Attorneys General of the States of Arizona, California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Michigan, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Wisconsin, and the District of Columbia

May 30, 2023

Via Regulations.gov
Water Docket
EPA Docket Center
U.S. Environmental Protection Agency
Mail Code: 28221T
1200 Pennsylvania Ave. NW
Washington, D.C. 20460

Re: Comments on *Preliminary Regulatory Determination and Proposed Rule; PFAS National Primary Drinking Water Regulation Rulemaking*, 88 Fed. Reg. 18638 (Mar. 29, 2023)

Docket ID No. EPA-HQ-OW-2022-0114

Dear Administrator Regan:

The Attorneys General of the States of Arizona, California, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Massachusetts, Michigan, New Jersey, New York, North Carolina, Oregon, Pennsylvania, Wisconsin, and the District of Columbia (collectively, the States) offer these comments in support of the U.S. Environmental Protection Agency's (EPA) preliminary regulatory determination and proposed rule to set enforceable drinking water standards for certain per- and polyfluoroalkyl substances (PFAS) (PFAS Rule).[1] The PFAS Rule would set Maximum Contaminant Levels (MCL) and Maximum Contaminant Level Goals (MCLG) for six PFAS as follows:

- **Perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS)**: EPA proposes an MCL of four parts per trillion (ppt) and an MCLG of zero for each contaminant.[2]
- **Perfluorohexane sulfonic acid (PFHxS); hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salt (known collectively as GenX); perfluorononanoic acid (PFNA); and perfluorobutane sulfonic**

[1] *Preliminary Regulatory Determination and Proposed Rule; PFAS National Primary Drinking Water Regulation Rulemaking*, 88 Fed. Reg. 18638 (March 29, 2023).
[2] In March 2021, EPA issued a final regulatory determination to regulate PFOA and PFOS as contaminants under the federal Safe Drinking Water Act, 42 U.S.C. § 300f, et seq. (SDWA).

acid (PFBS): EPA makes a preliminary regulatory determination to regulate these four PFAS, and mixtures of these PFAS, as contaminants under the Safe Drinking Water Act (SDWA). EPA also proposes a Hazard Index approach to set a limit on these four PFAS and any mixture containing one or more of these four PFAS. EPA proposes a Hazard Index of 1.0 as the MCL and MCLG for these four PFAS and any mixture containing two or more of them.[3]

The States have a significant interest in ensuring that their residents have access to safe drinking water, and many have taken action to set their own drinking water standards for various PFAS.[4] We strongly support EPA's proposed action to set national standards to protect the public from the harmful health impacts of PFAS in drinking water and offer the following comments for the agency's consideration as it proceeds in this important effort. We also emphasize the need for significant resources for state and local governments to remove PFAS from drinking water supplies and to help with the cost of rule implementation and regulatory enforcement. The comments proceed as follows:

- First, we explain EPA's authority to set enforceable drinking water standards for these PFAS because they: (a) have known adverse health effects, (b) are likely to occur in public water systems, and (c) present a meaningful opportunity for health risk reduction, if regulated.

- Second, we explain that EPA has authority to issue a preliminary determination and simultaneously propose MCLs and MCLGs for PFAS in drinking water.

- Third, we offer support for the proposed Hazard Index approach to regulate PFHxS, HFPO-DA, PFNA, and PFBS and explain why the Hazard Index approach is both appropriate and justified to address the health effects of PFAS mixtures.

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[3] The Hazard Index is a tool used by EPA to evaluate the potential health risks from exposure to chemical mixtures. The PFAS Rule proposes a ratio for each of the four PFAS to be used to calculate a compliance value based on detected levels of these PFAS—a combination of these four ratios equaling or exceeding 1.0 will trigger the need to reduce their levels in drinking water; *see* EPA Fact Sheet: Understanding the PFAS National Primary Drinking Water Proposal Hazard Index, https://www.epa.gov/system/files/documents/2023-03/How%20do%20I%20calculate%20the%20Hazard%20Index._3.14.23.pdf.

[4] *See infra* at 13-14; *see also* Envt'l Council of the States, *Processes & Considerations for Setting State PFAS Standards* 7 (Feb. 2020; updated Mar. 2023), https://www.ecos.org/wp-content/uploads/2023/03/2023-ECOS-PFAS-Standards-Paper-Update.pdf.

- Fourth, we urge EPA to make technical and engineering resources available to public water systems so that the financial burden of removing PFAS does not unfairly fall on ratepayers and customers.

- Fifth, we urge EPA to issue the final rule as quickly as possible because these contaminants are so toxic, while at the same time giving States the opportunity to revise their programs.

- Sixth, after finalizing this PFAS Rule, we suggest that EPA should similarly consider setting drinking water standards for other PFAS both alone and in combination.

Background

PFAS are a class of synthetic chemicals that have been used in the United States since the 1940s and are still found in many common products. These chemicals have been widely used because they are resistant to water, heat, and stains. PFAS are highly stable and resistant to degradation—which is why PFAS are known as "forever chemicals." They have been used to produce countless consumer products, including textiles (like waterproof clothing, car seats, strollers, and stain repellent furnishings), non-stick cookware, and food packaging. Firefighting foam containing PFAS[5] has also been used for decades by the United States military, airports, industrial facilities, and local fire departments. PFAS are detectable in the blood of most people in the United States.[6] Because of their widespread and long-term use and method of production, PFAS are typically found in mixtures in the environment.

Our states face substantial threats to public health and the environment from PFAS. Many states, including many of the undersigned, have repeatedly urged both Congress and EPA to take prompt and aggressive actions to respond to the unfolding national PFAS crisis.[7] The science demonstrates that these chemicals are

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[5] Aqueous film-forming foam, or AFFF, has been in use since its development in the 1960s.

[6] Agency for Toxic Substances and Disease Registry, *PFAS in the U.S. Population*, https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html.

[7] *See, e.g.*, Multistate Comments dated April 13, 2022 regarding EPA's Fiscal Year 2022 Spend Plan for PFAS, https://www.michigan.gov/ag/-/media/Project/Websites/AG/releases/2022/April/State_Comments_on_EPAs_PFAS_Spend_Plan_FINAL_751106_7.pdf?rev=761235fc045d4b9c995b1a4427a2ad3c&hash=DB08B30565068BCA058CB3E5C331694C; Multistate Comments dated September 27, 2021 regarding EPA's Proposed TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances, 86 Fed. Reg. 33926 (June 28, 2021), https://www.regulations.gov/comment/EPA-HQ-OPPT-2020-0549-0086; Multistate Comments dated September 17, 2021 regarding EPA's Drinking Water Contaminant Candidate List 5 Draft, 86 Fed. Reg. 37948 (July 19, 2021), https://www.regulations.gov/comment/EPA-HQ-OW-2018-0594-0076; Multistate Comments dated May 10, 2021 regarding EPA's proposal to expand monitoring for PFAS under the UCMR5 (May 10, 2021), https://coag.gov/app/uploads/2021/05/510.21_PFAS_Comments.pdf;

highly toxic to humans and animals, with even miniscule exposures over time associated with significant and diverse adverse human health effects.[8] Moreover, PFAS in mixtures can have a dose-additive effect, which makes it critical to regulate combinations of PFAS in addition to individual chemicals, the approach the agency is pursuing in this rulemaking.[9]

Comments

1. **EPA has authority to set PFAS drinking water standards because PFAS have known adverse health effects, are likely to occur in public water systems, and such regulation provides a meaningful opportunity for reducing risks to human health.**

EPA is required to set enforceable drinking water standards if the EPA Administrator determines that a contaminant meets the following criteria: (a) it may have adverse human health effects; (b) it is known to occur or is substantially likely to occur in public water systems with a frequency and at levels of public health concern; and (c) its regulation presents a meaningful opportunity to reduce health risks for those served by public water systems.[10] These criteria are met here.

Multistate Letter to Congress dated July 16, 2021 regarding Support for 2021 PFAS Action Act, https://content.govdelivery.com/attachments/WIGOV/2021/07/23/file_attachments/1886815/Multi-State%20PFAS%20Letter%20071621.pdf; Multistate Comments dated June 10, 2020 regarding EPA's Preliminary Regulatory Determinations for Contaminants on the Fourth Drinking Water Contaminant Candidate List, 85 Fed. Reg. 14098, 14120 (Mar. 10, 2020), https://www.regulations.gov/comment/EPA-HQ-OW-2019-0583-0258; Multistate Comments dated April 17, 2020 regarding EPA's Supplemental Proposed Rule on Long-Chain Perfluoroalkyl Carboxylate and Perfluoroalkyl Sulfonate Chemical Substances; Significant New Use Rule, 85 Fed. Reg. 12479 (March 3, 2020), https://www.regulations.gov/comment/EPA-HQ-OPPT-2013-0225-0217; Multistate Comments dated February 3, 2020 regarding Addition of Certain PFAS; Community right to Know Toxic chemical Release Reporting, 84 Fed. Reg. 66369 (Dec. 4, 2019), https://www.regulations.gov/comment/EPA-HQ-TRI-2019-0375-0086; Multistate Comments to Congress dated July 30, 2019 regarding need for comprehensive PFAS Legislation, https://oag.ca.gov/system/files/attachments/press-docs/Multistate%20PFAS%20Legislative%20Letter_7.30.19_FINAL.pdf.

[8] *See* Pelch KE, Reade A, Kwiatkowski CF, Wolffe T, Merced-Nieves FM, Cavalier H, Schultz K, Rose K, Varshavsky J. 2021. *PFAS-Tox Database*, https://pfastoxdatabase.org/.
[9] *See e.g.*, Goodrum et al., *Application of a Framework for Grouping and Mixtures Toxicity Assessment of PFAS: A Closer Examination of Dose-Additivity Approaches*, Tox. Sciences (2021), https://doi.org/10.1093/toxsci/kfaa123.
[10] 42 U.S.C. § 300g-1(b)(1)(A).

a. EPA's proposed PFAS drinking water standards are necessary to protect public health.

EPA's proposed MCL for PFOA and PFOS of four parts per trillion (individually), and the agency's proposed Hazard Index-based MCL for mixtures containing PFHxS, GenX, PFNA, and/or PFBS are strongly supported by health effects data. The MCLs reflect both EPA's well-supported analysis of that data and its commitment to protecting human health.

Data about how these six PFAS chemicals affect human health comes from human and animal studies examining how these PFAS enter our bodies and the associated health effects. Much of the research has focused on the health effects of specific PFAS chemicals in isolation, but there is also substantial data demonstrating the adverse health effects of PFAS chemicals as components of a mixture.[11] In fact, there is sufficient data concerning certain PFAS chemicals for EPA to assess their toxicity and publish detailed assessments about their safety.[12] These PFAS chemicals are associated with a wide range of serious adverse health effects when people ingest them through drinking water, including without limitation, various cancers, liver disease and damage, issues with growth and development like low birth weight, changes in hormone levels, weakened immune system, diabetes, and fertility issues.[13]

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[11] A coalition of nonprofits, research institutes and universities have created a database concerning PFAS toxicology called the PFAS-Tox Database that includes, among many others, studies on PFHxS, GenX, PFNA, and PFBS. In addition, the database contains at least 204 studies on PFAS mixtures. *See* Pelch KE, Reade A, Kwiatkowski CF, Wolffe T, Merced-Nieves FM, Cavalier H, Schultz K, Rose K, Varshavsky J. 2021. *PFAS-Tox Database* available at https://pfastoxdatabase.org/.

[12] *See, e.g.*, United States Environmental Protection Agency, *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)*, EPA Document Number: 822-R-16-005, May 2016, https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_health_advisory_final_508.pdf; *see, e.g.*, United States Environmental Protection Agency, *Drinking Water Health Advisory for Perfluorooctane Sulfonate (PFOS)*, EPA Document Number 822-R-16-004, May 2016, https://www.epa.gov/sites/default/files/2016-05/documents/pfos_health_advisory_final_508.pdf.

[13] See the following illustrative examples of such studies. **Studies concerning PFAS and Cancer:** Jiang H., et al. *Associations between Polyfluoroalkyl Substances Exposure and Breast Cancer: A Meta-Analysis*. *Toxics.* 2022; https://doi.org/10.3390/toxics10060318; Keck School of Medicine of the University of Southern California, *Synthetic "forever chemical" linked to liver cancer*, https://keck.usc.edu/synthetic-forever-chemical-linked-to-liver-cancer/, (full study available at https://doi.org/10.1016/j.jhepr.2022.100550); Scott M. Bartell & Verónica M. Vieira (2021) *Critical review on PFOA, kidney cancer, and testicular cancer*, Journal of the Air & Waste Management Association, https://doi.org/10.1080/10962247.2021.1909668; Joseph J. Shearer, PhD, et al., *Serum Concentrations of Per- and Polyfluoroalkyl Substances and Risk of Renal Cell Carcinoma*,

PFOS and PFOA have been conclusively found to be highly harmful to human health even at miniscule levels of exposure, with both chemicals being linked to a wide variety of adverse health effects. The five health effects of PFOA and PFOS with the strongest human evidence are decreased vaccine response, delayed growth and development (e.g., decreased birth weight), increased cholesterol, increased levels of

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Journal of the National Cancer Institute, https://doi.org/10.1093/jnci/djaa143; Lisa M. Kamendulis et al., *Exposure to perfluorooctanoic acid leads to promotion of pancreatic cancer*, Carcinogenesis, https://doi.org/10.1093/carcin/bgac005; Imir OB, et al., *Per- and Polyfluoroalkyl Substance Exposure Combined with High-Fat Diet Supports Prostate Cancer Progression*. Nutrients. 2021; https://doi.org/10.3390/nu13113902. **Studies concerning PFAS and the Liver**: Elizabeth Costello et al., *Exposure to per- and Polyfluoroalkyl Substances and Markers of Liver Injury: A Systematic Review and Meta-Analysis*, Environ. Health Perspectives, https://doi.org/10.1289/EHP10092. **Studies concerning PFAS and Development:** Liew Z., et al., *Developmental Exposures to Perfluoroalkyl Substances (PFASs): An Update of Associated Health Outcomes*, Curr Environ Health Rep, https://doi.org/10.1007/s40572-018-0173-4; Bevin E. Blake, Suzanne E. Fenton, *Early life exposure to per- and polyfluoroalkyl substances (PFAS) and latent health outcomes: A review including the placenta as a target tissue and possible driver of peri- and postnatal effects*, Toxicology, https://doi.org/10.1016/j.tox.2020.152565; Kaberi P. Das, et al., *Developmental toxicity of perfluorononanoic acid in mice*, Reproductive Toxicology, https://doi.org/10.1016/j.reprotox.2014.12.012; Henrik Viberg, et al., *Adult dose-dependent behavioral and cognitive disturbances after a single neonatal PFHxS dose*, Toxicology, https://doi.org/10.1016/j.tox.2012.12.013; Silvia Manea, et al., *Exposure to PFAS and small for gestational age new-borns: A birth records study in Veneto Region (Italy)*, Environmental Research, https://doi.org/10.1016/j.envres.2020.109282. **Studies concerning PFAS and the Endocrine System:** Jenny Carwile, et al., *Serum PFAS and Urinary Phthalate Biomarker Concentrations and Bone Mineral Density in 12-19 Year Olds: 2011-2016* NHANES, The Journal of Clinical Endocrinology & Metabolism, https://doi.org/10.1210/clinem/dgac228. **Studies Concerning PFAS and the Immune System:** Haley Von Holst, et al., *Perfluoroalkyl substances exposure and immunity, allergic response, infection, and asthma in children: review of epidemiologic studies*, Heliyon, https://doi.org/10.1016/j.heliyon.2021.e08160; U.S. Department of Health and Human Services, National Toxicology Program, *NTP Monograph: Immunotoxicity Associated with Exposure to Perfluorooctanoic acid and Perfluorooctane Sulfonate*, September 2016, https://ntp.niehs.nih.gov/ntp/ohat/pfoa_pfos/pfoa_pfosmonograph_508.pdf. **Studies Concerning PFAS and Diabetes:** Gui, SY., et al. *Association between per- and polyfluoroalkyl substances exposureand risk of diabetes: a systematic review and meta-analysis*., J Expo Sci Environ Epidemiol, https://doi.org/10.1038/s41370-022-00464-3. **Studies Concerning PFAS and Fertility.** Mount Sinai, *Exposure to Chemicals Found in Everyday Products Is Linked to Significantly Reduced Fertility* (2023), https://www.mountsinai.org/about/newsroom/2023/exposure-to-chemicals-found-in-everyday-products-is-linked-to-significantly-reduced-fertility (full study available at https://pubmed.ncbi.nlm.nih.gov/36801327/); Wei Wang, *The effects of perfluoroalkyl and polyfluoroalkyl substances on female fertility: A systematic review and meta-analysis*, Environmental Research, https://doi.org/10.1016/j.envres.2022.114718.

an enzyme that is an indicator of liver damage, and (for PFOA) kidney and testicular tumors.[14]

For PFHxS, PFNA, PFBS and GenX, there is likewise substantial evidence that all are individually harmful to human health. Each contaminant has been the subject of numerous animal and/or human health studies that show likely health effects.[15] In each case, EPA appropriately used such studies to set levels of protection called Health Based Water Concentrations (HBWC) for PFHxS and PFNA, PFBS and GenX, to provide appropriate protections against adverse health impacts.[16] For example, EPA based its HBWC for PFHxS on an Agency for Toxic Substances and Disease Registry (ATSDR) intermediate-duration oral Minimal Risk Level (MRL).[17] The PFHxS MRL in turn was based on studies showing that PFHxS can harm the development of liver and thyroid tissue including a study on rats that showed risks to the thyroid at a certain level of exposure.[18] Both ATSDR and EPA appropriately used this study to identify an exposure level without appreciable risk for humans, accounting for relevant factors like age and other sensitivities that may differ between species and including an uncertainty factor to account for chronic exposure through drinking water.[19]

Multiple PFAS are often present in drinking water and other sources of PFAS exposure, and as a result, in human blood serum.[20] To evaluate the impacts of exposure to multiple PFAS, researchers also consider PFAS mixtures and their

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[14] Interstate Technology Regulation Council, *Human and Ecological Health Effects and Risk Assessment of Per- and Polyfluoroalkyl Substances (PFAS)* (Sept. 2022), https://pfas-1.itrcweb.org/wp-content/uploads/2022/09/HH_Eco_PFAS_Fact-Sheet_082422_508.pdf.

[15] Pelch KE, Reade A, Kwiatkowski CF, Wolffe T, Merced-Nieves FM, Cavalier H, Schultz K, Rose K, Varshavsky J. 2021. *PFAS-Tox Database* https://pfastoxdatabase.org/. Database listing 578 studies for PFHxS, 631 studies for PFNA, 150 studies for PFBS, and 29 studies for GenX.

[16] PFAS National Primary Drinking Water Regulation Rulemaking, 88 FR 18638-01 at 18645-47.

[17] *Id.* at 18645-46.

[18] *See*, Agency for Toxic Substances and Disease Registry (ATSDR*), Toxicological profile for Perfluoroalkyls,* http://dx.doi.org/10.15620/cdc:5919.

[19] PFAS National Primary Drinking Water Regulation Rulemaking, 88 FR 18638-01 at 18645-46.

[20] *See, e.g*, California State Water Resources Control Board, Geotracker – PFAS Map, https://geotracker.waterboards.ca.gov/map/pfas_map (searchable map linking to test results in water throughout California with data showing PFAS mixtures in many sampling events); Biomonitoring California, Results for Perfluoroalkyl and Polyfluoroalkyl Substances (PFASs), https://biomonitoring.ca.gov/results/chemical/2183 (showing that the PFAS at issue in this regulation are present in nearly all blood serum samples and in mixtures across several different cohorts).

impact on health.[21] For example, a recent study by the University of Southern California's Keck School of Medicine used human blood serum to examine the impacts of PFAS mixtures on the human thyroid and metabolism, and it found that exposure to a PFAS mixture is associated with an increase in a thyroid hormone. According to the researchers, this is especially concerning because thyroid hormones play an important role in child development during puberty, which can have important effects on a range of diseases later in life, including diabetes, cardiovascular disease and cancer.[22] Another recent study concerning PFAS mixtures found lower odds of "attaining a clinical pregnancy within one year of follow-up and delivering a live birth when the combined effects of seven PFAS as a mixture were considered."[23] These studies illustrate both the need to regulate the six PFAS subject to the PFAS Rule and EPA's sound judgment in employing the agency's Hazard Index approach, with its rulemaking based on the risks to human health posed by PFHxS, PFNA, PFBS and GenX individually and in mixtures.

b. EPA's proposed PFAS drinking water contaminant levels are known to occur or substantially likely to occur in public water systems with a frequency and at levels of public health concern.

EPA appropriately determined that "there is a substantial likelihood that the [PFAS] contaminants [subject to the PFAS Rule] will occur and co-occur with a frequency and at levels of public health concern in [public water systems] based on EPA's evaluation of the best available occurrence information."[24] To reach this determination, EPA considered data collected under the Third Unregulated Contaminant Monitoring Rule (UCMR3) program as well as data collected by states. The state data, using newer analytical methods that have lower reporting limits than those under UCMR3, show "widespread occurrence of PFOA, PFOS, PFHxS, PFNA, and PFBS in multiple geographic locations."[25] State sampling demonstrated that

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[21] *See* Pelch KE, Reade A, Kwiatkowski CF, Wolffe T, Merced-Nieves FM, Cavalier H, Schultz K, Rose K, Varshavsky J. 2021. *PFAS-Tox Database* https://pfastoxdatabase.org/ (listing 204 studies on "PFAS Mix").

[22] Keck School of Medicine of the University of Southern California, *Keck School of Medicine study finds "forever chemicals" disrupt key biological processes*, https://keck.usc.edu/keck-school-of-medicine-study-finds-forever-chemicals-disrupt-key-biological-processes/, published study available at: https://doi.org/10.1289/EHP11372.

[23] Mount Sinai, *Exposure to Chemicals Found in Everyday Products Is Linked to Significantly Reduced Fertility* (2023), https://www.mountsinai.org/about/newsroom/2023/exposure-to-chemicals-found-in-everyday-products-is-linked-to-significantly-reduced-fertility (study available at https://pubmed.ncbi.nlm.nih.gov/36801327/).

[24] 88 Fed. Reg at 18647.

[25] *Id.* at 18648.

millions of people drink water contaminated by the subject four PFAS.[26] For example, Massachusetts data disclosed PFHxS in over 31 percent of finished water samples, South Carolina found PFBS in over 38 percent of finished water samples, and Kentucky found HFPO-DA in 13 percent of finished water samples.[27] The data show that PFHxS, HFPO-DA, PFNA, and PFBS, and mixtures of these PFAS, occur and co-occur at levels of public health concern as they are measured at concentrations above their respective individual health reference levels (HRLs) or, when considering their dose additive impacts, exceed these levels.[28]

c. EPA's proposed PFAS drinking water standards present a meaningful opportunity for health risk reduction.

EPA correctly found that regulating the six PFAS subject to this rule presents a meaningful opportunity for health risk reduction for consumers of drinking water from public water systems. Four technologies are available to reduce the concentrations of these PFAS in water: granular activated carbon (GAC), aqueous ion exchange (AIX) resins, reverse osmosis (RO), and nanofiltration (NF). Because the four PFAS co-occur with other PFAS for which the Agency is not currently making a preliminary regulatory determination, regulation of the four PFAS represents a meaningful opportunity to reduce the overall public health risk from all other PFAS that co-occur and are co-removed with them.[29] In the rulemaking, EPA proposes these four technologies as Best Available Technologies, after considering: (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 and 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.[30] These technologies have demonstrated PFAS removal efficiencies that can exceed 99 percent,[31] with EPA finding GAC and AIX resins to be the most affordable technologies over a range of small water system sizes.[32] The PFAS Rule is well justified because the standards present a meaningful opportunity to reduce human health risk.

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[26] *Id.* at 18651.
[27] *Id.* at 18949-50.
[28] *Id.* Concentrations of PFBS, taken alone, did not exceed the HRL. But EPA determined that there is a substantial likelihood of its occurrence with a frequency and at levels of public health concern because of dose additivity with other PFAS found in mixtures and the elevated frequency with which PFBS occurrence has been observed over time. *Id.* at 18650.
[29] 88 Fed. Reg at 18651.
[30] *Id.* at 18683.
[31] *Id.* at 18684-85.
[32] *Id.* at 18687-88.

2. **EPA has authority to issue a preliminary determination and simultaneously propose MCLs and MCLGs for PFAS in drinking water.**

EPA's decision to issue a preliminary determination and simultaneously publish proposed MCLGs and national primary drinking water regulations for PFAS was proper and lawful. The SDWA, 42 U.S.C. § 300g-1(b)(1)(A), expressly authorizes EPA to proceed in this manner. Moreover, EPA has provided the required notice and opportunity to comment on its preliminary determination to regulate the subject four PFAS, in accordance with 42 U.S.C. § 300g-1(b)(1)(B)(ii). The Agency has also provided the required notice and opportunity for comment on its proposed rule publishing MCLGs and setting national primary drinking water regulations for the subject suite of six PFAS.[33]

EPA also acted reasonably in scheduling the comment periods to occur simultaneously for the preliminary determination to regulate the four PFAS and for the proposed rule to establish MCLGs and setting national primary drinking water standards for the subject PFAS. Simultaneous, rather than sequential, comment periods are not precluded by the SDWA and here serve the purposes both of best promoting public health and furthering administrative efficiency. Indeed, the Act expressly states that EPA may propose such a regulation "concurrent with the determination to regulate,"[34] and does not prohibit a proposal to set national primary drinking water standards made simultaneously with a proposed determination to regulate. And while the SDWA prescribes a deadline for EPA to propose a regulation setting national primary drinking water standards (subject to notice and comment), being "*no later than* 24 months after the determination to regulate,"[35] the Act does *not* set a time before which the agency may set a national primary drinking water standard (subject, of course, to notice and comment). Thus, the SDWA allows for simultaneous comment periods here.

Given the need to promptly address the significant demonstrated risks to human health posed by the four subject PFAS, EPA was well within its discretion to schedule these simultaneous comment periods. Moreover, these simultaneous comment periods promote appropriately efficient decision-making by EPA because the standard for a determination to regulate matches the standard for issuing a national primary drinking water regulation.[36] The standard for each turns on: (a) the contaminant's potential for adverse health effects, (b) the likelihood that the contaminant will occur sufficiently frequently in public water supplies, and (c)

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[33] *See* 42 U.S.C. § 300g-1(b)(1)(E); 5 U.S.C. § 553(c).
[34] 42 U.S.C § 300g-1(b)(1)(E).
[35] *Id.* (emphasis added).
[36] *See* 42 U.S.C. §§ 300g-1(b)(1)(B)(ii)(II), 300g-1(b)(1)(A).

whether regulation of the contaminant presents a meaningful opportunity for health risk reduction.[37] These simultaneous comment periods facilitate fuller, more comprehensive, and more efficient consideration by EPA of its rulemaking in accordance with these standards.

3. EPA's proposed Hazard Index approach to regulate PFHxS, GenX, PFNA, and PFBS is appropriate and justified to address the demonstrated adverse health effects of PFAS mixtures.

As previously discussed, *infra* at Comment 1.a., EPA's decision to regulate PFHxS, GenX, PFNA, and PFBS using a Hazard Index approach is amply supported by, among other studies, health effect studies concerning each chemical individually and from PFAS mixtures. As a result, EPA's Hazard Index approach, a method that employs a numerical value used in risk assessment to estimate the potential health risks associated with exposures to multiple chemicals or contaminants. The Hazard Index is determined by adding up the ratio of the concentration detected in drinking water to the HBWC for each of the four PFAS included in the Hazard Index. Here, the Hazard Index provides a scientifically sound way to evaluate the cumulative effects of exposure to the four subject PFAS and helps to determine whether the combined risk from multiple exposures is within acceptable levels or if further action is needed to protect human health. A Hazard Index greater than 1.0 indicates that the combined exposures may pose a potential risk to human health, while an index less than 1.0 suggests that the risks are likely to be low.

EPA's proposed use of a Hazard Index in this situation—where human exposure to a mixture of PFAS in drinking water is occurring simultaneously—is scientifically and technically sound and appropriate. Many States use Hazard Indices to address the risks of exposure to a mixture of contaminants.[38] In fact, one of the undersigned—Wisconsin—is currently using Hazard Indices for assessment of the hazards posed by a mixture of PFAS in drinking water and has released an informative video describing its function.[39] EPA's approach is well accepted both by regulators throughout the United States and by the scientific community and is

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[37] *Id.*

[38] Examples of states using Hazard Indices to assess the combined risk of mixtures of contaminants include: California (see https://dtsc.ca.gov/faq/how-are-the-toxicity-criteria-used-at-california-hazardous-waste-and-hazardous-substance-release-sites/); Minnesota (see https://www.health.state.mn.us/communities/environment/risk/guidance/gw/additivity.html); Oregon (see https://www.oregon.gov/deq/aq/cao/Documents/CAO-HIQuickLearn.pdf) and Wisconsin (see https://www.dhs.wisconsin.gov/publications/p03212.pdf).

[39] *See* Wisconsin DHS, *PFAS Hazard Index* (March 2022), *https://www.youtube.com/watch?v=vWyQgP7F0mM; see also* https://www.dhs.wisconsin.gov/publications/p03212.pdf.

appropriate and justified in addressing the demonstrated potential adverse health effects of PFAS mixtures in drinking water.

4. **We urge EPA to make technical and engineering resources available to public water systems so that the financial burden of removing PFAS does not unfairly fall on ratepayers and customers.**

In the PFAS Rule, EPA examined the treatment options to achieve compliance with the proposed standards. EPA identified BATs, or Best Available Technologies, based on their high removal efficiency, history of successful use, general applicability, reasonable cost, compatibility with other water treatment processes, and the ability to bring all the water in a system into compliance. The proposed BATs for PFAS removal from drinking water are GAC, AIX, and high-pressure membranes such as RO and NF.[40]

GAC and AIX are sorptive processes, which means that they involve substances attaching to other substances. Sorptive processes work by passing water through a vessel filled with a sorbent, which removes the contaminants.[41] High-pressure membranes are a separation process where water is split into two streams across a membrane. One stream has fewer contaminants, known as permeate, and the other stream contains concentrated contaminants, known as concentrate or retentate. The effectiveness of membrane systems is measured by flux, which is the amount of permeate produced per surface area and time.[42]

Regardless of whether a water provider opts for sorptive processes or high-pressure membranes, the cost to build, operate and maintain the treatment will be substantial.[43] Even if the costs are very substantial, the benefits associated with the anticipated drinking water improvements justify such expenditures. EPA should nevertheless acknowledge and reflect in its rulemaking that the costs imposed on providers and their ratepayers are high.

The costs of installing additional treatment technologies should not fall to state and local governments and taxpayers. Further, the proposed regulation may create significant burdens on State regulatory agencies, and it is essential that EPA secure sufficient resources for states to be able to successfully implement and enforce the new MCLs. As some of our States have alleged in pending lawsuits, certain chemical manufacturers have broken the law in their manufacture, sale and distribution of PFAS and caused much of the contamination in our drinking water supplies. For

[40] PFAS National Primary Drinking Water Regulation Rulemaking, 88 FR 18638-01 at 18684 to 18689.
[41] *Id.* at 18684-85.
[42] *Id.* at 18685-86.
[43] *Id.* at 18687-88 (analyzing costs of GAC, AIX, RO, and NF based on system size).

these reasons, we urge EPA to (1) provide substantial technical and engineering resources to water providers (including model plans); and (2) work with Congress to obtain and distribute federal funding for treatment, especially in underserved communities.

5. EPA should issue the final rule as quickly as possible because these contaminants are so toxic, while at the same time giving States the opportunity to revise their programs.

The toxicity of PFAS is well documented, and EPA references and discusses the human harms of PFAS throughout the proposed PFAS Rule, explaining that "[d]epending on the individual PFAS, health effects can include negative impacts on fetal growth after exposure during pregnancy, on other aspects of development, reproduction, liver, thyroid, immune function, and/or the nervous system; and increased risk of cardiovascular and/or certain types of cancers, and other health impacts."[44] Because of these serious adverse health impacts, swift regulatory action is warranted.

The process of implementing drinking water regulations can be lengthy, with National Primary Drinking Water Regulations generally set to take effect as long as three years after a regulation is promulgated.[45] And states can allow individual water systems up to two additional years to comply if that time is reasonably needed to implement the necessary capital improvements to comply.[46] That means an MCL promulgated today might not take effect for five years for some residents of our States.

Given the toxicity of these PFAS and this anticipated long implementation period, it is crucial that EPA finalize the PFAS Rule as quickly as possible.

6. After finalizing the PFAS Rule, EPA should consider drinking water standards for other PFAS both alone and in combination.

The States applaud EPA for taking this important step to regulate and set MCLs and MCLGs for PFOA, PFOS, PFHxS, GenX, PFNA, and PFBS. However, there are other PFAS that EPA should consider for regulation to protect human health. For example:

[44] 88 Fed. Reg. 18,638 (Mar. 29, 2023).
[45] 42 U.S.C. § 300g-1(b)(10).
[46] *Id.*

- The Massachusetts Department of Environmental Protection has adopted MCLs for six PFAS, including two PFAS not addressed by the proposed PFAS Rule: perfluorodecanoic acid (PFDA) and perfluoroheptanoic acid (PFHpA).[47]
- The Wisconsin Department of Health Services recommended groundwater standards for the protection of public health for 12 PFAS in addition to the PFAS regulated in the proposed PFAS Rule.[48]
- New York has proposed drinking water standards for two PFAS not addressed by the proposed PFAS Rule: PFDA and PFHpA.[49]
- The Michigan Department of Environment, Great Lakes, and Energy has adopted MCLs for seven PFAS, including all of those in EPA's proposed standards and one PFAS not addressed by the proposed PFAS Rule: perfluorohexanoic acid (PFHxA).[50]
- EPA released or plans to release Integrated Risk Information System Toxicological Reviews for perfluorobutanoic acid (PFBA), PFHxA, and PFDA.[51]

These regulatory actions support additional, broader federal drinking water regulations. EPA should actively review additional PFAS, and groups of PFAS, as viable targets for future enforceable drinking water standards, including setting MCLGs and MCLs for additional PFAS beyond the six in the proposed PFAS Rule. The undersigned States are available to work with the agency in considering for regulation additional PFAS that pose risks to human health through drinking water exposures.

Conclusion

The States appreciate this opportunity to submit these comments supporting EPA's proposed drinking water standards for PFOA, PFOS, PFHxS, GenX, PFNA, and PFBS. We urge EPA to promptly finalize the rule and proceed apace to consider regulating additional PFAS that pose demonstrable risks to human health.

Sincerely,

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[47] Development of a PFAS Drinking Water Standard (MCL) (mass.gov) (last visited May 4, 2023)

[48] https://dnr.wisconsin.gov/sites/default/files/topic/PFAS/DHSCycle11Letter20201106.pdf (last visited May 3, 2023).

[49] XLIV N.Y. Reg. 16-20 (Oct. 5, 2022).

[50] Michigan PFAS Action Response Team, *Maximum Contaminant Levels (MCLs)*, https://www.michigan.gov/pfasresponse/drinking-water/mcl (last visited May 26, 2023).

[51] EPA, Toxicological Review of Perfluorobutanoic Acid (PFBA) and Related Salts (Final Report 2022), https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=356425; EPA, Toxicological Review of Perfluorohexanoic Acid (PFHxA) and Related Salts (Final Report 2023), https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=357314; EPA, Toxicological Review of Perfluorodecanoic Acid (PFDA) and Related Salts (Draft Report 2023), https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=354408.

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