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August 25, 2020

Melissa Nadeau
Program Manager
Toxics In Packaging Clearinghouse
139 Main Street, Suite 401
Brattleboro, VT 05301

Re: TPCH Proposed Model Legislation

Dear Ms. Nadeau,

Thank you for the opportunity to provide comments on draft updates to the Toxics in Packaging Clearinghouse's (TPCH) model legislation for toxics in packaging. The Environmental Defense Fund (EDF) is pleased to see how the Clearinghouse has progressed since we shared similar ideas with your leadership in a meeting on October 18, 2017.

We support the draft and the approach of building on the legislation in Maine and Washington State by moving beyond food packaging, authorizing rulemaking agencies to implement the legislation, and establishing clear criteria to more effectively protect public health and the environment from classes of chemicals. We also agree with specifically naming per-and poly-fluorinated alkyl substances (PFAS) and ortho-phthalates in the draft and encourage you to expand the list of chemicals to others shown to meet the listing criteria including perchlorate and bisphenols.

EDF's mission is to preserve the natural systems on which all life depends. We have more than two million members and a staff of 700 scientists, economists, policy experts, and other professionals around the world. Guided by science and economics, we find practical and lasting solutions to the most serious environmental problems. This has drawn us to areas that span the biosphere: climate, oceans, ecosystems and health.

Our Health Program seeks to safeguard human health by reducing exposure to toxic chemicals and air pollution. In the past five years, our work has focused on reducing children's exposure to food contact substances like perchlorate, ortho-phthalates, and PFAS.

While we have been focused on contamination of food from food packaging, food ingredients, and food additives throughout the supply chain from farm to fork, we see the merits of addressing all packaging to address the full life-cycle impacts. These impacts can harm workers at the facilities where the chemicals are manufactured and processed as well as the environmental justice communities around those operations. The impacts extend to the sites where the packaging is recycled back into packaging,

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incinerated, or disposed of in landfills. And they, as we have seen from plastic in the ocean, include the real damage that can be created when the packaging is improperly disposed.

We make the following suggestions to refine the draft:

1. **Regulated metals**

We encourage the clearinghouse to reduce the 100 parts per million (ppm) limit for incidental presence of metals. As we understand the history of the legislation, the 100 ppm limit was set around 1990 and has not changed since then. In the intervening thirty years, we have learned lead is more harmful than understood at the time. We now know there is no threshold for the threat posed by lead to children's brain development.[1] Also, the risk of cardiovascular mortality from adult exposure to lead has become clear.[2] Additionally, cadmium contamination, specially of food, is a growing concern and children appear to be highly exposed.[3] We think that the limit should be tightened to 10 ppm, or at least, 50 ppm if there are serious achievability reasons to reduce exposure to lead throughout the supply chain for the packaging.

2. **Intentional Introduction and PFAS**

While much of the attention on PFAS in packaging has focused on its use as a greaseproofing agent in paper and paperboard, we are concerned that the Food and Drug Administration (FDA) has authorized its use as a mold release agent for plastics. We have identified eight Food Contact Substance Notifications (FCNs):

- FCN 736 allows the use of 1-propene,1,1,2,3,3,3-hexafluoro-polymer with 1,1-difluoroethene (CAS Reg. No. 9011-17-0) modified with a halogenated ethylene as described in the food contact notification limited to 1,000 ppm in the finished food-contact polymer.
- FCNs 260 and 1121 allow the use of tetrafluoroethylene-hexafluoropropylenevinylidene fluoride copolymers (CAS Reg. No. 25190-89-0) limited to 2,000 ppm in the finished food-contact polymer.
- FCNs 1255, 1448 and 1560 allow the use of vinylidene fluoride-hexafluoropropene copolymer (CAS Reg. No. 9011-17-0) limited to 2,000 ppm in the finished food-contact polymer.
- FCN 1601 allows the use of 2,3,3,4,4,5,5-Heptafluoro-1-pentene polymer with ethene and tetrafluoroethene (CAS Reg. No. 94228-79-2) for the property improvement in extrusion process of all polymers for food packaging, except for use in contact with infant formula and breast milk.

These uses would leave as much as 1,000 to 2,000 ppm of PFAS in the finished product. Under the definition of "Intentional Introduction" (Section 3.g, lines 48 to 57), mold release agents (either applied to the mold or added to the reagents) could be interpreted as exempt despite their presence on the surface of the final packaging, where they may be most mobile. We ask that the model legislation specifically include mold release agents as an intentional introduction.

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[1] National Toxicology Program, NTP Monograph Health Effects of Low-level Lead, 2012, https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf.

[2] *Id.* See also EPA, Science Inventory – Concentration-Response Functions for Lead and Cardiovascular Mortality, 2019, https://cfpub.epa.gov/si/si_public_pra_view.cfm?dirEntryID=342855&Lab=NCEE and Lanphear et al., Low-level lead exposure and mortality in US adults: a population-based cohort study, 2018, Lancet Public Health, https://doi.org/10.1016/S2468-2667(18)30025-2.

[3] Spungen JH. Children's exposures to lead and cadmium: FDA total diet study 2014-16. Food Additives and Contaminants: Part A https://doi.org/10.1080/19440049.2019.1595170

3. Listing perchlorate in model legislation

We ask that the model legislation specifically list perchlorate as a packaging chemical of high concern in a manner similar to ortho-phthalates and PFAS. The chemical fully meets the criteria for listing, and while it may not have garnered the attention of the other substances, presents a serious concern for children's brain development.

For the credible scientific evidence, we refer to three resources.

- EPA, Draft Report: Proposed Approaches to Inform the Derivation of a Maximum Contaminant Level Goal for Perchlorate in Drinking Water Volume I, September 2017.[4]
- European Food Safety Authority (EFSA), Scientific Opinion on the risks to public health related to the presence of perchlorate in food, in particular fruits and vegetables, 2014.[5]
- Maffini et al., Perchlorate and Diet: Human Exposures, Risks, and Mitigation Strategies, Curr Envir Health Rpt (2016) 3:107–117.[6]

Perchlorate meets the criteria at Section 6.1.A(1) because it is a developmental toxicant and an endocrine disruptor. The chemical interferes with the uptake of iodine into the thyroid, a critical gland in the endocrine system. As a result of pregnant woman who consume insufficient amounts of perchlorate (about one in five woman), experience hypothyroxinemia – a drop in the T4 hormone that is essential for fetal brain development. EPA conducted a thorough review of the literature and developed a quantitative dose response model for perchlorate and hypothyroxinemia. It showed that maternal exposure to perchlorate was associated with lower levels of T4 that affected brain development in the children.

Perchlorate meets the criteria at Section 6.1.B because EPA and EFSA have both made the finding that perchlorate is a developmental toxicant and endocrine disruptor.

Perchlorate meet the criteria at Section 6.1.C(1) because it has been measured in virtually all urinary biomonitoring samples in the National Health and Nutrition Evaluation Survey (NHANES).[7] The third element, 6.1.C(3), is also satisfied because FDA has specifically approved sodium perchlorate monohydrate as a conductivity enhancer in the manufacture of antistatic agents for use in polymeric finished articles in contact with dry food. The chemical may be present at levels up to 1.2 percent by weight of the finished polymer.[8] The manufacturer has documented that perchlorate migrates into dry food from this use, most likely through abrasion.[9] We would expect that non-food packaging would also contain perchlorate as an antistatic agency.

Since perchlorate already meets the criteria for list, we recommend that it be specifically listed in the model legislation alongside PFAS and ortho-phthalates. If this is an option, we can share specific language.

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[4] See https://www.regulations.gov/document?D=EPA-HQ-OW-2016-0438-0019. EPA published the peer review report in April 2018 at https://www.regulations.gov/document?D=EPA-HQ-OW-2016-0439-0012.
[5] EFSA Journal 2014;12(10):3869. See https://efsa.onlinelibrary.wiley.com/doi/abs/10.2903/j.efsa.2014.3869.
[6] See https://link.springer.com/article/10.1007/s40572-016-0090-3.
[7] See https://www.cdc.gov/biomonitoring/Perchlorate_BiomonitoringSummary.html. See also CDC, Fourth National Report on Human Exposure to Environmental Chemicals, Updated Tables, Volume 1, January 2019, at https://www.cdc.gov/exposurereport/index.html evaluating data from 2001 to 2014.
[8] See https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=TOR&id=2005-006.
[9] BASF Corp Appendix A Analysis Method (Redacted) re: Supplemental Comments from BASF Corporation (Keller and Heckman LLP), 2015. See https://www.regulations.gov/document?D=FDA-2015-F-0537-0020.

4. Listing bisphenol A to the model legislation

We ask that the model legislation specifically list bisphenol A (BPA) as a packaging chemical of high concern in a manner similar to ortho-phthalates and PFAS. The chemical fully meets the criteria for listing as described below. Due to the prevalence of replacing one bisphenol compound with another and to avoid regrettable substitutions, we recommend that the entire class of bisphenols defined as the chemicals included in the California Safer Consumer Products Program Candidate Chemical list[10] be included in the ban.

BPA meets the criteria at Section 6.1.A(1) because it is a reproductive toxicant and an endocrine disruptor. The chemical is known for its estrogenic activity since the 1930s. BPA has been associated with effects on multiple organs (e.g., the mammary gland) and systems including reproductive, nervous, immune, and metabolic. For credible scientific evidence we refer to the EFSA Scientific Opinion on the risks to public health related to the presence of BPA in foodstuff: Part II – Toxicological assessment and risk characterization.[11]

BPA also meets the criteria at Section 6.1.B Since 2018, the European Chemical Agency (ECHA) has classified BPA as a substance that has toxic effects on our ability to reproduce and require all manufacturers, importers, or suppliers of BPA to classify and label mixtures containing BPA as toxic for reproduction category 1B. Additionally, BPA has been identified as a substance with endocrine disrupting properties likely to cause serious human health problems and adverse effects in the environment.[12] The California Office of Environmental Health Hazard Assessment (OEHHA) has also designated BPA as a chemical known to the state of California to cause reproductive toxicity.[13]

BPA also meets the three elements included in criteria at Section 6.1.C. BPA has been consistently measured in the urine of children and adults tested by NHANES; it has been found to be present in packaging most notably plastic and metal, and it is added to packaging.

Since BPA already meets the criteria for list, we recommend that it be specifically listed in the model legislation alongside PFAS and ortho-phthalates. If this is an option, we can share specific language.

5. Clarifying several provisions

We suggest the following slight modifications to the draft to be clearer.

- Lines 126-127: We recommend slightly modifying the sentence to mirror the description for metals as follows:

  > The sum of the concentration levels of phthalates incidentally present in any package of packaging component shall not exceed 100 parts per million by weight (0.01%).

- Lines 130-132: PFAS used in food packaging usually consist of complex mixtures of individual PFAS of varying chain lengths. We recommend that the model legislation explicitly allow for compliance to be determined based on a screening test for total organic fluorine, as a proxy for the presence of PFAS.

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[10] https://calsafer.dtsc.ca.gov/cms/search/?type=Chemical
[11] EFSA Journal 2015;13(1):3978
[12] Bisphenol A. European Chemical Agency. https://echa.europa.eu/hot-topics/bisphenol-a
[13] https://oehha.ca.gov/proposition-65/crnr/bisphenol-listed-known-state-california-cause-reproductive-toxicity#:~:text=Effective%20May%2011%2C%202015%2C%20the,1986%20(Proposition%20651).

- Lines 137-139: Available testing laboratories, either within a company or commercial labs must have the analytical capacity to test for ortho-phthalates and PFAS at very low levels and that the data is trustworthy. We recommend adding the following text to Section 4:

  > Testing laboratories must certify they have undergone a third-party proficiency testing demonstrating that their protocols and analytical methods are capable of measuring ortho-phthalates at levels below 100 ppm (0.01% by weight).
  >
  > Laboratories testing for total organic fluorine must certify they have undergone third-party proficiency testing demonstrating that their protocols and analytical methods are capable of measuring total fluorine at levels at or below 10 ppm.

Thank you for your consideration of these comments. If you have questions or comments, please contact me at 317-442-3973 or tneltner@edf.org.

Sincerely,

Tom Neltner, JD, CHMM

Chemicals Policy Director