Together, improving life

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Toxics in Packaging Clearinghouse
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To whom it may concern:

Thank you for the opportunity to provide comments on the Toxics in Packaging Model Legislation. Gore values such work to both address important health and environmental topics, as well as promote regulatory consistency.

About Gore

W. L. Gore & Associates is a global materials science company dedicated to transforming industries and improving lives. Since 1958, Gore has solved complex technical challenges in demanding environments — from outer space to the world's highest peaks to the inner workings of the human body. With more than 10,500 Associates and a strong, team-oriented culture, Gore generates annual revenues of $3.7 billion.

Gore is a user of fluoropolymers, which are a sub-category of PFAS with distinct characteristics. We have over six decades of expertise using the unique properties of PTFE and other fluoromaterials to invent valuable products, including implantable medical devices such as vascular grafts and stents; technical applications such as components for aircraft, automobiles, mobile phones and computers; protective apparel for firefighters and first responders; high performance outerwear; and filters, seals, and vents that reduce emissions from power generation, industrial processes and packaging.

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Clarifying the scope of model legislation

Gore manufactures several products that could possibly be considered a package or packaging components. When reviewing the definitions of these two terms in sections 3j and 3k, it was unclear whether our products were intended to be within scope. Further clarification of the definitions may be helpful for accurate interpretation of the intent, including if there are certain important categories of packaging that are expressly excluded.
Here are a few illustrative examples from Gore's product portfolio:

- GORE® Packaging Vents which deliver reliable pressure equalization and reduce risk of leaks[1]
- GORE® LYOGUARD® Freeze-Drying Tray which is a single-use bulk lyophilization container used in pharmaceutical manufacturing[2]
- GORE® IMPROJECT® Plunger which is designed to protect complex, silicone-sensitive biologics in pre-filled pharmaceutical syringes[3]

We do not believe that these products should be within the scope of the model legislation, but additional clarity would be helpful. We expect there are other examples from companies with broader packaging related product portfolios that could also benefit from a clearer scope. Because Gore only has a limited number of packaging related products, we are not able to propose a comprehensive definition, but we do have a several suggestions:

- **Exclusion of packaging that is used during the manufacturing of a product but not used during the sale or distribution of a product;**
- **Exclusion of products regulated by the US Food & Drug Administration; and**
- **Exclusion of a component in packaging that will be less than 1% of the weight of the final package and serve an important health and safety function (such as pressure equalization).**

[1] https://www.gore.com/products/categories/venting?view=packaging-vents
[2] https://www.gore.com/products/gore-lyoguard-freeze-drying-trays
[3] https://www.gore.com/products/improject-silicone-free-syringe-plunger

A broad PFAS definition will have unintended consequences

PFAS is defined in section 3l as a class of chemicals and prohibited in section 4c. Not all PFAS are the same and prohibiting the entire group will eliminate the use of materials that are demonstrated to be non-toxic and deliver valuable safety benefits to packaging. The PFAS group includes thousands of substances with different properties: polymers and non-polymers; solids, liquids, and gases; persistent and non-persistent substances; highly reactive and inert substances; mobile and insoluble substances; and toxic and nontoxic chemicals. Therefore, we believe it is important to be specific when discussing PFAS.

We have observed that many groups who are working to address important health and environmental topics will use the term PFAS, when they are most interested in a distinct sub-group of PFAS (e.g., perfluoroalkyl acids or PFAAs, like PFOA) that is relevant to their concern. Many of those concerns are associated with selected properties of substances which may include water solubility, toxicity, the potential for a substance to bioaccumulate, and its propensity to degrade into other substances of concern. Some of these characteristics are appropriately listed in Section 6 of the model legislation.

Fluoropolymers are a distinct class within the broad PFAS group and are valuable in packaging applications. When evaluated according to the OECD criteria for polymers of low concern[4], many fluoropolymers are demonstrated to meet all the criteria and represent the low risk end of the spectrum for PFAS. Polytetrafluorethylene (PTFE) is a distinct member of the fluoropolymer class of PFAS. PTFE is non-toxic. High molecular weight fluoropolymers like PTFE, are highly stable, too large to be bioavailable, and do not have the potential to become widespread in the environment.[5] While they do contain one or more fully fluorinated carbon atoms, like other PFAS,

[4] Organization for Economic Co-operation and Development. 2009. Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern. OECD Task Force on New Chemicals Notification and Assessment, Expert Group Meeting on Polymers; 2007 Mar; Tokyo, Japan. Paris (FR)

[5] Henry BJ et al., 2018. 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, pp. 316–334.)

data show that their properties present low health and environmental hazards.

PFAS which meet the polymers of low concern criteria are clearly different from substances that are driving the most urgent needs about human health and the environment. The difference is evident from objective data on their properties, the biologically sensitive applications where they have been extensively used and studied for decades (e.g. medical devices[6] and pharmaceutical processing), and their absence from environmental media.

Example use of fluoropolymers in packaging

GORE® Packaging Vents enable various packaging designs to equalize pressure and at the same time remain liquid tight over a long period of storage and transportation. Packaging vents are typically very small compared to the overall packaging enclosure. In general, the weight percentage of PTFE in a GORE® Packaging Vent is less than 0.5% of the total enclosure weight. Chemicals such as hydrogen peroxide, bleach, professional cleaners or disinfectants require robust packaging ventilation. Without PTFE vents there is a reduced ability to ship and store these products safely. Leaks of such chemicals create risk for human health and environmental pollution.

GORE® Packaging Vents require the unique chemical resistant and microporous properties of PTFE to create a durable solution. They maintain effective pressure equalization, withstand aggressive chemicals, meet the container lifetime requirements, and can be applied across a range of package designs. Without the ability to use PTFE in these applications, venting performance would suffer leading to a higher risk of leaks.

Because there are PFAS, such as PTFE and other fluoropolymers, which are demonstrated to be non-toxic and serve important functions regarding the packaging safety, we respectfully request changes to the model legislation to focus on the specific PFAS that are relevant to health and environmental concerns.

Recommendation:

Edit section 4c, which references all PFAS, to list specific PFAS that meet the criteria for packaging chemicals of high concern listed in section 6.

[6] https://www.goremedical.com/products

Recognizing that there is variation in the amount of data currently available for substances within the broad PFAS group, an alternative approach would be to reference the specific list of PFAS that have recently been added to the US Environmental Protection Agency's Toxic Release Inventory: https://ofmpub.epa.gov/apex/guideme_ext/f?p=guideme:gd:::::gd:pfas_chemical_list

An additional resource on PFAS that may be useful for legislative and regulatory purposes can be found on the website for the Interstate Technology and Regulatory Council: (https://pfas-1.itrcweb.org/)

Align with other Regulatory Listings for Phthalates

The current revisions to TPCH Model Legislation also propose to prohibit ortho-phthalates over 100 ppm in the final packaging in Section 4b. Phthalates are another very broad class of chemicals with a range of characteristics. We believe the definition of phthalates needs to be more specific so that the requirements are clear to understand, risk assessments and compliance can be more easily determined and information along the supply chain can be shared consistently.

There is an opportunity to leverage the identification of specific phthalates by regulatory bodies in the US and EU where toxicity, prevalence in the environment, usage, and human exposure have been carefully considered.

Recommendation:
Edit the definition of phthalates in sections 3m and 4b to reference an established regulatory list, such as:

EPA Phthalate Action Plan
U.S. Environmental Protection Agency's (EPA's) current phthalate management plan includes the following eight phthalates: dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), butyl benzyl phthalate (BBP), di-n-pentyl phthalate (DnPP), di(2-ethylhexyl) phthalate (DEHP), di-n-octyl phthalate (DnOP), diisononyl phthalate (DINP), and diisodecyl phthalate (DIDP).
https://www.epa.gov/sites/production/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf

Annex XIV of REACH ("Authorization List")
REACH Annex XIV is also called REACH authorization list. It contains a list of substances subject to authorization under EU REACH regulation. Substances on this list are selected from REACH SVHC list and they cannot be placed on

the market or used after a given date ("sunset date"), unless an authorization is granted for their specific use, or the use is exempted from authorization. This list includes the following nine phthalates: dibutyl phthalate (DBP), diisobutyl phthalate (DIBP), butyl benzyl phthalate (BBP), di-n-pentyl phthalate (DnPP), di(2-ethylhexyl) phthalate (DEHP), diisopentyl phthalate (DIPP), dihexyl phthalate (DnHP), bis(2-methoxyethyl) phthalate (DMEP), and n-pentyl-isopentyl phthalate.

https://echa.europa.eu/authorisation-list

Gore welcomes the opportunity to provide our input and is available for follow-up discussion should that be considered helpful. Please feel free to contact me at 410-506-8669 or skapplem@wlgore.com

Sincerely,

Sheila A. Kappelmeier
Product and Chemical Stewardship (PaCS/PSD)