May 30, 2023

Via Regulations.gov
Assistant Administrator Radhika Fox
Office of Water
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking, Docket No. EPA–HQ–OW–2022–0114

Dear Assistant Administrator Fox:

The undersigned 36 organizations submit these comments on EPA's proposed National Primary Drinking Water Regulation for six per- and polyfluoroalkyl substances ("PFAS") (the "Proposed Rule").[1] Our organizations include communities with PFAS-contaminated drinking water, scientists who study the harms associated with PFAS, and longtime advocates for health-protective PFAS drinking water standards.

We strongly support EPA's issuance of PFAS drinking water standards, which are a critical and long overdue step to address a public health crisis that threatens the health and lives of hundreds of millions of people in the United States. For decades, communities across the country have been drinking tap water contaminated with PFAS, a large class of long-lasting and dangerous chemicals. People in those communities have lost parents, children, and other loved ones to cancer, liver and heart disease, and other diseases associated with PFAS. The longer that EPA waits to establish federal drinking water standards, the more people will be exposed, in violation of the Safe Drinking Water Act ("SDWA") mandate to reduce the harmful effects from drinking water contaminants as much as feasible.

The Proposed Rule is an important step forward. EPA correctly found that there is no safe exposure level for many PFAS, including PFOA and PFOS, and it proposed maximum contaminant levels ("MCLs") for PFOA and PFOS that are readily achievable using existing treatment technologies. EPA also recognized the serious health risks associated with exposures to mixtures of GenX, PFNA, PFBS, and PFHxS—PFAS that are frequently found in the same drinking water supplies—and it proposed an MCL that is designed to protect people who are exposed to those contaminants individually or in combination. EPA's proposed Maximum Contaminant Level Goals ("MCLGs") and MCLs are supported by an extensive factual record

[1] Preliminary Regulatory Determination and Proposed Rule, PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18,638 (Mar. 29, 2023). The six PFAS covered by the Proposed Rule are perfluorooctanoic acid ("PFOA"), perfluorooctane sulfonic acid ("PFOS"), perfluorohexane sulfonic acid ("PFHxS"), hexafluoropropylene oxide dimer acid and its ammonium salt ("GenX"), perfluorononanoic acid ("PFNA"), and perfluorobutane sulfonic acid ("PFBS") (collectively, the "Six PFAS").

and are required by the SDWA. EPA must resist efforts to weaken those levels and diminish the rule's protections.

At the same time, EPA must revise aspects of its Proposed Rule that would limit the rule's reach and undermine its effectiveness. First, EPA should update its Health Based Water Concentrations ("HBWCs")—the toxicity values that EPA uses to calculate the drinking water limits—for PFBS, GenX, PFNA, and PFHxS to address the dangers those chemicals pose to infants, children, and other higher-risk populations. Second, while EPA conducted an extensive economic analysis and found that the Proposed Rule's benefits outweigh its costs, that analysis understates the benefits of reduced PFAS exposures and should be expanded to better account for health benefits that EPA has acknowledged but has not yet quantified or monetized. Third, when determining compliance with the new drinking water standards, EPA should consider all monitoring results with detectable PFAS rather than treating samples with lower but still harmful levels of PFAS as though they were PFAS-free. Fourth, EPA should maintain the minimum requirement of quarterly PFAS monitoring for all water systems with prior PFAS detections and should not permit such systems to evade further detections and necessary treatment by monitoring just once or twice every three years. Finally, EPA should mandate public notification of MCL violations within 24 hours, as is required for all violations that may cause serious, short-term health effects.

With more than half of the nation drinking PFAS-contaminated water,[2] the Proposed Rule is urgently needed and should be finalized expeditiously, with the revisions outlined below. But as EPA Administrator Michael Regan acknowledged, "[w]hile this proposal is a step forward, there's no doubt there's more work left to do."[3] In a separate rulemaking, EPA should establish drinking water standards for the PFAS that are not covered by EPA's current proposal, including class-based standards that address the harms from additional PFAS mixtures. We urge EPA to use the full extent of its SDWA authority to ensure that no one suffers the harms associated with PFAS-contaminated drinking water.

I. EPA Must Expeditiously Finalize Health-Protective PFAS Drinking Water Standards

A. EPA Should Move Quickly to Finalize PFAS MCLs

As described by Dr. Patrick Breysse, the former Director of the Center for Environmental Health in the U.S. Centers for Disease Control and Prevention, PFAS present "one of the most

[2] David Q. Andrews and Olga V. Naidenko, *Population-Wide Exposure to Per- and Polyfluoroalkyl Substances from Drinking Water in the United States*, Env't. Sci. & Tech. Letters 931 (2020), https://doi.org/10.1021/acs.estlett.0c00713.

[3] Michael Regan, Admin., EPA, Remarks for the PFAS Drinking Water Standard Event, As Prepared for Delivery (Mar. 14, 2023), https://www.epa.gov/speeches/administrator-michael-regan-remarks-pfas-drinking-water-standard-event-prepared-delivery.

seminal public health challenges for the next decades."[4] When Dr. Breysse made that statement in October 2017, he estimated that "up to 10 million Americans" could be drinking water with unsafe levels of PFAS.[5] Today, that estimate is approximately 200 million.[6] Impacted communities experience increased risks of cancer and other severe effects, with some exposed to PFAS levels that are tens of thousands of times higher than the levels that EPA has already determined present serious health risks.[7]

Because of their chemical structure, PFAS are highly persistent, "indicat[ing] the potential for long-lasting environmental and human exposure … that is difficult to control and reverse."[8] Many PFAS also bioaccumulate in animals and people, with low-level exposures building up in people's bodies and causing serious harm. More than 98% of people tested in the United States have PFAS in their blood.[9] Communities of color often experience the greatest PFAS exposures and risks; a recent study found that the "watersheds serving higher proportions of Hispanic/Latino and non-Hispanic Black populations had significantly greater odds of containing PFAS sources."[10]

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[4] Pat Rizzuto et al., *CDC Sounds Alarm on Chemical Contamination in Drinking Water*, Bloomberg Env't (Oct. 17, 2017), https://news.bloomberglaw.com/environment-and-energy/cdc-sounds-alarm-on-chemical-contamination-in-drinking-water.

[5] *Id.*

[6] *See* Andrews & Naidenko (2020); Annie Sneed, *Forever Chemicals Are Widespread in U.S. Drinking Water*, Sci. Am. (Jan 22, 2021), https://www.scientificamerican.com/article/forever-chemicals-are-widespread-in-u-s-drinking-water/.

[7] *See, e.g.,* EPA, *Hoosick Falls, New York, Drinking Water and Groundwater Contamination, Frequently Asked Questions* (Jan. 12, 2016), https://www.epa.gov/sites/default/files/2016-01/documents/hoosickfalls_faqs.pdf (describing PFOA detections of 600 parts-per-trillion (ppt) in drinking water in Hoosick Falls, New York—150,000 times higher than EPA's health advisory level of .004 ppt); WRAL News, *Report: Extremely High Levels of GenX-like Chemicals in Wilmington Drinking Water for Years* (Oct. 9, 2019), https://www.wral.com/story/report-extremely-high-levels-of-genx-like-chemicals-in-wilmington-drinking-water-for-years/18688129/ (describing GenX detections of 130,000 ppt in the Cape Fear River near Wilmington, NC, drinking water intake—13,000 times higher than EPA's health advisory level of 10 ppt).

[8] *See, e.g.,* Ian T. Cousins et al., *Why is High Persistence Alone a Major Cause of Concern?*, 21 Env't Sci. Processes & Impacts 781 (2019), https://doi.org/10.1039/C8EM00515J.

[9] Antonia M. Calafat et al., *Polyfluoroalkyl Chemicals in the U.S. Population: Data from the National Health and Nutrition Examination Survey (NHANES) 2003–2004 and Comparisons with NHANES 1999–2000*, 115 Env't Health Persp. 1596 (2007), http://doi.org/10.1289/ehp.10598.

[10] Jahred M. Liddie et al., *Sociodemographic Factors Are Associated with the Abundance of PFAS Sources and Detection in U.S. Community Water Systems*, Env't Sci. Tech. (2023), https://pubs.acs.org/doi/pdf/10.1021/acs.est.2c07255.

The health risks associated with PFAS are well established and have been widely recognized by international scientific organizations,[11] federal and state regulatory agencies,[12] and other leading scientific bodies.[13] Individually, the PFAS covered by EPA's Proposed Rule are associated with cancer (PFOA, PFOS, and GenX), developmental harm (PFOA, PFOS, PFHxS, GenX, PFNA, and PFBS), reproductive harm (PFOA, PFOS, GenX, and PFNA), immune system toxicity (PFOA, PFOS, GenX, and PFNA), liver toxicity (PFOA, PFOS, PFHxS, GenX, and PFNA), thyroid toxicity (PFOA, PFOS, PFHxS, and PFBS) and kidney toxicity (PFOA, PFOS, GenX, and PFBS), among other adverse effects.[14] Because of these common health effects, people who are exposed to multiple PFAS—whether through their combined presence in drinking water or from other sources—face even greater risks of harm. Studies have shown that exposure to PFAS mixtures alter critical biological processes in the developing fetus, infants, and children that are separately associated with an increased risk of developmental disorders, cardiovascular disease, and many types of cancer.[15] Recent human birth cohort studies also reported associations between multiple PFAS exposures during pregnancy and adverse health outcomes, including an increased risk of gestational diabetes and altered glucose levels during pregnancy, altered levels of thyroid hormones in pregnant people and newborns, and liver injury

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[11] *See* United Nations Env't Programme, UNEP/POPS/POPRC.2/17/Add.5, *Report of the Persistent Organic Pollutants Review Committee on the Work of its Second Meeting* add. 25–26 (Nov. 2006) (Risk Profile on Perfluorooctane Sulfonate), http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-POPRC.2-17-Add.5.English.PDF; United Nations Env't Programme, UNEP/POPS/POPRC.12/11/Add.2, *Report of the Persistent Organic Pollutants Review Committee on the Work of Its Twelfth Meeting* add. 24–26 (Oct. 2016) (Risk Profile on Pentadecafluorooctanoic Acid (PFOA, Perfluorooctanoic Acid), its Salts and PFOA-related Compounds), http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-POPRC.12-11-Add.2.English.PDF.

[12] Agency for Toxic Substances and Disease Registry, *Toxicological Profile for Perfluoroalkyls,* at 5–21, 26–29 (May 2021) ("ATSDR 2021"), https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf; Cal. Env't Protection Agency, *Public Health Goals*: *Perfluorooctanoic Acid and Perfluorooctane Sulfonic Acid in Drinking Water (First Public Review Draft),* Off. of Env't Health Hazard Assessment, at 62–166 (July 2021), https://oehha.ca.gov/sites/default/files/media/downloads/crnr/pfoapfosphgdraft061021.pdf.

[13] Nat'l Acad. of Sci., Eng'g, & Med., *Guidance on PFAS Exposure, Testing, and Clinical Follow-Up,* at 6–8 (2022) ("NAS 2022"), https://nap.nationalacademies.org/catalog/26156/guidance-on-pfas-exposure-testing-and-clinical-follow-up; *see also* Arlene Blum et al., *The Madrid Statement on Poly- and Perfluoroalkyl Substances (PFASs)*, 123 Env't Health Persp. A107 (2015), https://ehp.niehs.nih.gov/doi/epdf/10.1289/ehp.1509934 (statement of more than 250 scientists expressing "concern[] about the production and release into the environment of an increasing number of [PFAS]").

[14] *See* Proposed Rule, 88 Fed. Reg. at 18,645–47, 18,656–63, 18,704, 18,718.

[15] Jesse A. Goodrich et al., *Metabolic Signatures of Youth Exposure to Mixtures of Per- and Polyfluoroalkyl Substances: A Multi-Cohort Study*, 131 Env't Health Persp. Art. No. 27005 (2023), https://ehp.niehs.nih.gov/doi/epdf/10.1289/EHP11372.

in children.[16] An accompanying analysis by Drs. Anna Reade and Katherine Pelch of the Natural Resources Defense Council discusses additional health effects that are linked to PFAS exposure, but which were not well described in EPA's toxicity assessments for PFOA and PFOS, such as disruption of mammary gland development and reduced duration of lactation.[17]

EPA has known of the harms associated with PFAS since at least 1998, and it has known of the presence of PFAS in drinking water since at least 2001.[18] More than two decades later, however, EPA has yet to establish any federal limits on PFAS levels in drinking water. The Proposed Rule, which would regulate six widespread and highly toxic PFAS, is necessary and long overdue. EPA should act swiftly to issue final drinking water standards for PFAS, with the changes recommended below.

B. EPA Should Pursue Additional, Class-Based PFAS Drinking Water Standards

While EPA's proposal marks an important step towards addressing the PFAS crisis, further action is needed to protect communities who are exposed to additional PFAS in their drinking water. A recent peer-reviewed, published study of tap water collected from 16 states, including more than 20 samples from public water supplies, detected 26 different PFAS, only six

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[16] Guoqi Yu et al., *Environmental Exposure to Perfluoroalkyl Substances in Early Pregnancy, Maternal Glucose Homeostasis and the Risk of Gestational Diabetes: A Prospective Cohort Study*, 156 Env't Int'l Art. No. 106621 (2021), https://pubmed.ncbi.nlm.nih.gov/33984575/. i: 10.1016/j.envint.2021.106621; Blanca Sarzo et al., *Maternal Perfluoroalkyl Substances, Thyroid Hormones, and* DIO *Genes: A Spanish Cross-sectional Study*, 55 Env't Sci. Tech. 11144 (2021), https://pubs.acs.org/doi/10.1021/acs.est.1c01452; Arash Derakhshan et al., *Association of Per- and Polyfluoroalkyl Substances with Thyroid Homeostasis During Pregnancy in the SELMA Study*, 167 Env't Int'l Art. No. 107420 (2022), https://www.sciencedirect.com/science/article/pii/S0160412022003476?via%3Dihub; Richard Christian Jensen et al., *Higher Free Thyroxine Associated with PFAS Exposure in First Trimester. The Odense Child Cohort*, 212 Env't Rsch. Art. No. 113492 (2022), https://pubmed.ncbi.nlm.nih.gov/35597289/; Jianqiu Guo et al., *Umbilical Cord Serum Perfluoroalkyl Substance Mixtures in Relation to Thyroid Function of Newborns: Findings From Sheyang Mini Birth Cohort Study,* 273 Chemosphere Art. No. 129664 (2021), https://pubmed.ncbi.nlm.nih.gov/33493812/; Qian Yao et al., *Prenatal Exposure To Per- and Polyfluoroalkyl Substances, Fetal Thyroid Hormones, and Infant Neurodevelopment*, 206 Env't Rsch. Art. No. 112561 (2022), https://www.sciencedirect.com/science/article/abs/pii/S0013935121018624?via%3Dihub; Nikos Stratakis et al., *Prenatal Exposure to Perfluoroalkyl Substances Associated With Increased Susceptibility to Liver Injury in Children*, 72 Hepatology 1758, 1758–70 (2020), https://onlinelibrary.wiley.com/doi/full/10.1002/hep.31483.

[17] Ltr. from Drs. Anna Reade and Katherine Pelch, Natural Resources Defense Council, re PFAS National Primary Drinking Water Regulation Rulemaking (May 30, 2023) ("Reade and Pelch 2023") (attached as **Exhibit A**).

[18] Scott Faber, *For 20-plus Years, EPA Has Failed to Regulate 'Forever Chemicals',* Env't Working Grp. (Jan. 9, 2020), https://www.ewg.org/research/20-plus-years-epa-has-failed-regulate-forever-chemicals.

of which are covered by EPA's proposed rule.[19] Another study of U.S. surface waters found 35 PFAS across 29 states and the District of Columbia, with one or more PFAS detected in 83% of the water bodies sampled.[20] Many of the PFAS detected but not covered by EPA's proposal, such as perfluorobutanoic acid ("PFBA") and perfluoroheptanoic acid ("PFHpA"), are associated with an increased risk of thyroid toxicity, liver damage, and developmental impairment, exacerbating the harms from the PFAS that are subject to EPA's proposed standards.[21] Notably, PFBA, perfluorohexanoic acid ("PFHxA"), and perfluorodecanoic acid ("PFDA"), all have finalized or draft toxicity assessments performed by EPA's Integrated Risk Information System ("IRIS").[22]

Like GenX, PFBS, PFNA, and PFHxS (collectively, the "Hazard Index PFAS" or "HI PFAS"), these other detected PFAS also meet the three statutory criteria for regulation under the SDWA.[23] EPA has found that PFBA, PFHxA, and PFDA "may have an adverse effect on the health of persons," [24] and that they are associated with many of the same health effects observed following exposure to other PFAS, as summarized in Table 1 below. There are sufficient occurrence data from state monitoring efforts to support the need to protect against exposure to these PFAS in drinking water.[25] Regulation of these PFAS in drinking water, individually and as

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[19] Katherine E. Pelch et al., *70 Analyte PFAS Test Method Highlights Need for Expanded Testing of PFAS in Drinking Water*, 876 Sci. of the Total Env't Art. No.162978 (2023), https://www.sciencedirect.com/science/article/pii/S0048969723015966.

[20] Waterkeeper All., *Invisible, Unbreakable, Unnatural: PFAS Contamination of U.S. Surface Waters,* at 13 (Oct. 2022), https://waterkeeper.org/wp-content/uploads/2022/10/Waterkeeper-Alliance-PFAS-Report-FINAL-10.14.22.pdf.

[21] EPA, *IRIS Toxicological Review of Perfluorobutanoic Acid (PFBA, CASRN 375- 22-4) and Related Salts,* at 4-1–4-2 (Dec. 2022), https://www.epa.gov/system/files/documents/2022-12/10945-%20PFBA%20ToxReview%20Final%20December%202022-HERO_partial-508%20%28updated%20page%20100%29.pdf; Health and Env't All., *The Curious Case of PFHpA and Why This and All Forever Chemicals Should be Banned Under REACH* (Dec. 13 2022), https://www.env-health.org/the-curious-case-of-pfhpa-and-why-this-and-all-forever-chemicals-should-be-banned-under-reach/.

[22] EPA, *IRIS Toxicological Review of Perfluorobutanoic Acid*; EPA, *IRIS Toxicological Review of Perfluorohexanoic Acid [PFHxA, CASRN 307-24-4] and Related Salts* (Apr. 2023), https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0704tr.pdf; EPA, *IRIS Toxicological Review of Perfluorodecanoic Acid [PFDA, CASRN 335-76-2] and Related Salts (Public Comment and External Review Draft)* (Apr. 2023), https://ordspub.epa.gov/ords/eims/eimscomm.getfile?p_download_id=546623.

[23] *See* 42 U.S.C. § 300g-1(b)(1)(A) (requiring EPA to develop MCLGs and national primary drinking water regulations for contaminants that EPA determines "may have an adverse effect on the health of persons," are known or substantially likely to occur in public water systems "with a frequency and at levels of public health concern," and present "a meaningful opportunity for health risk reduction for persons served by public water systems").

[24] *Id.* § 300g-1(b)(1)(A)(i).

[25] *See id.* § 300g-1(b)(1)(A)(ii).

a mixture with other PFAS, "presents a meaningful opportunity for health risk reduction for persons served by public water systems."[26]

TABLE 1 Adverse Effects	PFBA[27] osRfD[28] (mg/kg-d)	PFHxA[29] osRfD (mg/kg-d)	PFDA[30] osRfD (mg/kg-d)
Hepatic	**1 x 10^{-3}** **Increased hepatocellular hypertrophy in adult rats**	4 x 10^{-4} Increased hepatocellular hypertrophy in adult rats	7 x 10^{-7} Increased relative liver weight in female rats **subchronic RfD only*
Thyroid	**1 x 10^{-3}** **Decreased total T4 in adult rats**	1 x 10^{-3} Decreased free T4 in adult male rats **subchronic RfD only*	
Developmental	6 x 10^{-3} Developmental delays in mice	**5 x 10^{-4}** **Decreased F_1 body weight at PND 0 in rats**	**3 x 10^{-10}** **Decreased birth weight in male and female children**
Hematopoietic	-	5 x 10^{-3} Decreased red blood cells in adult rats	
Immune			**4 x 10^{-10}** **Decreased serum antibody concentrations for tetanus and diphtheria in children at age 7 years**
Male reproductive			5 x 10^{-6}

[26] *Id*. § 300g-1(b)(1)(A)(iii).
[27] EPA, *IRIS Toxicological Review of Perfluorobutanoic Acid,* at xiii (Table ES-1. Evidence integration judgements and derived toxicity values for PFBA).
[28] Organ/system-specific oral reference dose.
[29] EPA, *IRIS Toxicological Review of Perfluorohexanoic Acid [PFHxA, CASRN 307-24-4] and Related Salts*, at xv (Apr. 2023).
[30] EPA, *IRIS Toxicological Review of Perfluorodecanoic Acid (PFDA) and Related Salts (Public Comment and External Review Draft*, at xvii-xviii (Apr. 2023).

			Decreased absolute whole epididymis weight in rats **subchronic RfD only*
Female reproductive			3×10^{-6} Increased number of days spent in diestrus in rats **subchronic RfD only*

Health effects in **bold** were selected by EPA as the chronic or lifetime RfD.

Moreover, with more than 1,000 PFAS already in commerce and dozens of new PFAS awaiting EPA approval, EPA cannot fully protect public health or the environment by regulating individual PFAS (or even small sub-groups of PFAS) one at a time. Separate from its Proposed Rule, EPA should pursue a broader, class-based PFAS drinking water standard. Leading scientists have called for class-based standards[31] and the European Union has established a drinking water standard, which will take effect in January 2026, for "the totality of per- and polyfluoroalkyl substances."[32] Similarly, the Canadian government recently found that "a precautionary, class-based approach to addressing PFAS is needed to protect the environment and people from anticipated adverse effects."[33] "Addressing PFAS as a class of chemicals would also reduce the chance of regrettable substitution," or the replacement of PFAS that regulated under the SDWA with equally toxic but less studied PFAS that are not subject to SDWA controls.[34]

The SDWA does not require detailed information about every member of the class to protect the public from their cumulative health effects. EPA previously established a class-based drinking water limit for polychlorinated biphenyls ("PCBs") despite acknowledging that "the

[31] Carol F. Kwiatkowski et al., *Scientific Basis for Managing PFAS as a Chemical Class*, 7 Env't Sci. & Tech. Letters 532, 532–43 (2022), https://pubs.acs.org/doi/10.1021/acs.estlett.0c00255.
[32] Directive 2020/2184 of the European Parliament and of the Council of the European Parliament and of the Council of 16 December 2020 on the Quality of Water Intended for Human Consumption, 2020 O.J. (L 435), https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32020L2184; *see also* Health Canada, *Draft Objective for Per- and Polyfluoroalkyl Substances in Canadian Drinking Water: Rationale,* https://www.canada.ca/en/health-canada/programs/consultation-draft-objective-per-polyfluoroalkyl-substances-canadian-drinking-water/rationale.html (last updated Feb. 10, 2023) (proposing 30 ppt drinking water limit for "total PFAS in drinking water," using detection methods capable of measuring at least 18 PFAS).
[33] Environment and Climate Change Canada and Health Canada, *Draft State of Per- and Polyfluoroalkyl Substances (PFAS) Report* at 113-114 (May 2023), https://www.canada.ca/content/dam/eccc/documents/pdf/pded/pfas/draft-state-pfas-report.pdf.
[34] *Id.* at 116.

toxicity of [the 209 possible PCB isomers] has not been fully characterized.[35] Here, too, the presence of multiple PFAS in the same drinking water supplies, as well as those chemicals' shared persistence and potential for common health effects, supports a class-based MCL. In addition to finalizing the Proposed Rule to protect communities with PFOA, PFOS, and the HI PFAS in their drinking water, EPA should also pursue a separate rulemaking process, beginning with a class-based PFAS regulatory determination, to establish drinking water standards that cover all mixtures of PFAS in drinking water.

II. The Proposed MCLs are Required by the SDWA and Supported by an Extensive Factual and Scientific Record

A. Statutory and Regulatory Background

"The Safe Drinking Water Act … was enacted to ensure that public water supply systems meet minimum national standards for the protection of public health."[36] To prevent drinking water contamination, the SDWA requires EPA to establish National Primary Drinking Water Regulations ("NPDWRs") that specify the "maximum levels for contaminants that may have an adverse effect on the health of consumers."[37]

EPA's obligation to issue NPDWRs is triggered by the Administrator's determination that: (1) a contaminant "may have an adverse effect on the health of persons," (2) "the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern," and (3) "regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems."[38] EPA's regulatory determinations, and other science-based decisions under the SDWA, "shall use . . . the best available, peer-reviewed science and supporting studies."[39] Here, EPA made regulatory determinations for PFOA and PFOS in March 2021, and it made a preliminary regulatory determination for the HI PFAS in the Proposed Rule.[40]

An NPDWR must contain either a "maximum contaminant level" or a "treatment technique."[41] A maximum contaminant level, or "MCL," is "the maximum permissible level of a contaminant in water which is delivered to any user of a public water system."[42] An MCL must be set at a level that is "as close . . . as is feasible" to the "level at which no known or anticipated

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[35] National Primary Drinking Water Regulations—Synthetic Organic Chemicals and Inorganic Chemicals; Monitoring for Unregulated Contaminants; National Primary Drinking Water Regulations Implementation; National Secondary Drinking Water Regulations, 56 Fed. Reg. 3,526, 3,546 (Jan. 30, 1991).
[36] *Nat'l Wildlife Fed'n v. EPA*, 980 F.2d 765, 768 (D.C. Cir. 1992).
[37] *Id.* (citing 42 U.S.C. § 300g-1).
[38] 42 U.S.C. § 300g-1(b)(1)(A).
[39] *Id*. § 300g-1(b)(3)(A)(i).
[40] Proposed Rule, 88 Fed. Reg. at 18,638; *see also* 42 U.S.C. § 300g-1(b)(1)(E) (authorizing EPA to publish a proposed NPDWR "concurrent with the determination to regulate").
[41] 42 U.S.C. § 300f(1)(C).
[42] *Id*. § 300f(3).

adverse effects on the health of persons occur and which allows an adequate margin of safety," also known as the Maximum Control Level Goal or "MCLG."[43] The analysis of feasibility "tak[es] costs into consideration,"[44] but it does not prioritize those considerations over public health protection or require EPA to find that the economic benefits of an MCL outweigh the costs.[45]

EPA has broad authority under the SDWA to set MCLs for groups of related contaminants. The SDWA broadly defines "contaminant" as "any physical, chemical, biological, or radiological substance or matter in water," encompassing both individual chemicals and chemical mixtures that are found in the same water supplies.[46] EPA set, and the D.C. Circuit Court of Appeals upheld, a single MCL for combined levels of radium-226 and radium-228 based on those substances' co-occurrence in drinking water and common carcinogenic effects.[47] Similarly, EPA's NPDWR for disinfectants and disinfection byproducts set combined MCLs for four different trihalomethanes ("THMs") and five different haloacetic acids ("HAA5").[48] In setting its original drinking water standards for THMs, EPA rejected calls to establish chemical-specific MCLs for individual THMs, such as chloroform, explaining that "as a family of compounds, the THMs are similar in chemical composition and nature" and are commonly found together in drinking water.[49] As explained above, EPA's NPDWR for PCBs established a single MCL for "complex mixtures" of up to 209 possible PCB isomers.[50] In each of those rules, the use of a class-based MCL protects communities that are exposed to mixtures of related contaminants and furthers the SDWA's purpose of "prevent[ing] the harmful contamination of public water systems."[51]

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[43] *Id*. § 300g–1(a)(4). The SDWA authorizes, but does not require, EPA to set an MCL above the most health-protective, feasible level if EPA determines that the "benefits of [the] maximum contaminant level … would not justify the costs of complying with the level." *Id.* § 300g–1(b)(6)(A). EPA did not make such a finding in its proposed rule, and, as described in greater detail below, EPA's analysis of the rule's costs and benefits precludes such a finding. *See* pp. 18-20 *infra.*

[44] 42 U.S.C. § 300g-1(a)(4)(D).

[45] *See* S. Rep. No. 104-169, at 33 (Nov. 7, 1995) ("The Administrator is not precluded from … set[ting] a maximum contaminant level as close to the maximum contaminant level goal as feasible, even if the Administrator determines that the benefits of the MCL at this level do not justify the costs."); *see also* 42 U.S.C. § 300g-1(b)(3)(C)(i) (requiring EPA to consider "nonquantifiable health risk reduction benefits" when establishing MCLs); *City of Portland, Oregon v. EPA*, 507 F.3d 706, 712 (D.C. Cir. 2007).

[46] 42 U.S.C. § 300f(6) (emphasis added).

[47] *See* Final Rule, National Primary Drinking Water Regulations; Radionuclides, 65 Fed. Reg. 76,708, 76,718, 76,720 (Dec. 7, 2000); *City of Waukesha v. E.P.A.*, 320 F.3d 228 (D.C. Cir. 2003).

[48] Final Rule, National Primary Drinking Water Regulations: Disinfectants and Disinfection Byproducts, 63 Fed. Reg. 69390 (Dec. 16, 1998).

[49] Final Rule, National Interim Primary Drinking Water Regulations; Control of Trihalomethanes in Drinking Water, 44 Fed. Reg. 68,624, 68,627 (Nov. 29, 1979).

[50] 56 Fed. Reg. at 3,546.

[51] *Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 387 (D.C. Cir. 1992).

B. EPA's MCLs for PFOA and PFOS are Consistent with the SDWA and Supported by the Record

i. EPA Correctly Determined That There is No Safe Exposure Level for PFOA or PFOS

EPA's proposed MCLGs for PFOA and PFOS are consistent with the SDWA's mandate to identify the "level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety."[52] EPA appropriately proposed MCLGs of 0 ppt based on its longstanding policy of "establish[ing] MCLGs of zero for carcinogens … where there is insufficient information to determine … a threshold dose below which no carcinogenic effects have been observed."[53] There is substantial evidence that both PFOA and PFOS are carcinogenic, with no known safe level of exposure. "The carcinogenicity of PFOA has been observed in both human epidemiological and animal toxicity studies."[54] EPA documented the evidence of PFOA's carcinogenicity in its 2016 PFOA Health Effects Support Document, and subsequent studies have only strengthened and reinforced that finding.[55] A 2022 report from the National Academies of Sciences, Engineering and Medicine ("NAS") found "that there is sufficient evidence for an association between PFAS," including PFOA, "and kidney cancer,"[56] and the Agency for Toxic Substances and Disease Registry ("ATSDR") has reported "increases in the risk of testicular and kidney cancer associated with PFOA."[57] Similarly, human and animal studies of PFOS "reported elevated risk of bladder, prostate, kidney, and breast cancers after chronic PFOS exposure."[58] California's Office of Environmental Health Hazard Assessment ("OEHHA") has listed both PFOA and PFOS as chemicals "known . . . to cause cancer," based on its independent review of the scientific literature.[59] Additionally, OEHHA has published draft public health goals for PFOA and PFOS in drinking water based on their

[52] 42 U.S.C. § 300g–1(b)(4)(A).
[53] Proposed Rule, 88 Fed. Reg. at 18,659.
[54] *Id*. at 18,656.
[55] *Id.*
[56] NAS 2022 at 74.
[57] ATSDR 2021 at 523.
[58] Proposed Rule, 88 Fed. Reg. at 18,660.
[59] OEHHA, *Notice to Interested Parties, Chemical Listed Effective February 25, 2022, As Known to the State of California to Cause Cancer: Perfluorooctanoic Acid* (2022)("OEHHA 2022"), https://oehha.ca.gov/media/downloads/crnr/listingnoticepfoa022522.pdf; OEHHA, *Notice to Interested Parties, Chemicals Listed Effective December 24, 2021, As Known to the State of California to Cause Cancer: Perfluorooctane Sulfonic Acid (PFOS) and Its Salts and Transformation and Degradation Precursors* (2021), https://oehha.ca.gov/media/downloads/crnr/noticepfossandsaltstransdegradprecursor122421.pdf.

carcinogenicity.[60] EPA thus appropriately concluded that both PFOA and PFOS are "likely to be carcinogenic to humans."[61]

EPA's established practice, which has been endorsed repeatedly by EPA's Science Advisory Board, the NAS, and other leading authorities, assumes that cancer risks follow a linear dose response curve, with no safe exposure threshold, in the absence of "scientific evidence demonstrating a threshold level of exposure below which there is no appreciable cancer risk."[62] Here, there is no evidence of a safe level for PFOA and PFOS, and accordingly no basis to depart from EPA's standard approach. Based on substantial evidence of their carcinogenicity and the absence of a safe exposure threshold, EPA appropriately determined that there is no safe level for either PFOA or PFOS.

EPA's proposed MCLGs are further supported by PFOA's and PFOS's severe non-cancer effects, which occur at levels far below those that can be detected in drinking water. As recognized EPA's toxicity assessments for both PFOA and PFOS, those contaminants cause immune system harm (including reduced vaccine effectiveness in children), developmental toxicity, and heart and kidney damage at levels ranging as low as 3×10^{-8} mg/kg/day (PFOA) and 1×10^{-7} mg/kg/day (PFOS).[63] Those levels equate to drinking water toxicity in the parts-per-quadrillion range, well below the detection limit for either chemical.[64] While cancer risks alone are sufficient to support the proposed zero ppt MCLGs for PFOA and PFOS, their serious noncancer risks reinforce the need for EPA to reduce exposure to both chemicals as much as feasible.

ii. EPA's Proposed PFOA and PFOS MCLs are Feasible Using Readily Available Detection and Treatment Technologies

EPA's proposed PFOA and PFOS MCLs are "as close . . .as is feasible" to those chemicals' MCLGs, as required by the SDWA.[65] The SDWA defines feasibility as "feasible with the use of the best technology" that has been tested under "field conditions" and is "available."[66] When it amended the SDWA in 1986, Congress specified that "granular activated carbon is feasible for the control of synthetic organic chemicals," like PFAS.[67] Congress added that "other

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[60] OEHHA, *Public Health Goals, Perfluorooctanoic Acid and Perfluorooctane Sulfonic Acid in Drinking Water* (*First Public Review Draft),* at 10 (2021) ("OEHHA 2021"), https://oehha.ca.gov/sites/default/files/media/downloads/crnr/pfoapfosphgdraft061021.pdf.
[61] Proposed Rule, 88 Fed. Reg. at 18,659–60.
[62] *Id.* at 18,652–53; *see also* EPA, *Guidelines for Carcinogen Risk Assessment,* at 3-21–3-22 (2005).
[63] Proposed Rule, 88 Fed. Reg. at 18,659, 18,662–63.
[64] *See id.* at 18,669 ("The level at which no known or anticipated [non-cancer] effects on the health of persons would occur is well below current analytical quantitation level for PFOA and PFOS.").
[65] 42 U.S.C. § 300g-1(b)(4)(B).
[66] 42 U.S.C. § 300g-1(b)(4)(D).
[67] Pub. L. No. 99-339, 100 Stat. 642, 644-645 (June 19, 1986) (currently codified at 42 U.S.C. § 300g–1(b)(4)(D)).

means found to be the best available for the control of synthetic organic chemicals must be at least as effective in controlling synthetic organic chemicals as granular activated carbon."[68]

Here, EPA correctly found that granular activated carbon ("GAC"), anion exchange, and high pressure membranes such as those used in reverse osmosis systems "can achieve [PFAS] concentrations less than 4 [ppt]" and may "exceed >99 percent [PFAS removal]."[69] Those technologies are not only readily available, but they have been deployed and proven effective in communities across the country. The Cape Fear Public Utility Authority reported no PFAS detections in water treated by granular activated carbon at a Wilmington, NC drinking water treatment plant, despite high levels of PFAS in the water before treatment.[70] In nearby Brunswick County, another utility used reverse osmosis to reduce PFOA and PFOS to non-detectable levels.[71] The use of granular activated carbon treatment in New Jersey yielded similar results:

> Seven different GAC treatment plants operating for years . . . removed PFOA, PFOS, and other PFAS chemicals to nondetectable levels. Three of those GAC plants were treating groundwater with concentrations of PFOA or PFOS of >500 ppt to nondetectable levels. Since 2019, 12 New Jersey plants, seven that use GAC and five that use IEX, have been achieving nondetectable levels of PFOA and PFOS in >99.9% of treated water with detection limits ranging from 0.53 to 5 ppt.[72]

Moreover, as described below, EPA's benefit-cost analyses found that these systems are cost-effective, with health benefits exceeding treatment costs in many circumstances.

Despite acknowledging that existing technologies can reduce PFOA and PFOS levels below 4 ppt, EPA proposed a 4 ppt MCL based on those chemicals' practical quantitation levels ("PQL"), or the lowest level that can be detected "by capable analysts at 75 percent or more of

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See id.

[68] *Id.*

[69] Proposed Rule, 88 Fed. Reg. at 18,684–86.

[70] *See* WECT News, *CFPUA: No PFAS Found in Water Treated by GAC Filters* (Oct. 11, 2022), https://www.wect.com/2022/10/11/cfpua-no-pfas-found-water-treated-by-gac-filters/.

[71] Brunswick Cnty. Gov. Complex, *Brunswick County Commissioners Receive Final Report Showing PFAS Not Detected in LPRO Treated Water* (Apr. 17, 2018), https://www.brunswickcountync.gov/brunswick-county-commissioners-receive-final-report-showing-pfas-not-detected-in-lpro-treated-water/; CDM Smith, *Advanced Treatment Options for the Northwest Water Treatment Plant: Brunswick County*, App'x A (Apr. 2018), https://www.brunswickcountync.gov/wp-content/uploads/2018/04/CDM-Smith-Brunswick-Final-Report-April-2018.pdf.

[72] Elizabeth Southerland & Linda S. Birnbaum, *What Limits Will the World Health Organization Recommend for PFOA and PFOS in Drinking Water*, 57 Env't Sci. & Tech. 7103, 7103–7105 (2023), https://doi.org/10.1021/acs.est.3c02260; N.J. Drinking Water Quality Inst., Treatment Subcomm., *Recommendation on Perfluorinated Compound Treatment Options for Drinking Water, at* 6–8 (June 2015), https://www.nj.gov/dep/watersupply/pdf/pfna-pfc-treatment.pdf.

the laboratories using a specified analytical method[.]"[73] Because no laboratories can currently measure PFOA or PFOS levels down to the 0 ppt MCLG and not all labs can reliably measure those chemicals below the PQL, "EPA often bases the MCL on the PQL."[74] EPA's latest six-year review of National Primary Drinking Water Treatment Standards identified at least 14 contaminants for which EPA set MCLs based on the PQL, including benzo[a]pyrene, PCBs, and 2,3,7,8-Tetrachlorodibenzo-p-Dioxin.[75] Similarly, setting the PFOA and PFOS MCLs at the PQL is consistent with the SDWA and with EPA's past practice.

As testing technologies advance, however, EPA must review and reduce those MCLs. The SDWA provides that "not less often than every 6 years," EPA must "review and revise, as appropriate, each national primary drinking water regulation promulgated under this subchapter."[76] As EPA acknowledges, laboratory testing capacity "can improve over time," and "the Six-Year Review process is an opportunity to evaluate whether new information . . . shows that PQLs for carcinogens can be reduced, which introduces the possibility of reducing the MCLs[.]"[77] Many labs already have the ability to measure PFOA and PFOS well below the MCLs, and some emerging technologies can detect PFOA, PFOS, GenX, and PFBS in the parts-per-quadrillion range.[78] EPA should reassess laboratories' PFOA and PFOS detection capacity during each six-year review period and decrease the MCL whenever new information supports a lower PQL.

C. EPA's Proposed MCL for GenX, PFBS, PFNA and PFHxS is Consistent with the SDWA and Supported by the Record

i. A Hazard Index Is a Well Established and Appropriate Method of Addressing the Risks Posed by Mixtures of Multiple PFAS

For the HI PFAS, EPA proposed an MCLG and MCL using an approach that addresses the harms caused by each of those contaminants individually, as well as by their combined presence in drinking water supplies. This approach is well grounded in the SDWA, and it is needed to protect communities that have multiple PFAS in their drinking water supplies.

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[73] Proposed Rule, 88 Fed. Reg. at 18,666–67.
[74] EPA, *EPA 810-R-16-002, Development of Estimated Quantitation Levels for the Third Six-Year Review of National Primary Drinking Water Regulations (Chemical Phase Rules),* Off. of Water, at 1-3 (Oct. 2016), https://www.epa.gov/sites/default/files/2016-12/documents/810r16002.pdf.
[75] *Id*. at 1-3 – 1-4.
[76] 42 U.S.C. § 300g–1(b)(9).
[77] EPA, *EPA 810-R-16-002, Development of Estimated Quantitation Levels for the Third Six-Year Review of National Primary Drinking Water Regulations (Chemical Phase Rules),* at 1-2.
[78] Phenomenex, *Achieving Low Parts-per-Quadrillion Detection Limits for PFAS Analysis in Drinking Water (TN-1316),* at 1, https://www.phenomenex.com/documents/2022/09/29/17/52/achieving-low-partsperquadrillion-detection-limits-for-pfas-analysis-in-drinking-water-tn1316.

A hazard index is "commonly used" to measure and regulate risks from mixtures, or combinations, of contaminants that cause similar health effects.[79] Under this approach, EPA calculates each contaminant's "hazard quotient," or individual risk, by dividing the level of human exposure (i.e., the concentration of the contaminant in drinking water) by the level at which the contaminant presents risk to human health (referring to be EPA as a Health-Based Water Concentration or "HBWC").[80] A hazard quotient below 1 indicates an individual chemical is present below the level that is known to cause risk. To calculate the risk from the mixture, EPA adds the chemicals' hazard quotients to calculate a hazard index, with a hazard index above 1 generally indicating elevated risk to human health.[81] However, the use of a hazard index of 1 as an adequate health threshold relies on EPA's ability to address all of the harms associated with the chemicals at issue in their underlying toxicity assessments. Given the uncertainties inherent in the estimation of risk and the multitude of factors that are not included in EPA calculations– including the effects of non-chemical stressors and co-exposures to other PFAS that are not covered by the Proposed Rule – EPA should consider the use of a hazard index below 1 to provide the "adequate margin of safety" required by the SDWA.[82]

Hazard indices have long been used by EPA offices and endorsed by leading scientific authorities, including EPA's Science Advisory Board. EPA calculates hazard indices under the Comprehensive Environmental Response, Compensation, and Liability Act to measure the cumulative effects of multiple contaminants at a Superfund site and to develop health-protective clean-up goals.[83] They are also used under the Clean Air Act to calculate chronic risks from multiple chemicals released by a given source category.[84] Hazard indices address the potential for "low levels of multiple [chemicals] that individually would not likely result in adverse health effects . . .to result in adverse health effects" when combined in a mixture. This approach to calculating risk – also known as dose additivity – "has found widespread acceptance as an

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[79] Proposed Rule, 88 Fed. Reg. at 18,639.
[80] *Id.*
[81] *Id.*
[82] 42 U.S.C. § 300g–1(b)(4)(A); *see also* Devon Payne-Sturges et al., *Cumulative Risk Evaluation of Phthalates Under TSCA,* 57 Env't Sci. & Tech. 6403, 6409 (2023), https://pubs.acs.org/doi/full/10.1021/acs.est.2c08364 (challenging the "traditional use of HI ≤ 1 as being 'safe' or acceptable for mixtures/multiple chemical exposures" and proposing "the use of a HI of 0.1–0.2 as a benchmark").
[83] *See* EPA, *EPA/540/1-89/002, Risk Assessment Guidance for Superfund: Volume I Human Health Evaluation Manual (Part A)*, Off. of Emergency and Remedial Response, at 8-11–8-13, https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=2000KLZ9.txt ("At most Superfund sites, one must assess potential health effects of more than one chemical … Estimating risk or hazard potential by considering one chemical at a time might significantly underestimate the risks associated with simultaneous exposures to several substances … To assess the overall potential for noncarcinogenic effects posed by more than one chemical, a hazard index (HI) approach has been developed based on EPA's (1986b) *Guidelines for Health Risk Assessment of Chemical Mixtures*.")
[84] *See* National Emission Standards for Hazardous Air Pollutants: Cyanide Chemicals Manufacturing Residual Risk and Technology Review*,* 86 Fed. Reg. 3906, 3910-11 (Jan. 15, 2021).

assessment concept for combined exposures to multiple chemicals . . . and is extensively used by regulatory authorities as a protective default approach."[85]

Here, a hazard index is necessary and appropriate to address the harms associated with the HI PFAS. As EPA found, "PFHxS, [GenX], PFNA, and PFBS … result[] in common adverse effects on several biological systems including thyroid hormone levels, lipid synthesis and metabolism, as well as on development, and immune and liver function."[86] Exposure to mixtures of those chemicals poses greater risks than exposure to each chemical in isolation, such that setting individual chemical MCLs would not fully protect people who have combinations of the HI PFAS in their drinking water. EPA also found, based on nationwide monitoring data, that "there is a substantial likelihood PFHxS, [GenX], PFNA, and PFBS will occur and co-occur with a frequency of public health concern."[87] "When three or four HI PFAS were monitored, over 40 percent of systems reported detections of two to three of the HI PFAS."[88] An MCL that ignores those co-exposures could leave millions of people at risk.[89]

This is the precise scenario that has justified prior, mixture-based MCLs. In its disinfection byproducts rule, EPA set a combined MCL for five THMs that are detected together in drinking water and cause similar health effects.[90] Because of their combined effects, regulating each component of that mixture in isolation would "permit a substantial number of communities . . . to avoid any improvement of treatment practice and, by implication, water quality."[91] As described above, EPA also regulated all PCBs under a single MCL because individual isomer limits would understate their combined risks.[92] Here, too, EPA cannot protect communities with multiple HI PFAS in their drinking water unless its MCL accounts for the harms associated with those chemicals' mixtures.

ii. EPA Should Maintain its Hazard Index Approach to Setting the MCLGs and MCLs for the HI PFAS While Updating its Hazard Index Calculations to Reflect the Best Available Science

With appropriate inputs, a hazard index of 1 reflects "the level at which no known or anticipated adverse effects on the health of persons occur" from exposure to the HI PFAS, as required for an MCLG.[93] Because the HI PFAS cause a range of harmful effects at different exposure levels, simply setting a maximum concentration for their combined presence in

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[85] Org. for Econ. Coop. and Dev., *ENV/JM/MONO(2018)37, Considerations for Assessing the Risks of Combined Exposure to Multiple Chemicals: Series on Testing and Assessment No. 296*, at 19 (Dec. 6, 2018), https://www.oecd.org/chemicalsafety/risk-assessment/considerations-for-assessing-the-risks-of-combined-exposure-to-multiple-chemicals.pdf.
[86] Proposed Rule, 88 Fed. Reg. at 18,647.
[87] *Id.*
[88] *Id.* at 18,676.
[89] *See id.* at 18,678
[90] 44 Fed. Reg. at 68,624, 68,626-28.
[91] *Id.* at 68,628.
[92] 56 Fed. Reg. at 3,546.
[93] 42 U.S.C. § 300g–1(b)(4).

drinking water, as EPA has done for prior contaminant mixtures, would not address their "known or anticipated" adverse effects.[94] By dividing each contaminant's exposure level by the lowest level at which the contaminant is known to pose harm, EPA can calculate hazard quotients that are tailored to each contaminant and that protect against effects that occur at higher exposure levels. And by adding those quotients to calculate the hazard index, EPA can protect against adverse effects from mixtures of the HI PFAS and ensure that people who are exposed to multiple HI PFAS are not placed at risk.[95] However, this approach requires EPA to set HBWCs—the denominators in its hazard quotient equations[96]—at levels that protect against all of a contaminants' adverse health effects, including effects to "subgroups . . . such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations[] that are identifiable as being at greater risk of adverse health effects due to exposure to contaminants in drinking water than the general population."[97] As explained below, EPA's proposed HBWCs do not address the HI PFAS' increased risks to infants and must be revised in a manner consistent with the best available science. We urge EPA to use the reduced HBWCs recommended below when calculating the Hazard Index for the purposes of setting the HI PFAS MCLG.

A hazard index of 1 is also "feasible with the use of the best [available] technology," and is a proper MCL. Here, as well, EPA should revise the denominators for its hazard index calculations. Because the HBWCs proposed below are significantly lower than the practical quantitation level for the HI PFAS, laboratories may not be able to detect MCL exceedances that are based on those levels. Therefore, when calculating the hazard index for the purpose of setting and implementing the MCL, we recommend that EPA use the PQL for each HI PFAS as the denominator, similar to EPA's approach for PFOA, PFOS, and other chemicals that pose health risks below their respective PQLs. This would ensure that the HI PFAS MCL is feasible, because (1) laboratories can already detect each HI PFAS down to the PQL and (2) water systems can reduce levels of the HI PFAS below their respective PQLs by using the same treatment technologies that EPA has proposed to address PFOA and PFOS, including granular activated carbon and reverse osmosis.[98] Similar to PFOA and PFOS, many communities are already using those technologies to treat water contaminated with GenX and other HI PFAS.

The SDWA does not dictate the form of an MCL or MCLG; it merely requires the MCLG to be set at a health-protective "level" and the MCL to be set as close as feasible to that level. EPA's Proposed Rule, with the changes recommended herein, satisfies those statutory requirements. In the past, EPA has set MCLs based on the percentage of water samples that detected a class of contaminants (total coliforms), as opposed to a density-based limit, because "the presence-absence concept is simpler and mathematically more precise than the current

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[94] *Id.*

[95] As described below, EPA should update its toxicity values (or Health Based Water Concentrations) for the HI PFAS to reflect the latest available science on those chemicals' hazards. Those revisions would not change the MCL or MCLG; they would merely ensure that the calculations that EPA used to calculate the hazard index are fully protective of human health.

[96] Proposed Rule, 88 Fed. Reg. at 18,665.

[97] 42 U.S.C. § 300g–1(b)(1)(C).

[98] Proposed Rule, 88 Fed. Reg. at 18,665-66.

density standard for total coliforms[.]"[99] Similarly, a hazard index provides a "more precise" estimate of the HI PFAS' effects than a concentration-based limit, consistent with the SDWA's mandate to minimize those contaminants' adverse effects to the extent feasible.

III. EPA Should Take Steps to Strengthen the Economic Analysis Supporting the Proposed Rule

As required by the SDWA, EPA's Proposed Rule is supported by a draft Economic Analysis ("Draft EA") that assesses the proposal's "[q]uantifiable and nonquantifiable health risk reduction benefits," its "[q]uantifiable and nonquantifiable costs," the incremental costs and benefits of the alternative MCLs considered, the effects of the Six PFAS on the general population and greater-risk subpopulations, any increased health risks associated with compliance with the Proposed Rule, and other relevant factors such as uncertainties in the analysis.[100] As described in the accompanying expert review of EPA's Draft EA by Dennis Guignet, Ph.D., many features of the Draft EA are exceptionally thorough and transparent,[101] and the Draft EA provides ample justification for EPA's conclusion that the Proposed Rule's quantified and unquantified benefits justify its costs.[102] Further, as discussed in the accompanying expert review by Elin Betanzo, EPA's treatment cost estimates are robust and, if anything, may overstate actual costs.[103] Nevertheless, there are important steps EPA can and should take to strengthen the EA to better support the proposed drinking water standards.

At the outset, we encourage EPA to maintain, and consider expanding upon, several key methodological strengths of the Draft EA.[104] The Draft EA is predicated on a detailed, data-driven Monte Carlo simulation model that supports comprehensive sensitivity analyses, which evaluate the impact of specific variables on estimates of the Proposed Rule's net benefits. As described by Dr. Guignet, this is the most thorough approach to account for multiple sources of uncertainty in the economic analysis simultaneously.[105] The Draft EA accounts appropriately for existing state-level drinking water standards when estimating the costs and benefits attributable

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[99] Drinking Water; National Primary Drinking Water Regulations; Total Coliforms (Including Fecal Coliforms and E. coli), 54 Fed. Reg. 27,544, 27,548 (June 29, 1989).
[100] 42 U.S.C. § 300g-1(b)(3)(C)(i); *see* EPA, *Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation* (EPA Doc. No. EPA-822-P-23-001) (Draft for Public Comment) (Mar. 2023).
[101] Memorandum from Dennis Guignet, Ph.D., to Earthjustice, Re. Review of the Economic Analysis for the Proposed PFAS NPDWR (May 26, 2023) ("Guignet 2023") (Attached as **Exhibit B**).
[102] *See* Proposed Rule, 88 Fed. Reg. at 18,689, 18,727–29. At the same time, we stress that EPA has the authority to set the MCL "as close to the [MCLG] as feasible, even if [EPA] determines that the benefits of the MCL at this level do not justify the costs." S. Rep. No. 104-169 at 33.
[103] Elin Betanzo, Safe Water Engineering, *Analysis of the USEPA Proposed PFAS National Primary Drinking Water Regulation Treatment Costs and Comparison to the AWWA National PFAS Cost Model Report* (May 30, 2023) ("Betanzo 2023") (Attached as **Exhibit C**).
[104] *See* Guignet 2023 at 2–7.
[105] *Id.* at 2–3.

to the Proposed Rule.[106] In addition, the EA relies appropriately on unquantified health benefits (though, as discussed below, the record supports quantification of additional health benefits).[107] EPA's reliance on unquantified health benefits is consistent with the agency's standard practice,[108] and is expressly required by the SDWA, which mandates that EPA's health risk reduction and cost analysis account for all "[q]uantifiable and nonquantifiable health risk reduction benefits for which there is a factual basis in the rulemaking record to conclude that such benefits are likely to occur" due to compliance with the MCL.[109] Congress "require[d] [EPA] to determine whether the benefits of a [drinking water] standard 'justify' (rather than 'exceed' or 'outweigh') the costs to reflect the nonquantifiable nature of some of the benefits and costs that may be considered. [EPA] is not required to demonstrate that the dollar value of the benefits are greater (or lesser) than the dollar value of the costs," and "[a]ll costs and benefits, both quantifiable and nonquantifiable, must be considered when making determinations under this authority."[110]

EPA's analysis of treatment costs associated with the Proposed Rule is also well supported and more accurately forecasts costs than the competing analysis submitted by the American Water Works Association ("AWWA").[111] For example, in contrast to AWWA, EPA properly screened the PFAS occurrence data incorporated into its treatment cost assessment to avoid bias in the data set from non-public water system PFAS samples and samples collected by water systems investigating known PFAS contamination.[112] EPA also appropriately calculated treatment costs based on the number of water system entry points with modeled MCL violations, whereas AWWA assumed without justification that *every* entry point within a water system will require treatment if *any* entry point within the system violates the MCL.[113] Critically, EPA also incorporated detailed estimates of the compliance strategies that water systems are likely to select—including non-treatment options —and associated costs.[114] EPA's cost estimates also

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[106] *Id.* at 5.
[107] *Id.* at 6–7.
[108] *Id.*
[109] 42 U.S.C. § 300g-1(b)(3)(C)(i)(I)–(II).
[110] S. Rep. No. 104-169 at 33. Moreover, Congress recognized the inherent difficulty and subjectivity in fully quantifying the economic benefits of rules, so the SDWA authorizes EPA to establish an MCL at a feasible level even if the agency cannot formally determine that MCL is justified by the economic costs. *Id.* We note that, for example, there are often equity considerations, as there are with PFAS, whereby certain populations, often low-income communities and communities of color, bear disproportionate burdens from exposure to environmental contaminants. *See* Jahred M. Liddie et al., *Sociodemographic Factors Are Associated with the Abundance of PFAS Sources and Detection in U.S. Community Water Systems*, Env't Sci. Tech. (2023), https://pubs.acs.org/doi/pdf/10.1021/acs.est.2c07255. Such equity considerations often are not reflected in economic analyses but are valid considerations under the SDWA.
[111] Betanzo 2023; *see* Am. Water Works Ass'n, *PFAS National Cost Model Report* (Black & Veatch 2023).
[112] Betanzo 2023 at 4, 6.
[113] *Id.* at 4–5.
[114] Guignet 2023 at 4; Betanzo 2023 at 2–3, 9–11.

rely appropriately on inventoried flow rates, whereas AWWA utilizes a standardized 150 gpm/person flow rate that is biased high and fails to account for regional water-use differences.[115] Overall, EPA's cost estimate is "robust" and "there is no evidence that EPA is consistently underestimating occurrence or costs," while AWWA's estimate includes excess treatment costs of at least $2.6 billion.[116]

In addition to maintaining or expanding upon these robust features of the Draft EA, there are several ways that EPA can and should strengthen the EA. These are outlined in detail in Dr. Guignet's analysis, and we highlight several key recommendations here:

First, EPA should utilize the best available scientific and economic information to quantify and/or monetize additional benefits of the rule in the final EA. In the Proposed Rule, EPA correctly determined that:

> PFAS exposure is associated with a wide range of adverse health effects including reproductive effects such as decreased fertility; increased high blood pressure in pregnant women; developmental effects or delays in children, including low birth weight, accelerated puberty, bone variations, or behavioral changes; increased risk of some cancers, including prostate, kidney, and testicular cancers; reduced ability of the body's immune system to fight infections, including reduced vaccine response; interference with the body's natural hormones; and increased cholesterol levels and/or risk of obesity.[117]

Yet EPA quantified only "three PFOA- and PFOS-related health endpoints in [the economic] analysis," while recognizing that the rule is "expected to produce substantial benefits that have not been quantified."[118]

We urge EPA to expand upon its quantification and, where supported, monetization of the Proposed Rule's benefits. As explained by Dr. Guignet, EPA's economic analysis guidance dictates that the agency

> should try to get as far as possible in first *identifying* all key benefit and cost categories. The next step (when possible) is to then *quantify* the projected change in each benefit and cost outcome that is expected to result from the policy option, relative to the baseline. Quantifying in this case means to measure the change in terms of some quantitative metric, such as the number of lives saved, number of cases prevented, etc. The final step is to monetize the quantified change, meaning that a dollar value is assigned.[119]

Here, consistent with recently proposed revisions to OMB's Circular A4, EPA should assess and disclose the expected magnitude of benefits that EPA recognized but did not quantify.[120] This

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[115] Betanzo 2023 at 5, 12.
[116] *Id.* at 22.
[117] Proposed Rule, 88 Fed. Reg. at 18,725.
[118] *Id.*
[119] Guignet 2023 at 9.
[120] *Id.* at 10.

would enable some quantification of additional benefits, even if fully monetizing a benefit category is not possible. In addition, where quantification is not possible, EPA should utilize available monetary cost-of-illness or willingness to pay estimates to illustrate the potential magnitude of benefits discussed qualitatively.[121]

In addition, as summarized in the accompanying analysis by Drs. Anna Reade and Katherine Pelch, the best available science supports EPA's consideration, and potential quantification and monetization, of additional regulatory benefits.[122] When measuring the Proposed Rule's benefits, EPA ignored or improperly dismissed evidence of the connection between PFAS and liver disease, impaired mammary gland development and reduced lactation duration, and immune system suppression and increased susceptibility to infectious disease. EPA thus failed to measure all of the benefits attributable to the Proposed Rule's reduction in PFAS exposures. At a minimum, EPA should assess these benefits qualitatively and it should utilize the analysis provided by Drs. Reade and Pelch to attempt to quantify and, where possible, monetize these benefits as well.[123]

EPA should also reconsider its omission of reduced testicular cancer incidence from its assessment of the Proposed Rule's benefits. To justify that omission, EPA asserts in the Draft EA that "testicular cancer is rarely fatal which implies low expected economic value of reducing this risk because Value of Statistical Life is the driver of the economic benefits evaluated in the EA."[124] But that assertion is not well supported. While the Draft EA relies on the Value of Statistical Life metric "[t]o estimate the economic value of avoided premature deaths" associated with the rule, it utilizes the cost of illness (COI) valuation approach "[t]o estimate the economic value of avoided morbidity (i.e., non-fatal heart attacks and ischemic strokes, birth weight decrements, and cancers)," with the COI values "reflect[ing] medical care expenditures and opportunity costs associated with managing/treating the condition."[125] EPA has not explained why COI-based valuation of avoided non-fatal testicular cancer cases is not justified. EPA also has not provided a reasoned basis to dismiss as "implie[dly] low" the expected economic value of reducing testicular cancer risks associated with PFOA exposure because EPA has not attempted to estimate the economic value of reducing this risk.[126] Moreover, as explained by Dr. Guignet, the COI values EPA did employ to evaluate the benefits of reducing other non-fatal health effects incorrectly omit the opportunity cost of time, which, as elaborated below, "likely results in a significant underestimate of the benefits."[127] For this reason too, EPA's speculation that the economic value of avoided testicular cancer cases would be "low" is unsupported. In the final EA, EPA should estimate the economic value of reduced testicular cancer cases associated

[121] *Id.*
[122] *See generally* Reade and Pelch 2023.
[123] *Id.*; Guignet 2023 at 10.
[124] Draft EA at 6-21– 6-22.
[125] *Id.* at 2-4.
[126] *Id.* at 6-21.
[127] Guignet 2023 at 12.

with the Proposed Rule.[128] In doing so, EPA should utilize COI estimates that properly account for the opportunity cost of time in addition to avoided medical expenses or use willingness-to-pay estimates where supported by the literature.[129]

Second, while it is appropriate for EPA to consider co-benefits when estimating the health benefits of the Proposed Rule,[130] EPA's analysis of co-benefits is incomplete. The Draft EA considers only reduced bladder cancer risks from co-removal of disinfection byproducts associated with PFAS drinking water technology,[131] ignoring the benefits that will arise from co-removal of additional synthetic organic contaminants, including additional PFAS that are not directly regulated by the Proposed Rule.

Third, EPA should apply no (or at most a very low) discount rate to account for the intergenerational harms associated with PFAS and the nature of the rule's economic impacts.[132] In the event a discount rate for future benefits is applied, we agree with EPA's conclusion in the Draft EA that a lower, consumption-based discount rate is "more appropriate for this rulemaking" than a higher, capital-based discount rate[133] given the 80-year timeframe for analysis, the impacts on future generations, and the extent of uncertainties in the magnitude of future health benefits.[134] Thus, if a discount rate is used, EPA should ensure that both the final EA and the final rule reflect and explain EPA's determination that a lower, consumption-based discount rate is more appropriate.[135] EPA's draft preamble does not include or explain this determination and instead presents benefit estimates based on a 3% consumption-based discount rate and a 7% capital-based discount rate as equally relevant to assessing the net benefits of the rule.[136] Further, if EPA continues to apply a discount rate in the final EA, it should consider

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[128] Peer-reviewed literature is available to support the monetization of avoided testicular cancer cases. *See, e.g.,* Michael Aberger et al., *Testicular Self-Examination and Testicular Cancer: A Cost Utility Analysis*, 3 Cancer Med. 1629 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4298389/.

[129] Guignet 2023 at 12.

[130] *Id.* at 5.

[131] Proposed Rule, 88 Fed. Reg. at 18,721.

[132] *See, e.g.,* Frank Ackerman and Lisa Heinzerling, *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection*, 150 U. Pa. L. Rev. 1553, 1571 (2002), https://scholarship.law.upenn.edu/penn_law_review/vol150/iss5/6 (questioning the use of discounting to address long-term, intergenerational harms, including those associated with "persistent toxins"); *see also* Institute for Policy Integrity, *Comments on National Primary Drinking Water Regulations: Lead and Copper Rule Revisions* (Feb. 12, 2020), https://policyintegrity.org/documents/EPA_Lead_Copper_Rule_Comments_2020.02.11.pdf (arguing for a "3% or lower discount rate" for benefits of EPA drinking water rule).

[133] Draft EA at 2-3.

[134] Guignet 2023 at 11; Peter Howard & Jason A. Schwartz, *Valuing the Future: Legal and Economic Considerations for Updating Discount Rates*, 39 Yale J. Regul. 595, 599, 603 (2022) (explaining why a consumption-based discount rate is appropriate for estimating benefits of rules designed to affect public health over a long time horizon).

[135] Draft EA at 2-3.

[136] *E.g.*, Proposed Rule, 88 Fed. Reg. at 18,724, table 66.

utilizing a reduced consumption-based discount rate—below 2%—as the 3% rate used in the Draft EA does not reflect the best available economic data and literature.[137]

Fourth, as noted above, EPA should account for opportunity costs, in addition to avoided medical expenditures, in its final cost-of-illness estimates for non-fatal health effects associated with PFAS exposure.[138] As Dr. Guignet explains, "assuming the opportunity cost of time associated with these adverse health outcomes is zero (as the EPA currently does) is not correct" and likely yields a substantial underestimate of the COI-based benefits for reducing non-fatal adverse health effects.[139] While recognizing limitations in the relevant literature, Dr. Guignet has identified multiple approaches for EPA to account for these benefits in the final EA.

Fifth, EPA should develop an estimate of the benefits of managing spent filtration materials as hazardous waste, which would reduce environmental releases of PFAS and associated human exposures. In assessing the Proposed Rule's costs in the Draft EA, EPA correctly excludes the incremental costs to water systems from potential future requirements to manage spent filtration materials as hazardous waste, electing instead to calculate such costs as part of an illustrative sensitivity analysis because these costs are not attributable to the rule under consideration.[140] While EPA's inclusion of this sensitivity analysis enhances the transparency value of the EA, it improperly considers only the costs of potential hazardous waste management requirements, without accounting for the benefits.[141] If EPA maintains this illustrative analysis as part of the final EA, it also must include a benefits estimate to ensure that its analysis is comprehensive and balanced.[142]

Finally, EPA should evaluate a regulatory option that is more stringent than the proposed MCLs. Contrary to OMB Circular A4 and EPA's economic analysis guidelines, all the alternatives analyzed in the Draft EA are less stringent than the proposed option. EPA should evaluate a more stringent regulatory option in the final EA or, at a minimum, explain why such an analysis is not appropriate.[143]

IV. EPA Should Strengthen its Proposed Rule to Protect the Public and Promote Compliance

A. EPA Should Revise its Health Based Water Concentrations ("HBWCs") to Fully Address the HI PFAS' Harms to Susceptible Populations

[137] Howard & Schwartz (2022) at 595–96, 599, 610–11, 617–19; *see also* White House Off. of Mgmt. and Budget, *Circular A-4 (Public Review Draft),* at 76 (Apr. 6, 2023) (proposing consumption-based discount rate of 1.7%), www.whitehouse.gov/wp-content/uploads/2023/04/DraftCircularA-4.pdf.
[138] Guignet 2023 at 11–12.
[139] *Id.*
[140] *Id.* at 4–5.
[141] *Id.* at 5.
[142] *Id.*
[143] *Id.* at 10.

EPA's proposed MCLG and MCL for the HI PFAS incorporate HBWCs to indicate the levels at which PFBS, GenX, PFNA, and PFHxS pose no known adverse health effects.[144] When establishing MCLs, the SDWA requires EPA to consider contaminants' effects not only on the general population but also on "groups . . . such as infants, children, pregnant women, the elderly, individuals with a history of serious illness, or other subpopulations that are identified as likely to be at greater risk of adverse health effects due to exposure to contaminants in drinking water[.]"[145] However, EPA's proposed HBWCs fail to address risks to infants and other populations that experience the greatest risks from the HI PFAS, leaving those populations exposed to serious harm. In its final rule, we urge EPA to revisit and strengthen its HBWCs for each of the HI PFAS.

Developing infants and children are most at risk of the long-term effects of PFAS exposure. There are two reasons for this. First, the fetal and early childhood life stages are when the body's systems are being established and developed. Small changes that disrupt or permanently alter the course of development can increase the risk of later-life disease. Second, formula fed infants and lactating people consume more drinking water per unit of body weight.[146] Infants, for example, may be exposed to PFAS via contaminated breastmilk and/or infant formula prepared with PFAS contaminated water. It is important that these factors are adequately accounted for in the MCL or health-based value calculation process, since developing children are both the most sensitive population as well as the population with the highest estimated exposure.

Unless there is substantial data showing that an endpoint studied in adults is not relevant in infants and children, it is EPA's responsibility to set standards that are protective of all populations. Furthermore, the assumption for PFAS should be that there is a need to protect infants and children. Given the similarity among PFAS, EPA does not require developmental studies each particular PFAS to conclude that infants and children are susceptible to harm from exposure. In this case, drinking water intake assumptions for infants and children should be used. As stated by EPA in the Drinking Water Health Advisory for PFBS, "[w]hen multiple potentially sensitive populations or life stages are identified based on the critical effect or other health effects data (from animal or human studies), EPA selects the population or life stage with the greatest [drinking water intake rate adjusted for body weight] DWI-BW" because it is the most health protective."[147] Despite this strong statement and the potential for developmental effects

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[144] As described above, EPA divides the measured concentration of each HI PFAS by its HBWC to calculate a hazard quotient, which is then added to the other HI PFAS' hazard quotients to calculate the hazard index.

[145] 42 U.S.C. § 300g–1(b)(3)(C)(i)(V) (requiring EPA to assess health impacts on greater-risk populations when establishing MCLs).

[146] EPA, *EPA/600/R-18/259F, Update for Chapter 3 of the Exposure Factors Handbook: Ingestion of Water and Other Select Liquids*, Off. of Rsch. and Dev., at 3-14, 3-23 (Feb. 2019), https://www.epa.gov/sites/default/files/2019-02/documents/efh_-_chapter_3_update.pdf.

[147] EPA, *EPA/822/R-22/006, Drinking Water Health Advisory: Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3*), Off. of Water, at 18–19 (June 2022), https://www.epa.gov/system/files/documents/2022-06/drinking-water-pfbs-2022.pdf.

from PFAS exposure in the Proposed Rule, EPA consistently failed to use the more protective DWI-BW for infants or children, even when the critical effect is developmental, as is the case for PFNA. EPA chose a DWI-BW for lactating women for PFNA and GenX, a DWI-BW for "women of childbearing age" for PFBS and a DWI-BW for the adult general population for PFHxS.[148] The application of DWI-BW for these PFAS is not the most health protective and puts infants and children at risk.

Health protective approaches are used in other steps of risk assessment when evidence is lacking, for example, when deriving a chronic reference dose in the absence of a chronic study. Risk assessors often determine the risk of acute, subchronic, and chronic exposures to a chemical. For PFAS in drinking water, the most protective and realistic exposure scenario is typically a chronic exposure. However, since chronic exposure studies are not always available, EPA derives reference doses ("RfDs") for chronic exposure from subchronic studies by applying an uncertainty factor instead of improperly assuming a RfD based on a subchronic exposure is protective of chronic exposure.

Furthermore, NAS has recommended the use of an additional uncertainty factor of 10 to ensure protection of fetuses, infants and children groups which are often are not sufficiently protected from toxic chemicals such as pesticides by the traditional intraspecies uncertainty factor.[149] Congress adopted this requirement in the Food Quality Protection Act ("FQPA") for pesticides in or on foods.[150] The uneven application of this additional uncertainty factor to protect these vulnerable populations across EPA is concerning. Considering the many health effects linked to PFAS that affect these vulnerable populations and the substantial data gaps on exposure and toxicity of these compounds in complex mixtures, EPA must do a better job of protecting sensitive and vulnerable populations in its assessments and actions on all toxic chemicals, regardless of their regulatory context.

i. EPA Should Revise its HBWC for PFHxS to 2 ng/L

When calculating its HBWC for PFHxS, EPA relied on a RfD derived by ATSDR for thyroid follicular cell damage in adult male rats from a study by Butenhoff et al.[151] However, in March 2022, OEHHA published a risk assessment analysis for PFHxS as part of its Notification Level Recommendation for PFHxS in Drinking Water.[152] In its analysis, OEHHA evaluated the

[148] EPA, *EPA-822-P-23-004, Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PFNA, and PFHxS*, Off. of Water, at 9 (Mar. 2023), https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0906.
[149] Nat'l Acad. of Sci., *Pesticides in the Diets of Infants and Children. National Research Council* 361 (1993), https://www.ncbi.nlm.nih.gov/books/NBK236275/.
[150] 21 U.S.C. § 346a(b)(2)(C)(ii)(II).
[151] *See* ATSDR 2021 at 21, A54–A57 (citing John L. Butenhoff et al., *Evaluation of Potential Reproductive and Developmental Toxicity of Potassium Perfluorohexanesulfonate in Sprague Dawley Rats*, 27 Reprod. Toxicology 331, 331–334 (June 2009)).
[152] OEHHA, *Notification Level Recommendation: Perfluorohexane Sulfonic Acid in Drinking Water* (Mar. 2022), https://oehha.ca.gov/media/pfhxsnl031722.pdf.

same studies as ATSDR and a newer toxicological study by the National Toxicology Program ("NTP").[153] Ultimately, OEHHA derived Public Health-Protective Concentrations (equivalent to EPA's health-based water concentrations) for three sensitive endpoints because they occur in different populations.[154] In contrast, ATSDR only derived a single RfD. The analysis of multiple sensitive endpoints in deriving a final drinking water value is critical to ensure protection from all adverse health effects in all populations.

First, choosing the lowest human equivalent dose ("HED") to derive a RfD does not guarantee that the RfD will protect against all health effects. A less sensitive HED could reasonably result in a lower RfD due to differences in study design and overall application of uncertainty. The IRIS PFAS assessments follow best practices in calculating organ-specific RfDs for multiple identified health effects.[155] OEHHA also followed these best practices and derived RfDs for decreased thyroxine (T4) (which is associated with thyroid toxicity) in adult male rats, decreased litter size in female mice, and increased relative liver weight in female rats.[156] Whereas the lowest HED was for decreased litter size, the lowest RfD was identified as decreased total T4 due to the application of different uncertainty factors to the two outcomes.[157]

Secondly, choosing the lowest RfD to derive an HBWC does not guarantee that all health effects will be protected against. The influence of population specific drinking water exposure assumptions is also important to consider. In the case of OEHHA's analysis, the final health-protective concentration in drinking water was lowest for decreased T4 (2 ng/L), when protecting against possible health effects in infants.[158]

In its analysis, OEHHA states, "[f]or PFHxS, there are no developmental studies of thyroid hormone levels in animals, and no mouse studies reporting T4 or T3 levels. Despite this uncertainty, the point of departure ("POD") for decreased T4 in male rats is a suitable candidate for PFHxS HPC derivation due to the severity of possible developmental consequences of decreased T4 in humans."[159] Therefore, because infants are a sensitive group for decreased total T4, OEHHA applied a 0- to 6-month infant DWI-BW of 0.237 L/kg/day to derive a health-based water concentration.

We strongly support OEHHA's health-protective approach to the lack of developmental data on thyroid hormone disruption for PFHxS. There is no reason to assume that this health effect is limited to an adult male population. Rather, when data are available, decreased T4

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[153] *Id.* at 15 (citing, *inter alia*, NTP, *NTP Technical Report on the Toxicity Studies of Perfluoroalkyl Sulfonates (Perfluorobutane Sulfonic Acid, Perfluorohexane Sulfonate Potassium Salt, and Perfluorooctane Sulfonic Acid)* (August 2019), https://cebs.niehs.nih.gov/cebs/publication/TOX-96)).
[154] *Id.* at 30.
[155] *See, e.g.,* EPA, *Toxicological Review of Perfluorohexanoic Acid and Related Salts,* at 5–28.
[156] OEHHA, *Notification Level Recommendation: Perfluorohexane Sulfonic Acid in Drinking Water*, at 26.
[157] *Id.* at 28.
[158] *Id.* at 28–29.
[159] *Id.* at 26.

during development has been identified as a sensitive endpoint for other PFAS. Importantly, OEHHA and IRIS have argued that even though decreased thyroid hormone levels appear less severe than classical hypothyroidism and are not associated with increased levels of thyroid-stimulating hormone (TSH), decreased T4 is correlated with neurodevelopmental and cognitive deficits in children, highlighting the importance of protecting the developing fetus, infants, and children against PFAS exposure.[160]

The analysis by OEHHA indicates that a HBWC of 2 ng/L should be set to protect the most vulnerable and sensitive populations. Because that level is lower than the PQL of 3 ng/L, when calculating the hazard index for the purpose of establishing and monitoring compliance with the PFHxS MCL EPA should rely on the PQL, as opposed to EPA's currently proposed and under-protective HBWC.[161]

ii. EPA Should Revise its HBWC for PFBS to 240 ng/L

EPA's highest, and least protective, HBWC is for PFBS, a chemical that is often "considered [as] a replacement for PFOS."[162] EPA's proposed HBWC of 2000 ppt PFBS is significantly higher than toxicity values and drinking water standards adopted by California (500 ppt), Michigan (420 ppt), Washington (345 ppt), and Minnesota (100 ppt).[163]

In deriving a RfD for PFBS, EPA, California, Michigan and Washington used the same health effect (impaired thyroid development) and the same approach for calculating a human equivalent dose, resulting in similar RfDs.[164] However, EPA's PFBS Lifetime Health Advisory for drinking water, which serves as the foundation for EPA's proposed HBWC, deviated from state risk assessments most notably in the choice of DWI-BW (rate of water intake). In order to protect infants from harmful PFBS exposures, California, Michigan, and Washington selected a

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[160] *See id.* at 20.

[161] Proposed Rule, 88 Fed. Reg. at 18,680. Although we strongly recommend EPA adopt the analysis conducted by OEHHA, we acknowledge and support EPA's choice to apply an additional UF of 10 to adjust for subchronic-to-chronic duration (i.e., UFS), per agency guidance. *Id.* at 18,645–46.

[162] EPA, *Drinking Water Health Advisories for PFAS Fact Sheet for Communities*, at 2 https://www.epa.gov/system/files/documents/2022-06/drinking-water-ha-pfas-factsheet-communities.pdf.

[163] Cal. Water Boards, *Notification Level Issuance*, State Water Res. Control Bd. (Mar. 5, 2021), https://www.waterboards.ca.gov/drinking_water/certlic/drinkingwater/pfas.html; Mich. PFAS Action Response Team, *Maximum Contaminant Levels (MCLs)*, https://www.michigan.gov/pfasresponse/drinking-water/mcl (last accessed May. 25, 2023); Wash. State Dep't of Health, *Recommended State Action Levels for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water: Approach, Methods, and Supporting Information* (Nov. 1, 2021), https://doh.wa.gov/sites/default/files/2022-02/331-673.pdf; Minn. Dep't of Health, *Per- and Polyfluoroalkyl Substances (PFAS) and Health,* at 3–4 (Sept. 6, 2022), https://www.health.state.mn.us/communities/environment/hazardous/docs/pfashealth.pdf.

[164] We support the use of a more chemical-specific dose adjustment factor in EPA's final toxicity assessment versus the allometric scaling performed in EPA's draft document.

higher value for drinking water intake associated with infant drinking water consumption when deriving their drinking water limits for PFBS.[165] EPA, on the other hand, relied on a lower water intake rate associated with "women of childbearing age"[166] and thus failed to address PFBS' increased risks to infants, a "potentially susceptible life stage[] for the types of effects observed in animal testing with PFBS."[167] Thus, EPA's HBWC for PFBS falls short of protecting one of the most "sensitive population(s) or life stage(s) (i.e., those that may be more susceptible or sensitive to a chemical exposure)."[168]

The thyroid harm identified by EPA resulted from decreased serum levels of T4 from PFBS exposure during a developmental life stage, effects that begin prenatally and continue into infancy. Decreased levels of T4 indicate dysfunction or underdevelopment of the thyroid gland. While a decrease in T4 affects the pregnant mice, those effects can also carry over to their offspring and "persist[] until the pubertal and adult periods."[169] The authors of the study that EPA relied upon concluded that PFBS "may impair thyroid development in offspring, leading to permanent hypothyroxinemia"[170] Infants with hypothyroxinemia experience impaired growth and development because the thyroid orchestrates processes that are critical to their growth, including brain development. Thus, many infants with hypothyroxinemia experience intellectual disabilities and growth failures that require treatment through puberty and, in some cases, into adulthood.[171] While women of childbearing age are sensitive to developmental toxicity and persistent changes in thyroid hormone levels associated with PFBS, maternal thyroid hormones play a critical role in fetal and infant growth and neurodevelopment. Thyroid development and stores of T4 are especially important in infants whose T4 stores are lower and not as capable of

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[165] OEHHA, *Notification Level Recommendation: Perfluorobutane Sulfonic Acid in Drinking Water,* at 29–30 (Jan. 2021), https://oehha.ca.gov/media/downloads/water/chemicals/nl/pfbsnl121820.pdf; Wash. Dep't of Health, *Recommended State Action Levels for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water: Approach, Methods, and Supporting Information,* Off. of Pub. Health Sci., at 80– 81 (Nov. 1, 2021), https://doh.wa.gov/sites/default/files/2022-02/331-673.pdf.

[166] EPA, *EPA-822-P-23-004, Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): HFPO-DA and its Ammonium Salt (also known as GenX Chemicals), PFBS, PFNA, and PFHxS*, Off. of Water, at 12 (Mar. 2023), https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0906.

[167] Wash. Dep't of Health, *Recommended State Action Levels for PFAS,* at 79.

[168] EPA, *MCLG Summary Document for a Mixture of Four PFAS,* at 5.

[169] Xuejiao Feng et al., *Exposure of Pregnant Mice to Perfluorobutanesulfonate Causes Hypothyroxinemia and Developmental Abnormalities in Female Offspring*, 155 Toxicological Sciences, 409, 417 (2017), https://doi.org/10.1093/toxsci/kfw219.

[170] *Id.* at 414.

[171] *See generally* Noora Moog et al., *Influence of Maternal Thyroid Hormones During Gestation on Fetal Brain Development,* 342 Neuroscience 68, 68–100 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4819012/; Stanford Medicine, *Congenital Hypothyroidism in Children,* Childrens Health, https://www.stanfordchildrens.org/en/topic/default?id=hypothyroidism-in-children-90-P01963.

offsetting declines.[172] Drinking water intake is a pertinent exposure factor that is "intended to protect sensitive populations and life stages within the general population from adverse effects."[173] EPA's failure to consider the increased drinking water intake of infants understates the exposure to PFBS and its health effects on a sensitive population. EPA's HBWC may provide protections for adults and fetuses but it ignores the risks that PFBS poses for infants and does not address "adverse effects can result from short or intermittent exposure during a critical period of development."[174]

Using the DWI-BW listed on Table 3 of the Drinking Water Health Advisory for PFBS[175] for formula fed infants (0.249 L/kg/day), the HBWC for PFBS should be no more than 240 ng/L.

HBWC = (RfD/DWI-BW)*RSC

= ((0.0003 mg/kg-bw/day) / (0.249 L/kg-bw/day)) *0.2

= 0.00024 mg/L = 240 ng/L

iii. EPA Should Revise its HBWC for PFNA to 2 ng/L

In deriving a health-based water value for PFNA from ATSDR's RfD, EPA chose the drinking water intake estimate for lactating women (0.0469 L/kg-bw/day).[176]

However, the critical effects selected by ATSDR (decreased body weight and developmental delays including delayed eye opening, preputial separation and vaginal opening) occur during development.[177] Furthermore, a transgenerational toxicokinetic model for PFNA has been developed and used by some states which demonstrates a significantly higher level of exposure for breastfed infants.[178] We recommend that EPA either evaluate and use this transgenerational toxicokinetic model or apply a drinking water intake rate for infants. Using the

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[172] Francesca Coperchini et al., *Thyroid Disrupting Effects of Old and New Generation PFAS*, 11 Frontiers in Endocrinology Art. No. 612320 (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7851056/; Hui Min et al., *Maternal Hypothyroxinemia-Induced Neurodevelopmental Impairments in the Progeny*, 53 Molecular Neurobiology 1613, 1613–1624 (2016), https://pubmed.ncbi.nlm.nih.gov/25666160/; Miller, M.D., et al., *Thyroid-Disrupting Chemicals: Interpreting Upstream Biomarkers of Adverse Outcomes*, 117 Env't Health Persp. 1033, 1033–41 (2009), https://pubmed.ncbi.nlm.nih.gov/19654909/.

[173] EPA, *Drinking Water Health Advisory: Perfluorobutane Sulfonic Acid Potassium Perfluorobutane Sulfonate,* at 18.

[174] *Id.* at 17 (citing EPA, *EPA/600/FR-91/001, Guidelines for Developmental Toxicity Risk Assessment,* (Dec. 5, 1991), https://www.epa.gov/sites/default/files/2014-11/documents/dev_tox.pdf).

[175] EPA, *Drinking Water Health Advisory: Perfluorobutane Sulfonic Acid and Perfluorobutane Sulfonate*, at 19.

[176] EPA, *MCLG Summary Document for a Mixture of Four PFAS,* at 15.

[177] *Id.* at 13.

[178] Wash. Dep't of Health, *Recommended State Action Levels for PFAS,* at 21–24.

drinking water intake rate for formula fed infants (0.249 L/kg-bw/day) (see above), the health-based value goal for PFNA should be no more than 2 ng/L.

HBWC = (RfD/DWI-BW)*RSC

= ((0.000003 mg/kg-bw/day) / (0.249 L/kg-bw/day)) * 0.2

= 0.0000024 mg/L = 2 ng/L

The HBWC for PFNA should be no higher than 2 ng/L to protect the most vulnerable and sensitive populations. Because that level is lower than the PQL of 4 ng/L, when calculating the hazard index for the purpose of establishing and monitoring compliance with the PFNA MCL, EPA should rely on the PQL, as opposed to EPA's currently proposed and under-protective HBWC.[179]

iv. EPA Should Revise its HBWC for GenX to 2 ng/L

EPA finalized the Human Health Toxicity Assessment for GenX in October 2021.[180] In the development of the Lifetime Health Advisory for GenX, EPA "identified three potentially sensitive life stages for GenX chemical exposure—women of childbearing age (13 to < 50 years), pregnant women, and lactating women."[181] In setting its HBWC, EPA ultimately chose the drinking water intake estimate for lactating women, stating that this would be protective of the other two populations as well (i.e., pregnant women and women of childbearing age).[182] However, there is no analysis to suggest that infants and young children would be sufficiently protected from liver or other developmental effects due to exposure during this critical stage. Furthermore, the NOAEL for developmental effects linked to GenX exposure is within the same range as the NOAEL for liver effects (i.e., within one order of magnitude).[183] We therefore

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[179] Proposed Rule, 88 Fed. Reg. at 18,680.

[180] *See* EPA, *Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3), Also Known as 'GenX Chemicals* at 86-88 (Oct. 2021), https://www.epa.gov/system/files/documents/2021-10/genx-chemicals-toxicity-assessment_tech-edited_oct-21-508.pdf. We support the changes to the draft document that were made in response to the public comment process. Specifically, we support the NTP Pathology Working Group findings on liver lesions, which were based on more contemporary pathology guidelines than were used in prior analyses. We further support the application of a full uncertainty factor to account for the use of a study with less chronic exposure and a full uncertainty factor for database deficiencies.

[181] EPA, *Drinking Water Health Advisory: Hexafluoropropylene Oxide (HFPO) Dimer Acid (CASRN 13252-13-6) and HFPO Dimer Acid Ammonium Salt (CASRN 62037-80-3), Also Known as 'GenX Chemicals,* Off. of Water, at 21 (June 2022), https://www.epa.gov/system/files/documents/2022-06/drinking-water-genx-2022.pdf.

[182] EPA, *MCLG Summary Document for a Mixture of Four PFAS,* at 9.

[183] EPA, *Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3) Also Known as 'GenX Chemicals,*' (Oct. 2021) https://www.epa.gov/system/files/documents/2021-10/genx-chemicals-toxicity-assessment_tech-edited_oct-21-508.pdf

recommend that EPA apply a DWI-BW for infants. Using the DWI-BW listed on Table 3 of the Drinking Water Health Advisory for GenX for formula-fed infants (0.249 L/kg/day), the health-based value goal for GenX should be no more than 2 ng/L.

HBWC = (RfD/DWI-BW)*RSC

= ((0.000003 mg/kg-bw/day) / (0.249 L/kg-bw/day)) *0.2

= 0.0000024 mg/L = 2 ng/L

The HBWC for GenX should be no higher than 2 ng/L to protect the most vulnerable and sensitive populations. Because that level is lower than the PQL of 5 ng/L, when calculating the hazard index for the purpose of establishing and monitoring compliance with the GenX MCL EPA should rely on the PQL, as opposed to EPA's currently proposed and under-protective HBWC .[184]

* * *

We reiterate our support for EPA's use of a hazard index, or some other method that accounts for adverse effects associated with mixtures of the HI PFAS, when setting its MCLG and MCL. In order to comply with the SDWA and protect communities who are exposed to those PFAS mixtures, however, the HBWCs that EPA uses to calculate the hazard index must reflect the "best available science" on those chemicals' risks to infants and other susceptible subpopulations. EPA's proposed HBWCs would permit unsafe levels of the HI PFAS to remain in drinking water and diminish the protectiveness of EPA's proposed MCLs. We urge EPA to strengthen the HBWCs in its final rule.

B. EPA Should Account for PFAS Detections Below the PQL When Determining MCL Compliance

To ensure compliance with the MCL and to protect communities from dangerous PFAS exposures, EPA must consider all PFAS detections when calculating MCL compliance. EPA has proposed determining initial MCL compliance based on a "running annual average," which considers a water provider's average PFOA concentration, PFOS concentration, or hazard index over four consecutive quarters to determine whether the provider has exceeded the MCL.[185] But when calculating the running annual average, EPA has proposed treating all PFAS detections below a chemical's PQL—4 ppt for PFOA, PFOS, and PFNA; 5 ppt for GenX; and 3 ppt for PFHxS and PFBS—as if they were non-detects.[186] This approach ignores measurable PFAS exposures and understates PFAS risks. For instance, if a water provider detected quarterly PFOA concentrations of 3.8 ppt, 3.8 ppt, 3.8 ppt, and 15 ppt, the mathematical average would be 6.6 ppt—more than 50 percent higher than the 4 ppt MCL. However, the average for the purpose of determining MCL compliance would be 3.75 ppt, since all of the 3.8 ppt detections would be replaced with zeros, meaning the provider would be considered in compliance with the MCL and

[184] Proposed Rule, 88 Fed. Reg. at 18,680.
[185] *Id.* at 18,667.
[186] *Id.* at 18,667; *see id.* at 18,680 (listing PQLs for different PFAS chemicals).

no additional treatment would be required. EPA's discounting of sub-PQL detections is scientifically unsupported, contrary to longstanding SDWA regulations, and inconsistent with other parts of EPA's proposed rule.

As EPA acknowledges, "almost all laboratories" can detect the PFAS at issue at levels below the chemicals' respective PQLs.[187] The PQL reflects the capacities of some of the least sophisticated laboratories; it is, according to EPA, the "minimum quantitation level that . . . can be achieved by capable analysts at 75 percent or more of the laboratories using a specified analytical method."[188] In a prior rulemaking, EPA found that "49 of the 54 laboratories seeking EPA approval" to test PFAS in drinking water "included a lowest PFAS calibration standard level at 1 ppt or lower, with the median lowest calibration level among all laboratories at 0.5 ppt." [189] Given that "the overwhelming majority of laboratories" can detect PFOA, PFOS, and other PFAS below their PQLs, there is no reason for EPA to disregard those detections and treat PFAS-contaminated water as if it were PFAS-free when determining MCL compliance.

EPA's proposed approach is contrary to longstanding EPA regulations, which consider all detections above the method detection limit ("MDL"), a level that is distinct from—and lower than—the PQL. The MDL reflects the "minimum measured concentration of a substance that can be reported with 99% confidence that the measured concentration is distinguishable from method blank results."[190] As a "general rule," EPA sets the PQL at a level that is 5–10 times greater than the MDL.[191] EPA's SDWA regulations governing monitoring and analytical requirements for organic chemicals, such as PFAS, state that "[i]f a sample result is less *than the detection limit*, zero will be used to calculate the annual average."[192] Similarly, EPA's SDWA regulations governing inorganic chemicals, such as arsenic and mercury, provide that "any sample *below the method detection limit* shall be calculated at zero for the purpose of determining the annual average."[193] EPA acknowledges that the consideration of sub-PQL detections is "consistent with EPA's [National Primary Drinking Water Regulations] related to other [synthetic organic chemicals] and has the potential to . . . increase the public health protection provided by this proposed regulation."[194] EPA should apply that same health-protective approach in its PFAS NPDWR.

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[187] *Id.* at 18,667.
[188] *Id.* at 18,666.
[189] *Id.* at 18,667; *see also id*. (finding that "the overwhelming majority of laboratories with the necessary instrumentation to support PFAS monitoring have the capability to provide screening measurement results above … 1⁄3 of the MCL (i.e., 1.3 ppt for PFOS or PFOS)."
[190] 40 C.F.R. Part 136 App'x B; 40 C.F.R. § 141.2.
[191] *Id.* at 18,666; National Primary Drinking Water Regulations; Volatile Synthetic Organic Chemicals, 50 Fed. Reg. 46, 902, 46,906 (Nov. 13, 1985) ("EPA believes that setting the PQLs in a range between 5 and 10 times the MDL achieved by the best laboratories is a fair expectation for most State and commercial laboratories.").
[192] 40 C.F.R. § 141.24(f)(15)(v) (emphasis added).
[193] 40 C.F.R. § 141.23(i)(1) (emphasis added).
[194] Proposed Rule, 88 Fed. Reg. at 18,682–83.

EPA's justification for disregarding sub-PQL PFAS detections is unsupported and internally inconsistent. EPA claims that, even though most laboratories are able to detect PFAS below the PQL, "quantifying concentrations below the PQL for compliance purposes may decrease the precision and accuracy of the measured value."[195] But EPA's proposed approach is even less precise and accurate, since it would treat detectable PFAS levels as if they did not exist. Even if EPA has more confidence in PFAS detections above the PQL than below it, the relevant question is whether a detection above the MDL but below the PQL is more likely to reflect actual contamination or a false positive. EPA itself has acknowledged that "[f]or results between the detection limit and the PQL, EPA has determined that utilities would be able to reliably conclude analyte presence," meaning EPA's proposed approach of treating of all sub-PQL detections as zero understates real-world exposures and risks.[196] Moreover, elsewhere in its proposed rule, EPA considers detections at or below one-third of the PQL sufficiently reliable to "trigger . . . less frequent compliance monitoring."[197] In particular, EPA allows water systems to reduce their monitoring frequency from quarterly to once-every-three-years if their average PFAS concentrations are less than one-third of the MCL (i.e., 1.3 ppt for PFOA and PFOS and a hazard index of 0.33 for the HI PFAS).[198] In calculating that average, EPA considers PFAS detections that are well below the PQL. But there is no basis for considering sub-PQL detections to reduce water systems' monitoring obligations while ignoring those same detections when determining water systems' treatment obligations. For PFOA, PFOS, and the HI PFAS, EPA should instead consider all detections above the MDL to calculate a water system's annual running average and determine MCL compliance, including in hazard index calculations for HI PFAS.

C. EPA Should Strengthen the Proposed Monitoring Requirements to Comply with the SDWA and Enhance Public Health Protections

We urge EPA to strengthen the compliance monitoring requirements in the proposed rule by (1) relying on the MDL as the "trigger level" that can qualify a PWS for reduced monitoring where that value is lower than one-third of the PQL, and (2) requiring PWSs with consistent detections below the MDL to monitor annually for the regulated PFAS instead of triennially. EPA's proposed monitoring requirements are insufficient to ensure compliance with the proposed MCLs, would undermine the potential health benefits of the rule, and would deprive the public of vital information regarding exposures to PFAS in drinking water at levels that threaten human health.

At the outset, we support EPA's proposal to disallow monitoring waivers as part of the PFAS NPDWR in light of the "ubiquity, environmental persistence and transport abilities of PFAS."[199] But as explained below, these same factors—as well as the toxic effects of PFAS at very low concentrations—undermine EPA's proposal for reduced monitoring requirements for

[195] *Id.* at 18,682.
[196] *Id.* at 18,670.
[197] *Id.* at 18,681.
[198] *Id.*
[199] *Id.* at 18,683.

systems with initial PFAS detections below EPA's proposed trigger level of one-third the relevant MCL.[200]

The SDWA requires NPDWRs to include monitoring requirements that will "[e]nsure compliance" with the relevant MCLs.[201] EPA's proposal does not satisfy this requirement insofar as it gives primacy agencies discretion to reduce required compliance monitoring to just 1–2 monitoring events per three-year compliance period if a system's initial year of monitoring documents PFAS concentrations below the proposed trigger level.[202] Indeed, EPA's proposal does not attempt to demonstrate that this reduced monitoring scheme would be adequate to "insure" compliance with the MCLs,[203] claiming instead that its proposal would "save resources" for purportedly "lower-risk water systems."[204] As explained below, existing PFAS monitoring data, as well as literature on PFAS toxicity and fluctuations in drinking water sources, indicate that EPA's proposal must be strengthened to ensure compliance with the MCLs.

Available data from PWSs that have tested for PFAS on a quarterly or more frequent basis demonstrate significant variation in PFAS detections and measured concentrations, which indicates that consistent monitoring is needed to ensure that PFAS levels remain below the MCLs.[205] For example, the Merrimack Village Water District reported non-detect results for PFOS at the Turkey Hill Road location within its drinking water distribution system during four sampling events between December 2, 2021, and July 27, 2022, then detected 15.20 ppt of PFOS during a subsequent sampling event on October 19, 2022, followed by another non-detect result on January 25, 2023.[206] Monitoring data from industrial PFAS dischargers likewise demonstrates the potential for significant intra-annual variation in PFAS discharges to drinking water sources, which will in turn impact the levels of PFAS in finished drinking water from systems that have not installed PFAS treatment technology.[207] Peer-reviewed literature also documents significant

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[200] *Id.* at 18,681.
[201] 42 U.S.C. § 300f(1)(D).
[202] *See* Proposed Rule, 88 Fed. Reg. at 18,681; Economic Analysis at 5-32.
[203] 42 U.S.C. § 300f(1)(D).
[204] Proposed Rule, 88 Fed. Reg. at 18,682.
[205] *See*, *e.g.*, Merrimack Vill. Dist. Water Works, *Historical Charts for PFAS Water Sampling Test Results*, https://www.mvdwater.org/historical-water-sampling-charts/, and *PFAS Results, Distribution Sys.*, https://www.mvdwater.org/wp-content/uploads/2023/03/PFAS-Distribution-System-02-15-2023.pdf (distribution system notes); City of Ann Arbor, Mich., *Drinking Water Sampling Data*, https://www.a2gov.org/departments/water-treatment/Documents/PFAS-forweb-RESERVIOR-031523.pdf (updated Mar. 15, 2023); Orange Water and Sewer Auth., *Trends in PFAS Detections in Finished Drinking Water (Quarterly Sample Results),* Detections in Drinking Water, https://www.owasa.org/pfas-monitoring-program/ (scroll down to the "Complete Set of Historical PFAS Monitoring Data" and select "Raw Data." Review table on upper left corner titled "Finished Drinking Water").
[206] Merrimack Vill. Water Dist. Water Works, *PFAS Results, Distribution Sys.*, at 8.
[207] *See, e.g.*, Colo. Dep't of Public Health & Env't, *Suncor Water Quality Permits*, *Surface Water Suncor PFAS Data (Outfall 20)*, https://cdphe.colorado.gov/suncor-water-quality-permits (updated Apr. 2023) (scroll down to the section titled "Resources and Pollution Data" and select

intra-annual variation in PFAS concentrations in both source water and finished drinking water due to factors including variable flow rates, variation in industrial processes/production cycles, variable stormwater runoff from contaminated sites, mobilization of legacy PFAS contamination in sediment or groundwater, and the potential introduction of new sources of PFAS contamination.[208] Taken together, this evidence indicates that allowing compliance monitoring as infrequently as 1–2 times per three-year compliance period may mask dangerous PFAS concentrations in monitored drinking water and potential violations of the MCLs.

Further, as EPA acknowledges, PFAS subject to the proposed NPDWRs can pose health risks at concentrations substantially lower than the proposed trigger values. Indeed, in the Proposed Rule EPA acknowledges that PFOA and PFOS can cause adverse health effects at "near zero" levels.[209] While EPA has previously justified significant monitoring reductions on the grounds that "analytical results . . . below the MCL" for the contaminants at issue "do not pose a health threat,"[210] that logic is demonstrably inapposite for PFAS. Under EPA's proposal, exceedances of one or more PFAS MCL(s) could persist for years before they are detected and treatment is required, posing significant health risks for people served by the affected water system. And in situations where a water system has detectable PFAS concentrations below the proposed trigger values, EPA's proposal would deprive the public of information relevant to assessing health risks from consuming that PFAS-contaminated drinking water.[211]

Finally, as discussed above, EPA's proposal to allow reduced monitoring based on PFAS detections below the trigger values, which in some cases are substantially below the relevant PQL, is inconsistent with EPA's proposal to zero-out all detections below the PQL for purposes of demonstrating MCL compliance. This approach is also inconsistent with EPA's assertion that detections "at the proposed rule trigger level" are "primarily useful in determining whether the contaminant is present in a sample . . . rather than to determine its specific concentration."[212]

To address these issues, EPA should modify its proposal to (1) set the trigger value at the MDL where that value is lower than one-third of the MCL, and (2) provide that systems with four consecutive quarters of non-detects for the 6 PFAS may reduce to *annual* monitoring.

"Toxic firefighting foam chemicals (PFAS)" from the drop drown menu. Select and view "Surface water Suncor PFAS data (Outfall 20)").

[208] *See* Minh A. Nguyen et al. *Seasonal Trends of Per- and Polyfluouroalkyl Substances in River Water Affected by Fire Training Sites and Wastewater Treatment Plants*, 308 Chemosphere Art. No. 136467 (2022), https://doi.org/10.1016/j.chemosphere.2022.136467; M.-A. Pétré et al., *Per- and Polyfluoroalkyl Substances (PFAS) in River Discharge: Modeling Loads Upstream and Downstream of a PFAS Manufacturing Plant in the Cape Fear Watershed, North Carolina*, 831 Sci. of the Total Env't Art. No. 154763 (2022), https://doi.org/10.1016/j.scitotenv.2022.154763.

[209] Proposed Rule, 88 Fed. Reg. at 18,715.

[210] 56 Fed. Reg. at 3,526, 3,562.

[211] *See* 42 U.S.C. 300j-4(g)(6) (providing for inclusion in public database of "information on the detection of [regulated] contaminant[s] at a quantifiable level in public water systems (including detection of the contaminant at levels not constituting a violation of the maximum contaminant level for the contaminant).").

[212] Proposed Rule, 88 Fed. Reg. at 18,681–82.

Lowering the trigger value would better align the proposal with EPA's Standardized Monitoring Framework for Synthetic Organic Compounds[213] as well as monitoring requirements in state-level PFAS MCLs.[214] Allowing annual, instead of triennial, monitoring for PWSs with consistent detections below the trigger value also would align the federal requirements with existing requirements in multiple states.[215]

D. EPA's Proposed Tier 2 Designation for Violations of its PFAS MCLs Does Not Account for Acute Toxicity and Must be Amended

To "ensure[] that consumers will know if there is a problem with their drinking water," the SDWA requires "each owner or operator of a public water system" to give notice to consumers of all violations of a NPDWR through public notice.[216] "The public notice requirements for each violation or situation," "are determined by the tier to which [the violation or situation] is assigned."[217]

Tier 1 notice is required for violations and situations "with significant potential to have serious adverse effects on human health as a result of short-term exposure" and must be provided as soon as practical but no later than 24 hours after the system learns of the violation.[218] Tier 2 notice applies to all violations and situations not designated as Tier 1 but which have the "potential to have serious adverse effects on human health" and must be provided as soon as practical but no later than 30 days after the system learns of the violation.[219] Finally, Tier 3 notice is required for all NPDWR violations and situations not included in Tier 1 and Tier 2 and must be provided "not later than one year after the public water system learns of the violation or situation or begins operating under a variance or exemption."[220]

In the Proposed Rule, EPA proposes designating violations of the MCLs for the Six PFAS as requiring "Tier 2" public notice.[221] This proposal ignores the acute toxicity of the Six PFAS, and EPA must modify its proposal to require Tier 1 public notice for violations of all the proposed MCLs so consumers can be informed of the potential for significant harm in a timely manner.

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[213] *See* 40 C.F.R. § 141.24(f)(11)(i) (requiring quarterly monitoring for organic contaminants detected above 0.0005 mg/L).
[214] *See* N.J. Admin. Code § 7:10-5.2(a)(5)(i)(2), (ii)(2) (requiring quarterly monitoring for PFOA, PFOS, and PFNS when detected above 0.002 ppt); N.Y. Comp. Codes R. & Regs. tit. 10 § 5-1.52 (establishing MDL as trigger value for reduced PFAS monitoring).
[215] *See* N.J. Admin. Code § 7:10-5.2(a)(5)(ii)(3), (iii)(3); N.Y. Comp. Codes R. & Regs. tit. 10 § 5-1.52; Mich. Admin. Code R 325.10717d(9), (11).
[216] Proposed Rule, 88 Fed. Reg. at 18,684; 40 C.F.R. § 141.201(a), (c).
[217] 40 C.F.R. § 141.201(b).
[218] *Id*. §§ 141.202(a)(9), 141.202(b)(1).
[219] *Id*. §§ 141.201(b), 141.203(b).
[220] *Id*. § 141.204(b).
[221] Proposed Rule, 88 Fed. Reg. at 18,684.

EPA's proposal "that violations of the three MCLs . . . be designated as Tier 2" for purposes of the public notification rule ignores scientific evidence establishing a link between serious adverse health effects and short-term exposure to the Six PFAS.[222] EPA acknowledges that exposure to PFOA and PFOS "may have an adverse effect on the health of persons" and that PFHxS, GenX, PFNA, and PFBS "may individually and in a mixture each result in adverse health effects, including disrupting multiple biological pathways that result in common adverse effects on several biological systems including the endocrine, cardiovascular, developmental, immune, and hepatic systems."[223] However, while EPA acknowledges that these PFAS can cause serious harms, its analysis focuses significantly on chronic harms at the expense of a careful analysis of the harms these PFAS pose in the short-term.[224] As a result of the short shrift EPA gave to acute toxicity studies, it has mis-designated the violation of the proposed MCLs for public notification purposes.

The Six PFAS all pose short-term health harms. Acute and short-term health effects for PFOA, PFOS, PFHxS, and PFNA are summarized in ATSDR's Toxicological Profile for Perfluoroalkyls.[225] Acute PFOA exposure is associated with liver, immunological, reproductive, and developmental effects.[226] Acute PFOS exposure is associated with liver, immunological, and developmental effects.[227] Acute PFNA exposure is associated with liver and immunological effects as well as changes in body weight.[228]

Acute exposure to PFOS has also been found to affect the plasticity of brain synapses, creating neurotoxic harm,[229] and damage the liver.[230] For PFOA, one study found that "cellular effects exerted after 24 h[our] exposure to perfluorooctanoic acid are non-reversible after a 48 h[our] recovery period."[231] Another study found that acute exposure to PFOA can "disrupt[] key hormones in the pancreas" and "induce[] lipid accumulation in the liver."[232] Acute exposure to

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[222] *Id*. "The proposed rule also designates monitoring and testing procedure violations as Tier 3[.]" *Id.* at 18,699.
[223] *Id.* at 18,644–45.
[224] *Id*. at 18,645–46 (citing studies of mice dosed for 42–44 days or 53–64 days, for example).
[225] ATSDR 2021 at 62, 84, 88-99.
[226] *Id.* at 62.
[227] *Id.* at 84.
[228] *Id.* at 88-90.
[229] Qian Zhang et al., *Effects Of Perfluorooctane Sulfonate and its Alternatives on Long-Term Potentiation in The Hippocampus CA1 Region if Adult Rats* in vivo*,* 5 Toxicology Rsch. 539, 539–546 (2016), doi: 10.1039/c5tx00184f.
[230] Jiali Xing, *Toxicity Assessment Of Perfluorooctane Sulfonate Using Acute and Subchronic Male C57BL/6J Mouse Models*, 210 Env't Pollution 388–96 (2016), https://pubmed.ncbi.nlm.nih.gov/26807985/.
[231] Peropadre et al., *An Acute Exposure to Perfluorooctanoic Acid Causes Non-Reversible Plasma Membrane Injury in Hela Cells*, 260 Env't Pollution Art. No. 11400 (2020), https://pubmed.ncbi.nlm.nih.gov/31995777/.
[232] Xinmou Wu et al., *Effect of Acute Exposure to PFOA On Mouse Liver Cells In Vivo And In Vitro*, 24 Env't Sci and Pollution Rsch. Int'l 24201, 24203 (2017), https://pubmed.ncbi.nlm.nih.gov/28887612/.

PFNA has been found to impair reproductive health,[233] and negatively impact liver functionality in diabetic mice.[234]A study on PFHxS found that "a single neonatal exposure to PFHxS can cause irreversible neurotoxic effects in mice."[235] PFHxS has also been found to pose similar brain development concerns as PFOS in response to acute exposure.[236] PFBS has been found to have an effect on the liver which "may represent an acute response to the chemical at a high dose."[237] Additional acute studies of PFBS are identified in the Toxicity Assessment for PFBS.[238]

EPA's Toxicity Assessment for GenX reviews 10 studies for acute toxicity and four studies for short term toxicity (seven-day dosing).[239] Since the publication of that assessment, additional acute and short-term toxicity studies have been published. For example, Cannon et al. found that a single dose of GenX administered by oral gavage caused decreases in P-glycoprotein (P-gp) transport activity and breast cancer resistance protein (BCRP) transport

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[233] Shilpi Singh & Shio Kumar Singh, *Acute Exposure To Perfluorononanoic Acid in Prepubertal Mice: Effect on Germ Cell Dynamics and an Insight into the Possible Mechanisms of its Inhibitory Action on Testicular Functions*, 183 Ecotoxicology Env't Safety Art No. 109499, 1667 (2019), https://pubmed.ncbi.nlm.nih.gov/31398581/; Shilpi Singh & Shio Kumar Singh, *Prepubertal Exposure to Perfluorononanoic Acid Interferes with Spermatogenesis and Steroidogenesis in Male Mice*, 170 Ecotoxicology Env't Safety 590, 598 (2019), https://pubmed.ncbi.nlm.nih.gov/30576894/; Shilpi Singh & Shio Kumar Singh, *Effect of Gestational Exposure to Perfluorononanoic Acid On Neonatal Mice Testes,* 39 J. of Applied Toxicology 1663, 1665 (2019), https://pubmed.ncbi.nlm.nih.gov/31389053/; Yixing Feng et al., *Effects of PFNA Exposure on Expression of Junction-Associated Molecules and Secretory Function in Rat Sertoli Cells*, 30 Reprod. Toxicology 429–37 (2010), https://pubmed.ncbi.nlm.nih.gov/20580666/.

[234] Fang X, *Perfluorononanoic Acid Disturbed the Metabolism of Lipid in the Liver of Streptozotocin-Induced Diabetic Rats*, 25 Toxicology Mechanisms & Methods 622, 626 (2015), https://pubmed.ncbi.nlm.nih.gov/26056853/.

[235] Henrick Viberg et al., *Adult Dose-Dependent Behavioral and Cognitive Disturbances After a Single Neonatal PFHXS Dose,* 304 Toxicology 185–91 (2013) https://pubmed.ncbi.nlm.nih.gov/23287389/.

[236] Qian Zhang et al., *Effects of Perfluorooctane Sulfonate and its Alternatives on Long-Term Potentiation in The Hippocampus CA1 Region if Adult Rats,* at 539 ("In addition, PFHxS and Cl-PFAES exhibited comparable potential to PFOS in disturbing LTP.").

[237] Lau et al., *Pharmacokinetic Profile of Perfluorobutane Sulfonate and Activation of Hepatic Nuclear Receptor Target Genes in Mice*, 441 Toxicology 152522 (2020), https://pubmed.ncbi.nlm.nih.gov/32534104/.

[238] EPA, *Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3)* (2021) at 50–51.

[239] EPA, *Human Health Toxicity Values for Hexafluoropropylene Oxide (HFPO) Dimer Acid and Its Ammonium Salt (CASRN 13252-13-6 and CASRN 62037-80-3) Also Known as 'GenX Chemicals*' at 35-37.

activity in the brain capillaries of exposed rats.[240] Further, a pair of studies by Conley et al. exposed rats from gestation day 14–18 or gestation day 17–21 respectively (*i.e.*, 5 days of exposure) and found effects in both the dosed mothers and developing fetuses.[241] In animals exposed from gestation day 14–18, fetal and maternal livers had increased expression of genes in the PPAR signaling pathway, and rats exposed to GenX gained less weight during their pregnancy and had larger livers than unexposed animals.[242] Results were similar for animals exposed from gestation day 17–21.[243] Additionally, Blake et al. (2023) exposed CD-1 mice from gestation day 1.5 to 11.5 or 17.5 (i.e. 10 days or 17 days of exposure) and found that exposed mothers gained more weight during the dosing period, had larger livers that showed "abnormal ultrastructure with enlarged hepatocytes," had larger kidneys and altered blood clinical chemistry, including increased cholesterol, HDL, and ALT levels.[244] GenX exposed fetuses had a larger embryo:placenta weight ratio and increased placental lesions.[245]

These health risks are significant and require swift public notice so consumers can take immediate action to protect themselves from exposure. Accordingly, EPA should adjust the proposed public notice designation for violations of the PFAS MCLs from Tier 2 to Tier 1 in the final rule.

Conclusion

For the millions of people with PFAS in their tap water, strong federal drinking water standards are essential and long overdue. We appreciate EPA's leadership in developing this proposed rule, and we urge EPA to resist efforts to weaken its proposal. We further urge EPA to revise its proposed HBWCs and to incorporate the changes outlined above. Finally, EPA should move quickly to finalize this rule and to pursue s for the PFAS that are not addressed in the proposed rule.

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[240] Cannon et al., *Effect of GenX on P-Glycoprotein, Breast Cancer Resistance Protein, and Multidrug Resistance-Associated Protein 2 at the Blood-Brain Barrier*, 128 Env't Health Persp. 37002 (March 2020), https://doi.org/10.1289/EHP5884.

[241] Conley et al., *Adverse Maternal, Fetal, and Postnatal Effects of Hexafluoropropylene Oxide Dimer Acid (GenX) from Oral Gestational Exposure in Sprague-Dawley Rats*, 127 Env't Health Persp. 037008 (Mar 2019), https://doi.org/10.1289/EHP4372 ("Conley 2019"); Conley et al., *Hexafluoropropylene Oxide-Dimer Acid (HFPO-DA or GenX) Alters Maternal and Fetal Glucose and Lipid Metabolism and Produces Neonatal Mortality, Low Birthweight, and Hepatomegaly in the Sprague-Dawley Rat*, 146 Env't Int't 106204 (Jan. 2021) https://doi.org/10.1016/j.envint.2020.106204 ("Conley 2021").

[242] Conley 2019 at 037008-6 to 037008-8.

[243] Conley 2021 at 106204-4 to 106204-10.

[244] Blake et al., *Evaluation of Maternal, Embryo, and Placental Effects in CD-1 Mice Following Gestational Exposure to Perfluorooctanoic Acid (PFOA) or Hexafluoropropylene Oxide Dimer Acid (HFPO-DA or GenX)*, 128 Env't Health Persp. 128 (Feb. 2020), https://doi.org/10.1289/EHP6233.

[245] *Id.*

If you have any questions about these comments, please contact Jon Kalmuss-Katz (jkalmusskatz@earthjustice.org) or Katherine O'Brien (kobrien@earthjustice.org) at Earthjustice or Erik Olson (eolson@nrdc.org), Anna Reade (areade@nrdc.org) or Katherine Pelch (kpelch@nrdc.org) at the Natural Resources Defense Council.

Respectfully submitted,

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Alliance for the Great Lakes
Buckeye Environmental Network
Center for Biological Diversity
Clean Cape Fear
Clean Water Action
Delaware Riverkeeper Network
Earthjustice
Elevate Energy
Environmental Advocates NY
Environmental Defense Fund
Environmental Justice Task Force -Tucson
Environmental Working Group
Fight for Zero
Green Science Policy Institute
Holy Spirit Missionary Sisters, USA-JPIC
Lawyers for Good Government
Merrimack Citizens for Clean Water
Mountain Watershed Association
National PFAS Contamination Coalition
Natural Resources Defense Council
North Carolina Conservation Network
Ohio Environmental Council
Ohio River Foundation
Passaic River Coalition
People Over Petro Coalition
PfoaProject NY
Religious Coalition for the Great Lakes
Save The River, Upper St. Lawrence Riverkeeper
Save Our Sky Blue Waters
Sierra Club
Toxic Free NC
Union of Concerned Scientists
Vermont Natural Resources Council
Waterkeeper Alliance
Zero Waste Washington

Exhibit A

May 30, 2023

Via Regulations.gov
Assistant Administrator Radhika Fox
Office of Water
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: PFAS National Primary Drinking Water Regulation Rulemaking, Docket No. EPA–HQ–OW–2022–0114

Dear Assistant Administrator Fox:

While EPA's proposed National Primary Drinking Water Standards acknowledge a broad range of adverse health effects from PFAS exposures, EPA has not fully accounted for those effects, or the corresponding benefits of the proposed regulation, in its analysis of the rule's economic impacts.[1] This document summarizes several of the health effects that EPA failed to quantify and provides resources and information that EPA should use to estimate additional benefits of the proposed drinking water standards.

Together, we have extensive experience reviewing the health and toxicological effects associated with PFAS exposure. As co-leads on the development of the PFAS-Tox Database, we have reviewed over 1,000 studies that evaluate the health impact of PFAS exposure.[2] We have also

[1] Preliminary Regulatory Determination and Proposed Rule, PFAS National Primary Drinking Water Regulation Rulemaking, 88 Fed. Reg. 18,638 (Mar. 29, 2023) (the "Proposed Rule"). The six PFAS covered by the Proposed Rule are perfluorooctanoic acid ("PFOA"), perfluorooctane sulfonic acid ("PFOS"), perfluorohexane sulfonic acid ("PFHxS"), hexafluoropropylene oxide dimer acid and its ammonium salt ("GenX"), perfluorononanoic acid ("PFNA"), and perfluorobutane sulfonic acid ("PFBS") (collectively, the "Six PFAS").

[2] Katherine E. Pelch, Anna Reade, Carol F. Kwiatkowski, Francheska M. Merced-Nieves, Haleigh Cavalier, Kim Schultz, Taylor Wolffe, and Julia Varshavsky, *The PFAS-Tox Database: A Systematic Evidence Map of Health Studies on 29 per- and Polyfluoroalkyl Substances,* Environment International 167 (September 1, 2022): 107408, https://doi.org/10.1016/j.envint.2022.107408; Katherine E. Pelch, Anna Reade, Taylor A. M. Wolffe, and Carol F. Kwiatkowski, *PFAS Health Effects Database: Protocol for a Systematic Evidence Map,* Environment International 130 (September 1, 2019): 104851,

provided public comment on ATSDR's "Toxicological Profile for Perfluoroalkyls", EPA's PFAS toxicity assessments for PFOA, PFOS, PFBA, PFHxA, GenX, and PFBS, and Health Canada's Draft Objective for Drinking Water.[3] We have also critically evaluated and commented on health and risk assessment documents for PFAS developed by California, Illinois, Michigan, New Hampshire, New Jersey, New York, Vermont, and Washington.[4] These activities inform

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https://doi.org/10.1016/j.envint.2019.05.045; Katherine E. Pelch and Carol F. Kwiatkowski, *Invited Perspective: The Promise of Fit-for-Purpose Systematic Evidence Maps for Supporting Regulatory Health Assessment,* Environmental Health Perspectives 130, no. 5 (May 2022): 051303, https://doi.org/10.1289/EHP10743.

[3] Anna Reade, *Comments on ATSDR Toxicological Profile on Perfluoroalkyls 2018 Draft,* September 6, 2018. https://www.nrdc.org/sites/default/files/comments-on-atsdr-toxicological-profile-on-perfluoroalkyls-2018-draft_2018-08-21.pdf; Katherine Pelch, *Technical comments to the Science Advisory Board on the U.S. Environmental Protection Agency external peer review draft: Proposed approaches to the derivation of a draft maximum contaminant level goal for perfluorooctanoic acid (PFOA) (CASRN 335-67-1) in drinking water and External peer review draft: proposed approaches to the derivation of a draft maximum contaminant level goal for perfluorooctane sulfonic acid (PFOS) (CASRN 1763-23-1) in drinking water*, December 23, 2021; Katherine Pelch and Anna Reade, *Comments on EPA's Draft Toxicological Review for Perfluorobutanoic Acid (PFBA)*, November 8, 2021; Katherine Pelch, *Comments on EPA's Draft Toxicological Review for Perfluorohexanoic Acid (PFHxA)*, April 4, 2022; Katherine E. Pelch, Anna Reade, Sonya Lunder, David Q. Andrews, and Ansje Miller, *Comments on EPA's Draft Toxicity Assessments for Perfluorobutane Sulfonic Acid (PFBS) and Hexafluoroproyplene Oxide (or GenX Chemicals)*, January 22, 2019. https://www.nrdc.org/sites/default/files/comments-assessments-of-pfbs-and-genx-01222019.pdf; Katherine E. Pelch and Anna Reade, *RE: Draft Objective for per- and Polyfluoroalkyl Substances in Canadian Drinking Water,* April 12, 2023.

[4] Anna Reade, Avinash Kar, and Katherine E. Pelch, *Technical Comments RE: Consideration of Perfluorooctane Sulfonic Acid (PFOS) and Its Salts and Transformation and Degradation Precursors for Possible Listing under Proposition 65 Based on Carcinogenicity,* November 2021; Anna Reade, Avinash Kar, and Andria Ventura, *Comments RE: Consideration of Perfluorononanoic Acid (PFNA) and Perfluorodecanoic Acid (PFDA) and Their Salts for Possible Listing under Proposition 65 Based on Developmental Reproductive Toxicity*, November 15, 2021; Anna Reade, Katherine E. Pelch, Nicole Saulsberry, and Iyana Simba, *Technical Comments Re 35 Ill. Adm. Code 620; Groundwater Quality Pre-Filing Public Comment Period. Joint Comments by Natural Resources Defense Council, Illinois Environmental Council and Sierra Club, Illinois Chapter,* June 5, 2021; Anna Reade, Tracy Quinn, Judith S Schreiber, and Schreiber Scientific, *Scientific and Policy Assessment for Addressing Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water*, March 15, 2019, https://www.nrdc.org/sites/default/files/assessment-for-addressing-pfas-chemicals-in-michigan-drinking-water.pdf; Anna Reade and Cyndi Roper, *Comments of the Natural Resources Defense Council on the Michigan Department of Environment, Great Lakes, and Energy's Proposed PFAS MCLs Pending Rule Set: 2019-35-EG,* January 31, 2020; Katherine E. Pelch and Carol F. Kwiatkowski, *Comments on New Hampshire Department of Environmental Services Proposed Rulemaking to Set Public Drinking Water and Groundwater Standards for PFOA, PFOS, PFNA, & PFHxS (Env-Dw 700-800 and Env-Or 603.03)*, November 7, 2018; Katherine E. Pelch, *Comments Re: Setting Public Drinking Water and Groundwater Standards for PFOA, PFOS,*

our additional comments regarding EPA's proposed National Primary Drinking Water Standards, specifically identifying health effects that should have been better incorporated into the economic benefits analysis.

I. Lactation duration[5]

EPA has not fully considered the impact of PFAS exposure on mammary gland development and function, and specifically on lactation duration. Given the importance of breastfeeding and its association with many other health impacts, this is a major oversight. Breastfeeding is associated with short- and long-term health benefits for both mother and child, but <30% of mothers in the U.S. continue any breastfeeding until the American Academy of Pediatrics (AAP) recommended 12 months.[6] The benefits of human milk for children are well described, with health benefits extending into adulthood.[7] Potential health benefits of lactation for the mother are often described with the "reset" hypothesis, whereby the adverse cardiometabolic changes during gestation (insulin resistance, hyperlipidemia, and visceral fat of pregnancy) are ameliorated by breastfeeding. In contrast, without breastfeeding, these metabolic changes persist.[8] Meta-

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PFNA, & PFHxS (Env-Dw 700-800; Env-Or 603.03), April 12, 2019; Katherine E. Pelch and Carol F. Kwiatkowski, *Comments Re: Setting Public Drinking Water Standards for PFOA and PFOS*, December 21, 2018; Anna Reade, Tracy Quinn, and Judith S Schreiber, *Comments Re: Proposed Maximum Contaminant Level for Perfluorooctanoic Acid (PFOA) and Perfluorooctanesulfonic Acid (PFOS), DEP Dkt. No. 02-19-03,* May 31, 2019, https://www.nrdc.org/sites/default/files/pfas-comments-nj-05312019.pdf; Anna Reade, Katie Pelch, Miriam Rotkin-Ellman, and Erik D. Olson, *Comments to New York State Governor Hochul and New York State Commissioner Bassett on the Need to Establish Comprehensive, and Health Protective, Drinking Water Standards for PFAS*, September 9, 2022; Anna Reade and Katherine E. Pelch, *Technical Comments Re: Advance Notice on the Regulation of Perfluoroalkyl, Polyfluoroalkyl Substances (PFAS) as a Class*, November 16, 2022, https://www.nrdc.org/sites/default/files/pfas-class-technical-comments-20201116.pdf; Erika Schreder and Katherine E. Pelch, *Comments on Washington Department of Health's Draft Recommended State Action Levels for per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water: Approach, Methods and Supporting Information (Chapter 246-290 WAC)* January 2020.

[5] We acknowledge helpful technical support and feedback from Dr. Megan Romano in the development of this section.

[6] Arthur I. Eidelman, Richard J. Schanler, Margreete Johnston, Susan Landers, Larry Noble, Kinga Szucs, and Laura Viehmann, *Breastfeeding and the Use of Human Milk,* Pediatrics 12, no. 3 (March 2012): e827–41, https://doi.org/10.1542/peds.2011-3552; CDC, *Results: Breastfeeding Rates,* Centers for Disease Control and Prevention, April 4, 2023, https://www.cdc.gov/breastfeeding/data/nis_data/results.html.

[7] Stanley Ip, Mei Chung, Gowri Raman, Priscilla Chew, Nombulelo Magula, Deirdre DeVine, Thomas Trikalinos, and Joseph Lau, *Breastfeeding and Maternal and Infant Health Outcomes in Developed Countries,* Evidence Report/Technology Assessment, no. 153 (April 2007): 1–186, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4781366/.

[8] Alison M. Stuebe and Janet W. Rich-Edwards, *The Reset Hypothesis: Lactation and Maternal Metabolism,* American Journal of Perinatology 26, no. 1 (January 2009): 81–88, https://doi.org/10.1055/s-0028-1103034.

analyses with over 200,000 women confirmed relationships between breastfeeding for 12 months and protection against common adverse cardiometabolic health outcomes, including a 30% risk reduction for diabetes and a 13% risk reduction for hypertension.[9]

Importantly, shortened duration of breastfeeding has been associated with PFAS exposure in human studies. Six human studies, published between 2010 and 2022 were recently reviewed and evaluated in a meta-analysis.[10] Four of the five included studies reported shortened total duration of breastfeeding with higher PFOS and PFOA exposure. The human epidemiological findings are consistent with findings from experimental animal studies. Despite these consistencies and the importance of breastfeeding duration on maternal and infant health, EPA failed to adequately review and consider shortened lactation duration in the 2023 Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water. In that document, EPA reviewed the animal evidence for impacts on mammary gland development and function but did not evaluate the corresponding epidemiological evidence.[11]

The 2023 Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water cites but does not thoroughly discuss two of the epidemiological studies that are included in the recent meta-analysis on breastfeeding (Timmerman et al. 2017 and Romano et al. 2016)[12], and fails to cite or discuss the four additional studies, including those published before the review cut-off date (Fei et al., 2010, Nielsen et al.,

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[9] Rabel Misbah Rameez, Divyajot Sadana, Simrat Kaur, Taha Ahmed, Jay Patel, Muhammad Shahzeb Khan, Sarah Misbah, Marian T. Simonson, Haris Riaz, and Haitham M. Ahmed, *Association of Maternal Lactation With Diabetes and Hypertension: A Systematic Review and Meta-Analysis*, JAMA Network Open 2, no. 10 (October 16, 2019): e1913401, https://doi.org/10.1001/jamanetworkopen.2019.13401.

[10] Amalie Timmermann, Oyemwenosa N. Avenbuan, Megan E. Romano, Joseph M. Braun, Janne S. Tolstrup, Laura N. Vandenberg, and Suzanne E. Fenton, *Per- and Polyfluoroalkyl Substances and Breastfeeding as a Vulnerable Function: A Systematic Review of Epidemiological Studies*, Toxics 11, no. 4 (April 2023): 325, https://doi.org/10.3390/toxics11040325.

[11] US EPA, *Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water,* Office of Water, March 14, 2023, https://www.epa.gov/system/files/documents/2023-03/MAIN_Proposed%20MCLG%20for%20PFOA%20in%20Drinking%20Water_3.9.23_For%20Proposal.pdf.

[12] Clara Amalie Gade Timmermann, Esben Budtz-Jørgensen, Maria Skaalum Petersen, Pál Weihe, Ulrike Steuerwald, Flemming Nielsen, Tina Kold Jensen, and Philippe Grandjean, *Shorter Duration of Breastfeeding at Elevated Exposures to Perfluoroalkyl Substances*, Reproductive Toxicology, Developmental Origins of Disease, 68 (March 1, 2017): 164–70, https://doi.org/10.1016/j.reprotox.2016.07.010; Megan E. Romano, Yingying Xu, Antonia M. Calafat, Kimberly Yolton, Aimin Chen, Glenys M. Webster, Melissa N. Eliot, Cynthia R. Howard, Bruce P. Lanphear, and Joseph M. Braun, *Maternal Serum Perfluoroalkyl Substances during Pregnancy and Duration of Breastfeeding*, Environmental Research 149 (August 1, 2016): 239–46, https://doi.org/10.1016/j.envres.2016.04.034.

2022, Rosen et al., 2018, and Timmerman et al., 2021).[13] None of the epidemiological studies are cited or discussed in the 2016 Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA).[14] Though the animal literature is discussed in the document, the 2016 Drinking Water Health Advisory for PFOA did not consider any candidate reference doses (RfDs) based on mammary gland effects.

Perhaps EPA's failure to adequately consider mammary gland and lactational effects in the 2023 toxicity assessment is, in part, a result of mammary gland impacts being improperly diminished in earlier documents. Evidence for this can be seen in the conclusions EPA makes in the 2023 toxicity assessment. In the 2023 Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water document EPA states, "no differences in response to a lactation challenge were seen in PFOA-exposed CD-1 mouse dams with delayed mammary gland development, and no significant effects on body weight gain were seen in pups nursing from dams with less fully developed mammary glands (White, 2011, 1276150)."[15] Similarly, ATSDR stated "… the mammary gland effect did not result in an adverse effect on lactational support at maternal doses as high as 1 mg/kg/day, based on normal growth and survival in F2 pups (White et al. 2011). Given that milk production was adequate to support growth, the biological significance of the delayed development of the

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[13] Chunyuan Fei, Joseph K. McLaughlin, Loren Lipworth, and Jørn Olsen, *Maternal Concentrations of Perfluorooctanesulfonate (PFOS) and Perfluorooctanoate (PFOA) and Duration of Breastfeeding,* Scandinavian Journal of Work, Environment & Health 36, no. 5 (September 2010): 413–21, https://doi.org/10.5271/sjweh.2908;Christel Nielsen, Ying Li, Magdalena Lewandowski, Tony Fletcher, and Kristina Jakobsson, *Breastfeeding Initiation and Duration after High Exposure to Perfluoroalkyl Substances through Contaminated Drinking Water: A Cohort Study from Ronneby, Sweden*, Environmental Research 207 (May 1, 2022): 112206, https://doi.org/10.1016/j.envres.2021.112206; Emma M. Rosen, Anne Lise Brantsæter, Rachel Carroll, Line S. Haug, Alison B. Singer, Shanshan Zhao, and Kelly K. Ferguson, *Maternal Plasma Concentrations of Per- and Polyfluoroalkyl Substances and Breastfeeding Duration in the Norwegian Mother and Child Cohort*, Environmental Epidemiology (Philadelphia, Pa.) 2, no. 3 (September 2018): e027, https://doi.org/10.1097/EE9.0000000000000027; Clara Amalie Gade Timmermann, Marianne Skovsager Andersen, Esben Budtz-Jørgensen, Henriette Boye, Flemming Nielsen, Richard Christian Jensen, Signe Bruun, Steffen Husby, Philippe Grandjean, and Tina Kold Jensen, *Pregnancy Exposure to Perfluoroalkyl Substances and Associations With Prolactin Concentrations and Breastfeeding in the Odense Child Cohort,* The Journal of Clinical Endocrinology and Metabolism 107, no. 2 (September 13, 2021): e631–42, https://doi.org/10.1210/clinem/dgab638.

[14] US EPA, *Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA)*, May 2016, https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final-plain.pdf.

[15] US EPA, *Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water,* Office of Water, March 14, 2023, https://www.epa.gov/system/files/documents/2023-03/MAIN_Proposed%20MCLG%20for%20PFOA%20in%20Drinking%20Water_3.9.23_For%20Proposal.pdf.

mammary gland observed at very low doses is uncertain and was not considered a suitable basis for the MRL."[16]

However, these summaries simplify the complex behaviors that are observed during lactation between a mother (dam) and offspring (pup). The lactation challenge in White et al. 2011 only evaluated the amount of milk passed from the dam to the pups in a single nursing event; it did not account for compensatory behaviors that may have been present in the pups.[17] The study authors added this additional context, stating "[t]hese data suggest that nursing behavior of the neonates may have changed (i.e., increased number of nursing events per day or longer nursing per event) to compensate for the decreased potential in milk production by the F1 dam, but we did not evaluate these end points in this study."[18] We previously submitted comments to ATSDR highlighting the agency's misinterpretation of the study by White et al. (2011), pointing out that "an estimated 3-6 million mothers each year are unable to produce milk or have difficulty breastfeeding. The cause of this remains unclear, however, exposure to toxic environmental chemicals are one candidate explanation for the inability to initiate and/or sustain breastfeeding."[19]

Importantly, a 2009 workshop of experts in mammary gland biology and risk assessment came to the consensus that changes in mammary gland growth and differentiation, including changes in developmental timing, are a relevant human health concern.[20] Altered mammary gland development may lead to difficulty in breastfeeding and/or an increase in susceptibility to breast cancer later in life.

Although Michigan and New Jersey did not directly base their risk assessments for PFOA on mammary gland effects or changes in lactation duration, they did address the increased risk for this effect through their application of uncertainty factors. Michigan stated that mammary gland effects may not be considered adverse, but that they could be representative of endocrine

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[16] ATSDR, *Toxicological Profile for Perfluoroalkyls*, May 2021, https://www.atsdr.cdc.gov/toxprofiles/tp200.pdf.

[17] Sally S. White, Jason P. Stanko, Kayoko Kato, Antonia M. Calafat, Erin P. Hines, and Suzanne E. Fenton, *Gestational and Chronic Low-Dose PFOA Exposures and Mammary Gland Growth and Differentiation in Three Generations of CD-1 Mice,* Environmental Health Perspectives 119, no. 8 (August 2011): 1070–76, https://ehp.niehs.nih.gov/doi/epdf/10.1289/ehp.1002741.

[18] *Id.*

[19] Anna Reade, *Comments on ATSDR Toxicological Profile on Perfluoroalkyls 2018 Draft,*" September 6, 2018, https://www.nrdc.org/sites/default/files/comments-on-atsdr-toxicological-profile-on-perfluoroalkyls-2018-draft_2018-08-21.pdf.

[20] Ruthann A. Rudel, Suzanne E. Fenton, Janet M. Ackerman, Susan Y. Euling, and Susan L. Makris, *Environmental Exposures and Mammary Gland Development: State of the Science, Public Health Implications, and Research Recommendations,* Environmental Health Perspectives 119, no. 8 (August 2011): 1053–61, https://doi.org/10.1289/ehp.1002864.

(hormone) effects at doses below Michigan's selected point of departure.[21] Michigan therefore applied an additional uncertainty factor for database limitations regarding endocrine effects.[22]

New Jersey stated that the mammary gland effect is "the most sensitive systemic endpoint for PFOA with data appropriate for dose-response modeling. It is a well-established toxicological effect of PFOA that is considered to be adverse and relevant to humans for the purposes of risk assessment."[23] However, New Jersey also concluded that because altered mammary gland development had yet to be used as the basis for a risk assessment it would not select it as the critical effect, but did apply an uncertainty factor to protect for this more sensitive effect.[24]

In finalizing the toxicity assessment and economic analysis, EPA should reconsider the effects of PFOA on mammary gland development and function, with specific attention to impacts on lactation duration. EPA could then quantify the number of people who may be impacted by the proposed regulation. For example, using data available from the meta-analysis by Timmerman et al. (2023), an attributable risk for shortened lactational duration could be calculated as follows:

$AR = I_o\ (RR\text{-}1)$[25]

- where RR is the relative risk of the outcome of interest - In our case stopping any breastfeeding before 6 months. In this example we will use the data from Romano et al., 2016[26]

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[21] Jamie C. DeWitt, Kevin Cox, and David A. Savitz, *Health Based Drinking Water Value Recommendations for PFAS in Michigan,* June 27, 2019, https://www.michigan.gov/-/media/Project/Websites/PFAS-Response/Reports/2019-Health-Based-Drinking-Water-Value-Recommendations-PFAS-MI.pdf?rev=1779be946a5c41439f1db4f3eeaec4ec.

[22] *Id.*

[23] New Jersey Drinking Water Quality Institute, *Health-Based Maximum Contaminant Level Support Document: Perfluorooctanoic Acid (PFOA),* February 15, 2017, https://www.nj.gov/dep/watersupply/pdf/pfoa-appendixa.pdf.

[24] Note that Texas has used altered mammary gland development in its PFAS risk assessment prior to NJ Drinking Water Quality Institute's comments. The report was formerly available from the Texas Commission on Environmental Quality (TCEQ) at https://www.tceq.texas.gov/assets/public/implementation/tox/evaluations/pfcs.pdf, but an update is now available: TCEQ, *Per- and Poly-Fluoroalkyl Substances (PFAS)*, February 14, 2023, https://www.tceq.texas.gov/downloads/toxicology/pfc/pfcs.pdf.

[25] Noel S. Weiss and Thomas D. Koepsell, eds, *Epidemiologic Methods: Studying the Occurrence of Illness*. Second edition. Oxford University Press, 2014, https://academic.oup.com/book/24995.

[26] Megan E. Romano, Yingying Xu, Antonia M. Calafat, Kimberly Yolton, Aimin Chen, Glenys M. Webster, Melissa N. Eliot, Cynthia R. Howard, Bruce P. Lanphear, and Joseph M. Braun, *Maternal Serum Perfluoroalkyl Substances during Pregnancy and Duration of Breastfeeding*, Environmental Research 149 (August 1, 2016): 239–46, https://doi.org/10.1016/j.envres.2016.04.034.

- where I_o is the disease incidence in the unexposed - Here we estimate this based on data from the National Immunization Survey, which suggests that the prevalence of children who were breastfed at 6 months in the U.S. was 55.8% for 2019.[27]
- This means that 44.2% of children are not breastfed at 6 months, which can be used as an estimate of cumulative incidence.[28]

Calculation Inputs:

	PFOA	PFOS	PFHxS	PFNA
RR	1.41*	1.25*	1.22	1.13
I_0	0.442	0.442	0.442	0.442

*These RRs were statistically significant in the original paper, so there is more confidence in the precision of these estimates. The others were borderline significant, so though they are still reasonable, they are also possibly less precise.

Given the calculation inputs provided above, the attributable risk for stopping breastfeeding by 6 months can be calculated for those with the highest serum PFAS level in pregnancy (i.e., in the 4th quartile in the HOME Study) compared to those the lowest serum PFAS exposure (1st quartile in the HOME study). The HOME Study is the Health Outcomes and Measures of the Environment study) which was used in Romano et al., 2016.

The resulting attributable risks are:

- AR_{PFOA}= 18 per 100 mothers
- AR_{PFOs}= 11 per 100 mothers
- AR_{PFHxS}= 9 per 100 mothers
- AR_{PFNA}= 5 per 100 mothers

In other words, 18 additional mothers (per 100 mothers) stopped breastfeeding before 6 months of age in the highly exposed PFOA group versus the lowest exposed PFOA group.

More conservatively, one could assume that the incidence of stopping breastfeeding among truly unexposed women is ¼ that of the general population (11.05%). If that is the case, then the attributable risks are as follows.

- AR_{PFOA}= 5 per 100 mothers
- AR_{PFOs}= 3 per 100 mothers
- AR_{PFHxS}= 2 per 100 mothers
- AR_{PFNA}= 1 per 100 mothers

[27] CDC, *Results: Breastfeeding Rates,* Centers for Disease Control and Prevention, April 4, 2023. https://www.cdc.gov/breastfeeding/data/nis_data/results.html.

[28] Ideally the cumulative incidence is based on the disease incidence in an unexposed population. However, with PFAS, the general population is not a truly unexposed population. Therefore, the cumulative incidence, and consequently the attributable risk, may be overestimated. Therefore, an alternative analysis with a more conservative assumption of the cumulative incidence is also provided.

Monetization of the impact of shortened lactation duration is also possible.[29] An online tool that estimates the cost of not breastfeeding suggests that in the US there is an additional $28 million in healthcare system treatment costs when children are not breastfed due to increased maternal and child infections, and additional costs due to cognitive losses and the need for households to purchase breastmilk substitutes.[30]

II. Immunotoxicity

In its explanation of why immune effects were not selected for economic analysis, EPA states:

"While immune effects had indicative evidence of associations with exposure to PFOA and PFOS, EPA did not identify the necessary information to connect the measured biomarker responses (i.e., decrease in antibodies) to a clinical effect that could be valued in the economic analysis."[31]

While it is difficult to quantitate the relationship between altered immune responses, such as decreases in antibody production, and frequency or severity of disease in inherently diverse human populations, these "subclinical" effects are associated with increased disease risk and economic cost and are therefore important to address. Small shifts within the range of normal clinical values can still have devastating population-level impacts. Specifically, the cellular and humoral immune response to vaccination is thought to be a sensitive indicator of immunosuppression.[32] In a literature review from 2018 the authors conclude that, "[t]aken together, we find that results of epidemiological studies, supported by findings from toxicological studies, provide strong evidence that humans exposed to PFOA and PFOS are at risk for immunosuppression."[33] In a more recent review, authors find that, "there is ample evidence illustrating PFAS affect multiple aspects of the immune system, which supports the overall conclusion that not only PFOA and PFOS, but also other members of the PFAS family

[29] Dylan D. Walters, Linh T H Phan, and Roger Mathisen, *The Cost of Not Breastfeeding: Global Results from a New Tool,* Health Policy and Planning 34, no. 6 (July 2019): 407–17, https://doi.org/10.1093/heapol/czz050.
[30] Alive & Thrive, *In the USA, Breastfeeding Impacts Families, Communities, and the Economy*, 2022, https://www.aliveandthrive.org/en/country-stat/usa.
[31] US EPA, *Draft for Public Comment: Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation*, March 14, 2023, https://www.epa.gov/system/files/documents/2023-03/Proposed%20PFAS%20NPDWR%20EA_final_03_09_2023_0.pdf.
[32] Ronald Glaser, Gary R. Pearson, Robert H. Bonneau, Brian A. Esterling, Cathie Atkinson, and Janice K. Kiecolt-Glaser, *Stress and the Memory T-Cell Response to the Epstein-Barr Virus in Healthy Medical Students*, Health Psychology 12, no. 6 (1993): 435–42, https://doi.org/10.1037/0278-6133.12.6.435.
[33] Jamie C. DeWitt, Sarah J. Blossom, and Laurel A. Schaider, *Exposure to Per-Fluoroalkyl and Polyfluoroalkyl Substances Leads to Immunotoxicity: Epidemiological and Toxicological Evidence,* Journal of Exposure Science & Environmental Epidemiology 29, no. 2 (March 2019): 148–56, https://doi.org/10.1038/s41370-018-0097-y.

alter immune functions in humans."[34] They go on to confirm that the "most reported immunotoxic effect in humans is immunosuppression, reflected by reduced vaccine antibody levels and increased risk of common infectious diseases."[35]

Importantly, immunosuppression has been defined by experts as "a reduced ability of the immune system to respond to a challenge from a level considered normal, regardless of whether clinical disease results."[36] However, there are clinical consequences of mild-to-moderate chronic immunosuppression, including an increase in the incidence of infectious diseases. Even small changes in infectious disease frequency can have major social and economic impacts, particularly on vulnerable populations. The elderly experience age-related declines in immune function and factors that contribute to immunosuppression in this population can increase the risk of morbidity and mortality. Adults 65 and older make up approximately 90% of the total pneumonia and influenza-related deaths in the U.S.[37] Furthermore, vaccines are less effective in the elderly.[38] The young are particularly susceptible to infectious agents that require adult-level immune responses. For example, the ability to produce antibodies develops slowly, with infants (1-3 months old) starting off with approximately 30% of adult antibody levels and children (12-16 years old) still only producing around 70% of adult levels.[39] Agents that induce immunosuppression can exacerbate the inherent deficits in infants' and children's immature and still developing immune systems.[40]

In a recent epidemiology study, authors looked directly at the link between PFAS exposure and persistent infections.[41] They found that, "[e]ach PFAS was individually associated with

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[34] Veronika Ehrlich, Wieneke Bil, Rob Vandebriel, Berit Granum, Mirjam Luijten, Birgitte Lindeman, Philippe Grandjean, et al, *Consideration of Pathways for Immunotoxicity of Per- and Polyfluoroalkyl Substances (PFAS),* Environmental Health 22, no. 1 (February 22, 2023): 19, https://doi.org/10.1186/s12940-022-00958-5.

[35] *Id.*

[36] Jamie C. DeWitt, Dori R. Germolec, Robert W. Luebke, and Victor J. Johnson. *Associating Changes in the Immune System with Clinical Diseases for Interpretation in Risk Assessment,* Current Protocols in Toxicology 67 (February 1, 2016): 18.1.1-18.1.22, https://doi.org/10.1002/0471140856.tx1801s67.

[37] C. P. Mouton, O. V. Bazaldua, B. Pierce, and D. V. Espino, *Common Infections in Older Adults,* Health Care Food & Nutrition Focus 18, no. 3 (November 2001): 1, 3–7.

[38] Richard Aspinall, Giuseppe Del Giudice, Rita B. Effros, Beatrix Grubeck-Loebenstein, and Suryaprakash Sambhara, *Challenges for Vaccination in the Elderly,* Immunity & Ageing: I & A 4 (December 11, 2007): 9, https://doi.org/10.1186/1742-4933-4-9.

[39] E. R Stiehm and H. H. Fudenberg, *Serum Levels of Immune Globulins in Health and Disease: A Survey* Pediatrics 37, no. 5 (May 1966): 715–27.

[40] Jamie C. DeWitt, Dori R. Germolec, Robert W. Luebke, and Victor J. Johnson, *Associating Changes in the Immune System with Clinical Diseases for Interpretation in Risk Assessment,* Current Protocols in Toxicology 67 (February 1, 2016): 18.1.1-18.1.22, https://doi.org/10.1002/0471140856.tx1801s67.

[41] Catherine M. Bulka, Vennela Avula, and Rebecca C. Fry, *Associations of Exposure to Perfluoroalkyl Substances Individually and in Mixtures with Persistent Infections: Recent*

significantly higher pathogen burdens and the most pronounced associations were observed in adolescents [e.g., among adolescents, a doubling of PFOS was associated with 30% (95% CI: 25–36%) higher pathogen burden]. Quantile g-computation revealed PFAS mixtures as a whole were also associated with higher pathogen burdens. Taken together, these results suggest PFAS exposure may increase susceptibility to and foster the clustering of persistent infections, particularly among adolescents."[42]

Impacts associated with mortality and morbidity from common pathogens (such as influenza and pneumonia) have been studied and estimated. These can serve as a basis for beginning to quantitate and even monetize the benefit of reducing the risk of immunotoxicity associated with PFAS exposure as these common pathogens are more likely to increase mortality and morbidity in those who are mildly to moderately immunosuppressed, i.e., the young, the elderly, and those with toxicant-induced PFAS immunosuppression. Relevant data includes:

Quantitative data on morbidity[43]

- In 2010, influenza and pneumonia together were ranked the ninth leading cause of death in the U.S. for all ages.
- For infant deaths in 2010, influenza was ranked 46th and pneumonia was ranked 47th.
- For the elderly population, chronic lower respiratory disease was ranked 3rd and influenza-pneumonia was ranked 7th in leading causes of death in 2004.

Cost estimates

- Total cost of influenza and pneumonia was estimated to be $40.2 billion in the U.S.[44]
- Ear infections (otitis media) is the most common indication for antibiotic use and outpatient visits in children – $2.88 billion in added annual health care expense in the U.S.[45]
- Annual cost of treating RSV for children under 5 in 2000 was $652 million[46]

Taken together, the data support the identification of protecting against immune system effects, particularly immunosuppression, as a key benefit resulting from the proposed MCLs. The data also suggests that EPA has sufficient information to quantify this benefit. Examples include the number of infection-related deaths avoided, the number of infectious disease cases avoided, and the increased proportion of the population with successful responses to immunization. Finally,

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Findings from NHANES 1999–2016, Environmental Pollution 275 (April 15, 2021): 116619, https://doi.org/10.1016/j.envpol.2021.116619.

[42] *Id.*

[43] M. Heron, *Deaths: Leading causes for 2010,* National Vital Statistics Reports. 2013; 62.

[44] American Lung Association, *Influenza and pneumonia: State of lung disease in diverse communities,* 2010.

[45] Sameer Ahmed, Nina L. Shapiro, and Niel Bhattacharyya, *Incremental Health Care Utilization and Costs for Acute Otitis Media in Children,* The Laryngoscope 124 (2014): 301–5, https://doi.org/10.1002/lary.24190.

[46] L. Clark Paramore, Vincent Ciuryla, Gabrielle Ciesla, and Larry Liu, *Economic Impact of Respiratory Syncytial Virus-Related Illness in the US,* PharmacoEconomics 22, no. 5 (April 1, 2004): 275–84, https://doi.org/10.2165/00019053-200422050-00001.

there is information detailing some of the costs related to common infectious diseases that can be used to monetize some of these benefits. In finalizing the economic analysis EPA should quantitate and monetize, where possible, the health benefits of reduced PFAS-related immunotoxicity that the proposed MCLs will provide.

III. Liver disease

We disagree with EPA's conclusions that the hepatic effects that have been observed are modest and unquantifiable. The reality is that the experimental literature and human literature are substantial, mutually reinforcing, consistent, and point to a problem of PFAS hepatotoxicity.[47] Few findings in environmental health are as consistent as the experimental and epidemiological evidence that PFAS, notably but not limited to PFOA and PFOS, are associated with liver damage.[48]

Across species and toxicological studies, PFAS exposure causes increased ALT (alanine aminotransferase) levels and liver steatosis (fat accumulation), which is the starting point for NAFLD (nonalcoholic fatty liver disease). Yet, EPA has argued that 1) the connection from increased ALT to liver disease is lacking and 2) that the changes in ALT after PFAS exposure is modest (implying lacks importance).

1) Connecting increased ALT to liver disease:

Specifically, with respect to connecting increases in ALT to liver disease, EPA states, "Elevated ALT levels could be one of several contributors to the non-alcoholic fatty liver disease. Additionally, high ALT levels can be associated with alcohol consumption, heart failure, hepatitis (A, B, and C), medication use (e.g., Tylenol and statins), and obesity (Mayo Clinic, 2022) and this wide range of associations makes it difficult to model economic benefits of non-specific ALT level changes in response to reduced exposures."[49] Most health effects are associated with more than one risk factor. This does not mean that quantifying the benefit of reducing one of these multiple risk factors is not possible.

Multiple studies show that PFAS exposure causes liver toxicity and fatty liver disease across animal species, without known species exceptions so far. There is no reason to expect humans to be the exception.

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[47] Elizabeth Costello, Sarah Rock, Nikos Stratakis, Sandrah P. Eckel, Douglas I. Walker, Damaskini Valvi, Dora Cserbik, et al, *Exposure to Per- and Polyfluoroalkyl Substances and Markers of Liver Injury: A Systematic Review and Meta-Analysis,* Environmental Health Perspectives 130, no. 4 (April 27, 2022): 046001, https://doi.org/10.1289/EHP10092.
[48] *Id.*
[49] US EPA, *Draft for Public Comment: Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation*, March 14, 2023, https://www.epa.gov/system/files/documents/2023-03/Proposed%20PFAS%20NPDWR%20EA_final_03_09_2023_0.pdf.

Evaluating environmental contributors to NAFLD in cross-sectional studies is difficult due to how and when the disease is diagnosed. NAFLD is seldom diagnosed in early stages in clinical practice and may not be coded as among the comorbidities for other diagnoses. Therefore, cross-sectional studies that have relied on medical record review (ICD-code verified) of NAFLD are likely to suffer from outcome misclassification. However newer studies, not reliant on ICD-code verification, but rather on imaging of livers, have linked PFAS exposure with deleterious effects on fatty liver findings.[50] In a biopsy-proven cohort of 105 patients with NAFLD, PFAS were found to be adversely associated with liver fat content, lipid metabolism, and bile acid metabolism.[51]

2) Addressing the biological significance of "modest" changes in ALT

EPA states that the effects of PFAS exposure on observed ALT levels are modest, but fails to recognize that more recently, professional societies have recommended more appropriate, physiologically-based cutoffs for what is considered a normal or abnormal ALT level based on the important societal need to address the NAFLD epidemic.[52]

A large epidemiological study of more than 30,000 participants in a community with PFOA exposures ranging from national background levels to very high levels of contamination, concluded participants in the fifth quintile had 16% increased odds of having above-normal ALT (95% CI: odds ratio: 1.02, 1.33%).[53] There is a near monotonic increase in ALT with increasing PFOA, with the dose-response beginning at what are considered to be "background" levels of population exposure.

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[50] Xinchen Wang, Xiaoqian Jin, Hancheng Li, Xianyu Zhang, Xi Chen, Kuan Lu, and Chenliang Chu, *Effects of Various Interventions on Non-Alcoholic Fatty Liver Disease (NAFLD): A Systematic Review and Network Meta-Analysis,* Frontiers in Pharmacology 14 (2023), https://www.frontiersin.org/articles/10.3389/fphar.2023.1180016.

[51] Partho Sen, Sami Qadri, Panu K. Luukkonen, Oddny Ragnarsdottir, Aidan McGlinchey, Sirkku Jäntti, Anne Juuti, et al., *Exposure to Environmental Contaminants Is Associated with Altered Hepatic Lipid Metabolism in Non-Alcoholic Fatty Liver Disease,* Journal of Hepatology 76, no. 2 (February 1, 2022): 283–93, https://doi.org/10.1016/j.jhep.2021.09.039.

[52] Naga, Chalasani, Zobair Younossi, Joel E. Lavine, Michael Charlton, Kenneth Cusi, Mary Rinella, Stephen A. Harrison, Elizabeth M. Brunt, and Arun J. Sanyal, *The Diagnosis and Management of Nonalcoholic Fatty Liver Disease: Practice Guidance from the American Association for the Study of Liver Diseases,* Hepatology 67, no. 1 (January 2018): 328, https://doi.org/10.1002/hep.29367; Jin Hwa Park, Jun Choi, Dae Won Jun, Sung Won Han, Yee Hui Yeo, and Mindie H Nguyen, *Low Alanine Aminotransferase Cut-Off for Predicting Liver Outcomes; A Nationwide Population-Based Longitudinal Cohort Study,* Journal of Clinical Medicine 8, no. 9 (September 11, 2019): 1445, https://www.mdpi.com/2077-0383/8/9/1445.

[53] Lyndsey A. Darrow, Alyx C. Groth, Andrea Winquist, Hyeong-Moo Shin, Scott M. Bartell, and Kyle Steenland, *Modeled Perfluorooctanoic Acid (PFOA) Exposure and Liver Function in a Mid-Ohio Valley Community,* Environmental Health Perspectives 124, no. 8 (August 2016): 1227–33, https://doi.org/10.1289/ehp.1510391.

A reanalysis of the above data was performed using the updated physiologically-based cutoffs for ALT as recommended by the medical liver disease societies.[54] This reanalysis showed an increased association of PFOA to abnormal ALT and emphasized the near monotonic increases in ALT with increasing dose. For example, males in the 5th quintile of measured PFOA were 35% more likely and females 20% more likely to have abnormal ALT, with mean continuous increases of 9% per quintile for men and 4% for women.[55]

Independent of PFAS, populations with higher biomarkers of liver distress such as ALT have worse outcomes for morbidity and mortality.[56]

In finalizing the economic analysis EPA should reconsider the conclusions drawn regarding the literature exploring ALT and NAFLD in relationship to PFAS exposure and attempt to quantitate the number of people who would benefit from reduced risk of liver effects from the proposed MCLs. EPA should also attempt to monetize the health benefit from reduced NAFLD cases, as there are studies available that provide estimates of the economic burden associated with NAFLD.

For example, one study from 2016 estimated that in the U.S., "over 64 million people are projected to have NAFLD, with annual direct medical costs of about [$103.3] billion ($1,613 per patient)" but that the "burden is significantly higher when societal costs are included."[57] The study estimated societal costs to be $188.9 billion, yielding a total cost of $292.2 billion. These cost estimates account for drugs, healthcare, and changes in quality of life, but they under-value other indirect costs such as lost productivity and federal benefits for disability. They also underestimate even the pharmaceutical costs, as they rely on formal diagnoses and it is clear that

[54] Alan Ducatman, Youran Tan, Brian Nadeau, and Kyle Steenland, *Perfluorooctanoic Acid (PFOA) Exposure and Abnormal Alanine Aminotransferase: Using Clinical Consensus Cutoffs Compared to Statistical Cutoffs for Abnormal Values, Toxics* 11, no. 5 (May 2023): 449, https://doi.org/10.3390/toxics11050449.
[55] *Id.*
[56] Paul Y. Kwo, Stanley M. Cohen, and Joseph K. Lim, *ACG Clinical Guideline: Evaluation of Abnormal Liver Chemistries,* American Journal of Gastroenterology 112, no. 1 (January 2017): 18–35, https://journals.lww.com/ajg/Fulltext/2017/01000/ACG_Clinical_Guideline__Evaluation_of_Abnormal.13.aspx; Naga Chalasani, Zobair Younossi, Joel E. Lavine, Michael Charlton, Kenneth Cusi, Mary Rinella, Stephen A. Harrison, Elizabeth M. Brunt, and Arun J. Sanyal, *The Diagnosis and Management of Nonalcoholic Fatty Liver Disease: Practice Guidance from the American Association for the Study of Liver Diseases,* Hepatology 67, no. 1 (January 2018): 328, https://doi.org/10.1002/hep.29367.
[57] Zobair M. Younossi, Deirdre Blissett, Robert Blissett, Linda Henry, Maria Stepanova, Youssef Younossi, Andrei Racila, Sharon Hunt, and Rachel Beckerman, *The Economic and Clinical Burden of Nonalcoholic Fatty Liver Disease in the United States and Europe,* Hepatology 64, no. 5 (2016): 1577–86, https://doi.org/10.1002/hep.28785.

NAFLD treatment, hospitalization, and indirect costs can precede the diagnosis and treatment.[58] Despite these limitations, EPA can still use this information to begin to monetize the benefit of reduced NAFLD cases from the proposed MCLs.

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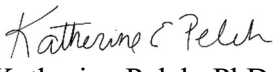
EPA failed to quantify several of the health effects associated with PFAS exposure. We have provided resources and information that EPA should use to estimate the proposed drinking water standards' additional benefits of protecting against PFAS-associated effects on mammary gland development, the liver and immune system.

Sincerely,

Anna Reade, PhD
Senior Scientist
Natural Resources Defense Council



Katherine Pelch, PhD
Scientist
Natural Resources Defense Council

[58] Myriam Alexander, A. Katrina Loomis, Jolyon Fairburn-Beech, Johan van der Lei, Talita Duarte-Salles, Daniel Prieto-Alhambra, David Ansell, et al., *Real-World Data Reveal a Diagnostic Gap in Non-Alcoholic Fatty Liver Disease,* BMC Medicine 16, no. 1 (August 13, 2018): 130. https://doi.org/10.1186/s12916-018-1103-x.

Exhibit B

Memorandum

To: Earthjustice

From: Dennis Guignet, PhD.

Subject: Review of the Economic Analysis for the Proposed PFAS NPDWR

Date: May 26, 2023

Purpose

The purpose of this memorandum is to evaluate the U.S. Environmental Protection Agency's Economic Analysis of the proposed Per- and Polyfluoroalkyl Substances (PFAS) National Primary Drinking Water Regulation, and to identify ways the economic analysis (EA) can be further improved.

As a trained economist with a PhD in Agricultural and Resource Economics, and over a decade of experience, I am qualified to identify analytical strengths and weaknesses in the EA, and recognize potential areas where the EA can be further strengthened. I served as a research economist in the National Center for Environmental Economics at the U.S. Environmental Protection Agency (EPA) for seven years (from 2011 to 2018). During that time, I helped develop, review, and revise EAs of regulatory actions. I have taught environmental economics courses at the University of Maryland and American University, as well as a graduate and undergraduate-level course in benefit-cost analysis at Appalachian State University, where I am currently employed as an Assistant Professor of Economics. My research focuses on applied quantitative analysis, benefit-cost analysis of environmental policies, and the estimation of environmental and human health benefits, with a particular focus on toxic chemicals. I have 25 publications in peer-reviewed journals, and significant related experience that adds to my qualifications (see the attached Exhibit 1 for my full curriculum vitae).

Overall, based on my professional experience, the EA that has been developed for the proposed PFAS National Primary Drinking Water Standards (NPDWS) is one of the most well-organized, thorough, and transparent EAs I have reviewed. The quantified benefits entail reduced mortality and non-fatal health outcomes from decreased exposures to PFAS, including reduced risks of cardiovascular disease, low infant birthweight, and renal cell carcinoma. Additionally, reduced risk of bladder cancer due to the co-removal of non-PFAS pollutants is a co-benefit that is quantified. For all four health outcomes, the number of avoided fatal and non-fatal cases that result from each regulatory option, relative to the baseline, are estimated. These quantified benefits are monetized based on the Value of a Statistical Life (VSL) for reduced fatal cases (i.e., reduced mortality risks), and based on avoided cost-of-illness (COI) estimates for reduced non-fatal cases (i.e., reduced morbidity risks). Both are common and well-accepted approaches for monetizing (i.e., assigning a dollar value to) human health-related benefits in policy analysis.

The quantified costs mainly include public water system (PWS) costs for implementing treatment and non-treatment technologies when the proposed maximum contaminant levels (MCLs) are exceeded, as well as monitoring and reporting costs, and administrative costs to PWSs and implementing agencies.

This memorandum is organized as follows. First, key strengths of the EA are highlighted. Then I discuss potential areas where the analysis could be improved.

Strengths of the Economic Analysis.

There are several strengths of the EA that are worth highlighting. These features should be maintained and potentially built upon for the final rule EA.

1. **The entire EA is centered on a detailed, data-driven Monte Carlo simulation model that has been calibrated based on existing federal and state data on point-of-entry water concentrations of PFOS, PFOA, and other PFAS.**

This carefully laid approach relies on existing data to project baseline and policy scenarios under the various regulatory options. Point-of-entry pollutant concentrations are predicted across PWSs, while at the same time accounting for various system-specific factors. A particularly advantageous feature of this approach is in enabling data-driven, comprehensive sensitivity analyses. The analysis utilizes Monte Carlo simulations entailing 4,000 iterations. This allows the Agency to derive a distribution of benefit and cost estimates, and in turn quantitatively and simultaneously account for key points of analytical uncertainty by providing a range of possible net benefit calculations (e.g., a 90% confidence interval). Monte Carlo simulations like this are a common and defensible approach to account for uncertainty (EPA 2014), and are the most thorough way to simultaneously account for numerous sources of uncertainty in economic analyses (Boardman et al. 2018; OMB 2003).

As outlined in the Office of Management and Budget's Circular A-4, the Executive Branch's seminal guidance for conducting regulatory analysis, there are basically three broad approaches for accounting for analytical uncertainties (OMB 2003). In terms of increasing levels of complexity and rigor, these approaches include:

- A qualitative discussion of the main uncertainties;
- A quantitative sensitivity analysis, such as a "partial sensitivity analysis" or "worst- and best-case analysis"; and
- A probabilistic quantitative analysis using Monte Carlo simulations.

In cases where the necessary data and information are not available to assess the likelihood and outcomes of various contingencies under alternative assumptions, then a qualitative discussion of the key uncertain assumptions and potential implications for the results of the EA should be included. And in cases where the available information is limited, EPA does in fact include such qualitative assessments; for example, see Table 5-22 and Tables 6-48 through 6-53 in Chapters 5 and 6, respectively.

Other more quantitative sensitivity analyses are recommended when some quantitative information is available, but where information on the probability of alternative contingencies (or outcomes) is not. For example, "partial sensitivity analysis" is when one varies one assumption at a time, and assesses how the estimated net benefits vary across alternative assumptions (Boardman et al. 2018). This approach has two main drawbacks. First, varying only one assumption at a time may not fully bound the plausible range of results, especially in cases where there may be interactive or cascading effects across assumptions. Although one could vary multiple sets of assumptions at a time, there are only so many distinct scenarios an analyst can reasonably estimate. The second weakness is that even with a large menu of distinct scenarios, one can say nothing about the likelihood of any one scenario or results of central tendency (e.g., an average), due to the lack of an estimated probability distribution.

An alternative type of quantitative sensitivity analysis sometimes labelled "worst- and best-case analysis" (Boardman et al. 2018), allows analysts to bound the plausible range of net benefits. This is done by estimating a worst-case scenario, where for all key analytical decision points, model parameters, etc., the "worst-case" plausible assumptions are made that would result in the highest estimates of the costs and lowest estimates for the benefits. Then on the other extreme, a best-case scenario is estimated, where the underlying key assumptions are set such that the analysis will yield the highest plausible estimates for the benefits and lowest estimates of the costs. This overcomes the first weakness described above by varying all key assumptions at once, and thus providing upper- and lower-end bounds on the net benefits, and it accounts for interactive and cascading effects across assumptions. The second weakness, however, is still not addressed. One still would not know where the eventually realized benefits and costs are most likely to fall within those bounds. In other words, "worst- and best-case analysis" can reasonably bound the range of plausible net benefits, but tells us nothing about how likely one scenario is over another, or where within that range we are most likely to fall.

This final weakness is overcome by the third, and most thorough type of analysis of uncertainty – Monte Carlo simulations. Detailed Monte Carlo simulations form the underlying foundation for the entire EA for the proposed PFAS NPDWR. By taking advantage of existing data on PFAS concentrations in drinking water sources, as well as past treatment decisions of PWSs (discussed below in comment #2), the Agency was able to estimate a range of benefits and costs, as well as a probability associated with each potential realization of these estimates. In short, this yields several advantages by allowing the Agency to (i) assess the simultaneous impacts across multiple key assumptions, (ii) account for the likelihood of those assumptions and the resulting estimates of the benefits and costs that would be realized, and finally (iii) account for a range based on, for example, the 90% confidence interval, as well as the estimates of the benefits and costs that will be realized, on average. The Agency went through great efforts to gather the necessary data to not only pursue this most rigorous approach to account for analytical uncertainty, but they did so in a way that accounts for numerous points of uncertainty, and that relies squarely on existing data (as opposed to, for example, best professional judgment).

2. EPA uses an equally thorough, data-driven approach for estimating what treatment and non-treatment technologies would be adopted to comply with the rule.

EPA recognizes that there would likely be variation in what technologies PWSs adopt to comply with the proposed rule, and as such they did not simply assume all PWSs with PFAS levels above the proposed MCLs would adopt the seemingly cheapest technology. Instead, based on system and source water-specific parameters, EPA estimated systems' choices of treatment and non-treatment technologies based on data of past technology adoption choices. More specifically, a decision tree was developed to determine what treatment technologies or non-treatment approaches are feasible based on entry point, water source, and system characteristics, as well as the regulatory option being considered. Then among the feasible options, the estimated compliance approach is randomly chosen for each PWS based on the probability distribution of recently observed choices made by PWSs. In other words, holding all system and water-source characteristics constant, if a certain technology has tended to be chosen more often in practice, then that increased likelihood is accounted for in EPA's technology adoption models and subsequent cost estimates.

EPA then developed over 3,500 individual cost equations to estimate the costs of the chosen technologies based on key factors, including the corresponding technology bed life (i.e., the length of time that a technology can maintain a target pollutant removal percentage), water source, flow, etc.

Overall, this detailed, data-driven approach to estimate treatment and non-treatment approaches towards compliance, and the subsequent costs, strengthens the analysis because the cost estimates are based on empirical evidence (i.e., observed choices made by PWSs), rather than theoretical assumptions and subjective best judgements. The randomization of PWS compliance choices and subsequent costs based on the observed distribution of PWS adoption choices is layered on top of the Monte Carlo simulations discussed in comment #1, and thus further exhibits all the advantages of such an approach that are discussed above.

3. EPA correctly excludes any incremental costs to PWSs that would result from the need to dispose of spent filtration materials as hazardous waste.

The PFAS addressed by EPA's proposed NPDWRs—PFOS, PFOA, PFHxS, HFPO-DA and its ammonium salt, PFNA, and PFBS—are not currently regulated as hazardous materials under federal law, and therefore additional disposal costs that would be required by federal law for the disposal of hazardous materials should not be applied in this EA of the proposed NPDWS. In my professional experience, it is standard practice to only account for other regulations in the baseline if those regulations have been promulgated as of the time of the EA. Accounting for future potential regulations in the baseline is uncommon, and trying to account for all potential future contingencies in this regard would quickly make any EA unmanageable. If EPA later determines that PFOS, PFOA, and other regulated PFAS are hazardous materials, then any incremental increase in disposal costs for such materials over normal spent filtration material

disposal costs would be a cost of that future regulation, and not of the currently proposed NPDWS.

Overall, EPA's choice to not incorporate in its cost analysis the expense of treating spent filtration materials as hazardous waste is well-grounded in economic theory and common practice. Nonetheless, in response to stakeholder comments EPA did include such costs in an illustrative sensitivity analysis. Although beyond standard practice, this illustrative exercise demonstrates the Agency's responsiveness and desire for full transparency in the regulatory development process. As discussed in comment #11 in the next section of this memorandum, if EPA maintains this illustrative cost analysis, then the Agency should also estimate the corresponding health and environmental benefits of treating spent filtration materials as hazardous waste. This is necessary in order to make this sensitivity analysis comprehensive and balanced.

4. EPA correctly accounts for existing state-level drinking water standards for PFAS in the baseline.

EPA undertook a detailed and thorough approach to account for existing state-level standards that limit the allowable levels of certain PFAS in drinking water. These states include NJ, VT, NH, MA, MI and NY. When baseline PFAS concentration levels for system points-of-entry in these states are estimated to exceed existing state-specific MCLs, then the estimated concentrations are instead assumed to equal the state-level MCLs – i.e., it is assumed that PWSs are in full compliance with any existing state standards for PFAS in drinking water. In making this adjustment, any incremental improvements already achieved by the state programs would be correctly accounted for in the baseline, and not falsely contribute to the estimated benefits and costs of the proposed federal PFAS NPDWS. This accounting of existing state-level standards in the baseline correctly results in a reduction in both benefits and costs compared to a baseline that would incorrectly disregard existing state regulations.

5. The inclusion of co-benefits (or ancillary benefits) in benefit-cost analyses is well-grounded in economic theory.

Roughly 14% to 18% of the estimated quantified benefits of the PFAS NPDWS are due to reduced bladder cancer risks, which in the current context is a co-benefit or ancillary benefit – i.e., a benefit that results from a regulatory action but that is not the direct intent of that action (OMB 2003). More specifically, the proposed PFAS NPDWS is anticipated to also reduce disinfection byproducts, and in turn reduce the risks of bladder cancer associated with exposure to those byproducts. The inclusion of such benefits in benefit-cost analysis is directed under the Safe Drinking Water Act (SDWA) and is well-grounded in economic theory (EPA 2014, OMB 2003).

6. EPA provides a balanced and detailed qualitative accounting of the benefits and costs that could not be quantified.

Ideally, all benefits and costs of a regulatory action would be quantified and monetized, but analysts are often limited by the available information, as well as resource constraints when conducting an EA. EPA prioritizes the quantification of benefits, for example, based on the contaminants and endpoints (i.e., adverse health outcomes) where (i) the weight of evidence linking the contaminant to key biomarkers is strongest, (ii) it is possible to link the contaminant or related biomarkers to a health endpoint (e.g., cardiovascular disease) that can be monetized (i.e., valued in dollar terms based on available economic literature and practices), and (iii) the endpoint does not overlap with another benefit category. Based on my professional experience, the first two criteria are standard practice when prioritizing analytical efforts given the practical constraints in conducting empirical analyses. The third criterion helps EPA avoid "double counting." As stated in EPA's Guidelines for Preparing Economic Analyses, when estimating the effects separately for each health endpoint "it is important to avoid double counting benefits across effects as much as possible" (EPA, 2014, pg. 7-3). Additionally, given limited resources, EPA prioritizes quantification of benefits and costs that are anticipated to be the largest. In my professional experience, prioritizing in this manner is sometimes necessary, and it is an appropriate way to prioritize given the objective of providing the best and most comprehensive information possible to inform the regulatory development process.

It is important to emphasize that the lack of quantification does not imply that any unquantified benefits and costs are not relevant. Following standard practice (EPA 2014, OMB 2003), EPA goes to great lengths to detail benefits and costs that could not be quantified, but that are still relevant for the EA and the ultimate determination of whether the benefits of the proposed PFAS NPDWS exceed the costs. A systematic summary is provided in Table 7-5 in Chapter 7, and further details are discussed in Chapters 5 and 6. Based on my own professional experience, the qualitative discussion in this EA is more rigorous than others I have reviewed. The Agency goes into a lot more detail, combs the literature more thoroughly, and touches on a larger number of potential health endpoints.

Although the net benefits for the central estimates of the proposed regulatory option are negative in some scenarios (e.g., under an assumed 7% discount rate), the Agency lays out convincing evidence that the net benefits are likely positive. The net benefits are positive under an assumed 3% discount rate (see Table 7-1), and the qualitative evidence and sheer number of unquantified benefit endpoints suggest that the benefits likely do exceed the costs. Furthermore, although consideration of alternative 3% and 7% discount rates is currently the standard practice for EAs of federal regulations (OMB 2003), the lower 3% discount rate may be more appropriate in this context. See comment #15 below for details.

In any case, the reliance of the key conclusions of this EA on qualitatively discussed health benefits is not atypical. A review by Petrolia et al. (2021) of EAs for all major EPA rules from 2008 to 2019 revealed that of the 43 analyses that included non-fatal health outcomes, nine (21%) *only* included unquantified health benefits (see Figure 2 in Petrolia et al. 2021); and additional qualitative health benefits were included in the other EAs that did quantify at least one

health endpoint. In OMB's recently proposed revised guidance for economic analysis, it is emphasized that:

> "relying on materially incomplete monetized BCA [net benefits] does not offer an adequate summary of evidence intended to inform determination of the most beneficial alternative, and such reliance could even be misleading. You [(analysts)] should exercise professional judgement in identifying the importance of non-quantified factors and assess as best you can how they might change the ranking of alternatives based on estimated net benefits" (OMB 2023, pg. 5).

Potential Areas to Improve the Economic Analysis.

Although the EA for the proposed PFAS NPDWS is quite thorough and transparent, there are several areas where the EA can be further improved. The below comments entail suggestions on where further clarification or support would be helpful, as well as a few cases where additional or revised analysis should be considered.

7. The analysis assumes that population is held constant based on 2021 levels for the entire 80-year study period.

If population is projected to increase over this time, then this constant population assumption would result in an underestimate of the benefits and of the costs. The EA would be improved if EPA considers available projections and/or current population trends when estimating future benefits and costs. EPA recognizes this area for improvement, and in Chapter 6 (Table 6-48) EPA discusses how they intend to account for population trends in the final rule EA. I encourage the Agency to pursue such revisions for the final rule EA.

8. Concentrations of PFOS, PFOA, and other PFAS at system entry points are simulated/projected based on data of past occurrences, and as such EPA is assuming that entry point PFAS concentrations are constant over time.

This assumption is explicitly stated on page 4-23, but the validity of this assumption is unclear. There are assumptions being made here in terms of stock PFAS concentrations in water sources, and implicitly the future use and releases of PFAS into drinking water sources. The high degree of persistence of PFAS, along with various confounding trends over time that the EA mentions (e.g., voluntary phaseout programs, industry trends, and trends in human exposure[1]) make it difficult to assess the validity of this assumption. Put plainly, how representative are the data of current and recently observed PFAS concentrations compared to those expected in the future under the baseline (i.e., business as usual) scenario? To the extent that baseline stock concentration levels and the use of PFOS, PFOA, and other PFAS chemicals in industrial processes and consumer products, and subsequent releases into the environment, have been

[1] For example, on page 2-1 of the EA it is noted that that PFOA human blood levels have been decreasing.

decreasing, then both benefits and costs in the EA would be overestimated. The opposite is true if current baseline trends suggest an increase in future concentration levels of these chemicals at PWS points-of-entry.

The EA would be improved by providing additional support for the assumption that future baseline PFAS concentrations will be similar to recently observed concentrations, and/or by adding discussion of the resulting uncertainties regarding this assumption to Table 4-34.

9. Do the occurrence and concentrations of PFAS in water at PWS points-of-entry vary depending on whether the source is surface water or groundwater?

The Monte Carlo simulations used to predict baseline and policy scenario levels of these pollutants is very thorough in accounting for key factors that may lead to differences in pollutant levels (e.g., system size). However, it does not seem that the water source was accounted for when estimating point-of-entry concentration levels. If observed concentrations in the past vary across surface versus ground water sources in the data used to calibrate the Monte Carlo simulations, then this is another source of heterogeneity that should be explicitly accounted for to improve those models.

The agency was careful to make distinctions in the technology cost curves based on water source, so perhaps such heterogeneity is also important for modelling the occurrence and concentrations of PFAS at PWS points-of-entry.

10. Are the state-level water quality data used to supplement the federal data when calibrating the Monte Carlo simulation models representative?

EPA relies primarily on federal water quality data to estimate point-of-entry concentrations of PFOA, PFOS, PFNA, HFPO-DA and its ammonium salt, PFHxS, and PFBS. EPA took an extra step and supplemented the federal data with state-level data from 11 states on point-of-entry concentrations. The state-level data are described as being useful because of the lower detection limits for identifying PFAS concentrations (pg. 4-20). At the same time, the EA would be strengthened with additional discussion regarding the representativeness of these state-level data. In particular, is there a potential selection bias to consider?

Additional qualitative discussion of this potential lack of representativeness may be sufficient. Or perhaps additional descriptive statistics can be provided to demonstrate the representativeness of the state-level data from these 11 states compared to the rest of the U.S.; perhaps by comparing PFAS concentrations across states with versus without state-level data based on the more widely available UCMR 3 federal data.

11. EPA provides a supplemental, illustrative analysis of the costs of compliance with the proposed NPDWS if spent filtration materials were regulated as hazardous waste, but to be fully objective, this illustrative analysis should also demonstrate the benefits of such an action.

As noted in comment #3 in the above section, in the main analysis EPA correctly excludes any incremental increase in PWS disposal costs that are specific to hazardous materials. The Agency does, however, provide an illustrative analysis of the disposal costs if PFAS were regulated as a hazardous material.

In my professional opinion, it is misleading to present this illustrative exercise for just the costs, without also discussing the benefits. To be fully transparent and balanced, it would be informative to provide a companion illustrative analysis of the corresponding environmental and health benefits that would result from treating spent filtration materials as a hazardous waste.

12. Any environmental benefits anticipated to result from the proposed regulatory action should be included in the EA.

The quantified and qualitative benefits identified in the EA focus solely on human health. Given the persistence of PFAS pollutants, PFAS that are left untreated by a PWS in the baseline likely would be passed through the entire system and eventually released back into the environment. If this is the case, then the proposed MCLs would reduce the concentrations of PFAS in the public water before it is eventually discharged into the environment, and thus reduce any adverse impacts to ecosystem services and other environmental endpoints. EPA should consult with environmental risk assessors and ecotoxicologists, but if reasonable, then such benefits at the very least deserve a qualitative discussion and consideration in the EA.

13. EPA should reconsider whether additional health benefits can be quantified and/or monetized.

As described in comment #6, EPA went to impressive lengths to identify and qualitatively discuss potential health benefits that it asserted could not be quantitatively estimated. However, in developing the final rule EA, EPA should consider whether there is adequate information to support quantification and/or monetization of additional benefits. As per EPA's (2014) own economic guidelines, analysts should try to get as far as possible in first *identifying* all key benefit and cost categories. The next step (when possible) is to then *quantify* the projected change in each benefit and cost outcome that is expected to result from the policy option, relative to the baseline. Quantifying in this case means to measure the change in terms of some quantitative metric, such as the number of lives saved, number of cases prevented, etc. The final step is to *monetize* the quantified change, meaning that a dollar value is assigned. EPA spent significant effort in monetizing benefits when possible, and then qualitatively identifying and discussing other benefits, but the Agency should consider whether there is adequate information to at least quantify additional benefit categories in the final EA.

As suggested by OMB's recently proposed revisions to Circular A4 (OMB 2023), EPA should consider highlighting the expected magnitude of some of the qualitatively discussed benefits. For example, quantified estimates of the number of individuals potentially exposed, and/or that are susceptible to the increased risks and that would therefore benefit from the proposed regulatory options, would provide further insight and aid the qualitative discussion. In other words, perhaps the quantification step can be taken to some degree for some benefit categories, even if fully monetizing a benefit category is not possible.

Additionally, there may be health outcomes where quantification is not possible, but perhaps monetary cost-of-illness (COI) or willingness to pay (WTP) estimates exist. In such cases, as suggested by the Agency's own economic guidelines (EPA 2014), EPA should consider illustrative analyses or perhaps even a full-blown "break-even" analysis, to provide further insight to the potential magnitude of the qualitatively discussed benefits and plausibility that those unquantified benefits may further result in positive net benefits. Such analyses are recommended in cases where unquantified benefits could be meaningful (OMB 2003, 2023).

Finally, EPA should thoroughly evaluate information submitted during the public comment period for the proposed rule and assess whether additional health benefits can be identified, quantified, and ideally monetized in the EA for the final rule. For example, the comments submitted by Earthjustice and the Natural Resource Defense Council (NRDC) include estimates of lactation duration effects attributable to increased exposures to PFOA, PFOS, PFHxS, and PFNA. Impacts of PFAS exposure on breastfeeding, and the resulting impacts to infant and maternal health are not currently discussed in the EA. At the very least, this is a benefit category that deserves qualitative discussion, and as the commenters' analysis suggests, perhaps quantification and even monetization of these benefits is possible. As another example, on page 6-21 of the EA, EPA states that hepatic effects were not quantified or monetized because PFAS exposure could not be linked to a health endpoint (i.e., an increased incidence of disease). However, more recent studies discussed in the comments submitted by Earthjustice and NRDC may allow for quantification, and perhaps even monetization of this important benefit category.

14. The EA includes several alternative regulatory options, but all options are less stringent than the proposed option. Why were no more stringent regulatory options considered?

OMB's Circular A4 (2003) and EPA's (2014) economic guidelines suggest analyzing an array of alternative regulatory options, with at least one more stringent and one less stringent than the proposed option. The proposed PFAS NPDWR EA only includes less stringent alternative regulatory options. To strengthen the EA, EPA should evaluate a more stringent regulatory option or explicitly describe the rationale for not including a more stringent option. For example, Circular A4 (OMB 2003) states that more stringent regulatory alternatives are not required in cases where the proposed option is near or at the limits of what is technically feasible.

15. EPA should further consider whether the central EA results should focus more on the lower 3% discount rate.

Although equal consideration of alternative 3% and 7% discount rates is currently the standard practice for EAs of federal regulations (OMB 2003), EPA should consider whether the lower 3% discount rate is more appropriate in the current context. This could be the case for several reasons, including the long 80-year time period for the analysis, the fact that future generations are impacted, and the considerable uncertainties in the magnitude of the future health benefits.[2] Additionally, EPA states on page 2-3 of the EA that "OMB's Circular A-4 indicates that a 3 percent discount rate represents the rate that an average saver uses to discount future consumption and *is therefore more appropriate for this rulemaking*." [Emphasis added.] Given this rationale, discussions in the literature (e.g., Howard and Schwartz 2022), and the recently proposed revised guidance from OMB (2023) regarding discount rates, EPA should consider focusing the central analysis primarily on an assumed 3% (or even lower) discount rate, rather than treating the 3% and 7% assumptions as being equally valid in the main analysis.

16. Uncertainty around the cost of illness (COI) estimates for each non-fatal health endpoint that was quantified is not accounted for.

The quantified examination of analytical uncertainty is quite thorough throughout the EA with respect to other "upstream" analytical steps, and in points where it is not, EPA is still transparent in describing any shortcomings. Nonetheless, the reliance on just central COI estimates is a weakness that could be addressed. For example, a sensitivity analysis could be conducted based on the statistical distribution of the COI estimates from the literature, or perhaps other bounding values if the primary studies did not estimate the COI values using statistical methods. That said, perhaps such an exercise is not worth the additional effort if this source of uncertainty is expected to be trumped by numerous other points of uncertainty that are addressed in the Monte Carlo simulations. If this is expected to be the case, then EPA should make such assertions explicit in the EA.

17. Is it possible to incorporate broader opportunity costs into the cost-of-illness (COI) estimates for reduced risks of low birth weight, cardiovascular disease, and renal cancer?

The Agency correctly includes avoided direct expenditures for medical care, as well as broader opportunity costs – namely the opportunity cost of time (e.g., missed work days) – in the COI estimates for reduced risks of bladder cancer. But these broader opportunity costs are not accounted for in the COI estimates for reduced risks of low birthweight, cardiovascular disease, and renal cancer. The COI estimates for these three non-fatal health outcomes only account for

[2] See the "Discount Rates" section in the proposed revisions to Circular A-4 (OMB 2023), for example, for further details.

avoided medical expenditures. EPA recognizes this shortcoming in various parts of Chapter 6, and points out that these exclusions are due to the lack of available estimates in the literature.

Nonetheless, this omission likely results in a significant underestimate of the benefits. For example, Table 6-43 shows that for bladder cancer (the one non-fatal health outcome where broader opportunity cost estimates are included), the opportunity cost of time beyond medical expenditures makes up 27% to 32% of the total COI estimates for the first year. If a similar proportional scaling is applicable to the other non-fatal health outcomes, then the missing portion of the COI-based benefits for non-fatal cardiovascular disease, renal cancer, and low birthweight cases would be substantial. In the final rule EA, the Agency should consider whether it is possible to incorporate these broader opportunity costs into their COI estimates for these three non-fatal health outcomes.

Even if the inclusion of the broader opportunity costs into these COI estimates is legitimately not possible given the available literature, EPA should still consider a bounding exercise where the available COI estimates for low birth weight, cardiovascular disease, and renal cancer are scaled-up based on the COI estimates for bladder cancer, or perhaps for more similar non-fatal health endpoints where the available literature does provide more comprehensive COI estimates. Such a bounding exercise would require considerable judgement, but at the same time, we know that assuming the opportunity cost of time associated with these adverse health outcomes is zero (as the EPA currently does) is not correct.

18. Did EPA consider using willingness to pay (WTP) estimates to monetize reductions in non-fatal human health outcomes?

The use of COI estimates to monetize the benefits of reduced risks of non-fatal health outcomes, as EPA does, is standard (EPA 2014), and in my professional experience is generally deemed acceptable for policy analysis. Nonetheless, a theoretically more appropriate approach (when available) is to use estimates of WTP (OMB 2003). For example, WTP estimates better account for "pain and suffering and other quality-of-life effects" (OMB 2023, pg. 48). It is unclear whether such estimates are available in the peer-reviewed literature, but EPA should include a review of the literature and discussion of why available WTP estimates are or are not appropriate to use in the EA.

I would also like to point out that the Organisation for Economic Co-operation and Development (OECD) has implemented stated preference studies that estimate the public's WTP for reductions in the risks of various non-fatal health outcomes that result from reduced exposure to toxic chemicals (OECD, n.d.). Their research includes reductions in the risks of adult asthma, chronic kidney disease, fertility loss, and of particular relevance to the current EA, cases of low birth weight. It is unclear whether the results of the OECD's studies are yet available, but if they are available now or by the time of the final rule EA is being conducted, then the Agency should consider using such estimates (when applicable) in lieu of the current COI estimates.

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Exhibit 1:
Curriculum Vitae

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EDUCATION:

Ph.D. Agricultural and Resource Economics, University of Maryland, College Park, MD, 2011.

M.S. Agricultural and Resource Economics, University of Maryland, College Park, MD, 2009.

B.S. Environmental and Renewable Resource Economics, The Pennsylvania State University, State College, PA, 2006. *Highest Distinction*. Minor in Geographical Information Systems (GIS).

EMPLOYMENT:

Assistant Professor, Department of Economics, Appalachian State University, Boone, NC.	2018 - present
Research Economist, National Center for Environmental Economics, US Environmental Protection Agency, Washington, DC.	2011 – 2018
Lecturer, Department of Agricultural and Resource Economics, University of Maryland, College Park, MD.	2017 – 2018
Adjunct Assistant Professor, Department of Economics, American University, Washington, DC.	2016 – 2017
Research Assistant, Fondazione Eni Enrico Mattei (FEEM), Milan, Italy.	2010 – 2011
Research Assistant, Department of Agricultural and Resource Economics, University of Maryland, College Park, MD.	2006 – 2010
Research Assistant, Department of Agricultural Economics and Rural Sociology, The Pennsylvania State University, State College, PA.	2005 – 2006

TEACHING:

Appalachian State University

ECO 2030: Principles of Microeconomics. 2018-2022.
ECO 4660/5660: Benefit-Cost Analysis. 2019-2021.
ECO 4810: Seminar in Economics (Senior Capstone Course). 2022.

TEACHING (cont.):

University of Maryland

AREC 240: Introduction to Economics and the Environment. 2017.

American University

ECON 379: Economics of Environmental Policy. 2016-2017.

Teaching Assistant

AREC 200: The Chesapeake Bay Ecosystem: Intersection of Science, Economics, and Policy. University of Maryland. 2010-2011.

CHEM 12: Chemical Principles. The Pennsylvania State University Berks-Lehigh Valley. 2003.

PUBLICATIONS:

Guignet, Dennis, and Christoph Nolte (2023), "Hazardous Waste and Home Values: An Analysis of Treatment and Disposal Sites in the U.S.," *Journal of the Association of Environmental and Resource Economists*, forthcoming.

Walsh, Patrick J., Dennis Guignet, and Pamela Booth (2023), "Eliciting Policy Relevant Stated Preference Values for Water Quality: An Application to New Zealand," *Agricultural and Resource Economics Review*, forthcoming.

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PUBLICATIONS (cont.):

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WORKING PAPERS:

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Guignet, Dennis, Robin R Jenkins, Christoph Nolte, and James Belke (2023), "The External Costs of Industrial Chemical Accidents: A Nationwide Property Value Study," US EPA National Center for Environmental Economics Working Paper, 23-01, Washington, DC, February.

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WORKING PAPERS (cont.):

Guignet, Dennis, Christopher Moore, and Haoluan Wang (2020), "Hot Spots, Cold Feet, and Warm Glow: Identifying Spatial Heterogeneity in Willingness to Pay," US EPA National Center for Environmental Economics Working Paper, 20-01, Washington, DC, March.

Maguire, Kelly B., Chris Moore, Dennis Guignet, Chris Dockins, and Nathalie B. Simon (2018), "Muddying the Water? An Analysis of Non-Constant Baselines in Stated Preference Surveys," US EPA National Center for Environmental Economics Working Paper, 18-02, Washington, DC, May.

Guignet, Dennis (2014), "To Sell or Not to Sell: The Impacts of Pollution on Home Transactions," US EPA National Center for Environmental Economics Working Paper, 14-01, Washington, DC, January.

PRESENTATIONS:

"The External Costs of Industrial Chemical Accidents: A Nationwide Property Value Study," US Department of Agriculture Economic Research Service Seminar Series, Kansas City, MO, September 2022.

"The Impacts of Mitigating Hazardous Chemical Exposure on Infant Health," Association of Environmental and Resource Economists' Annual Summer Conference, Miami, FL, June 2022.

"The Property Value Impacts of Industrial Chemical Accidents," 2022 Appalachian Experimental and Environmental Economics Workshop, Appalachian State University, Boone, NC, April 2022.

"The Property Value Impacts of Industrial Chemical Accidents," Centre for Environmental and Resource Economics Seminar Series, Umeå University and the Swedish University of Agricultural Sciences, Umeå, Sweden, September 2021.

"Hazardous Waste and Home Values: An Analysis of Treatment and Disposal Sites in the U.S.," 2021 PLACES Webinar: Land, Water, and ZTRAX, Boston, MA, June 2021.

"Hazardous Waste and Home Values: An Analysis of Treatment and Disposal Sites in the U.S.," presented at the Northeastern Agricultural and Resource Economics Association's Virtual Conference, June 2021.

"Hazardous Waste and Home Values: A Nationwide Quasi-Experiment of RCRA Sites," presented at the Department of Economics Seminar Series, University of Calgary, Calgary, Canada, April 2021.

"Hazardous Waste and Home Values: A Nationwide Quasi-Experiment of RCRA Sites," presented at the Center for Health Economics and Policy Studies Seminar Series, San Diego State University, San Diego, CA, March 2021.

PRESENTATIONS (cont.):

"Quasi-experimental Methods to Value the Cost of Hazardous Releases and Cleanups," presented at the Private-Land Conservation Evidence (PLACES) Lab's Research and Data Workshop, Boston, MA, June 2020.

"Property Values and Water Quality: A Nationwide Meta-Analysis and the Implications for Benefit Transfer," presented at a US Department of "Applications and Potential of Ecosystem Services Valuations within USDA – Advancing the Science" Workshop, Washington, DC, April 2019.

"Examining Non-response Bias in Stated Choice Experiments," presented at the Southern Economic Association's Annual Conference, Washington, DC, November 2018.

"The Spatial Distribution of WTP and Status Quo Effects: An Application to the Chesapeake Bay Watershed," presented at the Northeastern Agricultural and Resource Economics Association's Annual Meeting, Philadelphia, PA, June 2018.

"Property Values and Water Quality: A Nationwide Meta-Analysis and the Implications for Benefit-Transfer," presented at the 10th Annual Conference of the Society for Benefit Cost Analysis, Washington, DC, March 2018.

"Stated Preference Methods & Valuing Surface Water Quality Improvements," presented at the National Socio-Environmental Synthesis Center's (SESYNC) Seminar Series, Annapolis, MD, May 2017.

"The Property Value Impacts of Groundwater Contamination: Agricultural Runoff and Private Wells," presented at the Northeastern Agricultural and Resource Economics Association's Water Quality Economics Workshop, Newport, RI, June 2015.

"Do Home Values Respond to Underground Storage Tank Releases? An Examination of High-Profile Cases Across the US," presented at the Northeastern Agricultural and Resource Economics Association's and the Canadian Agricultural Economic Society's Joint Annual Meeting, Newport, RI, June 2015.

"A Stated Preference Study of the Chesapeake Bay and Watershed Lakes," presented at the Allied Social Science Associations' (ASSA) 2015 Meeting, Boston, MA, January 2015.

"The Implicit Price of Aquatic Grasses," presented at Resources for the Future's (RFF) Academic Seminar Series, Washington, DC, October 2014.

"The Implicit Price of SAV: A Hedonic Study of the Chesapeake Bay," presented at the Northeast Agricultural and Resource Economics Association's Annual Meeting, Morgantown, WV, June 2014.

"To Sell or Not To Sell: The Impacts of Pollution on Home Transactions," presented at the 6th Annual Conference of the Society for Benefit Cost Analysis, Washington, DC, March 2014.

PRESENTATIONS (cont.):

"To Sell or Not To Sell: The Impacts of Pollution on Home Transactions," presented in Sponsored Session at the Association of Environmental and Resource Economists' 3rd Annual Summer Conference, Banff, Canada, June 2013.

"Can Property Values Capture Changes in Environmental Health Risks: Evidence from a Stated Preference Study in Italy and the UK," presented at the Association of Environmental and Resource Economists' 2nd Annual Summer Conference, Asheville, NC, June 2012.

"What do Property Values Really Tell Us? A Hedonic Study of Pollution from Underground Storage Tanks," presented at the Annual Conference of the Society for Benefit Cost Analysis, Washington, DC, October 2011.

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"A Hedonic Analysis of the Impact of LUST Sites on House Prices," presented at the Association of Environmental and Resource Economists' Inaugural Summer Conference, Seattle, WA, June 2011.

"Environmental Health Risks and Home Values: A Revealed and Stated Preference Analysis," presented in the Research Sketches Session at the National Bureau of Economic Research (NBER) Environmental and Energy Economics Workshop, Cambridge, MA, July 2010.

"The Effects of LUSTs on Home Values: Is Proximity Enough?," presented at the 4th World Congress of Environmental and Resource Economists, Montreal, Canada, July 2010.

"LUSTs as Contaminated Sites: What are the Effects on Property Values?," presented at the 17th Annual Conference of the European Association of Environmental and Resource Economists, Amsterdam, The Netherlands, June 2009.

"Participation in Voluntary Cleanup Programs: A Case Study of Maryland," presented at the International Atlantic Economic Conference, Savannah, GA, October, 2007.

FELLOWSHIPS AND GRANTS:

Faculty Research Fellowship, Office of Land and Emergency Management, US Environmental Protection Agency, Research Participation Program administered by the Oak Ridge Institute for Science and Education (ORISE), 2019-2024.

Undergraduate Research Assistant Support Grant, Office of Student Research, Appalachian State University, 2022, $2,200.

FELLOWSHIPS AND GRANTS (cont.):

Dean's Club Summer Research Grant, Walker College of Business, Appalachian State University, 2021-2022, $6,000.

Conducting Complex Research Together Grant, Research Institute for Environment, Energy, and Economics, Appalachian State University, 2019-2020, $4,650.

Dean's Club Grant, Walker College of Business, Appalachian State University, 2019-2020, $4,000.

Undergraduate Research Assistant Support Grant, Office of Student Research, Appalachian State University, 2019-2020, $2,000.

CONSULTING:

Earthjustice, United States (2023)
Organisation for Economic Co-operation and Development (OECD), France (2021-2022)
Landcare Research, New Zealand (2018-2019)

AWARDS:

Dean's Club Research Prize: 1st Place, Walker College of Business, Appalachian State University (2020, 2023)
Scientific and Technological Achievement Award: Level III Award, Office of Research and Development, US Environmental Protection Agency (2021)
Bronze Medal for Commendable Service, US Environmental Protection Agency (2016)
Partners of OW Award, Office of Water, US Environmental Protection Agency (2016)
Scientific and Technological Achievement Award: Honorable Mention, Office of Research and Development, US Environmental Protection Agency (2015)
Trudy A. Speciner Non-Supervisory Award for Advancing Environmental Protection, US Environmental Protection Agency (2014)
Superior Efforts and Contributions Award, Office of the Administrator, US Environmental Protection Agency (2012, 2014, 2016)
Young Professional Travel Grant, Agricultural and Applied Economics Assoc. (2011)
Award for Excellence and Innovation in Undergraduate Teaching in the Marquee Courses in Science and Technology, University of Maryland (2011)
Distinguished Teaching Assistant, University of Maryland (2010)
Jacob K. Goldhaber Travel Award, University of Maryland (2009)
Graduation Marshall, College of Agricultural Sciences, Pennsylvania State University (2006)
Evan Pugh Scholar Senior Award, Pennsylvania State University (2006)
Goizueta Scholars Award, The Goizueta Foundation (2005)
The Honor Society of Agriculture Gamma Sigma Delta's Junior Scholarship (2005)
Evan Pugh Scholar Junior Award, Pennsylvania State University (2004)
The Honor Society of Agriculture Gamma Sigma Delta's Sophomore Scholarship (2004)
President's Freshman Award, Pennsylvania State University (2002)
Eagle Scout, Boy Scouts of America (2001)

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Agricultural and Resource Economics Review (2022, 2019, 2015), *Ecological Economics* (2013), *Economics* (2017), *Energy Economics* (2021), *Environmental and Resource Economics* (2014, 2021, 2022), *Environment and Planning C: Government and Policy* (2013), *Environmental Economics and Policy Studies* (2018), *Health Affairs* (2011), *International Journal of Sustainable Transportation* (2016), *International Regional Science Review* (2014), *International Journal of Urban Sciences* (2017), *Journal of the Association of Environmental and Resource Economists* (2019), *Journal of Environmental Economics and Management* (2023, 2022, 2020, 2019, 2018, 2017, 2014, 2011, 2010), *Journal of Housing Economics* (2020), *Journal of Regional Science* (2020), *Land Economics* (2022, 2020, 2017, 2016, 2015, 2014, 2012), *Leisure Sciences* (2015), *Marine Resource Economics* (2020), *Policy Sciences* (2012), *Proceedings of the National Academy of Sciences* (2019), *Regional Science and Urban Economics* (2011), *Resource and Energy Economics* (2019, 2018, 2015, 2014), *Science of the Total Environment* (2018), *Sustainability* (2017, 2015), *Water Economics and Policy* (2015).

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Chair: Selected Papers Committee, Northeastern Agricultural and Resource Economics Association's 2023 Annual Conference, 2022-2023.
Panel Review Member: National Science Foundation (NSF), 2022.
Session Chair: Pollution Exposure and Children's Cognitive and Health Outcomes session at the Association of Environmental and Resource Economists' Conference, Miami, FL, 2022.
Panel Review Member: US Environmental Protection Agency, 2022.
Session Co-organizer: 2021 PLACES Webinar: Land, Water, and ZTRAX, 2021.
Discussant: Association of Environmental and Resource Economists' Virtual Conference, 2020.
Expert Reviewer: University of Wisconsin Water Resources Institute, 2019.
Expert Reviewer: Inter-American Development Bank, Workshop on Discrete Choice Experiment on Housing in Mexico City, 2019.
Program Committee Member: Association of Environmental and Resource Economists' sponsored sessions at the Southern Economic Association Annual Conference, 2019.
Reviewer: US Department of Agriculture sponsored workshop on Applications and Potential Ecosystem Services Valuation within USDA, 2018.
Session Chair: Benefit-Cost Analysis session sponsored by the Association of Environmental and Resource Economists at the Southern Economic Association's Annual Conference, Washington, DC, 2018.
Session Chair: Hedonic Price Studies and BCA session at the 10th Annual Conference of the Society for Benefit Cost Analysis, Washington, DC, 2018.
Book Reviewer: *Environmental & Natural Resource Economics* (11th ed.) by Tom Tietenberg & Lynne Lewis, Taylor & Francis, 2017.
Panel Review Member: US Department of Housing and Urban Development National Disaster Resilience Competition, 2015.
Moderator: The Northeastern Agricultural and Resource Economics Association's and the Canadian Agricultural Economic Society's Joint Annual Meeting, Newport, RI, 2015.
Member: Selected Papers and Symposia Committee, Northeastern Agricultural and Resource Economics Association's 2016 Annual Conference, 2015-2016.

Moderator: US Environmental Protection Agency sponsored workshop on the Economics of Water Quality Improvement in Chesapeake Bay, Washington, DC, 2011.
Discussant: The Agricultural and Applied Economics Association and Northeastern Agricultural and Resource Economics Association's Joint Annual Meeting, Pittsburgh, PA, 2011.
Discussant: 4th World Congress of Environmental and Resource Economists, Montreal, Canada, 2010.
Discussant: 17th Annual Conference of the European Association of Environmental and Resource Economists, Amsterdam, The Netherlands, June 2009.
Discussant: International Atlantic Economic Conference, Savannah, GA, Oct. 2007.

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Exhibit C

Analysis of the USEPA Proposed PFAS National Primary Drinking Water Regulation Treatment Costs and Comparison to the AWWA National PFAS Cost Model Report

May 30, 2023
Prepared by Elin Warn Betanzo, Safe Water Engineering, LLC
Peer reviewed by Professor Vanessa Speight, University of Sheffield, UK.

This report was funded by the Natural Resources Defense Council (NRDC). The views contained herein are those of the author and do not necessarily reflect those of NRDC.

Contents

Analysis of the USEPA Proposed PFAS National Primary Drinking Water Regulation Treatment Costs and Comparison to the AWWA National PFAS Cost Model Report

Prepared by Elin Betanzo, Safe Water Engineering, LLC

Executive Summary

The presence of per- and polyfluoroalkyl substances (PFAS) in drinking water sources has emerged as a pressing environmental and public health concern over the last decades. These persistent and bioaccumulative chemicals, commonly found in firefighting foam, nonstick cookware, and numerous other consumer products, have been linked to various adverse health effects. As a result, the United States Environmental Protection Agency (EPA) has undertaken the task of proposing regulations to limit the concentration of PFAS in drinking water.

The proposed regulation would establish enforceable maximum contaminant levels (MCLs) of PFAS in drinking water supplies. This analysis, requested and paid for by the Natural Resources Defense Council, focuses on the potential financial burden of installing treatment to comply with the EPA's proposed PFAS regulation. This analysis also includes a comparison with the American Water Works Association (AWWA) PFAS National Cost Model Report (AWWA, 2023), which provides an industry perspective on the costs associated with PFAS treatment.

These analyses seek to understand realistic treatment costs that would be triggered by the regulation. Furthermore, comparing the EPA's cost estimates to those provided by the AWWA National PFAS Cost Model Report will offer valuable insights into the potential variations and discrepancies between regulatory projections and industry-based assessments. This exploration of the intricacies of these analyses will help inform the overall Economic Analysis to ensure costs are assigned to the rule that will realistically allow water systems to install treatment and achieve the public health benefits anticipated for the new requirements.

Although the USEPA analyzed complete compliance costs for the proposed rule, including sampling and state oversight, this present analysis focuses only on the cost of treatment installation and annualized operations and maintenance (O&M). When AWWA published their analysis, the published proposed rule was not yet available. AWWA estimated the cost of 3 potential compliance options. Although the first AWWA compliance scenario, MCLs of 4 ppt for PFOA and PFOS, does not match the EPA proposed rule (which also includes a Hazard Index of 1.0), it does match USEPA's Option 1a. Because the same modeling methods are used in all options presented in each report, this analysis compares EPA's Option 1a to AWWA's first compliance scenario.

Table 1: EPA and AWWA Modeled Annualized Water System Treatment Costs for Achieving 4.0 ppt for PFOA and PFOS

	EPA	AWWA
Modeled Annualized WS Treatment Costs for achieving 4.0 ppt for PFOA and PFOS	$658,510,000	$3,803,926,000

Estimating national costs for drinking water rules requires applying assumptions and professional judgement, especially when there are limitations in availability of occurrence data. Although it is a tricky task, it is a necessary task to estimate the necessary funding for protecting public health. Both cost estimates inform and help move the conversation forward. This memo attempts to identify the sources of the $3.1 billion difference between these two cost estimates and identify which modeling assumptions are more likely to reflect a realistic compliance forecast and reasonable engineering judgement.

The analysis that follows shows that the $3.1 billion dollar difference in annualized cost can be explained by the following primary factors:

1. **Discount rate used.** EPA presented cost estimates using both a 3% and 7% discount rate, which is consistent with current OMB guidance. AWWA presented costs for only the 7% rate. In the Economic Analysis, EPA notes that the lower, consumption-based discount rate is more appropriate for this rulemaking (Economic Analysis at 2-3), a conclusion that is supported by the economics literature (Howard and Schwartz, 2002). This factor alone explains $1 billion of the cost difference (Appendix A). The AWWA approach in this case is an overestimate. Factoring other cost considerations described below, in addition to the excess discount rate, would increase the magnitude of impact of the different discount rates. Further, OMB recently published draft revisions to its guidance (White House Office of Management and Budget, 2023) that favor a substantially lower consumption-based discount rate of 1.7%, consistent with Howard and Schwartz (2002). EPA's assertion that the lower, consumption-based discount rate is more appropriate for this rulemaking is supported by the literature and OMB's proposed update to its guidance. Both indicate that even the 3% consumption-based discount rate EPA used here may be significantly higher than appropriate.

2. **Screening of occurrence datasets.** Both EPA and AWWA relied on UCMR3 data collected by water utilities across the country. In addition, both approaches also used state data. EPA, as documented in Cadwallader et al., 2022, screened state data to only look at finished water samples and limited to UCMR3 water systems so occurrence samples would not be biased high due to non-PWS PFAS samples or PWS samples collected by water systems investigating known PFAS contamination sites (not necessarily used as drinking water sources). The inclusion of non-PWS samples resulted in higher median PFOA and PFOS data in the AWWA analysis and explains AWWA's 4,709 small systems required to comply vs EPA's 3,251 (Appendix B). The potential bias in the AWWA method indicates either the EPA approach is more appropriate, or the actual answer is somewhere between the two estimates. On the other hand, AWWA found a lower occurrence rate in large systems compared to EPA. This may be due to reliance on the UCMR3 data with higher detection limits for large system sampling. A model was described in Cadwallader et al., 2022 to fill in the non-detect median PFOA and PFOS levels. Developing a model may have been beyond the scope of the AWWA 2023 estimate, resulting in the difference in large systems exceeding the MCLs.

3. **Treatment of Entry Points.** EPA calculates treatment and O&M cost per entry point to the distribution system (EPTDS) that exceeds the MCL using modeled system and flow characteristics. Some PWSs have more than one entry point that requires treatment; costs are assigned per entry point that exceeds the MCL. AWWA calculates the number of PWSs that

exceed the MCL, assumes that every PWS that exceeds the MCL has the average number of entry points per system for a system in that size category, and assumes every entry point in that system will require treatment regardless of whether a given entry point exceeds the MCL. This assumption results in 3,645 more entry points with treatment installation in the AWWA analysis that may not actually require treatment, and impacts both capital and O&M costs. A conservative estimate of the overall impact of this assumption, using the number of PWSs that AWWA estimated exceed the MCL along with EPA's metric of 1.3 entry points exceeding the MCL per PWS for small systems and 3.1 for large systems, is an overestimate of $1.4 billion (Appendix C).

4. **Non-treatment compliance options.** AWWA assumes all PWSs that exceed the MCL will install treatment at every entry point, and EPA assumes that small systems will explore interconnections with other complying systems and new sources before installing treatment. As one example, Michigan Department of Environment, Great Lakes, and Energy (EGLE) personnel have indicated that it is policy to investigate safe water options before considering installation of treatment on a source that exceeds an MCL (Smith, Personal Communication 2023). Michigan's analysis exploring the existing Michigan MCLs and the proposed EPA rule indicates that EPA's estimates of systems opting for non-treatment are reasonable and may even be low (Smith, Personal Communication 2023). Michigan anticipates that up to 26% of PWSs requiring treatment may be able to establish a new connection with another PWS that already meets the MCLs. In this case, both the EPA and the AWWA cost estimate for treatment may be high. Using EPA's assumptions for establishing new interconnections or new sources would result in at least $159 million in savings compared to AWWA. (Appendix D).

5. **Differences in flow calculations**. EPA and AWWA use different average flow assumptions. EPA uses inventory data, and AWWA assumes 150 gpd per person with published populations to calculate average flow. According to the USGS (Dieter et al., 2018), the AWWA assumption of 150 gpd per person is high, compared to their estimate of 82 gpd. This indicates that EPA flows may be more appropriate. The AWWA estimate also does not reflect regional differences in water use. Even though essentially the same peaking factors are used, AWWA ends up with higher design flows for systems serving <10,000 compared to EPA (Appendix E). The higher AWWA flows result in larger capital and O&M costs relative to actual flow requirements and are magnified even further when applied to the overestimate of entry points requiring treatment in small systems. On the other hand, Appendix E shows that for ground water CWSs serving >=10,000 EPA flows are higher than AWWA estimated flows. This is not an apples-to-apples comparison because the EPA estimate does not include surface water CWSs, but it means there may not be a differential impact in costs for systems serving >=10,000. The total magnitude of the net impact of differences in flow between the two estimates is unclear because equivalent datasets are not available. However, the AWWA excess flows assumed for small systems likely results in net larger magnitude costs in AWWA compared to EPA.

6. **Cumulative impact of cost assumptions for small systems (serving <10,000).** The EPA model assumes that package plants, at a lower cost point, are available for entry points <1 MGD. Package plants have been an option for reducing costs for small systems for decades (National Drinking Water Clearinghouse, 1997), but this option is not described as incorporated in the AWWA estimate. The EPA estimate for cost savings from package plants may be conservative as

some package plants may be available up to 6 MGD flows and PWSs typically seek the lowest cost option available for compliance. The cumulative impact of the points raised here: lack of package plants, higher than actual design flows, treatment of unnecessary entry points, and lack of non-treatment options means that AWWA does not provide a realistic cost estimate for small systems.

7. **Magnitude of treatment cost inputs**. EPA's Economic Analysis (2023a), Technologies and Costs document (2023b), and Work Breakdown Structure Model documents (e.g., 2021a) provide hundreds of pages of documentation of the EPA cost analysis process whereas AWWA 2023 provides 36 pages with no references. The difference in documentation makes it impossible to compare cost inputs one to one, but it is possible to insert AWWA's flow assumptions into the EPA model to explore the net magnitude of underlying cost assumptions by comparing average systems. Appendix F shows that for small system capital costs, AWWA estimates treatment for a single entry point up to two times higher than EPA (e.g., $2.2 million compared to $1.1 million per entry point for systems serving 500-1,000 people). For large system capital costs, the EPA model for midlevel ground water CWS costs generates larger costs than the AWWA published averages. In Appendix G, application of the EPA model using AWWA average flows generates annual O&M cost estimates that are the same or larger than AWWA's average cost estimates, indicating that AWWA O&M cost inputs may be lower than EPA's. AWWA does not provide a treatment forecast showing the percent of systems expected to implement any given treatment. This analysis provides limited insight on determining the cumulative difference of cost inputs between the EPA and AWWA analyses. The relative magnitude of underlying costs is unknown, but nonetheless has a major impact on the net outcome of total national costs.

The evidence provided in this memo demonstrates that the EPA cost estimate is robust. While there are several items that could not be directly compared to the AWWA cost model, there is no evidence that EPA is consistently underestimating occurrence or costs. According to calculations shown in Appendix G, if AWWA's O&M costs are accurate ($30,000-125,000 per entry point), this could mean that EPA's O&M cost estimates ($27,000-2,515,000) are larger than necessary and may be lower in practice. If Michigan's rate of non-treatment options is relevant nationwide, the total EPA cost would fall even further.

The EPA cost estimate of $658.5 million appears to be the more realistic result based on the calculations and findings presented here.

While professional judgement must be used in applying cost modeling assumptions, it appears that several of the assumptions in the AWWA cost model are too conservative. These assumptions consistently result in higher capital and O&M costs for treatment, especially for systems serving fewer than 10,000. As shown in Table 2, the analyses presented here demonstrate the AWWA estimate includes at least $2.6 billion in excess costs. Many of these overestimates have cascading effects that could not be modeled with available data. The cumulative impact of these corrections is likely even larger than estimated here. Subtracting the excess costs from AWWA's total estimate would result in a maximum annual cost of $1.2 billion for treatment installation and O&M.

Table 2: Total Magnitude of Quantified Excess Costs in the AWWA Cost Model

Cost Element	Magnitude of Excess Costs
Discount rate	$1,000,000,000
Overestimate for entry points requiring treatment	$1,400,000,000
Non-treatment compliance options	$159,000,000
O&M cost correction	$37,000,000
Total	**$2,596,000,000**

Analysis

Tables are presented below that compare the two cost modeling approaches and outcomes. These evaluate occurrence data, public water system (PWS) inventory data, capital cost data and analytical approaches, and O&M.

Table 3: Occurrence Factors

Cost element	EPA Cadwallader et al., 2022	AWWA Seidel and Samson, 2022 AWWA, 2023	Approach Generating Larger Cost Estimate	Discussion and Observations
Occurrence data	Only uses finished water samples. Investigative sampling excluded	No screening of finished water samples described; investigative samples included. Dataset Includes non-PWS sources: surface and ground water, landfills, military bases, etc. Magnitude of this contribution is unclear.	AWWA	As described in Seidel and Samson, 2022, AWWA results may be biased high.
Occurrence data	Only uses samples from PWS that participated in UCMR3 to prevent biasing toward states where data from additional PWS was available	Assumed existing occurrence data is representative of national occurrence, although potential for bias acknowledged	AWWA	Could result in underestimation from EPA while also biasing AWWA high. Net impact unclear.
Number of UCMR3 samples included in analysis	36,972	36,972	n/a	
Number of State samples included in analysis	6,645 PFOS 6,656 PFOA 4,715 PFHpA 5,114 PFHxS	19,791 PFOS 20,149 PFOA 15,138 PFHpA 17,649 PFHxS	AWWA	No screening of AWWA results for finished water samples is described, potentially biasing results high.

Cost element	EPA Cadwallader et al., 2022	AWWA Seidel and Samson, 2022 AWWA, 2023	Approach Generating Larger Cost Estimate	Discussion and Observations
Percent systems with detections	33% PFOS 40% PFOA 20% PFHpA 25% PFHxS	39% PFOS 34% PFOA 33%PFHpA 28% PFHxS	Unclear	Same percent exceedance of combined PFOS and PFOA. Costs for treatment of multiple species were included in AWWA analysis but not explicitly shown.
Medians of state data	1.76 PFOS 1.58 PFOA 0.66 PFHpA 1.09 PFHxS	2.0 PFOS 2.0 PFOA 1.7 PFHpA 1.7 PFHxS	AWWA	Cost impact is two-fold: Increase in number of systems that require treatment Increase in treatment cost to remove larger magnitude of contaminant.
Number of Systems serving <=10,000 Exceeding PFOS and PFOA 4 ppt	Table 4-19 3251	Table 6-1 minus the systems which have already addressed treatment due to state requirements (Table 6-3): 4709	AWWA	Nearly 1500 more small systems are expected to require treatment per AWWA. With AWWA cost estimates for small systems greatly exceeding EPA's, this has a significant impact on the bottom line.
Number of Systems serving >10,000 Exceeding PFOS and PFOA 4 ppt	Table 4-19 1060	Table 6-1 minus the systems which have already addressed treatment due to state requirements (Table 6-3): 277	EPA	EPA expects about 783 more large systems will need to install treatment to comply with the rule. EPA and AWWA costs per large system are closer to each other than for small systems. Cadwallader et al., 2022 used a model to fill in the non-detect median PFOA and PFOS levels for large systems, which may explain the difference in large systems exceeding the MCLs

Cost element	EPA Cadwallader et al., 2022	AWWA Seidel and Samson, 2022 AWWA, 2023	Approach Generating Larger Cost Estimate	Discussion and Observations
Number of System Entry Points serving <=10,000 Exceeding PFOS and PFOA 4 ppt	Table 4-23 in the Economic Analysis estimates: 4,327	Table 6-1 minus the entry points which have already addressed due to state requirements (Table 6-3): 10,049	AWWA	AWWA assumes all entry points at a water system with one MCL exceedance will install treatment. This overestimate is compounded multiple times throughout the cost estimate.
Number of System Entry Points serving >10,000 Exceeding PFOS and PFOA 4 ppt	Table 4-23 in the Economic Analysis estimates: 3,238	Table 6-1 minus the entry points which have already addressed due to state requirements (Table 6-3): 1,161	EPA	It's not clear why EPA estimates so many more large systems, and consequently, entry points, will exceed the MCLs compared to the AWWA estimate.
State data included in occurrence analysis	Colorado Illinois Kentucky Massachusetts Michigan New Hampshire New Jersey North Dakota Ohio South Carolina Vermont	Colorado Kentucky Massachusetts New Hampshire New Jersey South Carolina Vermont Alaska Arizona California Delaware Minnesota Missouri North Carolina New Mexico New York Pennsylvania Rhode Island West Virginia	Unclear	States with some of the lower detection rates (particularly for non-targeted PFAS data) were not included in the AWWA analysis (e.g., Illinois, Michigan, North Dakota, Ohio, Vermont); reason for not including is not clear. The AWWA dataset covers more geographies.

Table 4: Capital Treatment Selection and Costs

Cost element	EPA	AWWA	Approach Generating Larger Cost Estimate	Discussion and Observations
PWS Inventory for considering treatment	Uses standard PWS designs to estimate costs for a median sized system in each category.	Considers each PWS with occurrence data	Unclear	
Number of Entry Points to the Distribution System	Combination of UCMR3 and SDWIS/Fed facility data presented in Economic Analysis Table 4-6: GW <=100: 90% have only 1 EPTDS	AWWA Letter to Congressional Budget Office Re: S.1507 - PFAS Release Disclosure Act, dated August 8, 2019, which incorporated updates to information originally collected by EPA's Community Water System Survey. Range from 2.4-14.5.	AWWA	The relative magnitude and origin of the underlying numbers is unclear; they become significant with AWWA's assumption that all entry points must be treated (see below).
Average Flows	Geometries and Characteristics of PWSs (USEPA, 2000)	150 gpdpc	AWWA for smaller systems	Dieter et al. (2018) found average water use per capita at 82 gallons per day. Basing flow on population data doesn't account for regional differences in water use and the actual flow at the water system. Appendix E shows AWWA estimates are high for small systems compared to EPA flow data.
Peak Flows	Geometries and Characteristics of PWSs (USEPA, 2000)	Peaking Factor	same	Average/Design flow ratios are not substantially different (Appendix E).
Package Plants	EPA uses them <1 MGD, resulting in lower costs	Does not describe	AWWA	Impact is large on Size Categories 1-3.

Cost element	EPA	AWWA	Approach Generating Larger Cost Estimate	Discussion and Observations
Non-treatment options - new connections or wells included as compliance options	Non-treatment is considered only for entry points with design flows less than or equal to 3.536 MGD.	No non-treatment options are included in the analysis.	AWWA	Significant bias in AWWA cost. Using EPA's compliance forecast (appendix D), which may be low according to Michigan data (indicates up to 26% of systems may be able to interconnect), this assumption increases the AWWA estimate by at least $159 million.
Number of treatment points per PWS	SafeWater MCBC is used to apply costs for a treatment technology or nontreatment alternative only at each entry point in a PWS estimated to be out of compliance with the regulatory option under consideration.	If one EPTDS exceeds the regulatory option under consideration, assumes installation of a treatment system at each EPTDS regardless of contaminant levels. If a PWS is assumed to exceed an MCL at any EPTDS, the EPTDS treatment cost is multiplied by the average number of EPTDS.	AWWA	AWWA cost is biased higher in two ways: 1) treatment costs are assumed at locations that may not require treatment and 2) EPTDS that meet the MCL might be usable for blending to bring down treatment costs at the EPTDS that do exceed the MCL.
Treatment selection	Screens for viable options first, then option selected based on estimated cost, using cost equations for up to 49 different flow rates.	Treatment technology with lowest life-cycle cost selected. Costs were independently calculated for IX, GAC vessels, GAC basins, and RO. Does not include impact of TOC on selection or cost of treatment. Monte Carlo analysis is used to estimate the range of varying TOC, sulfate, pH, and alkalinity on treatment cost.	AWWA	It is possible that the high cost of EPA non-viable options might exclude these options from the AWWA estimate, which is based on lowest cost. However, EPA's inclusion of non-treatment options results in a lower capital cost estimate.

Cost element	EPA	AWWA	Approach Generating Larger Cost Estimate	Discussion and Observations
Compliance Forecast (% systems installing what treatment)	50-85% of entry points will install GAC	Not Provided	Unclear	Unable to compare EPA's method of excluding non-viable treatment options vs AWWA method of selecting the lowest cost treatment option and the lack of non-treatment options.
Safety Factor	Target effluent set at 80% of regulatory limit. Accounts for contaminants below MCL to account for chromatographic peaking.	Target effluent set at 80% of regulatory limit.	EPA	EPA assumption is more conservative than AWWA.
Technology exclusions	GAC is excluded if EPTDS influent TOC > 3.2 mg/L. IX is excluded if total influent PFAS > 7,044 ppt. GAC and IX are excluded if PFAS removal > 99% is required. GAC is excluded for bed lives <5,000 and IX excluded for bed lives <20,000.	None described	Unclear	Not clear if the increased cost of these options would automatically exclude them in the AWWA analysis.

Cost element	EPA	AWWA	Approach Generating Larger Cost Estimate	Discussion and Observations
Reverse Osmosis Costs	Although some systems will blend treated with untreated water, EPA uses the conservative assumption that blending is only used when less than 95% removal is required. More blending scenarios are likely during implementation.	No blending assumptions are described.	AWWA	Even though the EPA assumption is conservative and may result in a higher than actual compliance cost, the AWWA assumption of no blending results in an even higher Capital and O&M cost for RO.
Automation	Cost equations are for fully automated systems, minimizing the need for operator intervention and reducing operator labor costs.	Emphasis on automation in treatment selection to decrease O&M cost not described.	not clear	May increase EPA capital costs but decrease EPA O&M cost

Cost element	EPA	AWWA	Approach Generating Larger Cost Estimate	Discussion and Observations
Quantified Uncertainty	Monte-Carlo uncertainty analysis with the SafeWater MCBC. Applied to TOC value and compliance technology unit cost curve selection: random selection from a triangular distribution of low-, mid-, and high- cost equipment (25%, 50%, and 25% respectively). At the end of 4,000 iterations, SafeWater MCBC outputs the expected value as well as 90% confidence interval for each cost metric (bounded by 5th and 95th percentiles).	Monte Carlo analysis using major factors for GAC, ion exchange, and reverse osmosis/nanofiltration. Triangular distributions where assigned for all factors except RO recovery. For each modeled scenario, each of the modeled costs (10th percentile, 90th percentile, and most probable) was stored as a modeled output for each system represented in the occurrence database for use in determining the overall national cost of compliance with the modeled limit.	Not clear	Two similar but different procedures are described. Net result is unclear.

Cost element	EPA	AWWA	Approach Generating Larger Cost Estimate	Discussion and Observations
Estimate class and/or peer review	Peer review of GAC model indicated budget estimates would be +30 to -15% Peer review of IX model indicated estimates in range of +50 to -30, with an emphasis on the high range but has been revised since then. Non-treatment model peer review: costs ranged widely with the biggest unknown being land costs that vary regionally.	Capital costs generated for individual systems represent a Class 5 Association for the Advancement of Cost Engineering (AACE) estimate, at approximately 1 to 2 percent maturity level of deliverable definition. According to AACE, a class 5 estimate is more likely to be a high estimate than a low estimate, with the 80 percent confidence interval ranging at the low end from -20% to -50% to +30 to +100%.	AWWA	The AWWA estimate could range as high as twice the actual cost, whereas EPA estimate could be as high as 1.5 times the actual cost.
Cost curves	National database used for decades.	Empirically derived cost curves as a function of size using several decades of infrastructure project design and delivery at Black and Veatch to estimate cost for these major components.	Unclear	Net result is unclear.

Cost element	EPA	AWWA	Approach Generating Larger Cost Estimate	Discussion and Observations
Capital cost markups	Contingencies based on Project budget ranging from 4-7%. The WBS models assume contingency costs incurred only in high-cost scenarios (see Section 2.3). For low and medium cost estimates, none is incurred. EPA includes line items not in described in the AWWA model: • Residuals management equipment • Pilot testing • Geotechnical • Standby power • Sales tax • Financing	Includes 30% contingency for all treatment installations. The AWWA Contingency does not vary based on project dollar value.	AWWA	Although the EPA contingency may be an underestimate, the AWWA 30% contingency is on top of the Level 5 assessment. A realistic value may be between the two estimates.
Systems that have already installed treatment to comply	The EPA model accounts for systems and states that have already installed treatment to comply with PFAS MCLs.	Only accounts for systems in states with existing MCLs. For example, does not account for treatment installed at Cape Fear Public Utility Authority that is used for some treatment estimates.	AWWA	The cost to install treatment already in place should not be attributed to the new PFAS regulation.

Cost element	EPA	AWWA	Approach Generating Larger Cost Estimate	Discussion and Observations
Cost Inputs	Multiple technical documents are provided describing complex models built in Excel workbooks. Treatment forecasts are available, but discrete cost points are not.	High level approaches are described but no treatment forecast, discrete cost values or cost breakouts by treatment alternatives are provided.	Unclear	Calculations in Appendix F using EPA's formulas and AWWA inputs indicate AWWA cost inputs may exceed EPA by 1-2 times as much for small systems, but AWWA costs for large systems may be lower than EPA's.
NTNCWs	Includes cost of NTNCWS compliance.	Does not include NTNCWS compliance.	EPA	

Table 5: Operations and Maintenance Costs

Cost element	EPA	AWWA	Approach Generating Larger Cost Estimate	Discussion and Observations
Flows used to calculate O&M costs	Average Flows (modeled)	Average Flows (based on per capita consumption estimates)	AWWA	As described in Table 3, AWWA average flows appear high for small systems.
O&M Correction	N/A	Table A-2 shows that AWWA estimates lower O&M costs to comply with a more stringent standard for systems in categories 1 and 5. If it costs less to comply with a more protective standard, a PWS would select this alternative. Correcting for this assumption would result in additional $37 million in savings.	AWWA	See Appendix H for the calculation.
Media Life	Bed life estimates using linear equations based on pooled data from several studies of GAC and IX performance and reflect central tendency results under varying water quality conditions. Increments of 5,000 BV for GAC and 20,000 BV for IX, resulting in media replacement every 2-5 months depending on average flow at EPTDS.	Clark, 1987 non-linear model for GAC and IX. Values for GAC were derived from a pilot study for CFPUA. Values for IX were derived from CFPUA and LHHCWD pilot data.	Unclear	EPA uses a more representative dataset compared to the AWWA model that only uses data from two PWSs. The AWWA approach uses values from only two pilot studies to extrapolate to the entire country. It is unlikely that these two PWSs are representative of the average PWS nationwide.

Cost element	EPA	AWWA	Approach Generating Larger Cost Estimate	Discussion and Observations
Disposal Costs	Assumes PFAS-contaminated wastes are not considered hazardous wastes, but accounts for waste disposal costs.	Waste disposal is included in O&M Costs.	Unclear	Unclear
Cost Inputs	Multiple technical documents are provided describing complex models built in Excel workbooks. Discrete cost points are not easily extracted for comparison purposes.	Discrete cost values are available in Table 5-8 but the net difference in input costs and methodology are difficult to identify and calculate due to the very different methods in each approach.	EPA	In Appendix G, application of the EPA model using AWWA average flows generates O&M estimates that are the same or larger than AWWA's average cost estimates, indicating that AWWA O&M cost inputs are lower than EPA's.

A case study for actual costs incurred can be identified from the AWWA analysis. Table 6-3 quantifies one PWS serving >1,000,000 that installed treatment in response to state PFAS MCLs with an AWWA estimated capital cost of $407.5 million and an annualized cost of $47 million. The water utility was identified via UCMR3 monitoring data. Information on this water system (O'Connell and Kilcommons, 2023) states the following: "Through a mix of blending, GAC treatment, and taking wells offline that have contaminant detections over the MCL that they are currently in compliance with the state requirements. This PWS anticipates additional treatment may be needed to meet the proposed federal requirements." To date, they have spent:

- $15.0 million from 2016 – 2022 on PFAS related work
- $36.2 million on Emerging Contaminant Work
- $21.2 million on 1,4-Dioxane work

Although this is not the complete capital cost for the work (as more is pending), and some of the emerging contaminant and 1,4-Dioxane work may result in PFAS reduction benefits, the cost to date is significantly less than the estimated capital cost of $407.5 million presented in AWWA Table 6-3. Even if the $15 million is the actual annualized cost of PFAS treatment alone, it would be less than one third of the annualized cost shown in AWWA Table 6-3.

Unmodeled sources of uncertainty in both cost estimates

There are some unmodeled sources of uncertainty that were not included in both estimates. One factor for which inclusion would increase cost would be the potential for competition for supplies and supply chain issues driving up prices if thousands of PWS nationwide try to install treatment at the same time. On the other hand, there are sources of uncertainty not included in both estimates that would have the impact of decreasing overall costs, including:

- Innovation in the marketplace
- Innovation/new technology for PFAS destruction/disposal
- Future options for point-of-use (POU) compliance
- Increasing the number of PWS that consolidate with other PWS that meet MCLs instead of installing treatment.

In the case of this last option, according to EGLE, state primacy agencies focus on finding a safe source prior to exploring treatment options. Michigan expects up to 33% of PWS and 26% of CWS to connect to another system before installing treatment, indicating that EPA's estimate of 6-7% of systems with <3.536 MGD design flow is not only reasonable, but possibly low (Smith, personal communication May 23, 2023). This omission of non-treatment options by AWWA is the source of at least $159 million in difference between the AWWA and EPA cost estimates. If Michigan's results are found to hold true nationwide, up to $362 million in savings could be realized in comparison to the AWWA cost estimate.

Conclusion

As discussed throughout this memo, assumptions used in AWWA cost modeling of the proposed PFAS drinking water rule result in higher annualized capital and O&M costs for treatment, especially for

systems serving fewer than 10,000. While AWWA cost inputs for O&M may be lower than EPA's inputs, the larger number of entry points installing treatment per AWWA result in cumulative increased O&M costs. Although several details that are not provided cannot be quantified, the source of $2.6 billion in excess costs are clearly identified in this analysis and in Table 2. Many of these overestimates have cascading effects that are not readily calculated without access to the underlying cost models, so the cumulative impact of these corrections is likely even larger than estimated here. Subtracting the overestimates from the AWWA cost estimate results in a revised AWWA annual estimate of $1.2 billion for treatment and O&M to comply with the proposed MCLs. While there is a possibility that the actual result lies between the EPA and AWWA cost estimates, the calculations here indicate it is more likely to be closer to the EPA estimate.

The evidence provided in the executive summary and Tables 3-5 demonstrate that the EPA cost estimate is robust. While there are several items that could not be directly compared between the EPA and AWWA cost models, there is no evidence that EPA is consistently underestimating occurrence or costs. When looking toward which cost estimate is likely to better reflect future compliance decisions, the EPA cost estimate appears to be more realistic based on the calculations and findings presented here.

If AWWA's apparent lower O&M cost inputs are accurate, this could mean that EPA's O&M cost estimates are higher than necessary and will be lower during implementation. If Michigan's rate of non-treatment options is relevant nationwide, the total EPA estimated cost would fall even further. The EPA $658 million annual treatment cost projection is realistic, and there are several opportunities for actual costs to turn out even lower upon implementation.

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Appendix A: Recalculation at 3% discount rate

AWWA 4 ppt PFOA and PFOS at 3% plus corrected O&M

PWS Size	Population Range Annualized	Average CAPEX/PWS	Average O&M/PWS	Annualized PWS Cost	Estimated Number of Impacted PWSs	National C	Column1	Net Impacted PWS (Impacted PWS - State MCL Impacted PWS)
1	<100	$ 1,920,000	$ 72,000	$ 177,000	2167	$ 383,559,000		1406
2	101-500	$ 3,400,000	$ 60,000	$ 289,000	2469	$ 713,541,000		1660
3	501-1,100	$ 4,620,000	$ 63,000	$ 374,000	609	$ 227,766,000		359
4	1,001-3,300	$ 5,510,000	$ 57,000	$ 427,000	858	$ 366,366,000		746
5	3,301-10,000	$ 11,000,000	$ 176,000	$ 893,000	781	$ 697,433,000		538
6	10,001-50,000	$ 24,490,000	$ 372,000	$ 2,018,000	255	$ 514,590,000		156
7	50,001-100,000	$ 45,510,000	$ 512,500	$ 3,571,000	64	$ 228,544,000		58
8	100,001-1,000,000	$ 110,880,000	$ 891,000	$ 8,344,000	71	$ 592,424,000		60
9	>1,000,000	$ 507,500,000	$ 3,045,000	$ 37,157,000	4	$ 148,628,000		3
All Systems					7278	$3,872,851,000		4986

Discount Rate	0.03
Small systems	4709
Large Systems	277
Total AWWA Estimate with 3% discount rate - State PI	
$ 2,814,822,000	

State Costs in the report, recalculated at 3%.

PWS Size Category	Population Range	% Impacted	Average CAPEX/PWS	Average O&M/PWS	Annualized PWS Cost	Estimated Number of Impacted PWSs	Annualized Total Cost	Present Value of Lifecycle Cost
1	<100	7%	$1,920,000	$48,000	$177,000	761	$ 134,697,000	
2	101-500	5%	$3,400,000	$60,000	$289,000	809	$ 233,801,000	
3	501-1,100	5%	$4,620,000	$63,000	$374,000	250	$ 93,500,000	
4	1,001-3,300	1%	$5,510,000	$76,000	$446,000	112	$ 49,952,000	
5	3,301-10,000	5%	$10,560,000	$132,000	$842,000	243	$ 204,606,000	
6	10,001-50,000	3%	$24,180,000	$310,000	$1,935,000	99	$ 191,565,000	
7	50,001-100,000	1%	$43,050,000	$594,500	$3,488,000	6	$ 20,928,000	
8	100,001-1,000,000	3%	$98,340,000	$1,848,000	$8,458,000	11	$ 93,038,000	
9	>1,000,000	4%	$407,450,000	$8,555,000	$35,942,000	1	$ 35,942,000	
All Systems		4%				2292	$ 1,058,029,000	

Original AWWA Estimate (Table A-1 minus Table 6-3)	
$ 3,803,926,000	
incremental cost due to AWWA 7% discount rate	
$ 989,104,000	

Appendix B: Number of impacted systems and entry points

Table 4-19: Total Systems Impacted, Option 1a (PFOA and PFOS MCLs of 4.0 ppt)				Table 6-1 AWWA Systems Impacted Minus Impacted State PWSs of Table 6-3	4-23: Total Entry points Impacted, Option 1a	AWWA Table 6-1 minus impacted State EPTDS of Table 6-3
	5th Percentile	Mean	95th Percentile		Mean	Nationally impacted entry points
Small Systems <10,000						
Total Number of PWSs	61,463	61,463	61,463			
PWSs With PFOS Exceedance	1,801	2,905	4,260			
PWSs With PFOA Exceedance	836	1,520	2,422			
PWSs That Exceed One or More MCLs	2,111	3,251	4,676	4709	4,327	10,049
Large Systems >10,000						
Total Number of PWSs	4,433	4,433	4,433			
PWSs With PFOS Exceedance	721	791	868			
PWSs With PFOA Exceedance	803	878	959			
PWSs That Exceed One or More MCLs	975	1,060	1,145	277	3,238	1,161
All Systems						
Total Number of PWSs	65,896	65,896	65,896			
PWSs With PFOS Exceedance	2,522	3,696	5,128			
PWSs With PFOA Exceedance	1,639	2,399	3,381			
PWSs That Exceed One or More MCLs	3,086	4,310	5,821		7,564	11,211

Appendix C: Estimate of impact of excess EPTDS

Population Range	Impacted PWS	State Impacted PWS	Net PWS	Average EPTDS	AWWA EPTDS Requiring treatment	Annualized PWS Cost	Annualized cost per EPTDS	EPTDS Requiring Treatment Using EPA Rate	AWWA cost of EPTDS Requiring Treatment	EPA Cost of EPA EPTDS Requiring Treatment
<100	2167	761	1406	2.4	3374.4	$ 253,000	$ 105,417	1871	$ 355,718,000	$ 197,271,581
101-500	2469	809	1660	2.0	3320.0	$ 381,000	$ 190,500	2209	$ 632,460,000	$ 420,894,251
501-1,100	609	250	359	2.1	753.9	$ 499,000	$ 237,619	478	$ 179,141,000	$ 113,539,146
1,001-3,300	858	112	746	1.9	1417.4	$ 577,000	$ 303,684	993	$ 430,442,000	$ 301,530,304
3,301-10,000	781	243	538	2.2	1183.6	$ 1,173,000	$ 533,182	716	$ 631,074,000	$ 381,792,623
10,001-50,000	255	99	156	3.1	483.6	$ 2,684,000	$ 865,806	477	$ 418,704,000	$ 412,587,813
50,001-100,000	64	6	58	4.1	237.8	$ 4,808,000	$ 1,172,683	177	$ 278,864,000	$ 207,768,438
100,001-1,000,000	71	11	60	6.6	396.0	$ 11,357,000	$ 1,720,758	183	$ 681,420,000	$ 315,385,643
>1,000,000	4	1	3	14.5	43.5	$ 50,949,000	$ 3,513,724	9	$ 152,847,000	$ 32,200,298
			4986							
				Sum EPTDS	11,210			SUM	$ 3,760,670,000	$ 2,382,970,098
							Estimate of impact of excess EPTDS =			$ 1,377,699,902
		EPA Small System Impacted EPTDS/Impacted PWS ratio	1.3	AWWA Small system impacted EPTDS/Impacted PWS ratio	2.1					
		EPA Large System Impacted EPTRDS/Impacted PWS ratio	3.1	AWWA Large system Impacted EPTDS/Impacted PWS ratio	4.2					

Appendix D: Cost Savings of non-treatment options

Cost Savings via non-treatment options

Size Category	Population	MGD @150gpd WITAF 56 Average flows	Design Flows	Mid Cost Results for New Well T&C Document Figure 7-6	Mid Cost Results for New Well O&M T&C Document Figure 7-6	Annualized Costs Using EPA average cost and AWWA top of range flows	Impacted PWS	Impacted EPTDS	Estimated Number of New Well PWS (low = 2%)	Estimated Number of Impacted PWS (high = 10%)	Annualized National Cost (Low)	Annualized National Cost (High)
1	100	0.015	0.0645	$ 360,682.04	$ 4,173.14	$ 28,416.64	1406	3374	67	67	$ 1,917,782	$ 1,917,782
2	500	0.075	0.27	$ 458,211.74	$ 6,638.54	$ 37,437.56	1660	3320	66	66	$ 2,485,854	$ 2,485,854
3	1,000	0.15	0.495	$ 538,379.66	$ 9,550.52	$ 45,738.09	359	754	15	15	$ 689,639	$ 689,639
4	3,300	0.495	1.386	$ 1,121,295.27	$ 33,402.34	$ 108,770.99	746	1417	28	28	$ 3,083,440	$ 3,083,440
5	10,000	1.345	3.536	$ 2,564,950.50	$ 91,341.58	$ 263,746.55	538	1184	24	24	$ 6,243,408	$ 6,243,408
										Cost of New Wells	$ 14,420,124	$ 14,420,124
										AWWA treatment for same number of systems	$ 94,020,838	$ 94,020,838
										$ Saved with New Well assumption	**$ 79,600,714**	**$ 79,600,714**

Size Category	Population	MGD @150gpd WITAF 56 Average flows	Design Flows	Mid Cost Results for Interconnection T&C Document Figure 7-7	Mid Cost Results for Interconnection O&M T&C Document Figure 7-7	Annualized Costs Using EPA average cost and AWWA top of range flows	Impacted PWS	Impacted EPTDS	Estimated Number of New Well PWS (low = 6,7%)	Estimated Number of Impacted PWS (high = 25%)	Annualized National Cost (Low)	Annualized National Cost (High)
1	100	0.015	0.0645	$ 382,781.01	$ 18,072.28	$ 43,801.18	1406	3374	236	844	$ 10,346,189	$ 36,950,673
2	500	0.075	0.27	$ 420,653.92	$ 90,354.24	$ 118,628.79	1660	3320	232	830	$ 27,569,330	$ 98,461,893
3	1,000	0.15	0.495	$ 452,132.73	$ 180,706.68	$ 211,097.10	359	754	53	188	$ 11,140,227	$ 39,786,526
4	3,300	0.495	1.386	$ 543,407.09	$ 596,401.41	$ 632,926.90	746	1417	99	354	$ 62,797,741	$ 224,277,648
5	10,000	1.345	3.536	$ 682,442.58	$ 1,620,464.91	$ 1,666,335.77	538	1184	83	296	$ 138,059,252	$ 493,068,756
										Sum	$ 249,912,739	$ 892,545,495
										AWWA treatment for same number of systems	$ 329,072,933	$ 1,175,260,475
										$ Saved with Interconnection assumption	**$ 79,160,194**	**$ 282,714,980**
										Sum of cost savings via new wells and interconnections	$ 158,760,908	$ 362,315,694

Appendix E: Average and Design Flows

EPA			AWWA			
Design Flow (MGD)	**Average Flow (MGD)**	**Peaking Factor**	**Design Flow (MGD)**	**Average Flow (MGD)**	**Peaking Factor**	**Delta EPA-WITAF**
			0.007	0.0015	4.7	
			0.022	0.0054	4.1	
0.030	0.007	4.3	0.037	0.0095	3.9	0.4
			0.091	0.025	3.6	
0.124	0.035	3.5				
			0.18	0.054	3.3	
			0.27	0.084	3.2	
0.305	0.094	3.2	0.36	0.11	3.3	0.0
0.740	0.251	2.9	0.68	0.23	3.0	0.0
			1	0.3	3.3	
2.152	0.819	2.6	2	0.77	2.6	0.0
			3.5	1.4	2.5	
7.365	3.200	2.3	7	3	2.3	0.0
			17	7.8	2.2	
22.614	11.087	2.0	22	11	2.0	0.0
75.072	37.536	2.0	76	38	2.0	0.0

System Size	Table 4-9: Design and Average Daily Flow for CWSs EPA Ground Water			AWWA Equivalent			AWWA to EPA Design Flow Ratio
	Average Population	**Design Flow (MGD)**	**Average Flow (MGD)**	**Design Flow (MGD)**	**Average Flow (MGD)**	**Peaking Factor**	
≤ 100	61	0.028	0.007	0.043	0.009	4.7	1.54
101–500	250	0.107	0.030	0.169	0.038	4.5	1.58
501–1,000	734	0.301	0.093	0.363	0.110	3.3	1.21
1,001–3,300	1,865	0.733	0.248	0.895	0.280	3.2	1.22
3,301–10,000	5,673	2.121	0.806	2.127	0.851	2.5	1.00
10,001–50,000	20,697	7.305	3.171	7.140	3.105	2.3	0.98
50,001–100,000	67,222	22.512	11.031	20.167	10.083	2.0	0.90
100,001–1M	203,821	71.371	35.685	61.146	30.573	2.0	0.86

Abbreviations: CWS – community water systems; MGD – million gallons per day.

AWWA uses essentially the same peaking factors as EPA. The mean for AWWA average flows<=0.37 MGD is 4.2, a difference of 0.1. This may have the impact of lower EPA cost estimates for the lowest flows, however the EPA consideration of less expensive package plants for flows < 1 MGD likely results in an oversestimate of costs in the AWWA report.

Appendix F: Capital Cost Input Estimate

Size Category	Assumed Population	MGD @150gpd (AWWA Assumed Average flow)	Design Flow (AWWA peaking factor)	Mid Cost Results for Removal of PFAS from Groundwater Using Pressure GAC T&C Document Figure 7.2	Mid cost results for removal of PFAS from Groundwater using IX T&C Document Figure 7.3	Mid cost Results for Removal of PFAS from Groundwater using RO T&C Document Figure 7.4	Average of Midrange EPA Groundwater treatment costs using AWWA design flows for the top population of each size category	AWWA Average Capital cost per entry point (Table 6-1)	AWWA to EPA cost ratio
1	100	0.015	0.0645	$ 686,746.50	$ 144,418.66	$ 1,423,072.73	$ 751,412.63	$ 800,000.00	1.1
2	500	0.075	0.27	$ 778,085.22	$ 258,496.39	$ 1,733,665.26	$ 923,415.62	$ 1,700,000.00	1.8
3	1,000	0.15	0.495	$ 940,576.52	$ 376,607.25	$ 2,016,864.60	$ 1,111,349.45	$ 2,200,000.00	2.0
4	3,300	0.495	1.386	$ 2,159,302.43	$ 1,489,043.77	$ 3,401,507.67	$ 2,349,951.29	$ 2,900,000.00	1.2
5	10,000	1.5	3.75	$ 3,561,947.46	$ 2,845,388.48	$ 5,693,520.69	$ 4,033,618.88	$ 4,800,000.00	1.2
6	50,000	7.5	16.5	$ 9,631,776.59	$ 9,374,281.37	$ 15,117,104.00	$ 11,374,387.32	$ 7,900,000.00	0.7
7	100,000	15	30	$ 14,846,302.37	$ 16,003,911.78	$ 23,659,330.75	$ 18,169,848.30	$ 11,100,000.00	0.6
8	1,000,000	150	270	EPA mid-cost GW model does not cover design flow >200 MGD					
9	>1,000,000	350	520						

Appendix G: O&M Cost Input Estimate

Size Category	Assumed Population	MGD @150gpd (AWWA Assumed Average flow)	O&M Mid Cost Results for Removal of PFAS from Groundwater Using Pressure GAC T&C Document Figure 7.2	O&M Mid cost results for removal of PFAS from Groundwater using IX T&C Document Figure 7.3	O&M Mid cost Results for Removal of PFAS from Groundwater using RO T&C Document Figure 7.4	Average of Midrange EPA Groundwater treatment costs using WITAF 56 design flows for the top end of each size category	AWWA Average O&M cost ((Table A-1 Column 4)/ (Average EPTDS))	AWWA to EPA cost ratio
1	100	0.015	$ 28,243.53	$ 6,376.71	$ 48,097.57	$ 27,572.60	$30,000	1.1
2	500	0.075	$ 33,673.53	$ 15,800.31	$ 69,954.98	$ 39,809.61	$30,000	0.8
3	1,000	0.15	$ 43,510.21	$ 27,296.39	$ 93,801.74	$ 54,869.45	$30,000	0.5
4	3,300	0.495	$ 116,883.10	$ 75,656.86	$ 233,169.69	$ 141,903.22	$30,000	0.2
5	10,000	1.5	$ 228,798.78	$ 229,263.22	$ 628,114.08	$ 362,058.69	$80,000	0.2
6	50,000	7.5	$ 812,108.79	$ 1,154,598.53	$ 2,114,215.21	$ 1,360,307.51	$120,000	0.1
7	100,000	15	$ 1,460,783.53	$ 2,270,651.60	$ 3,812,647.18	$ 2,514,694.10	$125,000	0.0
8	1,000,000	150	EPA model does not cover average flow >100 MGD					
9	>1,000,000	350						

Appendix H: O&M Correction

Original AWWA Table A-1

PWS Size	Population Range Ann	Average CAPEX/PWS	Average O&M/PWS	Annualized PWS Cost	Estimate	National Cost
1	<100	$1,920,000	$72,000	$253,000	2167	$548,251,000
2	101-500	$3,400,000	$60,000	$381,000	2469	$940,689,000
3	501-1,100	$4,620,000	$63,000	$499,000	609	$303,891,000
4	1,001-3,300	$5,510,000	$57,000	$577,000	858	$495,066,000
5	3,301-10,000	$10,560,000	$176,000	$1,173,000	781	$916,113,000
6	10,001-50,000	$24,490,000	$372,000	$2,684,000	255	$684,420,000
7	50,001-100,000	$45,510,000	$512,500	$4,808,000	64	$307,712,000
8	100,001-1,000,000	$110,880,000	$891,000	$11,357,000	71	$806,347,000
9	>1,000,000	$507,500,000	$3,045,000	$50,949,000	4	$203,796,000
All Systems					7278	$ 5,206,285,000

Discount Rate 0.07

Substitute lower A-2 costs per system size into Table A-1 (if it costs less to meet a higher standard, why not always choose that technology option?)

PWS Size	Population Range Annua	Average CAPEX/PWS	Average O&M/PWS	Annualized PWS Cost	Estimated P	National Cost	
1	<100	$1,920,000	$48,000	$ 229,000	2167	$496,243,000	$ 229,234
2	101-500	$3,400,000	$60,000	$ 381,000	2469	$940,689,000	$ 380,936
3	501-1,100	$4,620,000	$63,000	$ 499,000	609	$303,891,000	$ 499,095
4	1,001-3,300	$5,510,000	$57,000	$ 577,000	858	$495,066,000	$ 577,105
5	3,301-10,000	$11,000,000	$154,000	$ 1,192,000	781	$930,952,000	$ 1,192,322
6	10,001-50,000	$24,490,000	$372,000	$ 2,684,000	255	$684,420,000	$ 2,683,683
7	50,001-100,000	$45,510,000	$512,500	$ 4,808,000	64	$307,712,000	$ 4,808,322
8	100,001-1,000,000	$110,880,000	$891,000	$ 11,357,000	71	$806,347,000	$ 11,357,288
9	>1,000,000	$507,500,000	$3,045,000	$ 50,949,000	4	$203,796,000	$ 50,949,410
All Systems					7278	$ 5,169,116,000	
			average annual	$ 8,075,111			

O&M correction savings= $ 37,169,000