Developing PFAS Standards and Toxicity Assessments – It Won't Be Easy

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Per- and polyfluorinated substances ("PFAS") are not all alike. Two – perfluorooctanoic acid ("PFOA") and perfluoroctane sulfonate ("PFOS") – are relatively well known and studied. And then there are the rest: by various estimates, some 3,000-5,000 compounds, each different. EPA's recently issued PFAS Action Plan focuses primarily on evaluation of the need for a federal drinking water standard for PFOA and PFOS and completion of toxicity assessments (such as oral reference doses ("RfDs")) for GenX chemicals and six other PFAS. EPA is also working with the Centers for Disease Control ("CDC") and the Agency for Toxic Substances and Disease Registry ("ATSDR") to develop methods that will allow EPA to make inferences about the toxicity of PFAS mixtures that commonly occur in real world exposures. These are important, scientifically sound steps, but they are not fast or easy, and the process is unlikely to satisfy public and political demands for quick answers on PFAS exposure and health impacts.

Already, citizen groups have labeled these steps "woefully inadequate" because they address "only a couple of chemicals" and criticized them as allowing the continued existence of a "known harm" from "the PFAS chemical class."[1] Similarly, many states and municipalities have continued to express the "need [for] an enforceable drinking water standard to protect our communities right now."[2] And at least one Democratic Presidential candidate has gone so far as to demand that "we have to ban … [this] entire class of chemicals."[3] Despite pressure for quick action and novel regulatory approaches that would essentially assume that all chemicals containing organic fluorides are equally toxic or apply other simplifying assumptions, for four principal reasons, the issues are complex, with scientific, legal, and practice aspects that will take time to analyze.

First, multiple PFAS have been found in groundwater and surface water at an increasing number of locations (e.g., one group of EPA scientists identified 75 "priority" PFAS), increasing the complexity of the analysis.

Second, regulators do not yet agree on either a methodology or appropriate regulatory levels for PFAS. EPA (and several states) trigger remedial action based on the sum of the concentration of PFOA and PFOS exceeding a 70 part per trillion ("ppt") limit. However, Connecticut, Massachusetts, and Vermont are setting limits for the sum of five different PFAS, not just PFOA and PFOS. New Jersey and New York use a lower concentration ceiling than EPA and other states (a 10 ppt limit for PFOA and PFOS). Vermont triggers action based on the sum of five PFAS exceeding 20 ppt. The Department of Defense derived a 380 ppt action trigger allegedly using EPA's reference dose and standard EPA groundwater clean up screening level assumptions.

Third, underlying toxicological information on the individual PFAS chemicals is sparse except for PFOA/PFOS, and interpretations differ as to the existing evidence. For example, a recent Society of Environmental Toxicology and Chemistry conference presentation concluded that, using methods outlined in EPA general guidance, it is appropriate to group PFOA, PFOS, and perfluorononanoic acid ("PFNA") together to set toxicity factors due to similar critical effects, half-lives, and structures, but three other PFAS compounds are not similar to PFOA and PFOS.[4] This view is consistent with EPA's conclusion that one of those compounds is 500 times less toxic than PFOA.[5]

EPA's PFAS plan says it is considering developing its own grouping of PFAS with similar effects and chemical structures using novel high through-put toxicity testing and its judgment as to the toxicity of PFAS mixtures, but this approach involves scientific "uncertainties that have not been well explored."[6] It is telling that when dioxin equivalency factors, relative potencies for polychlorinated biphenyls congeners, and relative cancer potencies for polyaromatic hydrocarbons were developed, the individual chemicals within these classes were far fewer in number and yet were found to have significantly differing toxicities. There currently is no widely accepted method to assess the toxicity of chemicals as a class on the scale presented by PFAS compounds and thus it will take time to develop one.

Fourth, speed must be balanced against the risk of legal defeats if EPA tries to expedite PFAS standard setting too much by circumventing longstanding regulatory principles. The Safe Drinking Water Act, other statutes, and, more broadly, prerequisites of administrative law require that all stakeholders be given the opportunity to provide input in a transparent manner. Thus, specific information on each chemical must be gathered, findings made, and standards or toxicity factors based on particularized toxicological information subjected to notice and comment before finalization, all of which will then be open to challenge in court. Providing due process inevitably takes time.

The regulatory process must be transparent and effective risk communication requires time and effort to explain that the ultimate regulatory decision involves policy, not just scientific, decisions. Further, oversimplification and a "rush to judgment" do not produce reliable, useful results. As one reality check, the CDC specifically stated in 2018 that "[f]inding a measurable amount of" PFCs, or more broadly PFAS, in blood "does not imply that the levels . . . cause an adverse health effect"[7] and "[s]mall amounts [of PFAS] may be of no health consequence."[8] The nature and strength of the scientific evidence and the benefits of current uses are all factors that are typically balanced in risk management decisions. Interested parties should take steps to engage as this process plays out for a range of PFAS chemicals.

Clark Hill attorneys are experienced in working with clients to develop effective legal strategies and advocacy approaches to address regulatory, legislative, and litigation concerns.

For more information, please contact a member of Clark Hill's Environment, Energy & Natural Resources practice group.

[1] National PFAS Contamination Coalition, PFAS Exposures Will Continue Under EPA Plan, Communities Warn (February 14, 2019), available at

https://toxicsaction.org/pfas-exposures-will-continue-under-epa-plan/.

[2] BBC World Service, EPA's PFAS Plan Draws Reaction From Enviros, Impacted Residents. By Allison Dunne (Feb 14, 2019), available at https://www.wamc.org/post/epas-pfas-plan-draws-reaction-enviros-impacted-residents.

[3] J. McMenemy, "Gillibrand Wants Ban on All PFAS Chemicals," fosters.com (March 15,2019), available at https://www.fosters.com/news/20190315/gillibrand-wants-ban-on-all-pfas-chemicals.

[4] Considerations for Grouping Different PFAS Together to Develop Guidance Values, available at https://gradientcorp.com/alerts/pdf/Conferences/SOT19_Kerper.pdf.

[5] EPA's calculated reference dose in EPA, Human Health Toxicity Values for Perfluorobutane Sulfonic Acid and Related Compound Potassium Perfluorobutane Sulfonate at 68 (November 2018), available at https://www.epa.gov/sites/production/files/2018-11/documents/pfbs_public_comment_draft_toxicity_assessment_nov2018-508.pdf) is 500 times lower than in EPA, Drinking Water Health Advisory for Perfluorooctanoic Acid (PFOA) at 51 (May 2016), available at https://www.epa.gov/sites/production/files/2016-05/documents/pfoa_health_advisory_final_508.pdf.

[6] Eric D. Watt et al, Uncertainty quantification in ToxCast high throughput screening, PLoS One. 2018; 13(7): e0196963. Published online 2018 Jul 25, available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6059398/.

[7] CDC, Biomonitoring Summary. Perfluorochemicals, available at https://www.cdc.gov/biomonitoring/PFAS_BiomonitoringSummary.html.

[8] CDC, Fourth National Report on Human Exposure to Environmental Chemicals, Executive Summary at 2 (2009), available at https://www.cdc.gov/exposurereport/pdf/FourthReport_ExecutiveSummary.pdf.