ONE SIZE DOES NOT FIT ALL: SETAC CONFERENCE WORKING GROUP RECOMMENDS PRAGMATIC APPROACH FOR PFAS HAZARD ASSESSMENT

Chemical structure often determines a substance's regulatory fate.

While all PFAS contain per- and/or polyfluoroalkyls as part of their molecular structure, other components of their molecular structure will affect and alter their chemical behavior in the environment or in an organism.

Regulators want to identify, quantify, and determine the source of fluorinated compounds in the environment as they strive to set thresholds for public health and environmental safety, but the universe of PFAS is vast and varied, making the task more complex.

Faced with this complexity, some scientists and regulators advocate for a complete ban on all PFAS. Others argue that PFAS are so different that each compound must be individually assessed and regulated. Neither option is practical given the thousands of PFAS in use in pharmaceuticals, veterinary drugs, industrial chemicals, pesticides, or the myriad of products of high societal value.

A critical review published recently in the Journal of Environmental Toxicology and Chemistry recapped key findings from a 2019 meeting Society of Environmental Toxicology and Chemistry (SETAC) Focused Topic. The meeting concluded that variations in both chemical and biological behavior present an immense challenge for PFAS regulation and risk management, but SETAC working groups suggest that by classifying and conceptualizing environmental risk groups for subsets of PFAS based on their attributes rather than chemical structure alone regulators could focus on those compounds that pose the greatest risks.

The paper cited a streamlined approach for PFAS grouping, hazard assessment and management proposed by Barbara J. Henry, a toxicologist with W. L. Gore & Associates. Henry's paradigm would apply 24 questions to polymeric and non-polymeric PFAS to ascertain their physical, chemical, and biological properties and then group them on a relative risk spectrum.

Regulation, restriction, and remediation depend on the ability to identify sources, pathways, and interactions of PFAS in the environment. In each of these areas, however, scientists found gaps in the research and practical limitations on the ability to gather and understand the information in a meaningful way.

Most poly-fluorinated compounds remain unstudied. For the majority of PFAS, scientists do not fully understand whether, how, and under what conditions PFAS degrade in the environment. Those compounds that have been studied, such as PFOA and PFOS, display a wide variety of behaviors depending on their composition and the environmental conditions that affect degradation.

CLASSIFYING BY CHEMICAL STRUCTURE IS NOT ENOUGH

These significant knowledge gaps compound to make it even more challenging to assess any hazards of PFAS en masse.

The challenge begins with the broad definition of PFAS. World scientific bodies have not agreed on a common definition for PFAS. The EPA lists more than 9,000 PFAS. The UN's Organization for Economic Cooperation and Development (OECD) lists 4,730 PFAS. The broadest definitions would lump together critical pharmaceutical drugs, such as Celebrex and Prozac, in the same regulatory scheme as products of considerably higher environmental and safety risk such as fire-fighting foam and pesticides.

This lack of a sharply defined, shared terminology makes it difficult to categorize PFAS into hazard assessments or regulatory groups.

One of the sharpest distinctions, the review noted, is the categorization of PFAS as polymer or non-polymer. PFAS polymers are further identified as belonging to one of three categories: fluoropolymers, perfluoropolyethers, and

side-chain fluoropolymers. Yet even within these three categories, scientists cannot generalize behavior.

Several international bodies have arrived at additional distinctions. An OECD Expert Group on Polymers designated polymers with "insignificant environmental and human health impacts" as "Polymers of Low Concern." PFAS polymers that fall into the "Polymer of Low Concern" category exhibit biological and chemical properties that are demonstrably different from other PFAS, such as perfluoroalkyl acids (PFAA), such as PFOA, PFOS, and GenX.

"All PFAS are not equal in human health or environmental impact, nor are all PFAS polymers," the critical review noted. "Therefore, using chemical, physical and biological properties to categorize PFAS polymers according to relative risk for human and ecological receptors, as the U.S. EPA and OECD and many others have concluded, may be prudent."

Fluoropolymers, for example, have high molecular weights and are not soluble in either water or most organic solvents. Polymers of Low Concern do not degrade in the environment and are not mobile, so they are unlikely to be found in water or air.

The diversity of chemical structures, physical properties, uses and behaviors in the environment "preclude simple generalizations regarding environmental risk," the review noted.

A PRAGMATIC APPROACH

The SETAC working groups suggest classifying and conceptualizing environmental risk groups for subsets of PFAS based on their attributes rather than chemical structure. This would allow regulators to focus on those compounds that pose the greatest risks.

The regime proposed by Henry and cited in the critical review suggests that PFAS could be screened for various properties and behaviors and then placed on a relative risk spectrum that corresponds with mitigation, use, and control measures.

PFAS can be sorted into different "buckets" based on shared chemical, physical, and biological traits. Once sorted, regulators can assess the hazards posed by each group against their value to society. Standards already in place at global regulatory agencies break down into 24 questions that can be used to evaluate every compound that meets the PFAS chemical definition of having one or more fully fluorinated carbon atom.

Such screening would ascertain nine physical attributes, four chemical attributes, and 11 biological attributes. The screening questions would be asked at each stage of the PFAS life cycle so scientists can account for every aspect of the compound's behavior from manufacture to end-of-life. Regulators would also consider whether the use presents any opportunities for exposure and whether any hazards can be mitigated.

Henry set out a four-step process to evaluate and group PFAS for regulation and/or restriction:

1. Define any health and environmental hazard posed by PFAS by answering questions about the chemical, physical, and biological properties predictive of human and environmental hazard.
2. Identify the uses of the PFAS.
3. Identify effective control measures for the PFAS.
4. If the residual risk from step 1 (hazard) and step 2 (uses) is not sufficiently minimized or mitigated by step 3 (control measures), consider further PFAS regulation and/or restriction.

The PFAS could then be grouped in health hazard categories, such as acute toxics or carcinogens, and environmental hazards, such as acute aquatic toxins or persistent and water soluble.

If the data on a particular PFAS is insufficient to determine the answers to all 24 questions, that PFAS defaults into a bucket with a higher hazard profile until scientific data proves otherwise.

This pragmatic approach employs the science we have now to protect human and environmental health while enabling the continued use and innovation of fluorinated chemistry where potential risk can be managed or avoided altogether.

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