



April 27, 2021

The Honorable Representative Pugh
House Committee on Human Services
115 State Street
Montpelier, VT 05633-5301

RE: American Chemistry Council High Phthalates Panel Supplemental Comments on Senate Bill 20 before the Vermont House Committee on Human Services

Background

Senate Bill 20, titled “An act relating to restrictions on perfluoroalkyl and polyfluoroalkyl substances and other chemicals of concern in consumer products,” 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. On various dates in April, 2021, the Vermont House Committee on Human Services heard statements regarding the scientific basis for Senate Bill 20. This document seeks to correct several inaccuracies presented to the Legislature concerning 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.

Testimony of Vermont toxicologist

During the April 20, 2021 hearing, Representatives made reference to the testimony of Dr. Vose concerning phthalates. Although we found no written statement in the record from Dr. Vose, a review of Dr. Vose’s testimony shows that she testified to potential reproductive and metabolic effects caused by phthalate exposure, and that she noted incorrectly that California’s Safer Consumer Products program has work underway to identify safer alternatives to the use of ortho-phthalates in food packaging. Her testimony did not differentiate between phthalates, and, as we noted in our prior testimony, all phthalates are not the same and have different physical properties, risk profiles, and individual uses.

1) DINP and DIDP have not been found to cause reproductive or developmental effects to children or adults

A large volume peer reviewed literature has been published since 2015 and has been systematically reviewed and evaluated using a weight of the evidence approach. In the 2018 weight of the evidence evaluation conducted by the European Chemicals Agency, DINP was determined to not be a reproductive or developmental toxicant. This finding reaffirmed the earlier conclusion reached on DINP and DIDP. These findings were also reiterated in the December 2020 risk evaluation from Environment and Climate Change Canada on the use of DINP and DIDP in all existing applications, including coated fabrics, sheet vinyl and food packaging. Canada 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."

Based on these evaluations and the information previously provided in our written testimony, the overwhelming evidence supports a conclusion that DINP and DIDP do not cause reproductive or developmental effect to children or adults.

2) Reported associations between DINP and DIDP and metabolic effects are not sufficient to imply causation

Dr. Vose noted in her oral testimony that ortho-phthalates are suspected obesogens, working to disrupt human metabolism. An axiom of epidemiology is that association does not equal causation. Rather, it is critical to determine if the observed relationship is real or a potential artifact due to an unmeasured effect. A systematic review of the literature looked at associations and potential confounders (unmeasured potential causes) and determined current epidemiological data do not support the hypothesis that phthalates act as obesogens [metabolic dysfunction] in humans.¹

In two cross-sectional epidemiology studies published in 2015, weak associations between systolic blood pressure and DINP and DIDP were reported² and between insulin resistance and DINP.³ The type of study is critical to note because the authors acknowledge, "causation cannot be inferred from a cross-sectional study."⁴ The authors note these effects are small and that no association was found between diastolic blood pressure, increased risk of pre-hypertension, triglycerides and high-density lipoprotein (HDL) with DINP and DIDP.⁵ The authors point to several critical confounders that were unmeasured and thus could not be controlled for in their study. Furthermore, in one study, the authors hypothesize insulin-resistant children often have unhealthy eating habits that include consumption of packaged food that happens to contain higher phthalate levels than the unpackaged foods consumed by healthier children; these eating habits may be a more plausible explanation for their findings. This alternative explanation would then suggest that the association of DINP/DIDP with insulin resistance is coincidental and is a non-causal association.⁶

¹ Goodman, J et.al. (2014). Do phthalates act as obesogens in humans? A systematic review of the epidemiological literature. *Critical Reviews in Toxicology* 44: 151-175.

²Trasande L, Attina TM. Association of exposure to di-2-ethylhexylphthalate replacements with increased blood pressure in children and adolescents. *Hypertension*. 2015;66(2):301–30.

³ Attina TM, Trasande L. Association of exposure to di-2-ethylhexylphthalate replacements with increased insulin resistance in adolescents from NHANES 2009-2012. *J Clin Endocrinol Metab*. 2015;100(7):2640–2650.

⁴ *Id.*

⁵ Trasande (2015).

⁶ Sharpe RM, Drake AJ (2013) Obesogens and obesity—An alternative view? *Obesity* 21: 1081-1083.



3) The California Department of Toxic Substances Control (DTSC) has decided not to pursue food packaging containing ortho-phthalates as a Priority Product

In February of 2021 California's DTSC released its Stakeholder Discussion Draft: Three Year Priority Product Work Plan (2021-2023), available at: <https://dtsc.ca.gov/wp-content/uploads/sites/31/2021/02/2021-2023-Priority-Product-Work-Plan-Stakeholder-Discussion-Draft.docx>. In that three-year work plan DTSC specifically announced that it has decided not to pursue food packaging containing ortho-phthalates as a Priority Product. Thus, contrary to the testimony of Dr. Vose, DTSC is not working to identify any alternatives to the use of ortho-phthalates in food packaging. DTSC noted that they will issue a decision document describing how they arrived at that decision.

Several documents introduced into the record were previously introduced into the record for a similar food packaging bill in Maine and contain numerous inaccuracies concerning high molecular weight phthalates such as DINP and DIDP

1) DINP and DIDP do not affect children's cognitive abilities

New research is being conducted to determine if environmental exposures can affect children's cognitive development. Early results demonstrate a similar pattern as the one observed for reproductive and developmental health effects; *that certain phthalates* may be associated with cognitive effects, but not DINP or DIDP, according to two studies published in 2019. Additionally, as noted above, association does not equal causation. A new study by Li et al. found associations between high levels of certain other phthalates and IQ decreases in 3 year olds.^{7,8} The Li study did not find an association or link between DINP and DIDP exposures and IQ changes.⁹

The same pattern was observed in a 2019 systematic review published by Zhang et al. examining the association between prenatal exposure to phthalates, cognition, and neurobehavior.¹⁰ A systematic review "collect[s] and analyze[s] all evidence that answers a specific question... a thorough search of the literature is performed and a critical analysis of the search results is reported and ultimately provides a current evidence-based answer to the specific question."¹¹ Zhang's systematic review identified 26 studies meeting their criteria. Out of these 26 studies, 5 examined DINP and/or DIDP exposures. Briefly,

⁷Li et al. (2019). Identifying periods of susceptibility to the impact of phthalates on children's cognitive abilities. *Environmental Research*. 172: 604-614.

⁸ Epidemiology studies look at the metabolites of the phthalate to determine exposure. For DEHP, the major metabolite is abbreviated MEHP (or the total of all metabolites Σ DEHP); Di-ethyl phthalate (DEP) = monoethyl phthalate (MEP); Butyl-benzyl phthalate (BBzP) = monobenzyl phthalate (MBzP).

⁹ Diisononyl phthalate (DINP) = Mono-carboxy-iso-octyl phthalate (MCOP); Diisodecyl phthalate (DIDP) = Mono-carboxy-iso-nonyl phthalate (MCNP).

¹⁰Zhang et al. (2019). The association between prenatal exposure to phthalates and cognition and neurobehavior of children-evidence from birth cohorts. *Neurotoxicology*. 73:199-212.

¹¹ CDC. <https://www.cdc.gov/library/researchguides/systematicreviews.html>.



Study	Effect Examined	No Associations
Olesen et al. 2018	Association between prenatal phthalate exposure and language development in children (M and F) aged 20–36 months	DINP No effects observed
Philippat et al. 2017	Association between prenatal phthalate exposure and neurobehavior in boys aged 3 and 5 years	DINP, DIDP No effects observed
Nakiwala et al. 2018	Association between in-utero exposure to phthalates and the intelligence quotient of boys at 5 years	DINP, DIDP No effects observed
Polanska et al. 2014	Association between pre and early postnatal phthalate exposure on child psychomotor development	Σ DINP (metabolites) No effects observed
Engel et al. 2018	Association between prenatal exposure to phthalates and clinically confirmed ADHD	Σ DINP (metabolites) No effects observed

The results of the Zhang et al. systematic review demonstrates DINP and DIDP are not associated with neurobehavioral or cognitive health effect in children.

2) DINP and DIDP are not endocrine disruptors

Certain chemicals are alleged to be endocrine disruptors hypothesized to be able to cause adverse health outcomes. The World Health Organization defines an endocrine disruptor as:

“an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations.”¹²

Neither DINP nor DIDP cause adverse health effects to reproduction or development at exposures during critical developmental time periods.

This conclusion is additionally supported by a National Academies of Science systematic review of the epidemiological data for the potential low dose effects from phthalates.¹³ The NAS had moderate confidence in the body of evidence and there was a low risk of bias for the studies looking at anogenital distance (AGD, a sensitive marker for lowered testosterone) and DINP. The NAS concluded there was no association between DINP and AGD, and no effects were found in the meta-analysis results, indicating low doses of DINP do not affect human testosterone levels.

¹² World Health Organization. 2002. Global assessment of the state-of-the-science of endocrine disruptors. https://www.who.int/ipcs/publications/new_issues/endocrine_disruptors/en/

¹³ National Academies of Sciences, Engineering, and Medicine. 2017. Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24758>.



A second systematic review and meta-analysis conducted by Bonde et al. (2017) rigorously evaluated the risk of cryptorchidism, hypospadias, low sperm counts and testicular cancer following in utero or infant exposure to chemicals that have been included on the European Commission's priority list of substances requiring further evaluation for endocrine properties.¹⁴ Based on the (null) results of their analyses, researchers challenged "the widely stated view that ubiquitous endocrine disrupting chemicals in our environment play a substantial role in the development of male reproductive disorders through prenatal and perinatal mechanisms." Notably, DINP was not associated with any of the outcomes considered in their systematic review.

Based on the results of these systematic reviews, there is sufficient data to conclude DINP and DIDP are not endocrine disruptors and do not cause adverse effects at low doses.

3) The testimony submitted to the record from Dr. Maricel Maffini includes inaccuracies and misrepresentations about phthalates

The testimony in the record dated April 17, 2019 from Dr. Maricel Maffini to the Maine Legislature contains numerous inaccuracies and misrepresentations concerning phthalates. We list below the statements made and the needed correction:

From page 3:

"FDA has approved 28 phthalates uses as diverse as plasticizers (most commonly to polyvinyl chloride plastic), binders, coating agents, defoamers, gasket closures and slimicide agents to process packaged food. . . . All of the chemicals were approved by the agency before 1985 and, although the scientific knowledge has advanced, there hasn't been a reevaluation of their safety since then."

These statements are misleading and incorrect. As noted in our previous written testimony, 26 phthalates have been phased out, and only 4 phthalates remain in food contact use today. See our comments submitted to the record, noting that US FDA is currently reviewing a petition to revoke food contact clearances for 30 ortho-phthalates, and reviewing a food additive petition from the flexible vinyl industry requesting the US FDA to amend food additive regulations to no longer provide for the use of 26 ortho-phthalates in various food contact applications, as these uses have long been abandoned. As part of its review, the US FDA released a report on its investigation of the use of plasticizers in PVC food packaging in 2018. The Agency concluded that the use of ortho-phthalates in food packaging in the United States is low, as most manufacturers have moved to alternative plasticizers.

Additionally, as noted in our previous testimony, there have been numerous re-evaluations of the safety of phthalates in food packaging by sister agencies to the US FDA across the globe in the last 10 years alone, including the UK FSA (2011), EFSA (2005 and 2019), FSAI (2014), FSANZ (2018), NZ MPI (2017), MERCOSUR countries (2019) and Health

¹⁴ Bonde, et al. (2017). The epidemiologic evidence linking prenatal and postnatal exposure to endocrine disrupting chemicals with male reproductive disorders: a systematic review and meta-analysis. Hum Reprod Update. 2016 Dec;23(1):104-125. Epub 2016 Sep 21.



Canada (2020). None have found a public health concern and most continue to permit the use of phthalates in food packaging - with similar conditions as exist in the US.

From page 3:

“FDA does not have limits to how much phthalates can be present in food; the agency recommends that the manufacturer follows good manufacturing practice, in other words, it can add as much phthalate as needed for the product’s functionality but not more. Because phthalates are not tightly bound to the materials they are added, they migrate into the food very easily.”

This statement wrongly implies that there is no regulatory oversight on how phthalates are used in food packaging. These statements are incorrect. For example, the FDA has narrow specifications for how DINP can be used in food packaging. 21 CFR §178.3740 (which is the only lawfully permitted use for DINP in food contact in the United States) restricts the use of DINP at levels of no more than 43% in food contact vinyl (polyvinyl chloride, or PVC), and only when used in contact with non-fatty and low alcohol foods. This specification is almost identical to that available in the EU.

With respect to the ability of phthalates to migrate into foods, this is not specific to phthalates alone. All plasticizers, phthalates or non-phthalates, are theoretically able to migrate to food. However, phthalates like DINP and DIDP are tightly bound to the PVC and do not migrate easily.

From page 4:

“Academic studies have linked some of these chemicals to various reproductive, developmental and endocrine health problems. In fact, every phthalate that has been studied for these types of health effects has been found to pose a risk.”

These statements are incorrect. As detailed in our comments above, DINP is not considered to be a reproductive/developmental hazard and/or risk in the EU, Australia or Canada. The US CPSC also confirmed in 2017 that DIDP is not anti-androgenic and is of negligible concern for children, pregnant mothers and other susceptible populations.

From page 4:

“The Consumer Product Safety Commission (CPSC)’s Chronic Hazard Advisory Panel evaluated the cumulative risk of phthalates grouped by their common effect on male reproductive development. Their advice was to permanently ban eight phthalates due to their increased health risk to children.”

This is incorrect. Although CPSC made permanent the ban on DINP in toys and childcare articles, CPSC removed the ban on DIDP and DnOP in toys and childcare articles as it found they posed no risk to children, pregnant women, or other susceptible individuals.

From page 4:

“Like CPSC’s approach, the European Chemical Agency also evaluated the cumulative risk of phthalates of four phthalates and the European Food Safety Authority has recently released its draft scientific opinion on the safety assessment of five phthalates and



estimated a tolerable daily intake for the group. One may disagree with some of rationale these agencies have put forward, but it is clear that regulating phthalates as a class is the best approach.”

These statements appear outdated, and omit the results of those evaluations. As noted in our comments above, ECHA found “no risk is expected from combined exposure to DINP and DIDP for children exposed via food and the indoor environment.” Additionally EFSA published its safety assessment in December 2019, concluding that “current exposure to these five phthalates from food is not a concern for public health.”

From page 4:

“Unlike its counterparts, FDA has not taken any measures to deal with phthalates in food.”

This statement is misleading, and suggests that other food safety regulatory agencies have restricted the use of phthalates in food packaging and that the US FDA is an outlier in not taking measures to deal with phthalates in food. In fact, all major food safety regulatory agencies around the world continue to maintain the use of phthalates in food packaging – the EU, Australia, NZ, Canada, China, Japan, etc. after evaluating such uses.

From page 5:

“The petition from the public interest groups showed that phthalates are a class of chemically- and pharmacologically-related substances associated with reproductive, developmental, and endocrine health effects. It demonstrated that, when the cumulative effect of these chemicals in the diet are considered as required by law, the FDA cannot conclude their use as food contact substance is safe.”

This statement is counter to the conclusions in the more than five risk assessments conducted by independent food safety agencies around the world, including EFSA, Health Canada, FSANZ, NZ MPI, UK FSA and Ireland’s FSAI, finding no appreciable public health risks, low exposures, etc. with the use of high molecular weight phthalates in food packaging.

Exposures, if any, to DINP and DIDP, if used in tubing or other aspects of the maple syrup industry would be extremely low

During the April 20th hearing several questions were posed by Representatives, including whether phthalates were used in tubing or other aspects of the maple syrup producing process. A brief review by our members looking at online supply houses shows materials other than PVC are used, and thus phthalate use would be unlikely. Although use in tubing might be possible, as the 2018 FDA use survey reported DIDP used in 1 out of 5 food contact tubing tested, any exposures would be expected to be extremely low, likely in the range of 1 ppb or less.



Conclusion

The ACC HPP recognizes and supports the efforts of the Vermont legislature in protecting the consumer. However, there is overwhelming evidence that high molecular weight phthalates, like DINP and DIDP, do not cause adverse reproductive, developmental, cognitive, or metabolic effects in children or adults and thus have been proven safe in sensitive applications, including food contact. 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.

Thank you for your attention to these comments.

Sincerely,

Eileen Conneely

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