March 2, 2020

Hazardous Waste and Toxics Reduction Program
Washington State Department of Ecology
P.O. Box 47600
Olympia, WA 98504-7696

Dear Washington State Department of Ecology,

On behalf of the High Phthalates Panel of the American Chemistry Council (ACC) I am submitting comments on the Safer Products for Washington draft report on priority consumer products. We welcome continuing engagement as Washington State continues to assess priority products, and we hope our comments help ensure that the program is based upon the best available science and the most complete information. To that end, we would welcome a follow-up meeting to further discuss high molecular weight phthalates.

Thank you,

Eileen Conneely

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ACC High Phthalates Panel Comments to Washington State DOE on Phthalates in Vinyl Flooring

Background

The Washington State Department of Ecology (hereinafter Washington State DOE) has released its first draft priority consumer products report[1] as part of Phase 2 of its implementation of the Safer Products for Washington law. The draft report identifies vinyl flooring as a priority product, with phthalates as the priority chemical constituent of vinyl flooring. The draft report identifies vinyl flooring as a significant source of phthalate exposure, with concerns expressed for potential exposure for infants, young children and the environment.

Phthalates are a broad class of chemicals with a range of physical, chemical, and toxicological properties and each chemical must be assessed individually

The toxicity of phthalates has been well studied over the past 30 years and has been the subject of numerous regulatory assessments. Phthalates constitute a broad class of chemicals with a range of physical, chemical and toxicological properties. The properties are structure-dependent. One differentiation is between Low Molecular Weight (LMW) phthalates with a C_3-C_6 carbon backbone (such as DEHP (DOP), DBP, and BBP) and High Molecular Weight (HMW) phthalates with a $\geq C_7$ backbone (such as DINP (di-isononyl phthalate) and DIDP (di-isodecyl phthalate). When evaluating the hazard profile of "*phthalates*," it is important to consider the molecular weight and to evaluate each distinct phthalate separately. The Washington DOE report however does not distinguish between phthalate categories, conflating known hazards of certain phthalates across the entire class, even where there is published evidence to the contrary. LMW phthalates are classified for reproductive toxicity in the EU. HMW phthalates like DINP and DIDP **<u>are not classified for any human health and/or environmental hazards</u>** by the European REACH regulation. 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.[2] 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.

The following comments are intended to address several misconceptions found in the report.

High molecular weight phthalate use has already been assessed in vinyl flooring and found to be safe

The Washington DOE report leaves out several publicly available risk evaluation reports that have found no public health concern with the use of HMW phthalates in vinyl flooring. For example, the European Union published a comprehensive hazard and risk assessment of DINP and DIDP in 2013.[3] The report evaluated dermal exposures to DINP and DIDP for children and adults through various consumer uses,

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[1] State of Washington Department of Ecology. Priority Consumer Products Draft Report to the Legislature. Safer Products for Washington Implementation Phase 2. January 2020, Publication 20-04-004. https://ecology.wa.gov/Events/HWTR/SPWA-stakeholder-engagement/Draft-report-on-priority-consumer-products.

[2] 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.

[3] 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. Final review report. https://echa.europa.eu/documents/10162/31b4067e-de40-4044-93e8-9c9ff1960715.

including vinyl flooring, child changing mats, baby diaper covers, cribs, playpens, gloves, footwear, wet weather gear, artificial leather pants and underwear, etc. The EU concluded that there was no concern associated with exposure to DINP and DIDP through any of those uses.

The Washington DOE references an example of vinyl flooring with DINP concentration of 18.9% in Table 12 of its report. The report should have noted that this example is taken from a State of California Proposition 65 safe use determination (SUD) for the use of DINP in vinyl flooring for professional installers.[4] To provide context, a California Proposition 65 SUD is a written statement issued by the California Office of Environmental Health Hazard Assessment (OEHHA) indicating that exposures to the indicated chemical is well below a level of concern to the general public and is thus considered safe for use. A similar SUD was also issued for use of vinyl flooring containing 18.9% DINP for residents of homes and other facilities by the State of California.[5]

Vinyl flooring has not been shown to be the cause of higher concentrations of phthalates in air and dust

The department of Ecology has expressed concern particularly "*with the potential for infants and young children to be exposed to phthalates in vinyl flooring*." This concern is misplaced. Although it is true that many studies have reported associations between vinyl flooring in the home and higher concentrations of urinary phthalate metabolites in infants, children and pregnant women, none of these studies have identified a clear causal link between phthalate exposure from vinyl flooring and adverse health effects in infants, children or pregnant women. By contrast, *numerous independent risk evaluations conclude that phthalates do not pose a concern to infants and children in dust and indoor air.*

a) In 2007, the European Scientific Committee on Health and Environmental Risks (SCHER) published a detailed opinion on risk assessment on indoor air quality.[6, 7] The SCHER concluded that it "***does not find consistent scientific evidence which indicate[s] that phthalates should be high concern chemicals in indoor air.***" Importantly, the SCHER report found no evidence that any phthalates were associated with asthma or rhinitis in children.

b) In 2013, the European Chemicals Agency (ECHA)[8] published a detailed risk evaluation of house dust and indoor and vehicular air exposure to high molecular weight phthalates such as di-isononyl phthalate (DINP) and (DIDP) (individually or combined) for infants and children 0-6 months, 6-12 months and 12-18 months. The total reasonable worst-case (i.e. assuming upper bound exposure estimates) risk characterization ratios for indoor/vehicular air and house dust ($RCR_{air/dust}$) for all three infant/toddler age groups and adults were well below levels of concern. With respect to

[4] California Office of Environmental Health Hazard Assessment (OEHHA). Issuance of a Safe Use Determination for Exposure to Professional Installers to Diisononyl Phthalate in Vinyl Flooring Products. https://oehha.ca.gov/proposition-65/crnr/issuance-safe-use-determination-exposure-professional-installers-diisononyl.

[5] California Office of Environmental Health Hazard Assessment (OEHHA). Issuance of a Safe Use Determination for Exposure to Residents to Diisononyl Phthalate in Vinyl Flooring Products. https://oehha.ca.gov/proposition-65/crnr/issuance-safe-use-determination-exposure-residents-diisononyl-phthalate-vinyl.

[6] GreenFacts – Indoor Air Quality – https://copublications.greenfacts.org/en/indoor-air-pollution/l-2/6-harmful-chemicals.htm.

[7] Scientific Committee on Health and Environmental Risks (SCHER). Opinion on risk assessment on indoor air quality (2007) – https://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_055.pdf.

[8] See footnote 3.

children, the 2014 European Commission report[9] on the ECHA risk assessment concluded that "***no risk is expected from combined exposure*** *["combined exposure" includes all routes, pathways, and sources of exposure to multiple chemicals]* ***to DINP and DIDP for children exposed via*** *food and* ***the indoor environment (indoor air and house dust).***" With respect to adults, the European Commission report concluded that "***exposure from*** *food and* ***the indoor environment are not very significant in the adult population, which is confirmed by the available biomonitoring data.***"

c) In 2015, Health Canada published detailed risk evaluations of indoor air and dust exposures to fourteen (14) phthalates, including DINP.[10] Health Canada found no risk associated with exposure to dust, even with infants/children 0.5 – 4 years of age.

d) In a 2019 study in Europe, phthalates (including DINP and DIDP) and alternative plasticizers were quantified in European floor dust from homes, offices, and daycare centers from different EU countries. Human exposure was evaluated via dust ingestion and skin absorption. The authors concluded that *"...****the risk for adverse human health effects from these plasticizers via dust ingestion and dermal absorption is unlikely.***"[11]

e) A 2011 study from South Korea assessed the health risks for children (0.5 – 2 years, 2 – 5 years, 5 – 6 years and 6 – 9 years) exposed to diethylhexyl phthalate (DEHP), diethyl phthalate (DEP), dibutyl phthalate (DBP) and butylbenzyl phthalate (BBP) through house dust, surface wipes and hand wipes in child facilities and indoor playgrounds and found no associated health risks.[12]

Children and adults living in homes with vinyl flooring appear within safe exposure levels to phthalates

The Washington State Dept. of Ecology cites a number of articles claiming that children and adults living in homes with vinyl flooring were associated with higher urinary BBP metabolite concentrations. However, no additional perspective is provided with respect to these exposures. For example, one of the cited articles (Hammel et al., 2019)[13] clearly states that "*the 95th percentile exposure of BBP for children in this study is approximately 4% of the listed RfD for BBP*." In other words, the highest possible exposures in these children are at least 25-times **below** the level that has been determined to be safe. To put other exposures

[9] European Commission – Phthalates entry 52: Commission conclusions on the review clause and next steps. Brussels, 15 January 2014.

[10] State of the Science Report Phthalate Substance Grouping – 1,2-Benzenedicarboxylic acid, diisononyl ester, 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (Diisononyl Phthalate; DINP), Environment Canada Health Canada, August 2015– https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=47F58AA5-1#Toc0931.

[11] Christia C, Poma G, Harrad S, de Wit CA, Sjostrom Y, Leonards P, Lamoree M, Covaci A (2019) Occurrence of legacy and alternative plasticizers in indoor dust from various EU countries and implications for human exposure via dust ingestion and dermal absorption. *Environmental Research* **171:** 204-212.

[12] Kim H-H, Yang J-Y, Kim S-D, Yang S-H, Lee C-S, Shin D-C, Lim Y-W (2011) Health Risks Assessment in Children for Phthalate Exposure Associated with Childcare Facilities and Indoor Playgrounds. *Environ Anal Health Toxicol* **26:** e2011008.

[13] Hammel SC, Levasseur JL, Hoffman K, Phillips AL, Lorenzo AM, Calafat AM, Webster TF, Stapleton HM (2019) Children's exposure to phthalates and non-phthalate plasticizers in the home: The TESIE study. *Environment International* **132:** 105061.

in perspective, we estimated the daily intake levels for the three other publications cited in the report and compared them to existing safe dose estimates for BBP (Table 1):

Table 1: Daily intake estimates for BBP

Study	Phthalate metabolite	Age of population	Urinary phthalate metabolite levels	Total daily intake (µg/kg bw/day)†	Margin of Safety††
Hammel et al., 2019	MBzP	Children 3-6 years	361 ng/ml (95th Percentile; SG-corrected)	7.4*	44.6
Just et al., 2015	MBzP	Children 5-10.7 years (mean 6.5 years, 91% less than 9 years)	170 ng/ml (95th Percentile; unadjusted)	9.93	33.2
Carlstedt et al., 2013	MBzP	Infants 2-6 months	7.6 ng/mol creatinine (geometric mean; creatinine adjusted)	1.07×10^{-6}	308×10^{6}
Shu et al., 2019	MBzP	Pregnant mothers, mean age of 31 years ± 4.8 years	30 nmol/mmol (95th Percentile; creatinine adjusted)	2.61	126.4

*Calculation provided in Table S13 in Hammel et al., 2019 – https://ars.els-cdn.com/content/image/1-s2.0-S0160412019319099-mmc1.pdf.

†See appendix for detailed calculations.

††Based on safe dose level of 330 µg/kg bw-d established by the US Consumer Product Safety Commission (CPSC) based on suppression of fetal testosterone synthesis in rats.[14]

As shown in Table 1, conservative estimates of the highest exposed toddlers and children (95th percentile) were <10 µg/kg bw. 95th percentile exposures in pregnant mothers was 2.6 µg/kg bw and mean exposure levels in 2-6 month-old infants was extremely small (0.00000107 µg/kg bw). In all cases, highest range of exposures were well below safe levels as established by federal regulatory agencies. We note that urinary estimates account for total exposures to BBP through all routes of exposure, where indoor exposures (e.g. indoor air, household dust, furniture, vinyl flooring etc.) contribute approximately 85% of total exposures to BBP.[15] In other words, ***when put in perspective, none of the BBP exposures cited by the Washington***

[14] Table D-8: Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (July 2014). Appendix D. Cumulative Risk. https://www.cpsc.gov/s3fs-public/Appendix-D-Hazard-Index-FINAL-Comp.pdf.

[15] Table E1-19 & E1-20: Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (July 2014). Appendix E1. Modeling Consumer Exposure to Phthalate Esters. https://www.cpsc.gov/s3fs-public/Appendix-E1-Phthalate-Exposure-FINAL.pdf.

State Dept. of Ecology provides any evidence of a human health concern with respect to vinyl flooring even at the highest exposure levels.

We note that all the examples cited above were with respect to LMW phthalates (BBP). As we noted in the previous sections, extensive evaluations of HMW phthalates like DINP and DIDP in household air and dust have found no evidence of a human health concern.

Vinyl flooring has not been shown to be the cause of asthma symptoms

Washington State Dept. of Ecology cites a couple of publications that claim to have found an association between phthalate exposures from vinyl flooring with worsening asthma symptoms. This is a typical example of mere "*associations*" or "*links*" from observational studies being misleadingly cited as direct evidence that phthalates cause asthma in children. As noted earlier, the European Scientific Committee on Health and Environmental Risks (SCHER) found no evidence that phthalates are associated with asthma or rhinitis in children.[16] In many cases, the results have been inconsistent, with some even showing a protective association between pre-natal phthalate exposure and asthma (Carroll et al, 2019). In some cases, positive associations identified based on "*self-reported*" questionnaires cannot be replicated when the comparison is made with actual asthma diagnosis by a health professional (Odebeatu et al, 2019).

It should be noted that the widespread nature of phthalate exposure in the population significantly increases the potential for chance associations.[17] Bornehag & Nanberg, 2010 evaluated the epidemiological and *in vivo* experimental data for potential explanatory mechanisms. Overall, the authors found limited correlation between experimental studies designed to outline the key mechanisms in the pathology of allergic asthma following phthalate exposure and epidemiological findings of phthalate association with asthma in humans. Many *in vivo* animal studies reviewed found no evidence of an immunological response related to asthma (Butala et al, 2004; Dearman et al, 2009; Larsen et al, 2004; Shin et al, 2014). Where effects were found, these were limited to adjuvant effects at environmentally unrealistic doses (5 mg/kg bw and higher in some cases) (Larsen et al, 2007) and using routes of administration (subcutaneous or intraperitoneal) that are not relevant to human contact with phthalates (Kimber & Dearman, 2010). Overall, Bornehag & Nanberg, 2010 concluded that despite the data available, "*important questions of clinical relevance of real life exposure and identification of molecular targets that can explain interactions largely remain to be solved*."

No phthalate esters have tested positive in standard assays (guinea pig maximization test and murine local lymph node assay) to identify chemical respiratory allergens (Kimber et al, 2007), and in some cases, phthalates like DEP have been used as non-sensitizing negative controls in the evaluation of *in vitro* methods for skin sensitization testing (Rovida et al, 2013). There has been no evidence of an increased risk for atopic or respiratory sensitization among occupational workers and no phthalate is classified for sensitization hazard under the EU REACH legislation.

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[16] See footnotes 6 and 7.
[17] Expert reaction to phthalates in pregnancy and asthma in children (September 17, 2014). https://www.sciencemediacentre.org/expert-reaction-to-phthalates-in-pregnancy-and-asthma-in-children/.

Studies cited by Washington State Dept. of Ecology Do Not Support the Asthma Theory

Bornehag et al, 2005

The Washington State Dept. of Ecology cited Bornehag et al, 2005 as evidence that presence of floor moisture and PVC significantly increased the risk of asthma. This citation is misleading. First, the association with PVC was only found in the crude analysis. According to the authors, "***the association between PVC as flooring material and symptoms found in the crude analyses disappeared in the adjusted analyses.***" The authors further clarified that "*PVC as flooring material was not unequivocally associated with symptoms in this study in adjusted multivariate analyses*." The only association the authors found in the adjusted analysis was with PVC in combination with water leakage/dampness. As the authors note, the association with the combination of water leakage and PVC "*is a proxy for something else*" rather than emissions from PVC, clear indication that phthalates are not involved.

Norback et al, 2000

The Washington State Dept. of Ecology cited Norbäck et al, 2000 as evidence that asthma symptoms were associated with phthalate degradation in PVC flooring, specifically DEHP. **First, it is critical to note that the only statistical finding in the study was an association between building dampness and asthma symptoms in workers**. It presumes that DEHP must be involved (without direct evidence) simply because of the presence of low levels of 2-ethyl-hexanol (a building block for DEHP) in the air. This conclusion is speculative and misleading.

1. The authors provide no evidence that DEHP was specifically and solely used in the PVC flooring for buildings where dampness was found.
2. The authors speculate that exposure to MEHP through alkaline degradation is likely responsible for the asthma symptoms, however, there is no evidence to show that internal exposure to MEHP was any different in workers with and without asthma symptoms.
3. As the authors themselves have cited in the references, dampness in and of itself is associated with adverse respiratory effects in humans, regardless of type of flooring used.

Tuomainen et al, 2004

The Washington State Dept. of Ecology cites Tuomainen et al, 2004 as evidence implicating PVC flooring with respiratory symptoms. This study provides no statistical evidence of an association between phthalate exposure and respiratory symptoms. It simply compares the number of complaints before and after building renovation to eliminate dampness. It then assumes that because 2-ethyl hexanol levels declined after renovation, the respiratory effects must have been related to phthalate exposure from PVC flooring. This is simply speculation.

There is no direct evidence of phthalates as a concern for sensitive environmental species

Washington State Dept. of Ecology contends that release of phthalates from vinyl flooring can contribute to environmental concentrations through release from product into air or dust. The main concern is that environmental release of phthalates may be a concern to sensitive species, especially as the Washington State Southern Resident Orca Task Force recently listed phthalates as "*chemicals of emerging concern that* *threaten the health of orcas and their prey*."[18] However, no direct evidence was provided to support this concern.

Available information confirms that the environmental concern regarding high molecular weight phthalates (e.g. DINP and DIDP) are unfounded, that they exhibit low toxicity to aquatic organisms, and are ranked low for persistence and bioaccumulation. Staples et al, 1997 reviewed the extensive database of acute and chronic aquatic toxicity data for 18 phthalate esters, evaluating nearly 400 test results covering more than 60 species of micro-organisms, algae, invertebrates and fish for both freshwater and saltwater species. The authors concluded that phthalate esters with alkyl chain lengths greater than 6-carbon atoms (e.g. DINP and DIDP) showed no acute or chronic toxicity in algae or fish. Although inconsistent results were reported with daphnids, these were attributed to physical effects as these were observed at exposure concentrations exceeding true water solubility.

A detailed exposure fate and risk characterization of DINP in sewage treatment plants, surface water, sediments and terrestrial compartment (soil), through each life cycle step (including manufacture, processing in PVC and non-PVC, uses in adhesives, sealants, inks, paints, etc.) is provided in Tables 3.47, 3.48 and 3.49 of the EU 2003 risk assessment of DINP.[19] In all cases, a "***no risk***" conclusion was reached for all organisms in all ecosystems evaluated. A similar detailed EU environmental fate and risk characterization of DIDP is also available and addresses exposures in sewage treatment plants, surface water, sediments and terrestrial compartment (soil), through each life cycle step (including manufacture, processing in PVC and non-PVC, uses in anti-corrosion paints, anti-fouling paints, sealing compounds and inks for textiles, etc.).[20] The EU found ***no risk*** associated with exposure to DIDP in all of the ecosystems evaluated.

Environment and Climate Change Canada (ECCC) evaluated the potential for DINP to cause ecological harm in a draft report published in 2015.[21] With respect to surface water, ECCC concludes that "*adverse effects are not expected to occur up to the water solubility limit of the substance*." With respect to sediment organisms, ECCC concluded that "*no adverse effects were observed in sediment testing up to the highest concentrations of DINP tested*." In acute and/or chronic testing with soil micro-organisms, including earthworms and ryegrass, the ECCC confirmed that "*no adverse effects were seen at highest test concentrations ranging from 1000 to 10000 mg/kg dw of soil*." Identical conclusions were reached for higher molecular weight phthalates like DIDP and DUP (di-undecyl phthalate).[22] The ECCC report also

[18] Southern Resident Orca Task Force: Final Report and Recommendations. November 2019. https://www.governor.wa.gov/sites/default/files/OrcaTaskForce_FinalReportandRecommendations_11.07.19.pdf.
[19] European Union Risk Assessment Report (2003). 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.
[20] European Union Risk Assessment Report (2003). 1,2-benzenedicarboxylic acid, di-C9-11-branched alkyl esters, C10-rich and di-"isodecyl" phthalate (DIDP). https://echa.europa.eu/documents/10162/190cf4c4-b597-4534-9b71-f79fce55050b.
[21] State of the Science Report Phthalate Substance Grouping 1,2-Benzenedicarboxylic acid, diisononyl ester 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich (Diisononyl Phthalate; DINP). Environment Canada Health Canada August 2015. https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=47F58AA5-1#Toc08.
[22] State of the Science Report Phthalates Substance Grouping Long-chain Phthalate Esters 1,2-Benzenedicarboxylic acid, diisodecyl ester (diisodecyl phthalate; DIDP) and 1,2-Benzenedicarboxylic acid, diundecyl ester (diundecyl phthalate; DUP). Environment Canada Health Canada August 2015. https://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=D3FB0F30-1#Toc08.

characterized the exposure and risk of exposure to DINP and DIDP for two fish-eating mammalian wildlife species, mink and river otter. ECCC concluded that daily intake rates of both phthalate esters "*would be very low and much lower than the lowest reported LOAEL*," and that potential adverse effects are unlikely to occur in either wildlife species.

Detailed overviews of the environmental fates of DINP, DIDP and DUP are provided in the respective ECCC reports published in 2015 and referenced in footnotes 20 and 21. According to the level III fugacity report referenced in the ECCC report, DINP has a low volatility (vapor pressure – 6.8×10^{-6} to 2.9×10^{-3} Pa at 25 ºC) and low water solubility (4.1×10^{-5} to 0.2 mg/L at 22 to 25 ºC). Hence, DINP released into water is likely to distribute primarily into the sediment compartment (79-89%), with <20% remaining in the water column. DINP distribution to air from water was considered to be minimal (0-0.1%). The model predicts that DINP released into soil will strongly sorb to organic matter in the soil and 100% remain in the soil compartment, due to its low water solubility and high partition coefficient. The model prediction of low mobility for DINP means that it is unlikely to leach through soil to groundwater or a surface source of drinking water. According to the Canadian report, DINP is rapidly biodegraded in aerobic aqueous environments, with 68% of the parent substance removed within 1 day and 90-100% removed within 5-28 days. The DINP half-life under aerobic aqueous conditions has been estimated to be 7-40 days. Overall, the physico/chemical properties of DINP (low water solubility and high partition coefficient/high hydrophobicity) are such that it is rapidly degraded in water and primarily partitions to suspended particulate fraction of surface waters in the event of spillage into water. Owing to its higher molecular weight, the Canadian report found identical environmental fate characteristics for DIDP and DUP.

Overall, there is no evidence to support the Washington State DOE concern regarding environmental exposures to high molecular weight phthalates, including exposures to sensitive wildlife species.

Existing regulations

The Washington State DOE section on existing regulations assumes that phthalates are heavily regulated in several sectors and hence regulating them for use in applications like vinyl flooring is justified. However, this line of reasoning is highly misleading, particularly for HMW phthalates. As noted previously, while the term "phthalates" represent a broad class of chemicals with a similar functional group, phthalates are structurally distinct from each other. The structural differences are reflected in their respective hazards and how they are classified and regulated around the world.

Currently, no U.S. federal regulations exist for phthalates in vinyl flooring

Washington DOE indicates that there are no US federal regulations for phthalates in vinyl flooring, this gives the misleading impression that this is a gap that needs to be filled by state regulations. While there are no specific regulations for phthalates in vinyl flooring in the EU, four LMW phthalates (DEHP, DBP, BBP and DIBP) are considered substances of very high concern (SVHC) and require authorization under the REACH regulation for use in the EU. This means, for example, that a manufacturer of a final article (e.g. vinyl flooring) containing one of the phthalates requiring authorization must notify ECHA if the product is manufactured in quantities above one ton/producer or importer per year and if one of these phthalates is present in the final article above a concentration of 0.1% (w/w).[23] By contrast, no such regulatory requirements exist for HMW phthalates like DINP and DIDP in the EU. This is not an oversight, but the result of a detailed regulatory review. In 2013, ECHA published a detailed review of the hazards and risks of the use of DINP and DIDP in various applications, including use in vinyl flooring.[24] ECHA found no evidence of a public health concern with children or adults. In 2017, Health Canada published a similarly detailed review of the hazards and risks of DINP and DIDP in several applications, including vinyl flooring.[25] It also found no evidence of a human or environmental health concern. Hence, while it is true that no US federal regulations exist for phthalates in vinyl flooring, it is hardly an outlier and is not evidence of a regulatory gap. **No regulations exist for HMW phthalates in vinyl flooring in the United States or internationally and this absence of regulation is based on clear scientific evidence of no human or environmental health concerns with product use**.

The EPA is evaluating five phthalates under the Toxic Substances Control Act (TSCA)

As Washington State DOE rightly points out, the US EPA is currently evaluating 5 phthalates under the revised Toxic Substances Control Act (TSCA).[26] However, each of these 5 phthalates (DBP, BBP, DEHP, DIBP and DCHP) are low molecular weight (LMW) phthalates that are classified as category 1B reproductive toxicants (toxic for reproduction under REACH Article 57c) and considered to be SVHCs under the REACH regulation[27]. By contrast, high molecular weight phthalates (e.g. DINP, DIDP, DnOP) are **not** considered to be reproductive toxicants, are **not** SVHCs and are **no**t identified as high priority for risk evaluation by the US EPA. Thus, each phthalate should be evaluated separately and high molecular weight phthalates such as DINP and DIDP should not be grouped with low molecular weight phthalates with respect to future regulatory action.

Due to the extensive body of research on HMW phthalates, and the fact that they have been reviewed by numerous government regulatory agencies in the last six years and found to be safe in current applications, manufacturers have requested that EPA conduct risk evaluations for the HMW phthalates DINP and DIDP under TSCA Section 6. As the manufacturers stated,[28] this was a voluntary initiative based on the need to have a similar thorough hazard and risk assessment of DINP and DIDP in the US as exists in the EU, Canada and Australia in the interest of consumer confidence.

State regulations are not based on scientific reviews

The majority of state regulations on phthalates are not based on the decisions of independent scientific state agencies that have identified any potential health or environmental concerns. Some examples include:

[23] REACH authorization – https://echa.europa.eu/substances-of-very-high-concern-identification-explained
[24] See footnote 3.
[25] See footnote 10.
[26] US EPA (2019). Chemical Substances Undergoing Prioritization: High-Priority. https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemical-substances-undergoing-prioritization-high
[27] European Chemicals Agency (ECHA). Candidate List of substances of very high concern for Authorisation. https://echa.europa.eu/candidate-list-table.
[28] ACC's High Phthalates Panel Requests Manufacturer Requested Review of DINP and DIDP – https://www.americanchemistry.com/Media/PressReleasesTranscripts/ACC-news-releases/ACCs-High-Phthalates-Panel-Requests-Manufacturer-Requested-Review-of-DINP-and-DIDP.html.

1. In Maine, DIDP is listed (under the Toxic Chemicals in Children's Products Law) as a chemical of concern because it is listed on California Prop 65 as a developmental toxicant. However, the US Consumer Product Safety Commission (US CPSC) has found that DIDP is **not** antiandrogenic and poses **no** reasonable certainty of harm to children, pregnant women, or other susceptible individuals.[29] As a result, DIDP is **not** restricted from use in children's toys or childcare articles in the United States as of April, 2018.

2. In Minnesota, the Toxic Free Kids Act of 2010 lists DIDP as a Chemical of High Concern for children based on its presence on the Maine Chemicals of Concern list, California Prop 65, Washington State Chemicals of High Concern for Children list and the US CPSC. As noted above, the Maine listing of DIDP is itself based on its presence on California Prop 65. As noted above, the US CPSC source is obsolete as the Agency has reversed the previous restriction on its use in children's toys and childcare articles.

3. Oregon (under its Toxic-Free Kids Act) lists DINP and DIDP in its High Priority Chemicals of Concern for Children's Health list. Both are adopted from Washington State's Department of Ecology's list of 66 chemicals of concern that was first published in 2015. Washington State's listing of DINP in its Chemicals of High Concern to Children list provides developmental toxicity as the basis. This basis is counter to the recent decision by the European Chemicals Agency (ECHA) to declare that DINP is **neither** a reproductive **nor** developmental hazard, following an exhaustive 3 year evaluation of the available scientific data.[30]

4. In 2019, Maine passed LD1433 (the Safe Food Packaging Act), which bans the use of phthalates in food packaging. This ban was not based on an identified science-based concern for the presence of phthalates in food by an independent regulatory agency. No such phthalates ban in food packaging exists anywhere else in the world and phthalates like DINP and DIDP remain permitted for use in food packaging in the United States, European Union, China and South Korea, on the strength of several regulatory assessments confirming that phthalates pose no concern in food contact, from the Food Safety Authority of Ireland (FSAI), the New Zealand Ministry of Primary Industries (MPI), Food Standards Australia and New Zealand (FSANZ), European Food Safety Authority (EFSA) and Environment and Climate Change Canada (ECCC). In contrast to Maine, on August 9, 2019, Japan announced the listing of DINP and DIDP in its first draft of materials that are permitted for safe use in food contact materials.

[29] Federal Register (82 FR 49938). Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates. https://www.federalregister.gov/documents/2017/10/27/2017-23267/prohibition-of-childrens-toys-and-child-care-articles-containing-specified-phthalates.

[30] 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.

These and many more examples are reasons why the mere presence of phthalates in existing US state regulations should not be the basis to consider DINP and DIDP as chemicals of concern.

The European Chemicals Agency (ECHA) considers 10 LMW phthalates as substances of very high concern (SVHC); no HMW phthalates are SVHCs

As noted by the Washington State DOE, 11 phthalates are listed on the EU candidate list of substances of very high concern (SVHC).[31] To avoid any misconception, it is important to put this in proper context:

1. All 11 phthalates are low molecular weight (LMW) phthalates [C_3-C_6 carbon backbone]. **No HMW phthalate [≥C_7 carbon backbone] are listed as SVHCs**.

2. The SVHC listing of all 11 phthalates is based on their classification as reproductive toxicants in category 1B (presumed human reproductive toxicant). **No HMW phthalate is classified as a reproductive toxicant**. In fact, the harmonized classification for DINP in the EU (since March 2018) is "***no classification***" for reproductive or developmental toxicity.

As has been noted previously, the use of the term "phthalates" can often mask the existing nuance in regulations and it is important that clear distinction be made showing the regulatory delineation of LMW and HMW phthalates.

Conclusions

- Phthalate properties, including how they are used, hazards, exposure profiles and associated risks, vary greatly depending on the length of the carbon backbone. Attempting to regulate them as a class would be synonymous with banning all alcohol based on the acutely toxic properties of methanol.
- Reviews of scientific studies and literature by competent authorities demonstrate agreement that the current use of high molecular weight phthalates in flooring does not pose harm to human health or the environment. In Europe, vinyl flooring containing high molecular weight phthalates is considered to be safe and is permitted for use, with no restrictions.
- The 2017 Environment and Climate Change Canada detailed review of the hazards and risks of phthalates led it to propose to conclude that DINP and DIDP (including use in vinyl flooring) "**do not meet the criteria under paragraph 64(c) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.**"
- Scientific reviews by the State of California demonstrate that it is safe to use DINP in flooring up to 18.9%.

[31] In the Agency's document, 10 phthalates are mentioned. However, a review of the EU SVHC list indicates that 11 phthalates are listed. Candidate List of substances of very high concern for Authorisation – https://echa.europa.eu/candidate-list-table

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Appendix

Estimation of daily intake values to butylbenzyl phthalate (BBP)

Carlstedt et al, 2013

To estimate infants' daily exposure/daily intake (DI) to BBzP from Carlstedt et al, 2013, we utilized an iteration of the equation in Koch et al, 2003 as follows:

$$DI\ (\frac{\mu g}{kg} bw = \frac{UE\ \left(\frac{\mu g}{mol}\right) \times CE\ \left(\frac{mol}{day}\right)}{F_{UE}\ \times bw\ (kg)} \times \frac{MW_{BBzP}}{MW_{MBzP}} - \textbf{\textit{Equation 1}}$$

Where UE is the creatinine-adjusted urinary excretion of the BBzP metabolite (MBzP) given in Carlstedt et al, 2003 as 7.6 ng/mol or 0.0076 µg/mol. CE is the 24-hr creatinine excretion rate for infants 2-6 months. CE was estimated using the equations in Mage et al, 2008. For the infant age range, we estimated an average CE of 71.5 mg/day or 632.7 x 10^{-6} mol/day[32]. F_{UE} is the molar fraction of the urinary excreted monoester related to the ingested diester. For MBzP, an F_{UE} of 0.73 was taken from Table D-1 of the US Consumer Product Safety Commission (CPSC) report on phthalate cumulative risk[33]. BW represents average body weight for infants 2-6 months, which was estimated to be 7.5 kg, based on estimates from the US EPA exposure factors handbook[34]. MW_{BBzP} and MW_{MBzP} represent molar weights of the diester (312 g/mol) and the monoester (256 g/mol).

$$DI\ (\frac{\mu g}{kg} bw = \frac{0.0076\ \left(\frac{\mu g}{mol}\right) \times 632.7 \text{ x } 10^{-6}\ \left(\frac{mol}{day}\right)}{0.73\ \times 7.5\ (kg)} \times \frac{312\ (\frac{g}{mol})}{256\ (\frac{g}{mol})}$$

$$\boldsymbol{DI\ = 0.00107\ ng/kg\ bw}$$

Shu et al, 2019

Shu et al, 2019 reported 95th percentile creatinine-adjusted urinary excretion of MBzP in pregnant mothers, average age of 31 ± 4.8 years, of 30 nmol/mmol. Using the molecular weight of MBzP (256 g/mol), this value is equivalent to 7.68 µg/mmol creatinine or 7.68 mg/mol creatinine[35]. In estimating dietary intake by the pregnant mothers, we used a modified version of equation 1 as shown below:

$$DI\ (\frac{\mu g}{kg} bw = \frac{UE\ \left(\frac{\mu g}{mol}\right) \times CE\ \left(\frac{mol}{kg} bw\right)}{F_{UE}} \times \frac{MW_{BBzP}}{MW_{MBzP}} - \textbf{\textit{Equation 2}}$$

In this equation, body weight is not specifically taken into account as the 24-hr creatinine excretion (CE) is normalized to body weight. CE for pregnant women was estimated to be 23 mg/kg-bw/day[36] or 203.5 x 10^{-6} mol/kg bw[37]. F_{UE}, MW_{BBzP} and MW_{MBzP} values remain constant from the previous calculation.

[32] 1 µmol creatinine = 0.113 mg creatinine.

[33] Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives (July 2014). Appendix D. Cumulative Risk. https://www.cpsc.gov/s3fs-public/Appendix-D-Hazard-Index-FINAL-Comp.pdf.

[34] US EPA Exposure Factors Handbook Chapter 8 (2011) – https://www.epa.gov/expobox/exposure-factors-handbook-chapter-8.

[35] To convert 30 nmol MBzP to a mass, we multiply by the molar mass of 256 g/mol = 7.68 µg.

[36] See footnote 2.

[37] Divide 23 mg creatinine by 0.113 = 203.5 µmol or 203.5 x 10^{-6} mol.

$$DI\ (\frac{\mu g}{kg}bw = \frac{7680\ \left(\frac{\mu g}{mol}\right)\times 203.5 \text{ x } 10^{-6}\ \left(\frac{mol}{kg\ bw}\right)}{0.73}\times\frac{312\ (\frac{g}{mol})}{256\ (\frac{g}{mol})}$$

$$\boldsymbol{DI\ = 2.61\ \mu g/kg\ bw}$$

Just et al, 2005

To estimate dietary intake (DI) for children based on urinary MBzP metabolite levels reported in Just et al, 2015 we used the equation in Koch et al, 2007 as follows:

$$DI\ (\frac{\mu g}{kg}bw = \frac{UE\ \left(\frac{ng}{ml}\right)\times UV\ \left(\frac{ml}{kg}bw\right)}{F_{UE}\ \times 1000}\times\frac{MW_{BBzP}}{MW_{MBzP}} - \boldsymbol{Equation\ 3}$$

According to Just et al, 2005, urinary phthalate metabolite levels were unadjusted (i.e. metabolite levels are reported as ng/ml of urine volume based on personal communication). As a result, the dietary intake calculation took urine volume into account. UV is the 24-hour urine volume per unit body weight. For children in a similar age range, Koch et al, 2003 reported reference urinary volume values of 0.019 to 0.035 L urine/kg bw/day. To be conservative, we used the higher end of this reference range.

$$DI\ (\frac{\mu g}{kg}bw = \frac{170\ \left(\frac{ng}{ml}\right)\times 35\ \left(\frac{ml}{kg}bw\right)}{0.73\ \times 1000}\times\frac{312\ (\frac{g}{mol})}{256\ (\frac{g}{mol})}$$

$$\boldsymbol{DI\ = 9.93\ \mu g/kg\ bw}$$

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