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Submitted electronically to financechair@nysenate.gov and wamchair@nyassembly.gov

The Performance Fluoropolymer Partnership (hereafter “Partnership”)¹ welcomes the opportunity to provide comments on the proposed Fiscal Year 2023 New York State Executive Budget for Transportation, Economic Development and Environmental Conservation Article VII Legislation.² We are writing specifically regarding the Toxics in Packaging Act in Section SS of the budget proposal (page 198, line 10).

The Partnership believes fluoropolymers should be removed from the scope of the Toxics in Packaging Act. 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.

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

The proposed Toxics in Packaging Act treats all PFAS substances as a single regulatory class or 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. 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.

The overly broad definition of PFAS in both H.2348 and S.1494 is inconsistent with a more specific and widely accepted definitions of PFAS that international regulators, the academic community and industry have adopted. For example, Buck *et al.* divided PFAS into two large categories, nonpolymeric and polymeric, and further identified classes within those two categories based on the molecular architecture.³ Such an approach is useful because molecular architecture can help to understand chemical and biological behavior among the diverse classes of PFAS.

¹ The Performance Fluoropolymer Partnership’s members are AGC, The Chemours Company, Daikin America, ExxonMobil, Gujarat Fluorochemicals, Honeywell, MilliporeSigma and Shamrock Technologies.

² Available at <https://www.budget.ny.gov/pubs/archive/fy23/ex/artvii/ted-bill.pdf>.

³ Buck *et al.* 2011. Perfluoroalkyl and polyfluoroalkyl substances in the environment: Terminology, classification, and origins. *Integrated Environmental Assessment and Management* 7(4):513-541. [Publicly available](#).

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. In this regard:

1. The threshold of 100 parts per millions by weight is arbitrary and ignores the principles of science-based risk assessment;
2. The proposed bill fails to consider the means to measure PFAS using a peer-reviewed, validated or reliably reproducible testing method; and
3. The proposed bill contains no notion of intentional use, which means all food packaging could face a ban given the presence of some PFAS compounds in the environment at trace 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.⁴ The criteria for “polymers of low concern” have been developed by governmental and intergovernmental regulators to protect human health and the environment^{5,6} and include consideration of the following characteristics:

- Polymer composition (structure and elemental composition);
- Molecular weight;
- Molecular weight distribution (consistency of molecule size in a sample);
- Particle size;
- Percent of oligomers weighing less than 1,000 Daltons;
- Electrical charge;
- Reactive functional groups;
- Presence of low molecular weight leachables;
- Resistance to physical, chemical, and biological transformation; and
- Thermal stability.

Where potential food contact applications are concerned, the U.S. Food and Drug Administration has established comprehensive regulations concerning fluoropolymers that detail the applications and conditions for their use.⁷ It is also worth noting that fluoropolymers have

⁴ 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.](#)

⁵ Organisation for Economic Co-operation and Development (OECD). 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.](#)

⁶ BIO by Deloitte. 2015. Technical assistance related to the review of REACH with regard to the registration requirements on polymers Final report prepared for the European Commission (DG ENV), in collaboration with PIEP. [Publicly available.](#)

⁷ 21 C.F.R. §§ 175.105, 176.170, and 177.1520, 1550, and 2600.

been found to be safe for use in internally implanted medical devices for over 30 years. 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.⁸ The data were generated under Good Laboratory Practices in compliance with stringent ISO, ASTM and OECD standards.

Finally, 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-polymeric PFAS in the environment.

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

The draft legislation would significantly restrict the use of all PFAS, including fluoropolymers, 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 legislation 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; and
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 proposed legislation based on their molecular size, stability and lack of reactivity. The regulatory threshold in the

⁸ See the Supplemental Data from B.J. Henry et al. 2018 referenced in footnote 3 above. [Open access.](#)

absence of a detection protocol is unworkable, and adequate provision must be made for unintentional, incidental presence. Finally, the legislation would have the unintended consequence of restricting 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. We would welcome the opportunity to schedule a meeting to discuss our comments and answer any questions you may have about fluoropolymers. Please feel free to contact me at Jay_West@americanchemistry.com.

Sincerely,

Jay West
Executive Director, Performance Fluoropolymer Partnership