KELLER AND HECKMAN LLP
Serving Business through Law and Science®

1001 G Street, N.W.
Suite 500 West
Washington, D.C. 20001
tel. 202.434.4100
fax 202.434.4646

Writer's Direct Access
Devon Wm. Hill
(202) 434-4279
hill@khlaw.com

August 24, 2020

Via Electronic Mail

Toxics in Packaging Clearinghouse
c/o Northeast Recycling Council
139 Main Street
Suite 401
Brattleboro, Vermont 05301

Re: Plastics Industry Association Comments on the Draft Update to the Toxics in Packaging Model Legislation

Dear Sir or Madam:

On behalf of the Plastics Industry Association (PLASTICS),[1] we are writing to submit comments on the draft update to the Toxics in Packaging Clearinghouse's Toxics in Packaging Model Legislation. We understand that the proposal would add poly- and per-fluorinated substances (PFAS) and ortho-phthalates as regulated substances and also would provide a process for identifying future chemicals of high concern in packaging. PLASTICS' members fully support effective, science-based policies that protect public health and the environment, and we believe that such efforts can be successfully drafted in ways that would not inhibit the marketing of safe packaging and allow for innovations that benefit consumers.

We appreciate the opportunity to comment on this model legislation. Our members have extensive knowledge about food packaging substances and assessments of their safety, and we believe that our organization can provide unique insight into the proposed update to the model legislation. PLASTICS has been involved in the model legislation since the legislation was first proposed and introduced standards for heavy metals in packaging. The original version of the model legislation was adopted by 19 states because it enjoyed a broad consensus of support. We believe that this proposed update to the model legislation should be drafted in a manner that

[1] PLASTICS was founded in 1937, as the Society for the Plastics Industry (SPI) and is the trade association that represents one of the largest manufacturing industries in the United States. PLASTICS' members represent the entire plastics industry supply chain, including processors, machinery and equipment manufacturers, and raw material suppliers.

would also gain a broad consensus of support from legislators and stakeholders. In addition, to be effective, the model legislation should be clear in the regulatory requirements it would create to foster a high level of compliance without being unduly burdensome on industry or create adverse impacts on the consumers it aims to protect. For these reasons, we ask that the Toxics in Packaging Clearinghouse carefully consider our comments, which are set forth below.

I. Definition of PFAS is Overly Broad

In Section 3(l) of the proposed update to the Toxics in Packaging Model Legislation, "perfluoroalkyl and polyfluoroalkyl substances" or "PFAS" are defined as "all members of the class of fluorinated organic chemicals containing at least one fully fluorinated carbon atom." This definition of PFAS is extraordinarily broad and encompasses many different types of fluorinated materials, many of which do not have any health or environmental concerns, and which safely serve important technological roles in packaging applications. An example of why this overly broad definition is unworkable is polytetrafluoroethylene (PTFE). PTFE is an extremely valuable technology that does not have adverse safety issues, and a ban on its use would not help with accomplishing a goal of protection of human health and the environment. As written, PTFE would be encompaased within the term PFAS. To avoid incorporating fluorinated substances that do not have toxicity concerns, we believe more targeted language that specifically identifies perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), which have been questioned as posing potential concerns, reflects the current science and would, like the original model legislation, represent a consensus approach that does not disrupt the use of safe products.

To focus regulation only on materials that may have adverse health effects, we strongly urge that the definition of PFAS in the Toxics in Packaging Model Legislation be limited to encompass only PFOS and PFOA. We believe that the Toxics in Packaging Model Legislation's PFAS definition should be revised to read "fluorinated organic chemicals containing or derived from perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA)."

II. PFAS Impurity Threshold Needed

The Toxics in Packaging Model Legislation draft requires that PFAS not be intentionally added to packaging and that PFAS may not be detectable in packaging. No guidance is given, however, regarding what qualifies as "no detectable" PFAS. First, as described in Section I above, the definition of PFAS should be restricted only to PFOS and PFOA. Second, materials derived from PFOS/PFOA were used for many years, and the presence of extremely low levels of these substances as impurities in packaging is not uncommon because they may be present in the environment. Because of the potential for unintentional and unknown PFOS/PFOA at very low levels in packaging, it is not practical to set a residual level of zero for these materials. Further, providing only a qualitative "not detectable" limit does not ensure that each package is subject to the same requirement, as it is not possible to determine the compliance of a package as

one could always argue that a test method with a lower limit of detection could be developed. This uncertainty generates a substantial burden on industry and state regulators to define what data would support compliance with the Toxics in Packaging Model Legislation. Thus, it is imperative that a defined quantitative limit be provided for PFOS/PFOA in the draft Toxics in Packaging Model Legislation to provide practical criteria for ensuring compliance with the model legislation.

We strongly urge that, consistent with the residual limit for the heavy metal impurities already present in the Toxics in Packaging Model Legislation and the residual limit proposed for ortho-phthalates, which are both 100 ppm, the residual level of PFOS/PFOA also be limited to 100 ppm in the packaging. It is important to point out that a 100 ppm residual limit does not equate to exposure to these substances at this level; instead, actual exposure to PFOS/PFOA from packaging containing this maximum residual level would be far less than 100 ppm under the intended use of packaging materials, *i.e.*, packaging materials are not directly ingested and all of the PFOS/PFOA would not migrate from the packaging. Thus, the last sentence of Section 4(c) should be revised to read as follows: "The concentration levels of PFOS/PFOA incidentally present in any package or packaging component shall not exceed 100 parts per million by weight (0.01%)."

III. Ortho-Phthalates May Be Safely Used in Specific Applications

In Section 3(m) of the proposed update to the Toxics in Packaging Model Legislation, phthalates are defined to include "all members of the class of organic chemicals that are esters of phthalic acid and that contain 2 carbon chains located in the ortho position." This definition assumes that all ortho-phthalates are equal in terms of the potential concerns they raise to human health from their use in packaging. In actuality, not all ortho-phthalates have a common mechanism of action and are not expected to have similar adverse toxicity.

In addition, ortho-phthalates are safe when used in specific applications. It is important to note that regulation should be based on risk and not on hazard alone. Hazard is simply the acknowledgment that a chemical can cause harm based on the intrinsic properties of the chemical. Hazard is typically described as adverse effects that may occur at a *certain dose* of a chemical. Just because a chemical has the ability to cause harm does not mean that it will. Thus, not all hazards represent a risk of harm. Hazard without risk is really no danger at all.

Risk, on the other hand, is the likelihood that the hazard will actually cause harm based on the anticipated exposure to the chemical (Risk = Hazard x Exposure). Although hazard identification is essential to conducting a risk assessment, it is the chance that the hazard will cause any harm, or risk, that is the question that must be answered when determining whether to regulate a chemical used in packaging materials.

Many packaging chemicals, including several ortho-phthalates, have a safe limit of acceptable exposure that has been derived from toxicological data. If exposure remains below this limit, which is the case for the ortho-phthalates currently used in packaging applications, there is no risk.

Food packaging represents the most sensitive type of packaging as a route of exposure to ortho-phthalates because low levels of dietary exposure could result from migration of ortho-phthalates to food. Only four ortho-phthalates are used in food packaging applications – bis(2-ethylhexyl)phthalate (DEHP), di-isononylphthalate (DINP), di-isodecylphthalate (DIDP), and dicyclohexyl phthalate (DCHP). Specifically, DEHP and DIDP are used only in repeated-use applications and in limited single-use beverage can liners and seals in contact with aqueous food only. DINP is used only in repeated-use applications and in limited single-use beverage closures in contact with aqueous food and film wrap in contact with dry food. DCHP is used only on the exterior of food-contact containers. The exposure to these four ortho-phthalates still in use is extremely low from these applications and is well within the safe levels of these substances derived from available toxicology data.

FDA is currently undertaking a re-assessment of the safety of several ortho-phthalates used in food packaging; specifically, DEHP, DINP, DIDP, and DCHP. An industry-sponsored petition is under consideration by FDA to remove the clearances for 26 other ortho-phthalates that are no longer used in food-contact applications. FDA's re-assessment is nearing completion, but we are confident that the Agency will base its decision on a thorough risk assessment of the hazards presented and the current levels of exposure to these substances. Because FDA's assessment is expected to be published soon, we strongly urge the Toxics in Packaging Clearinghouse to wait to consider ortho-phthalates until FDA completes its assessment.

FDA's re-assessment of these four ortho-phthalates highlights the rigorous federal regulatory scheme in place for food packaging chemicals, which represents the most sensitive use of packaging chemicals in all types of packaging. Before bringing a product to market, manufacturers must ensure that their food packaging complies with the Federal Food, Drug, and Cosmetic Act (FFDCA) and FDA's implementing regulations. FDA has assigned an entire office, the Division of Food Contact Substances, which employs over 30 scientists, for the sole purpose of evaluating the safety and environmental impact of chemicals used to produce food packaging. FDA's pre-market approval results either from the submission of a food additive petition or Food Contact Notification (FCN). Under the FCN program, which is the current way in which new food packaging materials are cleared, FDA reviews information about the identity of the substance, how it will be used, how much migration and dietary exposure is expected to result, and data demonstrating a lack of safety concern resulting from a lifetime exposure to the substance when it is used as intended. After a food additive regulation is finalized or an FCN becomes effective, the Agency continues to monitor public information and data regarding the safety of approved substances.

This robust regulatory scheme ensures that all substances used in food packaging are evaluated to establish their safety prior to being placed on the market and continually monitored to ensure that their safety is assured. In addition, many non-food packages also comply with FDA requirements to provide assurance of their safety. FDA can and does take action against previously reviewed materials if the Agency has reason to believe that the substance poses a health or safety concern. Because food packaging is the most sensitive type of packaging, FDA's regulations often provide a benchmark of safety for other types of packaging materials.

It is worth noting that the European Food Safety Authority (EFSA), which also conducts pre-market risk assessments of food packaging chemicals, recently completed its re-assessment of five ortho-phthalates used in food packaging applications: di-butylphthalate (DBP), butyl-benzyl-phthalate (BBP), DEHP, DINP, and DIDP.[2] EFSA concluded that current exposure to these five phthalates from food is not a concern for public health and that the current levels of exposure to these five phthalates were within the tolerable daily intake (TDI) levels derived for these substances. As noted above, FDA's re-assessment of certain ortho-phthalates has not yet been completed, but it would not be a surprise if FDA came to a conclusion similar to EFSA.

IV. Definition of Package is Overly Broad

Sections 3(j) and (k) of the proposed updated Model Legislation define "package" and "packaging component" to encompass a wide variety of materials from containers and components thereof to films, trays, bags, blocking, bracing, and weatherproofing, among other materials. These definitions would apply the requirements of the updated Model Legislation to materials that would not be expected to lead to any significant exposure of the regulated chemicals from their intended use. The likely exposure from certain materials that would fall under the broad definitions of "package" and "packaging component" in the current proposed draft of the Model Legislation should be considered to determine whether they warrant inclusion within the scope of the Model Legislation. For example, items such as "interior or exterior blocking, bracing, cushioning" likely do not represent a concern for exposure to the identified packaging chemicals of high concern warranting regulation. In addition, exposure to the identified packaging chemicals of high concern would be expected to be extremely low from repeated-use packaging, which would currently be included within the definitions in Sections 3(j) and (k). Considering the likely exposure to the various materials listed within the definitions for "package" and "packaging component," we suggest that the definitions be updated as follows:

---

[2] *See* Update of the risk assessment of di-butylphthalate (DBP), butyl-benzyl-phthalate (BBP), bis(2-ethylhexyl)phthalate (DEHP), di-isononylphthalate (DINP) and di-isodecylphthalate (DIDP) for use in food contact materials, EFSA Journal 2019;17(12):5838, available at http://www.efsa.europa.eu/sites/default/files/scientific_output/efs2_5838_Rev4.pdf.

- Section 3(j): "Package" means any single-use container, produced either domestically or in a foreign country, providing a means of marketing, protecting or handling a product. "Package" shall also mean and include such unsealed single-use receptacles as cups, pails, rigid foil and other trays, wrappers and wrapping films, bags, and tubs.

- Section 3(k): "Packaging component" means any individual assembled part of a package as described in Section 3(j) which is produced either domestically or in a foreign country, including coatings, closures, inks, dyes, pigments, adhesives, stabilizers, labels, or any other additives. Tin-plated steel that meets the American Society for Testing and Materials (ASTM) specification A623 shall be considered as a single package component. Electro-galvanized coated steel and hot dipped coated galvanized steel that meets the American Society for Testing and Materials (ASTM) specifications A653, A924, A879, and A591 shall be treated in the same manner as tin-plated steel.

V. Intentional Introduction Definition Should Be Updated to Reflect New Revisions

The definition of "intentional introduction" in Section 3(g) includes an exemption for processing agent uses of a regulated metal. Further in the same sentence, however, the exemption appears to apply to "incidental retention of a residue of said metal or chemical." Given the inconsistent language, it appears that the first part of the exemption was not updated when the draft Toxics in Packaging Model Legislation was updated to include other regulated chemicals. Thus, we suggest that the language in the second paragraph of Section 3(g) be updated as follows: "The use of a regulated metal or other regulated chemical as a processing agent or intermediate to impart certain chemical or physical changes during manufacturing, whereupon the incidental retention of a residue of said metal or chemical in the final package or packaging component is neither desired nor deliberate, is not considered intentional introduction for the purposes of this Act where said final package or packaging component is in compliance with Section 4 of this Act."

VI. Identification of a Packaging Chemical of High Concern Should be Based on Sound Science and Accepted Risk Assessment Principles

Section 6(1) of the proposed update to the Toxics in Packaging Model Legislation provides several criteria for identifying additional packaging chemicals of high concern. It is important that the stated criteria ensure that packaging chemicals that are identified as being of high concern have an adverse environmental or health impact. Many of the criteria for identifying a packaging chemical of high concern depend on credible scientific evidence demonstrating that one or more criteria has been met. "Credible scientific evidence" itself is defined in Section 3(c) to include a study that has undergone peer-review. We suggest that this definition of "credible scientific evidence" be updated to require a weight of evidence review of

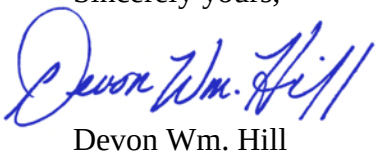
multiple peer-reviewed studies in more than one journal or publication to serve as the basis for identifying a chemical as a packaging chemical of high concern. A single study published in a peer-reviewed journal or by a governmental agency indicating an adverse effect is not sufficient to demonstrate that a chemical should be banned. As it currently reads, chemicals could be identified as packaging chemicals of high concern that are not truly of high concern. This could lead to an expenditure of finite resources on chemicals that do not pose any environmental or human health concerns.

We also suggest that one of the criteria identified in Section 6(1) be removed. Specifically, Section 6(1)(C)(1) allows a chemical to be listed based on biomonitoring study data in lieu of credible information demonstrating that a chemical is actually used in packaging. The presence of a chemical in the body could come from many other sources and should not be presumed to come from packaging. In addition, biomonitoring studies do not in themselves demonstrate that a chemical presents a health or environmental concern. Biomonitoring studies alone, in the absence of other studies indicating that it has potential adverse health or environmental effects, should not be a basis for identifying a chemical as a packaging chemical of high concern.

* * *

We appreciate this opportunity to comment on the proposed update to the Toxics in Packaging Model Legislation, and we look forward to working with the Toxics in Packaging Clearinghouse on the evolution of the model legislation. Should you have any questions or concerns, please do not hesitate to contact me.

Sincerely yours,



Devon Wm. Hill
General Counsel to PLASTICS' Food, Drug, and Cosmetic Packaging Materials Committee