TO: Washington State Department of Ecology

RE: Washington State Draft Phthalates Action Plan

The Washington State Department of Ecology (Ecology) is soliciting comments on its Draft Phthalates Action Plan (May 2023). The American Chemistry Council (ACC) High Phthalates Panel[1] is pleased to provide comments relating to the ongoing Washington State Phthalates Action Plan process. Below we set forth our comments specific to 1) Ecology's decision to address ortho-phthalates as a chemical class; 2) phthalates in the environment; 3) phthalates in industry and manufacturing, and 4) phthalates in products.

General Concerns Related to Ecology's Failure to Address the Significant Differences in the Physical, Chemical and Biological Properties of Phthalates

As we have stated in previous comments on the Action Plan process, it is not clear what the main concern is for phthalates. None of the five Advisory Committee meetings provided any specific evidence that phthalates are a human or environmental health concern in food, drinking water, consumer articles, aquatic/terrestrial organisms or benthic sediments.

Virtually all the questions being asked have been answered in extensive, publicly available regulatory hazard/exposure/risk evaluations by regulatory agencies around the world. For instance, a multi-year evaluation of the human and environmental risk associated with 28 phthalates was completed in late 2020 by Canada. All but one phthalate were confirmed **not** to "*pose a risk to health or the environment at current levels of exposure.*"[2]

The US EPA has commenced thorough risk evaluations of the seven most consumed phthalates in the United States. The risk evaluations will encompass all possible routes of human exposure (occupational, consumer and fenceline communities) and environmental fate and effects from waste management and discharge. The evaluations will also cover all conditions of use, including manufacturing, imports, transportation, processing, conversion to final articles, end-of-life disposal and recycling. The work conducted by Ecology seems duplicative of the current ongoing work at EPA.

[1] The American Chemistry Council (ACC) High Phthalates Panel is comprised of companies that manufacture, compound, convert, or import specific high molecular weight phthalates. These phthalates include di-isononyl phthalate (DINP) and di-isodecyl phthalate (DIDP), both of which are currently undergoing comprehensive manufacturer-requested risk evaluations under the EPA TSCA program.

[2] Phthalates - Canada.ca

While newer, highly sensitive analytical techniques now make it possible to measure parts per billion/trillion (ppb/ppt) levels of phthalates in water, soil, sludge etc., the presence of chemicals at such low levels are not, in isolation, indicative of concern.

Treating Ortho-phthalates as a Class is Not Scientifically Defensible

As Ecology states in the Draft Phthalates Action Plan, Ecology addresses ortho-phthalates as a chemical class, and does not examine or address each phthalate individually. Considering the clear and significant differences in the physical, chemical and biological properties of phthalates, recommendations for ortho-phthalates as a class likely cannot be done in a scientifically-defensible manner. Due to these distinctions, as well as use of phthalates in distinctly different applications, ACC continues to emphasize that phthalates should be treated as distinct categories based on toxicological similarity, specifically as low molecular weight (LMW) and high molecular weight (HMW) phthalates. The Draft Phthalates Action Plan acknowledges these differences on pg. 169 where Ecology makes a clear distinction for three different groupings of phthalates. Multiple groupings with recognized differences in physical-chemical properties and toxicities are appropriate.

1. Low molecular weight phthalates have a distinct hazard profile from high molecular weight phthalates.

LMW phthalates with 3 – 6 carbons in the straight chain backbones in the alkyl side chains have been shown to cause adverse reproductive effects in animal studies (Fabjan et al 2006). More specifically, toxicological effects observed in male rats after exposure to LMW phthalates during a critical window of male reproductive tract development include reproductive abnormalities characterized by malformations of the epididymis, vas deferens, seminal vesicles, prostate, external genitalia (hypospadias), cryptorchidism and testicular injury together with permanent changes (feminization) in the retention of nipples/areolae (sexually dimorphic structures in rodents) and demasculinization of the growth of the perineum resulting in a reduced anogenital distance (AGD) in adulthood (Gray and Foster, 2003; Foster, 2005; Foster, 2006). Four LMW phthalates have been classified for toxicity to reproduction in the EU based on these following effects (ie., cleft palate, neural tube defects, cryptorchidism, hypospadias, testicular tubular atrophy, complete ablation of spermatogenesis, fetal death).

These effects are **not** seen with HMW phthalates tested in similar study designs.

High molecular weight phthalates with the longest straight chain being 7 – 13 carbons in the alkyl side chains do not demonstrate adverse reproductive effects in animal studies (Boberg et al. 2011, Clewell et al., 2013a, Clewell et al., 2013b, Furr et al. 2014, Gray et al. 2016, Hannas et al. 2011, Hellwig et al 1997, Willoughby et al., 2000, Zirken et al. 1989). As an example, DINP has been tested at doses above 1000 mg/kg/day (Waterman et al. 2000, Masutomi et al. 2003) with no induction of the adverse outcomes on development of the male reproductive tract that are observed with certain other phthalates (most notably DEHP and DBP). This clearly differentiates the DINP dataset from the LMW phthalates on the basis of toxicological profile.

2. When a weight of evidence approach is followed, no further action is necessary for HMW phthalates due to inadequate evidence of fertility or developmental effects.

The human health effects data reported in Appendix 2 follows a narrative approach and is focused primarily on studies which provide positive evidence of an association between exposure and a health effect. For example, the 2017 National Academies of Science, Engineering, and Medicine report entitled "Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals" is referenced on page 148 of the Draft Phthalates Action Plan to support the conclusion that six phthalates are presumed or suspected to pose a reproductive hazard to humans based on reduced fetal testosterone and reduction of anogenital distance in male offspring of exposed mothers (NAS 2017). However, Ecology fails to highlight that some associations were evaluated by NAS and found to be inadequate (e.g., inadequate evidence for an association between DINP exposure and change in anogenital distance).

To increase transparency and objectivity, a science-based evaluation of all available data on each phthalate should be conducted, and conclusions on the association between individual phthalate exposure and health effect should be based on the weight of the evidence. When a weight of the evidence approach was followed by Dekant and Bridges (2016), clear distinctions were found between the toxicological profiles for LMW and HMW phthalates, where developmental effects resulting in classification are observed after LMW exposure. There was no evidence supporting classification for high molecular weight phthalates such as DINP and DIDP.

Phthalates in the Environment

As we stated in previous comments, the environmental fate and disposition of phthalates is a prime example of why evaluation of phthalates as a broad class is not appropriate. As noted above, phthalates include a variety of chemicals with ***distinct*** toxicological, physical and chemical properties. HMW phthalates have considerably low vapor pressure and high solid-phase partition coefficients. These physico/chemical parameters are extremely important in understanding how these substances behave in the environment.

<u>Air</u>
While some phthalates are listed as hazardous air pollutants (HAPs), HMW phthalates like DINP (5.4×10^{-7} mm Hg at 25 ºC) and DIDP are not. Due to their low vapor pressures, presence of these substances in ambient air is expected to be considerably low. For example, using ideal gas law, we

can estimate the saturated vapor concentration (SVC) (assume closed system) of DINP at 25 ºC. We estimate this as 12 μg/m^3. Assuming ambient air concentration is <1% of SVC[3], ambient vapor concentration of DINP at 25 ºC ➔ <0.12 μg/m^3. This concentration is too low to be of any significance.

Concern was raised during the Advisory Committee meetings regarding the potential presence of phthalates in particulates in air. Environment and Climate Change Canada (ECCC) published Level III fugacity models to predict environmental distribution of individual phthalates. For DINP[4] and DIDP,[5] the model predicts that >90% of plasticizer released to air will be sorbed to particulates in the air and subsequently deposited to soil, limiting potential for air transport. ECCC also noted that DINP degrades rapidly in air, with a half-life of <2 days.

Storm water and sediment

The ECCC fugacity model cited above also shows low partitioning of HMW phthalates to water. Less than 20% of plasticizer release to water remained in the water phase, with >75% partitioning to sediment. ECCC reported that DINP degrades rapidly in water, with a half-life of <6 months.

Soil

The ECCC fugacity model found that 100% of DINP released to soil remains in the soil compartment. Due to the high solid phase partition coefficient, the substance is expected to sorb to soil organic matter and is ***unlikely to leach through soil into groundwater***.

As we noted previously, during the Action Plan process, Ecology cited its Cleanup Levels and Risk Calculation (CLARC) study from 2020.[6] The study evaluated levels of certain phthalates in the marine environment of Puget Sound (WA). Frequency of detection for DINP was very low (10%), with an estimated concentration of 10-150 ng/L. The CLARC report identified a PNEC of 0.00051 μg/L for DINP, which is considerably below the estimated concentration. As a result, the CLARC report concluded that these low levels of DINP reported posed a risk to the marine environment. This is not supported by other more exhaustive data-driven environmental risk evaluations. The CLARC study does not indicate how its PNEC (0.00051 μg/L) is derived. The NORMAN database of ecotoxicology, cited as the source of this value, lists 21 freshwater acute and chronic studies in various organisms. No adverse effects were found in any of the studies and effect levels were well above water solubility.[7] As a result, no PNEC can be derived. In its risk

[3] Pengelly, I., Johnson, P., Investigation of relationship between saturated vapour concentration and real exposure to vapour. Health and Safety Executive, 2012.

[4] Environment and Climate Change Canada - State of the Science Report - Phthalate Substance Grouping - DINP

[5] Environment and Climate Change Canada - State of the Science Report - Phthalates Substance Grouping - Long-chain Phthalate Esters

[6] Zhenyu Tian, Katherine T. Peter, Alex D. Gipe, Haoqi Zhao, Fan Hou, David A. Wark, Tarang Khangaonkar, Edward P. Kolodziej, and C. Andrew James. *Environmental Science & Technology* **2020** *54* (2), 889-901

[7] According to the European Union Risk Evaluation of DINP, true water solubility of DINP is approximately 0.6 μg/L.

evaluation of DINP,[8] the European Commission concluded that calculation of a $PNEC_{sediment}$ was not possible because no aquatic PNEC could be derived "***due to the lack of identified adverse effects.***" The European Commission thus concluded that DINP "*has no adverse effects towards benthic organisms*." The Canadian State of the Science report on DINP reached the same conclusions.[9] Overall, the ECCC confirmed that "*tissue concentrations of DINP in sediment species are unlikely to reach levels predicted to result in acute or chronic effects due to baseline narcosis*". In line with the EU and Canadian evaluations, the true conclusion from the CLARC study should have been that DINP (as well as DIDP and DIUP) are found at a low frequency in marine sediments and do not pose a risk in these environments.

Biota

Ecology has indicated that it does not conduct routine biomonitoring studies on biota. There is no evidence that this is necessary for HMW phthalates. As noted, the European and Canadian risk assessment reports for DINP report no adverse effects related to exposure, either to fish, game or vegetation.[10]

Thus, the science supports the following conclusions concerning HMW phthalates:

1. Ambient air emissions and transport are negligible (due to low vapor pressures and rapid degradation in air).
2. HMW phthalates can be sorbed to air particulates, however these are deposited in soil and are not transported to any significant degree in air.
3. HMW phthalates released in water preferentially partition to sediments.
4. 100% of HMW phthalates deposited in soil strongly sorbs to organic matter, hence ability to leach into groundwater is negligible.

Specific Comments on Language from the Draft Action Plan:

1. p. 23 - "Failure to reduce these constant sources of phthalate release has led to recontamination of sediments in the Puget Sound area following large-scale chemical remediation efforts (Ecology, 2009a)."

p. 169 –"Failure to reduce these constant sources of phthalate release has led to the recontamination of sediments in the Puget Sound area following large-scale chemical remediation efforts (Ecology, 2010)."

This sentence suggests that the presence of phthalates in sediments negated previous remediation efforts of sediments, which is unlikely to be the case. The suggestion that phthalates were a primary driver for previous remediation efforts is also questionable. Ecology Publication 11-03-008, titled "Control of Toxic Chemicals in Puget Sound, Characterization of Toxic Chemicals in Puget Sound

[8] EU Risk Assessment Report (europa.eu)
[9] See footnote 3.
[10] See footnotes 3, 4 & 7. Staples, C.A., Adams, W.J., Parkerton, T.F., Gorsuch, J.W., Biddinger, G.R. and Reinert, K.H. (1997), Aquatic toxicity of eighteen phthalate esters. Environmental Toxicology and Chemistry, 16: 875-891.

and Major Tributaries, 2009-10," for example, does not appear to highlight phthalates at all, despite being authored in the same time period as the two references provided.

2. *P. 169 – "… the environmental fate of phthalates may differ based on molecular weight. For clarity, when discussing partitioning behavior, this section divides phthalates into three subgroups based on definitions laid out by Environment Canada and Health Canada (EC & HC, 2015a, 2015b, 2015c, 2015d). These categories are general groupings and may have some overlap within chemical properties and toxicities", "Low molecular weight or short-chain phthalates (containing sidechains of three carbons or fewer)…," "Short-chain phthalates also have high-water solubility compared to medium-chain (sidechains of three to seven carbons) and long-chain (sidechains of more than seven carbons) phthalates…"*

It is interesting that Ecology makes a clear distinction here for three different groupings of phthalates, while grouping phthalates together in other contexts. Multiple groupings with recognized differences in physical-chemical properties and toxicities are appropriate.

3. P. 170 – The extended discussion regarding algal degradation of phthalates and possible downstream impacts on the distribution of algal/toxins appears extremely speculative. It is not clear how this speculative discussion is appropriate here, particularly in the absence of discussion of other factors that could impact the algal community (e.g., nutrient loading).
4. P. 170 – It may be helpful to recognize the statement that *"…environmental concentrations of phthalates are unlikely to cause acute or chronic toxic effects in aquatic organisms (EC & HC, 2015a, 2015b, 2015c, 2015d),"* which seems to address at least half of an earlier comment on p.169, *"This leads to the potential for chronic exposure in aquatic and terrestrial systems, similar to that of persistent chemicals."*
5. *P. 144 – "The FDA regulates phthalates in cosmetics, pharmaceuticals, medical devices, and food contact substances (US EPA, 2012). In May 2022, the FDA revoked authorizations for the food contact use of 23 phthalates, while eight phthalates remained authorized for use as plasticizers and one phthalate as a monomer in food contact uses."*

This paragraph fails to provide the context that these authorizations were revoked because the specific uses were abandoned (87 Fed Reg. 31080). As written, it leaves the impression that these authorizations may have been revoked for other reasons.

Phthalates in Industry and Manufacturing

There are no known manufacturers of phthalate plasticizers in Washington, Oregon, or Idaho. The US Environmental Protection Agency is currently conducting a risk evaluation of seven phthalates, under the Toxic Substances Control Act (TSCA). These seven represent the majority of phthalates likely to be found in commerce. These risk evaluations are extensive and include examination of risks that could potentially arise from worker and environmental exposures, both from manufacturing, processing and final flexible vinyl article manufacturing sites across the United States. Any risk determination from these evaluations allows EPA to identify risk management measures to reduce exposure.

We would recommend that Ecology wait until the EPA risk evaluations are completed, as these are more than likely to address the various exposure and risk concerns.

Phthalates in Products

Potential sources of information on phthalates in product use
As part of its ongoing TSCA risk evaluation of seven phthalates (including di-isononyl phthalate [DINP] and di-isodecyl phthalate [DIDP]), the US EPA has developed publicly available individual use reports, identifying examples of where these phthalates are used. For example, Table 2-5 in the DINP use report[11] identifies real world products, product manufacturer, and percent weight in product.

Food processing
The use of phthalates in food contact applications is strictly governed by federal law. Several phthalates are permitted for safe use by several food safety authorities across the globe. For example, high molecular weight (HMW) phthalates like DINP (FCM #728) and DIDP (FCM #729) are listed in the European Union (EU) positive list of plastic materials and articles intended to come into contact with non-fatty foods [Commission Regulation (EU) No 10/2011]. These listings are based on an extensive dietary risk evaluation that concluded that current exposure from food "*is not a concern for public health*".[12] Similar safe use conclusions have been reached (and published) by Canada,[13] Australia,[14] New Zealand,[15] the United Kingdom,[16] and the Republic of Ireland.[17]

In the US, only a limited number of phthalates are used in food contact applications and only in a narrow range of such applications.[18] No phthalates were found to be used as primary plasticizers in PVC film for food service and commercial wraps (e.g. wrapping films for meat, vegetables or

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[11] Final Use Report for Di-isononyl Phthalate (DINP) CASRN 28553-12-0 & 68515-48-0) (epa.gov)
[12] FAQ: phthalates in plastic food contact materials | EFSA (europa.eu)
[13] Environment and Climate Change Canada. 2015a. 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).
[14] Food Standards Australia New Zealand. 2018. Survey of Plasticisers in Australian Foods: An Implementation Subcommittee for Food Regulation Coordinated Survey.
[15] Pearson A, van den Beuken J. 2017. Occurrence and risk characterisation of migration of packaging chemicals in New Zealand foods. Wellington, New Zealand.
[16] Bradley EL, Burden RA, Bentayeb K, Driffield M, Harmer N, Mortimer DN, Speck DR, Ticha J, Castle L. 2013. Exposure to phthalic acid, phthalate diesters and phthalate monoesters from foodstuffs: UK total diet study results. Food additives & contaminants Part A, Chemistry, analysis, control, exposure & risk assessment.30:735-742.
[17] Food Safety Authority of Ireland. 2016. Report on a Total Diet Study carried out by the Food Safety Authority of Ireland in the period 2012 – 2014. Dublin, Ireland: FSAo Ireland.
[18] Carlos KS, de Jager LS, Begley TH. 2018. Investigation of the primary plasticisers present in polyvinyl chloride (PVC) products currently authorised as food contact materials. Food additives & contaminants Part A, Chemistry, analysis, control, exposure & risk assessment. Jun; 35:1214-1222.

sandwiches at grocery stores and delis) or paper-based packaging for fast food.[19] Similar to positive listings in the EU, these phthalates are federally regulated in the US via e.g. 21 C.F.R. § 178.3740 ("*Plasticizers in polymeric substances*"), 21 C.F.R. § 177.1210 ("*Closures with sealing gaskets for food containers*"), and 21 C.F.R. § 177.2600 (*"Rubber articles intended for repeated use"*).

Building materials and consumer products

As noted previously, the ongoing US EPA risk evaluation of seven phthalates identifies uses in building materials as critical conditions of use to be evaluated. These will include potential for human and environmental exposures, through the lifecycle of these products (manufacturing to disposal or recycling). At present, there is minimal evidence that phthalate use in building materials is of any health and environmental concern. For example, extensive risk evaluations for DINP and DIDP continue to show no risk of exposure with consumer use.[20]

[19] Carlos KS, de Jager LS, Begley TH. 2021. Determination of phthalate concentrations in paper-based fast food packaging available on the U.S. market. Food Addit Contam Part A Chem Anal Control Expo Risk Assess. Mar; 38:501-512. Epub 20210125.

[20] European Chemicals Agency; Evaluation of new scientific evidence concerning DINP and DIDP In relation to entry 52 of Annex XVII to REACH Regulation (EC) No 1907/2006. 2013.

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