PFAS REGULATORY COALITION

May 30, 2023

Ms. Alexis Lan
Office of Ground Water and Drinking Water
Standards and Risk Management Division (Mail Code 4607M)
U.S. Environmental Protection Agency
1200 N. Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Re: Comments on EPA's Proposed PFAS National Primary Drinking Water Regulation Rulemaking
Docket ID No. EPA-HQ-OW-2022-0114

Dear Ms. Lan:

The PFAS Regulatory Coalition (the Coalition) submits the following comments on EPA's Proposed PFAS National Primary Drinking Water Regulation Rulemaking, ("the EPA Proposal") (88 Fed. Reg. 18638, Mar. 29, 2023).

The Coalition is a group of industrial companies, municipal entities, agricultural parties, aviation representatives and trade associations, each of which has facilities or members that are directly affected by the development of policies and regulations related to per- and poly-fluoroalkyl substances (PFAS). Coalition membership includes entities in the automobile, airport, coke and coal chemicals, iron and steel, municipal, paper, petroleum, and other sectors. None of the Coalition members manufacture PFAS compounds. Coalition members, for purposes of these comments, include: Airports Council International – North America; American Coke and Coal Chemicals Institute; American Forest and Paper Association; American Fuel and Petrochemical Manufacturers; American Iron and Steel Institute; American Petroleum Institute; Barr Engineering; Brown & Caldwell; City of Pueblo, CO; Gary Sanitary District (IN); HDR; Illinois Association of Wastewater Agencies; National Oilseed Processors Association; Portland Cement Association; Trihydro; and Western States Petroleum Association.

PFAS Regulatory Coalition member entities or their members own and operate facilities located throughout the country. Many of those facilities would incur substantial costs to comply with the new drinking water standards being proposed by EPA. In addition, these standards would affect other regulatory requirements that are regularly

imposed on Coalition members and their operations, including remediation mandates. The Coalition, therefore, has a direct interest in the EPA Proposal.

The Coalition had requested an extension of the comment period on the EPA Proposal, in a letter dated April 17, 2023. On May 5, 2023, EPA denied all requests for extension. The Coalition has prepared these comments in the limited timeframe allowed by EPA. Other issues may have been included if additional time for review and comment had been allowed by the Agency.

A. EPA's regulatory determinations for four additional PFAS are inappropriate.

1. The EPA Proposal fails to follow the procedures set forth in the Safe Drinking Water Act.

The Safe Drinking Water Act gives EPA the authority to establish national primary drinking water regulations "in accordance with the procedures established by this subsection." SDWA 1412(b)(1)(A). Yet, in the EPA Proposal, the Agency deviates from those procedures by combining three separate rulemakings into one – 1) drinking water standards for PFOA/PFOS; 2) regulatory determinations for four additional compounds; 3) drinking water standards for the four additional compounds.

The proposed drinking water standards for PFOA/PFOS first involved EPA, after what the Agency says was "careful consideration of public comments" (88 Fed. Reg. 18644), making a regulatory determination for these two compounds in a prior rulemaking in March 2021. More specifically, on March 10, 2020, EPA published a preliminary regulatory determination for eight contaminants on the Contaminant Candidate List (CCL 4), two which were PFOA and PFOS. 85 Fed. Reg. 14098 (Mar. 10, 2020). On March 3, 2021, EPA made a final regulatory determination for only PFOA and PFOS and decided not to regulate the other six contaminants. 86 Fed. Reg. 12272 (Mar. 3, 2021). After deliberating for an entire year, EPA moved forward to the next stage of regulation for only two of the eight compounds for which it had made a preliminary regulatory determination.

Here, in contrast, EPA is making a regulatory determination for four compounds and moving forward with proposed drinking water standards in the same step. The consolidation of the Regulatory Determination and proposed drinking water standards for the four additional compounds is problematic in that it provides neither EPA nor the public with the time or information for appropriate consideration of the Regulatory Determination, as required by the Safe Drinking Water Act, instead assuming an outcome and proceeding directly to a proposed drinking water standard. EPA took a year to deliberate on the regulatory determination for PFOA and PFOS, yet is only giving the public 62 days to consider and comment not just on the regulatory determination for PFHxS, PFNA, PFBS, and HFPO-DA but also on the novel approach of using a Hazard Index (HI) as an MCL. This is especially problematic when, through a response letter EPA

issued to the Coalition on May 5, 2023, EPA refused to grant an extension of the comment period.

EPA cites "public urgency" rather than consideration of best available science under the framework of the Safe Drinking Water Act as the rationale for this Proposal. 88 Fed. Reg. 18652. We understand that a sense of urgency is driving the Agency to move forward in this manner, but that must not be at the expense of due deliberation of the new and important issues raised in the EPA Proposal. EPA lacks authority to so sharply change course in setting MCLs. EPA's proposal to depart from its long-established MCL process and prior interpretations of its statutory authority is arbitrary and capricious.

2. There is a lack of occurrence data to support EPA's regulatory determinations for the four additional PFAS.

One of the key criteria for making a regulatory determination is that "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." SDWA Sec. 1412(b)(1)(A)(ii). EPA states that given the number of factors it considered it cannot identify a standard for occurrence data. But the statute provides the standard. Occurrence at levels of public health concern must be "known" or there must be a "substantial likelihood" of such occurrence. Clearly Congress intended that there be some levels and some frequencies that would be below the threshold of public health concern. EPA must articulate where it drew that line to allow for meaningful comment. For example, in seven out of the eleven states with occurrence data on which EPA relied, HFPO-DA was not present in more than 1% of the systems. 88 Fed. Reg. 18648, Table 1. Extrapolating this ratio to all 50 states means that 32 states would have this compound in less than 1% of their systems. EPA's approach would lead to a result where a compound can be absent, or present in less than 1% of systems, in nearly two-thirds of the states, yet that would be enough to justify the occurrence criterion.

EPA's conclusion that PFHxS, PFNA, PFBS, and HFPO-DA meet this "occurrence" criterion is also based, in part, on an assumption of an upward trend in detections: "EPA anticipates that national monitoring with newer analytical methods capable of quantifying PFAS occurrence to lower levels, significant occurrence and co-occurrence of these PFAS are likely to be observed." 88 Fed. Reg. 18650. Anticipation of data is not a basis on which to make regulation. Moreover, according to the Agency for Toxic Substances and Disease Registry, levels of PFOS and PFOA in blood have declined by more than 85% for PFOS, and 70% for PFOA. *See* ATSDR, "PFAS in the U.S. Population," available at https://www.atsdr.cdc.gov/pfas/health-effects/us-population.html#print. EPA's "anticipation" cannot support a determination that the contaminants are "substantially likely" to be present "at levels of public health concern." UCMR 5 data are

already being collected, so EPA should pause this rulemaking in order for the Agency to incorporate actual data, not supposition.

We also do not agree that PFBS meets the statutory "occurrence criterion." EPA acknowledges "that PFBS concentrations do not exceed their HRL [health reference level] of 2000 ppt when considered in isolation." 88 Fed. Reg. 18650. But instead of relying on this information to make its "occurrence" decision, EPA instead relies on an assumption that PFBS will co-occur with other PFAS to collectively reach levels of public health concern. This assumption is simply not supported by the data in EPA's Proposal. EPA reports the median sample range of the state sampling data as being between 1.99 – 7.26 ppt. Based on these results, the median contribution of PFBS to the Hazard Index ranges between:

$$1.99/2000 = 0.000995$$
$$7.26/2000 = 0.00363$$

If these very low levels are thresholds at which EPA believes co-occurrence can contribute to a public health concern, it is hard to imagine any substance that would not meet the "occurrence" test, an outcome that is clearly not supported by the language of the SDWA. Thus, EPA's determination that the data demonstrate that there is a "substantial likelihood" that PFBS will occur at levels of public health concern is not supported by the record.

3. EPA provides no rationale for why it is making regulatory determinations for the four additional PFAS.

It is not clear in the Proposal why EPA is making a regulatory determination for the four additional PFAS. EPA has recently issued health advisory levels (HALs) for PFBS and HFPO-DA, but the Agency has never issued HALs for PFNA or PFHxS. Additionally, EPA's targeting of these four PFAS is not correlated with state actions. Of the states that have issued MCLs, some have included some of these four PFAS in the state regulations, but we are not aware of any states that have singled out only these four substances for regulatory action. Looking to other EPA programs, this list also does not align with the longer list of PFAS compounds for which EPA is soliciting information as to possible designation as CERCLA hazardous substances. Advance Notice of Proposed Rulemaking, Addressing PFAS in the Environment, 88 Fed. Reg. 22399 (April 13, 2023) (the "CERCLA ANPRM"). EPA has provided no justification for why these four additional PFAS compounds have been targeted in this rulemaking. Understanding why EPA is focusing on these four compounds is also important for understanding how EPA has chosen to regulate them using a Hazard Index approach, as discussed further in Section C below.

B. The science does not support EPA's new classification of PFOS as a likely carcinogen.

In the Proposal, EPA has determined for the first time that PFOS is a likely carcinogen. EPA states that it has reviewed the weight of the evidence and determined that PFOS is *Likely to Be Carcinogenic to Humans*, as ''the evidence is adequate to demonstrate carcinogenic potential to humans but does not reach the weight of evidence for the descriptor Carcinogenic to Humans.'' 88 Fed Reg. 18663. Yet, before this Proposal, EPA had determined that PFOS was not a likely carcinogen, and it is not clear what "best available science" EPA is considering now in order to reach this new conclusion. Absent proper scientific support, EPA's new interpretation of largely the same data to reach different conclusions is arbitrary and capricious. EPA actually states at one point that reports preclude a definitive conclusion, but then in the next sentence, EPA points to only "one high confidence" study that found "associations" between PFOS and cancer before concluding that "available study findings support a plausible correlation between PFOS exposure and carcinogenicity in humans." 88 Fed. Reg. 18660, 18710.

It appears that EPA changed its classification of PFOS from "Suggestive Evidence of Carcinogenic Potential" to "Likely to be Carcinogenic to Humans" following the EPA Science Advisory Board's review of EPA's "Draft Proposed Approaches to the Derivation of a Draft Maximum Contaminant Level Goal for Perfluorooctane Sulfonic Acid (PFOS) (CASRN 1763-23-1) in Drinking Water." The SAB says: "The magnitude of the association between PFOS and kidney cancer was lower than that for PFOA, and after adjustment for other PFAS, the adjusted OR for the highest quartile was 1.14 and not statistically significant. However, these data should be presented clearly including a discussion of why the PFOS data from Shearer et al. (2021) were not considered sufficient for a higher designation of 'likely carcinogenic.'" Science Advisory Board Report, "Review of EPA's Analyses to Support EPA's National Primary Drinking Water Rulemaking for PFAS," at 36 (Dkt. No. EPA-HQ-OW-2022-0114-0078) (SAB Report).

The article referred to by the SAB Report is "Serum Concentrations of Per- and Polyfluoroalkyl Substances and Risk of Renal Cell Carcinoma," Shearer, J., et al., Journal of the National Cancer Institute, vol. 113, issue 5 (2021), at 580 (Dkt. No. EPA-HQ-OW-2022-0114-0847). It is notable that the abstract for this article says:

> *"It remains unclear whether PFOA or other PFAS are renal carcinogens or if they influence risk of renal cell carcinoma (RCC) at concentrations observed in the general population."*

Rather than improving the discussion of Shearer, et al. (2021), as recommended by the SAB, and despite the authors' conclusion quoted above, EPA's response to the SAB shows that EPA instead relied on this article to change its classification of PFOS to a "Likely Carcinogen." EPA Response to Final Science Advisory Board Recommendations (August

2022) on Four Draft Support Documents for the EPA's Proposed PFAS National Primary Drinking Water Regulation, at 26 (Dkt. No. EPA-HQ-OW-2022-0114-0043). That reliance, and the resulting determination of likely human carcinogenicity, are not supported by the best available science and not justified based on statements in that article itself.

In the Proposal, EPA concedes that scientific uncertainties exist surrounding the effects of PFOS exposure: "The available epidemiology studies reported elevated risk of bladder, prostate, kidney, and breast cancers after chronic PFOS exposure. While there are reports of cancer incidence from epidemiological studies, the study designs, analyses, and mixed results preclude a definitive conclusion about the relationship between PFOS exposure and cancer outcomes in humans." 88 Fed. Reg. at 18660. Also, EPA's Health Effects Support Document for Perfluorooctane Sulfonate (PFOS) EPA 822-R-16-002 states: (i) "Several human epidemiology studies evaluated the association between PFOS and cancers including bladder, colon, and prostate, but these data present a small number of cases and some are confounded by failure to adjust for smoking. The associations for most epidemiology endpoints are mixed," (ii) "The genotoxicity data are uniformly negative," (iii) "Human epidemiology studies did not find a direct correlation between PFOS exposure and the incidence of carcinogenicity in worker-based populations." In fact, results were so inconclusive that EPA cited 11 studies showing no association between increased serum PFOS and various types of cancer, and an additional two studies that showed a negative association between serum PFOS and breast or uterine cancer, indicating protective effect.

Facing this lack of clear evidence from human studies, EPA turned to one animal study for evidence of carcinogenicity in humans, as stated in the Proposal: "The one high confidence animal chronic cancer bioassay study provides evidence of multi-site tumorigenesis in both male and female rats" and the "single chronic cancer bioassay performed in rats is positive for multi-site and -sex tumorigenesis (Thomford, 2002; Butenhoff et al., 2012b)." 88 Fed. Reg. 18638. These statements do not support the conclusion that "evidence is adequate" as to human carcinogenicity. Moreover, observations of tumorigenesis in laboratory animals dosed at PFAS levels that are environmentally immaterial is not tantamount to risk of cancer in the general human population. Direct extrapolation down to 4 ppt (effectively the reporting limit for PFAS in water), based on animals dosed at PFAS levels much higher than those observed in the UCMR3 study is inconsistent with an understanding of human physiology and dictates a dose-response curve that is unsupported by science.

Further, EPA is inconsistent in its decisions as to the toxicological endpoints that it wants to rely on. The HALs that EPA issued in 2022 were based on immune response, whereas the conclusions in the EPA Proposal appear to be based on cancer studies in mice and rats. Which endpoint does EPA think is appropriate to use? EPA does not provide any explanation of why it has chosen different endpoints for the HAL than in the current Proposal.

As to the cancer endpoints that are discussed in the EPA Proposal, the studies that EPA cites did not adequately control for confounding factors. There are clear statements in those studies that PFOS effects were not separated from other cancer effects. For example, the effects of PFOS were not separated from the potential effects of PFOA.

Also, EPA's reliance on studies from mice/rats is problematic. The non-cancer toxicological endpoints selected for PFNA, HFPO-DA, PFHxS, and PFBS, and used to support the MCL/MCLGs, are based on laboratory animal responses, which do not correlate with the potential for clinical effects in human populations. Effects seen in mice, such as delayed development and decreased hormone regulation, have highly uncertain relevance in terms of human health. Barring consistency between animals and humans (allowing the basis of the MCL to have positive concordance, which would comply with EPA guidance and policy), toxicological endpoints used in developing MCLs/MCLGs should preferentially rely on human studies and account for adverse PFAS effects leading to clinically-relevant impacts, or have a robust, peer-reviewed and SAB-endorsed rationale for relying solely on rodent results.[1]

C. Use of the Hazard Index is inappropriate.

1. A Hazard Index does not meet the definition of an MCL.

The Safe Drinking Water Act defines MCL to mean: "the maximum permissible level of a contaminant in water which is delivered to any user of a public water system." SDWA Sec. 1401(3). Under the Hazard Index approach in the Proposal, EPA does not give a set "maximum permissible level." Instead, there is a range of levels for each of the four compounds, up to their respective "health-based water concentration" (HBWC), that could be either acceptable or unacceptable. The Proposal discusses how EPA has authority to regulate mixtures as "contaminants," but the examples that EPA provides are mixtures for which EPA has established fixed numbers. *See* 88 Fed. Reg. at 18644. EPA claims that it has authority to use a Hazard Index approach (*see e.g.*, 88 Fed. Reg. at 18663), but EPA does not explain how a Hazard Index meets the SDWA definition of "maximum contaminant level."

[1] In this context, it should be noted that recent evaluations have raised concerns about the human and animal data that EPA is relying on in this rulemaking, including as to immunotoxicity effects of PFOA and PFOS. *See, e.g.*, Garvey, et. Al., "Weight of evidence evaluation for chemical-induced immunotoxicity for PFOA and PFOS: findings from an independent panel of experts," Critical Reviews in Toxicology, 53:1, 34-51, DOI: 10.1080.10408444.2023.2194913.

2. A Hazard Index is not appropriate for compounds with different toxic modes of action.

A Hazard Index is not appropriate for compounds with different toxic modes of action. In this respect, the Hazard Index approach used in the Proposal is inconsistent with the approaches that are used in other EPA programs. EPA states that "the application of the HI approach under a regulatory purview is not novel," and the Agency cites CERCLA as an example of where the approach is used. 88 Fed. Reg. 18669. We agree that the HI approach is not novel, but what is novel is the very simplified approach EPA is using here. In EPA's 2000 "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," EPA lays out three approaches to conducting risk assessments for mixtures, recognizing how the state of the science influences which approach is appropriate. "Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," EPA Risk Assessment Forum Technical Panel, August 2000, at p. xi (hereinafter "Supplementary Guidance").

In that Guidance, EPA further states that the "major concerns for the user are whether the available data are on components or whole mixtures, whether the data are composed of either similar components or similar mixtures that can be thought of as acting by similar toxicologic processes, and whether the data may be grouped by emissions source, chemical structure, or biologic activity." *Id*. at xiv. Yet, in the EPA Proposal, the Agency provides no rationale as to why these four compounds can be grouped for a risk assessment that forms the basis of an HI. The EPA Proposal offers no support for a finding that these four additional PFAS compounds act by similar toxicologic processes or that they can be grouped by "emissions source, chemical structure, or biologic activity."

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 Hazard Index should be used as a screening tool only. *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). If, absent data showing that the mode of action is the same, a Hazard Index should not be used to characterize risk at a Superfund site. Therefore, it certainly should not be used to establish a regulatory threshold.

The four PFAS species included in the proposed HI summation, PFNA, HFPO-DA, PFHxS, and PFBS, are dissimilar, and EPA presents no data confirming that the dose additivity model applies to these compounds. In the Supplementary Guidance referenced above, EPA explains that the "term additivity is used when the effect of the combination of chemicals can be estimated directly from the sum of the scaled exposure levels (dose addition) or of the responses (response addition) of the individual components." Supplementary Guidance, at 10. EPA's Proposal merely assumes additivity without

adhering to either of the scientifically supported analytical approaches set forth in the Supplementary Guidance.

Further, EPA's additivity approach in the Proposal appears to prejudge issues that EPA is still considering as to PFAS compounds in other programs. In the CERCLA ANPRM issued in April 2023, EPA is specifically soliciting feedback on whether future CERCLA action could group PFAS compounds, including on the basis of modes of toxicological action:

> EPA is considering whether to initiate a future action that would potentially designate groups or categories of PFAS as hazardous substances. A group or category refers to a set of PFAS that share one or more similar characteristics. Characteristics of interest could include, but are not limited to, chemical structure (e.g., carbon chain length, functional group), physical and chemical properties, **mode of toxicological action**, precursors or degradants, or co-occurrence.

88 Fed. Reg. 22402-403 (emphasis added). EPA then gives an example of a Significant New Use Rule (SNUR) issued under the Toxic Substances Control Act (TSCA), in which grouping was based on chemical structure. 88 Fed. Reg. 22403.

In the TSCA program, EPA has developed Draft Principles for Cumulative Risk Assessment (CRA). In that draft document, EPA bases additivity on toxicological similarity: "Deciding, based on their toxicological similarity, which chemical substances to include in a cumulative chemical group that subsequently would be evaluated using dose additive models is an important element of a CRA." Draft Principles for Cumulative Risk Assessment, EPA Document # EPA-740-P-23-001, Feb. 2023, United States Office of Chemical Safety and Environmental Protection Agency, Pollution Prevention, lines 458-460, available at https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/cumulative-risk-assessment-under-toxic-substances. The four additional PFAS addressed in the EPA Proposal are not toxicologically similar, so EPA grouping them here is inconsistent with how EPA would group these chemicals under TSCA.

In sum, the Proposal provides no basis for grouping these four compounds through use of a Hazard Index. EPA tries to justify the grouping by co-occurrence, but that justification is not scientifically supported. As discussed in Section A.2 above, we do not believe that co-occurrence is supported by the data. Simply put, a Hazard Index of compounds that share nothing other than being part of a larger class is meaningless. Moreover, the inconsistency between EPA's Proposal and the rationale for the use of dose additivity in other programs, such as CERCLA and TSCA, supports that conclusion that use of an HI as a surrogate for an MCL for these four compounds is arbitrary and capricious.

3. The Coalition has concerns about the potential for expanded use of the Hazard Index approach.

The Coalition is concerned that use of the HI approach could be expanded. As discussed above, the Coalition doubts the validity of an HI as meeting the definition of an MCL, and the Coalition is opposed to use of the HI as presented in the Proposal, which adds across different modes of action - especially for compounds where the co-occurrence conclusion is not justified by the data. These concerns are made even stronger when EPA states that "additional PFAS can be added over time once more information on health effects, analytics, exposure, and/or treatment becomes available, and merits additional regulation as determined by EPA." 88 Fed. Reg. 18670. EPA also says that "this approach provides a framework for Federal and State agencies to consider using to address PFAS in the future as needed." *Id*. The Coalition does not agree that the framework presented is appropriate for adding compounds over time or for other agencies to consider using.

EPA also does not make clear how, if at all, it would update the HI if there are updates to the science. The HI is based on HBWCs for each of the individual compounds. If there is an update needed to one or more of the HBWCs, would EPA update the HI through a future rulemaking? The current HI approach relies on HBWCs that are a combination of previously published Health Advisory Levels (for GenX and PfBS) and HBWCs that were separately developed as part of the MCL derivation (for PFNA and PfHxS). None of these is a regulatory value. The HBWCs for PFNA and PfHxS are even more uncertain: EPA acknowledges that there is no published EPA toxicity assessment for either of these chemicals, offering only that these assessments are under development and expected to undergo external peer review sometime in 2023. What happens to the HI if peer review results in recommendations changes to these values? EPA has made dramatic swings in how it approaches PFOA and PFOS (*see*, *e.g.,* the discussion in Section B, *supra*), so it would not be surprising if similar changes in EPA's approach were to occur with the other PFAS compounds as the science develops.

Similarly, if EPA wants additional PFAS compounds to be subject to an HI in the drinking water standards, would the Agency add them to those already included in the proposed HI, or would EPA create a new group with an additional HI? Again, as EPA has provided no sound basis for why it is combining these four PFAS compounds in a HI , the Coalition cannot meaningfully comment on that proposal. The Proposal also does not explain the basis EPA would use to update the HBWCs and how EPA would choose whether and which additional PFAS to include in this HI or a new HI, again depriving the Coalition of notice of EPA's regulatory approach and the opportunity to comment on it.

4. If the four additional PFAS are to be regulated at all, it should be done by setting individual MCLs.

Given the concerns, questions and uncertainties regarding the Hazard Index that are set forth above, the Coalition suggests that if EPA is going to regulate the four compounds covered in the Hazard Index, it should instead develop individual MCLs for these compounds. The Coalition is not expressing an opinion as to whether the information that EPA has is sufficient to use in developing drinking water standards, but we would review and comment on that information if and when EPA issues such a rulemaking, following the process set forth in the Safe Drinking Water Act.

5. Use of a Hazard Index approach complicates risk communication to the public.

Our members frequently have to address risk communication challenges regarding PFAS. The Environmental Council of the States (ECOS) has recognized these challenges for state agencies as well. In ECOS's White Paper "Processes & Considerations for Setting State PFAS Standards," the theme of needing improved risk communications regarding developing PFAS regulations appears throughout. ECOS, Feb. 2020, updated March 2023, at p. 8, 9. 36, 38, and 39, available at: https://www.ecos.org/documents/ecos-paper-processes-and-considerations-for-setting-state-pfas-standards-2023-update/. To mitigate these challenges, the Coalition has long advocated for national standards, which allow for clearer risk communication than if there is a patchwork of state standards. It is difficult, for example, to explain to the public and other stakeholders why one state has MCLs for two PFAS compounds at certain levels, while another state regulates seven PFAS compounds at different levels. Uniform national standards allow for a more uniform understanding and clearer communication on these important issues. The use of a Hazard Index approach, however, frustrates the opportunity to provide clear communication to the public.

The Proposal demonstrates how unclear the HI approach is to communicate. EPA gives examples of how PFNA, HFPO-DA, PFHxS, and PFBS all can be below their respective HBWC, yet there is still an exceedance of the HI – which means there is an exceedance of the MCL. 88 Fed. Reg. at 18665 - 666. EPA adds to the confusion in its discussion of why only 4 compounds are included in the HI, and why it is not including PFOA and PFOS. The explanation that EPA gives as to why PFOA and PFOS are not part of the HI is that "the Agency believes doing so would not add meaningful health protection over setting an individual MCL." 88 Fed. Reg. at 18670. That statement is entirely inconsistent with the Agency's explanation of why it needs to use the HI approach. Further, this explanation is confusing and leaves the impression either an individual MCL or an HI may have more "meaningful health protection" than the other.

As recognized by ECOS and as experienced by our members, risk communication is vital with developing PFAS regulations. A national standard for drinking water should make risk communication easier, yet the HI approach makes it more difficult and confusing. This is yet another reason not to adopt an HI approach in drinking water standards.

D. Monitoring and compliance

1. It is not technically feasible to manage operations to meet a PQL.

Under the Safe Drinking Water Act, attainment of a MCL must be technologically feasible for public water systems. SDWA Secs. 1401(1)(i), 1412(b)(4). It is not feasible for public water systems to manage a system so that it will always achieve contaminant levels at the Practical Quantitation Limit (PQL), as EPA is proposing. EPA appears to be unjustifiably dismissive of these concerns.

In considering whether to set an MCL at 25% above the PQL, EPA states that in its outreach consultations, a commenter suggested a MCL of 5.0 ppt because "water systems operate with a margin of safety and plan for performance that maintains water quality below quantitation levels." In the commenter's opinion, "having an increased buffer between the PQL and the MCL may allow utilities to manage treatment technology performance more efficiently because utilities typically aim to achieve lower than the MCL to avoid a violation". 88 Fed. Reg. 18670. EPA dismissed this idea and instead states: "For results between the detection limit and the PQL, EPA has determined that utilities would be able to reliably conclude analyte presence, though this detection is less precise regarding specific concentration." It is arbitrary for EPA to rely on this imprecise presence/absence approach for managing compliance, when facilities are potentially subject to civil and criminal penalties if they are judged to be in noncompliance.

Due to variability in samples, sampling technique, laboratories, etc., managing a drinking water treatment process to the PQL does not make operational sense. Drinking water providers try to make sure they are not just reaching the levels of the MCLs, but are well below those levels, to provide some level of additional operational certainty. Setting MCLs at the PQL does not allow operators to do this.

2. It is not appropriate to set trigger levels below the PQL.

The Proposal suggests trigger levels at 1/3 the MCLs, which equates to 1.3 ppt for PFOA/PFOS and a 0.3 HI. EPA should not set trigger levels below what can be accurately measured.

In the Proposal, EPA itself recognizes the challenges of finding laboratories that can provide accurate quantitation below 4 ppt: "EPA anticipates there would not be sufficient laboratory capacity if the quantitation level were set at a level below 4.0 ppt. The rigorous laboratory certification and quality assurance/quality control (QA/QC) procedures could limit the number of laboratories that can achieve lower quantitation levels and many water systems would not be able to secure the services of laboratories that are capable of consistently providing precise and accurate quantitation of concentrations of PFOA and PFOS at levels lower than 4.0 ppt." 88 Fed. Reg. 18667.

In our members' experiences, laboratories do not routinely report data below the PQL. If a laboratory does report this date in response to a client's request, the data is typically qualified as "estimated." Estimated values should not be used for regulatory reporting due to the high levels of uncertainty when reporting below the PQL. In addition, when calibrating analytical instrumentation, most laboratories use their PQL as the lowest calibration standard. Therefore, any reported values below the PQL are outside the laboratory's calibration range. Again, this introduces significant uncertainty into the reliability of these results. In fact, Coalition members have received false positive results from laboratories.

There is no logical reason that EPA should allow a lesser level of confidence for trigger levels than it does for MCLs. Incorporating data with inherently lower levels of accuracy also further complicates risk communication. Given the additional regulatory obligations for monitoring and compliance that would apply if sampling results are above the trigger level, values below the PQL should not be used.

3. Concerns about laboratory capacity must be adequately considered and addressed.

The Coalition is concerned that there will not be adequate laboratory capacity to accommodate the enormous amount of testing across the country that would be required by the Proposal. Laboratories with PFAS analytical capabilities are already receiving increased demand for NPDES permit compliance testing, as well as for testing for remediation projects. Coalition members are already experiencing delays of six weeks to three months in turnaround times for PFAS analyses. The thousands of additional samples required under the Proposal would only exacerbate this problem. Even as more laboratories try to come on-line and offer PFAS analytical services, it takes time for them to do so and to provide consistent, reliable results. Laboratories are not immune to the challenges that other employers are facing in finding qualified and reliable personnel. EPA needs to fully consider these laboratory capacity concerns before proceeding further with this rulemaking. Without adequate laboratory capacity, attaining and maintaining an MCL is not technically feasible.

4. Even accredited laboratories are not all able to meet the sensitivity and reporting precision required by the Proposal.

The concerns raised above regarding laboratory accuracy and capacity are further underscored by a laboratory survey recently conducted by Environmental Standards, Inc. for the American Petroleum Institute. Environmental Standards Survey, May 2023. Environmental Standards identified and surveyed 51 accredited laboratories for US EPA Methods 533, 537, and/or 537.1 and received responses from 14 of this facilities (27%). The results indicated that while the current laboratory sensitivity and reporting precision can meet the US EPA-proposed MCLs for PFOA and PFOS for drinking water, the current laboratory sensitivity and reporting precision will not be met by all accredited facilities for the US EPA-proposed trigger levels for PFOA and PFOS.

Further, the current laboratory sensitivity and reporting precision can meet the US EPA-proposed HBWCs for PFHxS, HFPO–DA, PFNA, and PFBS, but the current sensitivity demonstrated by the accredited laboratories may not be sufficient to meet the US EPA-proposed HI MCLG for combined PFHxS, HFPO–DA, PFNA, and PFBS. This further demonstrates that the Proposal is technically infeasible with current laboratory capabilities.

E. Concerns and questions regarding EPA's analysis of treatment technologies and costs need to be considered and addressed.

The Coalition has reviewed the information in the Proposal and, as time has allowed, in the supporting document "Technologies and Costs for Technologies and Costs for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water" (February 2023), Dkt. No. EPQ-HQ-OW-2022-0114-0038. We have a number of questions and comments on EPA's analysis of treatment options and costs, which are set forth below.

a) *Can EPA provide more basis for its estimates of the range of bed volumes included in its analysis of GAC and IX?* EPA presents very large ranges but no details about the information on which the estimates are based. Based on our members' experience, the numbers appear high, which would equate to unduly low operational expenses of GAC systems. In particular, EPA has likely underestimated the quantity of spent GAC that will require treatment. In the Proposal, 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 replacement frequency. EPA's cost estimate basis for bed volume was a range of 5,000 to 150,000 for GAC. 88 FR 18695. 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) The recovery rates for RO appear higher than what our members' experience suggests. We believe that 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.

c) EPA should consider remineralization costs. Remineralization is sometimes needed for RO or IX treated water before it can be used again. EPA identified two full-scale applications of RO to treat PFAS in drinking water systems. The industrial facilities that the Coalition represents have experience using Reverse Osmosis units in their facilities (non-PFAS specific applications). From this experience, EPA did not adequately address 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. Technologies and Cost for Removing Per- and Polyfluoroalkyl Substances (PFAS) from Drinking Water, Fed. 2023, Dkt. No. EPQ-HQ-OW-2022-0114-0038.

d) *Does EPA have any more data large surface water treatment plants regarding treatment technologies and costs?* It appears there are limited data points and case studies on which to evaluate available technologies or to form a representative cost curve.

F. <u>The Proposal fails to propose MCLs at levels where costs are justified by the benefits, as required under statute.</u>

The Safe Drinking Water Act requires that an MCL be set at a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits." SDWA Section 1412(b)(6). The Proposal fails to meet this statutory requirement for several reasons, including that. EPA seriously underestimates the costs of the Proposal. Other organizations, including AWWA and the US Chamber of Commerce, have already submitted cost estimates to EPA and OMB, and each independently shows that EPA's cost estimates are much too low. Below, the Coalition outlines additional cost/benefit issues that need to be considered and addressed by the Agency.

1. EPA needs to provide more information as to several aspects of its cost analysis.

We have a number of questions and comments concerning EPA's compliance cost analysis, which are set forth below.

a) *Did EPA consider the costs for installing new or expanded public water systems (PWS)?* In EPA's cost/benefit model, the Agency includes the costs of monitoring/ compliance/treatment for PWS and non-community, non-transient water systems (NCNTWS) but it does not include any review of the potential compliance costs for new or expanding systems. This should include consideration of situations where, in

response to PFAS concerns, municipal water supplies are being extended to rural areas that primarily had relied on individual drinking water wells. For example, centralization is part of the Biden Administration's strategy for addressing PFAS in drinking water and the Bipartisan Infrastructure Law provides funding that can be used for such purposes. FACT SHEET: Biden-Harris Administration Combatting PFAS Pollution to Safeguard Clean Drinking Water for All Americans (June 15, 2022), available at https://www.whitehouse.gov/briefing-room/statements-releases/2022/06/15/fact-sheet-biden-harris-administration-combatting-pfas-pollution-to-safeguard-clean-drinking-water-for-all-americans/. OMB Circular A-4 requires agencies to include in its baseline consideration of the evolution of the impacted market. Circular A-4, at 15. At a minimum, EPA should conduct a sensitivity analysis to evaluate the impact of the capital investments as well as the ongoing operation/maintenance costs for new and expanded systems, as well as increased treatment costs due to increased volumes. These costs will likely be significant – millions or tens of millions of dollars per facility, depending on the size of the system. EPA must include an analysis of these costs – and the benefits - at the different levels of proposed MCLs (4 ppt, 5 ppt, 10 ppt), since the level chosen could greatly affect the scope of any new or expanded system and the related costs.

b) *Did EPA consider the costs and timing of the analysis that needs to occur to decide if and what kind of treatment may be necessary?* Table 35 of the Proposal estimates a range of 3 hours to 42 hours to "notify, consult, and submit a permit request for treatment installation." This does not appear to include – or if it does, it grossly underestimates – the costs of evaluating potential treatment options, designing and pilot testing a treatment system, etc. Some systems will be starting with no baseline information whatsoever. Many of these have not had to sample for PFAS before.

c) *Did EPA consider the costs/availability of treatment media?* The demand for treatment media is greatly increasing for remediation projects and will increase further due to this Proposal. EPA should consider how market demand will affect price and availability of the different treatment media.

d) *Did EPA review how treatment media are being handled by waste disposal facility today?* In our members' experience, PFAS-impacted media, including treatment media, are often being refused at regular landfills and only being accepted at hazardous waste landfills. EPA's approach, in which these costs are looked at only as part of a sensitivity analysis, ignores the true costs that are being experienced today, regardless of the regulatory status of the material being handled.

e) *Did EPA consider landfill capacity in its costs of waste disposal?* There is going to be greater demand for PFAS disposal options. Treatment media is only one aspect, but our members also have to deal with impacted biosolids, soils, and construction debris. As has been recently experienced in Maine with biosolids, landfill capacities are stressed – which of course affects costs. EPA should include these factors in its analysis.

f) *How did EPA choose 200 miles as its transportation distance for hazardous waste shipments?* In the appendix "Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation," EPA uses a 200-mile distance in its sensitivity analysis for hazardous versus non-hazardous waste disposal. EPA-822-P-23-001. However, small systems and non-transient, non-community systems are likely much farther away from an available hazardous waste disposal facility. EPA should include a more realistic distance in its analysis.

g) *Did EPA consider the increases in social costs resulting from increased energy use required treatment?* It appears that energy costs were considered only as part of O&M costs for lighting, ventilation and pump operations. But treatment for PFAS involves fairly energy-intensive activities. Therefore, EPA's energy cost estimates seem low EPA's analysis also needs to include increased social costs associated with that required increase of energy use.

h) *Did EPA consider the costs associated with RO reject disposal?* It appears that EPA assumed that reject streams would be directly discharged via NPDES permitted outfalls to non-potable receiving streams (oceans or brackish estuaries). However, EPA needs to recognize that discharging concentrated streams of PFAS-containing material to the environment via a permitted outfall may not be feasible, due to Whole Effluent Toxicity testing and other CWA-based requirements. Nor would that approach align well with EPA's overall strategy for regulation of PFAS.

2. EPA should consider increased costs for remediation.

Under Section 121(d) of CERCLA, Superfund remedies must achieve MCLGs when remediating impacted groundwater and other drinking water sources. CERCLA 121(d)(2)(A). Further, once promulgated the MCLs would become applicable or relevant and appropriate requirements (ARARs) that Superfund remedies must attain. *Id.* No separate rulemaking or other process is needed. Therefore, it is this Proposal that would result in increased costs at Superfund sites, and EPA must consider those costs in this rulemaking.

The Department of Defense (DOD) PFAS remediation estimates demonstrate how significant these costs can be. As of July 2022, DOD summarized its PFAS remediation costs as follows: "Through September 30, 2021, DOD has obligated $1.46 billion to investigate and clean up PFAS. DOD anticipates obligating $409.4 million in FY 2022 and an additional $2.12 billion after FY 2022 to continue these efforts." Per- and Polyfluoroalkyl Substances (PFAS) Cleanup: Schedule, Status, and Cost Estimates, DOD Office of the Under Secretary of Defense for Acquisition and Sustainment (July 2022). DOD does not separate these costs by media, but assuming that even just half of these costs are for water/groundwater remediation leads to costs in the billions of dollars.

Further, this EPA action is likely to stimulate the adoption of PFAS cleanup standards under state law. OMB circular A-4 requires consideration of the costs of such additional state regulation as well as direct federal regulation. Circular A-4, at 6. EPA needs to address those costs for all parties anticipated to incur remediation costs. As noted elsewhere in these comments, available estimates indicate that these new cleanup costs will amount to billions of dollars.

3. EPA's analysis is inconsistent with the approaches taken by states that have been issuing standards.

Several states have conducted their own rulemakings to establish MCLs or similar drinking water standards. None of these states justified standards at the PQL levels proposed by EPA. The most recent state to adopt standards, Pennsylvania, conducted a robust cost/benefit analysis and promulgated MCLs of 14 ppt for PFOA and 18 ppt for PFOS, which are three to five times greater than what EPA is proposing. 53 Pa.B. 333, Jan. 14, 2023; *available at*: https://www.pacodeandbulletin.gov/Display/pabull?file=/secure/pabulletin/data/vol53/53-2/46.html. EPA's Proposal is inconsistent with the conclusions reached by Pennsylvania and the other states that have established their own MCLs.

4. EPA's cost/benefit analysis relies too heavily on nonquantifiable costs and benefits.

EPA presents its evaluation of costs and benefits of MCLs at different MCL values and at both 3% and 7% discount rates, in Tables 66 through 69 of the Proposal. These tables show uneven net benefits, with only PFOA and PFOS MCLs set at 10 ppt projected to have positive next net benefits at both discount rates. Nevertheless, EPA proposes 4 ppt for each compound and concludes its cost/benefit analysis by stating: "To fully weigh the costs and benefits of the action the Agency considered the totality of the monetized values, the potential impacts of the unquantified uncertainties described above, and the nonquantifiable costs and benefits. The Administrator has determined that the benefits of this proposed regulation justify the costs." 88 Fed. Reg. 18729. The only way that EPA could reach this conclusion is if the unquantified uncertainties and the nonquantifiable costs and benefits were given more weight than the quantified values.

Given the concerns about costs that the Coalition has discussed above, EPA should conduct a new cost/benefit analysis. Considering the Agency's underestimation of costs, EPA has not met the Safe Drinking Water Act requirement that an MCL be set at a level that "maximizes health risk reduction benefits at a cost that is justified by the benefits." SDWA Section 1412(b)(6).

G. EPA's SBREFA panel review was incomplete.

The Regulatory Flexibility Act Section 609(b) requires EPA to conduct small business advocacy review panels when it is unable to certify that a rule will not have a significant economic impact on a substantial number of small businesses. The Small Business Regulatory Enforcement Fairness Act (SBREFA) mandates that these panels consist of representatives of the rulemaking agency, the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA), and the Small Business Administration's (SBA's) Chief Counsel for Advocacy. As explained by the SBA:

> The panel solicits information and advice from small entity representatives (SERs), who are individuals that represent small entities affected by the proposal. SERs help the panel better understand the ramifications of the proposed rule. Invariably, the participation of SERs provides extremely valuable information on the real-world impacts and compliance costs of agency proposals. *A Guide For Government Agencies: How to Comply with the Regulatory Flexibility Act* (at 51)(2017).

In this case, EPA convened a SBREFA panel. But the panel's recommendations are only as useful and relevant as the information provided to the panel by EPA. In this case, EPA only presented to the SERs the proposal to regulate PFOS and PFOA and stated that it might consider other PFAS chemicals or even groups of PFAS as supported by use of the best available science. EPA never presented the SERs with the concept of the HI approach or how it might be implemented. Hence, the SBREFA panel had no input from the SERs on the HI approach, which ultimately became a critical aspect of the EPA Proposal. EPA should have reconvened the SBREFA Panel once it determined that it would include an HI approach in that Proposal.

In addition, the Panel recommended that EPA conduct and present costs of both non-hazardous and hazardous waste generation as a result of likely treatment mandates associated with the Proposal. The Panel's recommendation is entirely logical. EPA has already indicated an intention to address PFOA and PFOS (along with other PFAS substances) as hazardous constituents under RCRA. Moreover, EPA not only has proposed designating PFOS and PFOA as hazardous substances under CERCLA, but also plans to propose to add PFOA, PFOS, PFBS, and GenX as RCRA hazardous constituents.

Given these ongoing and planned regulatory actions, it is very likely that solid waste disposal facilities will refuse to accept waste that contains these PFAS, greatly increasing disposal costs of treatment residuals and other contaminated media. EPA's Regulatory Impact Analysis must recognize these impacts. Instead, EPA claims it need not address these costs by claiming that such wastes "are not currently" regulated as hazardous wastes. 88 Fed. Reg. 18701. It agreed to a preliminary sensitivity analysis "for illustrative purposes only," which is not a good faith effort to truly provide accurate impacts on costs likely associated with the EPA Proposal.

Finally, the Panel recommended that EPA provide for compliance extensions in recognition of likely laboratory capacity-related challenges. EPA responded that it or a state may grant up to a 2-year extension, but that it was not planning on granting any nationwide extensions, leaving small systems to seek state extensions. EPA should reserve its judgment on nationwide extensions to see if, in fact, existing laboratory capacity is sufficient. Current experience with significant laboratory delays, coupled with a likely significant spike in demands over the next several years, makes it clear that EPA's pronouncement is premature.

H. The Proposal fails to adequately explain consultation with local governments.

The Proposal contains a "federalism summary impact statement," and says a "summary report of the views expressed during federalism consultations is available in the Docket." 88 Fed. Reg. 18733-734. Yet, no specific document reference is provided. There is some discussion on this topic in the "Final Report of the Small Business Advocacy Review Panel on EPA's Planned Proposed Rule Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation." Dkt. No. EPA-HQ-OW-2022-0114-0048.

If EPA means to state that local government consultation was conducted within the SBREFA process, then this consultation fails to comply with SBREFA for the reason stated in Section G above – that EPA failed to present the key information included in the Proposal. Additionally, this consultation would have been limited to small entities, and did not extend to other local government entities. It also appears, from the EPA Proposal, that the Agency had one virtual meeting with a large group of organizations representing state and local governments, over a year ago, and then let those organizations submit written comments. If that is the full extent of consultation with local governments that EPA has conducted, then it has not complied with its legal obligations regarding federalism concerns.

I. Conclusion

In these comments, the PFAS Regulatory Coalition has raised a series of substantial concerns with the EPA Proposal, which need to be addressed before EPA moves forward with any rulemaking setting drinking water standards for PFAS. The Coalition looks forward to continuing to engage with EPA on these issues. Please feel free to call or e-mail if you have any questions, or if you would like any additional information concerning the issues raised in these comments.

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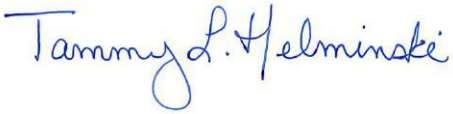

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Attachments

- ATSDR, "PFAS in the U.S. Population," December 22, 2022
- Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures," EPA Risk Assessment Forum Technical Panel, August 2000
- Draft Principles for Cumulative Risk Assessment, EPA Document # EPA-740-P-23-001, Feb. 2023, United States Office of Chemical Safety and Environmental Protection Agency, Pollution Prevention.
- Processes & Considerations for Setting State PFAS Standards, ECOS, Feb. 2020, updated March 2023
- FACT SHEET: Biden-Harris Administration, Combatting PFAS Pollution to Safeguard Clean Drinking Water for All Americans, June 15, 2022
- Environmental Standards Laboratory Survey, May 2023