



March 10, 2021

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

Subject: American Chemistry Council Comments on Maine Draft Food Contact Chemicals of High Concern Criteria Documentation (Maine Law 32 MRSA 1742(1))

Dear Ms. Malinowski:

The American Chemistry Council (ACC)<sup>1</sup> appreciates the opportunity to provide comments on the Maine Department of Environmental Protection (DEP) draft Food Contact Chemicals of High Concern (CHC) list published on February 8, 2021. This list was developed in response to Maine's Toxic Chemicals in Food Packaging legislation, which requires Maine to publish a list of up to but no more than ten food contact chemicals of high concern. The primary purpose of the list is to help the State gather information on whether these chemicals are currently used in food packaging in Maine. Our comments follow.

**DEP Should Extend the Comment Period to Receive Input and Ensure Adequate Notice to the Stakeholder Community of the Proposed List**

DEP posted the draft list and criteria documentation for comment on February 8<sup>th</sup> with a comment deadline a month later, March 10. ACC is concerned that this period is too short to provide affected stakeholders adequate notice or an opportunity to comment. We expect that many stakeholders may be unaware of this regulatory activity, and likewise be unaware of a notification requirement triggered by the list itself. This is particularly the case for smaller manufacturers, given that the statute defines manufacturer at §1741(12) as not just any person who manufactured a food package, but also any person whose "brand name is affixed to a food package," which could include small vendors at farmer's markets, for example.

The statute does not require that DEP finalize the list on any particular time frame. Section 1742 merely requires DEP to publish a list of no more than 10 food contact chemicals of high concern. Accordingly, we recommend that DEP extend (or reopen, as appropriate) the public comment

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<sup>1</sup> 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.



period for the required list to accept comment for an additional 60 days (total comment period of 90 days), accompanied by a public stakeholder workshop within the next 30 days to accept comment. These steps will help ensure adequate notice and the opportunity to be heard.

### **DEP Should Not Rely on the EU’s Endocrine Disruptor “Lists” as the Basis for Categorizing Chemicals**

The EU’s Endocrine Disruptor Assessment List includes substances undergoing an assessment under REACH or the Biocidal Products Regulation. The Explanatory Note makes clear that one possible outcome of such an assessment is that a substance is not considered to have ED properties. The EU’s REACH Candidate List for Authorization includes many chemicals that lack endocrine disrupting properties. These lists are not suitable for use to identify chemicals as “endocrine disruptors.” We encourage DEP to correct its Criteria Documentation accordingly, and to avoid using these lists for future designations.

### **DEP Should Provide Greater Clarity with Respect to the Criteria and Weighting Applied in the Selection of Chemicals for the List**

The statute does not merely allow DEP to pick chemicals from other lists as the basis for selecting them and creating a high priority list. It specifically requires DEP to determine that there is “strong credible scientific evidence” that a chemical to be listed is a reproductive or developmental toxicant, endocrine disruptor or human carcinogen and meets other criteria. DEP must apply appropriate analysis and deliberation in order to do this. The agency’s reasoning should be set out in the Criteria Documentation. Without this explanation, it is not clear that the agency has undertaken the reasoned decision making required by the Maine Administrative Procedure Act.

With respect to the statutory criteria, we recommend that DEP develop a set of risk-based principles to inform the selection of any chemicals to be designed as a high priority. The corollary is that these principles also yield a framework for chemicals that should be a low priority. For example, chemicals that are already well-regulated and low risk (i.e., determined by an authoritative body to be safe for use in food contact applications) should thus be low priority, and should not be designated. Considerations for not selecting a chemical for the list could include factors such as:

- The chemical has been the subject of a recent and rigorous scientific evaluation by an authoritative body, which has subsequently confirmed the safety of/low environmental impact of the chemical in the same food contact product(s) being considered by DEP;
- The chemical has recently completed risk evaluation by an authoritative body and found to have no unreasonable risk in the same food contact product(s) being considered by DEP;
- The chemical has completed a risk management process by an authoritative body with respect to the same food contact product(s) being considered by DEP;
- The chemical has been removed from one or more of the source lists of chemicals identified for this program;



- The chemical has completed a recent and rigorous alternatives analysis by an authoritative body or credible and qualified third party that applies to the same food contact product(s) being considered by DEP;
- Stakeholders submit credible evidence that purchase/access to the product(s) being considered by DEP is no longer available to a population of particular concern (e.g., children, workers);
- Stakeholders submit credible evidence that exposures to Maine residents to a chemical of interest from food contact product(s) is low.

By way of example, both BPA and styrene are already well regulated by the US Food and Drug Administration for use in food contact packaging. FDA, the National Toxicology Program (NTP), and the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH) recently completed a peer-reviewed study on BPA at FDA's National Center for Toxicological Research (NCTR). FDA subsequently updated its risk assessment of BPA, determining that BPA is safe as used in food contact packaging. This determination was based on a rigorous, two year review led by expert scientists, and is recent, with the publication of the peer-reviewed report in 2019. Disciplined application of science and risk-based criteria would suggest that BPA should be a low priority for selection. ACC recommends that DEP not move forward with the proposed list, but instead develop science and risk-based principles for identification. Whether a chemical is currently authorized by FDA as safe for use in specific food contact applications should also be part of the decision making framework. We further recommend that the agency provide formal notice of these principles and take public comment on them.

**DEP Should Confirm that any Chemicals it Selects for Listing are Currently in Food Packaging and that Presence of the Chemical in Food is from the Food Packaging**

Chemicals can be present in foods from sources other than food packaging, and in some cases, the chemical occurs naturally in the food itself. For example, styrene is a natural constituent in a variety of foods and beverages that can occur by fermentation. Detection of styrene in packaged cinnamon might not derive from the food packaging at all but from the cinnamon itself. DEP's selection process should conduct sufficient due diligence to sufficiently connect a chemical of interest to the food contact product. This exercise would be well-informed by a crosswalk exercise against current FDA food contact authorizations and current market data. Authorizations and market conditions for food contact materials can and do change over time, so DEP should use current information rather than rely on reports of what may have been in use or found historically. ACC recommends that DEP set out its determination, based on current and reliable information that there is an appropriate nexus between the chemical at issue, food packaging, and food to support each proposed listing.

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Thank you for your consideration of these comments. If you have any questions on ACC's comments, please feel free to contact me at [karyn\\_schmidt@americanchemistry.com](mailto:karyn_schmidt@americanchemistry.com).

Sincerely,



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Senior Director, Regulatory & Technical Affairs  
American Chemistry Council

cc: Melanie Loyzim, Commissioner  
Margaret Gorman, Brett Howard, Kuper Jones, ACC

