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To whom it may concern:

On July 9, 2020, the Toxics in Packaging Clearinghouse (TPCH) released a draft update to its Toxics in Packaging Model Legislation. This model legislation introduces a prohibition against the use of ortho-phthalates in any type of packaging, or packaging components beyond an incidental presence of 100 ppm. The Model Legislation defines phthalates as "*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*." Thus, the TPCH suggests that states should prohibit all ortho-phthalates from use in packaging, regardless of whether a given phthalate has been deemed safe for use in packaging. TPCH notes that recent legislative actions, including in Maine, provided a template for the proposed TPCH changes, noting that Maine enacted amendments to its food packaging law prohibiting the use of ortho-phthalates in food packaging that becomes effective in 2022 (LD 1433). It is important to note that the Maine law is not based on science, and is the only law in the US or in the world that prohibits the use of phthalates in food packaging.[1]

The Model Legislation seeks to protect the consumer from exposures to certain chemicals in all types of packaging. In order to determine if this legislation achieves this aim, it is important to note that:

1. Phthalate use in packaging, as defined by the Model Legislation, is limited.
2. Phthalates are not all the same, e.g. they are not toxicologically similar and are not used interchangeably.
3. Scientific studies and regulatory reviews support the safe use of high molecular weight phthalates in all existing applications.

The American Chemistry Council's (ACC) High Phthalates Panel (HPP) notes below the extensive available evidence of safe use of high molecular weight phthalates (HMW), including the ortho-phthalates DINP and DIDP, in current applications without restriction, including sensitive applications such as food contact.

[1] The ACC High Phthalates Panel filed extensive comments and supporting documentation for the safe use of DINP and DIDP in all current applications during the legislative process on the Maine legislation.

Phthalates in Packaging

The Model Legislation defines "*package*" as "*any container, produced either domestically or in a foreign country, providing a means of marketing, protecting or handling a product and shall include a unit package, an intermediate package or a shipping container as defined in American Society of Testing and Materials (ASTM) specification D 996. 'Package' shall also mean and include such unsealed receptacles as carrying cases, crates, cups, pails, rigid foil and other trays, wrappers and wrapping films, bags and tubs.*"

The Model Legislation also defines "*packaging component*" as "*any individual assembled part of a package which is produced either domestically or in a foreign country, such as, but not limited to, any interior or exterior blocking, bracing, cushioning, weatherproofing, exterior strapping, coatings, closures, inks, dyes, pigments, adhesives, stabilizers, labels or any other additives.*"

The most recent (2018) plasticizer[2] handbook[3] from IHS Markit lists the different applications for plasticizer consumption in the United States as follows:

a. Construction – i.e. resilient flooring, wall coverings, roofing etc.
b. Electrical – wire and cable jacketing, electrical tape
c. Consumer goods – footwear, toys, luggage, bookbinding, garden hose, etc.
d. **Packaging – meat and produce film, bottles and containers**
e. Transportation – automotive and truck upholstery, interior trim, floor mats, hose, sealants, underbody coating, etc.
f. Furnishings – upholstery, shower curtains, etc.
g. Medical – tubing, blood bags.

As noted above, plasticizer use in packaging is limited to meat/produce film (food packaging), bottles and containers. Phthalates are just one type of plasticizer among many. A 2018 US FDA survey evaluated the use of phthalates in food service wraps such as film wrapping for meat, vegetables, and sandwiches.[4] No phthalates were found in any of the PVC wraps (adipates are the plasticizer type used in these applications). A similar study by Health Canada's Bureau of Chemical Safety reviewed 118 samples of cling film/wraps used to contain beef, pork, chicken, fish and cheese.[5] None of the wraps were found to contain ortho-phthalates. With respect to bottles and containers, these are likely to be made of rigid PVC, which is made without plasticizer. We are not aware of any such application that requires the use of ortho-phthalate plasticizers.

Overall, it appears that the inclusion of ortho-phthalates makes little sense in Model Legislation intended to impact consumer health as it relates to packaging.

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[2] "*Plasticizer*" represents the broad spectrum of substances used to soften PVC including ortho-phthalates, tere-phthalates, aliphatics, epoxy, benzoates, trimellitates, phosphates, polymerics, etc.
[3] https://ihsmarkit.com/products/plasticizers-chemical-economics-handbook.html.
[4] Carlos, K.S., L.S. de Jager, and T.H. Begley: Investigation of the primary plasticisers present in polyvinyl chloride (PVC) products currently authorised as food contact materials. *Food Addit Contam Part A Chem Anal Control Expo Risk Assess* 35(6): 1214-1222 (2018).
[5] Cao XL, Zhao W, Churchill R, Hilts C. Occurrence of Di-(2-ethylhexyl) adipate and phthalate plasticizers in samples of meat, fish, and cheese and their packaging films. J Food Prot. 2014; 77(4):610-620.

All phthalates are not the same

The term "*ortho-phthalate*" simply refers to a family of chemicals that happen to be structurally similar, but which are functionally (in terms of use) and toxicologically distinct from each other. While all ortho-phthalate esters share the same basic 1,2-benzenedicarboxylate (phthalate) functional group, the carbon chain length of the alcohols (which make up the ester side chain of the phthalate) are significantly different. These differences are very important in understanding their safe use. Phthalates are categorized as high and low, depending on their molecular weight. The low molecular weight (LMW) phthalates have 3-6 carbon atoms in their backbone and the high molecular weight phthalates have 7 or more carbons in their backbone. Due to findings in some animal studies, some of the LMW phthalates have been classified as likely to cause adverse effects to reproduction in the European Union (EU). In contrast, high molecular weight (HMW) phthalates like DINP and DIDP have undergone rigorous regulatory review in the EU and based upon that review are not classified for any human health and/or environmental hazards, and are considered to be safe for use without restriction in existing applications in the EU.[6,7]

The hazard potential of DINP and DIDP has been studied for over 20 years

Reproductive and Developmental Toxicity

Whether DINP and DIDP have the potential to cause adverse health effects to reproduction or development has been the focus of research for over 20 years.[8,9] The EU conducted a comprehensive risk assessment on DINP, published in 2003, covering the range of human health hazard endpoints.[10] Since 2003, the EU has published two additional detailed risk evaluations of DINP, including a hazard evaluation to determine whether there is sufficient evidence to classify DINP for reproductive/developmental effects.[11,12] Both the 2003 and 2013 risk evaluations

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[6] European Chemicals Agency (2018) Opinion proposing harmonised classification and labelling at EU level of 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9- rich; [1] di-"isononyl" phthalate; [2] [DINP]. https://echa.europa.eu/documents/10162/56980740-fcb6-6755-d7bb-bfe797c36ee7.

[7] ECHA. 2013. Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. August 2013. https://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715.

[8] Kavlock, R., et al. (2002). NTP Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR): Phthalates expert panel report on the reproductive and developmental toxicity of di-isononyl phthalate. Reprod Toxicol 16:679–708.

[9] Kavlock, R, et al. (2002). NTP Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR): Phthalates expert panel report on the reproductive and developmental toxicity of di-isodecyl phthalate. Reprod. Toxicol. 16:655–678.

[10] European Chemicals Bureau. 2003. European Union Risk Assessment Report on 1, 2-benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich and di-"isononyl" phthalate (DINP). https://echa.europa.eu/documents/10162/83a55967-64a9-43cd-a0fa-d3f2d3c4938d [hereafter "ECB 2003"].

[11] European Chemicals Agency. 2013. Evaluation of new scientific evidence concerning DINP and DIDP in relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. August 2013. https://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715 [hereafter ECHA 2013].

[12] European Chemicals Agency Committee for Risk Assessment. 2018. Opinion proposing harmonised classification and labelling at EU level of 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9- rich; [1]di-"isononyl" phthalate; [2] [DINP]. CLH-O-0000001412-86-201/F. 9. March 2018.

concluded that there was no need for further testing or risk mitigation with respect to exposure to DINP for workers and consumers.[13] The ECHA 2013 report evaluated the risk of exposure to DINP for children and adults from several uses including toys and childcare articles (e.g. school supplies), skinny vinyl leather pants (assuming these are worn 10 hours/day for 2 weeks per month by pregnant women), indoor air, house dust and food.[14] The EU report found no risk with DINP exposure in any of the uses evaluated.[15] On March 9, 2018, the European Chemicals Agency (ECHA) Risk Assessment Committee (RAC) published its final opinion on the harmonized classification of DINP with respect to the potential for reproductive and/or developmental toxicity.[16] After a rigorous 3-year review, the RAC concluded that "*no classification for DINP for either effects on sexual function and fertility, or for developmental toxicity is warranted.*" This harmonized classification now applies to all EU member countries.

With respect to DIDP, the US Consumer Product Safety Commission completed a thorough hazard assessment on its ability to impact reproductive fertility and fetal development in humans in 2017. It found no concern with exposure to children, pregnant women or other susceptible individuals with an adequate margin of safety. As a result, the use of DIDP in children's toys and childcare articles is no longer restricted in the United States.[17]

Other Potential Effects

There is no evidence for any other alleged adverse effects. This is evidenced by the lack of a classification for any endpoint, whether with respect to human health or the environment, under the European Union's stringent standards for chemical management.

Uses of DINP and DIDP

In the United States DINP and DIDP are mainly used in applications such as wire and cable, film and sheet and automotive applications (e.g. underbody coatings), with limited use in paints, sealants and similar applications.[18]

DINP and DIDP are not used for applications that are within the scope of "*packaging*" as defined by the proposed bill. With respect to more sensitive packaging applications like food, DINP and DIDP are not used in food packaging (e.g. food service and commercial wraps).[19]

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https://echa.europa.eu/documents/10162/56980740-fcb6-6755-d7bb-bfe797c36ee7 [hereafter "RAC 2018"].

[13] ECB 2003, pp. IX & 259; ECHA 2013, pp. 7-8.

[14] ECHA 2013 pp. 267-276.

[15] Id., Tables 4.90, 4.93, 4.99, 4.105, 4.111, and 4.116.

[16] European Chemicals Agency (9, March, 2018) – Committee for Risk Assessment (RAC) Opinion proposing harmonised classification and labelling at EU level of 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkylesters, C9- rich; [1] di-"isononyl" phthalate; [2] [DINP] EC Number: 271-090-9 [1] 249-079-5 [2] CAS Number: 68515-48-0 [1] 28553-12-0 [2]. https://echa.europa.eu/documents/10162/56980740-fcb6-6755-d7bb-bfe797c36ee7.

[17] 82 FR 49938.

[18] See footnote 3.

[19] See footnote 4.

DINP and DIDP are safe for use in sensitive food contact applications

The safety in use of DINP and DIDP has been rigorously investigated with respect to the most sensitive consumer applications – food contact. All competent regulatory authorities have concluded that DINP and DIDP pose no human or environmental health concerns. For example, in December 2019, the European Food Safety Authority (EFSA) issued an update of the risk assessment of the phthalates DBP, BBP, DEHP, DINP and DIDP for use in food contact materials. Responding to the question of whether any of these phthalates pose a safety concern, EFSA concluded "*current exposure to these five phthalates from food is not a concern for public health*."[20] As a result, DINP and DIDP continue to be permitted for use in food contact applications in the European Union. Other regulatory agencies that have confirmed the safety of DINP and DIDP in food contact applications include the Food Safety Authority of Ireland (FSAI),[21] Food Standards Australia and New Zealand (FSANZ),[22] the New Zealand Ministry of Primary Industries (MPI)[23] and the UK Food Standards Agency (FSA).[24]

In May 2020, the Japan Ministry of Health, Labor and Welfare (MHLW) published its Positive List for food contact materials and articles made with synthetic resins (to take effect from June 1, 2020).[25] The list includes DINP and DIDP as additives that are considered safe for use in food contact (including packaging where applicable). In July 2019, the Common Market of the South (MERCOSUR; comprised of Brazil, Argentina, Uruguay and Paraguay) published its new Resolution on the Positive List of Additives for Use in Plastic Food-Contact Materials and Polymeric Coatings for Food-Contact Materials (GMC Resolution Nº 39/19).[26] The Resolution aligns with the EU regulation on food contact plastics (EU No. 10/2011) which permits the safe use of DINP and DIDP in food contact materials (including packaging). Other countries that permit the safe use of DINP and DIDP in food contact materials (including packaging) include China and South Korea.

In 2017, Environment and Climate Change Canada published a comprehensive risk evaluation of the use of DINP[27] and DIDP[28] in all existing applications, including coated fabrics, sheet vinyl and food packaging. The Agency found no human (for infants, children or adults) or environmental

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[20] https://www.efsa.europa.eu/en/news/faq-phthalates-plastic-food-contact-materials.
[21] Report on a Total Diet Study carried out by the Food Safety Authority of Ireland.
[22] https://www.foodstandards.gov.au/publications/Documents/Survey%20of%20plasticisers%20in%20Australian%20foods.pdf.
[23] https://www.mpi.govt.nz/dmsdocument/21871/loggedIn.
[24] https://cot.food.gov.uk/sites/default/files/cot/cotstatementphthalates201104.pdf.
[25] https://www.mhlw.go.jp/content/11130500/000625500.pdf.
[26] http://files.chemicalwatch.com/RES_039-2019_ES_RTM%20Lista%20Positiva%20Aditivos%20Plásticos%20-%20revoca%2032-07.pdf.
[27] Environment and Climate Change Canada; State of the Science report on DINP - http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=47F58AA5-1#Toc0931.
[28] Environment and Climate Change Canada; State of the Science report on DIDP - http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=D3FB0F30-1#Toc0931.

health concerns. As a result, the Agency plans to conclude that DINP and DIDP *"…are not harmful to the environment or to human health as set out in section 64 of CEPA 1999*."[29]

DINP and DIDP do not meet the TPCH criteria for packaging chemicals of high concern

The TPCH intends to include criteria for "*packaging chemicals of high concern.*" However, we contend that DINP and DIDP do not meet 3 of the 4 criteria identified:

a. *Credible scientific evidence of known developmental/health effects;*
   1. As noted previously, a comprehensive hazard assessment of the reproductive and developmental data on DINP by ECHA's Risk Assessment Committee (RAC) in 2018[30] concluded that DINP is not a reproductive/developmental toxicity hazard. As noted above, the US CPSC concluded that DIDP is not a concern to children or pregnant mothers in permitting its use in toys and childcare articles, without restriction in the United States.
   2. Competent regulatory authorities from Belgium, Denmark, France, the Netherlands and Sweden recently published the EU's list of over 100 substances that are either identified as endocrine disruptors (EDs) or under evaluation for endocrine disrupting properties within the EU.[31] **DINP and DIDP are not included on this list**.
   3. With respect to carcinogenicity, DINP and DIDP are not classified as carcinogens by any competent global regulatory agency including the European Chemical Agency's (ECHA) CLP legislation, Canada and Australia.

b. Credible scientific evidence of PBT/vPvB

As noted above, exhaustive evaluations of the environmental properties of DINP and DIDP are available. Neither substance is considered to be a PBT or vPvB according to the ECHA/GHS criteria, despite extensive risk evaluations since 2003. **Neither substance is classified as PBT or vPvB under EU CLP**.

c. Biomonitoring detection in human fluids/tissues

As indicated by the Centers for Disease Control and Prevention (CDC) National Report on Human Exposure to Environmental Chemicals (NHANES),[32] ortho-phthalates are simply one of many other chemicals that have been detected in human fluids/tissues. However, the mere presence of a substance in biomonitoring studies does not indicate that the substance poses a risk to humans. Biomonitoring studies are the basis for the numerous global risk evaluations of DINP and DIDP that have been conducted over the last 20 years, including the latest food safety

[29] https://www.canada.ca/en/health-canada/services/chemical-substances/substance-groupings-initiative/phthalate.html.
[30] See footnote 12.
[31] https://edlists.org/.
[32] https://www.cdc.gov/exposurereport/index.html.

evaluation by EFSA in 2019. Overall, these risk evaluations conclude that exposures to both substances are low and of no human health concern.

d. *Used/found in packaging;*

The predominant uses of DINP and DIDP in the United States are in wire and cable, film and sheet, and automotive applications.

Conclusion

There is overwhelming evidence that high molecular weight phthalates, like DINP and DIDP, have been proven safe in sensitive applications, including food contact applications, and are permitted for use in food contact applications all over the world on the basis of their safety profile. Unfortunately, rather than protect the consumer, the blanket prohibition of phthalates in all packaging does the following:

a. Ignores the fact that all phthalates do not have the same biological profiles and that DINP and DIDP remain safe for use according to all competent regulatory authorities globally.

b. Ignores the extensive human health record on DINP and DIDP which confirm that they are safe for use in all existing applications.

c. Ignores the fact that DINP and DIDP are permitted for safe use in all existing applications around the world, especially in sensitive applications like food contact, where there is sufficient evidence of a lack of human/environmental health concern.

In this regard, we urge the TPCH to exclude the blanket prohibition on phthalates from the current Model Legislation.

Sincerely,

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