

June 10, 2019

VIA ELECTRONIC FILING

Stiven Foster
Office of Land and Emergency Management
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

RE: Draft Interim Recommendations for Addressing Groundwater Contaminated with PFOA and PFOS; Docket No. EPA-HQ-OLEM-2019-0229

Dear Mr. Foster:

We, the undersigned organizations (collectively, the Associations), write to you to express our concerns regarding the U.S. Environmental Protection Agency's (EPA or Agency) draft set of recommendations for mitigating groundwater contaminated with perfluorooctanoic acid (PFOA) and/or perfluorooctane sulfonate (PFOS).¹

The Associations understand the importance of responsibly managing water resources and have been working to protect clean water for decades. Many of the Associations' members have manufactured or used products containing PFOS and/or PFOA in the past when they were previously in the U.S. stream of commerce, and we recognize the need for an appropriate risk-based federal approach to regulating these two chemicals that is based on the best available science and data. The Associations applaud EPA for recognizing that the government should not regulate PFAS as a class, and that PFAS is a broad family of chemicals with varying properties.

The risk evaluations used to develop the draft interim recommendations would be improved substantially by including the best available scientific data regarding PFOA and PFOS. As discussed further below, recent studies demonstrate that EPA's draft recommendations are overly conservative and would likely lead to cleanups that take longer to complete and have more expensive outcomes without improved public health and safety benefits.

Per- and polyfluoroalkyl substances (PFAS) are a broad class of chemical substances used across a wide-cross section of industries, including aerospace, automotive, construction, electronics, energy, first responder services, healthcare, and telecommunications. Beneficial products enabled by PFAS technologies include semiconductors, solar panels, high performance electronics, medical garments, and fuel-efficient automobiles, and certain fluorinated firefighting foams that are still needed for emergency response operations.

¹ U.S. ENVTL. PROT. AGENCY, *USEPA Draft Interim Recommendations to Address Groundwater Contaminated with Perfluorooctanoic Acid and Perfluorooctane Sulfonate* (Apr. 25, 2019), available at https://www.epa.gov/sites/production/files/2019-04/documents/draft_interim_recommendations_for_addressing_groundwater_contaminated_with_pfoa_and_pfes_public_comment_draft_4-24-19.508post.pdf.

EPA and other federal agencies are advancing additional options to assess and regulate specific PFAS chemistries, including PFOA and PFOS. In May 2018, EPA hosted a National Leadership Summit to address PFAS in the environment.²

EPA used this summit to share information on ongoing efforts to: (1) characterize risks from PFAS and develop monitoring and treatment/cleanup techniques; (2) identify specific near-term actions, beyond those already underway, that are needed to address challenges currently facing states and local communities; and (3) develop risk communication strategies that will help communities to address public concerns with PFAS.³ A variety of stakeholders from both the state and federal level attended the summit to provide their perspectives on the issue at hand.⁴

EPA then conducted a series of community engagement events over the course of the summer in localities affected by PFAS contamination.⁵ These events provided EPA with the opportunity to hear directly from the public as to how to best help states and communities that have been directly impacted by PFAS. EPA also opened a public docket for those stakeholders unable to attend an event to submit additional information for the Agency to consider.

These events, coupled with the information that EPA received electronically from stakeholders, helped inform EPA's "PFAS Action Plan."⁶ The PFAS Action Plan "represents the first time the EPA has built a national, multi-media, multi-program, research, management, and risk communication plan to address emerging chemicals of concern within a class like PFAS."⁷ The PFAS Action Plan identifies a host of short-term solutions and long-term strategies for addressing PFAS contamination.⁸

² See U.S. ENVTL. PROT. AGENCY, *PFAS National Leadership Summit and Engagement*, available at <https://www.epa.gov/pfas/pfas-national-leadership-summit-and-engagement>.

³ *Id.*

⁴ See U.S. ENVTL. PROT. AGENCY, *PFAS National Leadership Summit List of Confirmed Organizations* (May 22, 2018), available at https://www.epa.gov/sites/production/files/2018-05/documents/pfas_summit_list_of_confirmed_organizations_5.22.18.pdf.

⁵ See U.S. ENVTL. PROT. AGENCY, *PFAS Community Engagement*, available at <https://www.epa.gov/pfas/pfas-community-engagement> (EPA conducted community engagement events in: Exeter, New Hampshire; Horsham, Pennsylvania; Colorado Springs, Colorado; Fayetteville, North Carolina; Leavenworth, Kansas; and Spokane, Washington).

⁶ U.S. ENVTL. PROT. AGENCY, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan* (Feb. 2019), available at https://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf.

⁷ *Examining PFAS Chemicals and their Risks*, Hearing Before the Subcomm. on Environment of the H. Comm. on Oversight and Reform, 116th Cong. (Mar. 6, 2019) (statement of David P. Ross, Assistant Adm'r., EPA Office of Water, 4-5), available at https://www.epa.gov/sites/production/files/2019-03/documents/epa_ross_hor_pfas_testimony_-_final_for_march_6.pdf.

⁸ *Id.* at 5.

One of the short-term priority actions laid out in the PFAS Action Plan is for EPA to provide guidance for groundwater cleanup actions at contaminated sites.⁹ These recommendations will “provide a starting point for making site-specific cleanup decisions,” and, according to the Agency, “may be considered for federal facility and private-party cleanup” under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or Superfund),¹⁰ corrective action programs under the Resource Conservation and Recovery Act (RCRA),¹¹ and, where appropriate, state cleanup programs.¹²

The April 25, 2019 draft interim guidance provides recommendations on screening levels, as well as preliminary remediation goals (PRGs), which are initial targets for cleanup and may be adjusted on a site-specific basis as more information becomes available. Specifically, the draft interim guidance recommends:

1. Screening sites using a level set to a hazard quotient of 0.1 for PFOA or PFOS individually, which is currently 40 ng/L or parts per trillion (ppt);
2. Using the PFOA and PFOS hazard advisories of 70 ppt as the PRG for groundwater that is a current or potential source of drinking water, where no state or tribal maximum contaminant level (MCL) or other applicable or relevant and appropriate requirements (ARARs) exist; and
3. Addressing levels of PFOA and/or PFOS over 70 ppt in situations where groundwater is being used for drinking water.¹³

The Associations have concerns regarding EPA’s draft interim recommendations for addressing groundwater contaminated with PFOA and PFOS. In general, the Agency should not set groundwater cleanup levels to mirror a drinking water advisory level, given that they are two separate environmental media with different exposure profiles, and the standards have different purposes. Extending the orders of magnitude built into the drinking water advisory level to groundwater cleanup levels would result in a level of conservatism that would lead to unachievable standards, unrealistic expectations on the part of the community, and unreasonable costs to the public.

⁹ EPA’s PFAS Action Plan, *supra* note 6, at 3.

¹⁰ 42 U.S.C. § 9601, *et seq.*

¹¹ *Id.* at § 6901, *et seq.*

¹² *Supra* note 9.

¹³ Draft Interim Recommendations, *supra* note 1, at 1-2.

It is imperative that any regulatory action, including the development of interim guidance, taken to address any PFAS is based on the latest, evidence-based, peer-reviewed science. Agencies should identify sources of uncertainty and the research needed to reduce those uncertainties, and policies and guidance should remain flexible to accommodate emerging science.

EPA has taken extensive steps to develop its current scientific understanding of the toxicity of PFOA and PFOS. Beginning in 2009, EPA developed provisional lifetime Hazard Assessments (HA) for these PFAS based on a thorough evaluation of peer-reviewed science and literature on human health effects associated with those two chemicals.¹⁴ EPA issued draft chronic health effects support documents in 2014 and later finalized a lifetime drinking water HA of 70 ppt for the individual or combined concentrations of PFOA and PFOS in 2016.¹⁵ Lifetime drinking water health advisories are premised on the assumption that *all* water consumed every day – including drinking water, and water used to prepare coffee, tea, soups, and other food – contains PFOA and/or PFOS. In reality, only a subset of the water consumed by an individual is likely to come from a single source, such as groundwater, and, therefore, this assumption is overly conservative.

Additional new information also demonstrates that the 70 ppt levels are overly conservative, and would lead to unnecessarily stringent requirements without any additional human or public health benefits. For example, EPA should use information from the 2018 clinical trials conducted with ammonium perfluorooctanoate that would provide better estimates of PFOA half-life in humans.¹⁶ This is very important for predicting appropriate risk-based drinking water values as there are large pharmacokinetic differences between humans and animals for PFOA and PFOS that are highly dose dependent and show non-linear toxicokinetics.

Consequently, a modeled delivered dose can be much higher for humans predicted at a high external dose but lower when applying a human relevant dose. For example, a recent Health Canada evaluation correcting for this important observation showed that EPA underestimated the human clearance rate that results in a resulting human equivalent dose up to 500 times lower than what is currently predicted in the EPA HA and relevant supporting animal data that indicates that the proposed PRG and Hazard Quotients (HQ) are based on data that over-predicts responses in humans.¹⁷

A key element of any preliminary remediation goal should include a discussion of the uncertainties in the calculations. By setting the HQ at 0.1, the EPA's Office of Land and Emergency Management (OLEM) is essentially saying that screening needs to begin with the

¹⁴ Draft Interim Recommendations, *supra* note 1, at 2.

¹⁵ *Id.*

¹⁶ See M. Covertino, T.R. Church, G.W. Olsen, *et al.*, *Stochastic Pharmacokinetic-Pharmacodynamic Modeling for Assessing the Systemic Health Risk of Perfluorooctanoate (PFOA)*, *Toxicological Sciences*, 163(1), 293-306 (2018).

¹⁷ See HEALTH CANADA, *Water Quality – Reports and Publications*, available at <https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/water-quality.html>.

assumption that *10 times* more groundwater could be consumed than already considered in the lifetime drinking water HA for PFOA and PFOS, which is highly unlikely. This is, in effect, applying a 10-fold additional and unnecessary uncertainty factor on top of those conservative assumptions already built into the HA level derived by EPA's Office of Water (OW).

EPA has the opportunity to review additional scientific information to further understand the health effects, analytical methodologies, and treatment technologies associated with drinking water contaminated with PFOA or PFOS, and should consider revising the HAs, screening levels, and PRGs in a manner that reflects the best available science, consistent with Agency guidance documents and tools supporting these efforts.¹⁸

Additionally, the Associations believe that the Agency should clarify the applicability of these recommendations with respect to potential sources of drinking water. The science behind health effects related situations in which groundwater is used for drinking water is still emerging, and it is unclear what EPA considers to be a "potential source" and how they would be defined. On its face, the April 2019 draft interim recommendations appear to contradict EPA's 2016 memorandum, "Clarification about the Appropriate Application of the PFOA and PFOS Drinking Water Health Advisories."¹⁹ That memorandum from OW excludes application to non-drinking water (secondary) pathways and reiterates that these HAs identify the concentration of PFOA and PFOS *in drinking water* at which adverse health effects are not anticipated to occur in a lifetime.²⁰

For consistency with the EPA methodology for calculating other preliminary remediation goals and risk-based screening levels used nationwide, exposure assumptions (including groundwater ingestion rates) should be standardized and correspond to actual consumption. The HA Basis should be reexamined in light of the November 15, 2016, EPA memorandum that clarifies the strict applicability of the drinking water HA, and that outlines the many conservative assumptions already inherent in the HA methodology for PFOA and PFOS, thus obviating the need to effectively add an additional "safety factor" of 10 by requiring a screening hazard quotient of 0.1.

Finally, EPA should clarify that levels of PFOA and PFOS in water used for drinking should be compared to lifetime HA levels addressed at the point of use, rather than at the raw source, as HA are intended for finished drinking water, not raw source water prior to disinfection or any other transport or treatment.

¹⁸ Draft Interim Recommendations, *supra* note 1, at 2.

¹⁹ U.S. ENVTL. PROT. AGENCY, *Memorandum from Dr. Peter C. Grevatt, Director of EPA Office of Groundwater and Drinking Water, to Regions I – X Water Division Directors, Clarification about the Appropriate Application of the PFOA and PFOS Drinking Water Health Advisories* (Nov. 15, 2016), available at https://www.epa.gov/sites/production/files/2016-11/documents/clarification_memo_pfoapfos_dw_has.pdf.

²⁰ *Id.*

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The Associations appreciate EPA's efforts to set recommendations for cleaning up groundwater contaminated with PFOA and/or PFOS, the opportunity to comment on this important matter, and suggest that the Agency further update the guidance to reflect the most recent scientific evidence.

Sincerely,

U.S. Chamber of Commerce
American Forest & Paper Association
American Fuel & Petrochemical Manufacturers
American Petroleum Institute