

Food Contact Chemicals of High Concern

RESPONSE TO COMMENTS

Commenters

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Summary of Comments and Department Response

- 1. Comment:** Commenter suggests that the stakeholder comment period should be extended to provide effected stakeholders, particularly smaller manufacturers that may be captured by the statutory reporting requirements, with adequate opportunity to comment; suggesting that the Department reopen the comment period for an additional 60 days (creating a total comment period of 90 days) and include a stakeholder workshop scheduled within 30 days of the comment period's closing. Commenter states that the European Union's Endocrine Disruptor Listing is not suitable for use as an authoritative reference to meet a chemical's endocrine disruptor listing criteria. Commenter states that the Department must apply appropriate analysis and deliberation to determine that a chemical listed as a food contact chemical of concern meets the statutory listing criteria. Commenter recommends that the Department develop risk-based principles to inform the selection of chemicals chosen for listing. This would create a framework for also grouping chemicals that are well-regulated and low-risk, such that it becomes clear which considerations are used in the weighting of evidence for listing or not listing a chemical according to statutory criteria. Because some chemicals can be present in foods from sources other than food packaging, particularly when the chemical is naturally occurring, the commenter suggests that the Department use current and reliable information that creates a nexus between the chemical, the food packaging, and the food itself in order to best support each chemical's appearance on the regulatory list. (Commenter 1)

Response: The governing statute for this draft chemical list directs the Department to generate a list of no more than 10 food contact chemicals of high concern using specific criteria detailed in law. The process of determining which chemicals would become listed is not required to move through a rulemaking procedure, making the comment period provided by the Department an intentionally added opportunity to engage stakeholders. This voluntary step by the Department was intended to encourage thoughtful stakeholder participation and is an example of the agency's commitment to transparency. The 30-day comment period is common for the Department's stakeholder engagement process, and, whereas, several in-depth comments have been received, the Department is comfortable that the time provided for public comment has been sufficient.

Development of the proposed food contact chemicals of high concern list went through internal review and peer scrutiny before being published for public comment. The general deliberation process used to generate the proposed list of food contact chemicals of high concern centered on the procedure developed by Maine CDC to determine Maine's Chemicals of High Concern in Children's Products. However, because the food contact list of chemicals involves the potential of higher chemical concentrations having a more direct path of exposure by ingestion, the Department determined that exclusively adhering to such a narrow approach would be less protective given the statutory charge. Therefore, the Department broadened the scope of acceptable evidence to meet statutory listing criteria to include chemicals with health based classifications beyond those considered top tier.

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The Department acknowledges in the food contact chemicals of high concern draft documentation that the research performed is not exhaustive. Information, in a variety of forms and perspectives, can be vast and of varying quality. The Department's research focused on impartial, authoritative sources that would support a compound's inclusion on the draft list based on meeting statutory criteria. Given the elevated risk to consumers by an increased frequency of exposure and concentration presented by the ingestion of contaminated food, the Department deviated slightly from the narrow scope of reference criteria tied to listing only top tier classifications. In doing so, the Department will have a greater opportunity to understand how chemicals with concerning health effects may be used in food packaging in a way that could lead to consumer exposure and whether there is cause to pursue other protective policy measures.

- 2. Comment:** Commenter is concerned that styrene is incorrectly listed on the draft food contact chemicals of high concern. Specifically, commenter states that the draft list mistakenly cites an outdated European Union reference which does not classify styrene as a Category 1 endocrine disruptor, particularly considering that the report relied upon does not provide an objective assessment of the current state of the science on endocrine disruption. Commenter also states that the International Agency for Research of Cancer (IARC) erroneously classified styrene as a Group 2A carcinogen in 2018 based on changes to the technical guidelines IARC has made since its 2002 assessment of styrene. Commenter states that those changes fall short of meeting current scientific standards of transparency and objectivity. Commenter concludes that there are no strong or consistent indications that styrene causes any form of cancer in humans and that available evidence does not suggest that low exposures are a concern. All of which leads the commenter to state that styrene presents a low risk to consumers from food packaging exposure, and any potential risks to consumers may be within acceptable exposure and considered safe. (Commenter 2)

Response: During the development of this draft list of food contact chemicals of concern, the Department looked to the current list of Maine's Chemicals of Concern and Chemicals of High Concern under the Toxic Chemicals in Children's Products law to determine where there may be appropriate overlap for chemicals that could be used in food contact materials. Though its presence on Maine's Chemicals of Concern helps styrene meet the criteria for listing, the Department also provides additional references that further support the chemical's presence on this draft list of food contact chemicals of high concern; and found the chemical's classification as a Group 2A Carcinogen by the International Agency for the Research of Cancer compelling. The result provides confirmation that the criteria for listing styrene on this draft food contact chemical of high concern is met. The listing of this compound has the potential to provide the Department with important information about how styrene is currently being used in food packaging available to Maine consumers.

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- 3. Comment:** Commenter suggests that the Department group chemicals that are structurally related in order to pursue a class-based approach to chemical listing. Commenter suggests that in doing so the Department will be more closely following the intent of the statutory definition of “chemical”. Commenter also suggests that the proposed chemical list is deficient by its failure to include perchlorate and its salts on the draft list of food contact chemicals of high concern; citing references stating perchlorate shows endocrine disrupting impacts, with particularly targeted effects on the thyroid. Commenter notes that the section of statute describing a sales prohibition on the use of phthalates and PFAS chemicals in food packaging was absent from this draft list of food contact chemicals and should have been specifically noted in the draft document’s explanatory section so that stakeholders are not mislead to believe that phthalates and PFAS have not been addressed by regulation. (Commenter 3)

Response: The Department appreciates the commenter’s perspective on chemical class listing and the desire to capture a greater number of compounds on this draft list. The Department took advantage of the statutory definition of chemical by grouping some of the similarly structured chemicals present on the draft list where it made sense to do so. However, the Department found it of value to differentiate between some of the compounds that may be similar in order to highlight their use and the importance of their presence on this list.

The Department undertook a detailed review of perchlorate and its salts (to include magnesium perchlorate, potassium perchlorate, ammonium perchlorate, sodium perchlorate, and lithium perchlorate) and found that, while the potential thyroid effects of perchlorate are concerning, the criteria for listing could not be met for all of its associated salts equally. Each salt, having its own Chemical Abstract Service Registry Number, must be scrutinized to meet statutory criteria for listing, the same as any individual chemical. Beyond a lack of cohesive evidence linking all of the perchlorate salts to adverse health effects, there is a lack of evidence that each of the perchlorate salts is used in food packaging; for example ammonium perchlorate is well known for its use in rocket fuel and industrial applications (EPA IRIS Assessment (2005)) but not necessarily as a food contact chemical. Further, the U.S. Department of Health and Human Services reviewed findings of perchlorates in food, and the evidence suggests that most levels measured in food are from water contaminated with perchlorate being used in farm irrigation; this same report concludes that estimated dietary intake levels of perchlorate from food are not expected to affect human health (U.S. DHHS, ATSDR Toxicological Profile for Perchlorates (2008)). Without the evidence to confirm that the criteria is met for all chemicals that would appear as part of a group approach to the listing of this compound, the Department could not add perchlorate and its salts to the draft food packaging chemicals of high concern at this time.

The Department’s *Food Contact Chemicals of High Concern Criteria Documentation* is intended to provide the reader with insight into the criteria and references relied on for each of the chemicals present on this draft list. The primary location for information about

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Maine's food packaging regulation is the program's webpage [<https://www.maine.gov/dep/safechem/packaging/index.html>]. At the landing page for this program, a person reviewing information about the food packaging regulation is immediately presented with information about the State's sales prohibition on phthalate use in food packaging and related PFAS rulemaking. This information is presented prominently to make clear that there has been regulatory action taken on phthalates and PFAS use in food packaging; adding that extra information to the draft list of food contact chemicals of high concern would, therefore, be redundant and unnecessary.

- 4. Comment:** Commenter states that the Department does not provide sufficient justification that either nonylphenol (NP) or 4-octylphenol (4-OP) would be present in food contact packaging at sufficient levels to support listing these chemicals as food contact chemicals of high concern. Commenter explains that neither compound is intentionally added, as defined by the relative statute, but are used as processing agents or intermediates in the manufacturing process. Commenter also states that the biomonitoring data relied upon for listing 4-OP does not imply that the levels found cause adverse health effects, and that 4-OP is largely undetectable leaving the U.S. CDC to end its biomonitoring for 4-OP. Commenter also cites studies that challenge listing evidence of the reproductive hazard classification for nonylphenol. These include multigeneration rat studies that reviewed reproductive and fertility effects of NP, showing no indication of adverse effects. Commenter also cites a study that established a high margin for exposure to NP from a variety of food sources, including packaged food, which indicated reasonable certainty of no harm; indicating NP's presence on this list is not warranted. (Commenter 4)

Response: The Department appreciates the additional insight into the uses of 4-OP and NP. Evidence relied on to meet the criteria for listing these two compounds included their health hazard classification by impartial, authoritative government entities. The Department continues to have confidence in the work of those authoritative bodies and commonly relies on assessments produced by such sources to meet policy conditions. In addition to their health hazard classifications, criteria for listing 4-OP included its detection in commonly available foods and nonylphenol's detection in biomonitoring studies. Because of this, the Department is interested in better understanding whether these two compounds continue to be used in food packaging available to Maine consumers and if that presence might lead to concern for harm due to exposure through foods contained in those packages. It is also worth noting that nonylphenol has already been designated a Priority Chemical under the Toxic Chemicals in Children's Products law due to health concerns based on exposure from consumer products, giving the Department confidence that there is sufficient cause for concern about this chemical's use in food packaging and subsequent consumer exposure. As a point of clarification, evidence of a minimum level of a chemical in food contact packaging is not a requirement for a compound's listing on Maine's food contact chemicals of high concern.

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- 5. Comment:** Commenter points out that the Food and Drug Administration (FDA) regulates substances that have the potential to migrate from packaging to food and has established a rigorous pre-market program, which includes FDA's comprehensive risk-based approach to regulating food contact materials. Commenter states that the compounds on Maine's draft food contact chemicals of high concern list are generally not intentionally added to food packaging but are present as impurities. Commenter states that substances such as bisphenol A and styrene have been cleared as starting materials for use in specific food contact applications by the FDA and determined safe for this use. Commenter suggests that benzene may only be present in food packaging as an impurity and may only be present in food packaging at extremely low levels. Commenter also cites a robust study (CLARITY-BPA) which concluded that exposure to BPA is safe for currently authorized uses. Commenter interprets the governing statute as directing the Department to base listing determinations on current data that demonstrate that the chemicals are used in food packaging sold in Maine and states that many of the draft chemicals listed are not intentionally used in food packaging. Commenter states that the Department should clarify the nexus between chemicals identified, the resulting regulatory decisions made by DEP, and the public health of Maine's citizens when describing the rationale for the chemicals listed. (Commenter 5)

Response: The Department's approach to listing chemicals on the Draft Food Contact Chemicals Of High Concern included a review of Maine's current list of Chemicals of Concern and Chemicals of High Concern relative to the Toxic Chemicals in Children's Products law based on the similarities in listing criteria for both statutes. The result showed that concerns for public health due to the use of BPA in plastic material, particularly material in contact with food, has led to BPA's consistent presence on regulatory chemical lists. However, the scope of regulation has been narrow and it is only now that the Department has been provided a mechanism to consider how BPA may be used in a broader food packaging category and any resulting exposures. It is important to note that a consideration for a chemical's presence on the draft food contact chemicals of high concern is the lack of information in the public domain about how chemicals, such as BPA, are being used in food packaging that could result in human exposure to consumers in Maine. Therefore, it is worth clarifying that it is precisely this absence of specific information that leads the Department to determine that more information about a chemical's use is necessary in order to inform future decisions about how to better protect Maine's consumers.

- 6. Comment:** Commenter believes the chemical octamethylcyclotetrasiloxane (D4) should not be included in the draft list of food contact chemicals because commenter suggests it does not meet the statutory criteria for listing. Commenter states that D4 is an intermediate in the manufacturing process of silicone polymers, which are regulated by FDA for use in food contact applications. Based on FDA's approval for the use of siloxanes as food contact materials, such as D4, commenter suggests that there should be no concern about exposure to this compound through food contact materials. Additionally, commenter states that D4 is not directly added to food contact materials and thus may be present in low concentrations which indicate actual exposure from this source would also be low. Commenter states that the

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endocrine disruptor classification list relied on as evidence that D4 meets listing criteria is flawed, as the classification program of the European Union is a screening list not a regulatory determination or an actual hazard classification. Commenter provides a description of the silicone industry's robust research program which has shown that the reproductive effects of D4 exposure are rodent specific and may be secondary to high dose non-specific toxicity, and not a result of an endocrine mode of action. Commenter adds several details about research that indicates D4 will not produce effects in humans via the endocrine system and that the claims of endocrine activity are based on screening-level assays only. Commenter explains that the Category 2 Reproductive Toxicant classification of D4 was done by the silicone industry in the early stages of research of the potential health and environmental effects of siloxanes, and since that time extensive research has demonstrated those effects are not relevant to humans. Commenter describes that biomonitoring data does not provide information about sources of exposure nor indicate potential health effects. Commenter provides information about D4 exposure by all routes having demonstrated minimal absorption and a process of rapid elimination or metabolism when exposure occurs from intended conditions of use. Commenter urges the Department to exercise its discretion by listing only those substances where additional regulation may provide benefit to public health, and in the case of D4 its presence on Maine's food contact chemicals of high concern list provides no benefit for public safety and is inconsistent with the law's goal of reducing the toxicity of packaging and packaging waste. (Commenter 6)

Response: The Department appreciates the commenter's submission of detailed information about octamethyl cyclotetrasiloxane (D4) for consideration. Given the similarities between the criteria necessary for each list, and the level of confidence in the work previously completed by both the Department and Maine CDC in the development of Maine's Chemicals of Concern and Chemicals of High Concern relative to the Toxic Chemicals in Children's Products law (38 MRS §1693 and 1693-A), the Department deemed it appropriate to utilize this reference work. A review of Maine's Chemicals of High Concern published in 2015, maintained that D4 belongs on that list and has the potential for further scrutiny. During the development of the draft food contact chemicals of high concern, the Department built on that 2015 research to add additional evidence of potential health concerns relative to exposure in the general population. It is notable that the law is clear that a chemical may be included on the list of food contact chemicals of high concern if the chemical is included on the list of Chemicals of Concern published by the Department in accordance with Title 38, section 1693. The presence of D4 on Maine's Chemicals of Concern list, and as mentioned above also having the designation of appearing on Maine's Chemicals of High Concern list, adds to the weight of evidence considered for this chemical's inclusion on the Department's Draft Food Contact Chemicals Of High Concern.