RCRA regulatory or characteristic hazardous wastes. The EPA acknowledges that if Federal authorities later determine that PFAS-contaminated wastes require handling as hazardous wastes, there will be additional benefits to public health and the environment from reduced exposures to PFAS that have not been quantified as part of this analysis.

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G. Nonquantifiable Benefits of PFOA and PFOS Exposure Reduction

In this section, the 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 final NPDWR, in addition to the benefits that the EPA has quantified, because of their known toxicity and additive health concerns as well as occurrence and likely co-occurrence in drinking water. The EPA anticipates additional benefits associated with developmental, cardiovascular, liver, immune, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects beyond those benefits that the EPA has quantified. The evidence for these adverse health effects is briefly summarized here.

The EPA identified a wide range of potential health effects associated with exposure to PFOA and PFOS using five comprehensive Federal Government health effects assessments that summarize the recent literature on PFAS (mainly PFOA and PFOS, although many of the same health effects have been observed for the other PFAS in this rule) exposure and its health impacts: the EPA's HESDs for PFOA and PFOS, hereafter referred to as the EPA HESDs (USEPA, 2016c; USEPA, 2016d); the EPA's Final Human Health Toxicity Assessments for PFOA and

PFOS (USEPA, 2024c; USEPA, 2024d); and the U.S. Department of Health and Human Services (HHS) ATSDR *Toxicological Profile for Perfluoroalkyls* (ATSDR, 2021). Each source presents comprehensive literature reviews on adverse health effects associated with PFOA and PFOS. The EPA notes that NASEM also published a report which includes a review of the adverse health effects for numerous PFAS (NASEM, 2022). That document is included in the docket for this final rule.

The most recent literature reviews on PFAS exposures and health impacts, which are included in the EPA's *Final Human Health Toxicity Assessments for PFOA and PFOS* (USEPA, 2024c; USEPA, 2024d), describe the weight of evidence supporting PFOA and PFOS associations with health outcomes as either demonstrative, indicative (likely), suggestive, inadequate, or strong evidence supportive of no effect according to the evidence integration judgments outlined in the *ORD Staff Handbook for Developing IRIS Assessments* (USEPA, 2022f; USEPA, 2024c; USEPA, 2024d). For the purposes of the reviews conducted to develop the *Final Human Health Toxicity Assessments for PFOA and PFOS,* an association is deemed demonstrative when there is a strong evidence base demonstrating that the chemical exposure causes a health effect in humans. The association is deemed indicative (likely) when the evidence base indicates that the chemical exposure likely causes a health effect in humans, although there might be outstanding questions or limitations that remain, and the evidence is insufficient for the higher conclusion level. The association is suggestive if the evidence base suggests that the chemical exposure might cause a health effect in humans, but there are very few studies that contributed to the evaluation, the evidence is very weak or conflicting, or the methodological conduct of the studies is poor. 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 supports no effect when extensive evidence across a range of populations and exposure levels has identified no effects/associations. Note that the EPA considered information available as of September 2023 for the analyses presented herein.

Developmental effects: Exposure to PFOA and PFOS is linked to developmental effects including but not limited to the infant birth weight effects that the EPA quantified. Other developmental effects include small for gestational age (SGA), birth length, head circumference at birth, and other effects (Verner et al., 2015; Negri et al., 2017; ATSDR, 2021; Waterfield et al., 2020; USEPA, 2016c; USEPA, 2016d; USEPA, 2024c; USEPA, 2024d). SGA is a developmental health outcome of interest when studying potential effects of PFOA/PFOS exposure because SGA infants have increased health risks during pregnancy and delivery as well as post-delivery (Osuchukwu and Reed, 2022). The majority of epidemiology studies indicated increased risk of SGA with PFOA/PFOS exposure, although some studies reported null results (USEPA, 2024c; USEPA, 2024d). For instance, some studies suggested a potentially positive association between PFOA exposure and SGA (Govarts et al., 2018; Lauritzen et al., 2017; Wang et al., 2016; Souza et al., 2020; Wikström et al., 2020; Chang et al., 2022; USEPA, 2024c). In addition to decreases in offspring weight, toxicology studies on PFOA and PFOS exposures in rodents demonstrated relationships with multiple other developmental toxicity endpoints, including increased offspring mortality, decreased maternal body weight and body weight change, skeletal and soft tissue effects, and delayed eye-opening (USEPA, 2024c; USEPA, 2024d). For additional details on developmental studies and their individual outcomes, see chapter 3.4.4 (*Developmental*) in USEPA (2024c) and USEPA (2024d).

Cardiovascular effects: In addition to the CVD effects that the EPA quantified associated with changes in TC and blood pressure from exposure to PFOA and PFOS (see section 6.2 of USEPA (2024g)), available evidence suggests an association between exposure to PFOA and PFOS and increased low-density lipoprotein cholesterol (LDLC) (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d). High levels of LDLC are known as the 'bad' cholesterol because it can 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 or PFOS exposure and LDLC levels in adults and children (USEPA, 2024c; USEPA, 2024d). 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). Additionally, available evidence supports a relatively consistent positive association between PFOA or PFOS and low-density lipoprotein (LDL) in adults, especially those who are obese or prediabetic. Associations with other lipoprotein cholesterol known to increase cardiovascular risks were also positive, which increased confidence in the findings for LDLC. Available evidence regarding the impact of PFOA and PFOS exposure on pregnant women was too limited for the EPA to determine an association (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d). Toxicology studies generally reported alterations in serum lipid levels in mice and rats following oral exposure to PFOA (USEPA, 2024d) or PFOS (USEPA, 2024c), indicating 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 3.4.3 (*Cardiovascular*) in USEPA (2024c) and USEPA (2024d).

Liver effects: Several biomarkers can be used clinically to diagnose liver diseases, including alanine aminotransferase (ALT). Serum ALT measures are considered a reliable indicator of impaired liver function because increased serum ALT is indicative of leakage of ALT from damaged hepatocytes (Boone et al., 2005; Z. Liu et al., 2014; USEPA, 2002d). Additionally, evidence from both human epidemiological and animal toxicological studies indicates that increased serum ALT is associated with liver disease (Ioannou et al., 2006a; Ioannou et al., 2006b; Kwo et al., 2017; Roth et al., 2021). Human epidemiological studies have demonstrated that even low magnitude increases in serum ALT can be clinically significant (Mathiesen et al., 1999; Park et al., 2019). Additionally, numerous studies have demonstrated an association between elevated ALT and liver-related mortality (reviewed by Kwo et al., 2017). Furthermore, the American Association for the Study of Liver Diseases (AASLD) recognizes serum ALT as an indicator of overall human health and mortality (Kim et al., 2008). Epidemiology data provides consistent evidence of a positive association between PFOS/PFOA exposure and ALT levels in adults (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d). 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 (USEPA, 2024c). There is also consistent epidemiology evidence of associations between PFOS and elevated ALT levels. A limited number of studies reported inconsistent evidence on whether PFOA/PFOS exposure is associated with increased risk of liver disease (USEPA, 2024d). It is also important to note that while evaluation of direct liver damage is possible in animal studies, it is difficult to obtain biopsy-confirmed histological data in humans. Therefore, liver injury is typically assessed using serum biomarkers of hepatotoxicity (Costello et al., 2022). Associations between PFOA/PFOS exposure and ALT levels in children were less consistent than in adults (USEPA, 2024c; USEPA, 2024d).

PFOA toxicology studies showed increases in ALT and other serum liver enzymes across multiple species, sexes, and exposure paradigms (USEPA, 2024c). Toxicology studies on the impact of PFOS exposure on ALT also reported increases in ALT and other serum liver enzyme levels in rodents, though these increases were modest (USEPA, 2024d). Several studies in animals also reported increases in the incidence of liver lesions or cellular alterations, such as hepatocellular cell death (USEPA, 2024c; USEPA, 2024d). For additional details on the ALT studies and their individual outcomes, see section 3.4.1 (Hepatic) in USEPA (2024c) and USEPA (2024d).

Immune effects: Proper antibody response helps maintain the immune system by recognizing and responding to antigens. The available 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 and childhood serum concentrations of PFOA (ATSDR, 2021; USEPA, 2024c). Data reporting on associations between PFOA exposure and antibody response to vaccinations other than tetanus and diphtheria (*i.e.,* rubella and hand, foot, and mouth disease) are limited but supportive of associations between PFOA and decreased immune response in children (USEPA, 2024c). Available studies supported an association between PFOS exposure and immunosuppression in children, where increased PFOS serum levels were associated with decreased antibody production in response to tetanus, diphtheria, and rubella vaccinations (USEPA, 2024d). Studies reporting associations between PFOA or PFOS exposure and immunosuppression in adults are less consistent, though this may be due to a lack of high confidence data (USEPA, 2024c; USEPA, 2024d). Toxicology evidence suggested that PFOA and PFOS exposure results in effects similarly indicating immune suppression, such as reduced response of immune cells to challenges (*e.g.,* reduced natural killer cell activity and immunoglobulin production) (USEPA, 2024c; USEPA, 2024d). For additional details on immune studies and their individual outcomes, see section 3.4.2 (*Immune*) in USEPA (2024c) and USEPA (2024d).

Endocrine effects: Elevated circulating thyroid hormone levels can accelerate metabolism and cause irregular heartbeat; low levels of thyroid hormones can cause neurodevelopmental effects, tiredness, weight gain, and increased susceptibility to the common cold. There is suggestive evidence of a positive association between PFOA/PFOS exposure and thyroid hormone disruption (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d). Epidemiology studies reported inconsistent evidence regarding associations between PFOA and PFOS exposure and general endocrine outcomes, such as thyroid disease, hypothyroidism, and hypothyroxinemia (USEPA, 2024c; USEPA, 2024d). However, for PFOA, epidemiological studies reported suggestive evidence of positive associations for serum levels of thyroid stimulating hormone (TSH) and the thyroid hormone triiodothyronine (T3) in adults, and the thyroid hormone thyroxine (T4) in children (USEPA, 2024c; USEPA, 2024d). For PFOS, epidemiological studies reported suggestive evidence of positive associations for TSH in adults, positive associations for T3 in children, and inverse associations for T4 in children (USEPA, 2024d). Toxicology studies indicated that PFOA and PFOS exposure leads to decreases in serum thyroid hormone levels[26] and adverse effects to the endocrine system (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d; USEPA, 2024h). Overall, changes in serum thyroid hormone levels in animals indicate PFOS and PFOA toxicity potentially relevant to humans (USEPA, 2024c; USEPA, 2024d). For additional details on endocrine effects studies and their individual outcomes, see appendix C.2 (*Endocrine*) in USEPA (2024h) and USEPA (2024i).

Metabolic effects: Leptin is a hormone that, along with adiponectin, can be a marker of adipose tissue dysfunction. Chronic high levels of leptin lead to leptin resistance that mirrors many of the characteristics associated with diet-induced obesity, including reduced leptin receptors and diminished signaling. Therefore, high leptin levels are associated with higher body fat mass, a larger size of individual fat cells, overeating, and inflammation (*e.g.,* of adipose tissue, the hypothalamus, blood vessels, and other areas). Evidence suggests an association between PFOA exposure and leptin levels in the general adult population (ATSDR, 2021; USEPA, 2024c). Based on a review of human epidemiology studies, evidence of associations between PFOS and metabolic outcomes appears inconsistent, but in some studies, positive associations were observed between PFOS exposure and leptin levels (USEPA, 2024d). 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 appendix C.3 (*Metabolic/Systemic*) in USEPA (2024h) and USEPA (2024i).

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; USEPA, 2024c; USEPA, 2024d). Gestational hypertension (high blood pressure 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 pose significant risks to both the fetus and mother. Risks to the fetus include impaired fetal growth due to the lack of oxygen and nutrients, stillbirth, preterm birth, and infant death (NIH, 2017). Even if born full term, the infant may be at risk for later problems such as diabetes, high blood pressure, and congestive heart failure. Effects of preeclampsia on the mother may include kidney and liver damage, blood clotting problems, brain injury, fluid on the lungs, seizures, and mortality (NIH, 2018). The epidemiology evidence yields mixed (positive and null) associations, with some suggestive evidence supporting positive associations between PFOA/PFOS exposure and both preeclampsia and gestational hypertension (ATSDR, 2021; USEPA, 2024c; USEPA, 2024d). For additional details on reproductive effects studies and their individual

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[26] Decreased thyroid hormone levels are associated with effects such as changes in thyroid and adrenal gland weight, hormone fluctuations, and organ histopathology, as well as adverse neurodevelopmental outcomes (ATSDR, 2021; USEPA, 2024c).

outcomes, see appendix C.1 (*Reproductive*) in USEPA (2024h) and USEPA (2024i).

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. The available epidemiology evidence suggests 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; USEPA, 2024c). Some studies found that PFOA/PFOS exposure was linked to osteoarthritis, in particular among women under 50 years of age (ATSDR, 2021). There is limited evidence from studies pointing to effects of PFOS on skeletal size (height), lean body mass, and osteoarthritis (USEPA, 2024d). Evidence from some studies suggests that PFOS exposure has a harmful effect on bone health, particularly measures of bone mineral density, with greater statistically significance of effects occurring among females (USEPA, 2024d). 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 appendix C.8 (*Musculoskeletal*) in USEPA (2024h) and USEPA (2024i).

Cancer Effects: In the EPA's *Final Human Health Toxicity Assessment for PFOA,* the agency evaluates the evidence for carcinogenicity of PFOA that has been documented in both epidemiological and animal toxicity studies (USEPA, 2024c; USEPA, 2024j). 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 or for particular breast cancer types. 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 (USEPA, 2024c; USEPA, 2024j). The 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 (USEPA, 2024c; USEPA, 2024j). The EPA's benefits analysis for avoided RCC cases from reduced PFOA exposure is discussed in section XII.E of this preamble and in section 6.6 of USEPA (2024g).

In the EPA's *Final Human Health Toxicity Assessment for PFOS,* the agency evaluates the evidence for carcinogenicity of PFOS and found that several epidemiological studies and a chronic cancer bioassay comprise the evidence database for the carcinogenicity of PFOS (USEPA, 2024d; USEPA 2024j). The available epidemiology studies report elevated risk of liver cancer, consistent with increased incidence of liver tumors reported in male and female rats. There is also mixed but plausible evidence of bladder, prostate, kidney, and breast cancers in humans. The animal chronic cancer bioassay study also provides evidence of increased incidence of pancreatic islet cell tumors in male rats. The 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.'' The EPA's national-level benefits sensitivity analysis for avoided liver cancer cases from reduced PFOS exposure is detailed in appendix O of the EA.

The EPA anticipates there are additional nonquantifiable benefits related to potential testicular, bladder, prostate, and breast cancer effects summarized above. Benefits associated with avoiding cancer cases not quantified in the EPA's analysis could be substantial. For example, a study by Obsekov et al. (2023) reports the number of breast cancer cases attributable to PFAS exposure ranges from 421 to 3,095 annually, with an estimated direct cost of 6-month treatment ranging from $27.1 to $198.4 million per year ($2022). This study also finds that approximately 5 (0.076 percent) annual testicular cases are attributable to PFOA exposure with an estimated direct cost of treatment of $173,450 per year ($2022). Although the methods used by Obsekov et al. (2023) differ from those used to support the national quantified benefits of the rule, the information provided in the study is helpful in portraying the costs of cancers that are associated with PFAS exposures. For additional details on cancer studies and their individual outcomes, see chapter 3.5 (*Cancer*) in USEPA (2024c) and USEPA (2024d).

After assessing available health and economic information, the 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 and readily available data for monetization, namely cardiovascular effects, developmental effects, and carcinogenic effects. Several other health endpoints that had indicative or suggestive evidence of associations with exposure to PFOA and PFOS have not been selected for the EA:

- While immune effects had indicative evidence of associations with exposure to PFOA and PFOS, the EPA did not identify the necessary information to connect the measured biomarker responses (*i.e.,* decrease in antibodies) to a disease that could be valued in the EA;
- Evidence indicates associations between PFOA and PFOS exposure and hepatic effects, such as increases in ALT. While increased ALT is considered an adverse effect, ALT can be one of several contributors to a variety of diseases, including liver disease, and it is difficult to therefore quantify the relationship between this biomarker and a disease that can be monetized. Similar challenges with the biomarkers representing metabolic effects (*i.e.,* leptin) and musculoskeletal effects (*i.e.,* bone density) prevented economic analysis of these endpoints;
- There is evidence of association between exposure to PFOA and testicular cancer in human and animal studies; however, the available slope factor in rats implied small changes in the risk of this endpoint. Because testicular cancer is rarely fatal and the Value of Statistical Life is the driver of economic benefits evaluated in the EA, the benefit of decreased testicular cancer expected with this rule was smaller in comparison and not quantified;
- There is evidence of association between exposure to PFOS and hepatic carcinogenicity in human and animal studies. The EPA quantified benefits associated with reduced liver cancer cases and deaths as part of a sensitivity analysis for the final rule in response to public comments received on the proposed rule requesting that the EPA quantify additional health benefits (see appendix O of the EA (USEPA, 2024e));
- Finally, other health endpoints, such as SGA and LDLC effects, were not modeled in the EA because they overlap with effects that the EPA did model. More specifically, SGA infants are often born with decreased birth weight or

receive similar care to infants born with decreased birth weight. LDLC is a component of TC and could not be modeled separately as the EPA used TC as an input to the ASCVD model to estimate CVD outcomes.

H. Nonquantifiable Benefits of Removal of PFAS Included in the Final Regulation and Co-Removed PFAS

The EPA also qualitatively summarized the potential health benefits resulting from reduced exposure to PFAS other than PFOA and PFOS in drinking water. The final rule and all regulatory alternatives are expected to result in additional benefits that have not been quantified. The final rule will reduce exposure to PFHxS, HFPO–DA, and PFNA to below their individual MCLs. It will also reduce exposure to PFBS to below the Hazard Index MCLG and MCL of 1 when the mixture contains two or more of PFHxS, PFNA, HFPO–DA, and PFBS. Benefits from avoided cases of the adverse health effects discussed in this section are expected from the final rule due to co-occurrence of these contaminants in source waters containing PFOA and/or PFOS, as described in the *Per- and Polyfluoroalkyl Substances (PFAS) Occurrence & Contaminant Background Support Document* (USEPA, 2024b) and part VI of this preamble. In addition, PFAS, including PFHxS, PFNA, HFPO–DA, and PFBS and their mixtures affect common target organs, tissues, or systems to produce dose-additive effects from their co-exposures with each other, as well as PFOA and PFOS (USEPA, 2024a). The EPA expects that compliance actions taken under the final 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 final rule 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 et al., 2014; Eschauzier et al., 2012; Ochoa-Herrera and Sierra-Alvarez, 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) is removed approximately as well as PFBS (*i.e.,* sulfonic acid with a four-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 final 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, the 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 the EPA has not quantified these additional benefits, the agency expects that these important co-removal benefits will further enhance public health protection.

The EPA identified a wide range of potential health effects associated with exposure to PFAS other than PFOA and PFOS using documents that summarize the recent literature on exposure and associated health impacts: the ATSDR's *Toxicological Profile for Perfluoroalkyls* (ATSDR, 2021); the EPA's toxicity assessment of HFPO–DA (USEPA, 2021b); publicly available IRIS assessments for PFBA and PFHxA (USEPA, 2022g; USEPA, 2023p); the EPA's toxicity assessment of PFBS (USEPA, 2021a); 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 and associated health effects are based on information available as of September 2023.

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, PFHxA, PFNA, HFPO–DA, PFUnA, and PFBS. Specifically, data from toxicology studies support this association for PFBS, PFBA, PFHxA, and HFPO–DA, while both toxicology and epidemiology studies support this association for PFHxS, PFDA, PFUnA, and PFNA (ATSDR, 2021; USEPA, 2021b; USEPA, 2022g; USEPA, 2023e; Wright et al., 2023). In general, epidemiological studies did not find associations between exposure and adverse pregnancy outcomes (miscarriage, preterm birth, or gestational age) for PFNA, PFUnA and PFHxS (ATSDR, 2021; NASEM, 2022). Epidemiological studies support an association between PFNA, PFHxS or PFDA exposure and developmental effects such as decreases in infant birth weight and birth length, small for gestational age and increased risk of low birth weight (Valvi et al., 2017; Bach et al., 2016; Louis et al., 2018; Wright et al., 2023; Manzano-Salgado et al., 2017; Starling et al., 2017). Few epidemiologic studies also indicate that PFDA exposure is associated with developmental effects (Wikström et al., 2020; Valvi et al., 2017; Luo et al., 2021; Yao et al., 2021). The EPA has determined that evidence indicates that exposure to PFBA or PFHxA likely causes developmental effects, based on moderate evidence from animal studies and indeterminate evidence from human studies (USEPA, 2022g; USEPA, 2023p).

Cardiovascular effects: Epidemiology and/or toxicology studies observed evidence of associations between PFNA, PFDA, and PFHxS exposures and effects on total cholesterol, LDLC, and HDLC. Epidemiological studies report consistent associations between PFHxS and total cholesterol in adults (Cakmak et al., 2022; Dunder et al., 2022; Canova et al., 2020; Lin et al., 2019; Liu et al., 2020; Fisher et al., 2013).

In an analysis based on studies published before 2018, evidence for associations between PFNA exposure and serum lipid 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. Epidemiological studies report consistent associations between PFDA and effects on total cholesterol in adults (Cakmak et al., 2022; Dunder et al, 2022; Liu et al., 2020; Dong et al., 2019). Positive associations between PFDA and other serum lipids, adiposity, cardiovascular disease, and atherosclerosis were observed in some epidemiology studies, but findings were inconsistent (Huang et al., 2018; Mattsson et al., 2015; Christensen et al., 2016). A single animal study observed decreases in cholesterol and triglyceride levels in rats at PFDA doses above 1.25 mg/kg/d for 28 days (NTP, 2018b). There was no association between PFBA and serum lipids in a single epidemiology study and no animal studies on PFBA evaluated cardiovascular endpoints (USEPA, 2022g).

Other PFAS for which lipid outcomes were examined in toxicology or epidemiology studies showed limited to no evidence of associations. Studies have examined possible associations between various PFAS and blood pressure in humans or heart histopathology in animals. Epidemiological studies report positive associations between PFHxS and hypertension in adolescents and young adults (Averina et al., 2021; Li et al., 2021; Pitter et al., 2020), but not in other adults (Lin et al., 2020; Chen et al., 2019; Christensen et al., 2018; Liu et al., 2018; Bao et al., 2017; Christensen et al., 2016) or children (Papadopoulou et al., 2021; Khalil et al., 2018; Manzano-Salgado et al., 2017). No evidence was observed of associations between PFHxS and cardiovascular diseases (Huang et al., 2018; Mattsson et al., 2015). Overall, studies did not find likely evidence of cardiovascular effects for other PFAS except for PFOA and PFOS (USEPA, 2024c; USEPA, 2024d).

Hepatic effects: Toxicology and/or epidemiology studies have reported associations between exposure to PFAS (PFBA, PFDA, PFUnA, PFDoDA, PFHxA, PFHxS, HFPO–DA, and PFBS) and hepatotoxicity. The results of the animal toxicology studies provide strong evidence that the liver is a sensitive target of PFHxS, PFNA, PFDA, PFUnA, PFBS, PFBA, PFDoDA, HFPO–DA and PFHxA toxicity. Observed effects in rodents include increases in liver weight, hepatocellular hypertrophy, hyperplasia, and necrosis (ATSDR, 2021; USEPA, 2021b; USEPA, 2022g; USEPA, 2023p). Increases in serum enzymes (such as ALT) and decreases in serum bilirubin were observed in several epidemiological studies of PFNA and PFDA (Nian et al., 2019; Jain and Ducatman, 2019; Liu et al., 2022; Cakmak et al., 2022). Associations between exposure to PFHxS and effects on serum hepatic enzymes are less consistent (Cakmak et al., 2022; Liu et al., 2022; Jain and Ducatman, 2019; Salihovic et al., 2018; Gleason et al., 2015). Mixed effects were observed for serum liver enzymes in epidemiological studies for PFNA (ATSDR, 2021).

Immune effects: Epidemiology studies have reported evidence of associations between PFDA or PFHxS exposure and antibody response to tetanus or diphtheria (Grandjean et al., 2012; Grandjean et al., 2017a; Grandjean et al., 2017b; Budtz-Jørgensen and Grandjean, 2018). There is also some limited evidence for decreased antibody response for PFNA, PFUnA, and PFDoDA, although there were notable inconsistencies across studies examining associations for these compounds (ATSDR, 2021). 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 inconsistent study results (ATSDR, 2021). The small number of studies investigating immunotoxicity in humans following exposure to PFHpA and PFHxA did not find associations (ATSDR, 2021; USEPA, 2023p; NASEM, 2022). Toxicology studies have reported evidence of associations between HFPO–DA exposure and effects on various immune-related endpoints in animals (ATSDR, 2021; USEPA, 2021b). 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 and PFBA. A study on PFNA found decreases in spleen and thymus weights and alterations in splenic lymphocyte phenotypes (ATSDR, 2021). Changes in spleen and thymus weights were reported in female mice and male/female rats in two 28-day gavage studies of PFDA, although the direction and dose-dependency of these changes in rats was inconsistent across studies (Frawley et al., 2018; NTP, 2018b).

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% CI: 1.09, 2.87) after adjustment for age, sex, sampling site, and interval between blood sampling and diagnosis. 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 total PFAS (sum of 12 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. Although these studies provide a suggestion of possible associations, the body of evidence does not permit conclusions about the relationship between COVID–19 infection, severity, or mortality, and exposures to PFAS.

In addition to the adverse health effects listed above, there was little or no evidence that exposure to the various PFAS is associated with the additional health effects summarized in this section.

Endocrine effects: Epidemiology studies have observed associations between serum PFHxS, PFNA, PFDA, and PFUnA and effects on thyroid stimulating hormone (TSH), triiodothyronine (T3), or thyroxine (T4) levels in serum or thyroid disease; however, there are notable inconsistencies across the studies identified in the available reports (ATSDR, 2021; NASEM, 2022). Toxicology studies have reported consistent associations between exposure to PFHxS, PFBA, PFHxA, and PFBS and effects on thyroid hormones, thyroid organ weight, and thyroid histopathology in animals; the endocrine system was a notable target of PFBS and PFHxS toxicity (ATSDR, 2021; USEPA, 2021a; USEPA, 2022g; USEPA, 2023p; NTP, 2018b; Ramhøj et al., 2018; Ramhøj et al., 2020; Butenhoff et al., 2009).

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). Exposure to PFDA has been associated with an increase in adiposity in adults (Blake et al., 2018; Christensen et al., 2018; Liu et al., 2018). However, evidence of associations was not suggestive or likely for any PFAS in this summary except for PFOA and PFOS (USEPA, 2024c; USEPA, 2024d). Evidence for changes such as maternal body weight gain, pup body weight, or other developmentally focused weight outcomes is strong but is considered under the Developmental effects category (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; USEPA, 2023p). Toxicology studies have not observed impaired renal function or morphological damage following exposure to PFHxS, PFDA, PFUnA, PFBS, PFBA, PFDoDA, or PFHxA (ATSDR, 2021). Associations with kidney weight in animals were observed for PFBS and HFPO–DA and was a notable target for PFBS toxicity (ATSDR, 2021; USEPA, 2021a; USEPA, 2021b; USEPA, 2023p).

Reproductive effects: A small number of epidemiology studies with inconsistent results evaluated possible associations between reproductive hormone levels and PFHxS, PFNA, PFDA, PFUnA, PFDoDA, or PFHxA. Some associations between PFAS (PFHxS, PFHxA, 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; Bach et al., 2018; Vélez et al., 2015). 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 and PFDoDA, and no histological alterations were observed for PFBS 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). Decreased uterine weights, changes in hormone levels, and increased time spent in diestrus were observed in studies of PFDA or PFHxS exposures (NTP, 2018b; Yin et al., 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; Khalil et al., 2016; Khalil et al., 2018). Toxicology studies reported no morphological alterations in bone or skeletal muscle in animals exposed to PFBA, PFDA, PFHxA, PFHxS, or PFBS, but evidence is based on a very small number of studies (NTP, 2018b; ATSDR, 2021; USEPA, 2022g; USEPA, 2023p).

Hematological effects: A single uninformative epidemiological study reported on blood counts in pregnant women exposed to PFHxA (USEPA, 2023p). 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 relatively high doses of PFHxS, PFDA, PFUnA, PFBS, PFBA, or PFDoDA (ATSDR, 2021; USEPA, 2022g; NTP, 2018b; 3M Company, 2000; Frawley et al., 2018). Toxicology studies observed robust evidence of association between PFHxA or HFPO–DA exposure and hematological effects, including decreases in red blood cell (RBC) number, hemoglobin, and percentage of RBCs in the blood (USEPA, 2021b; USEPA, 2023p). A small number of toxicology studies observed slight evidence of associations between exposure to PFHxS, PFDA, or PFBA and decreases in multiple red blood cell parameters and in prothrombin time; however, effects were not consistent (USEPA, 2022g; Butenhoff et al., 2009).

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 in this summary except for PFOA and PFOS (ATSDR, 2021; USEPA, 2021a; USEPA, 2023p).

Cancer effects: A small number of epidemiology studies reported limited associations between multiple PFAS (*i.e.,* PFHxS, PFDA, PFUnA, and FOSA) and cancer effects. No consistent associations were observed for breast cancer risk for PFHxS, PFHxA, PFNA, PFHpA, or PFDoDA; increased breast cancer risks were observed for PFDA and FOSA, but this was based on a single study (Bonefeld-Jørgensen et al., 2014), and one study observed non-significant increased risk for breast cancer risk and PFDA (Tsai et al., 2020). Exposure to PFHxS was associated with increased breast cancer risk in one study and with decreased breast cancer risk in two related studies (Bonefeld-Jørgensen et al., 2014; Ghisari et al., 2017; Tsai et al., 2020). No associations between exposure to 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 (Hardell et al., 2014), and PFUnA, but not for PFNA (ATSDR, 2021; USEPA, 2022g; USEPA, 2023p). A decreased risk of thyroid cancer was associated with exposure to PFHxS and PFDA in a single study (Liu et al., 2021). Epidemiological studies examining potential cancer effects were not identified for PFBS or PFBA (ATSDR, 2021; USEPA 2022g). No animal studies examined carcinogenicity of PFHxS or PFBA. Aside from a study that suggested an increased incidence of liver tumors in rats exposed to high doses of HFPO–DA, the limited number of available toxicology studies reported no evidence of associations between exposure to other PFAS (*i.e.,* PFDA and PFHxA) and risk of cancer (ATSDR, 2021; USEPA, 2021b; USEPA, 2023p). At this time, there is inadequate information to assess carcinogenic potential for PFAS other than PFOA, PFOS, and HFPO–DA.

I. Benefits Resulting From Disinfection By-Product Co-Removal

As part of its HRRCA, the 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 final PFAS NPDWR, co-occurring chemical contaminants such as SOCs, VOCs, and DBP precursors. In this section, the EPA presents a quantified estimate of the reductions in DBP formation potential that are likely to occur as a result of compliance with the final PFAS NPDWR. The methodology detailed here and in section 6.7.1 of USEPA (2024g) to estimate DBP reductions was externally peer reviewed by three experts in GAC treatment for PFAS removal and DBP formation potential (USEPA, 2023m). The external peer reviewers supported the EPA's approach and edits based on their recommendations for clarity and completeness are reflected in the following analysis and discussion.

DBPs are formed when disinfectants react with naturally occurring materials in water. There is a substantial body of literature on DBP precursor occurrence and THM4 formation mechanisms in drinking water treatment. Under the Stage 2 Disinfectants and Disinfection Byproducts Rule (Stage 2 DBP Rule, USEPA, 2006a), the EPA regulates 11 individual DBPs from three subgroups: THM4, HAA5, and two inorganic compounds (bromate and chlorite). 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; Beane Freeman et al., 2017; King and Marrett, 1996; Regli et al., 2015; USEPA, 2019d; Villanueva et al., 2004; Villanueva et al., 2006; Villanueva et al., 2007). These studies considered THM4 as surrogate measures for DBPs formed from the use of chlorination that may co-occur. The relationships between exposure to DBPs, specifically THM4 and other halogenated compounds resulting from water chlorination, and bladder cancer are further discussed in section 6.7 of USEPA (2024g). Reductions in exposure to THM4 is expected to yield public health benefits, including a decrease in bladder cancer incidence (Regli et al., 2015). Among other things, Weisman et al. (2022) found that there is even a stronger weight of evidence linking DBPs and bladder cancer since the promulgation of the 2006 Stage 2 DBP regulations (USEPA, 2006a) and publication of Regli et al. (2015). While not the regulated contaminant for this rulemaking, the expected reduction of DBP precursors and subsequent DBPs that result from this rulemaking are anticipated to reduce cancer risk in the U.S. population.

GAC adsorption has been used to remove SOCs, 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 and Higgins, 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 BAT for the Stage 2 DBP Rule. Dissolved organic matter (DOM) can be removed by GAC through adsorption and biodegradation (Crittenden et al., 1993; Kim et al., 1997; Yapsakli et al., 2010). GAC is well-established for removal of THM and HAA precursors (Cheng et al., 2005; Dastgheib et al., 2004; Iriarte-Velasco et al., 2008; Summers et al., 2013; Cuthbertson et al., 2019; Wang et al., 2019). 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 and Summers, 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, there is limited information about PFAS removal and co-occurring reductions in DBPs, specifically THMs. To help inform its EA, the EPA relied on the DBP Information Collection Rule Treatment Study Database and DBP formation studies to estimate reductions in THM4 (ΔTHM4) 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 EPA's 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. Evaluation of the expected reductions in bladder cancer risk resulting from treatment of PFAS in drinking water involves five steps:

1. Estimating the number of systems expected to install GAC treatment in compliance with the final 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 excess 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; and
5. Estimating the economic value of reducing bladder cancer morbidity and mortality from baseline to regulatory alternative levels, using COI measures and the Value of a Statistical Life, respectively.

The EPA expects PWSs that exceed the PFAS MCLs to consider both treatment and nontreatment options to achieve compliance with the drinking water standard. The EPA assumes that the populations served by systems with EP expected to install GAC based on the compliance forecast detailed in section 5.3 of USEPA (2024g) will receive the DBP exposure reduction benefits. The 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 the EPA assumed no additional DBP benefits for an estimated percentage of systems that elect this compliance option. Lastly, the 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. The EPA also assumed that the PWSs included in this analysis use chlorine only for disinfection and have conventional treatment in place prior to GAC installation.

The EPA used the relationship between median raw water TOC levels and changes in THM4 levels estimated in the 1998 DBP Information Collection Rule to estimate changes in THM4 concentrations in the finished water of PWSs fitted with GAC treatment. For more detail on the approach the EPA used to apply changes in THM4 levels to PWSs treating for PFAS under the final rule, please see section 6.7 of USEPA (2024g).

The EPA models a scenario where reduced exposures to THM4 begin in 2029. Therefore, the 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 2029) and to reduced THM4 levels from 2029 through 2105. Rather than modeling individual locations (*e.g.,* PWS), the 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, the EPA used national-level population estimates to distribute the SDWIS populations based on single-year age and sex and to extrapolate the age- and sex-specific populations to future years. Appendix B of USEPA (2024g) provides additional details on estimation of the affected population.

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. 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 10,000 exposed individuals (10^{-4}) per 1 µg/L increase in THM4. The linear slope factor developed by Regli et al. (2015) enables estimation of the changes in the lifetime bladder cancer risk associated with lifetime exposures to reduced THM4 levels. Weisman et al. (2022) applied the dose-response information from Regli et al. (2015) and developed a robust, national-level risk assessment of DBP impacts, where the authors estimated that approximately 8,000 of 79,000 annual U.S. bladder cancer cases are attributable to chlorination DBPs, specifically associated with THM4 concentrations.

The EPA estimated changes in annual bladder cancer cases and annual excess 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.

The 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. The estimated risk reduction from lower exposure to DBPs in drinking water was calculated based on changes in THM4 levels used as inputs to the Regli et al. (2015)-based health impact function, described in more detail in section 6.7 of USEPA (2024g). 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. 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 excess bladder cancer population mortality.

The EPA used the Value of a Statistical Life to estimate the benefits of reducing mortality associated with bladder cancer in the affected population. The EPA used the cost of illness-based valuation to estimate the benefits of reducing morbidity associated with bladder cancer. Specifically, the EPA used bladder cancer treatment-related medical care and opportunity cost estimates from Greco et al. (2019). Table 63 shows the original cost of illness estimates from Greco et al. (2019), along with the values updated to $2022 used in this analysis.

The EPA received public comments on the EA for the proposed rule related to the EPA's use of cost of illness information for morbidity valuation. Specifically, a couple of commenters recommended that the EPA use willingness to pay information (instead of cost of illness information) when valuing the costs associated with non-fatal illnesses, stating that willingness to pay information better accounts for lost opportunity costs (*e.g.,* lost productivity and pain and suffering) associated with non-fatal illnesses (USEPA, 2024k). To better account for these opportunity costs, the EPA used recently available willingness to pay values in a sensitivity analysis for morbidity associated with bladder cancer. The sensitivity analysis results show that when willingness to pay values are used in bladder cancer benefits analysis, morbidity benefits are increased by approximately 19.9 percent. See appendix O of the EA for full details and results on the willingness to pay sensitivity analyses.

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Table 63: 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 ($2022)**[c]	**Cost in Subsequent Years ($2022)**[c]
Non-invasive	Medical care	9,133	916	$12,851	$1,289
	Opportunity cost	4,572	24	$6,212	$33
	Total cost	13,705	941	$19,062	$1,321
Invasive	Medical care	26,951	2,455	$37,922	$3,454
	Opportunity cost	10,513	77	$14,283	$105
	Total cost	37,463	2,532	$52,205	$3,559

Notes:

[a] 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.

[b] The estimates come from Greco et al. (2019).

[c] To adjust for inflation, the EPA used U.S. Bureau of Labor Statistics Consumer Price Index for All Urban Consumers: Medical Care Services in U.S. (City Average).

Tables 64 to 67 presents the estimated changes in non-fatal bladder cancer cases and bladder cancer-related deaths from exposure to THM4 due to implementation of GAC treatment by option. The EPA estimated that, over the evaluation period, the final rule will result in annualized benefits from avoided bladder cancer cases and deaths of $380 million.

Table 64: National Bladder Cancer Benefits, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L, each and Hazard Index of 1) (Million $2022)

Benefits Category	2% Discount Rate		
	5th Percentile[1]	Expected Benefits	95th Percentile[1]
Number of Non-Fatal Bladder Cancer Cases Avoided	5,781.0	7,313.0	8,912.7
Number of Bladder Cancer-Related Deaths Avoided	2,029.6	2,567.8	3,129.9
Total Annualized Bladder Cancer Benefits (Million $2022) [2, 3]	$300.64	$380.41	$463.74

Notes: Quantifiable benefits are increased under final rule table results relative to the other options presented because of modeled PFHxS occurrence, which results in additional quantified benefits from co-removed PFOA and PFOS.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized annualized benefits in this table.

[3] When using willingness-to-pay metrics to monetize morbidity benefits, total annualized bladder cancer benefits are increased by $75.87 million.

Table 65: National Bladder Cancer Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L) (Million $2022)

Benefits Category	**2% Discount Rate**		
	5th Percentile[1]	**Expected Benefits**	**95th Percentile[1]**
Number of Non-Fatal Bladder Cancer Cases Avoided	5,789.3	7,312.9	8,896.0
Number of Bladder Cancer-Related Deaths Avoided	2,032.5	2,567.8	3,123.2
Total Annualized Bladder Cancer Benefits (Million $2022)[2]	$301.06	$380.41	$462.73

Notes:

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized annualized benefits in this table.

Table 66: National Bladder Cancer Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L) (Million $2022)

Benefits Category	**2% Discount Rate**		
	5th Percentile[1]	**Expected Benefits**	**95th Percentile[1]**
Number of Non-Fatal Bladder Cancer Cases Avoided	4,739.4	6,034.0	7,367.1
Number of Bladder Cancer-Related Deaths Avoided	1,664.0	2,118.7	2,587.1
Total Annualized Bladder Cancer Benefits (Million $2022) [2]	$246.48	$313.88	$383.32

Notes:

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized annualized benefits in this table.

Table 67: National Bladder Cancer Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L) (Million $2022)

Benefits Category	**2% Discount Rate**		
	5th Percentile[1]	**Expected Benefits**	**95th Percentile[1]**
Number of Non-Fatal Bladder Cancer Cases Avoided	2,326.9	3,087.9	3,885.3
Number of Bladder Cancer-Related Deaths Avoided	816.8	1,084.3	1,364.3
Total Annualized Bladder Cancer Benefits (Million $2022) [2]	$120.97	$160.62	$202.14

Notes:

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.J of this preamble and Table 75. This range does not include the uncertainty described in Table 62.

[2] See Table 72 for a list of the nonquantifiable benefits, and the potential direction of impact these benefits would have on the estimated monetized annualized benefits in this table.

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J. Comparison of Costs and Benefits

This section provides a comparison of the incremental costs and benefits of the final rule, as described in chapter 7 of the EA. Included here are estimates of total quantified annualized costs and benefits for the final rule and regulatory alternative MCLs under options 1a-1c, as well as considerations for the nonquantifiable costs and benefits. The EPA's determinations as to whether the costs are justified by the benefits must be based on an analysis of both the quantified costs and benefits as well as the nonquantifiable benefits and nonquantifiable costs, per SDWA 1412(b)(3)(C)(I)–(III).

The incremental cost is the difference between quantified costs that will be incurred if the final rule is enacted over 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 final rule.

Table 68 provides the incremental quantified costs and benefits of the final rule at a 2 percent discount rate in 2022 dollars. The top 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, the estimates are the expected (mean) values and the 5th percentile and 95th percentile quantified estimates 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. Therefore, these distributions reflect the joint effect of the multiple sources of variability and uncertainty for quantified costs, quantified benefits, and the baseline uncertainties such as PFAS occurrence, as detailed in sections 5.1.2, 6.1.2, and chapter 4 of the EA, respectively (USEPA, 2024g). For further discussion of the quantified uncertainties in the EA, see section XII.K of this preamble.

The third row shows net quantified benefits (benefits minus costs). The net annual quantified incremental benefits are $760,000. Because of the variation associated with the use of statistical models such as SafeWater MCBC, the modeled quantified net benefits are nearly at parity. The uncertainty range for net benefits is a negative $622 million to $725 million. Additional uncertainties are presented in Table 72.

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Table 68: Annualized Quantified National Costs and Benefits, Final Rule (PFOA and PFOS MCLs of 4.0 ng/L each, PFHxS, PFNA, and HFPO-DA MCLs of 10 ng/L each, and Hazard Index of 1) (Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Total Annualized Rule Costs [2,3,4]	$1,435.70	$1,548.64	$1,672.10
Total Annualized Rule Benefits [4]	$920.91	$1,549.40	$2,293.80
Total Net Benefits	-$621.99	$0.76	$725.07

Notes:

Detail may not add exactly to total due to independent rounding. Quantifiable benefits are increased under final rule table results relative to the other options presented because of modeled PFHxS occurrence, which results in additional quantified benefits from co-removed PFOA and PFOS.

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.K of this preamble and Tables 74 and 75. This range does not include the uncertainty described in Table 43 for costs and Table 62 for benefits.

[2] The national level cost estimates for PFHxS are reflective of both the total national cost for PFHxS individual MCL exceedances, and Hazard Index MCL exceedances where PFHxS is present above its HBWC while one or more other Hazard Index PFAS is also present in that same mixture. Total quantified national cost values do not include the incremental treatment costs associated with the co-occurrence of PFNA, HFPO-DA, and PFBS. The EPA has considered the additional national costs of the Hazard Index and individual MCLs associated with HFPO-DA, PFBS, and PFNA occurrence in a quantified sensitivity analysis; see appendix N, section 3 of the EA (USEPA, 2024e) for the analysis and more information.

[3] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic 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, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N, section 2 of the EA (USEPA, 2024e) for additional detail.

[4] See Table 72 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.

Tables 69 to 71 summarize the total annual costs and benefits for options 1a, 1b, and 1c, respectively.

Table 69: Annualized Quantified National Costs and Benefits, Option 1a (PFOA and PFOS MCLs of 4.0 ng/L) (Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Total Annualized Rule Costs [2,3]	$1,423.60	$1,537.07	$1,660.30
Total Annualized Rule Benefits [3]	$913.05	$1,542.74	$2,280.10
Total Net Benefits	-$613.79	$5.67	$722.09

Notes:

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.K of this preamble and Tables 74 and 75. This range does not include the uncertainty described in Table 43 for costs and Table 62 for benefits.

[2] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic 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, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N, section 2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 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.

Table 70: Annualized Quantified National Costs and Benefits, Option 1b (PFOA and PFOS MCLs of 5.0 ng/L) (Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Total Annualized Rule Costs [2,3]	$1,102.60	$1,192.13	$1,291.40
Total Annualized Rule Benefits [3]	$768.55	$1,296.84	$1,919.30
Total Net Benefits	-$414.34	$104.71	$710.38

Notes:

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.K of this preamble and Tables 74 and 75. This range does not include the uncertainty described in Table 43 for costs and Table 62 for benefits.

[2] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic 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, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N, section 2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 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.

Table 71: Annualized Quantified National Costs and Benefits, Option 1c (PFOA and PFOS MCLs of 10.0 ng/L) (Million $2022)

	2% Discount Rate		
	5th Percentile[1]	**Expected Value**	**95th Percentile[1]**
Total Annualized Rule Costs [2,3]	$462.87	$499.29	$540.68
Total Annualized Rule Benefits [3]	$397.28	$664.45	$970.70
Total Net Benefits	-$96.42	$165.16	$468.54

Notes:

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

[1] The 5th and 95th percentile range is based on modeled variability and uncertainty described in section XII.K of this preamble and Tables 74 and 75. This range does not include the uncertainty described in Table 43 for costs and Table 62 for benefits.

[2] PFAS-contaminated wastes are not considered RCRA regulatory or characteristic 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, the EPA conducted a sensitivity analysis with an assumption of hazardous waste disposal for illustrative purposes only. See appendix N, section 2 of the EA (USEPA, 2024e) for additional detail.

[3] See Table 72 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

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The benefit-cost analysis reported dollar figures presented above reflect benefits and costs that could be quantified for each regulatory alternative MCL given the best available scientific data. The EPA notes that these quantified benefits are estimated using a cost-of-illness approach. In the sensitivity analysis, the EPA also calculated quantified benefits using a willingness-to-pay approach instead of cost of illness information, for non-fatal RCC and bladder cancer illnesses. In this case, the estimated expected quantified annualized costs are approximately $1,549 million and the estimated expected quantified annualized benefits increase to approximately $1,632 million, resulting in approximately $84 million in expected annualized net benefits. See appendix O of the EA for further discussion.

The quantified benefit-cost results above are not representative of all benefits and costs anticipated under the final NPDWR. Due to occurrence, health, and economic data limitations, there are several adverse health effects associated with PFAS exposure and costs associated with treatment that the EPA could not estimate quantitatively.

PFAS exposure is associated with a wide range of adverse health effects, including reproductive effects such as decreased fertility; 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. Based on the available data at rule proposal and submitted by public commenters, the EPA is only able to quantify three PFOA- and PFOS-related health endpoints (*i.e.,* changes in birth weight, CVD, and RCC) in the national analysis.

The EPA also evaluated the impacts of PFNA on birth weight and PFOS on liver cancer in quantitative sensitivity analyses (See appendices K and O of USEPA, 2024e, respectively). Those analyses demonstrate that there are potentially significant other quantified benefits not included in the national quantified benefits above: for example, the EPA's quantitative sensitivity analysis for PFNA (found in appendix K of USEPA, 2024e) found that the inclusion of a 1 ng/L PFNA reduction could increase annualized birth weight benefits by a factor of 5.6–7.8 in a model system serving 100,000 people, relative to a scenario that quantified a 1 ng/L reduction in PFOA and a 1 ng/L reduction in PFOS only. In the case of PFOS impacts on liver cancer, the EPA has estimated an expected value of $4.79 million in benefits via the reduction in liver cancer cases anticipated to be realized by the final rule. All regulatory alternatives are expected to produce substantial additional benefits from all the other adverse health effects avoided, but that cannot be quantified at this time. Treatment responses implemented to remove PFOA and PFOS under regulatory alternative MCLs under options 1a-1c 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 & Contaminant Background Support Document* (USEPA, 2024b). The final rule is expected to produce the greatest reduction in exposure to PFAS compounds as compared to the three regulatory alternative MCLs because it includes PFHxS, PFNA, HFPO–DA, and PFBS in the regulation. Inclusion of the Hazard Index will trigger more systems to treat (as shown in section 4.4.4 of the EA) and provides enhanced public health protection by ensuring reductions of these additional compounds when present above the Hazard Index of 1. Specifically, as Hazard Index PFAS are reduced, the EPA anticipates additional public health benefits from avoided cardiovascular, developmental, and immune effects. For further discussion of the quantitative and qualitative benefits associated with the final rule, see section 6.2 of the EA.

The EPA also expects that the final rule will result in additional nonquantifiable costs. As noted above, the Hazard Index and individual MCLs are expected to trigger more systems into more frequent monitoring and treatment. In the national cost analysis, the EPA quantified the national treatment and monitoring costs associated with the PFHxS individual MCL and the Hazard Index associated costs based on PFHxS occurrence only. Due to occurrence data limitations, cost estimates for PFNA, PFBS, and HFPO–DA are less precise relative to those for PFOA, PFOS, and PFHxS compounds, and as such, the EPA performed a quantitative sensitivity analysis of the national cost impacts associated with Hazard Index exceedances resulting from PFNA, PFBS, and HFPO–DA and the PNFA and HFPO–DA individual MCLs to understand and consider the potential magnitude of costs associated with treating these three PFAS. The EPA found that in addition to the costs associated with PFHxS exceedances, which are included in the national cost estimate, the Hazard Index and individual MCLs for PFNA and HFPO–DA could cost an additional $82.4 million per year. In cases where these compounds co-occur at locations where PFAS treatment is implemented because of nationally modeled PFOA, PFOS, and PFHxS occurrence, treatment costs are likely to be marginally higher as treatment media estimated bed-life is shortened. In instances where concentrations of PFNA, HFPO–DA, and PFBS are high enough to cause or contribute to a Hazard Index exceedance when the concentrations of PFOA, PFOS, and PFHxS would not have already otherwise triggered treatment, the national 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 its respective HBWC in isolation (*i.e.,* less than 10 ng/L) then the quantified costs underestimate the impacts of the final rule. See appendix N.3 of the EA for a sensitivity analysis of additional treatment costs at systems with Hazard Index exceedances (USEPA, 2024e). See appendix N.4 for a sensitivity analysis of the marginal costs of HFPO–DA and PFNA MCLs. For further discussion of how the EPA considered the costs of the five individual MCLs and the HI MCL, see section XII.A.4 of this preamble.

Commenters suggested that another potential source of non-quantified cost comes from the fact that the EPA has proposed designating PFOA and PFOS as CERCLA hazardous substances (USEPA, 2022l). Stakeholders have expressed concern to the 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. The designation of PFOA and PFOS as CERCLA hazardous substances would not require waste (*e.g.,* biosolids, treatment residuals, etc.) to be treated in any particular fashion, nor disposed of at any specific particular type of landfill. The designation also would not restrict, change, or recommend any specific activity or type of waste at landfills. In its estimated national costs, the EPA has maintained the assumption that disposal does not have to occur in accordance with hazardous waste standards thus national costs may be underestimated. The 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 of USEPA, 2024e).

Table 72 provides a summary of the likely impact of nonquantifiable benefit-cost categories. In each case, the 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 of the EA identify the key methodological limitations and the potential effect on the cost or benefit estimates, respectively. Additionally, Table 73 summarizes benefits and costs that are quantified and nonquantifiable under the final rule.

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Table 72: Potential Impact of Nonquantifiable Benefits (B) and Costs (C)

Source	**(Final Rule)**	**Option 1a**	**Option 1b**	**Option 1c**
Nonquantifiable PFOA and PFOS health endpoints	B: underestimate	B: underestimate	B: underestimate	B: underestimate
Limitations with available occurrence data for PFNA, HFPO-DA, and PFBS	B+C: underestimate	n/a	n/a	n/a
Nonquantifiable HI (PFHxS, PFNA, HFPO-DA, and PFBS) health endpoints	B: underestimate	n/a	n/a	n/a
Limitations with available 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 (including HI)	B+C: underestimate	B+C: underestimate	B+C: underestimate	B+C: underestimate

Table 73: Summary of Quantified and Nonquantifiable Benefits and Costs in the National Analysis

Category	**Quantified**	**Non-quantified**	**Methods (EA Report Section where Analysis is Detailed)**
	Costs		
PWS treatment costs [1]	X		Section 5.3.1
PWS sampling costs	X		Section 5.3.2.2
PWS implementation and administration costs	X		Section 5.3.2.1
Primacy agency rule implementation and administration costs	X		Section 5.3.2
Hazardous waste disposal for treatment media		X	Section 5.6
POU not in compliance forecast		X	Section 5.6
	Benefits		
PFOA and PFOS birth weight effects	X		Section 6.4
PFOA and PFOS cardiovascular effects	X		Section 6.5
PFOA and PFOS RCC	X		Section 6.6
Health effects associated with DBPs, specifically bladder cancer	X		Section 6.7
Other PFOA and PFOS health effects		X	Section 6.2.2.2
Health effects associated with HI compounds (PFHxS, PFNA, HFPO-DA, PFBS)		X	Section 6.2
Health effects associated with other PFAS		X	Section 6.2

Notes:

1 The national level cost estimates for PFHxS are reflective of both the total national cost for PFHxS individual MCL exceedances, and HI MCL exceedances where PFHxS is present above its HBWC while one or more other HI PFAS is also present in that same mixture. Total quantified national cost values do not include the incremental treatment costs associated with the cooccurrence of HFPO-DA, PFBS, and PFNA. EPA has considered the additional national costs of the HI and individual MCLs associated with HFPO-DA, PFNA, and PFBS occurrence in a quantified sensitivity analysis; see appendix N, section N.3 for the analysis and more information. See appendix N, section N.3 for a sensitivity analysis of additional treatment costs from systems with HI and PFNA and HFPO-DA MCL exceedances. For further discussion of how the EPA considered the costs of the five individual MCLs and the HI MCL, see section XII.A.4 of this preamble.

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Sections XII.B to XII.K of this preamble summarize the results of this final rule analysis. The EPA discounted the estimated monetized cost and benefit values using a 2 percent discount rate, consistent with OMB Circular A–4 (OMB, 2003; OMB, 2023) guidance. The U.S. White House and Office of Management and Budget recently finalized and re-issued the A–4 and A–94 benefit-cost analysis guidance (see OMB Circular A–4, 2023), and the update includes new guidance to use a social discount rate of 2 percent. The updated OMB Circular A–4 states that the discount rate should equal the real (inflation-adjusted) rate of return on long-term U.S. government debt, which provides an approximation of the social rate of time preference. This rate for the past 30 years has averaged around 2.0 percent per year in real terms on a pre-tax basis. OMB arrived at the 2 percent discount rate figure by considering the 30-year average of the yield on 10-year Treasury marketable securities, and the approach taken by OMB produces a real rate of 1.7 percent per year, to which OMB added a 0.3 percent per-year rate to reflect inflation as measured by the personal consumption expenditure (PCE) inflation index. The OMB guidance states that Agencies must begin using the 2 percent discount rate for draft final rules that are formally submitted to OIRA after December 31, 2024. The updated OMB Circular A–4 guidance further states that ''to the extent feasible and appropriate, as determined in consultation with OMB, agencies should follow this Circular's guidance earlier than these effective dates.'' Given the updated default social discount rate prescribed in the OMB Circular A–4 and also public input received on the discount rates considered by the EPA in the proposed NPDWR, for this final rule, the EPA estimated national benefits and costs at the 2 percent discount rate for the final rule and incorporated those results into the final economic analysis. Since the EPA proposed this NPDWR with the 3 and 7 percent discount rates based on guidance in the previous version of OMB Circular A–4, the EPA has kept the presentation of results using these discount rates in appendix P. The Administrator reaffirms his determination that the benefits of the rule justify the costs. The EPA's determination is based on its analysis under in SDWA section 1412(b)(3)(C) of the quantifiable benefits and costs at the 2 percent discount rate, in addition to at the 3 and 7 percent discount rate, as well as the nonquantifiable benefits and costs. The EPA found that significant nonquantifiable benefits are likely to occur from the final PFAS NPDWR.

The quantified analysis is limited in its characterization of uncertainty. In section XII.I, Table 68 of this preamble, the EPA provides 5th and 95th percentile values associated with the 2 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 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 TOC in a system's source water (which impacts GAC O&M costs); the demographic composition of the system's 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 RCC; and the cap placed on the cumulative RCC risk reductions due to reductions in serum PFOA. These modeled sources of uncertainty are discussed in more detail in section XII.K of this preamble. While the agency reports only the 5th and 95th percentile values, the EPA notes that additional information can be obtained from looking at the whole uncertainty distribution of annualized net benefits (*i.e.,* the distribution of annualized differences between total monetize benefits and total monetized costs).

The quantified 5th and 95th percentile values do not include a number of factors that 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 final rule cost estimates that are not quantified in the uncertainty analysis are detailed in Table 43 of this preamble. 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 the EPA's estimated distribution. The 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 62 of this preamble 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 the 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 (cardiovascular, developmental, and renal cell carcinoma) do not occur; the distribution of population by size and demographics across EP 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 Value of Statistical Life. 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 PWSs with 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 EP within individual systems; and the Value of Statistical Life 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 the EPA with regard to population size at NTNCWSs, 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 source of 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 (cardiovascular, developmental, and renal cell carcinoma) do not occur. One source of possible underestimation of benefits not accounted for in the quantified analysis 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 72 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 benefits. Tables 43 and 62 also provide additional information on a number of these nonquantifiable categories.

For the nonquantifiable costs, the 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 individual MCLs for PFNA and HFPO–DA or the Hazard Index and have to install PFAS treatment. The EPA expects that the quantified national costs, which do not include HFPO–DA, PFNA, and PFBS treatment costs are marginally underestimated (on the order of 5%) as a result of this lack of sufficient nationally representative occurrence data. In an effort to better understand and consider the costs associated with treatment of the PFNA and HFPO–DA MCLs and potentially co-occurring HFPO–DA, PFNA, and PFBS at systems both with and without PFOA, PFOS and PFHxS occurrence in exceedance of the MCLs the EPA performed a quantitative sensitivity analysis of the national cost impacts associated with Hazard Index MCL exceedances resulting from HFPO–DA, PFNA, and PFBS and/or individual MCL exceedances of PFNA and HFPO–DA. The analysis is discussed in section 5.3.1.4 and appendix N.3 of the EA (USEPA, 2024l; USEPA, 2024e). 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 final rule could both increase costs to the extent that they reduce media life. The 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 final 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 costs. Additionally, appendix N.2 of the EA (USEPA, 2024e) contains a sensitivity analysis that estimates possible additional national annualized costs of $99 million, which would accrue to systems if the waste filtration media from GAC and IX were handled as RCRA regulatory or characteristic hazardous waste. This sensitivity analysis includes only disposal costs and does not consider other potential environmental benefits and costs associated with the disposal of the waste filtration media.

There are significant nonquantifiable sources of benefits that were not captured in the quantified benefits estimated for the proposed rule. While the EPA was able to monetize some of the PFOA and PFOS benefits related to CVD, infant birth weight, and RCC effects, the agency was unable to quantify additional reductions in negative health impacts in the national quantitative analysis. In addition to the national analysis for the final rule, the agency developed a sensitivity analysis assessing liver cancer impacts, which is detailed in appendix O of the EA (USEPA, 2024e). The 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. See section XII.F of this preamble for additional information on the nonquantifiable impacts of PFOA and PFOS. Further, the agency did not quantify any health benefits associated with the potential reductions in Hazard Index PFAS, which include PFHxS, HFPO–DA, PFNA, and PFBS, or other co-occurring non-regulated PFAS which would be removed due to the installation of required filtration technology at those systems that exceed the final MCLs. The nonquantifiable benefits categories associated with exposure to PFHxS, HFPO–DA, PFNA, and PFBS include developmental, cardiovascular, immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, and carcinogenic effects. In addition, the EPA did not quantify the potential developmental, cardiovascular, immune, hepatic, endocrine, metabolic, reproductive, musculoskeletal, or carcinogenic impacts related to the removal of other co-occurring non-regulated PFAS. See section XII.G of this preamble 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 additional positive health benefits. In total these nonquantifiable benefits are anticipated to be significant and are discussed qualitatively in section 6.2 of the EA (USEPA, 2024g).

To fully weigh the costs and benefits of the action, the agency considered the totality of the monetized values, the potential impacts of the nonquantifiable uncertainties described above, the nonquantifiable costs and benefits, and public comments received by the agency related to the quantified and qualitative assessment of the costs and benefits. For the final rule, the EPA is reaffirming the Administrator's determination made at proposal that the quantified and nonquantifiable benefits of the rule justify its quantified and nonquantifiable costs (88 FR 18638; USEPA, 2023f).

K. Quantified Uncertainties in the Economic Analysis

The EPA characterized sources of uncertainty in its estimates of costs expected to result from the final rule. The EPA conducted Monte-Carlo based uncertainty analysis as part of SafeWater MCBC. With respect to the cost analysis, the EPA modeled the sources of uncertainty in Table 74.

Table 74: Quantified Sources of Uncertainty in Cost Estimates

Source	Description of Uncertainty
EP concentration of PFAS compounds	The concentration and co-occurrence at each PWS EP of each modeled compound is unknown. The cost analysis uses EP concentrations simulated with system level distributions produced by the Bayesian hierarchical Markov chain Monte Carlo (MCMC) occurrence model (see section 4.4 in EA). The iterative MCMC approach (4,000 iterations) probabilistically estimates parameters for system-level distributions to capture uncertainty. The simulated EP concentrations then reflect the system-level distribution from which they are drawn across 4,000 iterations. Further details on the MCMC model are available in Cadwallader et al. (2022). For more information on the application of the model in this analysis, see chapter 4.4 and appendix A. For more information on the data and analyses that the EPA used to develop national estimates of PFAS occurrence in public drinking water systems see USEPA (2024b).
TOC concentration	The TOC value assigned to each system is from a distribution derived from the SYR4 ICR database (see section 5.3.1.1 in EA)
Compliance technology unit cost curve selection	Cost curve selection varies with baseline PFAS concentrations and includes a random selection from a distribution across feasible technologies (see section 5.3.1.2 in EA), and random selection from a triangular distribution of low-, mid-, and high-cost equipment (25 percent, 50 percent, and 25 percent, respectively).

For each iteration, SafeWater MCBC assigned new values to the three sources of modeled uncertainty as described in Table 74, 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 CI 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 appendices A and L of USEPA (2024e).

Additionally, the EPA characterized sources of uncertainty in its analysis of potential 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 final 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 75 provides an overview of the specific sources of uncertainty that the EPA quantified in the benefits analysis. In addition to these sources of uncertainty, reported uncertainty bounds also reflect the following upstream sources of uncertainty: baseline PFAS occurrence, affected population size and demographic composition, and the magnitude of PFAS concentration reductions. These analysis-specific sources of uncertainty are further described in appendix L of USEPA (2024e).

Table 75: 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 [1], and RCC) are based either on the EPA meta-analyses or medium- or high-confidence studies that provide a central estimate and a CI for the slope factors. The EPA assumed that the slope factors would have a normal distribution within their range.
RCC risk reduction cap	The EPA implemented a cap on the cumulative RCC risk reductions due to reductions in serum PFOA based on the population attributable fraction (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.

Note:

1 The slope factors contributing to the CVD benefits analysis include the relationship between TC and PFOA and PFOS, the relationship between HDLC and PFOA and PFOS, and the relationship between blood pressure and PFOS.

XIII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094 Modernizing Regulatory Review

1. Significant Regulatory Action

This action is a ''significant regulatory action,'' as defined under section 3(f)(1) of Executive Order (E.O.) 12866, as amended by E.O. 14094. Accordingly, the EPA submitted this action to the Office of Management and Budget (OMB) for E.O. 12866 review. Documentation of any changes made in response to E.O. 12866 review is available in the docket. The EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis, the Economic Analysis (EA; USEPA, 2024g), is also available in the docket and is summarized in section XII of this preamble.

2. Additional Analysis Under E.O. 12866

The EPA evaluated commenters recommendations summarized in this section to quantify the greenhouse gas (GHG) impacts associated with the rule in light of E.O. 12866, Regulatory Planning and Review, and E.O. 13990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. For the final rule, the EPA has conducted an additional analysis of the disbenefits associated with operation of treatment technologies to comply with the standard. This analysis is summarized here and detailed in the EA for the Final per- and polyfluoroalkyl substances (PFAS) National Primary Drinking Water Regulation (NPDWR; USEPA, 2024g).

a. Proposed Rule

In the proposed rule, the EPA did not quantify and monetize potential GHG emissions impacts that would occur as a result of operating treatment technologies to comply with the proposed rule because quantification of such impacts is not required for the Health Risk Reduction and Cost Analysis (HRRCA) under the Safe Drinking Water Act (SDWA). The EPA evaluated commenters recommendations and summarized that the EPA should quantify and monetize the GHG emissions impacts associated with the rule in light of E.O. 13990, Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis.

b. Summary of Major Public Comments and EPA Responses

Several commenters recommend ''. . . that the agency consider the social costs of carbon as part of any PFAS rule's cost analysis to be comprehensive as well as to understand how this rule may have unintended consequences like increased social costs relating to carbon dioxide emissions.'' Commenters asserted that ''[n]ot including the social costs of carbon and other social costs hinders the Administrator from having all necessary information to set the perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) drinking water standard at a level that maximizes health risk reduction benefits at a cost that is justified, given those benefits.'' Commenters pointed to the GHG emissions associated with production, reactivation, and delivery of treatment media, focusing on granular activated carbon (GAC) in particular; construction associated with the installation of the treatment technology at the entry point (EP); electricity used to operate treatment technologies; and transportation and disposal of drinking water treatment residuals to comply with the PFAS NPDWR. Two commenters provided their own quantified estimates for some aspects of CO_2 emissions. One commenter estimated that the climate disbenefits from CO_2 emissions associated with increased electricity use for additional pumping, lighting, and ventilation in treatment plants would be ''$2.5M to $6.8M at 2.5 and 1.5 percent discount rates, respectively, in 2026; and $3.6M to $8.6M at 2.5 and 1.5 percent discount rates, respectively, in 2046.'' Another commenter used a life cycle analysis paper that provides one estimate for the carbon footprint of producing and using GAC and estimates that the climate damages from the CO_2 emissions associated with increased GAC media use ''. . . could have a social cost of more than $160 million annually.'' One commenter stated that the EPA has performed this analysis in other rulemakings, specifically a 2023 proposed air rulemaking (88 FR 25080), and notes that in that regulatory impact analysis (RIA; USEPA, 2023u), ''EPA included the social cost of carbon for the electricity required to operate the air pollution controls.''

The EPA disagrees with commenters that SDWA requires the EPA to quantify and consider the climate disbenefits associated with GHG emission increases from this final rule in the HRRCA. The HRRCA requirements of SDWA 1412 (b)(3)(C) require the agency to analyze ''quantifiable and nonquantifiable costs . . . that are likely to occur *solely* as a result of compliance with the maximum contaminant level'' (emphasis added). Therefore, the EPA considered as part of its HRRCA analysis the compliance costs to facilities, including the costs to purchase electricity required to operate the treatment technologies. Since the climate disbenefits from GHG emissions associated with producing electricity necessary to operate the treatment technologies account for climate impacts associated with the CO_2 emissions and associated costs to society, they do not qualify as compliance costs to public water systems (PWSs) that are part of the required HRRCA analysis under SDWA. For this reason, the EPA included compliance costs to PWSs but not climate disbenefits from GHG emissions associated with the production, reactivation, and delivery of treatment media; construction associated with the installation of the treatment technology at EP; electricity used to operate treatment technologies; and transportation and disposal of drinking water treatment residuals in the cost consideration for the final PFAS NPDWR.

The EPA is committed to understanding and addressing climate change impacts in carrying out the agency's mission of protecting human health and the environment. While the EPA is not required by SDWA 1412(b)(3)(C) to consider climate disbenefits under the HRRCA the agency has estimated the potential climate disbenefits caused by increased on-site electricity demand associated with removing PFAS from drinking water. As explained in section V of this preamble, the EPA's final rule is based on the EPA's record-based analysis of the statutory factors in SDWA 1412(b), and this disbenefits analysis is presented solely for the purpose of complying with E.O. 12866. Circular A–4 states ''[l]ike other benefits and costs, an effort should be made to quantify and monetize additional effects when feasible and appropriate'' (OMB, 2023). The scope of the monetized climate disbenefits analysis is limited to the climate impacts associated with the CO_2 emissions from increased electricity to operate the treatment technologies that will be installed to comply with the PFAS NPDWR.

The EPA did not quantify the potential CO_2 emissions changes associated with the production and delivery of treatment media, construction required for the installation of treatment technology, and transportation and disposal of treatment residuals. The EPA recognizes that many activities directly and indirectly associated with drinking water treatment produce GHG emissions; however, the agency determined that it could not accurately quantify all the potential factors that could increase and decrease greenhouse gas emissions that are not solely attributable to the direct onsite operations of the plant beyond increased electricity use at the plant. The EPA has information, to varying degrees, that the agency could use to potentially estimate emissions from some of these activities. To accurately understand the total potential climate disbenefits of this rule, the EPA should consider GHG emissions in the baseline scenario where the agency also takes no action. However, the EPA lacks the data needed to consider the potentially significant climate disbenefits and other costs to society of the EPA taking no action (*i.e.,* not finalizing the PFAS NPDWR). If the EPA were to not finalize the rule, this could likely trigger other activities that would increase GHG emissions. For example, significant climate disbenefits may be realized from the public increasing purchases of bottled water in an effort to avoid PFAS exposure from drinking water provided by PWSs. More members of the public switch to drinking bottled water if they do not trust the safety of their utility supplied drinking water (Grupper et al. 2021, Levêque and Burns, 2017). Bottled water has a substantially larger carbon footprint than the most highly treated tap water, including the significant energy necessary to produce plastic bottles and transport water from where it is bottled to the point of consumption (Gleick and Cooley, 2009). This carbon footprint can be hundreds of times greater than tap water on a per volume basis (*e.g.,* see Botto, 2009). In addition, this is the first drinking water regulation in which the EPA has estimated disbenefits associated with increases or reductions in GHG emissions. The EPA expects that the approach for quantifying such benefits or disbenefits will continue to evolve as our understanding of the potential relationships between quality of drinking water treatment, impacts on consumer behavior, and other factors influencing GHG emissions improves. Considering the limitations described above and consistent with past EPA rulemakings,[27] the EPA is limiting the scope of the analysis to the major sources of emissions from the direct operation of treatment technologies. The EPA did not quantify the CO_2 emissions associated with production of treatment technologies, construction, transportation, and disposal, as these activities are not solely attributable to the direct onsite operations of the plant and are beyond the scope of this analysis.

Furthermore, while some data exists to inform an estimate of the CO_2 emissions associated with production and reactivation of GAC, the EPA did not do so in this analysis due to significant uncertainties associated with the future CO_2 emissions associated with these technologies. The carbon footprint of GAC is likely to reduce over time, as research continues on novel applications for PFAS removal (*e.g.,* advanced reduction/oxidation processes, novel sorbents, foam fractionation, sonolysis, among others), alternative sources of materials to produce GAC (*e.g.,* biomass and other waste materials), and use of carbon capture technology expands in the future. Given these compounding uncertainties, the EPA did not quantify the climate disbenefits of GAC production and reactivation.

In this rule, the EPA determined that increased electricity use is the major source of emissions from the direct operation of treatment technologies to

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[27] Recent examples include *New Source Performance Standards (NSPS) for the SOC Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants (NESHAP) for the SOC Manufacturing Industry and Group I and Group II polymers and Resins Industry, NESHAP Gasoline Distribution NRPM, Supplemental Effluent Limitations Guidelines (ELGs)* and *Standards for the Steam Electric Power Generating Point Source Category.*

remove PFAS. In this analysis conducted pursuant to E.O. 12866, the EPA first quantified the CO_2 emissions from the additional electricity that is expected to be used for pumping, building lighting, heating, ventilation, and operation of other technology-specific equipment to remove PFAS. The EPA then monetized the climate disbenefits resulting from these CO_2 emissions by applying the social cost of carbon dioxide (SC–CO_2) estimates recommended by the commenter, as described in the following paragraphs.

After considering public comments that recommended the EPA consider the climate disbenefits of the rule, the EPA conducted an analysis similar to the one recommended by one commenter. As suggested by the commenter, the EPA used the estimates of consumption of purchased electricity available from the EPA's peer reviewed work breakdown structure (WBS) cost models to estimate the national electricity use associated with operation of PFAS removal treatment technologies. The EPA deviated from the commenter's suggested approach when estimating associated CO_2 emissions over time from producing electricity. The commenter estimates carbon emissions in a single year and presents that value as a constant reoccurring annual cost. Instead, the EPA estimated how CO_2 emissions would change through 2070, the calendar year to which the EPA has estimated CO_2 emissions from electricity production. The EPA applied readily available information from the latest reference case of the EPA's Integrated Planning Model (IPM) to represent CO_2 emissions associated with electricity production over time.[28] Given that emissions from producing electricity are expected to significantly decrease over time, this is a logical application consistent with other agency rulemakings estimating future emissions from the power sector including the EPA's final *Good Neighbor Plan* (USEPA, 2023q) and the EPA's *New Source Performance Standards for GHG Emissions from New, Modified, and Reconstructed Electric Utility Generating Units* (USEPA, 2023r). Finally, the EPA monetized the climate disbenefits resulting from the estimated CO_2 emissions by applying the SC–CO_2 estimates presented in the regulatory impact analysis of the EPA's December 2023 Final Rule, ‘‘Standards of Performance for New, Reconstructed, and Modified Sources and Emissions Guidelines for Existing Sources: Oil and Natural Gas Sector Climate Review'' (USEPA 2023s). These are the same SC–CO_2 estimates the EPA presented in a sensitivity analysis in the RIA for the agency's December 2022 supplemental proposed Oil and Gas rulemaking that the commenter recommended for use in this action. The SC–CO_2 estimates incorporate recent research addressing recommendations of the National Academies of Science, Engineering, and Medicine (NASEM 2017), responses to public comments on the December 2022 supplemental proposed Oil and Gas rulemaking, and comments from a 2023 external peer review of the accompanying technical report. The methodology underlying the SC–CO_2 estimates is described in the agency's technical report *Report on the Social Cost of Greenhouse Gases: Estimates Incorporating Recent Scientific Advances* (USEPA, 2023t), and is included in the docket for this final rule. For additional details on the climate disbenefits analysis see chapter 9.1 of the EPA's EA for the final PFAS NPDWR.

c. Final Analysis

The EPA did not include an estimate of the monetized climate disbenefits from increased GHG emissions associated with the rule in the HRRCA as recommended by commenters because under the SDWA, the EPA only analyzes compliance costs to PWSs solely as a result of the Maximum Contaminant Level (MCL). The EPA analyzed the climate disbenefits of CO_2 emissions associated with the increased electricity use at PWSs as a result of compliance with the PFAS NPDWR, the EPA estimates annualized climate disbenefits associated with this rule of $5.5 million per year[29] (under a 2 percent near term discount rate[30]), which constitutes less than 0.4 percent of the monetized benefits of the rule at a 2 percent discount rate. As noted earlier, the EPA's action is justified based on the statutory factors in SDWA section 1412(b) and this disbenefits analysis is presented solely for the purposes of complying with E.O. 12866.

B. Paperwork Reduction Act (PRA)

The information collection activities in this final rule have been submitted for approval to the Office of Management and Budget under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned the EPA ICR number 2732.02 and OMB control number 2040–0307. You can find a copy of the ICR in the docket for this rule at *https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114*, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The monitoring information collected as a result of the final rule should allow primacy agencies and the EPA to determine appropriate requirements for specific systems and evaluate compliance with the NPDWR. For the first three-year period following rule promulgation, the major information requirements concern primacy agency activities to implement the rule including adopting the NPDWR into state regulations, providing training to state and PWS employees, updating their monitoring data systems, and reviewing system monitoring data and other requests. Certain compliance actions for drinking water systems, specifically initial monitoring, would be completed during the three years following rule promulgation. Other compliance actions for drinking water systems (including ongoing compliance monitoring, administration, and treatment costs) would not begin until after three years due to the MCL compliance date of this rule. More information on these actions is described in section XII of this preamble and in chapter 9 from the EA of the Final PFAS NPDWR (USEPA, 2024g).

Respondents/affected entities: The respondents/affected entities are PWSs and primacy agencies.

Respondent's obligation to respond: The collection requirements are mandatory under SDWA (42 U.S.C. 300g–7).

Estimated number of respondents: For the first three years after publication of the rule in the **Federal Register**, information requirements apply to an average of 33,594 respondents annually, including 33,538 PWSs and 56 primacy agencies.

Frequency of response: During the initial three-year period, PWSs will conduct one-time startup activities. The one-time burden associated with reading and understanding the rule and adopting the rule is estimated to be an average of 4 hours per system. The one-time burden associated with attending one-time training provided by primacy agencies is an average of 16 hours for systems serving ≤3,300 people and 32 hours for systems serving >3,300 people. The burden associated with initial sampling requirements is an estimated 207,000 hours. The total burden for these activities, for the three-year period, for all systems is estimated to be 1,519,000 hours. During the initial

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[28] See *https://www.epa.gov/power-sector-modeling.*

[29] Disbenefits are annualized over the years 2024–2080.

[30] See the EPA's EA for the Final PFAS NPDWR for results at all discount rates.

three-year period, primacy agencies will incur burdens associated with one-time startup activities. The burden associated with reading and understanding the rule, adopting the regulatory requirements, and training internal staff is estimated to be an average of 4,320 hours per primacy agency. The burden associated with primacy agency review of initial monitoring data is 207,000 hours. The total burden for these activities, for the three-year period, for all 56 primacy agencies is estimated to be 533,000 hours.

Total estimated burden: For the first three years after the final rule is published, water systems and primacy agencies will implement several requirements related to one-time startup activities and monitoring. The total burden hours for public water systems are 1,519,000 hours. The total burden for primacy agencies is 533,000 hours. The total combined burden is 2,052,000 hours.

Total estimated cost: The total costs over the three-year period is $176.8 million, for an average of $58.9million per year (simple average over three years).

An agency may not conduct or sponsor, and a person is not required to respond to, a collected for 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. When OMB approves this ICR, the agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

Pursuant to sections 603 and 609(b) of the RFA, the EPA prepared an initial regulatory flexibility analysis (IRFA) for the proposed rule and convened a Small Business Advocacy Review (SBAR) Panel to obtain advice and recommendations from small entity representatives (SERs) that potentially would be subject to the rule's requirements. Summaries of the IRFA and Panel recommendations are presented in the proposed rule (USEPA, 2023f).

As required by section 604 of the RFA, the EPA prepared a final regulatory flexibility analysis (FRFA) for this action. The FRFA addresses the issues raised by public comments on the IRFA for the proposed rule. The complete FRFA is available for review in section 9.4 of the EA in the docket and is summarized here.

For purposes of assessing the impacts of the final rule on small entities, the EPA considered small entities to be water systems serving 10,000 people or fewer. This is the threshold specified by Congress in the 1996 Amendments to SDWA for small water system flexibility provisions. As required by the RFA, the EPA proposed using this alternative definition in the **Federal Register** (USEPA, 1998d), sought public comment, consulted with the Small Business Administration (SBA), and finalized the small water system threshold in the agency's Consumer Confidence Report (CCR) Regulation (USEPA, 1998e). As stated in the document, the alternative definition would apply to all future drinking water regulations.

The SDWA is the core statute addressing drinking water at the Federal level. Under the SDWA, the EPA sets public health goals and enforceable standards for drinking water quality. As previously described, the final PFAS NPDWR requires water systems to reduce certain PFAS in drinking water below regulatory levels. The EPA is regulating these PFAS in drinking water to improve public health protection by reducing drinking water exposure to these and other PFAS in drinking water.

The final rule contains provisions affecting approximately 62,000 small PWSs. A small PWS serves between 25 and 10,000 people. These water systems include approximately 45,000 community water systems (CWSs) that serve the year-round residents and approximately 17,000 non-transient non-community water systems (NTNCWSs) that serve the same persons over six months per year (*e.g.,* a PWS that is an office or school). The final PFAS NPDWR includes legally enforceable regulatory standards with requirements for monitoring, public notification, and treatment or nontreatment options for water systems exceeding the regulatory standards. This final rule also includes reporting, recordkeeping, and other administrative requirements. States are required to implement operator certification (and recertification) programs under SDWA section 1419 to ensure operators of CWSs and NTNCWSs, including small water system operators, have the appropriate level of certification.

Under the final rule requirements, small CWSs and NTNCWs serving 10,000 or fewer people are required to conduct initial monitoring or demonstrate recent, previously collected monitoring data to determine the level of certain PFAS in their water system. Based on these initial monitoring results, systems are required to conduct ongoing monitoring at least every three years or as often as four times per year. Systems that exceed a drinking water standard will be required to choose between treatment and nontreatment as the compliance option. Under the final rule, the EPA estimates that approximately 16,542 small CWSs (37 percent of small CWSs) could incur annual total PFAS NPDWR related costs of more than one percent of revenues, and that approximately 8,199 small CWSs (18 percent of small CWSs) could incur annual total costs of three percent or greater of revenue. See section 9.3 of the final PFAS NPDWR EA for more information on the characterization of the impacts under the final rule.

The EPA took a number of steps to solicit small entity stakeholder input during the development of the final PFAS NPDWR. Sections XIII.E and XIII.F of this preamble contain detailed information on stakeholder outreach during the rulemaking process, including material on the Federalism and Tribal consultation processes. The EPA also specifically sought input from small entity stakeholders through the SBAR Panel process. On May 24, 2022, the EPA's Small Business Advocacy Chairperson convened the Panel, which consisted of the Chairperson, the Director of the Standards and Risk Management Division within the EPA's Office of Ground Water and Drinking Water, the Administrator of the Office of Information and Regulatory Affairs within OMB, and the Chief Counsel for Advocacy of the SBA. Detailed information on the overall panel process can be found in the panel report available in the PFAS NPDWR docket (EPA–HQ–OW–2022–0114).

In response to the proposal, the EPA received one comment specifically on the analytical approach used in the IRFA. The commenter states that ''[d]etailed analysis on the impacts to NTNCWSs should be conducted to inform the cost/benefit analysis. For example, treating PFAS with GAC at the low levels proposed is much more costly than current treatment for currently regulated contaminants, and a 2008 study is not a reliable indicator of future costs. Lack of both actual data on occurrence in these systems and reliable information on cost of compliance makes finalizing the MCL as to NTNCWSs too uncertain.'' The EPA disagrees that the agency has not analyzed the impacts of the PFAS NPDWR on NTNCWS. The EPA has used both actual data on occurrence at NTNCWSs from the third Unregulated Contaminant Monitoring Rule (UCMR 3) and state data, as well as reliable information on costs to NTNCWSs using the WBS treatment cost models to assess the impact of the rule on NTNCWSs. As the EPA stated in the proposal, the EPA lacks information on the revenues of NTNCWS, therefore the agency does not take the same approach used for CWSs in the Significant Economic Impact on a Substantial Number of Small Entities (SISNOSE) screening analysis where costs are compared to 1 and 3 percent of revenues. Instead, the EPA used the best available data, the EPA's *Assessment of the Vulnerability of Noncommunity Water Systems to SDWA Cost Increases* (USEPA, 1998f), to find that NTNCWSs are less vulnerable to SDWA related increases than a typical CWS. The EPA proceeded with the SBAR Panel process, as previously detailed in this section.

The EPA received many comments on the rule proposal, including from the Chief Counsel for Advocacy of the SBA, on small system and IRFA related topics including lack of funding availability for small water systems, the EPA's alleged underestimation of the impacts of the rule on small systems, the EPA's alleged overestimation of reliance on Federal funding to defray compliance costs for small water systems, and ''other factors that will further deter timely compliance'' such as personnel shortages, supply chain disruptions, limited lab and disposal capacity, and availability of treatment technologies. The EPA has addressed these comments and provided for maximum flexibility for small systems while ensuring sufficient public health protection for populations served by these systems. For the EPA's response to SBA and other comments on funding availability, please see section II of this preamble. For the EPA's response to SBA and other comments on the estimated costs to small water systems, please see section XII of this preamble. For the EPA's response to SBA and other comments on lab capacity, see sections V and VIII. For the EPA's response to SBA and other comments on technology and disposal capacity, see section X. For responses to SBA's and other commenters' recommendations to the EPA to provide burden-reducing flexibilities for small water systems, including finalizing one of the regulatory alternatives and phasing in the MCL, as well as providing additional time for compliance, see section V of this preamble. For response to SBA and other commenters concerned about the EPA's concurrent proposal of a preliminary determination and a proposed regulation for four PFAS, see section III of the preamble. The FRFA, available for review in section 9.4 of the EA in the docket, also provides detailed information on the recommendations of the SBAR Panel and the EPA's actions taken to minimize the significant economic impact of the final rule on small systems.

As a mechanism to reduce the burden of the final rule requirements on small entities the EPA has promulgated compliance flexibilities for small CWSs serving 10,000 or fewer persons. These flexibilities include the use of previously collected PFAS monitoring data to satisfy initial monitoring requirements, allowing reduced initial monitoring for small groundwater systems serving 10,000 or fewer, the addition of annual monitoring to the ongoing compliance monitoring framework, and modified rule trigger levels for reduced monitoring eligibility. For more information on these flexibilities, see section VIII of this preamble. The EPA is also exercising its authority under SDWA section 1412(b)(10) to implement a nationwide two-year capital improvement extension to comply with MCL. The agency notes that SDWA section 1416(a) and (b)(2)(C) describe how the primacy agencies may also grant an exemption for systems meeting specified criteria that provides an additional period for compliance. PWSs that meet the minimum criteria outlined in the SDWA section 1416 may be eligible for an exemption of up to three years. Exemptions for smaller water systems (≤3,300 population), meeting certain specified criteria may be renewed for one or more two-year periods, but not to exceed six years. States exercising primacy enforcement responsibility must have adopted the 1998 Variance and Exemption Regulation for a water system to be eligible for an exemption in that state. Finally, the EPA notes that if point-of-use (POU) devices are certified to meet the NPDWR standard in the future, this could reduce 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).

The EPA also assessed the degree to which the final PFAS NPDWR small system flexibilities would mitigate compliance costs. The EPA estimates that the use of previously collected PFAS monitoring data will reduce the economic burden on small systems nationally by $7 million dollars per year for three years. The EPA expects that reduced monitoring for small groundwater systems will reduce the economic burden on small systems nationally by $21 million per year for three years. The EPA estimates that under the final rule approximately 4,300 to 7,000 small PWSs may have regulated PFAS occurrence between the trigger levels and the MCLs, and therefore may be eligible for annual monitoring following four consecutive quarterly samples demonstrating they are ''reliably and consistently'' below the MCLs. The EPA anticipates further compliance cost mitigations stemming from the decision to set the reduced monitoring trigger levels at one-half of the MCLs, rather than one-third of the MCLs as proposed. While the MCL compliance period extension does not change the treatment or non- treatment actions that small systems will be compelled to undertake, it will reduce the compliance burden faced by small water systems by allowing for more time for them to obtain and install capital improvements. Finally, the EPA recognizes the possibility of small system compliance cost reduction particularly for very small water systems should POU certifications be updated in the future and POUs meet the small system compliance technology (SSCT) criteria for the final NPDWR. See chapter 9, section 9.3.4 of the final PFAS NPDWR EA (USEPA, 2024g) for more information on the characterization of the impacts under the final rule.

In addition, the EPA is preparing a Small Entity Compliance Guide to help small entities comply with this rule. The EPA expects the *Small System Compliance Guide* will be developed in the first three years after rule promulgation and will be made available on the EPA's PFAS NPDWR website.

D. Unfunded Mandates Reform Act (UMRA)

This action contains a Federal mandate under UMRA, 2 U.S.C. 1531–1538, that may result in expenditures of $100 million or more for state, local, and Tribal governments, in the aggregate, or the private sector in any one year. Accordingly, the EPA has prepared a written statement required under section 202 of UMRA that is included in the docket for this action (see chapter 9 of the EA for the Final PFAS NPDWR) and briefly summarized here.

Consistent with UMRA section 205, the EPA identified and analyzed a reasonable number of regulatory alternatives to determine the MCL requirement in the final rule. The agency notes, however, that the provisions of section 205 do not apply when they are inconsistent with applicable law; in the case of NPDWRs, the UMRA section 205 requirement to adopt the least costly, most cost-effective, or least burdensome option is inconsistent with SDWA regulatory development requirements. See section XII of this preamble and chapter 9 of the EA for the Final PFAS NPDWR (USEPA, 2024g) for alternative options that were considered. Consistent with the intergovernmental consultation provisions of UMRA section 204, the EPA consulted with governmental entities affected by this rule. The EPA describes the government-to-government dialogue and comments from state, local, and Tribal governments in sections XIII.E. (E.O. 13132: Federalism) and XIII.F. (E.O. 13175: Consultation and Coordination with Indian Tribal Governments) of this document.

This action may significantly or uniquely affect small governments. The EPA consulted with small governments concerning the regulatory requirements that might significantly or uniquely affect them. The EPA describes this consultation in the RFA, section XIII.C. of this preamble.

E. Executive Order 13132: Federalism

The EPA has concluded that this action has federalism implications because it imposes substantial direct compliance costs on state or local governments, and the Federal Government will not provide the funds necessary to pay those costs. However, the EPA notes that the Federal Government will provide a potential source of funds necessary to offset some of those direct compliance costs through the Bipartisan Infrastructure Law (BIL). The EPA estimates that the net change in primacy agency related cost for state, local, and Tribal governments in the aggregate to be $4.7 million.

The EPA provides the following federalism summary impact statement. The EPA consulted with state and local governments early in the process of developing the proposed action to allow them to provide meaningful and timely input into its development. The EPA held a federalism consultation on February 24, 2022. The EPA invited the following national organizations representing state and local elected officials to a virtual meeting on February 24, 2022: The National Governors' Association, the National Conference of State Legislatures, the Council of State Governments, the National League of Cities, the U.S. Conference of Mayors, the National Association of Counties, the International City/County Management Association, the National Association of Towns and Townships, the County Executives of America, and the Environmental Council of States. Additionally, the EPA invited the Association of State Drinking Water Administrators (ASDWA), the Association of Metropolitan Water Agencies (AMWA), the National Rural Water Association (NRWA), the American Water Works Association (AWWA), the American Public Works Association, the Western Governors' Association, the Association of State and Territorial Health Officials, the National Association of Country and City Health Officials, and other organizations to participate in the meeting. In addition to input received during the meeting, the EPA provided an opportunity to receive written input within 60 days after the initial meeting. A summary report of the views expressed during federalism consultations is available in the rule docket (EPA–HQ–OW–2022–0114). The EPA also received public comments from some of these organizations during the public comment period following the rule proposal. These individual organization comments are available in the docket.

Comments provided by the organizations during both the consultation and public comment periods covered a range of topics. The overarching comments from multiple organizations related to the NPDWR compliance timeframe and implementation flexibilities, the proposed MCLs for PFOA and PFOS and the Hazard Index PFAS, the EPA's estimated costs of the NPDWR and funding considerations, PFAS treatment disposal, and other EPA actions to address PFAS in the environment. Specifically, several of these organizations expressed that the EPA should allow an extended compliance timeframe to comply with the MCLs due to supply chain disruptions and availability of treatment materials, as well as maximize the implementation flexibilities for water systems and primacy agencies, including those related to monitoring. Regarding rule costs, some organizations contended that the EPA's costs were underestimated, and that the EPA should consider the disposal of PFAS treatment residuals and associated costs particularly if determined to be hazardous wastes in the future under other EPA statutes such as the Resource Conservation and Recovery Act (RCRA). A couple of organizations requested that the EPA should provide more direct funding for local governments to comply with the NPDWR noting the available BIL funding would not be sufficient to cover the rule costs and these funds cannot be used for certain rule compliance costs. A few organizations suggested that the agency should raise the proposed PFOA and PFOS MCLs, with some of these commenters offering that the EPA should not move forward with the Hazard Index MCL for perfluorohexane sulfonic acid (PFHxS), perfluorononanoic acid (PFNA), hexafluoropropylene oxide dimer acid (HFPO–DA), and perfluorobutane sulfonic acid (PFBS). Finally, several organizations provided that the agency should focus on addressing PFAS holistically and expedite its efforts on source water protection and other actions to address PFAS in the environment beyond drinking water. The EPA considered these organizations' concerns and has taken this input to address many of these in the final PFAS NPDWR while ensuring sufficient public health protection those served by PWSs.

Related to compliance timeline and other rule implementation flexibilities, the EPA is exercising its authority under SDWA section 1412(b)(10) to implement a nationwide two-year capital improvement extension to comply with MCL. The agency notes that SDWA section 1416(a) and (b)(2)(C) describe how the EPA or states may also grant an exemption for systems meeting specified criteria that provides an additional period for compliance. See section XI.D for more information on extensions and exemptions. The EPA has promulgated compliance flexibilities for monitoring implementation including the use of previously collected PFAS monitoring data to satisfy initial monitoring requirements and allowing reduced initial monitoring for small groundwater systems serving 10,000 or fewer. Other monitoring implementation flexibilities include the addition of annual monitoring to the ongoing compliance monitoring framework and higher rule trigger levels for reduced monitoring eligibility. For more information on these flexibilities, see section VIII of this preamble.

For the final rule, the EPA has evaluated the concerns related to the rule costs and maintains that the estimated benefits of the rule justify the costs. Regarding financial costs to water systems if regulated PFAS were to be required to be disposed of as hazardous waste in the future, the EPA reaffirms that no PFAS are currently listed, or proposed to be listed, as hazardous wastes under RCRA. However, the EPA has included a sensitivity analysis to determine the impact on this action should be PFAS-containing treatment materials be considered RCRA regulatory or characteristic hazardous waste in the future (see section X.C. for more detail). For funding concerns and information, the EPA has provided information, detailed further in section II.G. of this preamble related to potential funding opportunities, particularly those available through BIL funds including the EPA's Emerging Contaminants in Small or Disadvantaged Communities (EC–SDC) grants program.

For organizations recommending that the EPA raise the proposed PFOS and PFOS MCLs, with some of these organizations suggesting that the Hazard Index MCL is not justified and should not be finalized, as described in section V of this preamble, the EPA has demonstrated these levels are justified under the requirements of SDWA. Therefore, the agency is maintaining these MCLs for the final rule but has offered compliance flexibilities as described previously.

Lastly, several organizations provided that the agency should focus on addressing PFAS through source water protection efforts beyond drinking water, under the agency's *PFAS Strategic Roadmap* and associated actions, the EPA is swiftly working to address PFAS contamination in the environment and reduce human health PFAS exposure through all pathways. While beyond the scope of this rulemaking, the EPA is making progress implementing many of the commitments in the *Roadmap,* including those that may significantly reduce PFAS source water concentrations.

In addition to the federalism consultation, regarding state engagement more specifically, the EPA notes there were multiple meetings held by ASDWA where the EPA gathered input from state officials and utilized this input to inform this rule. The EPA also considered all comments provided by individual states and state organizations provided during the public comment period and used these comments to inform the final rule.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action has Tribal implications, it imposes direct compliance costs on Tribal governments, and the Federal Government will not provide funds necessary to pay those direct compliance costs. However, the EPA notes that the Federal Government will provide a potential source of funds necessary to offset some of those direct compliance costs through the BIL.

The EPA has identified 998 PWSs serving Tribal communities, 84 of which are federally owned. The EPA estimates that Tribal governments will incur PWS compliance costs of $9.0 million per year attributable to monitoring, treatment or nontreatment actions to reduce PFAS in drinking water, and administrative costs, and that these estimated impacts will not fall evenly across all Tribal systems. The final 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 groundwater 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.

Accordingly, the EPA provides the following Tribal summary impact statement as required by section 5(b) of E.O. 13175. The EPA consulted with federally recognized Tribal governments early in the process of developing this action to permit them to have meaningful and timely input into its development. The EPA conducted consultation with Indian Tribes beginning on February 7, 2022, and ending on April 16, 2022. The consultation included two national webinars with interested Tribes on February 23, 2022, and March 8, 2022, where the EPA provided proposed rulemaking information and requested input. A total of approximately 35 Tribal representatives participated in the two webinars. Updates on the consultation process were provided to the National Tribal Water Council and the EPA Region 6's Regional Tribal Operations Committee upon request at regularly scheduled monthly meetings during the consultation process. As part of the consultation, the EPA received written comments from the following Tribes: Little Traverse Bay Bands of Odawa Indians and Sault Ste. Marie Tribe of Chippewa Indians. In addition to the comments from these Tribal governments, the EPA received comments the National Tribal Water Council. A summary report of the consultation, webinars, and views expressed during the consultation is available in the Docket (EPA–HQ–OW–2022–0114).

The EPA received a variety of comments from Tribal officials and representatives during both the consultation and public comment periods. These comments can be found in more detail within the Docket through the individual public comments and within the consultation summary report. Specifically, comments included those related to initial monitoring requirements, use of monitoring waivers, concerns related to treatment options and disposal of treatment materials, particularly if determined to be hazardous in the future, as well as funding concerns. The EPA has addressed these officials' comments through finalizing monitoring requirements which allow for small systems flexibilities including the use of previously collected monitoring data to be used to satisfy initial monitoring requirements and not allowing the use of monitoring waivers (see section VIII) of this preamble. Related to treatment considerations, the EPA has identified best available technologies (BATs) as described in section X which have been shown to reduce regulated PFAS levels, but also allows for other treatment technologies not identified as BATs to be used to address MCL exceedances if they can remove PFAS to the regulatory standards. Additionally, the EPA has developed a sensitivity cost analysis to describe the additional financial costs to water systems if the regulated PFAS were to be required to be disposed of as hazardous waste in the future (see appendix N, section 2 of the EA for additional detail). For funding concerns, the EPA has provided information, detailed further in section II of this preamble, related to potential funding opportunities, particularly those available through the EPA's EC–SDC grants program.

The EPA reviewed these comments received from Tribal groups, the estimated cost data, and the quantified and nonquantifiable benefits associated with the PFAS NPDWR and determined that the regulatory burden placed on Tribes is outweighed by the positive benefits. Given that the majority of Tribal systems serve fewer than 10,000 persons, as noted previously, the EPA has provided regulatory relief in the form of small system compliance flexibilities related to monitoring requirements. For additional information on these compliance flexibilities and their estimated impacts see sections VIII of this preamble and chapter 9.4, of the final PFAS NPDWR EA (USEPA, 2024g).

As required by section 7(a) of E.O. 13175, the EPA's Tribal Official has certified that the requirements of the E.O. have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

Executive Order 13045 directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is subject to E.O. 13045 because it is a significant regulatory action under section 3(f)(1) of E.O. 12866, and the EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children. Accordingly, the EPA has evaluated the environmental health or safety effects of the regulated PFAS found in drinking water on children and estimated the risk reduction and health endpoint impacts to children associated with adoption of treatment or nontreatment options to reduce these PFAS in drinking water. The results of these evaluations are contained in the EA of the Final PFAS NPDWR (USEPA, 2024g) and described in section XII of this preamble. Copies of the EA of the Final PFAS NPDWR and supporting information are available in the Docket (EPA–HQ–OW–2022–0114).

Furthermore, the EPA's *Policy on Children's Health* also applies to this action. Information on how the Policy was applied is available in section II.B. of this preamble.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The public and private water systems affected by this action do not, as a rule, generate power. This action does not regulate any aspect of energy distribution as the water systems that are proposed to be regulated by this rule already have electrical service. Finally, the EPA has determined that the incremental energy used to implement the identified treatment technologies at drinking water systems in response to the regulatory requirements is minimal. The EPA estimates that the final rule will result in an increased electricity use of approximately 229 GWh per year, for more information see section XIII.A; total U.S. electricity consumption in 2022 was approximately 4.05 million GWh (USEIA, 2023). Therefore, the electricity consumed as a result of the final rule represents approximately 0.005 percent of total U.S. electricity consumption. Based on these findings, the EPA does not anticipate that this rule will have a significant adverse effect on the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act of 1995

This action involves technical standards. The rule could involve voluntary consensus standards in that it requires monitoring for regulated PFAS, and analysis of the samples obtained from monitoring based on required methods. As part of complying with this final rule, two analytical methods are required to be used for the identification and quantification of PFAS in drinking water. The EPA Methods 533 and 537.1 incorporate quality control criteria which allow accurate quantitation of PFAS. Additional information about the analytical methods is available in section VII of this preamble. The EPA has made, and will continue to make, these documents generally available through *www.regulations.gov* and at the U.S. Environmental Protection Agency Drinking Water Docket, William Jefferson Clinton West Building, 1301 Constitution Ave. NW, Room 3334, Washington, DC 20460, call (202) 566–2426.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

1. Proposal

The EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice (EJ) concerns. Consistent with the agency's *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (USEPA, 2016f), for the proposed rule, the EPA conducted an EJ analysis to assess the demographic distribution of baseline PFAS drinking water exposure and impacts anticipated to result from the proposed PFAS NPDWR. The EPA conducted two separate analyses: an EJ exposure analysis using the agency's EJSCREENbatch R package, which utilizes data from EJScreen, the agency's Environmental Justice Screening and Mapping Tool (USEPA, 2019e), and from the U.S. Census Bureau's American Community Survey (ACS) 2015–2019 five-year sample (United States Census Bureau, 2022), and an analysis of the EPA's proposed regulatory option and alternatives using SafeWater Multi-Contaminant Benefit Cost Model (MCBC; detailed in section XII of this preamble). The EPA's analyses examined EJ impacts on a subset of PWSs across the country, based on availability of PFAS occurrence data and information on PWS service area boundaries. In the EPA's analysis, results for income, race, and ethnicity groups were generally summarized separately due to how underlying ACS statistics are aggregated at the census block group level; for more information, please see: *https://www.census.gov/data/developers/data-sets/acs-5year.html* (United States Census Bureau, 2022). Additional information on both analyses can be found in chapter 8 of USEPA (2024g) and appendix M of USEPA (2024e).

The EPA's EJ exposure analysis using the EJSCREENbatch R package utilized hypothetical regulatory scenarios, which differed from the EPA's proposed option and regulatory alternatives presented in the proposed rule. The EPA's analysis demonstrated that across hypothetical regulatory scenarios evaluated, elevated baseline PFAS drinking water exposures, and thus greater anticipated reductions in exposure, were estimated to occur in communities of color and/or low-income populations. For this analysis, the EPA examined individuals served by PWSs with modeled PFAS exposure above baseline concentration thresholds or a specific alternative policy threshold. The EPA also summarized population-weighted average concentrations in the baseline as well as reductions that would accrue to each demographic group from hypothetical regulatory scenarios.

The EPA's analysis in SafeWater MCBC evaluated the demographic distribution of health benefits and incremental household costs anticipated to result from the PFAS NPDWR. The EPA's proposed option and all regulatory alternatives were anticipated to provide benefits across all health endpoint categories for all race/ethnicity groups. Across all health endpoints, communities of color were anticipated to experience the greatest reductions in adverse health effects associated with PFAS exposure, resulting in the greatest quantified benefits associated with the EPA's proposed rule, likely due to disproportionate baseline exposure. When examining costs anticipated to result from the rule, the EPA found that cost differences across demographic groups were typically small, with no clear unidirectional trend in cost differences based on demographic group. In some cases, the EPA found that communities of color were anticipated to bear minimally increased costs but in other cases, costs to communities of color were anticipated to be lower than those across all demographic groups. In general, incremental household costs to all race/ethnicity groups were found to decrease with increasing system size, an expected result due to economies of scale.

Additionally, on March 2, 2022, and April 5, 2022, the EPA held public meetings related to EJ and the development of the proposed NPDWR. The meetings provided an opportunity for the EPA to share information and for communities to offer input on EJ considerations related to the development of the proposed rule. During the meetings and in subsequent written comments, the EPA received public comment on topics including establishing an MCL for PFAS, affordability of PFAS abatement options, limiting industrial discharge of PFAS, and the EPA's relationship with community groups. For more information on the public meetings, please refer to the *Environmental Justice Considerations for the Development of the Proposed PFAS Drinking Water Regulation Public Meeting Summary* for each of the meeting dates in the public docket at *https://www.regulations.gov/docket/EPA-HQ-OW-2022-0114*. Additionally, the written public comments are included within the public docket.

2. Summary of Major Public Comments and EPA Responses

Many commenters expressed support for the rule and the EPA's EJ analysis, underscoring the rule's alignment with the administration's commitment to advancing EJ. Commenters point to evidence which suggests that PFAS exposure disproportionately affects communities with EJ concerns. Further, commenters state that these communities are particularly vulnerable to PFAS exposure and the associated health outcomes. Several commenters also assert that the rule is anticipated to benefit these communities with EJ concerns who are at a higher risk of PFAS exposure. Through this rule, the EPA reaffirms the importance of EJ considerations in agency activities, including rulemaking.

Many commenters expressed concern about potential EJ implications of the final rule and urged the EPA to further consider these implications prior to final rule promulgation. Specifically, commenters presented concerns that the rule will disproportionately impact communities that already are overburdened with sociodemographic and environmental stressors. Additionally, several commenters voiced EJ concerns associated with implementation of the rule. Many commenters asserted that communities with EJ concerns may not have sufficient financial capacity to implement the rule (*e.g.,* install treatment) and that this may further exacerbate existing disparities associated with PFAS exposure. Additionally, commenters stated that additional resources would likely be needed for communities with EJ concerns to successfully implement the rule, including targeted monitoring and sampling in these areas.

The EPA acknowledges commenters' concerns regarding potential EJ implications of the rule. Under E.O. 14096, the EPA is directed to identify, analyze, and address disproportionate and adverse human health or environmental effects of agency actions on communities with environmental justice concerns (USEPA, 2023v). The EPA believes that its EJ analysis accompanying the final rule has achieved this directive, as the EPA has assessed the demographic distribution of baseline PFAS exposure in drinking water as well as the anticipated distribution of benefits and costs that will result from the rule. For more information on the EPA's EJ analysis, please see chapter 8 of USEPA (2024g) and appendix M of USEPA (2024e). The EPA acknowledges the potential for implementation challenges for communities with EJ concerns; however, there may be opportunities for many communities to utilize external funding streams to address such challenges. The BIL, the Low-Income Water Household Assistance Program through the American Rescue Plan, and other funding sources may be able to provide financial assistance for addressing emerging contaminants. In particular, the BIL funding has specific allocations for disadvantaged and/or small communities to address emerging contaminants, including PFAS. For example, the *Emerging Contaminants in Small or Disadvantaged Communities (EC–SDC) grants program,* which does not have a cost-sharing requirement, will provide states and territories with $5 billion to provide grants to public water systems in small or disadvantaged communities to address emerging contaminants, including PFAS. Grants will be awarded non-competitively to states and territories.

Many commenters stated that the costs of the rule will disproportionately fall on communities with EJ concerns. Additionally, some commenters asserted that the EPA's EJ analysis does not appropriately consider the distributional impacts of rule costs, with one commenter incorrectly stating that the analysis ''fails to consider how these increased compliance costs will impact EJ communities, as required by Executive Order 12898''. Commenters recommended that the EPA revise its analysis to reflect the impact that compliance costs of the rule will have on communities with potential EJ concerns.

The EPA disagrees with commenters that the EPA has failed to appropriately consider the impact that costs required to implement the rule may have on communities with potential EJ concerns. The agency has fulfilled its commitments in this rulemaking by conducting an analysis consistent with E.O. 14096 and has shared information on the demographic distribution of impacts evaluated in its EJ analysis to facilitate the public's understanding on potential environmental justice impacts of the rule. In section 8.4.2.2 of its EJ Analysis (found in chapter 8 of the HRRCA (USEPA, 2024l)), the EPA estimated the distribution of annualized incremental household costs across different race/ethnicity groups. As described in section XIII.J.1 above, the EPA found that cost differences across demographic groups are typically small, with no clear unidirectional trend in cost differences based on demographic group. In some cases, the EPA found that communities of color are anticipated to bear minimally increased costs but in other cases, costs to communities of color are lower than those across all demographic groups. In response to commenters, the EPA has updated its analysis to also examine the distribution of benefits and costs across income groups. With respect to the distribution of costs, the EPA found that, similar to its findings based on race/ethnicity group, differences in annual incremental household costs across income groups were small with no unidirectional trend in cost differences based on income level.

Additionally, one commenter recommended that the EPA disaggregate Asian and Pacific Islander data in its EJ analysis, asserting that the ''EPA must comply with OMB Statistical Directive 15''. The EPA disagrees that its EJ analysis must disaggregate Asian and Pacific Islander data in order to comply with OMB Statistical Directive 15 (SPD 15). SPD 15 establishes standards for maintaining, collecting, and presenting

Federal data on race and ethnicity and applies to ''all Federal reporting purposes'' (OMB, 1977). This term is not defined and does not clearly apply to analyses developed to support rulemaking efforts. SPD 15 is targeted primarily toward data collection efforts, the development of data for public consumption, and the enforcement of civil rights laws. As SPD 15 is not applicable in the context of rulemakings, the EPA is not required to revise its EJ analysis in accordance with the standards for data disaggregation set forth in the OMB directive. However, the EPA acknowledges that reporting results separately for these groups can help to reveal potential disparities that may exist across Asian and Pacific Islander subpopulations. In response to this comment, the EPA has added a qualitative summary of the literature provided by the commenter and has updated its analysis to include separate Asian and Pacific Islander demographic groups. These updates are reflected in chapter 8 of USEPA (2024g) and appendix M of USEPA (2024e) for the public's information and understanding.

3. Final Rule

The EPA's EJ exposure analysis for the final rule demonstrates that some communities of color are anticipated to experience elevated baseline PFAS drinking water exposures compared to the entire sample population. The percentage of non-Hispanic Black and Hispanic populations with PFAS in drinking water detected above baseline thresholds is greater than the percentage of the total population served with PFAS exposure above these thresholds for all PFAS analytes examined in the EPA's analysis. Similarly, when results are separately analyzed by system size, non-Hispanic Black and Hispanic populations are more likely to be served by large systems with PFAS detected above baseline thresholds compared to the percentage of the total population served across all demographic groups. For small systems, non-Hispanic Asian and non-Hispanic Black populations are more likely to be served by systems with PFAS concentrations above baseline thresholds for some PFAS analytes compared to the total population served across all demographic groups.

The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. Across all hypothetical regulatory thresholds, elevated exposure—and thus reductions in exposure under the hypothetical regulatory scenarios—is anticipated to occur in communities of color and/or low-income populations. The EPA estimates that the most notable reductions in exposure would be experienced by Hispanic populations, specifically when using UCMR 5 minimum reporting level values as hypothetical regulatory thresholds. Hispanic populations are estimated to experience exposure rates that are at least two percentage points higher than exposure for the total population served across all demographic groups and for all PFAS analytes included in this analysis. Hispanic populations are therefore also expected to have greater reductions in exposure compared to the entire sample population. In addition, under hypothetical regulatory thresholds set at the UCMR 5 minimum reporting levels, the EPA anticipates some of the largest reductions in exposure to PFOA and PFHxS occur for non-Hispanic Native American or Alaska Native and non-Hispanic Pacific Islander populations due to relatively high concentration levels when these PFAS are detected at PWSs serving these groups. For more information on the results of this EJ exposure analysis, see chapter 8 of USEPA (2024g) and appendix M of USEPA (2024e).

For the final rule, the EPA has updated its EJ exposure analysis to include separate Asian and Pacific Islander demographic groups, which were previously combined for the proposed rule. Additionally, the EPA has updated the demographic categories utilized in the EJ exposure analysis to ensure that consistent information is used or applied throughout the PFAS NPDWR EA to the extent possible and to reduce double counting across demographic categories. For the proposed rule, the EPA's EJ exposure analysis used different demographic categories than its distributional analysis conducted in SafeWater, with the former partly including racial groups that were inclusive of Hispanic individuals and the latter including racial groups that were exclusive of Hispanic individuals. Because the EPA's EJ exposure analysis for the proposed rule employed some demographic categories that were inclusive of Hispanic individuals (*e.g.,* American Indian or Alaska Native) and others that were not (*e.g.,* non-Hispanic White), this introduced double counting across groups in the analysis, which complicated making comparisons of exposure across populations of concern. This issue was described in the EJ analysis at proposal, and the EPA solicited comment on alternative methods for defining affected population groups.

Additionally, after considering public comments, the EPA has also updated its EJ analysis conducted in SafeWater MCBC to include an assessment of the distribution of benefits and costs anticipated to result from the final rule across income groups. Findings from the EPA's EJ analysis conducted in SafeWater MCBC for the final rule reaffirm the conclusions of the assessment of the distribution of benefits and costs conducted for the proposed rule across demographic groups. Across all health endpoints evaluated by the EPA, communities of color (*i.e.,* Hispanic, non-Hispanic Black, and/or Other race/ethnicity groups) are anticipated to experience the greatest reductions in adverse health effects associated with PFAS exposure, resulting in the greatest quantified benefits associated with the final rule. For instance, non-Hispanic Black populations are expected to experience 7.48 avoided non-fatal ischemic stroke (IS) cases and 3.90 avoided cardiovascular disease (CVD) deaths per 100,000 people per year, as compared to 3.78 avoided non-fatal IS cases and 1.26 avoided CVD deaths per 100,000 people per year for non-Hispanic White populations. Additionally, under the final rule, while in most cases the difference in cases of illnesses and deaths avoided across income groups is small, quantified health benefits are higher for low-income communities (*i.e.,* populations with income below twice the poverty level) across all health endpoints evaluated, compared to populations with income above twice the poverty level.

As found in its analysis for the rule proposal, when examining costs anticipated to result from the final rule, the EPA found that cost differences across both race/ethnicity and income groups are typically small, with no clear unidirectional trend in cost differences based on demographic group. In some cases, the EPA found that communities of color and low-income communities are anticipated to bear minimally increased costs but in other cases, costs to communities of color and low-income communities are anticipated to be lower than those across all race/ethnicity groups or populations with income above twice the poverty level, respectively. Additionally, incremental household costs to all race/ethnicity and income groups generally decrease as system size increases, which is expected due to economies of scale. This is especially true if systems serving these communities are required to install treatment to comply with the final rule. For example, systems serving 3,300 to 10,000 people that will be required to install treatment to comply with the final rule have substantially higher costs than systems in all larger size categories, irrespective of demographic group. To alleviate potential cost disparities identified by the EPA's analysis, there may be an opportunity for many communities to utilize BIL (Pub. 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.

The information supporting this E.O. 12898 review is contained in chapter 8 of USEPA (2024g) and appendix M of USEPA (2024e) and is available in the public docket for this action. This documentation includes additional detail on the methodology, results, and conclusions of the EPA's EJ analysis.

K. Consultations With the Science Advisory Board, National Drinking Water Advisory Council, and the Secretary of Health and Human Services

In accordance with sections 1412(d) and 1412(e) of the SDWA, the agency consulted with the National Drinking Water Advisory Council (NDWAC, or the Council); the Secretary of U.S. Department of Health and Human Services (HHS); and with the EPA Science Advisory Board (SAB).

1. Science Advisory Board

The SAB PFAS Review Panel met virtually via a video meeting platform on December 16, 2021, and then at three (3) subsequent meetings on January 4, 6, and 7, 2022, to deliberate on the agency's charge questions. Another virtual meeting was held on May 3, 2022, to discuss their draft report. Oral and written public comments were considered throughout the advisory process. The EPA sought guidance from the SAB on how best to consider and interpret life stage information, epidemiological and biomonitoring data, the agency's physiologically based pharmacokinetic (PBPK) analyses, and the totality of PFAS health information to derive an MCLG for PFOA and PFOS, combined toxicity framework, and CVD. The documents sent to SAB were the EPA's *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335–67–1) in Drinking Water* (USEPA, 2021i); the EPA's *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763–23–1) in Drinking Water* (USEPA, 2021j); the EPA's *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)* (USEPA, 2021e); and the EPA's Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water. On May 3 and July 20, 2022, the EPA received input from SAB, summarized in the report *Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS* (USEPA, 2022i).

In response to the EPA's request that the SAB review the EPA's four draft documents listed above, the SAB identified subject matter experts to augment the SAB Chemical Assessment Advisory Committee (CAAC) and assembled the SAB PFAS Review Panel to conduct the review.

In general, the SAB recognized the time constraints for completing the rulemaking process and was supportive of the EPA's efforts to the utilize the latest scientific finding to inform their decisions. The SAB applauded the agency's efforts to develop new approaches for assessing the risk of PFAS mixtures and the benefits arising from reducing exposure to these chemicals as adopted by the EPA in the Hazard Index approach in this rule. In general, the SAB agreed with many of the conclusions presented in the assessments, framework, and analysis. The SAB also identified many areas that would benefit from further clarification to enhance their transparency and increase their utility. The SAB provided numerous recommendations which can be found in the SAB's final report (USEPA, 2022i) and some highlights are outlined in the following section.

a. Approaches to the Derivation of Draft MCLGs for PFOA and PFOS

The primary purpose of the *Proposed Approaches to the Derivation of Draft MCLGs for PFOA and PFOS* (USEPA, 2021i; USEPA, 2021j) was to develop Maximum Contaminant Level Goals (MCLGs) based on the best available health effects information for PFOA and PFOS. Each MCLG draft document includes derivation of an updated chronic oral reference dose (RfD), cancer slope factor (CSF) when relevant data were available, and a relative source contribution (RSC) for SAB review. The health effects information used to derive these toxicity values and RSC values built upon the information in the 2016 EPA PFOA and PFOS Health Effects Support Documents (HESDs; USEPA, 2016c; USEPA, 2016d). The EPA has considered all SAB consensus advice in the development of the final values derived in this health effects assessment and subsequently derived MCLGs for the NPDWRs for PFOA and PFOS based on the best available science and the EPA guidance and precedent. Please see section IV of this preamble for discussions on the process for derivation of the MCLGs and the resulting proposed MCLG values for this final action.

The SAB charge questions for the MCLG draft documents addressed the systematic review study identification and inclusion, non-cancer hazard identification, cancer hazard identification and slope factor, toxicokinetic (TK) modeling, RfD derivation, and RSC. The complete list of charge questions was included in the EPA's documents prepared for the SAB (USEPA, 2022i). The SAB provided numerous specific recommendations to consider alternative approaches, expand the systematic review steps for the health effects assessment, and to develop additional analyses in order to improve the rigor and transparency of the EPA's documents. The complete list of SAB consensus advice is described in their final report (USEPA, 2022i).

Regarding the approaches to deriving MCLG draft documents, the SAB stated that the systematic review methods could be more transparent and complete. Specifically, study identification and criteria for inclusion could be improved. The EPA made revisions to the systematic review description and process by updating and expanding the scope of the literature search; providing greater transparency regarding the study inclusion criteria; and adding additional systematic review steps and transparently describing each of these steps in the PFOA and PFOS systematic review protocols.

In the charge questions, the EPA sought advice on the noncancer health assessment, and the SAB recommended that the EPA separate hazard and dose-response assessment systematic review steps. In response, the EPA made revisions to the noncancer hazard identification by expanding systematic review steps beyond study quality evaluation to include evidence integration to address the need to separate hazard identification and dose-response assessment and to ensure consistent hazard decisions; and strengthening rationales for selection of points of departure for the noncancer health outcomes. Additionally, the SAB advised the EPA to focus on the health endpoints with the strongest evidence (*i.e.,* liver, immune, serum lipids, development, and cancer).

The EPA consulted with the SAB on the cancer risk assessment. On the cancer Hazard Index and CSF, the SAB agreed that PFOA was a ''likely'' designation but recommended undertaking and describing a more structured and transparent discussion of the ''weight of evidence'' for both PFOA and PFOS. The EPA revised this assessment by following the structured approach in the EPA cancer guidelines (USEPA, 2005a) to develop a weight of evidence narrative for cancer, to consider the data for selecting the cancer classification, evaluating and integrating mechanistic information, and strengthening the rationales for decisions.

With respect to the TK model for which the EPA sought advice, SAB requested more details on the TK modeling including model code and parameters and recommended that the EPA consider expressing the RfD in water concentration equivalents to better account for possible life-stage specific differences in exposure rates and TKs. The EPA considered the alternate approach suggested by SAB and made revisions by evaluating alternative TK models and further validating the selected model.

The EPA also sought advice on the draft RfD derivation. The SAB advised that the EPA consider multiple human and animal studies for a variety of endpoints and populations. The SAB also stated a need for stronger and more transparent justification of BMR selections and asked the EPA to consider adopting a probabilistic framework to calculate risk-specific doses. SAB also recommended that the EPA clearly state that RfDs apply to both short-term and chronic exposure. The EPA made revisions based on these recommendations by providing additional descriptions and rationale for the selected modeling approaches and conducting new dose-response analyses of additional studies and endpoints.

On the RSC charge question, SAB supported the selection of a 20 percent RSC, but asked that the EPA provide clarity and rationale to support the value. To address this recommendation, the EPA added clarifying language related to the RSC determination from the EPA guidance (USEPA, 2000d), including the relevance of drinking water exposures and the relationship between the RfD and the RSC.

b. Combined Toxicity Framework

The EPA sought advice from the SAB on the *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of PFAS* document (USEPA, 2021e). The main purpose of this document was to provide a data-driven framework for estimating human health risks associated with oral exposures to mixtures of PFAS. The charge questions for the SAB pertaining to the framework draft documents included whether the EPA provided clear support for the assumption of dose additivity, and application of the Hazard Index, relative potency factor (RPF), and mixtures benchmark dose (BMD) approaches for the evaluation of mixtures of PFAS. The full list of charge questions was included in the EPA's documents prepared for the SAB (USEPA, 2022i). The SAB agreed in general with dose additivity at the level of common health effect, and application of the Hazard Index, RPF and mixture BMD approaches for the evaluation of mixtures of PFAS. The SAB identified instances in which the communication of the analyses and approaches in the EPA's framework document could be improved to be clearer.

On the EPA's charge question for dose additivity, the SAB agreed with the use of the dose additivity assumption when evaluating PFAS mixtures that have similar effects and concluded that this approach was health protective. The SAB recommended a more thoroughly and clearly presented list of the uncertainties associated with dose additivity along with information supporting this approach. The EPA made revisions that added clarity to the text by expanding upon the uncertainties and including additional support for using dose additivity.

The SAB panel agreed with the use of the Hazard Index as a screening method and decision-making tool. The SAB advised that the EPA should consider using a menu-based framework to support selection of fit-for-purpose approaches, rather than a tiered approach as described in the draft mixtures document. Based on this feedback, the EPA has since reorganized the approach to provide a data-driven ''menu of options'' to remove the tiered logic flow and is adding text to clarify the flexibility in implementation.

The EPA sought the SAB's opinion on the RPF approach for estimating health risks associated with PFAS mixtures and the SAB panel considered the RPF approach to be a reasonable methodology for assessing mixtures. On the mixture BMD, the SAB agreed that the mixture BMD approach was a reasonable methodology for estimating a mixture-based point of departure (POD). For both the RPF and mixture BMD approach, the SAB recommended that the EPA's approach be strengthened by the use of PODs from animal studies that are based on HEDs rather than administered doses. The SAB also requested clarification as to the similarities and differences among the RPF and mixture BMD approaches. The SAB also asked the EPA to provide additional information on how the proposed mixtures BMD approach would be applied in practice. To address these recommendations, the EPA made revisions to provide better context and delineation about the applicability of the data across these approaches.

c. Cardiovascular Disease Analysis

The EPA consulted with the SAB on the agency's methodology to determine the avoided cases of CVD events (*e.g.,* heart attack, stroke, death from coronary heart disease) associated with reductions in exposure to PFOA and PFOS in drinking water to support a benefits analysis. Specifically, the EPA sought SAB comment on the extent to which the approach to estimating reductions in CVD risk is scientifically supported and clearly described. The EPA posed specific charge questions on the exposure-response information used in the analysis, the risk model and approach used to estimate the avoided cases of CVD events, and the EPA's discussion of limitations and uncertainties of the analysis. Overall, the SAB supported the EPA's approach to estimating reductions in CVD risk associated with reductions in exposure to PFOA and PFOS in drinking water. The SAB provided feedback on several areas of the analysis; main points of their feedback and the EPA's responses are discussed in this section.

The SAB noted a discrepancy between the draft CVD document's focus on CVD risk, and the draft MCLG documents' conclusions that the evidence of CVD was not sufficient to form the basis of a RfD. Based on SAB feedback on the draft MCLG document's assessment of CVD related risks, the EPA has developed an RfD for total cholesterol (TC). (For more information see USEPA, 2024c; USEPA, 2024d.) The derivation of an RfD for this endpoint addresses the SAB's concerns about inconsistency between the two documents. The SAB also recommended that the EPA ensure that recommendations for the draft MCLG documents relating to evidence identification and synthesis are applied to the CVD endpoint. All studies in the EPA's CVD benefits analysis were evaluated for risk of bias, selective reporting, and sensitivity as applied in the EPA's *Public Comment Draft—Toxicity Assessment and Proposed MCLGs for PFOA and PFOS in Drinking Water* (USEPA, 2023g; USEPA, 2023h).

The SAB recommended that the EPA provide more discussion as to the rationale for selecting CVD for risk reduction analysis and that the approach follows the pathway that links cholesterol to cardiovascular events rather than looking at the reported effects of PFAS directly on CVD. The SAB also recommended that the EPA consider risk reduction analyses for other endpoints. In section 6.5 of the EA, the EPA discusses the rationale for quantifying CVD and analytical assumptions. Sections 6.4 and 6.6 discusses the agency's quantified risk reduction analyses for other adverse health effects, including infant birthweight effects and renal cell carcinoma (RCC), respectively. In section 6.2.2, the EPA assesses the qualitative benefits of other adverse health effects of PFAS.

Although the SAB generally agreed with the meta-analysis, life table and risk estimation methods, the SAB recommended that the EPA provide additional clarity as to the application of these approaches and conduct additional sensitivity analyses. In response to these comments, the EPA expanded documentation and conducted additional sensitivity analyses to evaluate the impact of inclusion or exclusion of certain studies in the meta-analyses of exposure-response estimates. Further, the EPA expanded documentation and conducted additional sensitivity analyses to assess the effects of using a key single study approach versus the meta-analysis approach to inform the exposure-response estimates. The EPA identified two suitable key studies for use in the single study approach. The EPA found that the single study approach resulted in increased benefits, and this trend was driven by the larger estimates of PFAS–TC slope factors and inverse associations in the high-density lipoprotein cholesterol (HDLC) effect for one or both contaminants in the key single studies. The EPA elected to retain the meta-analysis approach in the benefits analysis because the agency identified several studies on adults in the general population with large numbers of participants and low risk of bias, and in this case the meta-analytical approach offers an increased statistical power over the single study approach. While the single study approach is common for RfD derivations, the meta-analysis pooled estimate provides a slope factor that represents the average response across a larger number of studies, which is useful in evaluating benefits resulting from changes in CVD risk on a national scale.

The SAB also recommended that the EPA evaluate how inclusion of HDLC effects would influence the results and provide further justification for the inclusion or exclusion of HDLC and blood pressure effects. The EPA found that, as expected, inclusion of HDLC effects decreases annualized CVD benefits and inclusion of blood pressure effects slightly increases annualized CVD benefits. Because HDLC was shown to have a stronger effect than blood pressure on annualized CVD benefits, inclusion of blood pressure and HDLC effects together decreases annualized CVD benefits. For more information see sensitivity analyses evaluating these effects in appendix K of the EA. Inclusion of HDLC effects into the national analysis would reduce national benefits estimates but would not change the EPA's bottom-line conclusion that the quantifiable and nonquantifiable benefits of the rule justify the quantifiable and nonquantifiable costs. After further examination of the evidence for HDLC and blood pressure effects, the EPA elected to include blood pressure effects because the findings from a single high confidence study and several medium confidence studies conducted among the general population provided consistent evidence of an association between PFOS exposure and blood pressure. The EPA did not include HDLC effects in the national benefits analysis because available evidence of associations between PFOS exposures and HDLC levels is inconsistent and there is no evidence of an association between PFOA exposures and HDLC levels.

Finally, the SAB noted that while the Atherosclerotic Cardiovascular Disease (ASCVD) model is a reasonable choice for estimating the probability of first time CVD events, it is not without limitations. The panel recommended that the EPA include more discussion of the accuracy of its predictions, particularly for sub-populations. The EPA expanded its evaluation of the ASCVD model's limitations, including a comparison of the ASCVD model predictions with race/ethnicity and sex-specific CVD incidence from Centers for Disease Control and Prevention's (CDC's) public health surveys (See section 6.5.3.2 and appendix G of the EA for details). Results show 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.

Comments on the SAB consultation and review were raised by public commenters. As a result, the comments have been addressed by the EPA in the final rule, supporting documents in the record, and throughout this preamble, specifically in sections III.B, IV, and XII.A.

2. National Drinking Water Advisory Council (NDWAC)

The agency consulted with the NDWAC prior to the rule proposal during the Council's April 19, 2022, virtual meeting. During the meeting, the EPA provided information related to the development of the proposed rule. A summary of the NDWAC input from that meeting is available in the *NDWAC, Fall 2022 Meeting Summary Report* (NDWAC, 2022) and the docket.

On August 8, 2023, the EPA consulted with the NDWAC prior to the final rule during a virtual meeting where the EPA presented on the proposed PFAS NPDWR, including the proposed MCLs, monitoring and PN requirements, and treatment and economic considerations. The EPA reiterated that the PFAS NPDWR was developed with extensive consultation from state, local and Tribal partners to identify avenues that would reduce PFAS in drinking water and reaffirmed its commitment to working with these partners on rule implementation. The EPA carefully considered the information provided by the NDWAC during the development of a final PFAS NPDWR. A summary of the NDWAC input from that meeting is available in the *NDWAC Summary Report* (NDWAC, 2023) and the docket.

3. Department of Health and Human Service

On September 28, 2022, the EPA consulted with the Department of HHS on the proposed PFAS NPDWR. On November 2, 2023, the EPA consulted with the HHS on the final rule. The EPA received and considered comments from the HHS for both the proposed and final rules through the interagency review process described in section XIII.A.

L. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action meets the criteria set forth in 5 U.S.C.804(2).

XIV. Severability

The purpose of this section is to clarify the EPA's intent with respect to the severability of provisions of this rule. Each Maximum Contaminant Level (MCL) is independent of the others and can be implemented on its own. For that reason, if any individual or Hazard Index MCL is determined by judicial review or operation of law to be invalid, the EPA intends that the partial invalidation will not render any other

MCL invalid. In addition, each per- and polyfluoroalkyl substance (PFAS) included in the Hazard Index is independent from any other PFAS included in the Hazard Index. As a result, if any PFAS regulation is determined by judicial review or operation of law to be invalid, that partial invalidation should not render any other PFAS regulation included in the Hazard Index or the Hazard Index PFAS MCL invalid. Moreover, the Hazard Index approach and Hazard Index PFAS MCL can remain operable and applicable so long as there are at least two contaminants subject to the Hazard Index as a mixture because the EPA's definition of mixture in this final rule is of two or more of the Hazard Index PFAS. In addition, each individual Maximum Contaminant Level Goal (MCLG) is independent of each of the other MCLGs and, because they perform different functions under the Act, of each of the MCLs. As a result, if an MCL is determined to be invalid, that partial invalidation should not render the associated MCLG invalid. The monitoring requirements are independent and capable of operating without any MCLs. Likewise, if any provision of this rule other than the MCLGs, or MCLs, is determined to be invalid (such as monitoring waivers or the capital improvements extension), the remainder of the rule can still be sensibly implemented; as a result, the EPA intends that the rest of the rule (such as monitoring requirements) remain operable and applicable.

XV. Incorporation by Reference

In this action, the EPA requires that systems must only use the analytical methods specified to demonstrate compliance with the rule. EPA Method 533: Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry, November 2019, 815–B–19–020, and EPA Method 537.1,Version 2.0: Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS), March 2020, EPA/600/R–20/006, are incorporated by reference in this final rule and are publicly available in the EPA's Docket ID No. EPA–HQ–OW–2022–0114. The EPA Method 533 and EPA Method 537.1, Version 2.0 are solid phase extraction liquid chromatography-tandem mass spectrometry methods for the detection and determination of select per-and polyfluoroalkyl substances in drinking water. In addition to being available in the aforementioned rule docket, both methods can be accessed online at *https://www.epa.gov/pfas/epa-pfas-drinking-water-laboratory-methods.*

XVI. References

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List of Subjects

40 CFR Part 141

Environmental protection, Incorporation by reference, Indians—lands, Intergovernmental relations, Monitoring and analytical requirements, Per- and polyfluoroalkyl substances, Reporting and recordkeeping requirements, Water supply.

40 CFR Part 142

Environmental protection, Administrative practice and procedure, Indians—lands, Intergovernmental relations, Monitoring and analytical requirements, Per- and polyfluoroalkyl substances, Reporting and recordkeeping requirements, Water supply.

Michael S. Regan,

Administrator.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR parts 141 and 142 as follows:

PART 141—NATIONAL PRIMARY DRINKING WATER REGULATIONS

■ 1. The authority citation for part 141 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

■ 2. Amend § 141.2 by adding in alphabetical order the definitions for ‘‘Hazard Index (HI)’’, ‘‘Hazard quotient (HQ)’’, ‘‘Health-based water concentration (HBWC)’’, ‘‘HFPO–DA or GenX chemicals’’, ‘‘PFBS’’, ‘‘PFHxS’’, ‘‘PFNA’’, ‘‘PFOA’’, and ‘‘PFOS’’ to read as follows:

§ 141.2 Definitions.

* * * * *

Hazard Index (HI) is the sum of component hazard quotients (HQs), which are calculated by dividing the measured regulated PFAS component contaminant concentration in water (*e.g.,* expressed as parts per trillion (ppt) or nanograms per liter (ng/l)) by the associated health-based water concentration (HBWC) expressed in the same units as the measured concentration (*e.g.,* ppt or ng/l). For PFAS, a mixture Hazard Index greater than 1 (unitless) is an exceedance of the MCL.

Hazard quotient (HQ) means the ratio of the measured concentration in drinking water to the health-based water concentration (HBWC).

Health-based water concentration (HBWC) means level below which there are no known or anticipated adverse health effects over a lifetime of exposure, including sensitive populations and life stages, and allows for an adequate margin of safety.

HFPO–DA or *GenX chemicals* means Chemical Abstract Service registration number 122499–17–6, chemical formula C6F11O3-, International Union of Pure and Applied Chemistry preferred name 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propanoate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

* * * * *

PFBS means Chemical Abstract Service registration number 45187–15–3, chemical formula C4F9SO3-, perfluorobutane sulfonate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

PFHxS means Chemical Abstract Service registration number 108427–53–8, chemical formula C6F13SO3-, perfluorohexane sulfonate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

PFNA means Chemical Abstract Service registration number 72007–68–2, chemical formula C9F17O2-, perfluorononanoate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

PFOA means Chemical Abstract Service registration number 45285–51–6, chemical formula C8F15O2-, perfluorooctanoate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

PFOS means Chemical Abstract Service registration number 45298–90–6, chemical formula C8F17SO3–, perfluorooctanesulfonate, along with its conjugate acid and any salts, derivatives, isomers, or combinations thereof.

* * * * *

■ 3. Amend § 141.6 by revising paragraph (a) and adding paragraph (l) to read as follows:

§ 141.6 Effective dates.

(a) Except as provided in paragraphs (b) through (l) of this section the regulations set forth in this part take effect on June 24, 1977.

* * * * *

(l) The regulations pertaining to the per- and polyfluoroalkyl substances (PFAS) chemicals set forth in subpart Z of this part are effective June 25, 2024. See § 141.900 for the compliance dates for provisions under subpart Z. Compliance with reporting requirements under subpart Z, in accordance with subparts O (the consumer confidence rule) and Q (the public notification rule) of this part are required on April 26, 2027, except for notification requirements in § 141.203 related to violations of the MCLs. The compliance date for the PFAS MCLs in § 141.61, as specified in § 141.60, and for § 141.203 notifications of violations of the PFAS MCLs is April 26, 2029.

■ 4. Amend § 141.24 by revising paragraph (h) introductory text to read as follows:

§ 141.24 Organic chemicals, sampling and analytical requirements.

* * * * *

(h) Analysis of the contaminants listed in § 141.61(c) for the purposes of determining compliance with the maximum contaminant level shall be conducted as follows, with the exceptions that this paragraph (h) does not apply to regulated PFAS (see § 141.902) and no monitoring is required for aldicarb, aldicarb sulfoxide, or aldicarb sulfone:

* * * * *

■ 5. Amend § 141.28 by revising paragraph (a) to read as follows:

§ 141.28 Certified laboratories.

(a) For the purpose of determining compliance with §§ 141.21 through 141.27, 141.40, 141.74, 141.89, 141.402, 141.901, and 141.902, samples may be considered only if they have been analyzed by a laboratory certified by EPA or the State except that measurements of alkalinity, disinfectant residual, orthophosphate, pH, silica, temperature, and turbidity may be performed by any person acceptable to the State.

* * * * *

■ 6. Amend § 141.50 by:

■ a. Adding periods at the ends of paragraphs (a)(1) through (23);

■ b. Adding paragraphs (a)(24) and (25); and

■ c. In the table to paragraph (b), revising the heading for the second column and adding in numerical order the entries ‘‘(34),’’ ‘‘(35),’’ ‘‘(36),’’ and ‘‘(37)’’ and footnote 1.

The additions and revision read as follows:

§ 141.50 Maximum contaminant level goals for organic contaminants.

(a) * * *

(24) PFOA.

(25) PFOS.

(b) * * *

Contaminant	MCLG in mg/l (unless otherwise noted)
* * * * * *	*
(34) Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA)	1 (unitless).[1]
(35) HFPO–DA	0.00001.
(36) PFHxS	0.00001.
(37) PFNA	0.00001.

[1] The PFAS Mixture Hazard Index (HI) is the sum of component hazard quotients (HQs), which are calculated by dividing the measured component PFAS concentration in water by the corresponding contaminant's health-based water concentration (HBWC) when expressed in the same units (shown in ng/l). The HBWC for PFHxS is 10 ng/l; the HBWC for HFPO–DA is 10 ng/l; the HBWC for PFNA is 10 ng/l; and the HBWC for PFBS is 2000 ng/l. A PFAS Mixture Hazard Index greater than 1 (unitless) indicates an exceedance of the health protective level and indicates potential human health risk from the PFAS mixture in drinking water.

$$\text{Hazard Index} = ([\text{HFPO–DA}_{\text{water}}\ \text{ng/l}]/[10\ \text{ng/l}]) + ([\text{PFBS}_{\text{water}}\ \text{ng/l}]/[2000\ \text{ng/l}]) + ([\text{PFNA}_{\text{water}}\ \text{ng/l}]/[10\ \text{ng/l}]) + ([\text{PFHxS}_{\text{water}}\ \text{ng/l}]/[10\ \text{ng/l}])$$

HBWC = health-based water concentration

HQ = hazard quotient

ng/l = nanograms per liter

PFAS$_{\text{water}}$ = the concentration of a specific PFAS in water

■ 7. Amend § 141.60 by adding paragraph (a)(4) to read as follows:

§ 141.60 Effective dates.

(a) * * *

(4) The effective date for paragraphs (c)(34) through (40) of § 141.61 (listed in table 4 to paragraph (c)) is April 26, 2029.

* * * * *

■ 8. Amend § 141.61 by:

■ a. In paragraph (a), revising the introductory text and adding a table heading;

■ b. In paragraph (b), revising the introductory text and the table heading;

■ c. Revising and republishing paragraph (c); and

■ d. Adding paragraphs (d) and (e).

The revisions and additions read as follows:

§ 141.61 Maximum contaminant levels for organic contaminants.

(a) The following maximum contaminant levels for volatile organic contaminants apply to community and non-transient, non-community water systems.

TABLE 1 TO PARAGRAPH (a)—MAXIMUM CONTAMINANT LEVELS FOR VOLATILE ORGANIC CONTAMINANTS

* * * * *

(b) The Administrator, pursuant to section 1412 of the Act, hereby identifies as indicated in table 2 to this paragraph (b) granular activated carbon (GAC), packed tower aeration (PTA), or oxidation (OX) as the best technology, treatment technique, or other means available for achieving compliance with the maximum contaminant level for organic contaminants identified in paragraphs (a) and (c) of this section, except for per- and polyfluoroalkyl substances (PFAS).

TABLE 2 TO PARAGRAPH (b)—BAT FOR ORGANIC CONTAMINANTS IN PARAGRAPHS (a) AND (c) OF THIS SECTION, EXCEPT FOR PFAS

* * * * *

(c) The following maximum contaminant levels (MCLs) in tables 3 and 4 to this paragraph (c) for synthetic organic contaminants apply to community water systems and non-transient, non-community water systems; table 4 also contains health-based water concentrations (HBWCs) for selected per- and poly-fluoroalkyl substances (PFAS) used in calculating the Hazard Index.

TABLE 3 TO PARAGRAPH (c)—MCLS FOR SYNTHETIC ORGANIC CONTAMINANTS, EXCEPT FOR PFAS

CAS No.	Contaminant	MCL (mg/l)
(1) 15972–60–8	Alachlor	0.002
(2) 116–06–3	Aldicarb	0.003
(3) 1646–87–3	Aldicarb sulfoxide	0.004
(4) 1646–87–4	Aldicarb sulfone	0.002
(5) 1912–24–9	Atrazine	0.003
(6) 1563–66–2	Carbofuran	0.04
(7) 57–74–9	Chlordane	0.002
(8) 96–12–8	Dibromochloropropane	0.0002
(9) 94–75–7	2,4–D	0.07
(10) 106–93–4	Ethylene dibromide	0.00005
(11) 76–44–8	Heptachlor	0.0004
(12) 1024–57–3	Heptachlor epoxide	0.0002
(13) 58–89–9	Lindane	0.0002
(14) 72–43–5	Methoxychlor	0.04
(15) 1336–36–3	Polychlorinated biphenyls	0.0005
(16) 87–86–5	Pentachlorophenol	0.001
(17) 8001–35–2	Toxaphene	0.003
(18) 93–72–1	2,4,5–TP	0.05
(19) 50–32–8	Benzo[a]pyrene	0.0002
(20) 75–99–0	Dalapon	0.2
(21) 103–23–1	Di(2-ethylhexyl) adipate	0.4
(22) 117–81–7	Di(2-ethylhexyl) phthalate	0.006
(23) 88–85–7	Dinoseb	0.007
(24) 85–00–7	Diquat	0.02
(25) 145–73–3	Endothall	0.1
(26) 72–20–8	Endrin	0.002
(27) 1071–53–6	Glyphosate	0.7
(28) 118–74–1	Hexacholorbenzene	0.001
(29) 77–47–4	Hexachlorocyclopentadiene	0.05
(30) 23135–22–0	Oxamyl (Vydate)	0.2
(31) 1918–02–1	Picloram	0.5
(32) 122–34–9	Simazine	0.004
(33) 1746–01–6	2,3,7,8–TCDD (Dioxin)	3×10^{-8}

TABLE 4 TO PARAGRAPH (c)—MCLS AND HBWCS FOR PFAS

CAS. No.	Contaminant	MCL (mg/l) (unless otherwise noted)	HBWC (mg/l) for hazard index calculation
(34) Not applicable	Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA).	1 (unitless)[1]	Not applicable
(35) 122499–17–6	HFPO–DA	0.00001	0.00001
(36) 45187–15–3	PFBS	No individual MCL	0.002
(37) 108427–53–8	PFHxS	0.00001	0.00001
(38) 72007–68–2	PFNA	0.00001	0.00001
(39) 45285–51–6	PFOA	0.0000040	Not applicable

TABLE 4 TO PARAGRAPH (c)—MCLS AND HBWCS FOR PFAS—Continued

CAS. No.	Contaminant	MCL (mg/l) (unless otherwise noted)	HBWC (mg/l) for hazard index calculation
(40) 45298–90–6	PFOS	0.0000040	Not applicable

[1] The PFAS Mixture Hazard Index (HI) is the sum of component hazard quotients (HQs), which are calculated by dividing the measured component PFAS concentration in water by the relevant health-based water concentration when expressed in the same units (shown in ng/l for simplification). The HBWC for PFHxS is 10 ng/l; the HBWC for HFPO–DA is 10 ng/l; the HBWC for PFNA is 10 ng/l; and the HBWC for PFBS is 2000 ng/l.

$$\text{Hazard Index} = ([\text{HFPO–DA}_{water}\ \text{ng/l}]/[10\ \text{ng/l}]) + ([\text{PFBS}_{water}\ \text{ng/l}]/[2000\ \text{ng/l}]) + ([\text{PFNA}_{water}\ \text{ng/l}]/[10\ \text{ng/l}]) + ([\text{PFHxS}_{water}\ \text{ng/l}]/[10\ \text{ng/l}])$$

HBWC = health-based water concentration
HQ = hazard quotient
ng/l = nanograms per liter
PFAS_{water} = the concentration of a specific PFAS in water

(d) The Administrator, pursuant to section 1412 of the Act, hereby identifies in table 5 to this paragraph (d) the best technology, treatment technique, or other means available for achieving compliance with the maximum contaminant levels for all regulated PFAS identified in paragraph (c) of this section:

TABLE 5 TO PARAGRAPH (d)—BEST AVAILABLE TECHNOLOGIES FOR PFAS LISTED IN PARAGRAPH (c) OF THIS SECTION

Contaminant	BAT
Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA)	Anion exchange, GAC, reverse osmosis, nanofiltration.
HFPO–DA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFHxS	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFNA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFOA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFOS	Anion exchange, GAC, reverse osmosis, nanofiltration.

(e) The Administrator, pursuant to section 1412 of the Act, hereby identifies in table 6 to this paragraph (e) the affordable technology, treatment technique, or other means available to systems serving 10,000 persons or fewer for achieving compliance with the maximum contaminant levels for all regulated PFAS identified in paragraph (c) of this section:

TABLE 6 TO PARAGRAPH (e)—SMALL SYSTEM COMPLIANCE TECHNOLOGIES (SSCTS) FOR PFAS

Small system compliance technology[1]	Affordable for listed small system categories[2]
Granular Activated Carbon.	All size categories.
Anion Exchange	All size categories.
Reverse Osmosis, Nanofiltration[3].	3,301–10,000.

[1] Section 1412(b)(4)(E)(ii) of SDWA specifies that SSCTs must be affordable and technically feasible for small systems.

[2] The Act (ibid.) specifies three categories of small systems: (i) those serving 25 or more, but fewer than 501, (ii) those serving more than 500, but fewer than 3,301, and (iii) those serving more than 3,300, but fewer than 10,001.

[3] Technologies reject a large volume of water and may not be appropriate for areas where water quantity may be an issue.

■ 9. Amend § 141.151 by revising paragraph (d) to read as follows:

§ 141.151 Purpose and applicability of this subpart.

* * * * *

(d) For the purpose of this subpart, detected means: at or above the levels prescribed by § 141.23(a)(4) for inorganic contaminants, at or above the levels prescribed by § 141.24(f)(7) for the contaminants listed in § 141.61(a), at or above the levels prescribed by § 141.24(h)(18) for the contaminants listed in § 141.61(c) (except PFAS), at or above the levels prescribed by § 141.131(b)(2)(iv) for the contaminants or contaminant groups listed in § 141.64, at or above the levels prescribed by § 141.25(c) for radioactive contaminants, and at or above the levels prescribed in § 141.902(a)(5) for PFAS listed in § 141.61(c).

* * * * *

■ 10. Amend § 141.153 by adding paragraph (c)(3)(v) to read as follows:

§ 141.153 Content of the reports.

* * * * *

(c) * * *

(3) * * *

(v) *Hazard Index or HI.* The Hazard Index is an approach that determines the health concerns associated with mixtures of certain PFAS in finished drinking water. Low levels of multiple PFAS that individually would not likely result in adverse health effects may pose health concerns when combined in a mixture. The Hazard Index MCL represents the maximum level for mixtures of PFHxS, PFNA, HFPO–DA, and/or PFBS allowed in water delivered by a public water system. A Hazard Index greater than 1 requires a system to take action.

* * * * *

■ 11. Amend appendix A to subpart O, under the Contaminant heading ‘‘Synthetic organic contaminants including pesticides and herbicides:’’, by adding in alphabetical order entries for ‘‘Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA) (unitless)’’, ‘‘HFPO–DA (ng/l)’’, ‘‘PFHxS (ng/l)’’, ‘‘PFNA (ng/l)’’, ‘‘PFOA (ng/l)’’, and ‘‘PFOS (ng/l)’’ to read as follows:

Appendix A to Subpart O of Part 141—Regulated Contaminants

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
*	*	*	*	*	*	*
Synthetic organic contaminants including pesticides and herbicides:	*	*	*	*	*	*
*	*	*	*	*	*	*
Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA) (unitless).	1 (unitless)	....	1	1	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Per- and polyfluoroalkyl substances (PFAS) can persist in the human body and exposure may lead to increased risk of adverse health effects. Low levels of multiple PFAS that individually would not likely result in increased risk of adverse health effects may result in adverse health effects when combined in a mixture. Some people who consume drinking water containing mixtures of PFAS in excess of the Hazard Index (HI) MCL may have increased health risks such as liver, immune, and thyroid effects following exposure over many years and developmental and thyroid effects following repeated exposure during pregnancy and/or childhood.
*	*	*	*	*	*	*
HFPO–DA (ng/l).	0.00001	1,000,000	10	10	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Some people who drink water containing HFPO–DA in excess of the MCL over many years may have increased health risks such as immune, liver, and kidney effects. There is also a potential concern for cancer associated with HFPO–DA exposure. In addition, there may be increased risks of developmental effects for people who drink water containing HFPO–DA in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
*	*	*	*	*	*	*
PFHxS (ng/l)	0.00001	1,000,000	10	10	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Some people who drink water containing PFHxS in excess of the MCL over many years may have increased health risks such as immune, thyroid, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFHxS in excess of the MCL following repeated exposure during pregnancy and/or childhood.
PFNA (ng/l) ...	0.00001	1,000,000	10	10	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Some people who drink water containing PFNA in excess of the MCL over many years may have increased health risks such as elevated cholesterol levels, immune effects, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFNA in excess of the MCL following repeated exposure during pregnancy and/or childhood.
PFOA (ng/l) ...	0.0000040	1,000,000	4.0	0	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Some people who drink water containing PFOA in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including kidney and testicular cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOA in excess of the MCL following repeated exposure during pregnancy and/or childhood.

Contaminant (units)	Traditional MCL in mg/L	To convert for CCR, multiply by	MCL in CCR units	MCLG	Major sources in drinking water	Health effects language
PFOS (ng/l) ...	0.0000040	1,000,000	4.0	0	Discharge from manufacturing and industrial chemical facilities, use of certain consumer products, occupational exposures, and certain firefighting activities.	Some people who drink water containing PFOS in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including liver cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOS in excess of the MCL following repeated exposure during pregnancy and/or childhood.
*	*	*	*	*	*	*

* * * * *

■ 12. Amend appendix A to subpart Q by:

■ a. Adding under the Contaminant heading "D. Synthetic Organic Chemicals (SOCs)" entries for "31", "32", "33", "34", "35", and "36" in numerical order;

■ b. Adding, immediately before footnote 1, footnote *; and

■ c. Adding footnote 23 at the end of the table.

The additions read as follows:

Appendix A to Subpart Q of Part 141—NPDWR Violations and Other Situations Requiring Public Notice [1]

Contaminant	MCL/MRDL/TT violations [2]		Monitoring & testing procedure violations	
	Tier of public notice required	Citation	Tier of public notice required	Citation
* * * * * * *				
D. Synthetic Organic Chemicals (SOCs)				
* * * * * * *				
31. Hazard Index PFAS	[23] *2	141.61(c)	3	141.905(c)
32. HFPO–DA	*2	141.61(c)	3	141.905(c)
33. PFHxS	*2	141.61(c)	3	141.905(c)
34. PFNA	*2	141.61(c)	3	141.905(c)
35. PFOA	*2	141.61(c)	3	141.905(c)
36. PFOS	*2	141.61(c)	3	141.905(c)
* * * * * * *				

Appendix A—Endnotes

* * * * * * *

* Beginning April 26, 2029.

[1] Violations and other situations not listed in this table (*e.g.,* failure to prepare Consumer Confidence Reports), do not require notice, unless otherwise determined by the primacy agency. Primacy agencies may, at their option, also require a more stringent public notice tier (*e.g.,* Tier 1 instead of Tier 2 or Tier 2 instead of Tier 3) for specific violations and situations listed in this Appendix, as authorized under § 141.202(a) and § 141.203(a).

[2] MCL—Maximum contaminant level, MRDL—Maximum residual disinfectant level, TT—Treatment technique.

* * * * * * *

[23] Systems that violate the Hazard Index MCL and one or more individual MCLs based on the same contaminants may issue one notification to satisfy the public notification requirements for multiple violations pursuant to § 141.203.

■ 13. Amend appendix B to subpart Q by redesignating entries "55" through "89" as entries "61" through "95" and adding new entries "55" through "60" under the heading "E. Synthetic Organic Chemicals (SOCs)" to read as follows:

Appendix B to Subpart Q of Part 141—Standard Health Effects Language for Public Notification

Contaminant	MCLG[1] mg/L	MCL[2] mg/L	Standard health effects language for public notification
*	*	*	* * * *
E. Synthetic Organic Chemicals (SOCs)			
*	*	*	* * * *
55. Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA).	1 (unitless)	1 (unitless)	Per- and polyfluoroalkyl substances (PFAS) can persist in the human body and exposure may lead to increased risk of adverse health effects. Low levels of multiple PFAS that individually would not likely result in increased risk of adverse health effects may result in adverse health effects when combined in a mixture. Some people who consume drinking water containing mixtures of PFAS in excess of the Hazard Index (HI) MCL may have increased health risks such as liver, immune, and thyroid effects following exposure over many years and developmental and thyroid effects following repeated exposure during pregnancy and/or childhood.
56. HFPO–DA	0.00001	0.00001	Some people who drink water containing HFPO–DA in excess of the MCL over many years may have increased health risks such as immune, liver, and kidney effects. There is also a potential concern for cancer associated with HFPO–DA exposure. In addition, there may be increased risks of developmental effects for people who drink water containing HFPO–DA in excess of the MCL following repeated exposure during pregnancy and/or childhood.
57. PFHxS	0.00001	0.00001	Some people who drink water containing PFHxS in excess of the MCL over many years may have increased health risks such as immune, thyroid, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFHxS in excess of the MCL following repeated exposure during pregnancy and/or childhood.
58. PFNA	0.00001	0.00001	Some people who drink water containing PFNA in excess of the MCL over many years may have increased health risks such as elevated cholesterol levels, immune effects, and liver effects. In addition, there may be increased risks of developmental effects for people who drink water containing PFNA in excess of the MCL following repeated exposure during pregnancy and/or childhood.
59. PFOA	Zero	0.0000040	Some people who drink water containing PFOA in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including kidney and testicular cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOA in excess of the MCL following repeated exposure during pregnancy and/or childhood.
60. PFOS	Zero	0.0000040	Some people who drink water containing PFOS in excess of the MCL over many years may have increased health risks such as cardiovascular, immune, and liver effects, as well as increased incidence of certain types of cancers including liver cancer. In addition, there may be increased risks of developmental and immune effects for people who drink water containing PFOS in excess of the MCL following repeated exposure during pregnancy and/or childhood.
*	*	*	* * * *

* * * * * * *

[1] MCLG—Maximum contaminant level goal.
[2] MCL—Maximum contaminant level.

* * * * *

■ 14. Amend appendix C to subpart Q by adding entries for the acronyms ‘‘HI’’ and ‘‘PFAS’’ in alphabetical order to read as follows:

Appendix C to Subpart Q of Part 141—List of Acronyms Used in Public Notification Regulation

* * * * *

HI Hazard Index

* * * * *

PFAS Per- and Polyfluoroalkyl Substances

* * * * *

■ 15. Add subpart Z to read as follows:

Subpart Z—Control of Per- and Polyfluoroalkyl Substances (PFAS)

Sec.
141.900 General requirements.
141.901 Analytical requirements.
141.902 Monitoring requirements.
141.903 Compliance requirements.
141.904 Reporting and recordkeeping requirements.
141.905 Violations.

Subpart Z—Control of Per- and Polyfluoroalkyl Substances (PFAS)

§ 141.900 General requirements.

(a) The requirements of this subpart constitute the national primary drinking water regulations for PFAS. Each community water system (CWS) and non-transient, non-community water system (NTNCWS) must meet the requirements of this subpart including the maximum contaminant levels for the PFAS identified in § 141.61(c).

(b) The deadlines for complying with the provisions of this subpart are as follows:

(1) Each system must meet the analytical requirements in § 141.901 by June 25, 2024.

(2) Each system must report the results of initial monitoring, as described in § 141.902(b)(1), to the State by April 26, 2027.

(3) Each system must meet the compliance monitoring requirements in § 141.902(b)(2) by April 26, 2027.

(4) Each system must meet the MCL compliance requirements in § 141.903 by April 26, 2029.

(5) Each system must meet the reporting and recordkeeping requirements in § 141.904 by April 26, 2027.

(6) Violations described in § 141.905 include monitoring and reporting violations and violations of MCLs. Monitoring and reporting violations may be assessed beginning on April 26, 2027. MCL violations may be assessed beginning on April 26, 2029.

§ 141.901 Analytical requirements.

(a) *General.* (1) Systems must use only the analytical methods specified in this section to demonstrate compliance with the requirements of this subpart.

(2) The following documents are incorporated by reference with the approval of the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the EPA and at the National Archives and Records Administration (NARA). Contact the EPA's Drinking Water Docket at: 1301 Constitution Avenue NW., EPA West, Room 3334, Washington, DC 20460; phone: 202–566–2426. For information on the availability of this material at NARA, email: *fr.inspection@nara.gov*, or go to: *www.archives.gov/federal-register/cfr/ibr-locations.* The material may be obtained from the EPA at 1301 Constitution Avenue NW, the EPA West, Room 3334, Washington, DC 20460; phone: 202–566–2426; website: *https://www.epa.gov/pfas/epa-pfas-drinking-water-laboratory-methods.*

(i) EPA Method 533: Determination of Per- and Polyfluoroalkyl Substances in Drinking Water by Isotope Dilution Anion Exchange Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry, 815–B–19–020, November 2019.

(ii) Method 537.1, Version 2.0: Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS), EPA/600/R–20/006, March 2020.

(b) *PFAS*–(1) *Analytical methods.* Systems must measure regulated PFAS by the methods listed in the following table:

TABLE 1 TO PARAGRAPH (b)(1)—ANALYTICAL METHODS FOR PFAS CONTAMINANTS

Contaminant	Methodology	EPA method (incorporated by reference, see paragraph (a) of this section)
Perfluorobutane Sulfonate (PFBS)	SPE LC–MS/MS	533, 537.1, version 2.0.
Perfluorohexane Sulfonate (PFHxS)	SPE LC–MS/MS	533, 537.1, version 2.0.
Perfluorononanoate (PFNA)	SPE LC–MS/MS	533, 537.1, version 2.0.
Perfluorooctanesulfonic Acid (PFOS)	SPE LC–MS/MS	533, 537.1, version 2.0.
Perfluorooctanoic Acid (PFOA)	SPE LC–MS/MS	533, 537.1, version 2.0.
2,3,3,3-Tetrafluoro-2-(heptafluoropropoxy)propanoate (HFPO–DA or GenX Chemicals).	SPE LC–MS/MS	533, 537.1, version 2.0.

(2) *Laboratory certification.* Analyses under this section for regulated PFAS must only be conducted by laboratories that have been certified by EPA or the State. To receive certification to conduct analyses for the regulated PFAS, the laboratory must:

(i) Analyze Performance Evaluation (PE) samples that are acceptable to the State at least once during each consecutive 12-month period by each method for which the laboratory desires certification.

(ii) Beginning June 25, 2024, achieve quantitative results on the PE sample analyses that are within the following acceptance limits:

TABLE 2 TO PARAGRAPH (b)(2)(ii)—ACCEPTANCE LIMITS FOR PFAS PERFORMANCE EVALUATION SAMPLES

Contaminant	Acceptance limits (percent of true value)
Perfluorobutane Sulfonate (PFBS)	70–130
Perfluorohexane Sulfonate (PFHxS)	70–130
Perfluorononanoate (PFNA)	70–130
Perfluorooctanesulfonic Acid (PFOS)	70–130
Perfluorooctanoic Acid (PFOA)	70–130
2,3,3,3-Tetrafluoro-2-(heptafluoropropoxy)propanoate (HFPO–DA or GenX Chemicals)	70–130

(iii) For all samples analyzed for regulated PFAS in compliance with § 141.902, beginning June 25, 2024, report data for concentrations as low as the trigger levels as defined in § 141.902(a)(5).

§ 141.902 Monitoring requirements.

(a) *General requirements.* (1) Systems must take all samples during normal operating conditions at all entry points to the distribution system.

(2) If the system draws water from more than one source and the sources are combined before distribution, the system must sample at an entry point to the distribution system during periods of representative operating conditions.

(3) Systems must use only data collected under the provisions of this subpart to qualify for reduced monitoring.

(4) All new systems that begin operation after, or systems that use a new source of water after April 26, 2027, must demonstrate compliance with the MCLs within a period of time specified by the State. A system must also comply with initial sampling frequencies required by the State to ensure that the system can demonstrate compliance with the MCLs. Compliance monitoring frequencies must be conducted in accordance with the requirements in this section.

(5) For purposes of this section, the trigger levels are defined as shown in the following table.

TABLE 1 TO PARAGRAPH (a)(5)—TRIGGER LEVELS FOR PFAS CONTAMINANTS

Contaminant	Trigger level
Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, PFNA).	0.5 (unitless).
HFPO–DA	5 nanograms per liter (ng/l).
PFHxS	5 ng/l.
PFNA	5 ng/l.
PFOA	2.0 ng/l.
PFOS	2.0 ng/l.

(6) Based on initial monitoring results, for each sampling point at which a regulated PFAS listed in § 141.61(c) is detected at a level greater than or equal to the trigger level, the system must monitor quarterly for all regulated PFAS beginning April 26, 2027, in accordance with paragraph (b)(2) of this section.

(7) For purposes of this section, each water system must ensure that all results provided by a laboratory are reported to the State and used for determining the required sampling frequencies. This includes values below the practical quantitation levels defined in § 141.903(f)(1)(iv); zero must not be used in place of reported values.

(b) *Monitoring requirements for PFAS*—(1) *Initial monitoring.* (i) Groundwater CWS and NTNCWS serving greater than 10,000 persons and all surface water CWS and NTNCWS must take four consecutive samples 2 to 4 months apart within a 12-month period (quarterly samples) for each regulated PFAS listed in § 141.61(c).

(ii) All groundwater CWS and NTNCWS serving 10,000 or fewer persons must take two samples for each regulated PFAS listed in § 141.61(c) five to seven months apart within a 12-month period.

(iii) All groundwater under the direct influence of surface water (GWUDI) CWS and NTNCWS must follow the surface water CWS and NTNCWS monitoring schedule in paragraph (b)(1)(i) of this section.

(iv) All systems that use both surface water and groundwater must apply the requirements in paragraphs (b)(1)(i) through (iii) of this section depending on the source(s) of water provided at a given entry point to the distribution system (EPTDS). If the EPTDS provides surface water, the requirements for a surface water CWS/NTNCWS apply. If the EPTDS provides groundwater, the requirements for a groundwater CWS/NTNCWS apply, based on system size. If an EPTDS provides a blend of surface water and groundwater, the requirements for a surface water system apply. For systems that change the source water type at an EPTDS during the initial monitoring period (*i.e.,* one part of the year it is surface water and the remaining part of the year it is groundwater), the sampling requirements for a surface water system apply.

(v) Systems must monitor at a frequency indicated in the following table, though a State may require more frequent monitoring on a system-specific basis:

TABLE 2 TO PARAGRAPH (b)(1)(v)—INITIAL MONITORING REQUIREMENTS

Type of system	Minimum monitoring frequency	Sample location
Groundwater CWS and NTNCWS serving greater than 10,000 persons, all surface water CWS and NTNCWS, and all GWUDI systems.	Four consecutive quarters of samples per entry point to the distribution system (EPTDS) within a 12-month period, unless the exception in paragraph (b)(1)(viii) of this section applies. Samples must be taken two to four months apart..	Sampling point for EPTDS.
Groundwater CWS and NTNCWS serving 10,000 or fewer persons.	Two consecutive samples per EPTDS within a 12-month period, unless the exception in paragraph (b)(1)(viii) of this section applies. Samples must be taken five to seven months apart..	Sampling point for EPTDS.

(vi) A State may accept data that has been previously acquired by a water system to count toward the initial monitoring requirements if the data meet the requirements of § 141.901(b)(1), samples were collected starting on or after January 1, 2019, and otherwise meet the timing requirements specified in table 2 to paragraph (b)(1)(v) of this section. For the purposes of satisfying initial monitoring requirements, acceptable data may be reported to a concentration no greater than the MCLs. However, a system is only eligible for triennial monitoring at the start of the compliance monitoring period if the system demonstrates that concentrations in all samples it uses to satisfy the initial monitoring requirements are below the trigger levels as defined in paragraph (a)(5) of this section.

(vii) If systems have multiple years of data, the most recent data must be used.

(viii) For systems using previously acquired data that have fewer than the number of samples required in a continuous 12-month period for initial monitoring as listed in table 2 to paragraph (b)(1)(v) of this section: All surface water systems, GWUDI systems, and groundwater systems serving greater than 10,000 persons must collect in a calendar year one sample in each quarter that was not represented, two to four months apart from the months with available data; All groundwater systems serving 10,000 or fewer persons must collect one sample in the month that is five to seven months apart from the month in which the previous sample was taken.

(ix) In determining the most recent data to report, a system must include all results provided by a laboratory whether above or below the practical quantitation levels. These results must be used for the purposes of determining the frequency with which a system must monitor at that sampling point at the start of the compliance monitoring period.

(x) States may delete results of obvious sampling errors. If the State deletes a result because of an obvious sampling error and the system fails to collect another sample this is a monitoring violation as described in § 141.905(c).

(xi) Initial monitoring requirements, including reporting results to the State, must be completed by April 26, 2027.

(2) *Compliance monitoring.* (i) Based on initial monitoring results, at the start of the monitoring period that begins on April 26, 2027, systems may reduce monitoring at each sampling point at which all reported sample concentrations were below all trigger levels defined in paragraph (a)(5) of this section, unless otherwise provided for by the State. At eligible sampling points,

each water system must analyze one sample for all regulated PFAS during each three-year monitoring period, at a time specified by the State, in the quarter in which the highest analytical result was detected during the most recent round of quarterly or semi-annual monitoring. If a sampling point is not eligible for triennial monitoring, then the water system must monitor quarterly at the start of the compliance monitoring period.

(ii) If, during the compliance monitoring period, a system is monitoring triennially and a PFAS listed in § 141.61(c) is detected at a level equal to or exceeding the trigger levels defined in paragraph (a)(5) of this section in any sample, then the system must monitor quarterly for all regulated PFAS beginning in the next quarter at the sampling point. The triggering sample must be used as the first quarter of monitoring for the running annual average calculation.

(iii) For all source water types, a State may determine that all regulated PFAS at a sampling point are reliably and consistently below the MCL after considering, at a minimum, four consecutive quarterly samples collected during the compliance monitoring period. A sampling point that a State has determined to be reliably and consistently below the MCL is required to collect annual samples for at least the first three years after that determination is made. Annual samples must be collected in the quarter in which detected concentrations were highest during the most recent year of quarterly monitoring. If, after three consecutive years, annual samples all contain results that are below the trigger levels defined in paragraph (a)(5) of this section, the State may allow a system to begin triennial monitoring at the sampling point. The water system must collect triennial samples in the quarter with the highest concentrations during the most recent round of quarterly sampling. If an annual sample meets or exceeds an MCL or the State determines that the result is not reliably and consistently below the MCL for all regulated PFAS, then the system must monitor quarterly for all regulated PFAS beginning in the next quarter at the sampling point.

(iv) The three different compliance monitoring sampling schedules that may be assigned and the criteria for each are summarized in the following table:

Table 3 to paragraph (b)(2)(iv)—Compliance Monitoring Schedules and Requirements

Sampling frequency	Eligibility requirements [1]	Sample timing requirements
Triennial	At an individual sampling point, either: .... (1) All initial monitoring results demonstrate concentrations of all regulated PFAS below trigger levels;. (2) The most recent three consecutive annual monitoring results all demonstrated concentrations of all regulated PFAS below trigger levels; or. (3) The previous triennial sample demonstrated all regulated PFAS concentrations below trigger levels.. **Note:** After beginning compliance monitoring, a system may not transition directly from quarterly monitoring to triennial monitoring..	Sample must be collected at a time within the three-year period designated by the State, in the quarter that yielded the highest analytical result during the most recent round of quarterly sampling (or the most recent semi-annual sampling, if no quarterly sampling has occurred).
Annual	A State makes a determination that all regulated PFAS concentrations at the sampling point are reliably and consistently below PFAS MCLs, after considering, at a minimum, 4 consecutive quarterly samples collected during the compliance monitoring period..	Sample must be collected at a time designated by the State, within the quarter that yielded the highest analytical result during the most recent round of quarterly sampling.
Quarterly	At an individual sampling point, either: .... (1) Any regulated PFAS concentration meets or exceeds a trigger level during initial monitoring;. (2) Sampling is occurring quarterly during compliance monitoring and a State has not made a determination that all levels of regulated PFAS at the sampling point are reliably and consistently below the regulated PFAS MCLs; or. (3) A sample collected by a system required to conduct triennial monitoring contains regulated PFAS concentrations that meet or exceed trigger levels. The first of these samples meeting or exceeding the trigger level is considered the first quarterly sample.. (4) A sample collected by a system required to conduct annual monitoring contains regulated PFAS concentrations that meet or exceed an MCL. The first of these samples meeting or exceeding the MCL is considered the first quarterly sample..	Samples must be collected in four consecutive quarters, on dates designated by the State.

[1] The monitoring frequency at a sampling point must be the same for all regulated PFAS and is determined based on the most frequent sampling required for any regulated PFAS detected at a level at or exceeding the trigger level.

(v) The State may require a confirmation sample for any sampling result. If a confirmation sample is required by the State, the system must average the result with the first sampling result and the average must be used for the determination of compliance with MCLs as specified by § 141.903. A State may delete results of obvious sampling errors from the MCL compliance calculations described in § 141.903. If the State deletes a result because of an obvious sampling error and the system fails to collect another sample this is a monitoring violation as described in § 141.905(c).

(vi) The State may increase the required monitoring frequency, where necessary, to detect variations within the system (*e.g.,* fluctuations in concentration due to seasonal use, changes in water source).

(vii) Each public water system must monitor at the time designated by the State within each monitoring period.

(viii) When a system reduces its sampling frequency to annual or triennial sampling, the next compliance sample must be collected in the monitoring period that begins the calendar year following State approval of a reduction in monitoring frequency.

§ 141.903 Compliance requirements.

(a) Compliance with MCLs for regulated PFAS in § 141.61(c) must be determined based on the analytical results obtained at each sampling point.

(b) For systems monitoring quarterly, compliance with the MCL is determined by the running annual average at each sampling point.

(c) If a system fails to collect the required number of samples specified in § 141.902, this is a monitoring violation as described in § 141.905(c), and compliance calculations must be based on the total number of samples collected.

(d) Systems monitoring triennially whose sample result equals or exceeds the trigger level of 2.0 ng/l for either PFOS or PFOA, 5 ng/l for HFPO–DA, PFHxS, or PFNA, or a Hazard Index of 0.5 for the Hazard Index PFAS, must begin quarterly sampling for all regulated PFAS in the next quarter at the sampling point. Systems monitoring annually whose sample result equals or exceeds the MCL of 4.0 ng/l for either PFOS or PFOA, 10 ng/l for HFPO–DA, PFHxS, or PFNA, or a Hazard Index of 1 for the Hazard Index PFAS, must begin quarterly sampling for all regulated PFAS in the next quarter at the sampling point.

(e) Except as provided in this paragraph (e), if a sample result exceeds an MCL, the system will not be considered in violation of the MCL until it has completed one year of quarterly sampling at the sampling point with the triggering sample used as the first quarter of monitoring for the running annual average calculation. However, whenever a sample result in any quarter (or quarterly average, if more than one compliance sample is available in a quarter because a confirmation sample was required by the State) causes the running annual average to exceed the MCL at a sampling point regardless of the subsequent quarterly monitoring results required to complete a full year of monitoring (*e.g.,* the results from a single sample are more than 4 times the MCL), the system is out of compliance with the MCL immediately.

(f) Systems must calculate compliance using the following method to determine MCL compliance at each sampling point:

(1) For each PFAS regulated by an individual MCL:

(i) For systems monitoring quarterly, divide the sum of the measured quarterly concentrations for each analyte by the number of quarters samples were collected for that analyte during the consecutive quarters included in the calculation. If more than one compliance sample for that analyte is available in a quarter because a confirmation sample was required by the State, systems must average all the results in a quarter then average the quarterly averages. Rounding does not occur until the end of the calculation. If the running annual average exceeds the MCL, the system is not in compliance with the MCL requirements.

(ii) For systems monitoring annually, if the concentration measured is equal to or exceeds an MCL for regulated PFAS, the system is required to initiate quarterly monitoring for all regulated PFAS beginning in the next quarter at the sampling point, with the triggering sample result used as the first quarter of monitoring for the running annual average calculation.

(iii) For systems monitoring triennially, if the concentration measured is equal to or exceeds the trigger level, the system is required to initiate quarterly monitoring for all regulated PFAS beginning in the next quarter at the sampling point, with the triggering sample result used as the first quarter of monitoring for the running annual average calculation.

(iv) For the purpose of calculating MCL compliance, if a sample result is less than the practical quantitation level (PQL) for a regulated PFAS, in accordance with the following table, zero is used for that analyte solely to calculate the running annual average.

TABLE 1 TO PARAGRAPH (f)(1)(iv)—PRACTICAL QUANTITATION LEVELS (PQLS) FOR PFAS CONTAMINANTS

Contaminant	PQL (in parts per trillion)
HFPO–DA	5.0
PFBS	3.0
PFHxS	3.0
PFNA	4.0
PFOA	4.0
PFOS	4.0

(2) For each PFAS regulated under the Hazard Index MCL:

(i) For systems monitoring quarterly, divide the observed sample analytical result for each analyte included in the Hazard Index by the corresponding HBWC listed in § 141.61(c) to obtain a hazard quotient for each analyte for each sampling event at each sampling point. Sum the resulting hazard quotients together to determine the Hazard Index for the quarter. If the State requires a confirmation sample for an analyte in the quarter, systems must average these results for each analyte in that quarter and then determine the hazard quotient(s) from those average values, then sum the hazard quotients. Once the Hazard Indices for the individual quarters are calculated, they are averaged to determine a running annual average. If the running annual average Hazard Index exceeds the MCL and two or more Hazard Index analytes had an observed sample analytical result at or above the PQL in any of the quarterly samples collected to determine the running annual average, the system is in violation of the Hazard Index MCL. No rounding occurs until after the running annual average Hazard Index is calculated.

(ii) If the Hazard Index calculated using the results of an annual sample equals or exceeds the Hazard Index MCL, the system must initiate quarterly sampling for all regulated PFAS beginning in the next quarter at the sampling point, with the triggering sample result used as the first quarter of monitoring.

(iii) If the Hazard Index calculated using the results of a triennial sample equals or exceeds the Hazard Index trigger level, the system must initiate quarterly sampling for all regulated PFAS beginning in the next quarter at the sampling point, with the triggering sample result used as the first quarter of monitoring.

(iv) If a sample result is less than the practical quantitation level for a regulated PFAS, in accordance with the table 1 to paragraph (f)(1)(iv) of this section, zero is used for that analyte solely to calculate the running annual average.

§ 141.904 Reporting and recordkeeping requirements.

Systems required to sample must report to the State according to the timeframes and provisions of § 141.31 and retain records according to the provisions in § 141.33.

(a) Systems must report the information from initial monitoring specified in the following table:

Table 1 to Paragraph (a)—Data To Report From Initial Monitoring

If you are a . . .	You must report . . .
System monitoring for regulated PFAS under the requirements of § 141.902(b)(1) on a quarterly basis.	1. All sample results, including the locations, number of samples taken at each location, dates, and concentrations reported. 2. Whether a trigger level, defined in § 141.902(a)(5), was met or exceeded in any samples.
System monitoring for regulated PFAS under the requirements of § 141.902(b)(1) less frequently than quarterly.	1. All sample results, including the locations, number of samples taken at each location, dates, and concentrations reported. 2. Whether a trigger level, defined in § 141.902(a)(5), was met or exceeded in any samples.

(b) Systems must report the information collected during the compliance monitoring period specified in the following table:

Table 2 to Paragraph (b)—Data To Report From Compliance Monitoring

If you are a . . .	You must report . . .
System monitoring for regulated PFAS under the requirements of § 141.902(b)(2) on a quarterly basis.	1. All sample results, including the locations, number of samples taken at each location, dates, and concentrations during the previous quarter. 2. The running annual average at each sampling point of all compliance samples. 3. Whether a trigger level, defined in § 141.902(a)(5), was met or exceeded in any samples. 4. Whether an MCL for a regulated PFAS in § 141.61(c) was met or exceeded in any samples. 5. Whether, based on § 141.903, an MCL was violated.
System monitoring for regulated PFAS under the requirements of § 141.902(b)(2) less frequently than quarterly.	1. All sample results, including the locations, number of samples taken at each location, dates, and concentrations during the previous monitoring period. 2. Whether a trigger level, defined in § 141.902(a)(5), was met or exceeded in any samples. 3. Whether an MCL for a regulated PFAS in § 141.61(c) was met or exceeded in any samples. 4. Whether, based on § 141.903, an MCL was violated (*e.g.,* the results from a single sample are more than 4 times the MCL).

§ 141.905 Violations.

(a) PFAS MCL violations, both for the individual PFOA, PFOS, HFPO–DA, PFHxS, and PFNA MCLs, as well as the Hazard Index MCL, as listed in § 141.61(c), are based on a running annual average, as outlined under § 141.903.

(b) Compliance with § 141.61(c) must be determined based on the analytical results obtained at each sampling point. If one sampling point is in violation of an MCL, the system is in violation of the MCL.

(c) Each failure to monitor in accordance with the requirements under § 141.902 is a monitoring violation.

(d) Failure to notify the State following a MCL violation and failure to submit monitoring data in accordance with the requirements of §§ 141.904 and 141.31 are reporting violations.

(e) Results for PFAS with individual MCLs as listed in § 141.61(c) are compared to their respective MCLs, and results for mixtures of two or more of the Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA) are compared to the Hazard Index MCL as listed in § 141.61(c). For determining compliance with the Hazard Index MCL, if only PFBS is reported at any concentration and no other regulated PFAS are in the mixture, it is not violation of the Hazard Index MCL. If only one of the other PFAS within the Hazard Index (HFPO–DA, PFHxS, and PFNA) is detected and the level of this PFAS exceeds its MCL as determined by § 141.903(f)(1)(i), only an individual MCL violation is assessed for the individual PFAS detected, and it is not a violation of the Hazard Index MCL. Exceedances of the Hazard Index caused by two or more of the Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA) and exceedances of one or more individual MCLs can result in multiple MCL exceedances. However, in this instance, for purposes of public notification under appendix A to subpart Q of this part, a PWS must only report the Hazard Index MCL exceedance.

PART 142—NATIONAL PRIMARY DRINKING WATER REGULATIONS IMPLEMENTATION

■ 16. The authority citation for part 142 continues to read as follows:

Authority: 42 U.S.C. 300f, 300g–1, 300g–2, 300g–3, 300g–4, 300g–5, 300g–6, 300j–4, 300j–9, and 300j–11.

■ 17. Amend § 142.16 by adding paragraph (r) to read as follows:

§ 142.16 Special primacy requirements.

* * * * *

(r) *Requirements for States to adopt 40 CFR part 141, subpart Z, PFAS.* In addition to the general primacy requirements elsewhere in this part, including the requirements that State regulations be at least as stringent as Federal requirements, an application for approval of a State program revision that adopts 40 CFR part 141, subpart Z, must contain the following, in lieu of meeting the requirements of paragraph (e) of this section:

(1) The State's procedures for reviewing the water system's use of pre-existing data to meet the initial

monitoring requirements specified in § 141.902, including the criteria that will be used to determine if the data are acceptable. This paragraph (r)(1) is no longer applicable after the initial monitoring period ends on April 26, 2027.

(2) The State's procedures for ensuring all systems complete the initial monitoring period requirements that will result in a high degree of monitoring compliance by the regulatory deadlines. This paragraph (r)(2) is no longer applicable after the initial monitoring period ends on April 26, 2027.

(3) After the initial monitoring period, States establish the initial monitoring requirements for new public water systems and existing public water systems that plan to use a new source. States must explain their initial monitoring schedules and how these monitoring schedules ensure that new public water systems and existing public water systems that plan to use new sources comply with MCLs and monitoring requirements. States must also specify the time frame in which a new system or existing system that plans to use a new source must demonstrate compliance with the MCLs.

■ 18. Amend § 142.62 by revising and republishing paragraph (a) to read as follows:

§ 142.62 Variances and exemptions from the maximum contaminant levels for organic and inorganic chemicals.

(a) The Administrator, pursuant to section 1415(a)(1)(A) of the Act, hereby identifies the technologies listed in tables 1 and 2 to this paragraph (a) as the best available technology, treatment techniques, or other means available for achieving compliance with the maximum contaminant levels for the organic chemicals, including per- and polyfluoroalkyl substances (PFAS), listed in § 141.61(a) and (c) of this chapter, for the purposes of issuing variances and exemptions. A list of small system compliance technologies for the regulated PFAS for the purposes of providing variances and exemptions is provided in table 3 to this paragraph (a); for the purpose of this paragraph (a), small system is defined as a system serving 10,000 persons or fewer.

TABLE 1 TO PARAGRAPH (a)—BATS FOR PFAS LISTED IN § 141.61(c)

Contaminant	BAT
Hazard Index PFAS (HFPO–DA, PFBS, PFHxS, and PFNA)	Anion exchange, GAC, reverse osmosis, nanofiltration.
HFPO–DA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFHxS	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFNA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFOA	Anion exchange, GAC, reverse osmosis, nanofiltration.
PFOS	Anion exchange, GAC, reverse osmosis, nanofiltration.

TABLE 2 TO PARAGRAPH (a)—BATS FOR OTHER SYNTHETIC ORGANIC CONTAMINANTS LISTED IN § 141.61(c) AND VOLATILE ORGANIC CHEMICALS LISTED IN § 141.61(a)

Contaminant	Best available technologies		
	PTA [1]	GAC [2]	OX [3]
(1) Benzene	X	X	
(2) Carbon tetrachloride	X	X	
(3) 1,2-Dichloroethane	X	X	
(4) Trichloroethylene	X	X	
(5) para-Dichlorobenzene	X	X	
(6) 1,1-Dichloroethylene	X	X	
(7) 1,1,1-Trichloroethane	X	X	
(8) Vinyl chloride	X		
(9) cis-1,2-Dichloroethylene	X	X	
(10) 1,2-Dichloropropane	X	X	
(11) Ethylbenzene	X	X	
(12) Monochlorobenzene	X	X	
(13) o-Dichlorobenzene	X	X	
(14) Styrene	X	X	
(15) Tetrachloroethylene	X	X	
(16) Toluene	X	X	
(17) trans-1,2-Dichloroethylene	X	X	
(18) Xylense (total)	X	X	
(19) Alachlor		X	
(20) Aldicarb		X	
(21) Aldicarb sulfoxide		X	
(22) Aldicarb sulfone		X	
(23) Atrazine		X	
(24) Carbofuran		X	
(25) Chlordane		X	
(26) Dibromochloropropane	X	X	
(27) 2,4-D		X	
(28) Ethylene dibromide	X	X	
(29) Heptachlor		X	
(30) Heptachlor epoxide		X	
(31) Lindane		X	
(32) Methoxychlor		X	
(33) PCBs		X	
(34) Pentachlorophenol		X	

Table 2 to Paragraph (a)—BATs for Other Synthetic Organic Contaminants Listed in § 141.61(c) and Volatile Organic Chemicals Listed in § 141.61(a)—Continued

Contaminant	Best available technologies		
	PTA[1]	GAC[2]	OX[3]
(35) Toxaphene		X	
(36) 2,4,5-TP		X	
(37) Benzo[a]pyrene		X	
(38) Dalapon		X	
(39) Dichloromethane	X		
(40) Di(2-ethylhexyl)adipate	X	X	
(41) Di(2-ethylhexyl)phthalate		X	
(42) Dinoseb		X	
(43) Diquat		X	
(44) Endothall		X	
(45) Endrin		X	
(46) Glyphosate			X
(47) Hexachlorobenzene		X	
(48) Hexachlorocyclopentadiene	X	X	
(49) Oxamyl (Vydate)		X	
(50) Picloram		X	
(51) Simazine		X	
(52) 1,2,4-Trichlorobenzene	X	X	
(53) 1,1,2-Trichloroethane	X	X	
(54) 2,3,7,8-TCDD (Dioxin)		X	

[1] Packed Tower Aeration.
[2] Granular Activated Carbon.
[3] Oxidation (Chlorination or Ozonation).

Table 3 to Paragraph (a)—List of Small System Compliance Technologies (SSCTs)[1] for PFAS Listed in § 141.61(c)

Small system compliance technologies	Affordable for listed small system categories[2]
Anion Exchange	All size categories.
GAC	All size categories.
Reverse Osmosis,[3] Nanofiltration[3].	3,301–10,000.

[1] Section 1412(b)(4)(E)(ii) of SDWA specifies that SSCTs must be affordable and technically feasible for small systems.

[2] The Act (ibid.) specifies three categories of small systems: (i) those serving 25 or more, but fewer than 501, (ii) those serving more than 500, but fewer than 3,301, and (iii) those serving more than 3,300, but fewer than 10,001.

[3] Technologies reject a large volume of water and may not be appropriate for areas where water quantity may be an issue.

* * * * *

[FR Doc. 2024–07773 Filed 4–25–24; 8:45 am]

BILLING CODE 6560–50–P