

PFAS Update: EPA Proposes National Standard to Regulate PFAS in Drinking Water

20 March 2023

The U.S. Environmental Protection Agency (EPA) has for the first time proposed new national primary drinking water regulations (NPDWR) for six per- and polyfluoroalkyl substances (PFAS). Once effective (currently expected to be finalized in early 2024), this rulemaking would mark the first federally enforceable drinking water regulation to address PFAS. On March 13, 2023, EPA released a prepublication draft¹ of its proposed rule, which includes Maximum Contaminant Levels (MCLs) more stringent than any current state standard for two of the most-studied PFAS, perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS), as well as a “Hazard Index” regulatory approach for mixtures for four other types of PFAS. This *Alert* provides background on EPA’s proposed rule, summarizes and highlights notable components of the rule, and describes next steps – including potential ramifications for the regulated community. In other recent *Alerts*, we have discussed [the proposed PFAS ban spanning several European countries](#) and [EPA’s proposed rule to designate PFOA and PFOS as “hazardous substances” under the Comprehensive Environmental Response, Compensation, and Liability Act \(CERCLA\)](#).

Background

PFAS are a large group of synthetic chemicals that have been in widespread use since the 1940s. These compounds have physical and chemical properties making them highly stable and resistant to degradation. EPA has stated that individuals can be exposed to PFAS through consumer products, occupational exposure, and/or by consuming PFAS-containing food or drinking water, and that consuming water containing PFAS above certain levels may result in adverse health effects.²

In March 2021, EPA issued a final regulatory determination to regulate PFOA and PFOS as “contaminants” under the Safe Drinking Water Act (SDWA).³ PFOA and PFOS have been phased out of production by manufacturers over the past approximately 20 years in the U.S., but were used for decades in many consumer and industrial product applications, including protective coatings, stain- and water-resistant products, carpets, rugs, upholstered furniture, nonstick cookware, leather products, and firefighting foams used at locations such as airports, firefighter training facilities and military airfields.⁴ As part of EPA’s March 2021 regulatory determination, EPA indicated that it would also evaluate additional PFAS and consider regulatory actions to address groups of PFAS.

Summary and Notable Features of EPA’s Proposed Rule

In its March 2023 draft determination, EPA is issuing a preliminary regulatory determination to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as “GenX” chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of any one or more of these PFAS, as contaminants under the SDWA. These PFAS are utilized in many industrial applications, including in the medical, automotive, electronics, aerospace, energy and semiconductor industries.⁵

EPA is required by the SDWA to set enforceable NPDWRs for a drinking water contaminant and require monitoring of public water systems for that contaminant upon determining (1) that a given contaminant may adversely affect human health, (2) that the contaminant is “substantially likely” to occur in public water systems at elevated levels, and (3) that in the judgment of EPA’s Administrator, regulation of the contaminant may meaningfully reduce human health risk.⁶ EPA’s preliminary determination is that all three of these factors are met for the above substances.⁷

The proposed regulatory determinations have important ramifications for the regulated community, including most directly for public water systems. EPA’s latest proposal also includes a NPDWR and health-based Maximum Contaminant Level Goals (MCLG) for these four newly designated PFAS and their mixtures, as well as for PFOA and PFOS. Whereas an MCL is an enforceable standard that represents the maximum level a contaminant or group of contaminants (i.e., a mixture) in water that can be delivered to any public water system user, and an MCL is set using economic and technological feasibility as considerations, an MCLG is a non-enforceable, maximum level of a contaminant in drinking water at which no known or anticipated adverse effect on the health of persons would occur, and is set using only public health as a consideration.⁸ The SDWA generally requires EPA to set the MCL “as close as feasible to” the MCLG.⁹ EPA is

proposing to set the MCLG for PFOA and PFOS at zero, based on EPA-cited research purporting to show that PFOA and PFOS are “likely” to cause cancer and are associated with endocrine, hepatic, immunological, developmental, cardiovascular and other adverse health effects. Beyond these health-based values, EPA is proposing individual MCLs of 4.0 nanograms per liter (ng/L) or parts per trillion (ppt) for PFOA and PFOS, taking into account cost and technical feasibility and the current availability of methods for measurement and treatment of these chemicals in drinking water.

EPA also proposes to use what it describes as a “Hazard Index” (HI) approach for mixtures of PFHxS, HFPO-DA and its ammonium salt, PFNA, and PFBS, because the agency determined that many PFAS co-occur in drinking water sources and that mixtures of multiple PFAS can be expected to act in a “dose-additive manner.” EPA notes that its HI approach utilizes a ratio methodology to determine aggregate health hazards and is used in certain circumstances across federal agencies, including the Centers for Disease Control and Prevention.¹⁰ However, commentators have expressed concerns about the efficacy of the HI approach in the context of establishing concentration limits,¹¹ and the agency has yet to complete its health assessment for two of the four PFAS – PFHxS and PFNA – included in the HI approach.¹² EPA is proposing an HI of 1.0 as the MCLGs for these four PFAS and any mixture containing one or more of them. EPA has also determined that it is feasible to set the MCLs for these four PFAS and for a mixture containing one or more of them as an HI of 1.0.

Lastly, EPA proposes to classify PFOS as a chemical that is “Likely to Be Carcinogenic to Humans,” given its review of various studies.¹³ That classification is used to inform the future development of MCLGs for all other PFAS and may support designating PFOA and PFOS as hazardous substances under CERCLA, as well as inform screening tools for other environmental media programs. EPA references toxicity assessments and other studies to determine that non-cancer effects of exposure to the four newly designated PFAS – PFHxS, HFPO-DA, PFNA and PFBS – generally include adverse effects on development, reproduction and immune systems.¹⁴

Looking Ahead

The proposed rulemaking is expected to impact public drinking water systems and certain industries alike. If enacted, public water systems across the country will be required to conduct monitoring, publicly report their findings and reduce the noted PFAS to allowable levels – a task that may require installation and use of costly detection and treatment technologies, in particular to meet the 4 ppt MCL for PFOA and PFOS. Disagreement regarding the scientific basis for EPA’s rulemaking and the amount and allocation of compliance costs will likely remain at the forefront as the rulemaking progresses. For example, multiple trade organizations have already expressed skepticism with EPA’s analysis methodology.¹⁵ In addition, although EPA estimates the proposed regulation would result in approximately \$772 million in annual costs¹⁶ and that water utilities will be able to access federal funding,¹⁷ the American Chemistry Council contends that EPA’s approach “will likely result in billions of dollars in compliance costs.”¹⁸ In addition, available funds from the 2021 Infrastructure Investment and Jobs Act (also known as the Bipartisan Infrastructure Deal) may not fully address compliance costs and may prove insufficient to minimize cost-related disputes between water groups and industries that manufacture or use PFAS. If EPA’s final rule does not resolve issues raised by the regulated community during the public comment period, various water and industry groups may contest EPA’s rulemaking, including under the Administrative Procedure Act.

This draft proposal is one of several recent EPA actions to regulate PFAS, including the agency’s proposal to designate PFOS and PFOA as hazardous substances under the CERCLA. Notably, although a number of states have proposed or already adopted limits on PFAS in drinking water, of the ten states with enforceable drinking water standards for PFAS,¹⁹ none have standards equal to or lower than the 4 ppt that EPA proposes for PFOA and PFOS. If EPA’s proposal regarding PFAS drinking water standards becomes effective, every state with primacy under the SDWA will have to either adopt standards that are at least as stringent as the proposal or else relinquish any primary enforcement responsibility over public water systems.²⁰ In any event, EPA proposes to require states currently with primacy over public water systems to submit compliant standards within two years of a final PFAS NPDWR or otherwise request an extension of up to two years, which EPA may grant in certain circumstances – including when an individual system needs additional time for capital improvements or faces other compelling factors.²¹

EPA is seeking public comment on the proposed rule and will be holding a public hearing on May 4, 2023, when members of the public can provide verbal comments to EPA on the rule proposal.²² The public comment period will run for 60 days following its publication in the Federal Register. EPA currently plans to finalize the rule by January 2024.²³ The Kirkland environmental team continues to monitor regulatory, legislative and policy developments related to PFAS to provide updates and business guidance as needed.

1. https://www.epa.gov/system/files/documents/2023-03/Pre-Publication%20Federal%20Register%20Notice_PFAS%20NPDWR_NPRM_Final_3.13.23.pdf. ↵

2. *Id.* ↵

3. *Id.* “Contaminant” means any physical, chemical, biological or radiological substance or matter in water. 42 U.S.C. 300f(6). ↵

4. See, e.g., [EPA Interim Drinking Water Health Advisory: PFOA](#); [EPA Interim Drinking Water Health Advisory: PFOS](#); CA Prop 65 Webpage for [PFOS](#) and [PFOA](#); https://pfas-1.itrcweb.org/fact_sheets_page/PFAS_Fact_Sheet_History_and_Use_April2020.pdf. ↵
5. See, e.g., <https://www.epa.gov/system/files/documents/2022-06/drinking-water-genx-2022.pdf> and https://www.epa.gov/system/files/documents/2021-09/multi-industry-pfas-study_preliminary-2021-report_508_2021.09.08.pdf ↵
6. 42 U.S.C. 300g-1(b)(1)(A). See also <https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas>. ↵
7. https://www.epa.gov/system/files/documents/2023-03/Pre-Publication%20Federal%20Register%20Notice_PFAS%20NPDWR_NPRM_Final_3.13.23.pdf ↵
8. Compare 42 U.S.C. § 300g-1(b)(4)(B), (C), (D) (describing factors the EPA Administrator must consider to determine the feasibility of MCLs), with 42 U.S.C. § 300g-1(b)(4)(A) (indicating MCLGs are set based on health and an adequate margin of safety). ↵
9. 42 U.S.C. § 300g-1(b)(4)(B). ↵
10. [https://www.atsdr.cdc.gov/pha-guidance/conducting_scientific_evaluations/epcs_and_exposure_calculations/hazardquotients_cancerrisk.html#:~:text=Estimating%20Hazard%20Quotients&text=When%20you%20have'](https://www.atsdr.cdc.gov/pha-guidance/conducting_scientific_evaluations/epcs_and_exposure_calculations/hazardquotients_cancerrisk.html#:~:text=Estimating%20Hazard%20Quotients&text=When%20you%20have) ↵
11. See, e.g., “EPA Close to PFAS SDWA Proposal After Response to Agencies’ Concerns, Inside EPA, dated February 3, 2023, “[The EPA Science Advisory Board (SAB)] in its final report agreed with the use of hazard index as a screening method and decision-making tool, although SAB said there are ‘some limitations and potential complications in terms of the intended users such as states and public water systems applying this framework in the context of implementing the [SDWA]’; “US Plan to Limit PFAS in Water Draws Concern Over Cost, Science,” *Bloomberg Law*, dated March 15, 2023, “[A commentator] remarked the hazard index is “an unusual approach to limiting drinking water contaminants,” and “is more often used as a tool for deciding whether some kind of cleanup or other regulatory action is needed.”]” ↵
12. https://www.epa.gov/system/files/documents/2023-02/IRIS%20Program%20Outlook_Feb%202023.pdf (noting that the EPA’s research office expects to release drafts of its PFHxS and PFNA assessments, including for external peer review, this year) ↵
13. [EPA Toxicity Assessment and Proposed MCLG for PFOS in Drinking Water](#), Section 3.5.5 Cancer Classification ↵
14. [Proposed Rule](#), Section III(B) Statutory Criterion 1 – Adverse Health Effects (summarizing the toxicity assessments (if any) and other toxicity studies of PFHxS, HPFO-DA, PFNA, and PFBS) ↵
15. See, e.g., <https://subscriber.politicopro.com/article/eenews/2023/03/15/pfas-rule-sets-up-sprawling-legal-war-00087004>; <https://subscriber.politicopro.com/article/eenews/2023/03/14/epa-targets-forever-chemicals-in-historic-water-rule-00086959>; <https://news.bloomberglaw.com/environment-and-energy/us-plan-to-limit-pfas-in-water-draws-concern-over-cost-science> (“[T]reatment expenditures utilities already have incurred suggest the costs could exceed the agency’s estimate, AMWA CEO Tom Dobbins said in a statement.”) ↵
16. [Economic Analysis for the Proposed \[PFAS NPDWR\]](#), Section 5.1.3, Summary of Quantified National Cost Estimates of the Proposed Rule ↵
17. https://www.epa.gov/system/files/documents/2023-03/Proposed%20PFAS%20NPDWR%20EA_final_03_09_2023_0.pdf, see pg. 4-18, 4-19 (“[The infrastructure law] authorizes \$5 billion as part of the Emerging Contaminants in Small or Disadvantaged Communities grant program that can be used to reduce PFAS in drinking water in communities facing disproportionate impacts. BIL funds will be provided as grants and loan forgiveness associated with PFAS drinking water treatment capital expenditures.”) ↵
18. <https://www.americanchemistry.com/chemistry-in-america/news-trends/press-release/2023/acc-comments-on-mcl-proposal> ↵
19. States with enforceable standards or an MCL for PFAS in drinking water include Maine, Massachusetts, Michigan, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont and Wisconsin. ↵
20. [Proposed Rule](#), Section XII(A) Rule Implementation and Enforcement, What are the requirements for primacy? ↵
21. [Proposed Rule](#), Section XII(A) Rule Implementation and Enforcement, What are the requirements for primacy?; Section XII(D), Exemptions and Extensions ↵
22. <https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas>. ↵
23. <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=2040-AG18> ↵

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