November 19, 2019

Dr. Meredith Tipton
Chair, Maine PFAS Task Force
17 State House Station,
Augusta, ME 04333-0017

RE: Maine PFAS Task Force's Draft PFAS Report Outline

Dear Chairwoman Tipton:

FluoroCouncil appreciates this opportunity to provide comments on the Maine PFAS Task Force's Draft PFAS Report Outline. FluoroCouncil is a global organization representing the world's leading manufacturers of products based on per-and polyfluoroalkyl substances (PFAS), including fluoropolymers, fluoroelastomers, and fluorotelomer-based products.[1] FluoroCouncil has a fundamental commitment to product stewardship and rigorous, science-based regulation, and, as part of its mission, addresses science and public policy issues related to PFAS.

We understand the important issues currently facing Maine regarding detections of certain PFAS at levels of concern at different locations in the state. Further, we appreciate the significant efforts the Task Force has put into compiling the Draft PFAS Report Outline, which can serve as a critical tool in identifying potential actions to address these PFAS contamination issues. It is crucial that Maine takes a science- and risk-based approach grounded in a thorough understanding of the broad family of PFAS in order to develop a set of recommendations that will address these issues in an appropriate and effective manner.

FluoroCouncil is supportive of many of the recommendations outlined in the Draft PFAS Report Outline, which are enumerated below. However, as currently drafted, certain recommendations appear to inappropriately conflate the extremely broad and diverse group of chemicals referred to as "PFAS," which includes products and substances that do not present a significant risk to human health or the environment and are not relevant to the issues in Maine. We are encouraged by the thoughtfulness put into developing the Draft PFAS Report Outline and recommend that the Task Force refine the Report's focus to a more narrow and appropriate scope.

Below is a summary of our comments, and attached are slides previously presented by FluoroCouncil to the PFAS Task Force.

[1] FluoroCouncil's member companies are AGC Inc., Daikin Industries, Ltd., Solvay Specialty Polymers, The Chemours Company LLC, Archroma Management LLC (associate), Dynax (associate), and Tyco Fire Products LP (associate).

A. PFAS cannot be addressed as a broad class.

PFAS is a term that describes a wide variety of groups of chemical substances and polymers with very diverse properties. PFAS is too general to be useful for communication purposes and is insufficient to describe a regulatory class. Because there is so much variation among the alleged 4,700+ chemicals in the PFAS category,[2] no scientifically sound rationale exists for treating them all the same as a matter of public policy.

PFAS vary significantly in their hazard profiles. For instance, not all PFAS and related products are persistent, bioaccumulative, and/or toxic, particularly at concentrations typically present in the environment. While some PFAS remain in the environment for years, other PFAS are short-lived and convert to other substances in a matter of hours or days. Not all PFAS persist in biological tissues. Certain PFAS compounds, including short-chains, are readily eliminated from the human body and do not bioaccumulate.[3] Kinetics studies in animals further demonstrate that the persistence of PFAS compounds generally decreases with decreasing chain length.[4]

PFAS also do not share a common toxicity profile. For example, toxicity testing on some PFAS substances shows carcinogenic potential while similar testing on other substances does not show any evidence of carcinogenicity.[5] In addition, even when toxicity testing of PFAS substances may show some similarity of effects, the point of departure dose[6] associated with those effects can vary by orders of magnitude from substance to substance.[7]

Furthermore, PFAS chemicals that occur as mixtures may not share the same target organ, mode of action for toxicity, or dose-response relationship, across concentration ranges.[8] Sound science dictates that when multiple chemicals have differing toxicity characteristics, they cannot be

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[2] *See* OECD, Summary Report on Updating the OECD 2007 List of Per- and Polyfluoroalkyl Substances (PFASs), www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-JM-MONO(2018)7&doclanguage=en.

[3] Chengelis C.P., J.B. Kirkpatrick, N.R. Myers, M. Shinohara, P.L. Stetson, and D.W. Sved. 2009a. Comparison of the toxicokinetic behaviour of perfluorohexanoic acid (PFHxA) and nonafluorobutane-1-sulfonic acid (PFBS) in cynomolgus monkeys and rats. Reprod Toxicol, 27(3-4):342-351. Gannon S.A., T. Johnson, D.L. Nabb, T.L. Serex, R.C. Buck, S.E. Loveless. 2011. Absorption, distribution, metabolism, and excretion of [1-14C]-perfluorohexanoate ([14C]-PFHx) in rats and mice. Toxicology, 283: 55–62. Iwai H. 2011. Toxicokinetics of ammonium perfluorohexanoate. Drug and Chem. Toxicol. 34: 341–346.

[4] Chang S-C, K. Das, D. Ehresman, M.E. Ellefson, G.S. Gorman, J.A. Hart, P.E. Noker, Y-M Tan, P.H. Lieder, C. Lau, G.W. Olsen, and J.L. Butenhoff. 2008. Comparative pharmacokinetics of perfluorobutyrate in rats, mice, monkeys, and humans and relevance to human exposure via drinking water. Tox. Sci. 104: 40-53. Kudo, N., E. Suzuki-Nakajima, A. Mitsumoto, and Y. Kawashima. 2006. Responses of the liver to perfluorinated fatty acids with different carbon chain length in male and female mice: In relation to induction of hepatomegaly, peroxisomal beta-oxidation and microsomal 1-acylglycerophosphocholine acyltransferase. Biol. Pharm. Bull. 29:1952–57. Ohmori, K., N. Kudo, K. Katayama, and Y. Kawashima. 2003. Comparison of the toxicokinetics between perfluorocarboxylic acids with different carbon chain length. Toxicology 184:135–40.

[5] Klaunig, J.E., M. Sinohara, H. Iwai, C. Chengelis, J. Kirkpatrick, Z. Wang, and R. Bruner. 2015. Evaluation of the chronic toxicity and carcinogenicity of perfluorohexanoic acid (PFHxA) in Sprague-Dawley rats. Tox. Pathology 43:209-220.

[6] The term "point of departure" (POD) is used here to refer to a dose that corresponds with a specified response level, such as a 5% or 10% change in incidence of liver hypertrophy in rats, compared with a control group. The POD is used to calculate a toxicity reference value for purposes of deriving a risk-based drinking water action level.

[7] ATSDR. 2015. Draft toxicological profile for perfluoroalkyls. Agency for Toxic Substances and Disease Registry. U.S. Department of Health and Human Services Public Health Service, August.

[8] An *in vitro* study conducted by researchers at the USEPA Office of Research and Development (Wolf et al. 2013; Toxicology 316:43-54. 10.1016/j.tox.2013.12.002) found that binary pairs of PFAS exhibited inconsistency in concentration- and response-addition across dose ranges.

grouped together for risk assessment purposes.[9] Given the wide variations in toxicities and other hazard characteristics exhibited by different PFAS chemicals, it is scientifically inappropriate to group all PFAS together for purposes of risk assessment, or to assume that exposures to mixtures of PFAS result in concentration additivity.

The broad family of PFAS includes some substances that have been developed and are actually used in commercial applications; however, a large number have not been developed and many of the PFAS compounds cited in the OECD report are not items in commerce.[10] Additionally, it is important to understand that those PFAS with commercial uses are not used interchangeably. Different PFAS impart different properties, and those in the marketplace have been designed for specific uses, making it essential for public policy to be based on the risks associated with exposure to individual substances in particular uses. For example, fluoropolymers are not used to make grease-resistant food wrappers, and fluorotelomers are not used to make plastic parts. Consequently, the life-cycle impact of any particular compound within the PFAS category can differ by orders of magnitude.

As a result of this significant diversity within the family of PFAS, it is inappropriate to address PFAS as a broad class. Rather, regulatory and policy measures should be substance-specific.

B. Specific Comments on the Draft PFAS Report Outline.

1. PFAS in products

The Task Force was charged with identifying PFAS exposures in Maine, as well as resulting risks to human health and the environment, which is fitting, as any consideration of product deselection should be based on whether a material is of concern and at what level it presents a concern. Consequently, blanket bans and some of the Draft PFAS Report Outline's overly broad suggestions regarding reduction and/or elimination of PFAS-containing products are not only scientifically unsubstantiated, as PFAS can vary greatly as described above, but also may restrict access to many different products that provide unique and often critical benefits enabled by PFAS.

Multiple industries depend on high-performance PFAS, including aerospace, alternative energy (e.g., solar), automotive, building and construction, chemicals and pharmaceuticals, electronics, healthcare, oil and gas, outdoor apparel and equipment, and semiconductors, just to name a few. PFAS are used in a wide array of products and play a vital role in everything from designing automobiles with lower emissions and improved safety, reliability and fuel-efficiency to manufacturing semiconductors, solar panels and high performance electronics.

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[9] As OECD notes, equating the risks of various chemicals for which there are known differences in toxicity is not "scientifically warranted." *See* http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2014)4&doclanguage=en at 18. Similarly, if analysis of one chemical using information about another does not create "an accurate and credible assessment of the hazards for the substance in question," then it is inappropriate to read-across between the substances. http://www.ecetoc.org/wp-content/uploads/2014/08/ECETOC-TR-116-Category-approaches-Read-across-QSAR.pdf at 44.

[10] According to USEPA, approximately 600 PFAS compounds have been active in US commerce since 2006. *See, EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan* (February 2019) at 12 (www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf)

For instance, fluoropolymers, one type of PFAS, can be found in everyday items such as implantable medical devices, cell phones, and automobiles (including electric vehicles). Notably, fluoropolymers do not pose a significant risk to human health or the environment due to their stability and lack of bioavailability, among other properties. Therefore, any restriction on fluoropolymers' use in products would not provide any additional health protections to human health or the environment, but may instead unnecessarily restrict Maine's citizens from accessing critical, and often life-saving, technologies.

For instance, the Draft PFAS Report Outline recommends requesting that the federal government "reduce and eliminate the use of PFAS chemistry for non-essential applications" and require reporting of PFAS-containing consumer product manufacturers. As stated, both of these overly broad recommendations are scientifically unsubstantiated and undermine the regulatory framework, which is intended to utilize risk-based decision-making, taking into account both hazard and exposure. Alternatively, the Task Force's recommendation to "[m]odify the list of Chemicals of High Concern under the Toxic Chemicals in Children's Products … law to include all PFAS that meet statutory criteria" is a preferred approach, as it utilizes an existing regulatory framework and risk-criteria to determine whether certain PFAS chemistries meet specified criteria of concern, instead of broadly restricting or otherwise impacting their use in products.

Furthermore, the Draft PFAS Report Outline suggests listing the "PFAS family of compounds" as priority chemicals in food packaging under the state's newly amended law. The U.S. Food and Drug Administration (FDA) has regulatory oversight over these applications and is responsible for carrying out robust reviews of chemicals exposure from both food contact materials and from food itself, as food safety is of national concern. A significant body of data exists for the PFAS chemistries currently used in food contact applications permitted by FDA for use in the U.S. Maine should defer to the regulatory process to work as designed, with FDA using science to determine whether PFAS substances used in a food contact application are safe for their intended use.

While FluoroCouncil is generally supportive of the Task Force's recommendation regarding fluorinated class B firefighting foams (AFFF), we believe that any take-back program should be limited to long-chain based foams. AFFF remains the most effective tool for fighting high hazard flammable liquid fires, and we believe that the use of current AFFF formulations should remain available as a tool for firefighters to efficiently and effectively protect life and property.

FluoroCouncil is supportive of utilizing best management practices to minimize unnecessary exposures to the environment. Generally speaking, PFAS-containing products should only be used when necessary and users should only use what is needed; residual liquids should be reused/recycled, if possible, and waste and emissions should be minimized; and proper disposal practices should be employed. These best management practices apply to the handling and use of all PFAS applications, from fluorinated class B firefighting foams[11] to fluorinated repellant treatments utilized in the apparel industry. Implementing additional management practices, as opposed to blanket bans or restrictions on PFAS-containing products, are the most appropriate

[11] Legislation has passed in several states this year that codifies these best practices by heavily restricting or banning fluorinated foam use in non-emergency situations while allowing firefighters to have access to life and property-saving tools for appropriate emergency situations (e.g. VA, GA, NM) and is pending in others (e.g. OH, WI).

way for the Task Force to accomplish its goal of minimizing exposure and releases, while also preserving the use of critical technologies.

2. *Testing*

FluoroCouncil is supportive of Maine's plan to conduct prioritized testing to detect PFAS in different media. We encourage the Task Force to use EPA-validated laboratory methods for analysis of public drinking water, and consequently support the recommendation for additional laboratory methods to be developed at the federal level. Furthermore, we encourage the state to focus its efforts on PFAS analytes of greatest concern to ensure the most efficient use of resources. We also believe that the prioritized approach for determining which systems to test first is appropriate and efficient, and such an approach should be utilized for all of the state's testing and monitoring projects. For all analytical testing, we recommend that all analysis be conducted with appropriate QA/QC controls by appropriately trained analytical technicians, from sample collection through processing. These recommendations will help ensure that any testing provides meaningful information on the detection and quantification of specific PFAS analytes.

3. *Enforceable standards/guidelines and other regulatory programs*

FluoroCouncil appreciates the Task Force's recommendations regarding the promulgation of enforceable standards and guidelines for PFAS levels in different media (e.g., water, air, soil, products). FluoroCouncil also supports the recommendations that several of these standards be established at the federal level (e.g. Maximum Contaminant Level, adulterated food screening levels), but recommend that such standards focus on PFAS analytes of greatest concern. If the State decides to move forward with setting such standards on its own, FluoroCouncil recommends that the appropriate regulatory processes are utilized, providing for sufficient notice and comment from interested stakeholders, and that all standards and guidelines should be based on sound science and enforceable with applicable validated analytical methods.

Additionally, we are supportive of the caveats (e.g., "specified PFAS compounds," "a suite of PFAS compounds") qualifying the recommendation of adding certain PFAS chemistries to the state's Toxics Use Reduction Program and Toxics Release Inventory. As stated before, not all PFAS chemistries share the same properties; therefore, PFAS as a blanket class should not be considered for addition to any regulatory program, no matter if just for reporting purposes or otherwise.

4. *Public outreach and education*

Any public outreach and education regarding PFAS should be clear, specific, and descriptive, especially when discussing potential risks associated with exposure to drinking water or other media (including products) that contain PFAS. As discussed above, PFAS is a broad group of classes of chemistries with greatly varying uses and properties. Therefore, exposure to different PFAS chemistries may present different risks, depending on the PFAS chemistries present and the amount at which they are present. Maine's public messaging should have a strong focus on risk communication and not inappropriately make unsubstantiated blanket statements regarding PFAS chemistries that may unnecessarily concern the State's residents.

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FluoroCouncil understands and appreciates Maine's need to address the PFAS-related contamination issues in the state. Accordingly, it is critical that the approach taken to address those issues be focused on specific PFAS chemicals of concern found at levels of concern in the state. FluoroCouncil welcomes the opportunity to work with the task force to refine the Draft PFAS Report Outline to ensure it results in a targeted set of recommendations supported by a scientifically sound foundation. Please do not hesitate to contact me at 202-249-6708 or renee_lani@americanchemistry.com with any questions or clarifications.

Sincerely,

Renée M. Lani
On behalf of FluoroCouncil

Attachments:

- FluoroCouncil PFAS Overview Presentation (September 25)