



May 30, 2023

Docket Clerk  
U.S. Environmental Protection Agency  
EPA Docket Center  
Office of Ground Water and Drinking Water Docket, Mail Code 2822IT  
1200 Pennsylvania Avenue NW  
Washington, DC 20460

**Re: Docket No. EPA-HQ-OW-2022-0114;  
PFAS National Primary Drinking Water Regulation Rulemaking**

To Whom it May Concern:

Thank you for the opportunity to submit comments on the Environmental Protection Agency's (EPA's) determinations to regulate six per- and poly-fluoroalkyl substances (PFAS) as contaminants under the Safe Drinking Water Act (SDWA) and set regulatory limits for these PFAS in drinking water.

Founded in 1936, Consumer Reports (CR) is an independent, nonprofit and nonpartisan organization that works with consumers to create a fair and just marketplace. Known for its rigorous testing and ratings of products, CR advocates for laws and company practices that put consumers first. CR is dedicated to amplifying the voices of consumers to promote safety, digital rights, financial fairness, and sustainability. The organization surveys millions of Americans every year, reports extensively on the challenges and opportunities for today's consumers, and provides ad-free content and tools to 6 million members across the U.S.

In March 2021, EPA made a final regulatory determination to regulate perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) under the SDWA. With this notice, EPA is issuing a preliminary regulatory determination to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO-DA) and its ammonium salts (aka GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS) and mixtures of these PFAS as contaminants under SDWA.

We agree with EPA's preliminary determination to regulate these 4 PFAS and their mixtures as contaminants under SDWA. We also agree with EPA's proposed National Primary Drinking Water Regulation (NPDWR) and health-based maximum contaminant level goals (MCLGs) for these 4 PFAS and their mixtures as well as PFOA and PFOS. In addition, we support MCLGs of zero for PFOA and PFOS and enforceable maximum contaminant levels (MCLs) for PFOA and

PFOS in drinking water at 4.0 parts per trillion (ppt). We agree with EPA's proposal to use a Hazard Index (HI) approach to protecting public health from mixtures of PFHxS, HFPO-DA, PFNA and PFBS. We also support EPA's proposal to set a Hazard Index (HI) of 1.0 as the MCLGs and for the enforceable MCLs for these 4 PFAS and any mixture containing one or more of them.

More detailed comments are below.

### ***Section III: Preliminary Regulatory Determinations for Additional PFAS***

Under the provisions of Sections 1412(b)(1)(A) and 1412(b)(1)(B) of the SDWA, the EPA can regulate substances/chemicals as a contaminant in drinking water if the contaminant(s) can meet three criteria: i) that it may have an adverse effect on the health of a person, ii) that it is known to occur or there is a substantial likelihood that it will occur in public water systems (PWS) and iii) the EPA Administrator determines that regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by PWS.

EPA's review of the scientific literature clearly demonstrates that oral exposure to PFHxS, HFPO-DA, PFNA and PFBS may individually, and in mixture, each result in an adverse health effect, including disrupting multiple biological pathways that result in adverse effects a number of biological systems, including the endocrine, cardiovascular, developmental, immune, and hepatic systems.<sup>1</sup>

For each of the 4 PFAS, EPA has calculated a health-based water concentration (HBWC) which it defines as the "level protective of health effects over a lifetime of exposure, including sensitive populations." The EPA determined, based on the available science, that the HBWCs for PFHxS, GenX chemicals, PFNA and PFBS are 9 ppt, 10 ppt, 10 ppt and 2,000 ppt, respectively. We agree with EPA on the HBWCs for these four PFAS. For the Preliminary Regulatory Determination, the HBWCs were used as the Health Reference Level (HRL).

In terms of the occurrence of these four PFAS in drinking water, EPA analyzed data from the Unregulated Contaminant Monitoring Rule (UCMR) 3 sampling, which took place from 2013-2015, and from more recent data collected by states. The UCMR 3 study had 36,972 samples from 4,920 PWS that were analyzed for levels of PFHxS, PFNA and PFBS, but not GenX chemicals. The more recent data consisted of drinking water samples from 23 states that were also tested for PFHxS, PFNA, PFBS and GenX chemicals. The state data on detection frequency and concentration results that EPA presents for PFHxS, GenX, PFNA, and PFBS vary widely between the four PFAS and across states.

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<sup>1</sup> USEPA. 2023a. Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): GenX Chemicals, PFBS, PFNA and PFHxS. EPA-822-P-23-004. At: <https://www.epa.gov/system/files/documents/2023-03/PFAS%20HI%20MCLG%20Public%20Review%20Draft%2009%20March%202023.pdf>

That said, EPA notes that if you review the state data representing non-targeted monitoring, one or more of PFHxS, GenX chemicals, PFNA, and PFBS were reported in about 14% of the monitored systems. However, EPA also presents data to show that these four PFAS generally co-occur with each other, as well as with PFOA and PFOS. The state data also showed that for PFHxS, PFNA, PFBS, the levels found in drinking water often exceeded the HRLs of 9 ppt, 10 ppt, and 10 ppt, respectively. EPA made a determination that there is sufficient evidence of occurrence to support a preliminary determination that there is a substantial likelihood that PFHxS, GenX chemicals, PFNA, and PFBS will occur at frequencies and levels of public health concern. We agree with this assessment.

In terms of a meaningful opportunity to reduce the health risk of these 4 PFAS by regulating them, in addition to showing that the four PFAS and their mixtures cause adverse health impacts, and occur in the drinking water at frequencies and levels of public health concern, the data also show that PFHxS, GenX chemicals, PFNA, and PFBS and their mixtures are environmentally persistent. In addition, there are validated EPA-approved methods to measure PFHxS, GenX chemicals, PFNA, and PFBS, and mixtures of these contaminants.

Finally, there are available technologies—including granular activated carbon (GAC), AIX resins, reverse osmosis (RO), and nanofiltration (NF)—that are capable of reducing PFHxS, GenX chemicals, PFNA, and PFBS. A number of these technologies, particularly the ones using sorptive and high-pressure membrane technologies, have been shown to remove PFHxS, GenX chemicals, PFNA, and PFBS, and their mixtures and have also been documented to remove other PFAS contaminants.<sup>2</sup> Given that these removal/mitigation technologies can remove multiple PFAS, we agree with EPA that regulation of PFHxS, GenX chemicals, PFNA, and PFBS, and their mixtures will provide protection from PFAS that will not be regulated as part of this proposed NPDWR.

**To summarize, we agree that EPA has met the criteria laid out in Sections 1412(b)(1)(A) and 1412(b)(1)(B) of the SDWA to make a preliminary regulatory determination that PFHxS, GenX chemicals, PFNA, and PFBS, and their mixtures are contaminants to be regulated as part of this proposed NPDWR.**

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<sup>2</sup> McCleaf, P., Englund, S., Östlund, A., Lindegren, K., Wiberg, K., and Ahrens, L. 2017. Removal Efficiency of Multiple Poly- and Perfluoroalkyl Substances (PFASs) in Drinking Water using Granular Activated Carbon (GAC) and Anion Exchange (AE) Column Tests. *Water Research*, 120(2017):77–87.

<https://doi.org/10.1016/j.watres.2017.04.057>; Söregård, M., Östblom, E., Köhler, S., and Ahrens, L. 2020. Adsorption Behavior of Per- and Polyfluoroalkyl Substances (PFASs) to 44 Inorganic and Organic Sorbents and Use of Dyes as Proxies for PFAS Sorption. *Journal of Environmental Chemical Engineering*, 8(3):103744.

<https://doi.org/10.1016/j.jece.2020.103744>; Mastropietro, T.F., Bruno, R., Pardo, E., and Armentano, D. 2021. Reverse Osmosis and Nanofiltration Membranes for Highly Efficient PFASs Removal: Overview, Challenges and Future Perspectives. *Dalton Transactions*, 50(16):5398–5410. <https://doi.org/10.1039/d1dt00360g>

## ***Section V: Maximum Contaminant Level Goal***

Section 1412(a)(3) of the SDWA requires the EPA Administrator to propose a Maximum Contaminant Level Goal (MCLG) simultaneously with a NPDWR. The MCLG is defined as “the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.” EPA is proposing individual MCLGs for PFOA and PFOS and a separate MCLG to account for dose additive noncancer effects for a mixture of four PFAS (PFHxS, GenX chemicals, PFNA, and PFBS).

For contaminants that are carcinogenic, EPA policy is to set the MCLG at zero, unless there is data to show that there is a threshold for a carcinogenic effect. We agree with EPA’s conclusion that PFOA is *Likely to be Carcinogenic to Humans*, based on sufficient evidence of carcinogenicity in humans and animals and the lack of evidence that there is a threshold level of exposure to PFOA below which there is no appreciable cancer risk. We also agree with EPA that the weight of the evidence suggests that PFOS is *Likely to be Carcinogenic to Humans*. Thus, we support EPA setting the MCLG for PFOA and PFOS at zero.

The EPA considers noncancer effects when setting MCLGs. EPA can use the Reference dose (RfD), defined as the maximum acceptable oral dose of a toxic substance below which no adverse noncancer health effects should result from a lifetime of exposure. For PFOA, EPA followed the recommendations of the Science Advisory Board (SAB) to focus its review “on those health outcomes that have been concluded to have the strongest evidence, including liver disease, immune system dysfunction, serum lipid aberration, impaired fetal growth, and cancer.” EPA identified four prioritized health outcomes from all the toxicity data on PFOA: immune (decreased antibody production in response to vaccinations), developmental (low birth weight), cardiovascular (increased serum total cholesterol), and hepatic (elevated ALT). The RfDs for the immune, developmental and cardiovascular effects were the same, i.e.,  $3 \times 10^{-8}$  mg/kg/day, and are protective of effects that may occur in sensitive populations (i.e., infants and children). Thus, EPA set the overall RfD at  $3 \times 10^{-8}$  mg/kg/day for PFOA.

For PFOS, it turned out that EPA identified the same four prioritized health outcomes as for PFOA: immune (decreased antibody production in response to vaccinations), developmental (low birth weight), cardiovascular (increased serum total cholesterol), and hepatic (elevated ALT). The RfDs for the developmental and cardiovascular effects were the same, i.e.,  $1 \times 10^{-7}$  mg/kg/day. Thus, EPA set the overall RfD at  $1 \times 10^{-7}$  mg/kg/day for PFOS.

**We support EPA’s proposed RfDs for PFOA of  $3 \times 10^{-8}$  mg/kg/day and for PFOS of  $1 \times 10^{-7}$  mg/kg/day.**

For PFHxS, GenX chemicals, PFNA, and PFBS, and their mixtures, EPA has decided to use the Hazard Index (HI) methodology, which EPA regularly uses, for example in the Superfund program, to understand the health risks from chemical mixtures as the basis for setting a MCLG.

The HI approach assumes there is a dose additivity to the different chemicals in a mixture. This assumption of dose additivity is particularly clear in cases where each of the chemicals has a common mechanism of action and mainly affect the same human health endpoint. EPA considered two main types of HI approaches: 1) general HI which allows for each chemical in the mixture to have different health endpoints as the basis for the component chemical health-based reference value (e.g., RfD, HBWC) and 2) target-organ specific HI which relies on reference values based on the same organ or organ system (e.g., liver-, thyroid-, or developmental-specific).

The general HI is based on the overall RfD which is protective of all the effects for a given chemical regardless of organ or organ system, and thus a more protective estimate of risk, while the target-organ specific HI is a less protective estimate of risk since it focuses on only one target organ. For example, if a chemical has effects on multiple organs, the one target organ chosen for the HI may be one for which the effect may be less potent than on another organ or for which there may be significant currently unquantified effects due to lack of data. In addition, many PFAS lack human epidemiological or experimental animal hazard and dose-response data across a broad effect range which would limit determining target-organ specific values. EPA also considered the relative potency factor (RPF) approach, which represents the relative difference in potency of an effect/endpoint between a specific chemical and other chemicals in the mixture. The RPF approach has the same limitations as the organ-specific HI. EPA proposes to use the general HI as the most appropriate approach for considering PFAS mixtures, because the four PFAS chemicals frequently co-occur and can be expected to adversely impact multiple (but in many cases shared) health endpoints.

**We agree with EPA that the general HI is the most appropriate approach for setting a MCLG for mixtures of PFHxS, GenX chemicals, PFNA, and PFBS since this approach adds an appropriate margin of safety for a class of contaminants that have been shown to co-occur in mixtures and for which there may be dose additivity since they share similar profiles of health effect areas (e.g., liver, thyroid, developmental, cardiovascular, etc.). Neither the target-organ HI approach nor the RPF approach will add an appropriate margin of safety.**

The general HI is defined as the sum of the Hazard Quotient (HQ) for each chemical in a mixture. HQs are the ratio of potential exposure to a chemical and the level at which no health effects are expected. The HQ for a specific chemical is the exposure level (defined as its concentration in the drinking water) divided by the health reference value, in this case the HBWC (health-based water concentration) for that chemical. The MCLG for a mixture of PFHxS, GenX chemicals, PFNA, and PFBS is set at 1.

As noted previously, the HBWCs for PFHxS, GenX chemicals, PFNA, and PFBS are 9 ppt, 10 ppt, 10 ppt, and 2,000 ppt, respectively. Note that if the level of a specific chemical in drinking

water exceeds the HBWC, then the HQ would be  $> 1$ , e.g., that specific chemical would exceed the “safe” level. Using the general HI approach, the levels of each chemical can be below their “safe” level (the HBWC), e.g., their  $HQ < 1$ , yet the HI could exceed 1 and so the mixture could be considered unsafe. For example, let’s say that levels of PFHxS, GenX chemicals, PFNA, and PFBS in a drinking water sample are all 5 ppt, e.g., below the HBWC for each PFAS. The  $HI = (5 \text{ ppt}/9 \text{ ppt}) + (5 \text{ ppt}/10 \text{ ppt}) + (5 \text{ ppt}/10 \text{ ppt}) + (5 \text{ ppt}/2,000 \text{ ppt}) = .55 + .5 + .5 + .025 = 1.58$ . This shows the additive effect of the HI.

**We agree with EPA that the MCLG for the mixture of PFHxS, GenX chemicals, PFNA, and PFBS should be the same as the HI and set at 1.**

### ***Section VI. Maximum Contaminant Level***

Under section 1412(b)(4)(B) of SDWA, EPA must establish an enforceable MCL as close to the MCLG as feasible, taking costs into consideration. EPA has approved two analytical methods, USEPA Methods 537.1 and 533, for measuring PFAS regulated under this rule. For PFOA and PFOS, EPA has determined that 4.0 ppt is the “practical quantitation level” (or PQL), or the lowest concentration that, with 95 percent confidence, can be achieved by analysts at 75 percent or more of the laboratories using Method 533 and 537.1, according to the UCMR 5 rulemaking. Indeed, laboratory calibration data submitted as part of the UCMR 5 Laboratory Approval Program found that “49 of the 54 laboratories seeking EPA approval included a lowest PFAS calibration standard level to 1 ppt or lower, with the median lowest calibration level among all laboratories at 0.5 ppt.”<sup>3</sup> Thus, it appears that for virtually all laboratories, the PQLs for PFOA and PFOS of 4.0 ppt are at least 4 times greater than the lowest calibration standard meaning that it is technically feasible to set the MCL at the PQL.

Section 1412(b)(4)(d) of the SDWA defines feasibility in part as “feasible with the use of best available technologies.” EPA has determined that multiple technologies (i.e., GAC, AIX, RO and NF) are both available and have demonstrated PFAS removal efficiencies that may exceed  $>99$  percent and that achieve concentrations below 4.0 ppt for PFOA and PFOS. EPA proposes to determine that it is feasible to treat PFOA and PFOS to 4.0 ppt because multiple treatment technologies are effective and available at reasonable cost based on large and metropolitan water systems<sup>4</sup> and because there are methods available to reliably quantify PFOA and PFOS at 4.0 ppt.

**Given this, we support EPA’s proposal to set the MCL for PFOA and PFOS at the PQL of 4.0 ppt since it is feasible to test drinking water at that level and multiple treatment technologies exist to reduce PFOA and PFOS below 4.0 ppt at reasonable cost.**

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<sup>3</sup> See pg 18667 in <https://www.govinfo.gov/content/pkg/FR-2023-03-29/pdf/2023-05471.pdf>

<sup>4</sup> USEPA. 2023b. Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances from Drinking Water. EPA– 822–P–23–011.

The MCL for the mixtures of PFHxS, GenX chemicals, PFNA, and PFBS would be an HI = 1.0. The EPA has also determined that there are validated analytical methods (EPA Method 533 and 537.1) that can measure below the HBWC for each of these PFAS. EPA has determined that multiple technologies (i.e., GAC, AIX, RO and NF) are both available and have demonstrated PFAS removal efficiencies that may exceed >99 percent and that achieve concentrations below their PQLs (between 3.0–5.0 ppt) at a reasonable cost based on large and metropolitan water systems.

**We support EPA's proposal to set the HI for the mixtures of PFHxS, GenX chemicals, PFNA, and PFBS at an HI = 1.0, since it is feasible to test drinking water at that level and multiple treatment technologies exist to reduce PFHxS, GenX chemicals, PFNA, and PFBS to below their specific HBWC at reasonable cost.**

Best,

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