

Seeing the forest and the trees

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The discovery of per- and polyfluoroalkyl substances (PFAS) decades ago ushered in an entirely new and diverse family of chemicals. The strong chemical bond between fluorine and carbon imparts PFAS compounds with stability, resistance and durability to heat, water and oil. These enabling properties are critical to the performance of industrial and military applications and consumer products, such as fuel-efficient cars and planes, electronics, semiconductors, life-saving medical devices and firefighting materials.

Although PFAS is a helpful acronym, its common use and misuse among regulators, legislators and the general public masks the array of chemical structures within the PFAS family. As noted by a U.S. EPA scientist, "Thinking of them as [a] 'single' chemical or classes of chemicals can be problematic." Individual PFAS can differ dramatically from each other based on the size of the molecule and its chemical structure, among other parameters. These differences may impact the mobility, solubility, bioavailability, fate and persistence of PFAS in the environment; how humans may be exposed; and potential environmental and human health risks.

Generalizations and sweeping statements must become more precise and scientifically sound, especially when discussing the potential impacts of individual PFAS chemicals or subcategories of PFAS chemicals. We need to see both the forest and the trees.

Distinction With a Difference

Fluoropolymers, a subcategory of PFAS, are composed of carbon and fluorine molecules linked together to form a chain. They are widely regarded as safe, and extensively used in wire and cable coatings, as well as linings for pipes, tanks and equipment in chemical and pharmaceutical manufacturing. Other PFAS, known as long-chain perfluoralkyl acids, which include both perfluoroctanoic acid (PFOA) and perfluoroctanesulfuic acid (PFOS)—two of the most widely used

and studied PFAS—have been the subject of intense regulatory scrutiny and public concern. Due to their historic and widespread use, most Americans have been exposed to PFOA and PFOS at measurable levels, and governmental agencies, including EPA, have identified levels of exposure above which adverse health effects may occur.

In 2000, 3M announced it would voluntarily phase out and find substitutes for PFOS. A few years later, EPA launched the PFOA Stewardship Program in which manufacturers of PFOA committed to reduce PFOA from facility emissions and product content by 95% no later than 2010. This program also aimed to make companies work toward eliminating PFOA from emissions and product content no later than 2015. U.S. manufacturers now have fully transitioned to another subcategory of PFAS compounds referred to as short-chain perfluoralkly acids, "which are generally less bioaccumulative and potentially less toxic," according to EPA and researchers. Today, the number and type of PFAS chemicals in commerce is a small fraction of all the different PFAS chemicals manufactured since the 1940s.

Under EPA's new chemicals program, hundreds of PFAS have been scientifically reviewed by EPA before they were introduced into the marketplace. Since 2016, EPA must make a determination of a new chemical's safety before approving its entry into commerce. In a number of cases, EPA requested more data from manufacturers and imposed certain restrictions on these new PFAS. The Toxic Substances Control Act (TSCA) also provides EPA regulatory options to address risks posed by chemicals already in use, including PFAS. While industry pivoted to short-chain PFAS, EPA engaged in regulatory initiatives under TSCA to address concerns with PFAS chemicals, and further regulatory action is anticipated.

Because both PFOA and PFOS have not been manufactured in the U.S. for years, the burdens of these chemicals in the U.S. population have dramatically dropped. Nationwide sampling of drinking water sources, however, reveals the presence of PFOA and PFOS in both surface and groundwater. Not only are these chemicals soluble and persistent in the environment, but they also still may be found in useful products, like aqueous film-forming foam used at airports, military fire training areas and other locations. This has raised public concern in the U.S., not only regarding exposure to PFOA and PFOS, but also to other PFAS. In the absence of federal standards and in response to local contamination concerns, a number of states have proposed or developed PFOS and PFOA drinking water standards. However, these standards can differ between states depending on the health effects and uncertainty factors underlying the standards.

A Third Way

Some stakeholders have called on EPA to regulate all PFAS as a single class, rather than rely on the more traditional, time-intensive process of regulating chemical by chemical. Regulating all PFAS as a single class introduces large uncertainties by assuming all PFAS present the same level of risk, regardless of their structure, toxicological profile and exposure pathway. This simply is not the case.

Chemicals that might appear to differ only superficially may possess profound differences. A water molecule, for example, has two hydrogen atoms and one oxygen atom. The addition of one oxygen atom produces hydrogen peroxide, an antiseptic and bleaching agent. Similarly, PFAS can take on a range of chemical structures with significant or insignificant implications for human health and the environment.

The alternative to regulating by class is not necessarily regulating each and every individual PFAS, which of course presents its own administrative and logistical challenges. A third way prioritizes

PFAS with distinct categories of the chemicals based on shared properties, such as chain length and chemical structure, and then utilizes advances in computational and high throughput toxicology and ecotoxicology to screen PFAS within categories for further toxicity testing, risk assessment and potentially risk management.

This approach is not without technical challenges but it represents a way to rapidly fill data gaps, and EPA has embraced it. Among a number of research endeavors discussed in the PFAS Action Plan released in early 2019, EPA notes it "plans to use new approaches such as high throughput and computational approaches to explore different chemical categories of PFAS, to inform hazard effects characterization, and to promote prioritization of chemicals for further testing."

EPA's Disinfection Byproducts

EPA has along history of effectively addressing a broad class of contaminants in drinking water collectively referred to as disinfection byproducts (DBPs), and that could be instructive as EPA addresses certain PFAS in drinking water. In the late 1990s and early 2000s, EPA issued a series of regulations to reduce DBPs that form when chlorine and other disinfectants used to kill microbial pathogens in drinking water combined with organic and inorganic material from source water. Recognizing that different DBPs presented differing levels of risk based on epidemiological and toxicological data, EPA created categories of DBPs and ultimately issued separate drinking water standards, known as Maximum Contaminant Level (MCL) values, for each. Total trihalomethanes (TTHMs) constituted one such category. These categories also served as indicators of other DBPs present in disinfected water. By regulating categories of DBPs, EPA addressed other DBPs for which it had not explicitly promulgated standards.

In promulgating its regulatory approach, EPA utilized negotiated rulemaking-. This is a process that attempts to forge consensus among the participants of a negotiating committee with the help of a trained mediator, who facilitates the negotiation process conducted over recurrent meetings. Negotiated rulemaking committees fall under the strictures of the Federal Advisory Committee Act and as such their meetings are conducted in an open and transparent manner. Consensus agreed upon would effectively address all major issues prior to the publication of a proposed rulemaking for public comment.

The DBP regulatory negotiation committee was made of diverse stakeholders selected from state and local public health and regulatory agencies, public water systems, elected officials, consumer groups, environmental groups, and EPA. The active participation of public water systems was critical because those systems are tasked with ensuring clean drinking water to millions of customers. These entities are steadfastly working to address a broad range of drinking water contaminant issues to ensure that real public health risk reductions are achieved.

The committee successfully grappled with the challenge of balancing the need to chemically disinfect water to kill biological pathogens while simultaneously minimizing the health risks of DBPs. As noted by EPA, "The key outcomes of that regulatory negotiation effort were recommendations to proceed with rules addressing DBPs and microbial pathogens in two stages, and to collect relevant information from public water supplies for use in the development of these rules and the analysis of their impacts."

EPA's extensive DBP regulatory experience serves as a valuable model in crafting an approach to address PFAS in sources of drinking water. In a letter from David Ross, assistant administrator for EPA's Office of Water, to Democratic Sen. Tom Carper (Delaware), EPA unequivocally announced its

intentions "to establish a MCL for PFOA and PFOS..." It also agreed to gather and evaluate information to determine the need for a Safe Drinking Water Act (SDWA) regulation for PFAS on a broader level. Negotiating rulemaking may prove as valuable in the PFAS context as it was in addressing risks from DBPs. And a negotiated rulemaking committee provides the ideal forum in which stakeholders can wrestle with scientific and treatment questions about PFAS as they strive to reach consensus.

In proposing and promulgating drinking water standards, SDWA requires EPA consult its National Drinking Water Advisory Council, but there are other advisory bodies that EPA has yet to mobilize on PFAS issues, including the Science Advisory Board Drinking Water Committee. These bodies, through their scientific and technical input, could advance the work of a negotiated rulemaking committee.

As evidenced by the success of EPA's PFOA Stewardship Program, industry should continue to play a role in leading efforts to properly manage PFAS to reduce their presence in the environment. The global apparel and firefighting foam industries already have made significant strides in establishing guidelines and best practices. This includes the immediate reduction of environmental releases of firefighting foams, regardless of the chemicals they contain. Routine practice drills, whether by the military, airport personnel, or first-responders, should be carried out in a manner that precludes the release of firefighting foam to the environment.

Both EPA's PFAS public meetings held throughout the country in 2018 and the EPA PFAS Action Plan underscored the significant data gaps that span the gamut—from the development of analytical methods for detecting and measuring PFAS to exposure and toxicity information and understanding what water treatment techniques are cost-effective in reducing certain PFAS levels. There also is an urgent need to develop and disseminate clear risk communication information about PFAS and as stated in the EPA PFAS Action Plan, to "focus on the key questions with which the public is most concerned."

Without clarity, misinformation and hyperbole will prevail. Focusing on all PFAS rather than the unique characteristics of categories of PFAS is akin to seeing just the forest and not the trees.

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