



March 10, 2021

Sen. Virginia Lyons, Chair
Senate Health and Welfare Committee

RE: American Chemistry Council High Phthalates Panel Comments on Proposed Bill Senate 20 before the Vermont Senate Health and Welfare Committee

Background

On January 13, 2021, Senate Bill 20, titled “An act relating to restrictions on perfluoroalkyl and polyfluoroalkyl substances and other chemicals of concern in consumer products” was introduced to the Senate Health and Welfare Committee. This bill seeks to impose restrictions on the manufacture, sale, and distribution of a food package to which ortho-phthalates have been intentionally added in any amount greater than an incidental presence. S. 20 defines phthalates as “*any member of the class of organic chemicals that are esters of phthalic acid containing 2 carbon chains located in the ortho position.*” In other words, S. 20 seeks to prohibit all ortho-phthalates from use in food packaging, including high molecular weight phthalates such as diisononyl phthalate (DINP) and diisodecyl phthalate (DIDP) that are currently permitted for use in food packaging across the globe and for which there is overwhelming evidence of safety when used as components of food packaging.

The American Chemistry Council’s (ACC) High Phthalates Panel (HPP), notes the following:

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

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 (HMW) 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, the HMW



phthalates DINP and DIDP have undergone rigorous regulatory reviews in the EU in 2013 and 2018, and based upon the reviews 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.^{1,2}

Phthalate Use in Food Packaging is Limited in the United States

The proposed bill defines “*package*” as “*a container providing a means of marketing, protecting or handling a product and shall include a unit package, an intermediate package, and a shipping container and [] unsealed receptacles such as carrying cases, crates, cups, pails, rigid foil and other trays, wrappers and wrapping films, bags, and tubs.*”

The proposed bill defines “*packaging component*” as “*an individual assembled part of a package such as any interior or exterior blocking, bracing, cushioning, weatherproofing, exterior strapping, coatings, closures, inks, and labels.*”

While approximately 30 phthalates³ are currently permitted for use as food contact substances (including in food packaging and packaging components) by the US Food and Drug Administration (FDA), only four⁴ are currently used in these applications. To this end, in 2016, the US Flexible Vinyl Industry filed a Food Additive Petition requesting that the FDA revoke all food contact clearances for 26 phthalates,⁵ use of which are deemed to be abandoned. If the industry Food Additive Petition is granted in full, none of the 26 ortho-phthalates listed would be authorized for food additive use in FDA's regulations.

Additionally, the US FDA⁶ and Health Canada's Bureau of Chemical Safety⁷ recently conducted a survey of plasticizer⁸ use in food packaging and components of food packaging. The survey found limited use for DINP, DIDP, and di-(2-ethylhexyl) phthalate (DEHP) – tubing, conveyor belts and cap gaskets. No phthalate was found to be used in food packaging applications like food service and commercial wraps (e.g. cling-film, wraps for meat, vegetables and sandwiches).

¹ 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>.

² 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>

³ Any member of the class of organic chemicals that are esters of phthalic acid containing 2 carbon chains located in the ortho position.

⁴ Diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), di-(2-ethylhexyl) phthalate (DEHP) and dicyclohexyl phthalate (DCHP).

⁵ [Federal Register :: Flexible Vinyl Alliance; Filing of Food Additive Petition](#) (83 FR 56750).

⁶ 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).

⁷ 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.

⁸ “Plasticizer” represents the broad spectrum of substances used to soften PVC including ortho-phthalates, terephthalates, aliphatics, epoxy, benzoates, trimellitates, phosphates, polymeric, etc. Ortho-phthalates are just one type of plasticizer, among many.



Dicyclohexyl phthalate (DCHP) is mainly used as an adhesive component on the external surface of polypropylene bottles, an application that would not permit direct contact with food.

Phthalates Used in Food Packaging in the United States are Safe as Currently Used

We would like to draw the attention of the Committee to the extensive available evidence on the safe use of high molecular weight phthalates including DINP and DIDP in current applications without restriction, including sensitive applications such as food contact. The safety-in-use of the four phthalates used in food packaging in the United States has been thoroughly evaluated by food safety regulatory authorities globally for the last 10 years. All have concluded that all four phthalates are safe as currently used.

In December 2019, the European Food Safety Authority (EFSA) released an updated food safety assessment of phthalates (including DINP and DIDP) used in food contact materials in the European Union.⁹ 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.*” 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),¹⁰ Food Standards Australia and New Zealand (FSANZ),¹¹ the New Zealand Ministry of Primary Industries (MPI)¹² and the UK Food Standards Agency (FSA).¹³

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 N° 39/19).¹⁴ 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 (took effect from June 1, 2020).¹⁵ The list includes C9 dialkyl phthalates (DINP) and C10 dialkyl phthalates (DIDP) as additives that are considered safe for use in polyvinyl chloride (PVC) food contact (including packaging where applicable). 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.

⁹ [FAQ: phthalates in plastic food contact materials | European Food \(europa.eu\).](#)

¹⁰ [Report on a Total Diet Study carried out by the Food Safety Authority of Ireland.](#)

¹¹ [Survey of plasticisers in Australian foods.pdf \(foodstandards.gov.au\).](#)

¹² [Occurrence and risk characterisation of migration of packaging chemicals in New Zealand foods \(mpi.govt.nz\)](#)

¹³ [Microsoft Word - phthalates statement 04-11.docx \(food.gov.uk\).](#)

¹⁴ [http://files.chemicalwatch.com/RES_039-2019_ES_RTM%20Lista%20Positiva%20Aditivos%20Plásticos%20-%20revoca%2032-07.pdf.](http://files.chemicalwatch.com/RES_039-2019_ES_RTM%20Lista%20Positiva%20Aditivos%20Plásticos%20-%20revoca%2032-07.pdf)

¹⁵ [https://www.mhlw.go.jp/content/11130500/000625500.pdf.](https://www.mhlw.go.jp/content/11130500/000625500.pdf)



In December 2020, Environment and Climate Change Canada published a comprehensive risk evaluation of the use of DINP¹⁶ and DIDP¹⁷ in all existing applications, including coated fabrics, sheet vinyl and food packaging. The Agency found no human (for infants, children or adults) or environmental health concerns. As a result, the Agency concluded that DINP and DIDP “...are not harmful to the environment or to human health as set out in section 64 of CEPA 1999.”¹⁸

Conclusion

The ACC HPP recognizes and supports the efforts of the Vermont legislature in protecting the consumer. However, it is important that this effort is based on information that is accurate and provides tangible health benefits to the consumer. There is overwhelming evidence that high molecular weight phthalates, like DINP and DIDP, have been proven safe in sensitive applications, including food contact, and are permitted for use in food contact applications all over the world on the basis of their safety profile. Thus, DINP and DIDP should not be grouped with other phthalates. We urge the committee to revise the definition of “phthalates” in S. 20 so that it does not amount to a blanket prohibition on all phthalates, and to delay any action on S. 20 pertaining to phthalates until the FDA has completed its thorough evaluation of the pending food additive petition.

Thank you for your attention to these comments.

Sincerely,

Eileen Conneely

Eileen Conneely
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¹⁶ 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>.

¹⁷ 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>.

¹⁸ [Phthalate Substance Grouping – information sheet - Canada.ca](#)

