



May 30, 2023

VIA ELECTRONIC SUBMISSION

The Honorable Michael S. Regan
Administrator
Environmental Protection Agency
Washington, DC 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking (Docket ID: EPA-HQ-OW-2022-0114)

Dear Administrator Regan:

On March 29, 2023, the Environmental Protection Agency (EPA) published a proposed rule titled “PFAS National Primary Drinking Water Regulation Rulemaking.”¹ The Office of Advocacy (Advocacy) is concerned that small water systems will not have adequate funds to ensure timely compliance with EPA’s proposed requirements. Therefore, Advocacy recommends that the agency consider alternative standards and provide regulatory flexibilities to reduce the compliance burden on small water systems. Advocacy also recommends that EPA address small entity concerns with its proposed actions for PFHxS, GenX chemicals, PFNA, and PFBS, by issuing regulations in accordance with the Safe Drinking Water Act.²

I. Background

A. The Office of Advocacy

Congress established the Office of Advocacy under Pub. L. 94-305 to represent the views of small entities before Federal agencies and Congress. Advocacy is an independent office within the U.S. Small Business Administration (SBA). As such, the views expressed by Advocacy do not necessarily reflect the views of the SBA or the Administration. The Regulatory Flexibility Act (RFA),³ as amended by the Small Business Regulatory Enforcement Fairness Act

¹ 88 Fed. Reg. 18638 (March 29, 2023).

² 42 U.S.C. §300f et seq. (1974).

³ 5 U.S.C. §601 et seq.

(SBREFA),⁴ gives small entities a voice in the rulemaking process. For all rules that are expected to have a significant economic impact on a substantial number of small entities, the RFA requires federal agencies to assess the impact of the proposed rule on small entities and to consider less burdensome alternatives.

The Small Business Jobs Act of 2010 requires agencies to give every appropriate consideration to comments provided by Advocacy.⁵ The agency must include a response to these written comments in any explanation or discussion accompanying the final rule's publication in the *Federal Register*, unless the agency certifies that the public interest is not served by doing so.⁶

Advocacy's comments are consistent with Congressional intent underlying the RFA, that "[w]hen adopting regulations to protect the health, safety, and economic welfare of the nation, federal agencies should seek to achieve statutory goals as effectively and efficiently as possible without imposing unnecessary burdens on the public."⁷

B. The Proposed Rule

On March 29, 2023, EPA published its proposed National Primary Drinking Water Regulation (NPDWR) rulemaking, which includes the following per- and polyfluoroalkyl substances (PFAS):

- Perfluorooctanoic acid (PFOA),
- Perfluorooctane sulfonic acid (PFOS)
- Perfluorohexane sulfonic acid (PFHxS)
- Hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (also known as a GenX chemicals)
- Perfluorononanoic acid (PFNA)
- Perfluorobutane sulfonic acid (PFBS)

The proposed rule requires public water systems to monitor for these PFAS, notify the public of the levels of these PFAS, and reduce the levels of these PFAS in drinking water if they exceed the proposed standards. Reduction methods can include the installation of treatment technologies and disposal of PFAS residue from those treatment technologies such as granular activated carbon, anion exchange, nanofiltration and reverse osmosis or require switching to an alternative water source. The proposed rule would require compliance three years after promulgation.

The proposal contains several agency actions:

⁴ Pub. L. 104-121, Title II, 110 Stat. 857 (1996) (codified in various sections of 5 U.S.C. §601 et seq.).

⁵ Small Business Jobs Act of 2010 (PL. 111-240) §1601.

⁶ *Id.*

⁷ *Id.*

1. Proposed legally enforceable levels, called Maximum Contaminant Levels (MCLs), for PFOA and PFOS at 4 parts per trillion (ppt).
2. Proposed preliminary determination to regulate PFHxS, GenX chemicals, PFNA and PFBS, and mixtures of these PFAS.
3. Proposed MCLs for the above four PFAS at a unitless MCL of 1.0, based on a novel approach called a hazard index (HI), which is used to evaluate potential health risks from exposure to chemical mixtures.
4. Proposed health-based, non-enforceable Maximum Contaminant Level Goals (MCLGs) for these six PFAS. For PFOA and PFOS, the proposed MCLG is zero and for the PFAS mixture the agency proposes the same unitless 1.0 hazard index.

In advance of the proposed rule, EPA convened a small business advocacy review panel under SBREFA to consult with small entity representatives (SERs). EPA presented to the small entities some PFAS background, with only PFOA and PFOS specifically identified, and potential monitoring and reporting rule compliance considerations and treatment and feasibility considerations. EPA, however, did not provide the SERs with the identity of the other four PFAS, any MCL values, any MCLG values and the technical details and analyses supporting these additional elements.

II. Advocacy's Small Business Concerns

A. Advocacy is concerned that small water systems will not have funding for timely compliance with EPA's proposed rule.

Overwhelming feedback indicates that small water systems do not currently have, nor will they have access to the funding required to comply with this rule, either at all or to ensure timely compliance. Advocacy is concerned that EPA did not adequately consider critical significant alternatives to reduce the significant economic burden on small entities.

a. EPA has underestimated the impact of the rule on small water systems.

Advocacy is concerned that EPA has underestimated the impact of the proposed rule on small water systems. More specifically, the agency underestimates the number of systems that will be required to comply. EPA's proposed MCLs are set at the lowest concentration that PFOA and PFOS can be reliably quantified in a laboratory (i.e., 4.0 ppt). As a result, many systems will be subject to the proposed requirements. Advocacy is concerned that EPA's estimates for the number of impacted public water systems is not based on the best available data. EPA decided not to wait for the fifth Unregulated Contaminant Monitoring Rule (UCMR 5) occurrence data to inform its analysis for the number of water systems that will be subject to the proposed rule. The collection of this data started this year and is expected to continue into 2025. Under UCMR 5, EPA published the method reporting limit (MRL)⁸ of 4.0 ppt each for PFOA and PFOS, same as the proposed MCLs. Instead, for the proposal, EPA used UCMR 3 and state data with levels above the proposed monitoring or compliance levels in this proposal. Because it represents a

⁸ The method reporting level (MRL) is the level at which the test can report a quantifiable value with high confidence.

lower limit than UCMR 3, the results of UCMR 5 data will provide a more accurate accounting of water systems likely to be subject to EPA’s regulations, an outcome not currently acknowledged or accounted for in EPA’s analysis.

In addition, Advocacy is concerned that EPA also underestimates the compliance costs for small water systems. Small entities and their representatives have shared that the cost of setting up and running treatment systems is four to five times higher than EPA’s projections. For example, a Small Entity Representative to the SBREFA panel, presented the results of a case study at Advocacy’s environmental roundtable showing that the capital expenses for a granular activated carbon (GAC)⁹ showed that there was over a 300% percent difference compared to EPA’s predicted cost of treatment for PFOA and PFOS. Small entities have also expressed concern about the availability and rising costs of treatment technologies due to the expected increase in demand in anticipation of these proposed regulations. In addition, small entities shared that the cost of PFAS sampling will add significantly to their testing expenses (e.g., \$700-\$800 per sample).

Advocacy is also concerned about the significant increases in disposal costs if these PFAS are required to be managed as hazardous substances under the Comprehensive Environmental Response, Compensation, and Liability Act¹⁰ or designated as hazardous constituents under Resource Conservation and Recovery Act.¹¹ Because these actions are not yet final, the agency did not include these costs as part of the rule compliance costs.¹²

b. EPA has overestimated its reliance on federal funding to defray compliance costs for small water systems.

Advocacy is concerned that EPA has overestimated its reliance on federal funding to help small water systems comply with its proposed requirements. EPA relies on anticipated federal funding to defray compliance costs for small water systems citing that “[t]he passage of the Infrastructure Investment and Jobs Act, also referred to as the Bipartisan Infrastructure Law (BIL), invests over \$11.7 billion in the Drinking Water State Revolving Fund (SRF); \$4 billion to the Drinking Water SRF for Emerging Contaminants; and \$5 billion to Small, Underserved, and Disadvantaged Communities Grants.”¹³ The agency states that “[t]hese funds will assist many disadvantaged communities, small systems, and others with the costs of installation of treatment

⁹ Granular activated carbon (GAC) is a treatment technology used to remove PFAS. GAC is a separation process where contaminants become attached to specially treated carbon with a high surface area.

¹⁰ *Designation of Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS) as CERCLA Hazardous Substances*, 87 Fed. Reg. 54415, (Sept. 6, 2022).

¹¹ *Introduction to the Unified Agenda of Federal Regulatory and Deregulatory Actions-Fall 2022*, 88 Fed. Reg. 1066, 1150.

¹² EPA did provide a separate sensitivity analysis based on the hazardous waste disposal assumption which demonstrates that costs would increase for public water systems by 4% (\$30 million annually) at the 3% discount rate and 5% (\$61 million annually) at the 7% discount rate. See, *Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation*, [Economic Analysis] (March, 2023), Appendix N.

¹³ 88 Fed. Reg. at 18640.

when it might otherwise be cost-challenging.”¹⁴ EPA further explained that “these funds can also be used to address emerging contaminants like PFAS in drinking water through actions such as technical assistance, water quality testing, and contractor training, which will allow communities supplemental funding to meet their obligations under this proposed regulation and help ensure protection from PFAS contamination of drinking water.”¹⁵ These funding opportunities may be available but there is no guarantee that it will be provided to the small water systems to comply specifically with this proposed rule. Moreover, the funding is likely to be insufficient because it only covers capital costs and will not alleviate the costly burden associated with the operation and maintenance costs (O&M). Finally, even if funding was available to small water systems, it is unlikely that it will be utilized efficiently to ensure timely compliance with the rule.

Federal funding referenced by EPA is not allotted specifically for compliance with this rule. Once that federal funding is dispersed to the states, availability to small public water systems may be limited due to other competing priorities and is often laden with stipulations. For example, during one of EPA’s public hearings on the rule, a California stakeholder, who works with small and very small water systems, pointed out that available federal funding often gets encumbered once it gets to the states by being subjected to other priorities. This stakeholder recommended that the funds should be specifically designated for PFAS treatment and should be prohibited from being used for other requirements (e.g., state consolidation). A small entity representative of private primary schools in Wisconsin shared that without access to funding, either tuition will increase, or the school will close. Another commenter from EPA’s public hearing, an Arizona water company, expressed that water utilities need additional opportunities to obtain funds to comply with the proposed regulations.

Given EPA’s underestimated impacts of the rule (discussed above), the funding EPA relies on to defray the costs will not be sufficient. Especially, due to the number of systems that will likely need to implement treatment to comply with the low levels proposed, the funding sources cited by the agency will not be able to provide the compliance assistance required for the small water systems. In addition, as mentioned above, O&M costs will not be covered by the federal funding EPA references. These costs include labor, materials, energy, residual disposal/treatment, and other technology specific costs including trained personnel.

c. EPA does not account for other factors that will further deter timely compliance.

Even if small water systems somehow obtained the necessary funding to comply with the rule, significant challenges will complicate timely compliance. These challenges include personnel shortage, supply chain disruptions, limited lab capacity, limited disposal capacity and availability of affordable treatment technologies. A small entity representative to the SBREFA panel noted that PFAS treatment technologies require specialized training for sampling and a likely shortage of operators is imminent and will contribute to challenges associated with timely compliance. In addition, during Advocacy’s roundtable discussion on this proposed rule, a small entity

¹⁴ 88 Fed. Reg. at 18640.

¹⁵ *Id.* at 18644-45.

representative stated that small systems will bear the brunt of limited laboratory capacity for foreseeable future due to high sample cost, long turnaround times, and diminishing access to quality laboratories. Small entity representatives have also shared that given the low levels proposed, compliance will likely require treatment, which will lead to supply chain issues since most water systems will need to implement treatment technologies.

B. Advocacy recommends that EPA provide burden-reducing compliance flexibilities for small water systems.

To address the concerns raised above, the agency must consider and provide alternatives to reduce burden on small water systems. First, the agency should consider finalizing one of the regulatory alternatives to reduce the scope of the rule. Alternatively, the agency can phase in compliance by gradually lowering the MCLs to its target level (i.e., proposed MCLs). Finally, and most importantly, the agency must allow additional time for compliance for small water systems. If applied, these burden reducing flexibilities will allow the agency to achieve its statutory objective and reduce the significant economic burden on small water systems.

a. EPA should consider finalizing one of the regulatory alternatives in the proposal and/or consider phasing in the proposed MCLs.

EPA should consider finalizing one of the alternative standards included in the proposed rule. Alternatively, EPA should consider a phase-in approach using the alternative standard values to require compliance with the proposed MCLs. In the proposal, the agency considered regulatory alternatives for PFOA and PFOS MCLs at 4.0, 5.0 ppt and 10.0 ppt without regulating the other four PFAS. As mentioned above, EPA did not present any MCL values to the SERs during the SBREFA panel, therefore, EPA has not considered small water systems' feedback on the proposed and regulatory alternative MCL values and its impacts and their ability to comply. Also, EPA only specifically identified regulating PFOA and PFAS and did not discuss the other four PFAS. The agency should conduct targeted outreach with small water systems on the feasibility of the proposed and alternative MCLs. Advocacy recommends that EPA give full consideration to any direct or written feedback in support of alternative standards presented by the agency or those recommended by small water systems, including a phased-in approach for compliance with the proposed standards.

b. EPA should provide additional time for compliance based on funding availability and to address any anticipated capacity issues.

The challenges associated with obtaining and using federal or state funding for compliance will likely not allow timely compliance with EPA's proposed requirements. During EPA's public hearing, several stakeholders including those representing small water systems expressed concerns about the three-year timeframe. Specifically, a Colorado stakeholder shared that a recent implementation of a treatment technology spanned a five-year period. Advocacy is concerned that EPA neglected to adequately consider the regulatory flexibility to provide an extended compliance timeline for small entities. In the Initial Regulatory Flexibility Analysis,¹⁶ EPA declined to extend compliance timelines in response to the panel recommendation to

¹⁶ Economic Analysis at pgs. 9-7-9-8.

consider rule implementation delays for potential laboratory capacity-related challenges. Capacity-related challenges could potentially impact the ability of water systems to monitor for PFAS and reasonably comply with the proposed requirements. Instead, the agency referred to a state's ability to provide extensions under SDWA.¹⁷ Obtaining an extension from a state for capital improvements or for other compliance issues will likely deplete the limited resources of the small water systems. Advocacy recommends that EPA conduct extensive outreach with small entities to better understand their ability to comply, including access to funding, availability of resources such as training staff, any potential supply chain issues or construction delays and lab and disposal capacity issues. To address these concerns, Advocacy encourages the agency to take predevelopment timelines and the availability of resources into account when reconsidering the compliance timeframe. Therefore, to ensure compliance, Advocacy recommends that the EPA extend the compliance timeframe for small entities beyond the three years proposed.

III. Advocacy is concerned about the agency's concurrent proposal of a preliminary determination and the proposed regulation of four PFAS chemicals.

Advocacy is concerned about EPA's approach in issuing both a preliminary regulatory determination and national primary drinking water regulations for the four PFAS chemicals, (PFHxS, GenX chemicals, PFNA, and PFBS) in the same action. To support its justification for its concurrent proposal approach, EPA cites "[f]or each contaminant that the Administrator determines to regulate under subparagraph (B)...[EPA]may publish such proposed regulation concurrent with the determination to regulate."¹⁸ EPA's reliance, however, is misplaced because statutory language does not permit a proposed concurrent regulation with a preliminary determination; it only allows a concurrent proposal with a "determination to regulate." The agency equates the "determination to regulate" with a "regulatory process...that beings with a preliminary determination."¹⁹ "Determination" is defined as "the act of deciding definitely and firmly."²⁰ Therefore, it cannot be considered to be a preliminary process where a decision is being contemplated and is not yet decided. EPA further asserts that this provision authorizes a more expedited process. This is also incorrect. The SDWA includes a separate provision that allows for such an expedited process, to allow proposals concurrent with a preliminary determination because it allows EPA to "...promulgate an interim national primary drinking water regulation for a contaminant without making a determination for the contaminant..."²¹

Moreover, the agency is proposing to regulate the four PFAS chemicals under the novel HI approach. Many small entities and their representatives have expressed concerns about the

¹⁷ The agency cites to 42 U.S.C. §300g-1(b)(10) (a state or EPA may grant an extension of up to two additional years to comply with an NPDWR's MCL if the state or EPA determines a system needs additional time for capital improvements) and to 42 U.S.C. § 300g-4 (states may provide such as extension on an individual system basis which may address compliance issues associated with treatment, laboratory, and disposal capacity).

¹⁸ 88 Fed. Reg.18644 *citing* 42 U.S.C. §300g-1 (b)(1)(E).

¹⁹ *Id.* at 18644.

²⁰ See, Merriam Webster Dictionary. [Determination Definition & Meaning - Merriam-Webster](#) (last visited May 30, 2023).

²¹ 42 U.S.C. §300g-1(b)(1)(D).

validity of this approach. Advocacy encourages the agency to address the concerns raised by stakeholders on this topic. Most importantly, Advocacy recommends that the agency proceed in a step-by-step manner contemplated by the statute by first issuing a preliminary determination for the four PFAS and then after the agency finalizes its determination, it can then propose the appropriate NPDWR.

IV. Conclusion

Advocacy is concerned that small water systems will not have adequate funds to ensure timely compliance with EPA's proposed requirements. Therefore, Advocacy recommends that the agency consider alternatives standards and provide regulatory flexibilities to reduce the compliance burden on small water systems. Advocacy also recommends that EPA address small entity concerns with its proposed actions for PFHxS, GenX chemicals, PFNA, and PFBS, by issuing regulations in accordance with the SDWA.

If you have any questions or require additional information, please contact me or Assistant Chief Counsel Tayyaba Zeb at (202) 798-7405 or by email at tayyaba.zeb@sba.gov.

Sincerely,

/s/

Major L. Clark, III
Deputy Chief Counsel
Office of Advocacy
U.S. Small Business Administration

/s/

Tayyaba Zeb
Assistant Chief Counsel
Office of Advocacy
U.S. Small Business Administration

Copy to: Richard L. Revesz, Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget