



The PFAS Regulatory Coalition

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VIA ELECTRONIC MAIL

Suhair Shallal

EPA Designated Federal Officer (DFO)

shallal.suhair@epa.gov

Re: Comments of the PFAS Regulatory Coalition to the SAB PFAS Review Panel

Dear Ms. Shallal:

The PFAS Regulatory Coalition (Coalition) appreciates the opportunity to submit comments relating to the Scientific Advisory Board (SAB) PFAS Review Panel's committee charge and meeting materials related to EPA's development of National Primary Drinking Water Regulations (NPDWRs) for per- and polyfluoroalkyl substances (PFAS).

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 policies and regulations related to PFAS. Coalition membership includes entities in the airport, automobile, coke and coal chemicals, iron and steel, municipal, paper, petroleum, and other sectors. None of the Coalition members manufactures PFAS compounds.

II. The Coalition's Comments

EPA has made final determinations to regulate two contaminants, perfluorooctanesulfonic acid (PFOS) and perfluorooctanoic acid (PFOA), and is moving forward to implement the national primary drinking water regulation development process for PFAS. As part of that process, EPA has developed draft documents to support the National Primary Drinking Water Regulations (NPDWRs) for PFAS and has requested SAB review.

The Coalition supports EPA's development of federal Maximum Contaminant Level (MCL) standards for PFOA and PFOS—two of the most well-known and perhaps highest risk PFAS chemicals. A patchwork of 50 different state solutions would prove unworkable and contrary to how the United States has previously addressed similar

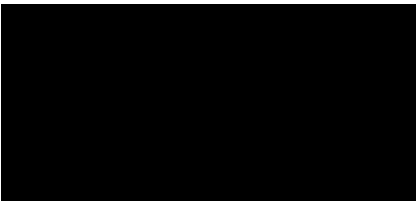
emerging-contaminant issues. While some limited variations in state regulation may be expected and appropriate, the highly variable regulatory health advisories, action levels and, in particular, drinking water standards currently being developed or under consideration across the country create unnecessary confusion and complexity for the public and the regulated community. Therefore, the Coalition supports EPA's efforts to develop and build a consensus around the science that will inform the NPDWR for PFAS. Nonetheless, the Coalition has concerns, summarized below, regarding some of the data and methodology underlying the proposed toxicity values for PFOS and PFOA.

- Additional data are needed to justify the toxicity values. Specifically, environmental epidemiological studies, absent supporting data from animal laboratory studies, are insufficient. For example, with use of epidemiological studies alone, there is uncertainty regarding exposure, confounding factors, and sample size. Accordingly, the Coalition recommends using the epidemiology to complement animal laboratory data and corroborate findings, but not as an independent basis for developing toxicity values.
- The data do not reflect the best available science for estimating the half-life of PFAS in humans, which range considerably and appear to show a gender difference for some PFAS. Moreover, the half-life estimates are overstated, as they do not appear to account for the higher elimination rates when concentrations of PFAS saturate human retention systems. EPA's review should consider the elimination of higher doses of PFAS.
- The data from environmental epidemiology studies regarding vaccine antibodies are not an appropriate basis for deriving MCL goals for PFOA and PFOS. The proposed MCL goals are based on reports of a reduction in vaccine antibodies in children of the Faroe Islands—a unique population with documented exposure to other environmental pollutants, such as methylmercury and PCBs. Beyond these confounding factors, any reduction in vaccine antibodies does not constitute an adverse health effect in itself.
- Different classes of PFAS should not be treated as additive. There are thousands of PFAS compounds, with unique chemical structures. The Coalition supports EPA's focus on PFOS and PFOA in the Agency's ongoing rulemaking effort. However, even when evaluating a single PFAS compound, additivity should not be assumed unless the mode of action and organ system being evaluated are the same.
- EPA has not justified deviating from the standard relative source contribution (RSC) of 20 percent. There are numerous other exposure pathways, including from food ingestion, inhalation, and dermal contact. Although PFAS may be pervasive in source water, the data do not show that PFAS is widely found in concentrations that justify deviating from the standard RSC value.

- EPA should not rely on the recent Shearer, et al. study as the key study for modeling results for cancer. The study failed to control for confounding factors, which results in modeling that does not reflect actual health risks. The concerns about this study include: 1) the advanced age of the study group (ranging from 55 to 70+ years), which fails to represent child and young receptors; 2) failure to recognize that renal cell carcinoma is a common occurrence in adults 60 to 70 years old but is rare in young subjects; and 3) a weak, inconsistent, and insignificant dose-response relationship. Other epidemiological studies exist that more accurately represent the general population. The Coalition urges EPA to reconsider its reliance on the flawed Shearer, et al. study.
- The RfDs proposed for PFOA and PFOS are as low or lower than some substances that are generally recognized as extremely toxic. If EPA believes that PFOA and PFOS are as toxic as those other substances, it must provide a clearer explanation for that assessment.

III. Conclusion

The Coalition appreciates the opportunity to comment concerning the SAB PFAS Review Panel's committee charge and meeting materials. We look forward to working closely with EPA to support an informed SAB review and throughout EPA's NPDWR rulemaking effort for PFAS. 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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