



March 10, 2021

***Via Electronic Mail***

Ms. Kerri Malinowski  
Maine Department of Environmental Protection  
17 State House Station  
Augusta, ME 04333-0017

**Re: Plastics Industry Association Comments on the Draft Food Contact  
Chemicals of High Concern Criteria**

Dear Ms. Malinowski:

We are submitting comments on the Maine Department of Environmental Protection's (DEP) Draft Food Contact Chemicals of High Concern Criteria Documentation on behalf of the Plastics Industry Association's (PLASTICS) Food, Drug, and Cosmetic Packaging Materials Committee (FDCPMC).<sup>1</sup> Maine has identified certain substances as "food contact chemicals of high concern" in accordance with the Toxic Chemicals in Food Packaging (TCFP) legislation<sup>2</sup> in order to gather information on their use in food packaging available in Maine.<sup>3</sup> We appreciate the opportunity to comment on the Maine Department of Environment Protection's (DEP) efforts to implement the TCFP law.

PLASTICS' members marketing food packaging materials are committed to providing safe food packaging materials to consumers in Maine and across the United States. Our members fully support effective, science-based regulations that protect public health and the

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<sup>1</sup> 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. The FDCPMC is composed of PLASTICS members with particular interest and expertise in packaging for food, drugs, cosmetics, and related products. The Committee has cooperated with government agencies on regulatory issues concerning packaging since its formation in 1957.

<sup>2</sup> This legislation amended the Act to Protect the Environment and Public Health by Further Reducing Toxic Chemicals in Packaging (32 MRSA §§1731-1747).

<sup>3</sup> See Food Contact Chemicals of High Concern Criteria Documentation, available at <https://www.maine.gov/dep/comment/comment.html?id=4119170>; see also Title 32, Chapter 26-B §1741-1747.

environment without unnecessarily inhibiting the marketing of safe food packaging. PLASTICS' members are pleased to assist Maine's DEP in its mandate under the TCFP, but we emphasize that food packaging manufacturers take the safety of their products used in the food supply very seriously. Our members rigorously evaluate the safety and legal compliance of every component of their materials, including any impurities that could be present. We note that the majority of substances identified by Maine's DEP in the criteria documentation are generally not intentionally used in food packaging or are used under conditions that ensure they would not pose a safety concern to consumers. We believe the criteria documentation should focus on chemicals actually used in packaging. Focusing on chemicals currently used would avoid raising unnecessary consumer concern about the safety of their food and would also focus Maine's resources on relevant public health concerns.

## **I. FDA Regulations Ensure that Food Packaging is Safe**

All food packaging marketed in the United States is required by law to be safe for its intended use. The Federal Food Drug and Cosmetic Act (FFDCA) authorizes the Food and Drug Administration (FDA) to regulate substances that have the potential to migrate from packaging to food and, since the passage of the 1958 Food Additives Amendment, FDA has established a rigorous pre-market program that ensures all products used in contact with food meet the same standard for safety as products used as or in food.

Food packaging serves a very important role ensuring the safety of the food supply. Food contact materials are carefully designed to be inert and are selected for their technical properties and safety. Food packaging protects food from contamination, including food-borne illness, and increases shelf-life, reducing food waste. FDA's comprehensive risk-based approach to the regulation of food contact materials and packaging manufacturers' assessments of the impurities that are present in the cleared materials, discussed below, assure the health and environmental safety of new and existing food packaging materials and allows for innovative technologies to come to market.

Before bringing a product to market, manufacturers must ensure that their food packaging complies with the FFDCA and all applicable FDA regulations. For intentionally-added substances, FDA's approval of a food-contact substance results either from an existing clearance in FDA's regulations or the submission of a Food Contact Notification (FCN). Under the FCN program, which is the current way in which many new food packaging materials are cleared, FDA reviews information regarding the identity of the substance, how it will be used, how much of the substance and any impurities could get into food and be consumed, and specific toxicity data supporting the safety of the substance. Importantly, the amount of data needed to support safety is directly correlated to the potential dietary exposure – the higher the exposure, the more toxicity data needed to support safety.

It is legally required for food packaging manufacturers to ensure that any impurities or contaminants that are present in food packaging materials are safe when the material is used as intended.<sup>4</sup> Manufacturers of food packaging carefully and routinely evaluate their products for the presence of contaminants, residual starting materials, and other manufacturing impurities to ensure that they are safe. As with intentionally-added components of food packaging, an evaluation of the safety of impurities entails an assessment of how the finished packaging will be used, the identity of the impurity, how much migration and dietary exposure is expected to result, and the toxicology data supporting the safety of the substance at the exposure level.

PLASTICS' FDCPMC and its members would be happy to engage with DEP to provide additional information regarding the steps that food packaging manufacturers take to ensure that the materials placed in contact with food are safe.

## **II. Maine's Food Contact Chemicals of High Concern are Generally Not Intentionally Added to Food Packaging**

Maine's TCFP requires DEP to identify no more than ten food contact chemicals of high concern,<sup>5</sup> and authorizes DEP to regulate food packaging manufacturers and distributors of those substances. We believe that several of the substances DEP has identified have never been intentionally used in food packaging. Several more of these substances were removed from use in food packaging years ago,<sup>6</sup> are present only as impurities, and result in extremely low-level exposures. The remaining substances, namely bisphenol A (BPA) and styrene, are explicitly cleared as starting materials for use in specific food contact applications by FDA and have been determined to be safe for these uses. For both BPA and styrene, industry and the federal government have recently invested a great deal of effort and financial resources toward conducting toxicology studies and robust risk assessments to confirm that the current uses of these substances in food packaging are safe.

One material on the proposed list of food contact chemicals of high concern that should be present in food packaging today only as an impurity is benzene. We may use benzene as an

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<sup>4</sup> 21 C.F.R. § 174.5 ("General provisions applicable to indirect food additives") requires in paragraph (a)(2) that the material be "of a purity suitable for its intended use."

<sup>5</sup> See 32 MRSA §1741(9) "'Food contact chemical of high concern'" means a chemical identified by the department pursuant to section 1742"; see also 32 MRSA §1732 "'Chemical' means a substance with a distinct molecular composition or a group of structurally related substances and includes the breakdown products of the substance or substances that form through decomposition, degradation or metabolism."

<sup>6</sup> Additionally, manufacturers of food packaging wherein those substances are present as contaminants are exempted from the requirements of TCFP. See 32 MRSA §1746(3).

example to illustrate how industry continues to ensure the safety of contaminants that may be present in food packaging at *de minimis* levels. Because benzene *per se* is not used as a solvent in food packaging applications, it would only be present at extremely low levels in food packaging currently on the market in Maine, if at all. Using a risk-based approach to evaluate exposures to benzene (and many other substances that could be contaminants in food packaging), FDA has developed an exposure standard that would require residual benzene levels in food packaging to be well below the 100 ppm *de minimis* level set by DEP.<sup>7</sup> A risk-based strategy that is protective of health and safety is employed for all contaminants in food packaging that may have toxicity concerns.

Although the use of BPA has been abandoned for use in baby bottle applications and has been deselected by brand owners in other applications, it is still subject to clearances in the food additive regulations for specific uses.<sup>8</sup> To determine whether the use of BPA is safe under these circumstances, FDA, the National Toxicology Program (NTP), and the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH) conducted an extremely robust two-year study at FDA's National Center for Toxicological Research (NCTR) as part of the Consortium Linking Academic and Regulatory Insights on BPA Toxicity (CLARITY-BPA). CLARITY-BPA was a multimillion-dollar, multi-year cooperative effort that resulted in perhaps the most robust government-sponsored toxicology study ever conducted. The results of the core study were published in 2018 and a peer review of the core study was conducted that same year. The core study and FDA's updated risk assessment concluded that exposure to BPA is safe from currently authorized uses. We respectfully submit that DEP should rely on the conclusions of the robust CLARITY-BPA study and FDA's risk assessment rather than contradict this herculean effort and reconsider listing BPA as a food contact chemical of high concern.

CLARITY-BPA represents the most robust investigation into the toxicity of BPA but was not cited as a reference in the Draft Food Contact Chemicals of High Concern Criteria Documentation. Given the breadth and scope of the CLARITY-BPA study, and its conclusions supporting the safe use of BPA as currently authorized in food packaging applications, we suggest that DEP review CLARITY-BPA when reconsidering whether to list BPA as a food contact chemical of high concern.

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<sup>7</sup> FDA requires exposures to contaminants that have carcinogenicity concerns be negligible, which is defined as a one-in-one million level of risk.

<sup>8</sup> BPA is primarily regulated as a monomer in the manufacture of polycarbonates (21 C.F.R. § 177.1580) and epoxy-based enamels and coatings (21 C.F.R. § 175.300).

### **III. DEP Has Failed to Properly Describe a Nexus between the Substances Identified and the Regulations Placed on Manufacturers**

As discussed above, the TCFP requires that DEP identify food contact chemicals of high concern and impose regulatory requirements upon food packaging manufacturers and distributors. Furthermore, the Department must determine that there is “strong credible scientific evidence” that the chemical is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen and meets other criteria. Therefore, the statute contemplates a nexus between the chemicals identified, the resulting regulatory decisions made by DEP, and the public health of Maine’s citizens. A rational reading of the statute requires that the chemical listings determined by DEP be based on current data that demonstrate that the chemicals are used in food packaging sold in Maine. As the regulating authority, DEP has an obligation to provide detailed information that documents the basis for a priority food contact chemical listing. The Draft Food Contact Chemicals of High Concern Criteria Documentation does not provide this nexus or detailed information.

As stated above, many of the listed food contact chemicals of high concern are not currently intentionally used in food packaging. Thus, regulating these chemicals would not provide a benefit to the public health of the citizens of Maine and would unnecessarily raise alarm regarding the safety of the food supply in Maine’s citizens. PLASTICS is happy to provide information on the use of specific substances in food packaging upon request.

Given the time allotted for providing comments on this regulatory action, our comments reflect only a brief overview of a selection of the substances DEP identified and their use (or lack thereof) in food contact applications. As noted throughout our comments, we welcome the opportunity to provide additional information on the safety of food packaging, generally, and specific information DEP may need to meet its statutory obligations. As stated above, PLASTICS would be happy to engage with DEP to discuss the steps that food packaging manufacturers take to ensure that food packaging is safe and does not adversely impact the health of Maine’s citizens or the broader U.S. public.

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We appreciate this opportunity to comment on the Draft Food Contact Chemicals of High Concern Criteria Documentation. Should you have any questions about our comments, please do not hesitate to contact me.

Ms. Kerri Malinowski  
March 10, 2021  
Page 6

Sincerely yours,

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