Comments of the U.S. Chamber of Commerce and its Coalition

EPA PFAS National Primary Drinking Water Regulation Rulemaking
Preliminary Regulatory Determination and Proposed Rule
Docket ID No. EPA-HQ-OW-2022-0114
88 Fed. Reg. 18638 (Mar. 29, 2023)

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Executive Summary

Under the Safe Drinking Water Act (SDWA), EPA is required to regulate contaminants in drinking water by following a multi-step process established in the statute. The critical finding for preliminary and final determinations to regulate requires EPA use the best available public health information to show that a contaminant may have an adverse effect on human health, it occurs frequently enough to present a health concern, and there is a meaningful opportunity for health risk reductions by regulating public water systems. If EPA, based on SDWA's rigorous scientific standards, decides to regulate, the Agency must not impose maximum contaminant levels (MCLs) for regulation that are more stringent than feasible, considering costs to regulated entities.

In this proposed rule, EPA targets six per- and polyfluoroalkyl substances (PFAS) for regulation under SDWA: perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA) and its ammonium salt (also known as GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS). EPA expects this action to directly affect 66,000 public water systems across the country. But in EPA's rush to regulate these six PFAS and address a priority for the Agency, it deviates from its statutory procedures under SDWA. EPA proposes near-zero levels of these six PFAS in drinking water and employs a novel approach to setting an MCL for the mixture of four of the six PFAS without having satisfied the required scientific, legal, or procedural requirements to justify the proposed rule. In addition, costs of the proposed rule, as presented in EPA's own analysis, could exceed $1,000 per household annually. As a result, EPA's proposed rule raises the following concerns:

- EPA substantially underestimates the potential costs that this proposed rule will impose on public water systems and overstates the benefits of the rule.

- EPA's preliminary determination to regulate PFHxS, HFPO-DA, PFNA, and PFBS is inconsistent with statutory criteria under SDWA because the available health data and occurrence data do not support a decision to regulate, and the data does not demonstrate that this rulemaking is a "meaningful opportunity" for health risk reduction.

- EPA skirted its own required procedures by proposing a preliminary determination for PFHxS, HFPO-DA, PFNA, and PFBS simultaneously with its proposed MCL and maximum contaminant level goal (MCLG), contrary to SDWA requirements, and deprived the public of sufficient time and opportunity to comment on the proposal.

- EPA has also failed to satisfy its obligations under SDWA when it did not consult with the Science Advisory Board (SAB) prior to proposing a National Primary Drinking Water Regulation (NPDWR) and MCLG for PFHxS, HFPO-DA, PFNA, and PFBS.

- EPA also fails to use the best available science in proposing the MCLs and MCLGs for all six PFAS.

- The Hazard Index approach proposed by EPA as the MCL and MCLG for PFHxS, HFPO-DA, PFNA, and PFBS violates SDWA because it does not reflect the use of the best available science and is not actually a proposed level for the contaminants.

- The Hazard Index approach is not a proposed level for a contaminant, but a mixture of contaminants. SDWA requires MCLs and MCLGs for individual contaminants rather than mixtures.

- EPA's re-interpretation of PFOS as a "likely carcinogen" is not supported by the science.

Consistent with the comments presented, significant scientific uncertainties and legal inadequacies must be addressed. EPA has not demonstrated that PFNA, PFHxS, PFBS, and HFPO-DA warrant regulation under SDWA, and EPA should withdraw the proposed MCL and MCLG for these four PFAS.

While the science is better developed for PFOA and PFOS, the documents EPA presented to the SAB were not sufficiently robust to allow the SAB to make actionable recommendations, and EPA did not adequately apply the SAB input to refine the documents prior to proposing the rule. Consequential uncertainties remain regarding the cancer classification for PFOS, and EPA is still awaiting robust and representative occurrence data from the Unregulated Contaminants Monitoring Rule (UCMR) 5 sampling for both PFOA and PFOS. EPA's cost and benefits analyses for these PFAS is flawed, both qualitatively and quantitatively, with notable underestimates of the costs and overestimates of the benefits. An MCL of 4 ppt is simply not justified, and the MCL must be adjusted upward to make this proposal feasible.

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I. Introduction

The U.S. Chamber of Commerce (the Chamber) and its coalition of companies, trade associations, and other stakeholders appreciate this opportunity to comment on EPA's proposed rule,[1] which (1) issues a preliminary regulatory determination for PFNA, PFHxS, PFBS, and HFPO-DA, and (2) proposes MCLs[2] and MCLGs for these four PFAS as well as PFOA and PFOS.[3] We represent member companies, trade associations, and state and local chambers that span key U.S. supply chains using PFAS chemistries and whose products and technologies are essential to America's economic growth, water infrastructure, and national security. Many of these companies operate public water systems, including Non-Transient Non-Community Water Systems (NTNCWS) that would be regulated. The Chamber and its coalition are committed to managing PFAS safely and protecting human health and the environment. The Chamber and the coalition support national drinking water standards for select PFAS based on the best science and risk, rather than the current patchwork of state approaches. Customers, employees, and the communities where Chamber and coalition members operate depend on clean, safe drinking water for a better quality of life and economic growth. But any regulation of PFAS must be informed by the best available science and comply with the rigorous mandates of SDWA.[4] The proposed rule falls short of those requirements, would impose significant and underestimated costs, and will lead to considerable challenges for the water utilities and many other industries.

II. EPA's Preliminary Determination To Regulate PFNA, PFHxS, PFBS, and HFPO-DA (and Mixtures of these PFAS) Is Inconsistent with the Requirements Under SDWA

In the proposed rule, EPA is issuing a preliminary regulatory determination to regulate perfluorohexane sulfonic acid (PFHxS), hexafluoropropylene oxide dimer acid (HFPO–DA) and its ammonium salt (also known as a GenX chemicals), perfluorononanoic acid (PFNA), and perfluorobutane sulfonic acid (PFBS), and mixtures of these PFAS as contaminants under SDWA.

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[1] 88 Fed. Reg. 18638 (Mar. 29, 2023).

[2] In these comments, we use the term "MCL" interchangeably with the term national primary drinking water regulation or "NPDWR." The NPDWR refers to EPA's regulation which specifies contaminants and a MCL or a treatment technique (if it is not economically or technologically feasible to ascertain the level of the contaminant). The MCL is the level set under the NPDWR—the maximum permissible level of a contaminant in water delivered to a user of a public water system. In this proposed rule, EPA proposes MCLs and MCLGs (not treatment techniques), which is why the term is used interchangeably.

[3] Throughout these comments references to specific PFAS also refer to all salts, isomers and derivatives, including derivatives other than the anionic form. This is consistent with EPA's approach in the proposed rule. However, we note that the inclusion of isomers for each PFAS is not justified as EPA presented virtually no scientific information on these various isomers and their environmental and human health effects. This expanded listing is problematic for multiple reasons.

[4] SDWA also requires the use of best available science, stating "In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use— (i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)." 42 U.S.C. § 300g-1(a)(3)(A).

As described in the final regulatory determination for PFOA and PFOS, EPA follows a three-phase process in making regulatory determinations: (1) data availability, (2) data evaluation, and (3) regulatory determination.[5] In the first phase, the Agency applies criteria to screen out contaminants that "clearly do not have sufficient data to support a regulatory determination."[6] If sufficient data are available to characterize the potential health effects and likely occurrence in drinking water, then EPA determines whether the contaminant meets three statutory criteria for regulation:

1. The 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. In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.[7]

Findings under these criteria must be based on the best available public health information, including the occurrence database.[8] If EPA determines a contaminant meets the three statutory criteria (determination to regulate), EPA must publish a MCLG and promulgate a NPDWR for the contaminant.

As discussed below, EPA does not demonstrate that PFNA, PFHxS, PFBS, and HFPO-DA meet the three statutory criteria regulation under Section 1412(b)(1)(A) of SDWA. Therefore, EPA's preliminary determination to regulate these four PFAS is improper. The human health and occurrence data do not support a determination to regulate PFNA, PFHxS, PFBS, and HFPO-DA or their mixtures at this time. In fact, had EPA followed its typical process, these contaminants should have been screened out in the Office of Water's first phase of regulatory determination work as not having sufficient data. While the Chamber and the coalition continue to support the appropriate and science-based regulation of PFAS chemicals, EPA must ensure that its regulations are based on robust scientific evaluations and meet statutory criteria, which this proposal fails to do. A fundamental flaw is that EPA's preliminary determination to regulate rests on potentially flawed predictions of *future* occurrence and not actual data, which does not meet SDWA requirements. In addition, the underlying science has not undergone the required review by the EPA Science Advisory Board (SAB).

[5] 86 Fed. Reg. 12272, 12274 (Mar. 3, 2021).
[6] *Id.*
[7] 42 U.S.C. § 300g-1(b)(1)(A).
[8] 42 U.S.C. § 300g-1(b)(1)(B)(ii)(II).

A. Health data do not support the proposed determinations to regulate PFNA, PFHxS, PFBS, and HFPO-DA (and mixtures of these PFAS) either individually or as a mixture

1. EPA did not perform human health assessments for all four contaminants and failed to conduct appropriate peer review

It is critical that, before finalizing a human health assessment, EPA ensures that appropriate peer review is conducted.[9] This peer review must be fit for purpose, and, as EPA states, Influential Scientific Assessments (ISIs) and Highly Influential Scientific Assessments (HISAs), including those that are more novel or complex and have greater cost implications, should undergo more extensive and more involved peer reviews. Despite EPA's own recognition that "[t]he mechanism of the peer review should match the importance and complexity of the work product," the SAB did not review the science for PFHxS, HFPO-DA, PFNA, and PFBS.[10] This is in sharp contrast to the process that occurred for PFOA and PFOS.

Troublingly, EPA has not completed its own human health assessments for PFHxS and PFNA. Instead, it relies on assessments from the Agency for Toxic Substances and Disease Registry (ATSDR). EPA did not oversee the peer review process of the ATSDR document, which covered the assessment of 12 PFAS. ATSDR conducted a letter peer review, which is inconsistent with EPA's own best practices for the peer review of ISAs or HISAs. For instance, as described by ATSDR, the peer reviewers were not provided with any of the public comments before the review.[11] EPA's Peer Review Handbook recognizes that a letter review is appropriate when a work product is "not controversial" and also recognizes that, for HISAs, a panel review is a preferable approach.[12] The ATSDR health assessments are not a valid substitute for the rigorous SAB peer review that is required for a HISA. Equally important, in describing how to use the ATSDR minimal risk levels that EPA relies upon, ATSDR describes these values as "[i]ntended to serve as screening levels, are used by ATSDR health assessors and other responders to identify contaminants and potential health effects that may be of concern at hazardous waste sites. **It is important to note that [Minimal Risk Levels] (MRLs) are not intended to define cleanup or action levels for ATSDR or other Agencies**" (emphasis added by ATSDR).[13]

While EPA has completed health assessments for HFPO-DA and PFBS, they were not reviewed by the SAB and did not undergo an appropriate peer review. HFPO-DA and PFBS underwent external peer review that was managed by a contractor, not the SAB. As stated in the EPA Peer Review Handbook, "HISAs or other scientific work products associated with highly visible or controversial environmental issues, or products that include novel scientific methods or

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[9] U.S. EPA, Peer Review Handbook, 4th edition, 2015, available at: https://www.epa.gov/sites/default/files/2015-10/documents/epa_peer_review_handbook_4th_edition_october_2015.pdf.
[10] *Id.* at 54.
[11] ATSDR Peer Review Agenda for the Toxicological Profile for Perfluoroalkyls (PFAS), available at: https://www.atsdr.cdc.gov/sites/peer_review/tox_profile_perfluoroalkyls.html.
[12] U.S. EPA, Peer Review Handbook, 4th edition, 2015, at pages 55-57, available at: https://www.epa.gov/sites/default/files/2015-10/documents/epa_peer_review_handbook_4th_edition_october_2015.pdf.
[13] See ATSDR description of minimal risk levels at: https://www.atsdr.cdc.gov/mrls/index.html.

approaches, are most suited to review by the SAB."[14] This is because the SAB process is far more robust than the processes run by external contractors. For instance, the SAB strives to reach consensus in all their reports because their final product is meant to be a consensus advisory report.[15] EPA provides no explanation why it used external contractors instead of the more robust SAB process.

The external peer reviewers of the contractor-led HFPO-DA and PFBS reviews did not strive to reach consensus, and, in fact, the final HFPO-DA report provided non-consensus opinions. Even the second round of external peer review of the HFPO-DA assessment cannot make up for the fact the peer-review process was not nearly as robust as an SAB process would have been. The second peer review report also provided EPA, and the public, with non-consensus opinions. When assessments are controversial and also considered to be HISAs because of the important and costly rulemakings that rely on them, a contractor-led external peer review is simply not as robust as SDWA-required SAB review. As such, the health assessments EPA relies on for the four contaminants in the regulatory determination are not of sufficient scientific quality and rigor and should be properly peer reviewed by the SAB to support an adequate regulatory determination.

2. High uncertainty in the human health assessments for PFHxS, HFPO-DA, and PFBS makes them inadequate to support a determination to regulate

Even if the scientific assessments for PFHxS, HFPO-DA, and PFBS had been appropriately reviewed, all three of these assessments are low confidence. The three assessments each have an aggregate uncertainty factor (UF) value of 3000 assigned to the underlying Reference Dose (RfD). **This is the maximum allowable aggregate UF value**. Above this point, EPA guidance recommends, consistent with current EPA practice, that reference values not be derived.[16] The values derived for these three contaminants meet the criteria for low confidence. "Low confidence indicates the judgment that the data supporting the [Reference Dose] RfD may be of limited quality and/or quantity and that additional information could result in a change in the RfD."[17] The PFBS assessment is very clear in stating that "[t]he overall confidence in the chronic RfD for thyroid effects is low,"[18] yet EPA relies on this endpoint and value for the health-based water concentrations (HBWC). For PFHxS and HFPO-DA, while the assessments are lacking the

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[14] *Id*. at 66.
[15] U.S. EPA, SAB Handbook for Members and Consultants, available at: https://sab.epa.gov/ords/sab/r/sab_apex/files/static/v403/Serving%20on%20the%20EPA%20Science%20Advisory%20Board%20SABSO-12-001.pdf.
[16] U.S. EPA, 2002. A review of the reference dose and reference concentration process, at page xviii and 4-41 where EPA states: "The Technical Panel recommends limiting the total UF applied for any particular chemical to no more than 3000 and avoiding the derivation of a reference value that involves application of the full 10-fold UF in four or more areas of extrapolation," available at: https://www.epa.gov/sites/production/files/2014-12/documents/rfd-final.pdf.
[17] *See* EPA Reference Dose (RfD): Description and Use in Health Risk Assessments, available at: https://www.epa.gov/iris/reference-dose-rfd-description-and-use-health-risk-assessments.
[18] U.S. EPA Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3), at page 4, available at: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=350888.

typical statement about the confidence in the value, due to the UFs of 3000 applied in both assessments, it is not possible to characterize these assessments as anything but low confidence.

It is worth noting that during the review of the PFBS assessment, one peer reviewer questioned why a single study could serve as the basis of U.S. national regulation. EPA responded that the "PFBS assessment is not a regulatory action but rather may in part inform risk remediation activities."[19] Notwithstanding that earlier caveat, *the single study* in the PFBS assessment is indeed a critical driver in EPA's proposed regulation to regulate PFBS.

3. The HBWCs are overly conservative and are not fit for purpose

EPA uses the following HBWCs for the four PFAS chemicals: 9.0 ppt for PFHxS, 10.0 ppt for HFPO-DA, 10.0 ppt for PFNA[20], and 2000 ppt for PFBS. For EPA's proposed hazard index approach (used to calculate the MCL for the mixture of these four PFAS), EPA is proposing to calculate the hazard index as the sum total of component PFAS hazard quotients (HQs), calculated by dividing the measured component PFAS concentration in water by these relevant HBWCs. The HBWCs are therefore critical to EPA's proposal to regulate these four PFAS. EPA derives HBWCs using three inputs: oral toxicity values (either the Reference Dose (RfD) or MRL), the body-weight adjusted drinking water intake level for the population of concern (DWI-BW), and the relative source contribution (RSC). However, as noted above, the science supporting the toxicity values for the four contaminants is highly uncertain, is not fit for purpose, and has not undergone the requisite SAB review. Thus, this input in the HBWC is flawed for all four contaminants.

In addition to using highly uncertain toxicity values, EPA uses a default RSC value (i.e., the amount of assumed exposure coming from drinking water) in each HBWC equation. EPA recognizes that "available data on PFHxS exposure routes and sources did not permit quantitative characterization of PFHxS exposure."[21] Given that lack of data, EPA chose the most conservative default value for the RSC (20%). Combining this RSC with the highly uncertain toxicity values leads to HBWC values that are so low, they are untethered from any realistic measure of potential risk to human health.

In applying the 20% RSC, EPA refers to the EPA 2000 Exposure Decision Tree.[22] However, this decision tree allows flexibility and encourages the review of information, when available, to make a reasonable determination of exposure, with the goal that the default would not have to be used. For PFHxS, HFPO-DA, PFNA, and PFBS, EPA has not made a sufficient effort to review the existing information to inform its use of the 2000 Decision Tree. For instance, HFPO-DA is used as a processing aid, and it is not found in consumer products. In determining that a 20%

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[19] U.S. EPA, Response to Peer Review Comments on the Draft Human Health Toxicity Values for Perfluorobutane Sulfonic Acid (CASRN 375-73-5) and Related Compound Potassium Perfluorobutane Sulfonate (CASRN 29420-49-3) October 2020, at page 16, available at: https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=350888.
[20] We note that 88 Fed. Reg. at 18647, EPA refers to the PFNA HBWC as being 100 ppt.
[21] 88 Fed. Reg. at 18646.
[22] U.S. EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health, EPA-822-B-00-004, available at: https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf.

RSC is appropriate, EPA cites to the EPA 2021 HFPO-DA Human Health Toxicity Value Assessment.[23] However, this assessment does not provide a robust discussion of potential human exposures, and it provides no justification for why a processing aid (chemical intermediate) that is not found in consumer products would warrant a default RSC of 20%. If EPA were to do a simple cursory review and follow its own 2000 Decision Tree, it would lead to the use of a RSC of 80%.[24] EPA has provided no information to support the choice of a 20% default for HFPO-DA.

EPA also chose a 20% RSC for PFHxS, PFNA, and PFBS without conducting a robust exposure review. For PFNA and PFHxS, EPA summarizes the occurrence data but still opts for a default of 20%.[25] By contrast, New Hampshire, Michigan, Minnesota, and Washington State all chose to use a RSC of 50% for PFHxS.[26] Similarly, for PFNA, New Hampshire, New Jersey, Michigan, and Washington state all chose to use a RSC of 50%.

In addition to the highly uncertain toxicity value, and the overly conservative RSC, EPA also appears to have erred in its calculation of the HBWC for PFHxS. Based on the inputs provided in the formula (which, as noted above, we do not support), the derived HBWC should be 12 ppt, not 9 ppt.[27]

4. In addition, the flaws in the individual toxicity assessments make a regulatory determination for a mixture of the four contaminants inappropriate at this time

For the reasons described above, EPA has not met the statutory or scientific requirements to make a positive regulatory determination for PFHxS, HFPO-DA, PFNA, or PFBS. EPA has not demonstrated that these PFAS may cause adverse health effects at the levels that EPA believes

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[23] U.S. 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." 2021; available at: https://www.epa.gov/chemical-research/human-health-toxicity-assessments-genx-chemicals.

[24] See step 7 of the Exposure Decision Tree as described in U.S. EPA Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health. EPA-822-B-00-004; available at: https://www.epa.gov/sites/default/files/2018-10/documents/methodology-wqc-protection-hh-2000.pdf, at page 4-8; and see also letter from Sheryl Telford, the Chemours Company, addressed to Elizabeth Behl, EPA, submitted to the Proposed Rule docket number EPA-HQ-OW-2022-0114, May 31, 2023 entitled Supplemental Data To Assist in the Development of Health Advisory.

[25] U. S. EPA. Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): GenX Chemicals, PFBS, PFNA and PFHxS, 2023, EPA–822–P–23–004, available at: https://www.epa.gov/system/files/documents/2023-03/PFAS%20HI%20MCLG%20Public%20Review%20Draft%2009%20March%202023.pdf.

[26] See ECOS Paper: Processes and Considerations for Setting State PFAS Standards, 2023 Update, available at: https://www.ecos.org/documents/ecos-paper-processes-and-considerations-for-setting-state-pfas-standards-2023-update/.

[27] U. S. EPA. Maximum Contaminant Level Goal (MCLG) Summary Document for a Mixture of Four Per- and Polyfluoroalkyl Substances (PFAS): GenX Chemicals, PFBS, PFNA and PFHxS, 2023, EPA–822–P–23–004, at pages 16-17, available at: https://www.epa.gov/system/files/documents/2023-03/PFAS%20HI%20MCLG%20Public%20Review%20Draft%2009%20March%202023.pdf.

may occur, and EPA has not conducted the requisite SAB review. As such, a determination to regulate a mixture of the four contaminants is also not supported.

B. Existing occurrence data does not support the regulatory determination

1. SDWA requires collection of UCMR data in order for EPA to make the regulatory determination

To fulfill the second criteria under Section 1412(b)(1)(A) of SDWA, the act requires that EPA demonstrate it knows 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."[28] Here, EPA has done nothing more than show that these PFAS *may* occur at levels of concern, falling short of the statutory requirement.

SDWA requires that once every five years, EPA issue a new list of unregulated contaminants to be monitored in drinking water,[29] known as the Unregulated Contaminants Monitoring Rule (UCMR). The contaminant occurrence data is a mechanism built into SDWA to obtain nationally representative occurrence data for contaminants in drinking water. Collecting data under the UCMR serves to better inform regulatory determinations, as contaminants are evaluated based on health effects and occurrence information.[30] EPA has historically relied on the UCMR process to collect occurrence data on contaminants to support a determination on whether to regulate them. In previous regulatory determinations, where both state and UCMR data were available, EPA has determined that UCMR data "are the best available data" representing the national scale.[31] EPA also notes this in the proposed rule as well.[32]

EPA has simply not collected sufficient data to meet the statutory requirement of knowing or demonstrating there is a substantial likelihood that the four PFAS will occur in public water systems with a frequency and at levels of public health concern. EPA relies on limited UCMR 3 data and state data from only 11 states. SDWA contemplates EPA's reliance on UCMR data, and, because EPA is currently collecting data on 29 PFAS as part of the UCMR 5, it is premature to propose a regulatory determination for these substances. This data collection will provide national representative information on the occurrence of all four contaminants and will be more relevant for EPA to evaluate in its decision to regulate.

2. UCMR 3 data and state data do not support a positive regulatory determination for HFPO-DA, PFNA, and PFBS

The existing data do not support a finding that the four contaminants of concern are occurring in drinking water with a frequency and at levels of public health concern. Furthermore, the

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[28] 42 U.S.C. § 300g-1(b).
[29] 42 U.S.C. § 300g-1(b)(1)(B).
[30] 87 Fed. Reg. 68060, 68062 (November 14, 2022).
[31] *See* 85 Fed. Reg. 43990, 44001 (Jul. 21, 2020).
[32] 88 Fed. Reg. 18672 states "UCMR 3 monitoring occurred between 2013 and 2015 and is currently the best nationally representative finished water dataset for any PFAS, including PFOA, PFOS, PFNA, PFBS, and PFHxS."

detection levels used in UCMR 3 are significantly higher than the derived HBWCs, making data interpretation difficult.

There is no nationally representative data for HFPO-DA. In the past, EPA has determined not to regulate contaminants based on the lack of nationally representative occurrence data.[33] While there is some non-representative state data (which likely suffers from self-selection bias), the majority of state samples detected HFPO-DA at occurrence levels below prior EPA determinations to regulate. Only three states had a percentage of detection that was above 0.5%, and the majority of states analyzed had detections below 0.3%.[34] The statutory standard is simply not met based on the limited HFPO-DA occurrence data.

For PFNA, the UCMR 3 data showed that only 0.05% of all samples had detections above the quantitation limit, or MRL.[35] These detections were found in 14 water systems that serve 526,341 people.[36] An MCL for PFNA seems to be unnecessary at a national scale.

PFBS was also detected at only 0.05% of water samples in UCMR 3, and the population served by the water systems with detections was 349,933 people.[37] For PFBS, the highest level detected was 370 ppt, which is far below the HBWC of 2,000 ppt. It is also worth noting that there were no PFBS exceedances above 2000 ppt, and the available state data also showed no detections above 199 ppt. Similarly, Department of Defense drinking water sampling results from drinking water systems and private wells located in covered areas adjacent to 50 installations showed no detection above 362 ppt. Similarly, the USGS National Water Information System (NWIS) showed a maximum detection level of 109 ppt.[38] An MCL for PFBS seems to be unnecessary at a national scale. EPA even admits as much stating "EPA notes that PFBS concentrations do not exceed their HRL of 2000 ppt when considered in isolation."[39] EPA then suggests that "dose additivity" is a reason to list PFBS.[40] This is not a valid reason to support a determination to regulate.

The levels of detection from the best available sampling data simply do not support a listing for HFPO-DA, PFNA, and PFBS.

EPA has determined not to regulate the following substances at a national level on the basis that they did not occur at a frequency or level of public health concern:

- Nitrobenzene: UCMR 1 collected 33,576 finished water samples from 3,861 PWSs (serving ~226 million people) for nitrobenzene, and it was detected in only a small

[33] 67 Fed. Reg. 38222, 38231 (Jun. 3, 2022) and 68 Fed. Reg. 42897, 42903 (Jul. 18, 2003). EPA determined not to regulate Acanthamoeba under the SDWA because EPA had no national monitoring data for Acanthamoeba occurrence in PWSs.
[34] 88 Fed. Reg. at 18649.
[35] U.S. EPA, PFAS Occurrence and Contaminant Background Support Document, 2023, EPA–822–P–23–010, at 160, available at: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0037.
[36] *Id*. at 162.
[37] *Id*. at 118-120 at exhibit 5-19 and 5-21.
[38] *Id*. at 120-137.
[39] 88 Fed. Reg. at 18650.
[40] *Id*.

number of those samples (0.01%) above the HRL (10 µg/L), which is the same as the minimum reporting level (10 µg/L).[41]

- RDX: UCMR 2 collected 32,150 finished water samples from 4,139 PWSs (serving ~229 million people) for RDX, and it was detected in only a small number of those samples (0.01%) at or above the minimum reporting level.[42]

In the above examples where EPA determined not to regulate the contaminants, the percentage of samples with detections were close to the percentage detection occurrence levels found for the four PFAS.

Further, in 2003, EPA made a determination that aldrin, a more hazardous substance than PFAS, did not occur at a frequency and a level of public health concern despite nationally representative data showing occurrence of aldrin above the health risk level in 0.2% of water systems.[43] In that case, over one million people were being served by the water systems that had detections above the health risk level. The representative occurrence data for HFPO-DA (state data varied, some as low as 0%), PFNA (0.28%), and PFBS (0.16%) are similar or less than the percentage of detections in PWS for aldrin.

3. The co-occurrence data do not support a listing for the mixture of the four PFAS

To attempt to support its proposal to regulate these four PFAS as a mixture, EPA uses the UCMR 3 data to evaluate co-occurrence of PFAS.[44] Focusing on detections (e.g., occurrences above the minimal reporting level), these data show 11 occurrences of PFNA, 27 occurrences of PFHxS, and 3 occurrences of PFBS. As presented, however, it is impossible to discern the co-occurrences of these four PFAS due to a lack of occurrences in the available data. If we include PFOA and PFOS in considering occurrence, only one occurrence also includes PFHxS and PFNA. As PFOA and PFBS only co-occurred twice, it is likely that PFBS never co-occurred with PFHxS, PFNA, PFOA, and PFOS. If it had, EPA likely would have presented those data. In the state data, there was co-occurrence of all six PFAS in only 0.3% of the samples.[45] While EPA relies on an analysis by Cadwallader et al., 2022, to evaluate co-occurrence, that study's model did not include PFBS and PFNA because the reported values from UCMR 3 were insufficient to fit a national model.[46] It is also worth noting that Cadwallader et al., 2022, referred to the state datasets as being "insufficient" to act in place of UCMR data.[47]

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[41] 86 Fed. Reg. at 12285.
[42] *Id*. at 12286.
[43] 85 Fed. Reg. at 43996.
[44] U. S. EPA, PFAS Occurrence and Contaminant Background Support Document, 2023, EPA–822–P–23–010, at 192-194, available at: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0037.
[45] *Id.* at exhibit 6-8.
[46] Cadwallader, A., Greene, A., Holsinger, H., Lan, A., Messner, M., Simic, M., and Albert, R. 2022. A Bayesian Hierarchical Model for Estimating National PFAS Drinking Water Occurrence. *AWWA Water Science,* 4(3):1284. https://doi.org/10.1002/aws2.1284.
[47] *Id.*

4. EPA inappropriately uses anticipated occurrence findings rather than existing data in its preliminary determination

EPA must make the determination to regulate based on existing data. However, EPA seems to include *anticipated* findings in their determination. EPA states: "EPA anticipates that national monitoring with newer analytical methods capable of quantifying PFAS occurrence to lower levels, significant occurrence and cooccurrence of these PFAS are likely to be observed."[48] Yet EPA does not provide any citation or data to support this statement. EPA assumes that the UCMR 5 data will show that the four contaminants are known to occur.[49] While that is one possibility, considering the costs and importance of this regulatory proposal, EPA should await the analysis of the UCMR 5 data to support its assumptions with respect to these four PFAS to determine whether there is representative data sufficient to demonstrate occurrence that would support a regulatory determination.

5. EPA does not explain how it applied criteria to determine whether these four PFAS meet the occurrence factor

In the proposed rule, EPA fails to explain how it applied criteria in determining that the four PFAS meet the occurrence factor—the statutory finding that the contaminants are "known to occur or there is a substantial likelihood that the contaminants will occur in public water systems with a frequency and at levels of public health concern." EPA acknowledges that it does not have a "bright line" threshold for occurrence in drinking water that triggers whether a contaminant is of public health concern; rather, this determination is based on various factors. The considerations include: the level at which the contaminant is found in drinking water; the frequency at which the contaminant is found and at which it co-occurs with other contaminants; whether there is an sustained upward trend that these contaminant will occur at a frequency and at levels of public health concern; geographic distribution; the impacted population; health effects; the potency of the contaminant; other possible sources of exposure; and potential impacts on sensitive populations or life stages.[50]

EPA fails to explain why the data it relies on meets these factors for occurrence at levels and frequency of concern. EPA bases its determination for the occurrence factor on UCMR 3 data for PFNA, PFBS, and PFHxS (no data were monitored for HFPO-DA in UCMR 3) and recent PFAS drinking water data collected by 11 states, which are not representative.[51] The UCMR data found that only 233 out of 36,972 samples had reported detections greater than or equal to the minimum reporting levels of at least one of the three PFAS. The percentage of systems where PFAS were found ranged from 0.1 to 56%. EPA does not explain why this data, which shows significant occurrence variability, and in some cases virtually no instances of occurrence, reflects a sufficient level of occurrence for all four PFAS to warrant regulation.

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[48] 88 Fed. Reg. at 18650.
[49] 88 Fed. Reg. at 18651.
[50] 88 Fed. Reg. at 18647.
[51] *Id.*

C. EPA has not demonstrated that this proposed regulation presents a "meaningful opportunity" for health risk reduction

Although the final element of the regulatory determination provides some discretion to define what constitutes a meaningful opportunity to address health risk reduction, that discretion is not unlimited. The Administrator's decision must be grounded on data, consider the costs of the decision, and have an articulable and understandable demonstration that the choice made is rationally related to the facts. It cannot be random choice without any reason or system.

EPA has failed to demonstrate with an adequate basis that the proposal to regulate PFNA, PFHxS, PFBS, and HFPO-DA (and mixtures of these PFAS) presents a meaningful opportunity for health risk reduction for persons served by the over 66,000 public water systems potentially impacted by this rulemaking. Keeping in mind that cost considerations are heavily imbedded in multiple elements of SDWA, those considerations are necessarily implicated in determining what is "meaningful." Failure to consider costs at this stage omits an essential element of the process that EPA must undertake before regulating these PFAS in public water systems, many of which are very small. EPA must also consider the downstream costs to the industries that rely on public water systems.

EPA provides very limited rationale for its meaningful-opportunity determination, primarily resting on speculative potential benefits. The proposal discusses the need to address the four PFAS due to the *potential* adverse human health effects, *potential* for co-exposures of these PFAS, and the availability of analytical methods to measure and treatment technologies (irrespective of costs) to remove them from drinking water. EPA does not enumerate a list of factors for its consideration of a meaningful opportunity for health risk reductions. In the past, EPA has looked to occurrence data and populations served by water systems to support a positive or negative determination based on the "meaningful opportunity" factor.[52] As discussed, the health data and the occurrence data for the four PFAS do not support such a determination.

Further, EPA does not factor in costs in its justification that there are treatment technologies available to remove the PFAS from drinking water. Even if these technologies are available, there will be a limited supply of technologies available for the thousands of water systems that will suddenly need them all at the same time, and high costs for public water systems to implement and maintain the treatment technologies. EPA has not assessed the impact of a shift in demand on GAC, ion-exchange resin, and membrane markets. Compliance with the rule would be cost-prohibitive and may result in systems having to shut down or pass the high costs down to their ratepayers. EPA must consider the extraordinary compliance challenges and costs that this rule would impose on water systems, and those industries that rely on these water systems, for regulating the four PFAS because these factors impact whether this approach to regulate the PFAS is a "meaningful" opportunity to reduce health risk.

In conclusion, absent substantial evidence in the record to support the three statutory criteria of health effects, occurrence, and a meaningful opportunity for health risk reduction, EPA's

[52] 86 Fed. Reg. at 12283.

preliminary determination to regulate PFNA, PFBS, PFHxS, and HFPO-DA is arbitrary and capricious and contrary to the requirements of SDWA.

III. The Proposed MCL and MCLG for PFNA, PFHxS, PFBS, and HFPO-DA (and Mixtures of These PFAS) Is Legally and Technically Flawed and Cannot Be Finalized in Its Current Form

EPA proposes (simultaneously with its preliminary determination) a MCL and MCLG of "1.0 (unitless) hazard index" for PFNA, PFHxS, PFBS and HFPO-DA as a mixture. The proposed MCL and MCLGs for PFNA, PFHxS, PFBS, and HFPO-DA (and mixtures of these PFAS) cannot be finalized because the procedures EPA used to propose the MCLs and MCLGs for these four PFAS violate SDWA. And, the Hazard Index approach is inconsistent with SDWA requirements. Should, in the future, data from UCMR 5 identify occurrence of these four PFAS at levels of public health concern EPA can revisit whether regulation is necessary consistent with SDWA requirements.

In March 2021, EPA issued a final regulatory determination to regulate PFOA and PFOS as contaminants under SDWA. Now, EPA proposes a MCL of 4 ppt and MCLG of 0 for PFOA and for PFOS. As discussed, the scientific data EPA uses to support the proposed MCLs and MCLGs for PFOA and PFOS do not comport with SDWA's mandate for EPA to use the best available science in carrying out national drinking water regulations.

A. EPA violated SDWA's Requirement to seek SAB review before proposing this regulation and the MCL for PFNA, PFHxS, PFBS, and HFPO-DA

Section 1412(e) of SDWA requires that EPA request comments from the SAB prior to proposal of a MCLG and NPDWR:

> The Administrator shall request comments from the Science Advisory Board (established under the Environmental Research, Development, and Demonstration Act of 1978) *prior to proposal of a maximum contaminant level goal and national primary drinking water regulation.* The Board shall respond, as it deems appropriate, within the time period applicable for promulgation of the national primary drinking water standard concerned. This subsection shall, under no circumstances, be used to delay final promulgation of any national primary drinking water standard.[53]

Unlike PFOA and PFOS, EPA did not seek input from the SAB on the MCL for PFNA, PFHxS, PFBS**,** and HFPO-DA. EPA offers no explanation for this departure from SDWA requirements. This error is likely in part due to the flawed attempt to rush to propose a regulatory determination and a regulation/MCL at the same time (discussed further below). SAB could not have reviewed the assessments within the "time period applicable" because they were proposed simultaneously. The typical process creates up to two years between a proposed regulatory determination and a final determination and a regulatory proposal. EPA must respect this detailed process that

[53] 42 U.S.C. § 300g-1(e).

Congress set up in SDWA to allow scientific peer review by the SAB and adequate public comment. Based on SDWA requirements, if it wishes to finalize this MCL for these substances, EPA must re-propose the rule after SAB has an opportunity to review.

B. EPA failed to follow the process mandated by SDWA in proposing the preliminary determinations for PFNA, PFHxS, PFBS, and HFPO-DA simultaneously with their proposed MCL and MCLG

EPA has decided in this proposal to simultaneously issue a preliminary regulatory determination for PFNA, PFHxS, PFBS, and HFPO-DA and a proposed MCL and MCLG for these four PFAS. In doing so, it has side-stepped the statutory process for regulating contaminants under SDWA and deprived the public of sufficient time to provide public comments on the proposal.

SDWA requires that a preliminary regulatory determination be made prior to proposing an MCL:

> For each contaminant that the Administrator determines to regulate under subparagraph (B), the Administrator shall publish maximum contaminant level goals and promulgate, by rule, national primary drinking water regulations under this subsection. The Administrator shall propose the maximum contaminant level goal and national primary drinking water regulation for a contaminant not later than 24 months *after the determination to regulate under subparagraph (B),and may publish such proposed regulation concurrent with the determination to regulate*. The Administrator shall publish a maximum contaminant level goal and promulgate a national primary drinking water regulation within 18 months after the proposal thereof. The Administrator, by notice in the Federal Register, may extend the deadline for such promulgation for up to 9 months.[54]

The "subparagraph (B)" referred to in this paragraph means the section of SDWA regarding EPA's determination to regulate contaminants "after notice of the preliminary determination and opportunity for public comment."[55] Therefore, the statutory procedure for regulation of contaminants is that EPA first issues a preliminary determination and provides an opportunity for comment. Then, after consideration of public comments, EPA may issue a final regulatory determination and concurrently (if the determination is positive) propose a NPDWR and MCLG for the contaminant for public comment. This statutory approach ensures that stakeholders could comment on the preliminary determination and then again after EPA makes a final determination on proposed MCLs and MCLGs for the contaminant. Indeed, this is the process that EPA has followed in the past.

In contrast to that usual course, EPA explains in the preamble that it interprets "determination to regulate" to mean the regulatory *process* for determining to regulate a contaminant, which begins with a *preliminary* determination. EPA thus claims that the statute allows it to issue a proposed regulation concurrent with a preliminary determination to regulate.[56]This interpretation of

[54] 42 U.S.C. § 300g-1(b)(1)(E) (emphasis added).
[55] 42 U.S.C. § 300g-1(b)(1)(B)(ii).
[56] 88 Fed. Reg. at 18644.

SDWA is flawed because a preliminary determination is not a "determination to regulate." The entire scheme Congress set out in SDWA reflects a step-by-step process in which EPA collects data on contaminants, seeks public input and consultation with scientific authorities, proposes to regulate or not regulate the contaminant based on evaluation of the three statutory factors, and proposes (and accepts comment on) and adopts regulatory limitations if it decides regulation is warranted. EPA's interpretation eliminates the distinction between preliminary and final determinations, upending Congress's intent to create multiple opportunities for public comment before EPA makes such an impactful decision. The text is clear, and EPA's proposed interpretation is not reasonable.

EPA justifies its corner-cutting with its goal to reduce these PFAS "expeditiously" and points to a "public urgency" to reduce PFAS concentrations in drinking water.[57] But EPA's desire to rush to the finish line cannot overcome the statutory process. By short circuiting the procedures for regulating contaminants, the Agency failed to provide the public with the opportunity to comment on the preliminary determination for these four PFAS and provide EPA with necessary data, including occurrence data EPA acknowledges it does not have, to make the threshold decision on whether the statutory criteria are met to justify the proposal of a NPDWR or MCLG for the four PFAS. As proposed, stakeholders had only 60 days to provide comment not only on EPA's preliminary determination that these four PFAS must be regulated but also on the proposed MCL and MCLG Hazard Index—a completely novel approach to setting an MCL and MCLG.

To comply with SDWA requirements for regulating contaminants, EPA must withdraw its proposed MCL and MCLG for the four PFAS and, instead, first consider public input on the preliminary determination, i.e., whether the four PFAS warrant regulation at all. Then, to cure the legal defect in the proposal, EPA would have to re-propose the final determination and the NPDWR with an additional comment period before finalizing the regulatory limits on these substances.[58]

C. The Hazard Index approach is inconsistent with SDWA's statutory requirements for setting MCLs

For each contaminant that EPA determines to regulate, it must either issue an MCL or, "if it is not economically or technologically feasible to so ascertain the level of such contaminant," use a treatment technique.[59] The novel Hazard Index approach is neither an MCL nor a treatment technique. Therefore, EPA's use of this approach to regulate PFNA, PFBS, HFPO-DA, and PFHxS violates SDWA.

[57] 88 Fed. Reg. at 18652.
[58] As EPA issued a previous regulatory determination for PFOA and PFOS, this comment is not applicable to the portion of the proposal setting MCLs for those substances.
[59] 42 U.S.C. § 300g-1(b)(7)(A).

1. SDWA contemplates setting *individual levels* for each contaminant

The term "maximum contaminant level" means "the maximum *permissible level of a contaminant* in water which is delivered to any user of a public water system."[60] Notably,

SDWA contemplates setting MCLs and MCLGs for *each contaminant*[61] individually and with a specific level so that regulated entities can understand the levels that must be achieved for compliance. In this proposal, EPA proposes an MCL and MCLG for PFNA, PFHxS, PFBS, and HFPO-DA as a mixture and uses a Hazard Index approach rather than a specific concentration level (ppm or ppt). SDWA does not contemplate setting MCLs for a mixture, let alone using a complex equation. The term "mixture" appears only twice in the statute, and it is related to drinking water studies of complex mixtures.[62] The statutory text thus reflects that Congress never intended for EPA to regulate mixtures of contaminants, rather than the individual contaminants themselves, using MCLs.

The Hazard Index approach is inconsistent with SDWA because it sets a limitation on a group of chemicals rather than the individual chemicals, and it does not set a "level" as contemplated by the statute. The Hazard Index approach is not a "level" at all—it is a sum of component HQs, calculated by dividing the measured regulated PFAS component contaminant concentration in water by the associated health-based water concentration. A sum of those quotients greater than 1 constitutes an exceedance of the MCL. EPA thus transforms the typical MCL or MCLG into a complex mathematical equation that leaves uncertainty regarding compliance, absent additional efforts to measure, calculate, and combine fractions of each individual contaminant. Indeed, the Hazard Index is a highly variable equation that can change over time as inputs change (as the health-based water concentration may change).

This approach is also inconsistent with the SDWA mandate that MCLs be only as close as feasible to the MCLG.[63] Under the Hazard Index approach, it would be impossible to fulfill this requirement as the proposed MCL and MCLGs have the same unitless value.[64]

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[60] 42 U.S.C. § 300f(3).

[61] 42 U.S.C. § 300g-1(b)(E) ("For *each contaminant* that the Administrator determines to regulate under subparagraph (B), the Administrator shall publish maximum contaminant level goals and promulgate, by rule, national primary drinking water regulations under this subsection." (emphasis added)). See also *City of Portland, Oregon v. EPA*, 507 F.3d 706 (D.C. Cir. 2007): "[The SDWA] requires EPA to set a 'maximum contaminant level goal' (MCLG) for *each identified contaminant* at a level at which no known adverse health consequences will occur" (emphasis added).

[62] 42 U.S.C. § 300j-18(b)(3).

[63] 42 U.S.C. § 300g-1(b)(4)(B).

[64] This novel approach to calculating a Hazard Index for a mixture of chemicals is not a treatment technique authorized by SDWA. *See* 42 U.S.C. § 300g-1(b)(7)(A).

2. The Hazard Index does not meet SDWA's requirement to use best available science

a. The Hazard Index approach used is only appropriate for initial screening, not for regulation

The SAB was asked to review a mixtures framework, which contained multiple approaches for estimating the likelihood of noncancer risks associated with PFAS. EPA provided the SAB with descriptions of additivity-based approaches including the Hazard Index approach, a relative potency factor (RFP) approach, and a mixture-benchmark dose (M-BMD) approach. The framework document applied these approaches using a hypothetical mixture of five PFAS. EPA did not ask the SAB to review the framework as it is being applied in this proposed rule to PFNA, PFHxS, PFBS, and HFPO-DA as a mixture.

While EPA notes it received a favorable review for developing the mixtures assessment approaches,[65] it concedes that the favorable review was for approaches "that rely on a health protective assumption of dose additivity based on a common health outcome, instead of a common mode of action (MOA)."[66] In this proposed rule, however, EPA is not applying a framework that relies on a common health outcome or a common mode of action. For the four PFAS, EPA is mixing and matching distinct endpoints. As a critical effect, EPA is relying on the thyroid endpoint for PFHxS and PFBS, bodyweight changes for PFNA, and liver lesions for HFPO-DA.

This approach, which combines disparate endpoints, appears to be unprecedented in a regulatory action. In its report to EPA, the SAB stated: "In general, the screening level Hazard Index (HI) approach, in which Reference Values (RfVs) for the mixture components are used regardless of the effect on which the RfVs are based, is appropriate for initial screening of whether exposure to a mixture of PFAS poses a potential risk that should be further evaluated."[67] The approach EPA proposes as an MCL, in the words of the SAB, is an approach for "initial screening." And if potential risks are seen, they should be "further evaluated."

A Hazard Index approach that relies on different effects is not endorsed or supported by the SAB as being scientifically robust for a regulation. EPA has not explained why this screening level analysis is appropriate for an MCL, particularly since it is being used in a quantitative manner, to inform an economically significant regulation. Furthermore, EPA's own policy, as recently stated by the EPA Office of Chemical Safety and Pollution Prevention, is that the appropriate

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[65] U.S. EPA. *Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS).* 2023, EPA–822–P–23–003, at page 4, available at: https://www.epa.gov/system/files/documents/202303/PFAS%20Mix%20Framework%20Public%20Review%20Draft%2009%20March%202023.pdf.

[66] *Id.*

[67] U.S. EPA. Transmittal of the Science Advisory Board Report titled, ''Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS.'' EPA–22–008, 202, at page 92, available at: https://sab.epa.gov/ords/sab/f?p=114:12:15255596377846.

approach to addressing risks found in a screening level evaluation is to refine the evaluation.[68] It is not appropriate to use a screening level approach to inform regulation when additional information exists to inform the assessment.

EPA also notes that a Hazard Index approach is not novel because EPA uses it in the Superfund program.[69] But EPA's proposed use of a Hazard Index approach is inconsistent with Superfund program guidance. According to EPA's Risk Assessment Guidance for Superfund, the Hazard Index approach is most properly applied to compounds that produce the same effect by the same mode of action. If that condition is not met, the Superfund program guidance specifies that the Hazard Index should be used a *screening tool* only, just as the SAB had recommended.[70]

b. The proposed Hazard Index approach is not appropriate because it blends different end points, is not best available science, and leads to illogical outcomes

The best available science with respect to setting a Hazard Index is to assess how the chemical affects a target organ, or an endpoint. Using this target organ-specific data within a Hazard Index framework is referred to as the TOSHI approach. In discussing this approach, the SAB stated: "The TOSHI approach presents additional robustness compared to the Screening Level HI given the identification of human health/toxicity values that are effect/endpoint specific."[71] EPA nevertheless suggests that a TOSHI approach is less health protective.[72] This is simply wrong. Target organ-specific reference values are derived to be protective against the adverse effect that occurs at the lowest level. If different contaminants have different target organ reference values, they can, and should, be evaluated separately. This is the scientifically robust approach to using the Hazard Index. The SAB recognized that target organ-specific information may be lacking for certain PFAS, which helped to inform why the approach EPA used was only recognized for initial screening. Even so, in the case of the four PFAS being proposed for regulation, EPA has target organ-specific data which the Agency could have used in a more refined manner. If the data are sufficient for setting HBWCs, then they should also be considered sufficient for a more refined Hazard Index approach.[73]

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[68] See EPA's *Draft Proposed Principles of Cumulative Risk Assessment under the Toxic Substances Control Act*, Feb. 2023, in which, when referring to assessing cumulative risk, EPA states, at page 14, that a "hierarchical approach" is used in which tiered exposure and hazard assessments are conducted and that "refinements are typically made when lower tier cumulative 483 assessments that rely on highly conservative assumptions do not demonstrate an adequate margin of 484 exposure (MOE)." When applying these same concepts to a HI approach, and a screening level approach shows concerns, additional refinements are appropriate. In this case, EPA has not provided any refinements. Available at: https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0008.

[69] 88 Fed. Reg. at 18,669.

[70] See Risk Assessment Guidance for Superfund Volume 1, Human Health Evaluation Manual (Part A), EPA/540/1-89/002, at 8-14, available at https://www.epa.gov/sites/default/files/2015-09/documents/rags_a.pdf.

[71] *Id*. at 92.

[72] 88 Fed. Reg. at 18655.

[73] We note that a recent panel of independent experts deliberated on the most scientifically justified method of grouping PFAS for the purposes of human health risk assessment and regulatory actions and concluded that grouping PFAS together without data supporting common mode of action and potency is inappropriate. See

Ignoring certain information available to it, EPA instead chose to use a screening level approach to derive an MCL and MCLG for mixtures of PFAS to inform this highly complex and economically significant proposed regulation. This, and the lack of presentation of this to the SAB, violates SDWA's mandate to use "the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices."[74] EPA's explanation that the screening level approach, which is referred to as "general HI approach," is "a more health protective indicator of risk"[75] does not eliminate its obligation to use best available science. SDWA mandates a rigorous science-driven approach to ensure the protection of health. It does not permit EPA to substitute a "reasonable policy choice"[76] and forego a more rigorous analysis using data that is available.

EPA's screening level approach also leads to illogical outcomes. The Hazard Index may not be greater than 1.0. But if any of the individual PFAS occur at their HBWC, the ratio for that individual PFAS would be equal to 1. So, if two PFAS are at their HBWC (or even at half their HBWCs), the Hazard Index would be exceeded. In other words, the approach EPA has developed is so "health protective" that if even one PFAS is detected above its HBWC, the Hazard Index will be exceeded. This defeats the purpose of a mixtures approach because there are exceedances at detection levels before any additivity is considered. EPA's efforts to be "health protective" have led to an approach that is so restrictive that it makes any scientific evaluation irrelevant.

c. The dose additivity concept underpinning the Hazard Index approach is flawed because the underlying data already accounts for the co-occurrence of these chemicals

As discussed, EPA argues that the data support the co-occurrence of the four PFAS. In justifying the use of a dose-additive Hazard Index approach, EPA argues that it is a "reasonable health-protective assumption"[77] because these PFAS have co-exposures. However, in each step of the derivation of the HBWC, EPA makes conservative assumptions that also account for the co-occurrence of these chemicals. For instance, despite the availability of information and data to inform a more realistic value, EPA chose the most conservative default value of 20% for the RSC. By combining multiple conservative assumptions, the Hazard Index approach is no longer tethered to actual data, which is not the best available science.

3. The trigger levels EPA proposes for the six PFAS cannot be reliably measured

In setting MCL levels EPA must also ensure that the Proposed Rule's trigger levels are also feasible. EPA proposes trigger levels that are one-third of the MCL for PFOA and PFOS (1.3

Anderson, J.K. et.al., *Grouping of PFAS for human health risk assessment: Findings from an independent panel of experts*, Reg. Tox. Pharm, 2022, 134 (105226). Available at: https://www.sciencedirect.com/science/article/pii/S0273230022001131.

[74] 42 U.S.C. § 300g-1(b)(3)(A)(i).

[75] 88 Fed. Reg. at 18655.

[76] *Id*. at 18655.

[77] 88 Fed. Reg. at 18663.

ppt), while also acknowledging that this is below the practical quantitation limit (PQL). Similarly, EPA proposes a trigger level that is 0.33 for the hazard index for PFHxS, HFPO-DA, PFNA, and PFBS. It is not realistic or feasible to set a national standard where measurement at the required trigger level is not reliably obtainable.[78]

IV. The Science Supporting the Proposed MCLs for PFOA and PFOS Is Not the Best Available Science

A. The science supporting the MCLs and MCLGs for PFOA and PFOS does not meet the statutory standard for use of the best available science

1. The period for SAB review was inappropriately truncated

The robustness of SAB review for the MCLs for PFOA and PFOS was severely diminished by exceedingly short timelines for each step of the process and by a lack of critical expertise. As described below, the peer review process was compromised and inconsistent with sound and objective scientific practices.

The *Federal Register* notices announcing the beginning of the process and the availability of supporting documents were November 10, 2021 and November 16, 2021, respectively.[79] The final report of the SAB was provided to EPA on August 22, 2022, only 279 days after documents were made available for review and only 243 days after the first meeting of the SAB. This is notably shorter than less complex reviews. For comparison, the SAB review of EPA's *Assessment of the Potential Impacts of Hydraulic Fracturing for Oil and Gas on Drinking Water Resources*, a 2015 document that was under 1,000 pages, took 400 days to complete.[80] This was 43% longer than the amount of time the SAB spent reviewing the four substantive PFAS documents. The SAB Panel which reviewed EPA's *Draft Toxicological Review of Ethyl Tertiary Butyl Ether* and *Draft Toxicological Review of tert-Butyl Alcohol (tert-Butanol)*, two technical documents like the PFOA and PFOS assessments but totaling only 547 pages, took 392 days to complete.[81] This was almost 40% longer for the review of documents what were approximately one-third the size of the relevant documents here.

If a member of the public wanted "timely consideration" of their comments by the SAB, comments were due on December 30, 2021. This provided a mere 44 days for the peer reviewers, and the public, to review over 1,750 pages of highly technical scientific assessments. The *EPA Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for*

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[78] See comments submitted by the PFAS Regulatory Coalition, submitted to the Proposed Rule docket number EPA-HQ-OW-2022-0114, May 31, 2023 which provide the report entitled "Survey Summary of Commercial Drinking Water Analytical Laboratories to Support the Proposed National Primary Drinking Water Maximum Contamination Levels (MCLs) for Perfluorooctanoic Acid (PFOA) and Perfluorooctane Sulfonic Acid (PFOS) and Proposed Hazard Index For Perfluorohexane Sulfonic Acid (PFHxS), Hexafluoropropylene Oxide Dimer Acid (HFPO-DA), Perfluorononanoic Acid (PFNA), and Perfluorobutane Sulfonic Acid (PFBS)."

[79] See 86 Fed. Reg. 62526 where EPA announced the meeting, but the draft documents were not released until Nov. 16, 2021, as announced at: https://www.epa.gov/newsreleases/epa-advances-science-protect-public-pfoa-and-pfos-drinking-water.

[80] See SAB report available at: https://sab.epa.gov/ords/sab/f?p=100:12:10700493575905.

[81] See SAB report available at: https://sab.epa.gov/ords/sab/f?p=100:12:10700493575905.

Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water (PFOA Draft Assessment) contained 59 pages of references and supporting studies, and the *EPA Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water* (PFOS Draft Assessment) contained 51 pages of references and supporting studies. With approximately 17 references per page, this equates to over 1,800 scientific references. These two Draft Assessments were not the only documents SAB was reviewing. In this same window, SAB was also asked to review EPA's *Draft Framework for Estimating Noncancer Health Risks Associated with Mixtures of Per- and Polyfluoroalkyl Substances (PFAS)* and EPA's *Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water*, and these documents' associated appendices.[82]

The length of review time provided was simply not commensurate with the breadth of scientific information the SAB and the public were asked to review. Nor was the review time commensurate with the importance and economic significance of the proposed rulemaking this peer review was conducted to inform. In fact, requests were made for extensions, but EPA and the SAB denied those requests.[83]

2. The SAB reviewers did not have adequate expertise required by EPA's own policies

The review was also compromised by a lack of expertise on critical endpoints that EPA relied upon. SAB policies recognize that there may be cases when experts are unable to reach consensus.[84] However, in this case, for one of the most critical endpoints that EPA relied upon in both assessments, the immunological endpoint, the SAB panel included only one reviewer with expertise in immunological effects.[85] The EPA Peer Review Handbook notes that "selected experts should include a range of technically legitimate points of view that fall along the continuum."[86] In order to have a range of points of view, the SAB panel should have included more than one expert in immunotoxicology. Another critical endpoint for PFOA and PFOS and needed to inform the review of the EPA report *Analysis of Cardiovascular Disease Risk Reduction as a Result of Reduced PFOA and PFOS Exposure in Drinking Water* is cardiovascular expertise. Unfortunately, the SAB panel included only one expert with

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[82] See the SAB meeting page for the review available at: https://sab.epa.gov/ords/sab/f?p=114:19:12110592892742:::19:P19_ID:963.
[83] See EPA response to Mr. Chaitovitz from Eric Burnseson, Director, Standards and Risk Management Division, Office of Ground Water and Drinking Water, EPA, dated May 5, 2023, stating that the provided comment period was "reasonable" and "EPA will not be extending the comment period for the proposed rule."
[84] SAB Handbook for Members and Consultants Serving on the EPA Science Advisory Board (SAB Handbook), at page 6, available at: https://sab.epa.gov/ords/sab/r/sab_apex/files/static/v403/Serving%20on%20the%20EPA%20Science%20Advisory%20Board%20SABSO-12-001.pdf.
[85] See SAB Determination Memo and List of Candidates where expertise of candidates is described. Only one chosen panelist, Dr. DeWitt, has expertise in immunotoxicology. Documents available at: https://sab.epa.gov/ords/sab/f?p=114:18:12110592892742:::RP,18:P18_ID:2601.
[86] EPA Peer Review Handbook at page 72.

cardiovascular expertise.[87] In addition, the SAB panel lacked any expertise in clinical medicine. While the SAB sought candidates that included expertise as a "physician/clinician with a focus on cardiology,"[88] the final SAB panel did not include any physicians or clinicians.[89] Thus, due to the multiple gaps in expertise, the SAB panel was critically deficient.

3. Peer review principles were not followed in the SAB process, largely due to a lack of time for review

When the chartered SAB panel was reviewing the draft report from the SAB, chartered SAB members noted that some of the flaws in the EPA documents, including the PFOA and PFAS Draft Assessments, could not be fixed.[90] One chartered SAB panelist questioned how the SAB could approve documents that didn't reflect the current state of practice and questioned if EPA should just start over. This panelist did not think the flaws could be quickly corrected. A second chartered SAB member suggested that, if the Draft Assessments were a manuscript, they should have been rejected. The overarching concerns were significant.[91] However, these comments were tempered by the requests from EPA leadership to the SAB to recognize the time constraints that EPA placed upon themselves to move the PFAS drinking water rulemaking along in a timely manner.

The final SAB report acknowledges and recognizes the time constraints. The SAB letter to the Administrator notes concerns about the study evaluation and evidence synthesis process used by EPA and urges EPA to address these problems.[92] EPA states in its response to the SAB comments that it made significant revisions.[93] However, these revisions did not undergo additional peer review. Instead, they are now the basis of economically significant rulemaking. When a journal manuscript is rejected, it must undergo another round of peer review after revisions are incorporated before going to publication. Consistent with this approach, one of the chartered SAB members recommended that the revised documents undergo another, albeit limited, form of peer review.[94] In response to this suggestion, an EPA staff member, the Director of the EPA SAB, interrupted the discussions of the SAB members to clarify the role of the SAB and steered the SAB chartered members away from recommending additional peer review.[95] There is nothing in the SAB handbook that precludes the SAB or the chartered SAB members

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[87] See SAB Determination Memo and List of Candidates where expertise of candidates is described. Only one chosen panelist, Dr. Lipworth, has expertise in cardiovascular disease. Documents available at: https://sab.epa.gov/ords/sab/f?p=114:18:12110592892742:::RP,18:P18_ID:2601.
[88] See SAB determination memo at page 1.
[89] We note that EPA received nominations for 41 candidates, which included a physician, but EPA chose not to put this expert on the SAB panel. See list and biosketches of candidates at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#pf.
[90] See Chartered SAB public meeting July 20, 2022 at 1:36-1:42 video available at: https://www.youtube.com/watch?v=UzDtzYDJB_I.
[91] *Id*.
[92] See SAB report to the EPA Administrator Aug 22, 2022, at page 2, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.
[93] See EPA Response to the Final SAB Recommendations, referred to as USEPA 2023f in the proposed rule.
[94] See Chartered SAB public meeting July 20, 2022 at 2:26-2:32 video available at: https://www.youtube.com/watch?v=UzDtzYDJB_I.
[95] *Id*.

from making a recommendation that the documents warrant additional peer review after substantial revisions are made by the Agency.[96]

The changes made by EPA in developing the *Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water* and *Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water* (Public Comment Draft Assessments) are significant enough that another peer review should have been conducted. For instance, as noted in the EPA Response to the Final SAB report, EPA developed many new elements to its assessment approach,[97] including elements such as a protocol. Consistent with today's best available scientific approaches, protocols are typically publicly released and reviewed before an assessment is conducted.[98] But, in this case, the protocol and other important modifications to the risk evaluation approach are being released for the first time as part of the MCL draft documentation, thus skirting the statutorily required SAB review (as discussed earlier in these comments). For this reason and for the additional reasons cited above, the underlying scientific evaluations do not meet the statutory standard.

4. The PFOA and PFOS MCLs are based on inadequate data

SDWA requires that data be collected by "best available methods (if the reliability of the method and the nature of the decision justifies use of the data)."[99] As discussed previously, UCMR data has always been and is still considered the most reliable data. As measurement methods have improved over time, the reliable quantitation limit, or minimum reporting levels for PFOA and PFOS have changed. In UCMR 3, the minimum reporting levels for PFOA and PFOS were 40 ppt and 20 ppt, respectively. In UCMR 5, the minimum reporting level for both PFOA and PFOS is 4 ppt, thus making the UCMR 5 data far more relevant for the regulatory action EPA is considering. In addition to having greater relevance, because PFOA and PFOS are able to be detected at much lower levels, the UCMR 5 data also represents the best available methods.

Considering the potentially economically significant costs of the proposed rulemaking, EPA must use the best available methods as these provide the most reliable and relevant data. When UCMR 5 sample collection and analysis is complete, EPA will have data from all public water

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[96] See SAB Handbook for Members and Consultants Serving on the EPA Science Advisory Board (SAB Handbook), available at: https://sab.epa.gov/ords/sab/r/sab_apex/files/static/v403/Serving%20on%20the%20EPA%20Science%20Advisory%20Board%20SABSO-12-001.pdf.

[97] See EPA Response to the Final SAB Recommendations, at pages 14-16, and 20 where EPA notes that they have: defined inclusion and exclusion criteria at each stage of the systematic literature review for PFOA and PFOS; added a new protocol to describe study quality evaluation procedures for epidemiological and animal toxicological studies; developed an evidence integration approach; and revised the non-cancer health effects synthesis and integrations sections, available at: https://sab.epa.gov/ords/sab/f?p=100:12:17203034137454.

[98] See EPA ORD Staff Handbook for Developing IRIS Assessments, released December 2022, which describes how the systematic review protocol is part of the IRIS Assessment Plan which is released early in the assessment process for public comment, at chapter 1, available at: https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=356370#tab-3.

[99] 42 U.S.C. § 300g-1(b)(3)(A)(ii).

systems serving more than 3,300.[100] The UCMR 3 data, due to the higher quantitation levels, is simply not sufficiently reliable. Nationwide UCMR 5 sampling will be complete in 2025 and these data will be the most reliable data to use to determine whether there is a substantial likelihood that these PFAS will occur frequently and at concentrations where they are likely to exceed their respective health risk levels. As proposed, EPA estimates that the number of impacted systems will be between 3,400 and 6,300.[101] In fact, the number of impacted entities is almost double what EPA estimates.[102]

B. Epidemiology data do not support an association for PFOA/PFOS immune, developmental, cholesterol, and hepatic (liver) endpoints

EPA has chosen to rely on epidemiology data for four critical endpoints for the development of the RfDs for the non-cancer effects of PFOA and PFOS and has inappropriately ignored high-quality animal data. An important comment made by the SAB was related to EPA's lack of transparent process for evidence synthesis and integration. SAB also directed EPA to consider multiple animal and human studies for a variety of endpoints.[103] Yet, for quantitative derivation of the RfD values, EPA did not follow SDWA requirement to use "best available public health information," and instead relied on non-binding EPA guidance and used human data for all endpoints, even when higher confidence animal data existed.[104] This non-binding guidance sets a bar at "sufficient information," which is not consistent with SDWA requirement for "best available public health information."

EPA must develop a consistent, transparent, and peer-reviewed approach for deriving and choosing candidate RfD values which is based on SDWA requirements. This means that candidate RfD values should be developed based on concordance of both animal and human data, and EPA should take comment on them and rely on the highest quality evidence, with a robust and transparent scientific rationale.[105] Instead, EPA relied on medium quality studies for three of the four endpoints and does not even present results from animal evidence in the *Federal Register* notice for the proposed rule. This choice made a material difference in the MCL levels. For instance, for hepatic effects of PFOS, if EPA had relied on the high quality animal data, rather than the medium quality human data, the resulting RfD would have been three orders of

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[100] Note that transient noncommunity water systems (TNCWSs) (i.e., non-community water systems that do not regularly serve at least 25 of the same people over 6 months per year) are not required to monitor under UCMR 5.86 Fed. Reg. 73131, 73132 (December 27, 2021).
[101] 88 Fed. Reg. at 18680.
[102] See PFAS National Cost Model Report, Black & Veatch Holding Company, prepared for the American Water Works Association, Appendix A (March 7, 2023): https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257 .
[103] See SAB report to the EPA Administrator Aug. 22, 2022, in the cover letter to Administrator Regan, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.
[104] 88 Fed. Reg. 18661 (EPA states: "The focus of this FRN is on epidemiological studies for the four prioritized health outcomes for which studies meeting this consideration were available, as human data are generally preferred 'when both laboratory animal data and human data with sufficient information to perform exposure-response modeling are available' (USEPA, 2022f).")
[105] As discussed previously, SAB review is also required by the SDWA. EPA's new framework for evaluating evidence and the resulting values from animal and epidemiological data should be reviewed by the SAB.

magnitude higher.[106] The approach provided in the proposed rule is not scientifically robust and not consistent with SDWA standards for scientific information.

There are also scientific concerns related to the choice of endpoints that are used for the candidate RfDs for PFOA and PFOS. The SAB review panel, which included only one panelist with expertise in immunology,[107] supported EPA's reliance on studies which evaluated anti-tetanus and anti-diphtheria antibody concentrations. But a recent publication that reviewed the weight of evidence for immunotoxicity of PFOA and PFOS concluded that, while there was moderate evidence from animal data for immunotoxic effects, species concordance and human relevance could not be established.[108] This publication, which presented an analysis and review of the most recent immunotoxicology literature, included five panelists with immunotoxicology expertise.[109] That expert panel also considered the clinical relevance of using vaccine antibody titer as a measure of immunotoxicity and noted limitations of relying on this as a critical endpoint. Steenland, et al., 2020, concluded that, despite a relatively large number of studies reporting that PFOA impairs immune function, the evidence that PFOA increases risk of human infectious disease is inconsistent.[110] In addition, public commenters, and the World Health Organization, relying on additional peer reviewed publications, have noted that the value used by EPA for benchmark dose modelling is clinically meaningless.[111]

Consideration of clinical relevance is also important when evaluating EPA's reliance on cholesterol as a marker of cardiovascular disease. In commenting on the Dong et al. 2019 study, which EPA relied upon for PFOA and PFOS, the SAB could not discern why this study was chosen, stated that EPA's lack of information on the study did not appear to support its use, and strongly recommended that EPA consider older studies.[112] However, in the proposed rule, EPA continues to rely on the Dong et al. 2019 study. Importantly, the SAB notes that the epidemiologic literature that provides strong support for an effect of PFAS on cholesterol does

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[106] See *Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water* (Public Comment Draft Assessments), at page 4-44, available at: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0034.

[107] See SAB Determination Memo and List of Candidates where expertise of candidates is described. Only one chosen panelist, Dr. DeWitt, has expertise in immunotoxicology. Documents available at: https://sab.epa.gov/ords/sab/f?p=114:18:12110592892742:::RP,18:P18_ID:2601.

[108] Gregory J. Garvey, Janet K. Anderson, Philip E. Goodrum, Kirby H. Tyndall, L. Anthony Cox, Mahin Khatami, Jorge Morales-Montor, Rita S. Schoeny, Jennifer G. Seed, Rajeev K. Tyagi, Christopher R. Kirman & Sean M. Hays (2023): Weight of evidence evaluation for chemical-induced immunotoxicity for PFOA and PFOS: findings from an independent panel of experts, Critical Reviews in Toxicology, DOI: 10.1080/10408444.2023.2194913.

[109] *Id.* at table 3.

[110] Steenland K, Fletcher T, Stein CR, Bartell SM, Darrow L, Lopez-Espinosa M-J, Ryan PB, Savitz DA. (2020) Review: Evolution of Evidence on PFOA and Health Following the Assessments of the C8 Science Panel, Environment International, Volume 145, 106125.

[111] See comments submitted by Nessa Horewitch Coppinger on behalf of the 3M Company, Dec. 30, 3021, available at: https://sab.epa.gov/ords/sab/f?p=100:19:16404771425364:::RP,19:P19_ID:963 and World Health Organization (WHO) PFOS and PFOA in Drinking-water, Version for public review Sept 2022, where WHO refers to the clinical relevance of these findings as "unclear", available at: https://www.cmbg3.com/library/WHO-Draft-Drinking-Water-Document.pdf.

[112] See SAB report to the EPA Administrator Aug. 22, 2022, at page 18, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.

not provide support for an effect of PFAS on the risk of cardiovascular disease.[113] Similarly, as pointed out by Steenland et al. 2020, in evaluating the C8 Science Panel data, while an association between PFOA and elevated cholesterol is plausible, there is no impact on the risk of cardiovascular disease.[114] In fact, the Proposed Rule states "EPA recognizes that the epidemiologic literature that provides strong support for an effect of PFOA and PFOS on cholesterol and blood pressure does not provide direct support for an effect of PFOA and PFOS on the risk of cardiovascular disease (CVD)."[115] Statements like these call into question why EPA continues to rely on this endpoint as a critical effect. In fact, additional recent studies continue to disprove any human CVD disease endpoint (such as stroke, myocardial infarction, or other measurable CVD), and highlight the overreach in attributing CVD to PFOA or PFOS.[116]

Similarly, EPA's justification for relying on birthweight as a critical adverse effect is also not supported by science. Public commenters have noted that this endpoint is not an established causal effect of PFOA or PFOS exposure,[117] but the revised documents ignore this concern. The SAB pointed out that the Wikstrom et al. 2020 study and the Sagiv et al. 2018 study, on which EPA relied for PFOA and PFOS birthweight endpoints, did not consider confounding by co-exposure to other PFAS (and realistically, other unmeasured chemicals and other stressors).[118] This omission would lead to an overestimate of the impacts of PFOA or PFOS on birthweight, yet it remains unaddressed in the Public Comment Draft Assessments or the Proposed Rule. Despite the SAB concerns, EPA considered these studies to be "high confidence" and does not address the concerns related to potential confounding.

Similar concerns, regarding the adversity of the chosen critical effect, arise with EPA's choice of ALT as an RfD endpoint for PFOA and PFOS. In the Draft Public Comment Assessment, in discussing the association between PFOS and ALT, EPA states:

> However, the associations were not large in magnitude, and it is unclear whether the observed changes are clinically adverse. Evidence for other liver enzymes and in children and adolescents is less consistent. Results for functional measures of liver toxicity, specifically histology results, are mixed. There is some indication of higher risk of liver disease with higher exposure, coherent with the liver enzyme

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[113] *Id*. at 102.
[114] Steenland K, Fletcher T, Stein CR, Bartell SM, Darrow L, Lopez-Espinosa M-J, Ryan PB, Savitz DA. (2020) Review: Evolution of Evidence on PFOA and Health Following the Assessments of the C8 Science Panel, Environment International, Volume 145, 106125.
[115] 88 Fed. Reg at 18709.
[116] Schillemans T, Donat-Vargas C, Lindh CH, de Faire U, Wolk A, Leander K, et al. (2022) Per- and polyfluoroalkyl substances and risk of myocardial infarction and stroke: a nested case-control study in Sweden. Environ Health Perspect130(3):37007, available at: https://ehp.niehs.nih.gov/doi/10.1289/EHP9791.
[117] See comments submitted by Nessa Horewitch Coppinger on behalf of the 3M Company, Feb. 10, 2022, available at: https://sab.epa.gov/ords/sab/f?p=100:19:16404771425364:::RP,19:P19_ID:963.
[118] See SAB report to the EPA Administrator Aug. 22, 2022, at page 54, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.

> findings, but there is inconsistency for lobular inflammation among the two available studies, which decreases certainty.[119]

EPA further states, "It is not possible to rule out potential confounding across PFAS with this evidence, but there is also no evidence that confounding can explain the observed associations." EPA's key supporting document for the proposed rule does not provide strong support for this chosen critical endpoint.

1. EPA's evidence integration approach is flawed

EPA's approach and presentation of its evidence integration findings is flawed and does not represent the best available science or the best available scientific approach to evaluating evidence. For instance, for PFOS, as discussed in the Public Comment Draft Assessment, the 2016 HESD assessment did not assess evidence for associations between CVD diseases and PFOS, besides the review of its effects on serum lipids. Since the 2016 HESD, EPA identifies 45 new epidemiological studies that report on the association between PFOS and "cardiovascular disease" (with endpoints widely ranging from outcomes such as hypertension [in 19 of 45 new studies], CVD, congestive heart failure, microvascular diseases, to mortality). EPA determined that 4 of these studies were high confidence and 23 were medium confidence.[120] EPA has misplaced its emphasis on quantity of "CVD" studies rather than considering the underlying endpoint relevance when determining if in fact any of the endpoints are scientifically attributable to the action of PFOS (via MOA discussion) given the numerous confounders present in every study cited. EPA then concludes, "Overall, the findings from a single high confidence study and several medium confidence studies conducted among the general population provided consistent evidence for an association between PFOS and blood pressure."[121] The concern here is that EPA is not discussing the weight of evidence of all the studies evaluated but is instead drawing its conclusion on the positive studies only. It is clear that there are also medium quality studies that do not show any association, but EPA appears to ignore them when reaching its weight of evidence conclusion.

EPA does not array these data in tabular form, as one would present in a meta-analysis, which would make it easier for readers to discern how EPA is integrating the evidence. EPA's apparent approach of relying on just a few of the positive studies is a not a scientifically sound approach. This is but one example; EPA follows this similar structure and framework for the majority of the non-cancer endpoints assessed in the Public Comment Draft Assessments. EPA has not sufficiently addressed the SAB concerns and has not provided a transparent and reproducible framework for evaluating the evidence.

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[119] See *Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water* (Public Comment Draft Assessments), at page 3-69, available at: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0034.
[120] *Id.* at 3-136.
[121] *Id*. at 3-144.

2. EPA takes an inappropriate approach to average/weigh all endpoints equally

For PFOA, EPA relies on the immune, developmental, and cardiovascular outcomes as co-critical effects. For PFOS, EPA relies on developmental and cardiovascular outcomes as the co-critical effects. EPA chooses these values because they are the lowest of the values presented, and EPA finds that they will be protective of other effects and protective of effects that may occur in sensitive populations.[122] EPA provides no scientific weight of evidence analysis and simply chooses the lowest numbers. If SDWA were a precautionary statute, then it would not direct EPA to use the best available public health information and data collected by the best methods. In this case, EPA ignores the statutory standard and picks the lowest numbers. SDWA also requires EPA to specify uncertainties, identify studies that would assist in resolving the uncertainties, and also reconcile inconsistencies in the scientific data.[123] While EPA discusses uncertainties in the benefit and costs analysis, the proposed rule does not provide any substantive discussion of the uncertainties associated with the derivation of the RfD values. Finally, while the proposed rule notes inconsistencies in some of the data sets, as described for some of the endpoints in comments above, EPA makes no effort to resolve these inconsistencies.

C. Cancer classification and slope factors for PFOA and PFOS are not supported by the scientific evidence

EPA has significant irregularities in review and justification for the cancer classifications of PFOA and PFOS. EPA has moved ahead with a carcinogenicity determination for PFOS without SAB comment or approval, and EPA, without explanation, interpreted the same studies on PFOS in two different manners in a 2021 and a 2023 assessment. Now that EPA has developed frameworks for evaluating the scientific evidence, additional peer review is essential before finalization of this rulemaking. Additionally, EPA has failed to respond to SAB direction to develop appropriate multiple candidate cancer slope factors and relied on low confidence epidemiological data.

In the PFOA and PFOS Draft Assessments reviewed by the SAB in 2021, EPA proposed that PFOA was "*likely to be carcinogenic*" and for PFOS there was "*suggestive evidence of carcinogenic potential.*" The SAB review provides, at best, tepid support for these findings, noting that EPA's rationale for the designations was not adequately provided and that EPA needed to provide a more structured framework to describe the criteria used for these designations.[124] For PFOS, the SAB report does not provide a recommendation for what the cancer classification should be. Because the documents provided to the SAB were not sufficiently transparent, the SAB was unable to directly respond to important charge questions and recommended significant changes, including a more structured framework, and inclusion and discussion of mechanistic data.

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[122] 88 Fed. Reg. 18659 and 18663.
[123] 42 U.S.C. § 300g-1(b)(3)(B)(iv).
[124] See SAB report to the EPA Administrator Aug. 22, 2022, at pages 32-38, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.

In response to the SAB requests, EPA presents in the Public Comment Draft Assessments a finding of "*likely to be carcinogenic*" for both PFOA *and PFOS*. This is striking because EPA did so without an SAB recommendation. The SAB Report did not recommend a "*likely to be carcinogenic*" classification for PFOS. This new classification for PFOS relies on the same exact data that EPA used in the Draft PFOS Assessment, but EPA has reinterpreted it to raise the classification. In the December 2021 Draft PFOS Assessment, EPA recommended the "*suggestive*" classification, explaining that "[t]he available epidemiological and animal toxicity data suggest a potential concern for carcinogenic effects in humans but are not sufficient for a stronger conclusion."[125] Yet, in the March 2023 Public Comment Draft Assessment, after discussing the same studies considered in 2016 HESD[126] and in the 2021 Draft Assessment, EPA states "EPA has now determined the available data for PFOS surpass many of the descriptions for Suggestive Evidence of Carcinogenic Potential."[127] EPA appears to reinterpret the studies by Thomford 2002 and Butenhoff 2012 without explanation.[128] EPA also adds a new criterion, which is not part of the EPA 2005 Guidelines for Carcinogens, and adds that "Structural similarities between PFOS and PFOA add to the weight of evidence for carcinogenicity of PFOS."[129] These findings also contradict EPA's 2023 Economic Analysis, which states "Evidence of a positive association between PFOS exposure and kidney cancer was inconclusive; the small number and limited scope of studies at the time were inadequate to make definitive conclusions (U.S. EPA, 2016e; U.S. EPA, 2023d)."[130]

EPA's 2023 reinterpretation of the same studies it reviewed in 2016 and 2021, as well as EPA's addition of new considerations (e.g., a novel consideration of similarity to other chemistries), requires external peer review. **This is not a minor change.** The effects of a change from "*suggestive to be carcinogenic*" to "*likely to be carcinogenic*" for PFOS are highly significant to this rulemaking. Because of this higher cancer classification, EPA is now proposing an MCLG of zero for PFOS; whereas, if EPA had retained the cancer classification from the 2016 HESD and the 2021 Draft Assessment, the MCLG would be higher. While SDWA requires that EPA request comments from the SAB prior to proposing the MCLG,[131] there is no record from the SAB to support EPA's new determination for PFOS, nor is there any SAB review of the new

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[125] See *Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water* (PFOS Draft Assessment), at page 312, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601.

[126] U.S. EPA (2016) Health Effects Support Document for Perfluorooctanoic Acid (PFOA). (EPA 822-R-16-003). (HESD) Washington, DC, U.S. Environmental Protection Agency, Office of Water. https://www.epa.gov/sites/default/files/2016-05/documents/pfoa_hesd_final-plain.pdf.

[127] See *Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water* (Public Comment Draft Assessments), at page 6-8, available at: https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0034.

[128] *Id*. at Section 6.4. In contrast, in the 2021 Draft Assessment, at page 312, EPA states: "Additionally, the animal evidence for PFOS is limited to a single chronic cancer bioassay. Although liver adenomas were significantly increased in male and female rats at the highest dose and a positive trend was observed ($p = 0.03$), a dose-response pattern was not observed. Incidence of thyroid follicular tumors and mammary gland tumors also did not show a direct response to dose."

[129] *Id.* at page 3-296.

[130] See EPA *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, at page 6-16.

[131] 42 U.S.C. § 300g-1(e).

structured framework that EPA developed to inform the most recent cancer classification. EPA's change in the cancer classification of PFOS without additional peer review of the new framework and its application to PFOS should not be finalized.

For the PFOA cancer classification, EPA bases the determination "on the evidence of kidney and testicular cancer in humans and LCTs, PACTs, and hepatocellular adenomas in rats."[132] EPA is clear that "there is not convincing epidemiological evidence supporting a causal association between human exposure to PFOA and cancer," and notes state that "there is *significant uncertainty* regarding the carcinogenic MOA(s) of PFOA, particularly for renal cell carcinomas and testicular cancer in humans" (emphasis added).[133] The epidemiological literature is very inconsistent, particularly for kidney cancer,[134] yet EPA relies on the Shearer et al. 2021 study, which did not show statistically significant increases in kidney cancer after adjusting for other PFAS, to justify the "*likely to be carcinogenic*" classification. In its review, the SAB stated that EPA's rationale for the cancer designation was "not adequately provided" and that additional "weight of evidence" narrative was needed.[135] Now that EPA has provided a new framework and justification, an additional SAB review is warranted. Without external peer review, stakeholders will not have the level of confidence that SDWA typically provides through the rigorous requirement for peer review. If more fulsome and complete documents had been provided to the SAB to inform its review, then additional peer review would not now be required.

EPA also inappropriately developed slope factors for PFOA and PFOS. While the SAB agreed that robust human epidemiological data is preferable when available, it stated in its report to EPA that "for PFOA, there is an absence of 'high confidence' epidemiologic data as summarized by EPA."[136] One of the reasons for this lower confidence is that epidemiological data available (presented in a Shearer et al. 2021 study assessing kidney cancer risk) was not fully evaluated for the impacts of one individual in the study who had elevated serum PFOA levels.[137] For these reasons, and others described in the SAB report, the SAB recommended that EPA develop multiple candidate cancer slope factors (CSFs) including values based on animal cancer bioassays, and SAB did not endorse using the Shearer et al. study that EPA relied upon in the 2021 Draft Assessment. Despite the lack of endorsement from the SAB, and the concerns expressed by the SAB regarding how the slope factor from the human studies did not align with the animal evidence, EPA continues to rely on the Shearer et al. 2021 study. In this proposal, EPA does not provide a scientific explanation to address the SAB concerns regarding the Shearer et al. study. Rather, EPA attempts to justify its choice by pointing to an EPA Office of Research and Development (ORD) Staff Handbook which states "when both laboratory animal data and human data with sufficient information to perform exposure-response modeling are available,

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[132] See *EPA Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) (CASRN 335-67-1) in Drinking Water* at page 3-306.
[133] *Id*. at 6-8 to 6-9.
[134] See comments submitted by Nessa Horewitch Coppinger on behalf of the 3M Company, Feb. 10, 2022, at page 13, available at: https://sab.epa.gov/ords/sab/f?p=100:19:16404771425364:::RP,19:P19_ID:963.
[135] See SAB report to the EPA Administrator Aug 22, 2022, at pages 32-33, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.
[136] *Id*. at 39.
[137] *Id*.

human data are generally preferred for the derivation of toxicity values."[138] EPA's rationale is misleading. This ORD guidance is merely repeating the same general admonition acknowledged by the SAB that using human data is preferrable if it is available and robust. It by no means is forcing EPA to rely on the lower confidence Shearer et al. study. EPA should not finalize this proposal without squarely addressing the SAB recommendations to discuss the strengths and limitations of different CSFs.[139] Further, until there is additional review and endorsement of EPA's proposed cancer classification for PFOS, EPA should not quantify the cancer effects of PFOS.

D. To the extent health advisories are retained by EPA, the science is not reliable to support them

EPA has stated "[a]fter EPA has considered public comments and issues a final NPDWR, EPA will decide whether to update or remove the interim health advisories for PFOA and PFOS and the final health advisories for PFBS and HFPO-DA."[140] As described in the comments above, the science in this proposal is so flawed that, if finalized, it should not be used to support even the existing health advisories for PFOA, PFOS, PFBS, and HFPO-DA chemicals. The compromised SAB review process and the short public comment period provided for this rulemaking do not allow for sufficient robust review of the science underlying this proposal.

For the reasons stated above, the information EPA uses to support its proposed MCLs for PFOA and PFOS do not represent the best available science. Therefore, relying on this information to regulate PFOA and PFOS would be contrary to SDWA requirements.

V. EPA's Cost Analysis Is Flawed, and it Is Infeasible for Regulated Entities To Comply with the Proposed MCLs

SDWA provides that, if EPA establishes an MCL for any contaminant, the MCL must be only as close to the MCLG as feasible. Further, the combination of technology, treatment techniques, or other means required to meet the level must not be more stringent than feasible.[141] Each NPDWR that establishes a MCL must list the technology, treatment techniques, and other means that EPA finds to be feasible for purposes of meeting the MCL.[142] The term "feasible" is defined by SDWA as "feasible with the use of the best technology, treatment techniques and other means which [EPA] finds … are available (taking cost into consideration)."[143] Notably, EPA is required to consider costs in its assessment of feasibility in setting an MCL. In proposing an MCL, EPA must publish an analysis of the compliance costs.[144]

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[138] See *Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctanoic Acid (PFOA) in Drinking Water,* Mar. 2023, at page 4-49.
[139] See SAB report to the EPA Administrator Aug. 22, 2022, at pages 42, available at: https://sab.epa.gov/ords/sab/f?p=100:18:16490947993:::RP,18:P18_ID:2601#report.
[140] See EPA Technical Overview Webinar Presentation: Proposed PFAS NPDWR, March 29, 2023, at slide 35, available at: https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas.
[141] 42 U.S.C. 300g-1(b)(B)(5)(B)(ii).
[142] 42 U.S.C. 300g-1(b)(E)(4)(i).
[143] 42 U.S.C. 300g-1(b)(B)(4)(D).
[144] 42 U.S.C. 300g-1(b)(3)(C)(i)(III).

As proposed, EPA grossly underestimates the potential compliance costs of this rulemaking on the thousands of public water systems across the country, including non-transient, non-community water systems (NTNCWSs), that will be required to monitor, sample (with limited certified laboratory capacity), and treat six PFAS at infinitesimal, almost-zero levels. As proposed, there is a high level of uncertainty with even detecting PFAS at these levels.

The Chamber released a report in November of 2022 indicating that "the consensus is that Meeting PFAS drinking water standards will likely require substantial investment," and that if the MCL is 10 ng/L[145] or less, nationwide PWS treatment costs will be significant: "At 10 ng/L there is a 50 percent probability that costs exceed $16 billion, whereas the 50 percent probability is $32.5 billion for the 4 ppt scenario and $59.4 billion for the non-detect scenario.[146] Also, the American Water Works Association (AWWA) published a report in March of 2023[147] that provides national cost estimates for setting an MCL of 4 ppt for PFOA and PFOS. It found the national cost for water systems to install treatment to remove PFOA and PFOS to levels required by this proposal exceed $3.8 billion *annually* and the national cost burden for 4 ppt MCLs for PFOA and PFOS are over $5.2 billion The report analyzed costs for installation of each treatment technology, including granular activated carbon (GAC) gravity basins; GAC, IX and Manganese pre-treatment pressure vessels; reverse osmosis systems (low and high pressure feed pumps and associated building, storage tanks, brine disposal, decarbonation system, and chemical treatment system); operating costs, and life cycle costs (for a 20-year life).

AWWA concluded that a vast majority of these treatment costs will be borne by communities and ratepayers.[148] Its report estimates that annual costs to households for removing PFAS from drinking water can range from $100 or more per year (for a population of over 1 million) to even $10,000 (for a population of less than 100), which is reflective of communities where new treatment facilities will need to be installed and operated.[149] And this estimate is just for compliance with PFOA and PFOS MCLs; it does not consider the costs for compliance with the other four PFAS and the burdens on water systems using of the newly proposed (and yet untested in any other MCL rulemaking) Hazard Index approach to determine compliance. While EPA accounts for capital costs, it fails to consider that most of the PFAS-related costs will be for ongoing operation and maintenance (O&M). EPA must consider the high costs of maintaining and replacing treatment technologies over time.

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[145] 10 ng/L is 10 ppt.
[146] "Potential Costs of Meeting Safe Drinking Water Act (SDWA) Standards for PFOA and PFOS," U.S. Chamber of Commerce (November 7, 2022): https://www.globalenergyinstitute.org/potential-costs-meeting-safe-drinking-water-act-sdwa-standards-pfoa-and-pfos. Note this report only estimated costs for PFOA and PFOS.
[147] "PFAS National Cost Model Report," Black & Veatch Holding Company, prepared for the American Water Works Association (March 7, 2023): https://www.awwa.org/Portals/0/AWWA/Government/2023030756BVFinalTechnicalMemoradum.pdf?ver=2023-03-14-102450-257. See also AWWA statement on proposed PFAS drinking water standards: https://www.awwa.org/AWWA-Articles/awwa-statement-on-proposed-pfas-drinking-water-standards.
[148] See AWWA Press Release at: https://www.awwa.org/AWWA-Articles/awwa-statement-on-proposed-pfas-drinking-water-standards.
[149] Report at 32.

EPA has seriously underestimated the costs of the proposed rule on regulated entities, and, by the Chamber's and others' estimates, the costs are expected to be significant. The significant costs of this rulemaking indicate EPA has failed to satisfy the SDWA requirements for feasibility in regulation, by failing to demonstrate that the proposed MCLs are as close to the MCLGs as "feasible" and that the combination of technology, treatment techniques, or other means required to meet the MCLs are not "more stringent than is feasible." EPA cannot finalize the rule as proposed without addressing these SDWA requirements.

A. EPA does not appropriately analyze costs associated with hazardous waste disposal

EPA has publicly committed to initiating rulemaking to address PFOA, PFOS, PFBS, and GenX as RCRA hazardous constituents.[150] As EPA acknowledges, costs will be even higher if residuals from the treatment of PFAS-contaminated water must be sent to hazardous waste disposal facilities. Despite that recognition, EPA claims that it did not address these costs in its national annualized costs because such wastes "are not currently" regulated as hazardous wastes.[151] EPA acknowledges, given the pending CERCLA rulemaking, solid waste facilities may refuse to accept these wastes whether or not such wastes are regulated as hazardous waste.[152] In the experience of the Chamber and its coalition, this outcome is likely.

While EPA assessed the potential impact on PWS treatment costs associated with hazardous residual management requirements in a sensitivity analysis on the proposed option, EPA underestimates these costs. EPA expects annual costs to increase by $30 - $61 million if water systems are required to dispose hazardous waste (spent GAC and resin) but does not explain how regulated entities will handle PFAS waste and the additional costs of managing PFAS waste as a direct result of this rulemaking. Landfills will likely require dewatering or containerization to accept the material and already strained capacity at waste incinerators capable of destroying PFAS will be further reduced. Further, EPA fails to address landfill capacity limitation. EPA must clarify how it expects thousands of water systems to properly dispose of PFAS waste and the costs for disposal. EPA also needs to finalize its PFAS disposal guidance before it can reasonably complete a cost analysis.[153]

Furthermore, EPA has likely underestimated the quantity of spent GAC that will require treatment. EPA identified proposed Bed Volumes for GAC that exceed the values that AWWA identified in their analysis. The generation rate of spent carbon is a function of bed volume and

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[150] See EPA response to Governor Michelle Lujan Grisham of New Mexico's petition to identify PFAS as hazardous waste under RCRA: https://www.epa.gov/newsreleases/epa-responds-new-mexico-governor-and-acts-address-pfas-under-hazardous-waste-law.
[151] 88 Fed. Reg. at 18701. EPA indicates that the national annualized costs do not reflect costs of hazardous waste disposal for GAC and IX media.
[152] 88 Fed. Reg. at 18688.
[153] In fact, the Interim Disposal Guidance demonstrates that hazardous waste management costs are an order of magnitude greater than non-hazardous waste management costs. See EPA Interim Guidance on Destroying and Disposing of Certain PFAS and PFAS-Containing Materials that Are Not Consumer Products at 56 Tables 3-1 and 3-2 (December 18, 2020): https://www.epa.gov/pfas/interim-guidance-destroying-and-disposing-certain-pfas-and-pfas-containing-materials-are-not.

replacement frequency. EPA's cost estimate basis for bed volume was a range of 5,000 to 150,000 for GAC.[154] AWWA's analysis limited the carbon life to a maximum of 40,000 bed volumes for GAC. Bed volumes directly impact operating costs of these systems; EPA's assumptions of longer bed volumes would result in incurring lower costs due to less frequent media exchange and disposal.

B. Costs will be compounded with potential costs of PFOA and PFOS hazardous substance designations under CERCLA

One direct, additional cost of this rulemaking establishing an MCL for the six PFAS is the cost of cleanup under CERCLA. EPA fails to consider the use of MCLs and MCLGs as cleanup standards. Section 121(d) of CERCLA requires remedial actions to meet a standard of control that "at least attains Maximum Contaminant Level Goals established under the Safe Drinking Water Act and water quality criteria established under section 304 or 303 of the Clean Water Act, where such goals or criteria are relevant and appropriate under the circumstances of the release or threatened release."[155] EPA acknowledges that MCLs are "relevant and appropriate as in situ cleanup standards where either surface water or ground water is or *may be used* for drinking water. When no promulgated standard exists for a given contaminant, proposed MCLs are to be given greater consideration among the to-be-considered advisories."[156] With a potential CERCLA designation for PFOA and PFOS, surface water-sourced systems will have to treat all grit (filtered solids from raw surface water) as containing a hazardous substance.

C. EPA assumes direct discharge of RO/NF concentrate to the environment

EPA assumes 5% of Public Water Systems that require treatment will elect to utilize reverse osmosis (RO) or nanofiltration (NF). These membrane-based treatment options will concentrate the PFAS and other constituents present in the source water that are removed from the treated water into a reject stream. EPA assumes that the reject stream will be 15-30% of the total flow to the treatment unit.

EPA states that the RO/NF cost model included an assumption that the reject stream from Reverse Osmosis and Nanofiltration units would be direct discharged via NPDES permitted outfalls to non-potable receiving streams (ocean or brackish estuaries).[157] The ability to discharge concentrated streams of PFAS material to the natural environment via a permitted outfall is not a reasonable assumption for this cost model, nor is it aligned with EPA's roadmap

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[154] 88 Fed. Reg. at 18695.
[155] 42 U.S.C. § 9621(d)(2)(A)(ii).
[156] U.S. EPA CERCLA Compliance with Other Laws Manual at 195 (August 1988): https://nepis.epa.gov/Exe/ZyNET.exe/10001VMG.TXT?ZyActionD=ZyDocument&Client=EPA&Index=1986+Thru+1990&Docs=&Query=&Time=&EndTime=&SearchMethod=1&TocRestrict=n&Toc=&TocEntry=&QField=&QFieldYear=&QFieldMonth=&QFieldDay=&IntQFieldOp=0&ExtQFieldOp=0&XmlQuery=&File=D%3A%5Czyfiles%5CIndex%20Data%5C86thru90%5CTxt%5C00000003%5C10001VMG.txt&User=ANONYMOUS&Password=anonymous&SortMethod=h%7C-&MaximumDocuments=1&FuzzyDegree=0&ImageQuality=r75g8/r75g8/x150y150g16/i425&Display=hpfr&DefSeekPage=x&SearchBack=ZyActionL&Back=ZyActionS&BackDesc=Results%20page&MaximumPages=1&ZyEntry=1&SeekPage=x&ZyPURL#.
[157] 88 Fed. Reg at 18696.

for regulation of PFAS. EPA's cost estimate would be higher if it included a cost estimate for disposal of brine concentrate as a RCRA hazardous waste.

EPA further notes two full-scale applications of RO to treat PFAS in drinking water systems.[158] In addition to those installations, the industrial facilities that the Chamber represents have experience using Reverse Osmosis units in their facilities. From this experience, EPA has not adequately addressed costs associated with the need for remineralization of RO permeate to make it non-corrosive to downstream piping and to make it suitable for consumption as a drinking water. The coalition also suggests EPA has underestimated the reject quantities that would be expected with the proposed pretreatment units identified by EPA. EPA should assume rejection rates of 25-30% when developing disposal costs for RO units.

D. EPA has not appropriately considered costs and implications for NTNCWSs

EPA's proposed rule will impact over 17,000 NTNCWSs that EPA intends to hold to the same regulatory requirements, including monitoring, sampling, and compliance, as community water systems (CWS). EPA recognizes that 99 percent of all NTNCWSs serve 3,300 or fewer people, with only two NTNCWSs serving more than 50,000 people.[159] Given the small size of the NTNCWSs and the costly monitoring and treatment that will be required, relative compliance costs will be greatly increased under this proposed rule. In fact, in some rural NTNCWS that serve remote industrial or other needs, the costs could threaten the viability of these systems and the users that depend on them. Additionally, EPA's assessment does not consider the amount of water used by NTNCWSs or the potential treatment costs. NTNCWSs are a diverse group, including agricultural operations, industrial facilities, and many other businesses, which may use water far in excess of what may be expected based on the number of personnel each NTNCWS serves. Thus, any analysis of the potential cost impacts for treatment must be based on the volume of water needed to be treated, not merely the number of people served. The cost of treatment for many of these locations may far exceed the treatment to be expected based solely on the number of ratepayers.

Yet, EPA chose not to specifically analyze the proposed rule's economic impact on NTNCWSs[160] and instead, based on a 2008 EPA Assessment, placed the cost of SDWA compliance at less than 1 percent of NTNCWS revenue.[161] And EPA assumes, with no supporting data, that the rise in compliance costs for the NTNCWSs will be no more than an additional 1 percent.[162] EPA's choice to forego actual analysis of impacts to the smallest systems is inappropriate. Detailed analysis on the impacts to NTNCWSs should be conducted to inform the cost/benefit analysis. For example, treating PFAS with GAC at the low levels proposed is much more costly than current treatment for currently regulated contaminants, and a 2008 study is not a reliable indicator of future costs. Lack of both actual data on occurrence in these systems

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[158] See EPA *Technical Support Document - Technologies and Cost for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water*, 2023, EPA-822-P-23-011.
[159] See EPA *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, at page 4-7 and Table 4-3.
[160] *Id.* at 9-10.
[161] *Id.* at 9-10.
[162] *Id.* at 9-10.

and reliable information on cost of compliance makes finalizing the MCL as to NTNCWSs too uncertain.

Furthermore, for small system compliance technologies, EPA identifies use of point-of-use RO, where currently not proposed as a compliance option because the regulatory options proposed require treatment to concentrations below the current NSF/ANSI certification standard for POU device removal of PFAS. EPA is anticipating third parties will develop new standards, and its affordability conclusions reflect the costs of devices certified under the current standard, not a future standard.[163] Also, POU systems are "at the kitchen sink" applications of which the "concentrate" is often sent to a sewer.[164] This also pushes additional costs to individuals / rate payers, creating a disproportional cost burden to individuals served by small systems.[165] EPA has underestimated administrative costs related to this rulemaking.

EPA assumed administrative startup costs incorporated a total of 4 hours per PWS to read the rule and 16-32 hours per PWS to attend a training on the rule.[166] EPA further assumed treatment administrative costs of 3 to 42 hours per entry point for a system to notify, consult, and submit a permit request for treatment.[167] This does not appear to include the costs associated with evaluating potential treatment options, design, or piloting treatment.

The times allotted by EPA do not appear to sufficiently capture the administrative time that PWSs will require to be prepared for this rulemaking. These times further do not consider that the majority of treatment system serving less than 3,300 people were not included in UCMR 3 of UCMR 5, and do not have an established baseline of PFAS in their PWS. To properly assess treatment needs, these systems will have to dedicate more time to develop new sampling plans, specifically understating the sample collection methodologies required of analytical methods for which they may not be familiar, and to understand the laboratory results.

With regards to primacy agencies, EPA has assumed there would be no costs related to reporting violations to EPA as result of this rule, which is not a realistic assumption. EPA also assumed that agencies would spend 1 hour per sample to review results; however, EPA did not assume the PWSs would require time to review their own analytical results.

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[163] 88 Fed. Reg. at 186687, Table 20 n.1-2: "POU RO is not currently listed as a compliance option because the regulatory options under consideration require treatment to concentrations below the current NSF International/American National Standards Institute (NSF/ANSI) certification standard for POU device removal of PFAS. However, POU treatment is reasonably anticipated to become a compliance option for small systems in the future if NSF/ANSI or other independent third-party certification organizations develop a new certification standard that mirrors EPA's proposed regulatory standard. The affordability conclusions presented here reflect the costs of devices certified under the current standard, not a future standard, which may change dependent on future device design. EPA's work breakdown structure (WBS) model for POU treatment does not cover systems larger than 3,300 people (greater than 1 million gallons per day [MGD] design flow), because implementing and maintaining a large-scale POU program is likely to be impractical."

[164] See EPA document on WaterSense Draft Specification for Point-of-Use Reverse Osmosis Systems Supporting Statement: https://www.epa.gov/watersense/point-use-reverse-osmosis-systems.

[165] 88 Fed. Reg. at 18688, Table 23.

[166] 88 Fed. Reg. at 18697, Table 32.

[167] 88 Fed. Reg. at 18699, Table 35.

E. EPA's reliance on other federal funding will not alleviate costs

EPA indicates that federal funding from the Bipartisan Infrastructure Law as a way to defray a small portion of the potential costs of installation and treatment when it "otherwise [might] be cost-challenging."[168] However, its reliance on temporary federal funding to address a long-term unfunded mandate is flawed in several respects. First, because EPA underestimates costs, the amount of funding available to address PFAS treatment is a much lower percentage, making the "cost-challenging" comment highly relevant, as indicated in the Chamber's modeling. Second, EPA's reliance on available federal funding does not alleviate costs for water systems in the long term, or to cover O&M costs. The obligations of public water systems will far outlast the short-term funding available. Once funding through the Bipartisan Infrastructure Law runs out, public water systems will need a new source of revenue to continue operating the PFAS treatment, most likely by raising rates. Further, federal funding is certainly not guaranteed for every impacted public water system.[169] Water systems will have to apply for funding while, in the meantime, incurring compliance costs if and until federal funding is received. Also, the funding available will likely be competing for other important priorities like the lead pipe replacement requirements in the lead and copper rule revision, which could negatively affect environmental justice communities by slowing lead pipe replacement. Further, the fact that public water systems may not, in some circumstances, have to directly bear a portion of the cost does not mean it is not a cost at all. Additional public spending to address a regulatory mandate is a cost to taxpayers and the economy. Finally, the Bipartisan Infrastructure Law specified allocations of funding for certain purposes and did not specify that all of the funds must be used towards addressing PFAS.[170]

F. EPA's models used in its cost assessment are flawed

EPA's models underestimate the costs of installed groundwater systems, surface water systems, GAC systems, reverse osmosis, or ion-exchange systems, and they do not come close to a comparable model by a major engineering firm that designs and installs PFAS treatment systems. One principal reason that EPA's models may deviate from reality is because they are outdated—they were developed from 2006 to 2012.[171] Another reason could be the lack of adequate independent peer review. EPA sought a three-person, letter peer review of the GAC model around 2006 and then made additional changes to the model that have not been peer reviewed.[172] EPA states that the IX model received even less of a comprehensive review since reviewers did

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[168] 88 Fed. Reg. at 18640.
[169] The $11.7 billion funds are for investment in the Drinking Water State Revolving Fund (SRF), $4 billion to the Drinking Water SRF for Emerging Contaminants, and $5 billion for the Small, Underserved, and Disadvantaged Communities Grants. EPA details the process for water systems to be eligible and apply for these funds, which are administered by states: https://www.epa.gov/dwsrf/how-drinking-water-state-revolving-fund-works#tab-1.
[170] See "Bipartisan Infrastructure Law: A Historic Investment in Water," U.S. EPA: https://www.epa.gov/system/files/documents/2021-11/e-ow-bid-fact-sheet-final.508.pdf.
[171] U.S. EPA, "Best Available Technologies and Small System Compliance Technologies for Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water," February 2023.
[172] U.S. EPA, "Work Breakdown Structure-Based Cost Model for Granular Activated Carbon Drinking Water Treatment," February 2023.

not review a complete model – more than 10 years ago.[173] EPA must use more up to date modeling and inputs in its cost estimates.

G. EPA fails to consider non-market social and other environmental costs

EPA should also estimate the social costs through economy-wide modeling of the lost productivity when higher water costs ripple through the economy and capital is diverted from other productive uses to build water treatment systems. We also note that there are potential costs to the environment by the use of GAC that are not accounted for by EPA. For example, a recent study from Maine found that PFAS mitigation using GAC may actually increase greenhouse gas emissions in the state: "greenhouse gas emissions for water treatment to bring PFAS down to the current interim standard are substantial, raising the footprint of an average user by 6.7–18 percent."[174] The report explains that GAC is sourced either directly from coal or generated by high-temperature treatment of biomass, and in some states (like Maine), there are no GAC manufacturers, so they must be transported by freight.[175] Also, the report discusses that GAC would be an "add-on" to many water treatment systems because it is not effective for typical drinking water contaminants like arsenic; thus, "[t]hese factors combined may mean substantial GHG emissions."[176]

VI. Proposed Benefits of Complying with the Proposed MCLs Do Not Justify the Costs

While the MCLG is set solely based on health risk reduction, SDWA requires EPA to engage in cost-benefit balancing in setting the level of the MCLs and also requires that EPA follow a science-based process. If EPA determines that the benefits of a MCL would not justify the costs of complying with the level, EPA may, after notice and opportunity for public comment, promulgate a MCL for the contaminant that maximizes health risk reduction benefits at a cost that is justified by the benefits.[177] Even at the grossly underestimated costs, as described in the section above, the benefits of EPA's proposal to regulate PFOA and PFOS at a MCL of 4 ppt and to regulate PFNA, PFBS, PFHxS, and HFPO-DA at a Hazard Index of 1 do not justify the costs. As discussed below, EPA's quantified benefits analysis is not grounded in science and overestimates benefits, and EPA's non-quantified analysis does not meet the statutory standard of SDWA.[178]

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[173] U.S. EPA, "Work Breakdown Structure-Based Cost Model for Ion Exchange Treatment of Per- and Polyfluoroalkyl Substances (PFAS) in Drinking Water," February 2023.
[174] Benjamin McAlexander, "Estimated Greenhouse Gas Emissions from EPAS Treatment of Maine Drinking Water," Maine Policy Review, Vol. 31 at 41 (2022): https://digitalcommons.library.umaine.edu/mpr/vol31/iss1/4/.
[175] *Id*. at 42.
[176] *Id*.
[177] 42 U.S.C. 300g-1(b)(6)(A).
[178] 42 U.S.C. 300g-1(a)(3)(A).

A. EPA's Health Risk Reduction and Cost Analysis (HHRCA) is flawed and overestimates benefits

In evaluating benefits of MCLs, there must be a factual basis by which to conclude that such benefits are *likely* to occur as a result of treatment (emphasis added).[179] As discussed below, the existing evidence does not support that many of the quantified health effects are likely to occur as a result of treatment. Similarly, while EPA discusses additional non-quantifiable benefits, many of these benefits are "possible" or "potential" benefits, but neither the existing record nor the EPA in this rulemaking has presented information to support these benefits as being "likely."[180] There is a higher bar for evidence to meet a likely standard, and EPA's speculative and precautionary benefits analysis does not meet this threshold.

1. Benefits assessment for cardiovascular disease (CVD) is not supported by the science

To evaluate CVD, EPA quantifies benefits, for PFOA and PFOS, by evaluating total cholesterol and high-density lipoprotein cholesterol (HDLC). EPA also quantifies benefits related to PFOS and blood pressure. In table 42, in the *Federal Register* notice, EPA clearly notes that for HDLC the "[e]vidence of the relationship between the PFAS compound and the health outcome is not conclusive."[181] Based on EPA's evaluation, it is not likely that these benefits will accrue, and this endpoint should not have been quantified. Similarly, it is not clear why EPA quantifies PFOS and blood pressure. Based on EPA's evaluation of PFOS science, blood pressure is not a prioritized health outcome in this rulemaking, and it was not a recommended health outcome from the SAB. Additionally, EPA's own evaluation, in summarizing the evidence integration for PFOS and blood pressure, states "While there is some evidence that PFOS exposure might also have the potential to affect blood pressure and other cardiovascular responses in humans given relevant exposure circumstances, the human evidence underlying this possibility is uncertain and without support from animal or mechanistic studies."[182] EPA's finding that PFOS might have "the potential" to affect blood pressure does not meet SDWA standard for inclusion in a benefits analysis.

EPA also quantifies benefits related to the relationship between PFOA and PFOS and total cholesterol. However, EPA states "EPA recognizes that the epidemiologic literature that provides strong support for an effect of PFOA and PFOS on cholesterol and blood pressure does not provide direct support for an effect of PFOA and PFOS on the risk of CVD."[183] Thus the

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[179] 42 U.S.C. 300g(b)(3)(C).
[180] See EPA *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, where the first sentence of EPA's benefits analysis chapter states: "This chapter discusses the *potential* quantified and nonquantifiable benefits to human health resulting from changes in PFAS levels in drinking water due to implementation of the proposed rule, as well as several regulatory alternatives." (emphasis added), at page 6-1.
[181] 88 Fed. Reg. at 18704 n.5.
[182] See *Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water* at page 3-175, https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0034.
[183] 88 Fed. Reg. at 18709.

quantification of these benefits comes with a great deal of uncertainty. As there is not a direct link between PFOA and PFOS exposure and CVD, EPA links changes in CVD risk biomarkers to changes in CVD risk. Nevertheless, by quantifying benefits that include avoided incidents and avoided deaths due to CVD, EPA is modeling a relationship that is not supported by the epidemiological literature. For PFOS, the estimated increase in total cholesterol, per ng/mL serum PFOS, is not statistically significant,[184] providing even more support for the concerns with the quantification of this health endpoint. Additional recent (2022) science is available to suggest that even if elevated cholesterol levels exist, no PFOA or PFOS-related increase in relevant endpoints (such as stroke, myocardial infarction, or other irreversible measures) occurs in humans, and should properly be considered.[185]

While the modeling for PFNA is not presented, it appears that EPA nevertheless quantifies the supposed CVD benefits that stem from reductions in PFNA.[186] As cholesterol and CVD outcomes are not a critical effect for PFNA, and most epidemiological studies do not show an association between PFNA and LDLC or HDLC,[187] these benefits should not be quantified. Additionally, EPA does not discuss the potential for CVD effects from PFHxS and HFPO-DA.[188] As such, when EPA makes broad statements about additional non-quantified benefits, it is imperative that EPA be clear that additional CVD benefits are not expected.

2. Benefits assessment for developmental impacts is not supported by the science

To evaluate developmental effects, EPA quantifies impacts on birthweight for PFOA, PFOS, PFNA, and PFHxS. In table 42, in the *Federal Register* notice, EPA clearly notes that for PFHxS the "[e]vidence of the relationship between the PFAS compound and the health outcome is not conclusive."[189] Based on EPA's evaluation, it is not likely that these benefits will accrue, and this endpoint should not have been quantified.

As discussed previously in these comments, EPA's justification for relying on birthweight as a critical adverse effect for PFOA and PFOS is also not supported by the body of scientific literature as a whole. The studies upon which EPA relied to justify a relationship did not consider confounding by other chemical and non-chemical stressors, including other PFAS. In addition, for quantification in the benefits analysis, EPA relied on other studies (Negri et al. 2017 and Seeland et al. 2018 for PFOA and Dzierlenga et al. 2020 for PFOS), which EPA noted as having

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[184] *Id*.
[185] Schillemans T, Donat-Vargas C, Lindh CH, de Faire U, Wolk A, Leander K, et al. (2022) Per- and polyfluoroalkyl substances and risk of myocardial infarction and stroke: a nested case-control study in Sweden. Environ Health Perspect130(3):37007, available at: https://ehp.niehs.nih.gov/doi/10.1289/EHP9791.
[186] See Table 42 in the proposed rule and also Table 6-6 in the Economic Analysis.
[187] See EPA *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, at page 6-23.
[188] *Id*.
[189] 88 Fed. Reg. at 18704 n.5.

important uncertainties due to bias from pregnancy hemodynamics.[190] While EPA acknowledges this uncertainty and the concerns with these studies, it has not addressed the concerns and continued to inappropriately use these studies to support quantitative analysis. As presented in Table 6-50 of EPA's economic analysis, there are significant limitations and uncertainties in the analysis of birthweight benefits.[191] While EPA asked the SAB to review the CVD modeling, the developmental effects modeling did not undergo any peer review. Considering the shortcomings of the studies used and the uncertainties in the modeling, peer review of the developmental effects modeling should be done to assess EPA's claimed benefits.

While EPA quantifies benefits related to PFNA and birthweight, it notes that this analysis is not precise, and the confidence intervals for the slope factor include zero, which means that the estimates EPA used were not statistically significant.[192] In discussing developmental effects of PFNA, EPA states that "mixed results" have been found for birth outcomes, particularly birth weight, and that in general associations between PFAS exposures and adverse pregnancy outcomes have not been seen for PFHxS, and PFNA.[193] EPA should not be quantifying these benefits for PFNA or other PFAS. EPA does not provide any discussion of adverse pregnancy outcomes with HFPO-DA in its benefits discussions. As such, when EPA makes broad statements about additional non-quantified benefits, it is imperative that EPA be clear that additional developmental benefits are not expected from other PFAS, including the additional four evaluated in this proposal.

3. Benefits assessment for cancer is not supported by the science

EPA quantifies the relationship between PFOA exposure and kidney cancer, specifically renal cell carcinoma (RCC). As discussed previously in these comments, and as noted by EPA, the epidemiological evidence does not support a causal association between PFOA and cancer. This concern is compounded by EPA's approach that quantified the benefits of reduced RCC using the Shearer et al. 2021 study, which the SAB expressed concerns about due to an outlier in the RCC group. As presented in Table 6-52 of EPA's economic analysis, there are significant limitations and uncertainties of the analysis of cancer benefits.[194] While EPA asked the SAB to review the CVD modeling, the cancer benefits modeling did not undergo any peer review. Considering the shortcomings of the study used, the SAB concerns with the study, and the uncertainties in the modeling, peer review is warranted.

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[190] See *Public Comment Draft Toxicity Assessment and Proposed Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) in in Drinking Water* at page, at page 3-219 and EPA's *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, at page 6-31.
[191] See EPA *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, at page 6-113 to 6-116.
[192] *Id.* at page 6-31.
[193] See EPA *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, at page 6-23.
[194] *Id.* at page 6-121.

4. Benefits assessment for bladder cancer is not supported by the science

A significant portion of the benefits that EPA is claiming for this rulemaking come from co-benefits that would stem from reductions in disinfection byproduct (DBP) formation that EPA predicts are likely to occur due to compliance with the MCLs in the proposed rule. These benefits do not flow directly from reductions in PFAS but are due to the identification of GAC as a possible treatment technology.[195] Use of GAC would decrease the levels of other contaminants, specifically trihalomethanes. EPA quantifies benefits of avoided bladder cancer cases and avoided bladder cancer-related deaths. The significant problem with this approach is that a causal link between DBP and bladder cancer has not been established.[196] While EPA cites Weisman et al. 2022 to support estimates of DBP-attributable bladder cancer, Weissman's overall conclusion calls into question the specific approach EPA is using by questioning the utility of using the four regulated trihalomethanes (THM4) as a surrogate for DBP mixtures.[197] Weisman et al. 2022 states "[w]e also identified several uncertainties that may affect the results from this study, primarily related to the use of THM4 as a surrogate measure for DBPs relevant to bladder cancer."[198] This paper also notes limitations related to the lack of a good animal model for THM-associated bladder cancer as well as the lack of an established mode of action.

The approach EPA is taking to estimate these benefits is not only highly uncertain but also complex and raises many questions. For instance, in the 2006 DBP rule, EPA includes a lag period in the modelling to account for when the reduction in exposure begins and when the full benefit might be realized.[199] However, the modeling in this proposed rule does not include a lag period for either the bladder cancers or the kidney cancers. While EPA acknowledges that they did not include a cessation lag, they simply note that this likely leads to an overestimate in benefits, and no effort is made to account for this overestimate.[200] EPA must explain why the modeling in this rule is not consistent with the approaches taken in the DBP rulemaking.

EPA realized its approach was complex and quietly, without any public input or awareness, had three anonymous peer reviewers respond to specific charge questions regarding EPA's approach

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[195] The proposed rule identifies GAC as a treatment technology but does not compel its use. Other approaches, including use of an alternative source of water supply, are available. 88 Fed. Reg. at 18,684.
[196] See EPA *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, at page 6-109 to 6-110.
[197] See: Weisman, R.J., Heinrich, A., Letkiewicz, F., Messner, M., Studer, K., Wang, L., and Regli, S. 2022. *Estimating National Exposures and Potential Bladder Cancer Cases Associated with Chlorination DBPs in US Drinking Water*. Environmental Health Perspectives,130(8):087002. https://doi.org/10.1289/EHP9985, which states: "Despite the increased weight of evidence established in recent years toward inferring a causal relationship between DBP exposure and bladder cancer, more work is needed to understand the possible mechanisms involved in that relationship, clarify different sources of uncertainty, and address the utility of THM4 as a surrogate measure of risk from the most relevant DBP mixtures of toxicological interest."
[198] *Id.* at results section.
[199] 71 Fed. Reg. 444 (Jan. 4, 2006).
[200] See EPA *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, at page 6-127.

through the use of a letter review.[201] EPA does not disclose the expertise of these anonymous reviewers, nor does EPA explain why this modeling and approach was not presented to the SAB. SAB review, which includes opportunity for transparency and public comment and is far more robust than a letter review, as discussed earlier in these comments, is warranted for influential scientific information that supports rulemaking. This novel and uncertain analysis does not meet the standards required by SDWA for estimating benefits.

5. EPA claims of non-quantified benefits are not supported by the science

For PFOA, PFOS, PFNA, PFBS, PFHxS, and HFPO-DA, EPA makes repeated claims about non-quantifiable benefits. These claims are not supported by EPA's own benefits analysis. For instance, while EPA purports that there are non-quantified benefits to the hepatic system from decreasing PFOS exposure, in discussing ALT levels, EPA notes that "[s]tudy results showed inconsistent evidence on whether the observed changes led to changes in specific liver disease"[202] EPA refers to the ALT endpoint, which it determined was a critical effect for the RfD, as a "non-specific biomarker."[203] When discussing endocrine effects, EPA states: "[e]pidemiology studies reported inconsistent evidence regarding associations between PFOA and PFOS exposure and general endocrine outcomes, such as thyroid disease, hypothyroidism, and hypothyroxinemia."[204] Regarding musculoskeletal effects EPA states: "[s]ome studies found that PFOA/PFOS exposure was linked to osteoarthritis, in particular among women under 50 years of age (ATSDR, 2021). However, other reviews reported mixed findings on the effects of PFOS exposure including decreased risk of osteoarthritis, increased risk for some demographic subgroups, or no association (ATSDR, 2021)."[205]

When discussing the non-quantified effects of other PFAS, the data are even more limited. For instance, while EPA mentions inconsistent evidence on associations between PFNA with cardiovascular effects, EPA also notes that for "[o]ther PFAS for which lipid outcomes were examined in toxicology or epidemiology studies observed limited to no evidence of associations. Studies have examined possible associations between various PFAS and blood pressure in humans or heart histopathology in animals. However, studies did not find suggestive or likely evidence for any PFAS in this summary except for PFOS."[206] Throughout the proposed rule, EPA makes overly conservative decisions to protect against what is portrayed to be an array of affects from additional PFAS not directly addressed by the proposal. However, the scientific information in EPA's benefits analysis, when held to the scientific requirements of SDWA, does not support this approach. For the large majority of health endpoints discussed, EPA has not

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[201] See *EPA Response to Letter of Peer Review for Disinfectant Byproduct Reduction as a Result of Granular Activated Carbon Treatment for PFOA and PFOS in Drinking Water: Benefits Analysis Related to Bladder Cancer.* 2023 EPA–815–B23–001.
[202] See EPA *Economic Analysis of the Proposed National Primary Drinking Water Regulation for Per- and Polyfluoroalkyl Substances*, 2023, at page 6-18.
[203] *Id.* at 6-21.
[204] *Id.* at 6-19.
[205] Id. at 6-20.
[206] *Id.* at 6-23.

provided a factual basis by which to conclude that such benefits are likely to occur when EPA decreases the levels of PFAS in drinking water.

B. In light of the costs, the stated benefits do not justify the cost of the proposed MCLs

As previously discussed, EPA has significantly underestimated the costs of this proposal. As discussed in this section, EPA has also overestimated both the quantified and non-quantified benefits. These comments do not address many other shortcomings, uncertainties, and limitations in EPA's analysis. For instance, EPA notes that 13-33% of the U.S. population consumes bottled water as their primary drinking water source, yet EPA did not take this into account in the modelling.[207] EPA also could have modelled costs and benefits at 20 ppt- 40 ppt where there is more certainty in the occurrence data. Yet EPA chose not to present these analyses, not even as an alternative analysis. It is also important to note that for some of the costs and benefits analyses, EPA modified approaches in published studies to derive its estimates. In most cases, EPA did not have these revised approaches peer reviewed.[208] This is inconsistent with SDWA approach that requires the HHRCA to rely on the best available science.

EPA must set the MCL at a level where the benefits justify the costs. EPA has an obligation to protect public health while relying on the best available science and while also ensuring that the cost of the standard is achievable. Considering the uncertainties and the lack of evidence supporting that effects are "likely," coupled with the significant costs of this rule, including the significant costs to individual households,[209] EPA should adjust the MCL upward to a more optimal, and more affordable balance. As EPA conducts more robust scientific assessments that are appropriately reviewed by the SAB and decreases the levels of uncertainty in the underlying science, including in the occurrence data, it should then modify the MCL as appropriate.

Based on the information presented in the Proposed Rule, the purported benefits do not justify the costs at the proposed MCL levels.

VII. The SBREFA Panel for This Rulemaking Did Not Have the Opportunity To Consider the Proposed Regulatory Action on PFNA, PFHxS, PFBS, and HFPO-DA

For purposes of considering impacts of the proposed rule on small entities, EPA completed an initial regulatory flexibility analysis on the proposed rule and convened a Small Business Regulatory Enforcement Fairness Act (SBREFA) panel under the Regulatory Flexibility Act (RFA) in May of 2022. While a SBREFA panel was convened for the PFOA and PFOS MCL, the panel was not presented with, nor did it specifically discuss, setting an MCL for PFNA, PFHxS, PFBS, or HFPO-DA. Rather, EPA indicated to the panel that it is developing a proposed MCL for PFOA and PFOS and "potentially other PFAS" and is "considering" groups or classes

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[207] *Id.* at 6-108.
[208] Only the CVD modelling was reviewed by the SAB.
[209] *Id.* at 9-29, where table 9-14 shows costs to individual households ranging from $57 to $1,153 annually. See also AWWA analysis on household costs available at: https://www.awwa.org/AWWA-Articles/awwa-statement-on-proposed-pfas-drinking-water-standards.

of PFAS.[210] The SBREFA panel also did not consider the Hazard Index approach for the four PFAS.

This lack of small entity input on a critical aspect of this proposed rule violates the RFA because EPA's proposed MCLs and MCLs for PFNA, PFHxS, PFBS, or HFPO-DA will have a significant impact on a substantial number of small entities. EPA acknowledges in the proposed rule that approximately 62,000 small public water systems could be impacted by the rule, which is a substantial number of small entities.[211] The costs of complying with the rule (including monitoring and treatment) described in Section VI will be even more burdensome for small entities. Small entities will also have problems with the insufficient compliance timeline that does not provide for time needed to meet the practical requirements to deploy treatment technologies. EPA must convene a separate SBREFA panel to consider regulation of the four PFAS and use of the Hazard Index approach before it finalizes any regulation pertaining to these PFAS. It is critical, and required by the RFA, that EPA consider small business impacts of regulating these specific PFAS and the use of its novel Hazard Index approach.

VIII. Conclusion

SDWA sets a high bar by requiring best available science because drinking water regulations are vital to protect human health. At the same time, SDWA can impose significant costs on many public water systems throughout the country. Accordingly, regulation for PFAS substances in water is important but must be done in a lawful and science-based process. This proposal falls short in both respects. Significant scientific uncertainties and legal inadequacies remain. EPA has not yet demonstrated that PFNA, PFHxS, PFBS, and HFPO-DA warrant regulation under SDWA. As such, it is premature to set MCL or an MCLGs. Because EPA skipped important steps in the statutory process, including by forgoing the advice of the SAB on these four PFAS, EPA's proposals for these four should be withdrawn.

While the science is more developed for PFOA and PFOS, the documents EPA presented to the SAB were not sufficiently robust to allow the SAB to make actionable recommendations. Where SAB made valuable and important recommendations, EPA appears to have failed to revise the proposals in a meaningful and cohesive manner. Consequential uncertainties remain regarding the cancer classification for PFOS, and EPA is still awaiting robust and representative occurrence data from the UCMR 5 sampling for both PFOA and PFOS. EPA's cost and benefits analyses for PFOA and PFOS is flawed (as it is for the other PFAS as well), both qualitatively and quantitatively, with notable underestimates of the costs and overestimates of the benefits. An MCL of 4 ppt is simply not justified, and the MCL must be adjusted upward to meet SDWA's feasibility requirements. Finally, if EPA moves forward with setting the proposed MCLs at near-zero levels based on the level of information available for the six PFAS and without adequate weight placed on cost and feasibility, it would set a precedent that is inconsistent with prior MCLs and one that would be difficult to meet when applied going forward.

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[210] Final Report of the SBAR Panel on EPA Planned Proposed Rule Per and Polyfluoroalkyl Substances NPDWR at 7 (August 1, 2022): https://www.regulations.gov/document/EPA-HQ-OW-2022-0114-0048.
[211] 88 Fed. Reg. at 18732.

The Chamber and coalition members welcome any questions and further discussion from EPA on this important, precedent-setting rulemaking. Please contact Chuck Chaitovitz, Vice President of Environmental Affairs and Sustainability at the U.S. Chamber of Commerce (cchaitovitz@uschamber.com), with any questions.

Sincerely,

American Council of Engineering Companies
American Forest & Paper Association
American Fuel and Petrochemical Manufacturers
American Petroleum Institute
Council of Industrial Boiler Owners
The Fertilizer Institute
Fluid Sealing Association
National Association of Chemical Distributors
National Association for Surface Finishing
National Association of Printing Ink Manufacturers
National Council of Textile Organizations
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