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Toxics in Packaging Clearinghouse
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To whom it may concern:

The American Chemistry Council (ACC)[1] is pleased to submit comments on the Toxic in Packaging Clearinghouse's (TPCH) Proposed Model Legislation for Toxics in Packaging (Proposed Model Legislation). ACC and its member companies are committed to making innovative chemical products that are used safely for their intended purposes. This commitment is embodied in the Responsible Care Product Safety Code which is mandatory for all ACC chemical manufacturing members.

ACC supports evidenced-based regulation and safety of packaging. In that vein, our industry endorsed past TPCH efforts to regulate heavy metals in packaging because safe packaging is absolutely essential in modern society and the products of chemistry enable a broad range of packaging materials. Plastic food packaging, for example, helps keep food fresh and clean, ultimately reducing food waste. The U.S. Environmental Protection Agency (EPA) estimates that more food reaches landfills and incinerators than any other single material in our everyday trash, constituting 22 percent of discarded municipal solid waste (MSW).[2] Packaging helps reduce the

[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. The business of chemistry is a $526 billion enterprise and a key element of the nation's economy. It is one of the nation's largest exporters, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

[2] Enviromental Protection Agency, "Sustainable Management of Food Basics," (Washington, DC), Website. https://www.epa.gov/sustainable-management-food/sustainable-management-food-basics#:~:text=EPA%20estimates%20that%20more%20food,of%20discarded%20municipal%20solid%20waste.

quantity of wasted food – 1.5 grams of plastic extends the freshness of cucumbers over 400% and packaging for grapes reduces waste by 20 percent.[3]

General Comments on Risk Assessments

ACC believes decisions regarding product safety—including packaging—should be made using a robust, risk-based approach. A risk-based approach considers the hazards, intended uses and exposure of the product while incorporating the best available science that takes into account weight of evidence. Assessments made in this manner are characterized by the following elements: 1) A chemical hazard assessment to identify the potential environmental and health impacts, based upon an evaluation of health and environmental effects data, physical properties, and other data. 2) An exposure assessment to identify those use scenarios that pose the greatest potential for exposure, with the inclusion of any associated exposure potentials for workers, consumers, the public and the environment. 3) A safety assessment of each of the chemicals used in a product that integrates available hazard and exposure information to evaluate the possible effects on human health and on the environment associated with exposure to the product based on a given use.

As presented, the Proposed Model Legislation is not a risk-based approach because it focuses on hazard alone. Section 6, which describes means to identify and prohibit "packaging chemicals of high concern", fails to outline exposure level requirements, thus leading to an incomplete picture of "risk" that potential additives in packaging may present. As discussed above, risk is a function of both hazard and exposure – without additional exposure requirements this section may exclude chemicals that are safe for their intended use, e.g. within packaging or to enable packaging performance.

Section 6 also fails to establish a *de minimis* threshold for newly identified chemicals of high concern. At minimum, a *de minimis* level for added chemicals will ensure Section 6 is logically consistent with Section 4, which contains limits of 100 ppm and LOD for metals and PFAS materials, respectively. Similarly, adding a threshold level will create alignment between Section 6 and OSHA, GHS, and other international reporting standards.

Accordingly, ACC is concerned that the Proposed Model Legislation will lead to flawed regulations—and chemical assessments based on these regulations—and may create public confusion, cause unwarranted alarm, and product de-selection. All of which serves to further erode public confidence in existing chemical management programs.

Recovery of packaging material

[3] Advisory Committee on Packaging, *Packaging in Perspective* (London, UK, 2008), http://www.thefactsabout.co.uk/files/98201010542packaginginperspective.pdf.

ACC supports efforts to recycle and recover packaging materials in an effort to increase these materials' functioning within a circular economy. To that end, ACC's Plastic Division members established a goal to reuse, recycle or recover 100 percent of plastic packaging in the US by 2040.[4] Consequently, we do not support removing the Section 5 exemption for packaging materials that are reusable in "closed looped system[s] with end of life recovery". Removing this exemption would de-emphasize circular plastic packaging recycling as a necessary goal for these materials.

Conflict with FDA Regulation of Food Contact and Medical Packaging Materials

The Proposed Model Legislation is redundant in that numerous regulations exist to help ensure the safety and design of packaging. In the U.S., there is a robust regulatory system in place for managing chemicals and packaging administered by EPA and the U.S. Food and Drug Administration (FDA). We are concerned that the proposed changes would bypass these important regulations and could have unintended consequences for product safety, packaging performance and overall life-cycle considerations such as recycling, and greenhouse gas reductions.

ACC firmly believes that the regulation of food contact and medical materials by FDA provides rigorous safety protections for consumers. Materials intended for food packaging, and the substances used to make them, are regulated by the FDA as "indirect" food additives,[5] sometimes called food contact substances (FCS),[6] to assure that they are safe for intended use.[7] The Federal Food, Drug and Cosmetic Act (Act) requires that an FCS manufacturer or supplier prove the safety of the substance in a Food Contact Notification (FCN) that must be declared effective by FDA before the substance is allowed on the market.[8] Moreover, the Food Additives Amendment, gives FDA authority over food additives—including indirect additives like plastic food packaging—and requires premarket approval before an item can be sold to consumers.

FDA's review under the Act ensures that any packaging material is safe for consumer use. An FCS is not meant to become a component of food or to have any effect on it, but it may come into contact with food. Because it is possible for small amounts of these substances to migrate from the

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[4] https://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/US-Plastics-Producers-Set-Circular-Economy-Goals-to-Recycle-or-Recover-100-Percent-of-Plastic-Packaging-by-2040.html

[5] 21 CFR 177

[6] 21 U.S.C. § 348(h)(6). All indirect food additives are FCSs. The FCS also includes substances that come into contact with food, but do not meet the definition of an indirect additive, such as a GRAS substance or a substance that does not migrate and become a component of food.

[7] The Center for Food Safety and Nutrition (CFSAN) is the FDA center responsible for the safety of food packaging and containers. The CFSAN web page is the source of substantial information concerning CFSAN's activities. The information is *available at* https://www.fda.gov/about-fda/fda-organization/center-food-safety-and-applied-nutrition-cfsan

[8] The Food and Drug Administration Modernization Act of 1997 created the FCN process as a means to speed up the premarket notification system for indirect food additives. Previously manufacturers filed a Food Additive Petition. When a petition was approved, the additive was listed in the Code of Federal Regulations.

packaging to the food, FDA thoroughly evaluates and regulates FCSs so that any migrating substance is safe if consumed. Said differently, these materials are regulated by FDA as part of a nation-wide, comprehensive program with a strong safety standard of "no harm" that must be proven through a robust set of scientific studies that satisfy FDA's testing requirements. ACC strongly believes that it is inappropriate for TPCH to circumvent and disregard this rigorous and comprehensive science-based regulatory program by prohibiting in Section 4 food contact substances that have successfully completed FDA review and that are authorized by FDA for use in food packaging in the US under prescribed conditions of use.

Similarly, ACC also has concerns regarding the "regulatory efficiency" provision of Section 6 of the Model Legislation. Under that provision, a state regulator contemplating regulation of a "toxic chemical" can take into consideration whether the substance is already adequately regulated under Federal or State law. Inexplicably, this flexibility is only allowed for newly identified "toxic chemicals" and similar flexibility is not provided with respect to the substances currently proposed for addition to the Model Legislation (PFAS and phthalates). There is no rational, science-based justification for this inconsistency.

All FCSs, including indirect food additives, must be established to be safe[9] before they can be used in food packaging or storage items.[10] To prove that an FCS is safe to the satisfaction of the FDA, the manufacturer must 1.) Demonstrate that there is a minimal amount of transfer between the package and the food and 2.) Establish that the level of migration does not pose a risk to human health. This involves the submission of comprehensive data estimating the exposure that could result from any migration of the substance, toxicological studies and chemistry data, and an analysis of any possible effect on health.

FDA's regulation of FCSs utilizes the highest principles of food safety evaluation, coupled with the agency's extensive history of regulating food additives. FDA requires the strict use of standard tests and protocols to ensure that each material receives the same degree of careful scrutiny and that each material satisfies the same rigorous standard of safety. Many conservative assumptions have been built into FDA's evaluation process, so that any safety determination represents the safety of an exposure even larger than what is likely to occur. Thus, FDA's safety determination

[9] 21 C.F.R. 170.3(i) Safe or safety means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered: (1) The probable consumption of the substance and of any substance formed in or on food because of its use. (2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet. (3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.

[10] 21 U.S.C. § 348(c)(3)(A).

accounts for not only expected use, but also incorporates extra safety factors for additional public protection.

FDA also has established extensive guidance for the types and numbers of toxicology studies that will be required to support the safety of both direct and indirect food additives. One of the principal factors affecting the amount of data required is the anticipated human exposure to a material. In general, if the cumulative exposure of an FCS exceeds 0.5 parts per billion (ppb), toxicological testing will be necessary to show that the level of exposure is safe. FDA scrutinizes exposure studies very carefully because these estimates determine the amount of toxicology testing that will be necessary to evaluate the safety of the material. FDA's "Redbook" sets forth strict toxicity testing requirements for food additives, including FCSs. The Agency developed this rigorous testing process based on its extensive and long-standing experience evaluating the safety of food additives. Furthermore, the FDA uses threshold exposure levels with additional safety factors to establish low risk levels for FCSs.

Similar FDA and international regulatory authorities' considerations are in place for medical device packaging and also take into account specific performance standards to ensure the safety of drugs and medical products in the supply chain. These standards include important considerations and requirements related to the life cycle of medical devices and packaging, including sterile barrier systems, storage, distribution, and disposal. The Proposed Model Legislation runs counter to the international regulation and standard and could undermine the ability to meet key packaging performance standards.

Specific Chemical Classes

TPCH's model legislation in its current form undermines sound science and the interests of consumers by restricting entire classes of chemicals in packaging materials, regardless of the differences between different members of the class. Each of these broad categories of chemistry includes many different individual compounds that have their own unique properties and uses, as well as environmental and health profiles. This one-size-fits-all approach to chemical regulation is neither scientifically accurate, nor appropriate. Painting all chemicals that share some generic name with a broad brush makes for bad policy that can prevent consumers from accessing important, safe and beneficial products they need. We are also concerned that this proposal would change key policies that support recycling and would create new criteria for managing substances in packaging that could undermine effective packaging design.

Phthalates, for example, are not all the same. DINP and DIDP have been subjected to rigorous evaluations of potential risk with dietary exposure by regulatory agencies around the world over the last 8 years. Without exception, every evaluation has arrived at the same conclusion – there is no health concern for DINP and DIDP in the diet. Additionally, the regulation of phthalates in food

packaging has been under active review by the FDA since March of 2016. The FDA review is being conducted in a timely and thorough manner with a decision now pending.

Likewise, PFAS includes an incredibly broad range of materials. There is clear recognition of the different substances and categories within this broad class of chemistry by government authorities including EPA, FDA, OCED and the Interstate Technology and Regulatory Council

Inappropriate Focus on Specific Chemistries

As noted above, the proposed model legislation inappropriately groups a broad range of substance and fails to take a risk-based approach to chemicals management. Any consideration of specific chemistries should be risk-based and take into account the important differences within these broad classes of chemistry.

The term "PFAS" encompasses an extremely large and diverse group of chemical compounds with widely disparate physical, chemical and hazard characteristics. The different members of this universe are not the same and should not be regulated as a single group. As an example, fluoropolymers are one small subset of PFAS. In the case of fluoropolymers, several high molecular weight substances have been shown to clearly meet established criteria for polymers of low concern. Fluoropolymers are large, stable, inert polymeric molecules that are too large to cross biological membranes and therefore present little potential for human or environmental exposure. Their large size and physical and chemical properties also inhibit their migration, so they present little potential for human or environmental exposure. At the same time, fluoropolymers provide important functionality for various types of packaging – including for critical items such as pharmaceuticals.

Given their benign hazard profile and their low exposure potential, it would be arbitrary and inappropriate to restrict the use of fluoropolymers in packaging. It could also cause significant market disruption including in critical applications such as pharmaceuticals. Yet this is the perverse consequence that would flow from the one-size-fits-all approach of regulating all PFAS as a single group under Section 4 of the Model Legislation.

Socio-Economic Considerations

The proposed legislation in its current form would have significant socio-economic implications including economic, public safety and sustainability impacts. These need to be carefully considered and should be fully assessed to guide any potential updates to the TCPH model legislation.

We respectfully request an opportunity to meet with TPCH to discuss how stakeholder feedback will be considered in the development of any next draft of the Model Legislation. If you have any

questions on ACC's comments, please feel free to contact me by phone at 202-249-6198 or by email at brett_howard@americanchemistry.com.

Sincerely,

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