BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

IN THE MATTER OF:	**)**	
	)	
PROPOSED AMENDMENTS TO	**)**	**R22-18**
GROUNDWATER QUALITY	**)**	**(Rulemaking – Public Water**
35 ILL. ADM. CODE 620	**)**	**Supply)**
	)	

NOTICE OF FILING

PLEASE TAKE NOTICE that on February 18, 2022, we electronically filed with the Clerk ofthe Pollution Control Board of the State of Illinois, the PFAS REGULATORY COALITION'S PRE-FILED QUESTIONS TO MS. CAROL L. HAWBAKER, copies of which is attached hereto and served upon you.

Dated: February 18, 2022

Respectfully submitted,

PFAS REGULATORY COALITION

By: */s/ Fredric P. Andes*
Fredric P. Andes

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CERTIFICATE OF SERVICE

I, Fredric Andes, hereby certify that I have filed the attached NOTICE OF FILING and PFAS REGULATORY COALITION'S PRE-FILED QUESTIONS TO MS. CAROL L. HAWBAKER, in PCB R2018-032 upon the below service list by electronic mail on February 18, 2022.

Dated: February 18, 2022 */s/ Fredric Andes*

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BEFORE THE ILLINOIS POLLUTION CONTROL BOARD

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PROPOSED AMENDMENTS TO	**)**	**R22-18**
GROUNDWATER QUALITY	**)**	**(Rulemaking – Public Water**
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PFAS REGULATORY COALITION'S
PRE-FILED QUESTIONS TO MS. CAROL L. HAWBAKER

The PFAS Regulatory Coalition, by and through its attorneys, Barnes & Thornburg, LLP, and pursuant to the Illinois Pollution Control Board's ("Board") Notice of Hearing dated January 13, 2022, submits the following Pre-Filed Questions of Illinois Environmental Protection Agency ("Agency" or "Illinois EPA") witness Ms. Carol L. Hawbaker for the hearing scheduled on March 9-10, 2022. While the questions below are directed to a specific witness, the Coalition has no objection to the answers being presented by the most appropriate Illinois EPA witness for each question.

1. Can you explain why the proposed standards for PFAS substances are orders of magnitude more stringent than the first version of the proposed standards, which were released in December 2019?

2. Did you consider the comments on that first version of the proposed PFAS standards, including those submitted by the PFAS Regulatory Coalition? If so, please explain how you considered and addressed each of the specific comments that were submitted.

3. A second version of the proposed PFAS standards was released by IEPA in May 2021. Did you consider the comments on that second version, including those submitted by the PFAS Regulatory Coalition? If so, please explain how you considered and addressed each of the specific comments that were submitted.

4. For each of the proposed PFAS standards, please explain exactly how you calculated the proposed standards, including how the risks to different organs were added together to yield the final values.

5. USEPA's current Lifetime Drinking Water Health Advisory level for PFOA and PFOS is 70 parts per trillion, which is a preliminary remediation goal for contaminated groundwater that is a current or potential source of drinking water. Can you explain why you rejected use of that Health Advisory Level for Illinois groundwater?

6. Don't Illinois regulations require IEPA to use USEPA reference oral doses in deriving standards when there is no EPA-set Maximum Contaminant Level Goal (MCLG)?

    a. If so, then for PFOS, why did you use a value from the Agency for Toxic Substances Disease Registry (ATSDR) instead?

    b. Are you aware of differences between ATSDR's method for deriving values as opposed to EPA's method? Have you considered those differences in deciding to rely on an ATSDR value?

7. For PFOA, is it true that EPA has not declared that this substance is a carcinogen? If that's so, then why are you basing the standard on cancer risk?

8. For PFOA, why are you using a California study of cancer risk? Are you aware of comments that have been submitted to the State of California, questioning the scientific basis for that study?

9. Comments submitted by the PFAS Regulatory Coalition to the State of California are attached as Exhibit 1. Have you considered the issues set forth in those comments? If not, why not? If so, do they change your assessment of whether and how the California study should be used by Illinois?

10. One of the five PFAS proposed standards, for PFBS, was based on a different type of value than the others – an EPA-derived Provisional Peer-Reviewed Toxicity Value (PPRTV). This set of values is scientifically preferred, and the PFBS value is significantly less stringent than the other proposed PFAS values. What does that tell you about the scientific validity of the other values? If they were based on PPRTVs, might they be less stringent as well?

11. Are there approved EPA test methods for PFAS in groundwater, or any other media other than drinking water? Even if not approved, are there any validated test methods for PFAS in groundwater, or any other media other than drinking water?

12. If there are no validated and approved test methods available for PFAS in groundwater, how can anyone have confidence in the validity of test results that are used to assess compliance with the new groundwater standards?

13. Has IEPA assessed potential treatment and disposal options for groundwater that is found to have PFAS levels above the proposed standards? If so, what are IEPA's conclusions?

14. Under the Board's enabling legislation, it is required to take into account "the technical feasibility and economic reasonableness of reducing the particular type of pollution." 415 ILCS 5/27(a). How has IEPA considered those factors as to the proposed PFAS standards?

15. Won't the groundwater standards, when finally adopted, be used in imposing remediation requirements for sites in Illinois that are found to have PFAS levels above the standards? If so, has IEPA determined the possible remediation costs?

16. Has IEPA determined whether options are available for disposing of PFAS-contaminated wastes from those remediation sites?

17. Has IEPA considered what the background levels of PFAS are in the environment? If so, has IEPA compared those levels to its proposed standards, to determine if the standards specify lower levels than are present in the environment in areas without known sources?

18. Does IEPA intend to require regulated parties to reduce PFAS levels below those that are present in the environment in areas without known sources? Is that even possible?

Dated: February 18, 2022

Respectfully submitted,

PFAS REGULATORY COALITION

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EXHIBIT 1

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October 28, 2021

VIA ELECTRONIC SUBMISSION
Pesticide and Environmental Toxicology Branch
Office of Environmental Health Hazard Assessment
California Environmental Protection Agency
P.O. Box 4010, MS-12B
Sacramento, California 95812-4010

Re: Comments of the PFAS Regulatory Coalition on California OEHHA's Proposed Public Health Goals for Perfluorooctanoic Acid and Perfluorooctane Sulfonic Acid in Drinking Water

Dear Sir or Madam:

The PFAS Regulatory Coalition (Coalition) appreciates the opportunity to submit comments regarding the California Office of Environmental Health Hazard Assessment's (OEHHA) proposed public health goals for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonic acid (PFOS) in drinking water.

I. The Coalition's Interest

The Coalition is a group of industrial companies, municipal entities, agricultural parties, and trade associations that are directly affected by the State's development of policies and regulation related to per- and polyfluoroalkyl substances (PFAS). Coalition membership includes entities in the automobile, 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; Barr Engineering; Brown & Caldwell; Gary Sanitary District (IN); Illinois Association of Wastewater Agencies; Lowell, MA; Pueblo, CO; Toyota; Trihydro, and Yucaipa Valley Water District (CA).

Coalition members support the State's efforts to collect data on the individual PFAS that pose risks to human health and the environment. However, the State's development of public health goals (PHGs) that will ultimately inform State drinking water standards, the Coalition urges the State to further address the limitations of the data relied on and better account for those limitations in its methodology.

II. Proposed Rulemaking

On July 30, 2021, OEHHA issued the first public review draft of its proposed PHGs for PFOA and PFOS in drinking water. The proposal includes a PHG of 0.007 ppt for PFOA and 1 ppt for PFOS. The proposal also includes a health-protective concentration of 3 ppt for PFOA and 2 ppt for PFOS.

The PFAS Coalition has significant concerns regarding the PHG values, which are orders of magnitude lower than many other guidelines, regulations, advisory levels, and health-based values for PFOA and PFOS proposed or developed in other states and by EPA. As discussed below, the Coalition requests that the State reconsider its proposal to address issues with the scientific methodology by which the PHGs were developed. Additionally, the Coalition urges OEHHA to consider the benefit of developing PHGs that cannot have any real-world application.

III. Coalition Analysis and Recommendations

In the comments below, the Coalition discusses some of the challenges that the State faces in attempting to promulgate enforceable regulations, as well as some of the challenges that Coalition members face if states promulgate standards that vary from any existing or future federal standards. The Coalition appreciates the State's desire to establish health-based goals that will inform future regulation, but urges California and other states to work with the federal government to develop a consensus on the leading data relating to the human health effects of PFOA and PFOS in order to promote a cohesive national strategy to help ensure national uniformity. A patchwork set of state-specific goals and standards that vary widely would likely cause significantly more confusion and overwhelming challenges for Coalition members that operate in multiple states or nationwide.

A. The Scientific Community Does Not Agree on Human Health Toxicity Values for PFAS

The term "PFAS" refers to a group of man-made chemicals that include perfluorooctanoic acid (PFOA), perfluorooctane sulfonic acid (PFOS), GenX,[1] and other fluorinated compounds. The most prevalent and available science regarding the incidence and potential health effects of PFAS is based on PFOA and PFOS, two compounds that are no longer manufactured in the United States due to voluntary phase outs over a decade ago.

[1] Note that GenX is a trade name for a specific PFAS compound, ammonium, 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoate. ITRC "Naming Conventions and Physical and Chemical Properties of Per- and Polyfluoroalkyl Substances (PFAS)," at 12, *available at* https://pfas-1.itrcweb.org/fact_sheets_page/PFAS_Fact_Sheet_Naming_Conventions_April2020.pdf (last visited June 24, 2021). More generically, GenX can be denoted by the abbreviation, "HFPO-DA."

For replacement chemicals, industry has begun using shorter-chain PFAS[2] that have different physical, chemical, and toxicological properties from long-chain PFOA and PFOS. The scientific understanding of how PFAS impact humans and the environment is still developing and, for thousands of PFAS compounds, much remains unknown. From a toxicological perspective, regulatory agencies must have adequate science for determining health-based values before promulgating individual-compound standards, limits, and related regulations.

Toxicologists, whether they work for various state agencies, USEPA, international standards-setting organizations, academia, or in private practice, have not yet established specific methodologies, resources, or even agreed on which of the hundreds of studies of PFAS compounds are the appropriate or critical studies that must or should support appropriate health-based values or regulatory standards. Different methodologies, levels of experience, procedural prerequisites to standards-setting, and even local political pressures are leading to consideration of very different standards in various states and at USEPA. The Coalition urges states to work with one another, and with USEPA, to continue advancing science and methodologies to inform and encourage a more uniform approach to federal and state development of health-based PFAS guidelines and standards.

B. Federal Action on PFAS

USEPA issued "Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS" in December 2019.[3] Those recommendations provide clear and consistent guidance for federal cleanup sites being evaluated and addressed under federal programs, including the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the Resource Conservation and Recovery Act (RCRA). The screening levels recommended for such cleanups are risk-based values that are used to determine if levels of contamination may warrant further investigation at a site. The recommendations are intended to be used as guidance for states to evaluate state cleanup and corrective action sites. The interim guidance recommends in relevant part:

- Using a screening level of 40 parts per trillion (ppt) to determine if either PFOA, or PFOS, or both, are present at a site and may warrant further attention.
- Using USEPA's PFOA and PFOS Lifetime Drinking Water Health Advisory level of 70 ppt as the preliminary remediation goal (PRG) for contaminated groundwater that is a current or potential source of drinking

[2] "Chain" refers to the number of fluorinated carbon molecules comprising the "tail" of the PFAS compound.

[3] USEPA Office of Land and Emergency Management, OLEM Directive No. 9283.1-47 (December 19, 2019), *available at* https://www.epa.gov/sites/production/files/2019-12/text_version_epas_interim_recommendations_for_addressing_groundwater_contaminated_with_pfoa_and_pfos_dec_2019.txt.

water, where no state or tribal MCL or other applicable or relevant and appropriate requirements (ARARs) are available or sufficiently protective.

In addition, USEPA is focusing significant resources on developing appropriate regulatory mechanisms specific to various PFAS compounds. For example, USEPA just issued the PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024 (Roadmap), which provides a multi-media, multi-program, national research and risk communication plan to address emerging PFAS challenges.[4] Part of USEPA's Roadmap involves expanding the scientific foundation for understanding and managing risk from PFAS, including researching improved detection and measurement methods, generating additional information about PFAS presence in the environment, improving the understanding of effective treatment and remediation methods, and developing more information regarding the potential toxicity of a broader set of PFAS. In turn, USEPA expects that this information will help states and others better manage PFAS risks. The Roadmap is an outgrowth of the PFAS Action Council established by Administrator Regan on April 27, 2021.[5] In addition, in October 2021, USEPA published its PFAS Strategic Roadmap: EPA Commitments to Action 2021-2042, which proposes, among other actions, an aggressive timeline for establishing a primary drinking water regulation for PFOA and PFOS.

In the Roadmap, USEPA reports that it will propose drinking National Primary Drinking Water Regulations (NPDWRs) for PFOA and PFOS in the Fall of 2022. USEPA anticipates a final regulation in the Fall of 2023. Further, in the Roadmap USEPA says it will continue to analyze whether further revisions to the NPDWRs can improve public health protection.[6]

While we recognize that not all states and stakeholders can agree on specific priorities or approaches to PFAS regulations, USEPA and Congress are leading important national initiatives that states should support through their contribution of expertise, resources, and efforts as the United States works to respond to PFAS exposure risks. Indeed, a patchwork of 50 different state solutions is unworkable and contrary to how the U.S. has previously addressed similar emerging-contaminant issues. While some limited variation may be expected and appropriate, the highly variable regulatory health advisories, action levels, and numeric standards currently being developed or under consideration across the country create unnecessary confusion and complexity for the public and the regulated community.

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[4] *See* USEPA "PFAS Strategic Roadmap: EPA's Commitments to Action 2021-2024" (October 18, 2021), *available at* https://www.epa.gov/pfas/pfas-strategic-roadmap-epas-commitments-action-2021-2024 (last visited October 28, 2021) (Roadmap).

5 *See* Memorandum Regarding Per- and Polyfluoroalkyl Substances (April 27, 2021) *available at* https://www.epa.gov/pfas/memo-epa-council-pfas.

[6] *See* Roadmap, at p. 13.

The Coalition recognizes that states have elected to utilize different methods and processes for communicating risks to their populations. However, standards-setting must reflect more national and uniform collaboration and cohesion. We must work to avoid the undesirable solution of 50 separate state rules. With this in mind, we urge the states to work closely with USEPA to establish science-based and peer-reviewed federal goals and standards that serve as the basis for comparable state goals and standards. Such an approach is consistent with how USEPA and the states have addressed environmental and human health risks since the creation of USEPA.

C. PFOA Study

The Coalition appreciates OEHHA's efforts to identify and utilize human studies to develop PHGs. However, the confounding factors were not well-controlled resulting in proposed PHGs that do not reflect actual health risks. For example, the Shearer, *et al*. study, which OEHHA relied on to develop a proposed PHG for PFOA, evaluated kidney cancer in human populations. Kidney cancer is a disease that often develops as humans age. Yet, the study's youngest participant was 55 years old. The study does not reflect the age of the general population and fails to adequately correct for age to account for the fact that kidney cancers often develop, independent of any PFOA exposure, in the older-aged population studied. The study attempts to correct for age, but because such limited data exists regarding a younger-aged population, the data cannot be accurately corrected. Because of the failure to properly account for the age and natural occurrence of kidney cancer in the population studied, the study fails to show that exposure to PFOA is associated with cancer.

By comparison, the Raleigh, *et al*. study that OEHHA declined to rely on in developing the proposed PHGs evaluated a younger population that is more representative of the general population. The Coalition disagrees with OEHHA's decision to disregard the Raleigh, *et al*. study in favor of the Shearer, *et al*. study, which is less representative of the age of the general population.

Additionally, the conclusions regarding the dose-response relationship in the Shearer, *et al*. study are flawed. The study evaluated four exposure categories with an increasingly high dose. The odds ratio actually decreased from the lowest to intermediate exposure category, and the odds ratio did not increase until the highest exposure category. The data suggests that the higher odds ratio for highest exposure group was an outlier. Absent this outlier with the highest PFOA exposure—an exposure level that would be extremely uncommon in the general population—there is no relationship between exposure and incidence of disease. In fact, absent the outlier, there appears to be an inverse relationship. Given these limitations, the Coalition disagrees that the Shearer, *et al*. study can be used to show that PFOA exposure correlates to cancer and supports the proposed PHG values.

Finally, in order to develop PHGs, cancer toxicity values must be established. OEHHA used only epidemiological studies for PFOA, which are less controlled than dose-response animal studies, and their sole use may introduce uncertainty into OEHHA's PFOA oral cancer slope factor [0.0026 (ng/kg-d)-1], despite attempts by the researchers to de-convolute other,

non-PFOA cancer-causing factors from the data. We note that USEPA has not yet established a cancer toxicity value for PFOA.

D. PFOS Study

The human studies relied on to establish the proposed PHG for PFOS had an extremely high number of highly exposed individuals. It is unclear whether this exposure was continuous, but it is unlikely that a lower exposure would have had the same adverse effects. The Coalition does not agree that the studies involving such extremely high exposures provide a good reference for the development of PHGs.

OEHHA also used data from studies on lab mice and rats to inform the proposed PHGs. Again, the Coalition disagrees that such studies are reliable and appropriate for use to determine adverse health effects of PFAS exposure in humans. Mice and rats have biological differences that make them more sensitive than humans to PFAS exposure. Accordingly, the Coalition does not believe that the incidence of tumors observed in the rat and mice lab studies are relevant or instructive for the purpose of developing health-based values, like the proposed PHGs.

Further, the PFOS cancer slope factor was not derived using epidemiological studies due to the small size of such available studies. The PFOS cancer slope factor 0.000015 $(ng/kg\text{-}d)^{-1}$ was derived using only animal dose-response studies, specifically only one rat dose-response study where male rats developed liver and pancreatic tumors after ingesting PFOS for two years (Butenhoff et al., 2012). Similar to PFOA, USEPA has not yet established a cancer toxicity value for PFOS.

E. Exposure-Based Assumptions

OEHHA's drinking water ingestion rate of 0.053 L/kg-d (equivalent to 3.71 L/day for a 70 kg adult) is notably higher than USEPA's 2014 default drinking water ingestion rates of 2 L/day for an adult and 1 L/day for a child. OEHHA's 3.71 L/day ingestion rate is not new, as it was established in 2012. Although this greater ingestion rate may be defensible given the hot summer climate in much of California, it is directly proportional to the PHG, such that the increased ingestion rate may result in an overly conservative drinking water standard for some populations and geographies, and will almost certainly result in a different PHG than would be established by EPA, all other input values being equal. This again underscores the importance of OEHHA working with the EPA towards the eventual development of consistent national standards.

F. PHGs and State Drinking Water Standards

The Coalition understands that PHGs are not regulatory requirements and are based solely on the protection of public health without regard to technical feasibility, costs, or other non-health-based factors. These PHGs, however, will ultimately inform the State's drinking water standards, which must be as close to the PHGs as is economically and technically feasible. The proposed PHGs, especially for PFOA, are so far below current laboratory detection limits that it is unclear how any technically feasible and affordable drinking water standard could be based on or rationally related to the proposed PHGs. As such, the Coalition questions whether it is appropriate to establish PHGs that are so far below any value that would be technically feasible or affordable as an enforceable regulatory standard. In addition to developing and reconsidering the data relied on to support the proposed PHGs, the Coalition urges the State to use its resources to support the development of national testing, treatment, and disposal technologies.

V. Conclusion

The Coalition appreciates the opportunity to comment concerning the proposed rulemaking. We look forward to working closely with the State in its development of PHGs and, ultimately, of appropriate, reasonable, and scientifically-defensible drinking water standards. 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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