



**Written Statement of
Kimberly W. White, Ph.D.
Senior Director
Chemical Products and Technology Division
American Chemistry Council**

**Before the
U.S. Senate Committee on Environment and Public Works (EPW)
Regarding a Hearing to Consider Six Bipartisan Bills, Which Would Address the Risks
Associated with Per- and Polyfluoroalkyl Substances (PFAS)**

May 22, 2019

**American Chemistry Council
700 2nd Street, N.E.
Washington, D.C. 20002**

Summary

Good morning, Chairman Barrasso, Ranking Member Carper and members of the Committee. My name is Dr. Kimberly Wise White. I am a toxicologist and have worked with the American Chemistry Council¹ (ACC) for the past seven years. My work at ACC has focused mainly on supporting scientific research and chemical risk evaluation processes that are firmly based on up-to-date scientific knowledge and are evaluated in accordance with the most relevant scientific approaches. I appreciate this opportunity to provide a scientist's perspective on several of the legislative proposals before this Committee today. Addressing concerns regarding potential public health risks of per- and polyfluoroalkyl substances or PFAS and ensuring access to safe drinking water for all Americans is critically important. The application of science-based approaches and policies to evaluate and manage potential risks are imperative for ensuring public confidence and trust in the regulatory process.

ACC shares this Committee's commitment to identifying ways to address and, where warranted, mitigate risk associated with PFAS chemistries. A holistic strategy is needed to coordinate overall efforts and focus resources toward immediate issues and areas of public concern. For this reason, the chemical industry supports a comprehensive approach to managing these substances, including specific measures to prioritize, evaluate, regulate, innovate, advance best practices, and monitor PFAS. ACC has worked with this Committee over the years to advance broad chemical regulation, which included passage of the 2016 amendments to the Toxic Substances Control Act (TSCA), an overwhelmingly bipartisan achievement. In those amendments, Congress established a process to reinforce public confidence in the U.S. Environmental Protection Agency's (EPA) evaluation of new and existing chemicals, requiring that the Agency use risk-based information, based on best available science, to evaluate chemicals and make affirmative regulatory decision on chemicals, in an open and transparent way. Having science at the forefront allows for the most relevant data on hazard and exposure, validated methodologies and relevant issue specific expertise to underlie decisions.

As Congress considers the issue of PFAS substances, I will focus my testimony on four areas that highlight the important role science has in any PFAS chemical management strategy.

I. Today's PFAS Chemistries Play an Essential Role in Modern Life

Fluorinated chemicals or PFAS, is a term that describes a wide and diverse array of substances characterized by the strong bond between fluorine and carbon. Because of this strong bond, PFAS provide strength, durability, stability, and resilience in a broad range of applications. These properties are critical to the reliable and safe function of a spectrum of products that are important for industry and consumers. For example, today's PFAS are used in: medical devices; the development of semiconductors in electronics; and applications in renewable energy and fuel efficiency. Multiple industries depend on today's high-performance PFAS substances because they provide unique properties that often cannot be replicated with non-fluorinated alternatives.

¹ The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing.

For example, fluoropolymers, which consist of a carbon-only polymer backbone with fluorines directly attached, are used in roof coatings to enhance durability and provide energy savings through solar reflectance and reduction of heat transfer into buildings. Fluorinated surfactants, are another example. These chemistries can be used in adhesives, sealants and caulks to strengthen the bond to surfaces and help prevent infrastructure failures caused by corrosion and weather. Taking an overly-broad approach to addressing PFAS chemistries that lacks a scientific foundation will make it difficult to implement effective regulatory policies. It will also impact an extensive swath of the economy, including a broad range of industries and businesses, as well as critical public entities like airports, hospitals, drinking water utilities, towns and municipalities. For these reasons, different PFAS substances require different regulatory approaches.

II. Application and Adherence to the Administrative Process is Critical for Effective PFAS Chemical Management

The Administrative Procedure Act (APA) governs the process by which federal agencies develop and issue regulations, including for example, regulations in chemical management under TSCA, drinking water regulations under the Safe Drinking Water Act (SDWA) and clean-up levels under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). Importantly, the APA includes requirements for public notice of proposed and final rulemaking, opportunities for public comment, and other elements to ensure adequate review and utility of proposed regulations. There is a robust regulatory system and established policies in place for managing chemicals in the United States. Circumventing the regulatory process by developing legislation that does not provide for public input and does not allow federal agencies to exercise their expertise undermines the process and may lead to regulatory decisions that lack a sound basis and which do not focus on priority issues. In any legislation under consideration to manage PFAS, Congress must employ the APA process requirements for agency rulemaking and regulation in order to prevent arbitrary regulatory decisions. Further, agencies such as EPA must apply their statutory authorities and procedures to utilize the best available science in their regulatory decision-making. To support this process clear timelines should be established to ensure policy decisions and regulatory outcomes are completed and implemented in a timely fashion.

III. Credible Science-Based Approaches Are Imperative for Proposed Legislation and Regulation

Ensuring the safety of products and addressing the potential risks from exposure to PFAS are important objectives. Implementing an approach that incorporates current knowledge about chemical hazards and relevant human exposures must be the foundation for establishing regulations and legislation in order to provide meaningful benefit to public health. ACC supports strong chemical regulations that are protective of the safety of drinking water. However, regulation must be science-based and driven by objective and transparent approaches. This includes consideration of a substance's hazard characteristics, its use and actual levels of exposure in order to assess the potential risk of PFAS to determine the most appropriate risk management measures. These fundamental principles have unfortunately been lost in the current debate about PFAS.

A robust body of science demonstrates the vast differences among individual PFAS, and peer-reviewed data shows that fluoropolymers and several other PFAS chemistries do not

present a significant risk to human health or the environment^{2,3,4,5}. For example, fluoropolymers present no significant toxicity, are inert, and are not water soluble. Another substance from today's PFAS – perfluorohexanoic acid (PFHxA) – has been found by French authorities⁶ to have a toxicity value significantly higher (meaning lower in toxicity) than another PFAS chemistry – perfluorooctanoic acid (PFOA). Given this information, it is not appropriate for any regulation or legislation to treat all PFAS chemistries the same. This includes when evaluating PFAS chemistries to establish drinking water levels, clean-up levels or lifetime safe exposure limits. For example, in making future regulatory decisions, section 1412(b)(3)(A)(i) of the SDWA outlines specific criteria for incorporation of science into the regulatory process. Subsequently, to be scientifically credible, proposed legislation that seeks to direct federal agencies to develop maximum contaminant levels for drinking water should be consistent with the SDWA requirements to: (a) utilize the best available and most relevant toxicology data for the PFAS substance to determine if it may adversely affect public health, (b) utilize available exposure and monitoring data for the PFAS substance to confirm that there is a substantial likelihood that it occurs in public water systems at a frequency and at levels of public health concern and (c) ensure that any proposed level will present a meaningful opportunity for public health risk reduction.

Similarly, to develop scientifically credible and meaningful clean up levels, any legislation or regulation should ensure that it is utilizing directly relevant scientific information for a PFAS chemistry to determine if it warrants a designation as a hazardous substance. Additionally, establishment of relevant clean up levels should be based on the available science relevant for that chemistry in order to minimize any identified public health concern. Most importantly, in working to establish any regulatory actions, federal agencies are in the best position to identify, evaluate and manage chemical risk. For example, EPA has established processes, principles, and best practices which guide site remediation activities. Thus the leadership of agencies, with a primary mission to protect human health and the environment, such as the EPA, is critical to successful implementation of any regulatory approach.

IV. A Single Class Approach to Evaluating PFAS is Not Scientifically Warranted

A number of proposals suggest using a single class approach to addressing PFAS. However, PFAS encompasses a large variety of chemistries with differing characteristics, structures, physical and chemical properties, health and environmental profiles, uses and benefits. Evaluation of available scientific information to determine possible risks associated with exposure from PFAS must be a key focus. No two PFAS substances are exactly alike, thus it is critically important that chemical specific information be the foundation for any evaluation

² Anderson, J. K., Luz, A. L., Goodrum, P., & Durda, J. (2019). Perfluorohexanoic acid toxicity, part II: Application of human health toxicity value for risk characterization. *Regulatory Toxicology and Pharmacology*, 103, 10-20.

³ Luz, A. L., Anderson, J. K., Goodrum, P., & Durda, J. (2019). Perfluorohexanoic acid toxicity, part I: Development of a chronic human health toxicity value for use in risk assessment. *Regulatory Toxicology and Pharmacology*, 103, 41-55.

⁴ Henry, B.J., Carlin, J.P., Hammerschmidt, J.A., Buck, R.C., Buxton, L.W., Fiedler, H., Seed, J. and Hernandez, O., (2018). A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrated Environmental assessment and Management*, 14(3), pp.316-334.

⁵ OECD Synthesis Paper on Per and Polyfluorinated Chemicals. Weblink: https://www.oecd.org/env/ehs/risk-management/PFC_FINAL-Web.pdf

⁶ Development of Oral-Administered Treatment for TRV by Perfluorohexanoic Acid (PFHxA). French Agency for Food, Environmental and Occupational Health & Safety (ANSES), Maisons-Alfort, France (2017) (June)

of potential human health or environmental risk. Arbitrarily making risk management decisions for a class of chemistries based on information that may not represent the attributes of all substances in the class lacks scientific credibility. Severe scientific limitations exist in treating all PFAS as a single class for hazard assessment, exposure assessment or risk evaluation purposes. Two notable issues include: (a) finding a basis for consistently defining relative toxicity and potencies across chemicals within the PFAS class (e.g., even those PFAS chemicals affecting the same apical endpoint may do so by different modes of action) and (b) defining the patterns of interaction at different exposure levels when dose-response patterns differ and when complex interactions are possible.

A one-size-fits-all approach is at odds with what scientists and other experts continue to determine. Notably, the National Academy of Science, Engineering and Medicine (NASEM) empaneled a Committee to evaluate the question of whether a single class approach could be applied to evaluate the potential hazards from another set of chemistries – organohalogen flame retardants. As a result of their review, the NASEM Committee concluded⁷ that a single-class approach was not scientifically credible. Importantly, instead of a single class approach NASEM suggested the identification of subclasses using information like chemical structure, physical and chemical properties, toxicology data and predicted biologic activity to facilitate decision-making for hazard characterization. ACC believes that a similar approach should be taken in addressing PFAS and notes that EPA’s Office of Research and Development currently is engaged in an effort to develop subclasses of PFAS for the purposes of prioritizing the Agency’s review of these chemistries.

Conclusion

In conclusion, ensuring that up to date, high quality data and science-based approaches underlie regulatory decision-making is critical to protecting human health and the environment from any potential risk that may be associated with PFAS chemistries. Congress has consistently recognized the importance of science as the foundation for regulatory decisions and codified scientific standards in the 2016 amended TSCA legislation to ensure the EPA’s activities are guided by high quality, reliable and relevant scientific information. A one-size-fits-all approach to chemical management and assessment of PFAS is not scientifically based. Without a scientific basis, any legislation or regulation lacks credibility which in turn undermines the public’s confidence in the government’s actions to regulate chemicals to protect health and the environment. Additionally, Federal agencies with the responsibility for chemical regulation must play a vital role in developing and implementing approaches.

Thank you for this opportunity to provide testimony. ACC looks forward to working with the Committee to ensure that science-based approaches are the foundation for regulatory decision making associated with PFAS. I look forward to addressing your questions.

⁷ National Academies of Sciences, Engineering, and Medicine. 2019. A Class Approach to Hazard Assessment of Organohalogen Flame Retardants. Washington, DC: The National Academies Press. <https://doi.org/10.17226/25412>.