PERFORMANCE FLUOROPOLYMER PARTNERSHIP

August 24, 2020

Submitted electronically to info@toxicsinpackaging.org

The Performance Fluoropolymer Partnership (hereafter "Partnership") welcomes the opportunity to provide comments on the Toxics in Packaging Clearinghouse's (TPCH) draft updated model legislation. The Partnership's members are some of the world's leading manufacturers of fluoropolymers, including fluoroplastics, fluoroelastomers and polymeric perfluoropolyethers.[1] The Partnership believes fluoropolymers should be removed from the scope of the draft legislation. Our comments below elaborate on the following points:

1. Perfluoroalkyl and polyfluoroalkyl substances (PFAS) should not be regulated as a single class of chemicals;
2. Fluoropolymers should be excluded based on their molecular size, stability and lack of reactivity; and
3. Fluoropolymers' unique combination of properties enable packaging critical for the storage of medicines, medical devices and other products critical to public safety.

1. PFAS should not be regulated as a single class of chemicals.

The draft model legislation treats all PFAS substances as a single regulatory group, an approach that is both inappropriate and unnecessary. PFAS is a large, diverse group of chemical compounds. All PFAS are not the same, and their properties vary widely. Regulating chemical substances arbitrarily as a large class can lead to unjustified restrictions that are not based on sound science. Authorities should regulate chemicals based on clearly identified risks to health and/or the environment assessed on a robust scientific basis.

The overly broad definition in the draft updated model legislation is inconsistent with a more specific and widely accepted definition of PFAS that international regulators, the academic community and industry have adopted. For example, the Organisation for Economic Co-operation and Development (OECD) defines PFAS as chemicals that contain one or more perfluoroalkyl moieties – C_nF_{2n}+1.[2] OECD further divides PFAS into two groups, non-polymers and polymers, and makes distinctions about chemical diversity within those groups. Chemical and structural differences among different types of PFAS result in vast differences in physical-chemical properties that underlie concerns about the potential health or environmental risks associated with some—but certainly not all—PFAS.

Not only is the proposal to treat all PFAS the same inconsistent with current scientific understanding of PFAS, it is also inconsistent with the approach TPCH has taken with metals. In the past, TPCH proposed the restriction of cadmium, lead, mercury and hexavalent

[1] The Performance Fluoropolymer Partnership's members are AGC, Inc., Daikin Industries, Ltd., and The Chemours Company, LLC.
[2] Organisation for Economic Co-operation and Development, OECD/UNEP Global PFC Group. Synthesis paper on per- and polyfluorinated chemicals (PFCs). Environment, Health and Safety, Environment Directorate. 2013. Publicly available.

chromium, but did not suggest regulating all metals in packaging as if they were the same. TPCH recognized that other metals may be used where strength and safety are required in a packaging system. PFAS as a category is as broad as, if not broader than, metals, and environmental and safety measures should be considered for individual PFAS or well-defined groups of PFAS that share similar characteristics relevant for understanding potential concerns.

Just as we believe that physical-chemical properties of specific substances should be used to define distinct classes of PFAS, we also believe that risk assessment should be based on an understanding of the inherent properties of substances and sound science should be used to determine the likelihood of harm from a specific exposure. The reference to a non-detection threshold for all PFAS (lines 131-132) not only ignores the principles of science-based risk assessment, but also fails to consider the means to measure or monitor PFAS using a peer-reviewed, validated, or reliably reproducible testing method. The lack of any mention of incidental presence for PFAS combined with a non-detection threshold means all packaging could face a ban given the ubiquity of some PFAS compounds in the environment even at trace (but detectable) levels.

2. Fluoropolymers should be excluded based on their molecular size, stability and lack of reactivity.

Fluoropolymers are large, stable, polymeric molecules that are too large to cross biological membranes and therefore present little potential for human or environmental exposure. Representative fluoropolymers have been demonstrated to meet the accepted OECD criteria to be considered "polymers of low concern" meaning they do not present a significant concern to human health or the environment.[3] The criteria for "polymers of low concern" have been developed by governmental and intergovernmental regulators to protect human health and the environment.[4]

In addition, fluoropolymers are not considered to present a toxicological risk. For example, a representative fluoropolymer, PTFE, was subjected to the battery of tests in ISO 10993-1, *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing,* and showed no treatment effects.[5] The data were generated under Good Laboratory Practices in compliance with ISO, ASTM and OECD standards.

Fluoropolymers are insoluble substances and are therefore highly unlikely to move between environmental media as dissolved chemicals. They are not water soluble and, as a result, are not found in sources of drinking water. Concerns about the mobility of highly water soluble PFAS substances do not apply to fluoropolymers. Fluoropolymers are neither bioavailable nor bioaccumulative, are not long-chain non-polymer PFAS (e.g. PFOA, PFOS), and do not transform into long-chain non-polymer PFAS in the environment.

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[3] Henry, B. J., et al. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. Integrated Environmental Assessment and Management. Volume 14, number 3, pages 316-334. May 2018. Open Access.

[4] Organisation for Economic Co-operation and Development. 2009. Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern. Document ENV/JM/MONO(2009)1. Paris, France. Publicly Available.

[5] See the Supplemental Data from B.J. Henry et al. 2018 referenced in footnote 3 above. Open access.

3. Fluoropolymers' unique combination of properties enable packaging critical for the storage of medicines, medical devices and other products.

The draft model legislation would effectively restrict all PFAS in packaging and packaging components. Fluoropolymer-enabled packaging takes advantage of fluoropolymers' extremely low permeability and resistance to corrosion and changes in temperature. Fluoropolymers have been used safely and effectively for decades in a wide range of industries, including pharmaceuticals and medical devices. The safety, purity and performance of fluoropolymers enables diagnostic and treatment technologies that save lives. Some examples of fluoropolymer use that would be restricted by the draft model bill include:

1. Oxygen and moisture barrier films for pharmaceutical blister packs that maintain the integrity of the medicine and extend its shelf life;
2. Films for septum liners used to store pharmaceuticals sensitive to moisture and oxygen;
3. Bags for storing cellular therapies and other medications that require cryogenic storage temperatures and no chemical contamination;
4. Shrink wrap packaging to prevent the contamination of endoscopic, laparoscopic or catheter-based surgery kits;
5. Bottles, tanks and trays used for storing and transporting high purity chemicals for semiconductor manufacturing;
6. Integrated circuit packaging with superior dielectric and dissipation performance that ensures the longevity of electronic components by protecting microchips from moisture, heat stress and other environmental challenges.
7. Potentially hundreds of applications where fluoropolymers are used as processing aids to produce tougher, stronger and lighter packaging that helps meet societal goals such as minimizing food waste, improving resource efficiency through less plastic and energy use, and reducing greenhouse gas emissions.

In summary, the Partnership believes all PFAS should not be considered as a single class for regulatory action, as it is possible to scientifically define distinct groups of PFAS based on shared properties. Fluoropolymers should be explicitly exempt from the model legislation based on their molecular size, stability and lack of reactivity. If non-polymeric PFAS are included in the model legislation, a "zero detection" standard is unworkable and adequate provision must be made for unavoidable incidental presence. Finally, the legislation would have the practical effect of eliminating the use of fluoropolymers in packaging for medicines, medical devices, semiconductors and other applications where packaging integrity is required to reduce waste and improve material use efficiency, and where no viable alternatives exist with the same material properties and level of performance.

Thank you for the opportunity to provide comments on the draft model legislation. We would welcome the opportunity to schedule a meeting to discuss our comments and answer any questions you may have about fluoropolymers and the critical role they play in the performance and design of packaging. Please feel free to contact me at Jay_West@americanchemistry.com.

Sincerely,

Jay West
Executive Director, Performance Fluoropolymer Partnership