TO: Washington State Department of Ecology

RE: Washington State Phthalates Action Plan

Washington State Department of Ecology (Ecology), as part of its Phthalates Action Plan program, has solicited feedback regarding recommendations needed to reduce use, release and exposure to phthalates in Washington State. The American Chemistry Council's (ACC) High Phthalates Panel[1] is pleased to provide comments relating to the ongoing Washington State Phthalates Action Plan. Below we set forth our general concerns, and then set forth detailed comments specific to three of the subject areas addressed at the action plan meetings.

General Concerns

We recognize the importance of assessing chemical risk to humans and the environment. However, the Phthalates Action Plan lacks sufficient context and needs to clearly set forth the concerns necessitating the Action Plan. For example:

- It is not clear what the main concern is for phthalates. None of the four (4) Advisory Committee meetings provided any specific evidence that phthalates are a human/environmental health concern in food, drinking water, consumer articles, aquatic/terrestrial organisms or benthic sediments.

- If any, are these concerns applicable to **all** phthalates or only to a subset of phthalates?

- If any, are these concerns relevant to **all** applications where phthalates can be used, including applications with limited human/environmental contact? For instance, what is the concern with phthalates used in wire and cable for automotive applications or server farms?

- Virtually all the questions being asked have been answered in extensive, publicly available regulatory hazard/exposure/risk evaluations by regulatory agencies around the world. Why is Ecology seeking to replicate these findings? For instance, a multi-year evaluation of the human and environmental risk associated with 28 phthalates was just completed in late 2020 by neighboring Canada. All, but one (1), 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 (7) 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, and conversion to final articles, end-of-life

[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 a comprehensive manufacturer-requested risk evaluation under the EPA TSCA program.

[2] Phthalates - Canada.ca

disposal and recycling. It is not clear how the current exercise by Ecology will be more informative than the ongoing assessments.

- What is the logical outcome of this exercise?

It is imperative to point out that 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., these data have limited use in determining potential for human exposure and/or risk.

Recommendations

One of the major issues that was immediately apparent at the Advisory Committee meetings is the need to provide some background information regarding what phthalates are, how they are manufactured, properties that govern how and where they can or cannot be used, and environmental fate. We feel that this type of information would be very helpful in guiding future discussions and to help ensure that future policy recommendations are clearly focused on a specific objective.

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 (7) phthalates, under the Toxic Substances Control Act (TSCA). These 7 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 7 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[3] 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*".[4] Similar safe use

[3] Final Use Report for Di-isononyl Phthalate (DINP) CASRN 28553-12-0 & 68515-48-0) (epa.gov)

[4] FAQ: phthalates in plastic food contact materials | EFSA (europa.eu)

conclusions have been reached (and published) by Canada,[5] Australia,[6] New Zealand,[7] the United Kingdom,[8] and the Republic of Ireland.[9]

In the US, only a limited number of phthalates are used in food contact applications and only in a narrow range of such applications.[10] 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 sandwiches at grocery stores and delis) or paper-based packaging for fast food.[11] 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"*).

Animal feed as a source of phthalate exposure

High Phthalates Panel members are not aware of any use of phthalates in animal feed. A potential concern raised during the Advisory Committee meeting centered on potential use of phthalates in pesticides. We are not aware of any such use. Pesticides and pesticide ingredients are regulated by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). DINP and DIDP, for instance, are listed as approved for ***non-food use*** (NF). This means that they cannot be used as pesticide ingredients on plants that can be consumed for food. These phthalates are used as carriers for anti-microbial formulations in PVC plastics.

Use in water transport

There were questions raised during the Advisory Committee meeting regarding potential use of phthalates in applications for water transport, e.g. cross-linked polyethylene (PEX) pipe and rigid PVC pipe. Ecology should note that >95% of HMW phthalates (e.g. DINP and DIDP) are used as plasticizers (or softeners) in **flexible PVC** applications.[12] The other 5% are used in similarly non-rigid applications such as sealants, adhesives, paints and lubricants. Thus, phthalate plasticizers are not used in PEX pipes or rigid PVC (for which rigidity is a crucial performance requirement).

Building materials and consumer products

As noted previously, the ongoing US EPA risk evaluation of seven (7) 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).

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[5] 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).

[6] Food Standards Australia New Zealand. 2018. Survey of Plasticisers in Australian Foods: An Implementation Subcommittee for Food Regulation Coordinated Survey.

[7] Pearson A, van den Beuken J. 2017. Occurrence and risk characterisation of migration of packaging chemicals in New Zealand foods. Wellington, New Zealand.

[8] 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.

[9] 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.

[10] 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.

[11] 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.

[12] 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.

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.[13]

A concern was raised regarding phthalate use as components of fragrance products. This use is now almost completely phased out.[14]

Phthalates in the environment

The environmental fate and disposition of phthalates is a prime example of why evaluation of phthalates as a broad class is not appropriate. Phthalates include a variety of chemicals with ***distinct*** toxicological, physical and chemical properties. Generally, phthalates are divided into two broad classes; low molecular weight (LMW) phthalates [for example dibutyl phthalate (DBP)] have a C_3-C_6 backbone, while high molecular weight phthalates have a $\geq C_7$ backbone (such as DINP and DIDP). 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.

Air

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[15], 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 meeting 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[16] and DIDP,[17] 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***.

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[13] 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.

[14] Hubinger JC. A survey of phthalate esters in consumer cosmetic products. J Cosmet Sci. 2010 Nov-Dec; 61(6):457-65.

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

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

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

Ecology cited its Cleanup Levels and Risk Calculation (CLARC) study from 2020.[18] 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 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.[19] As a result, no PNEC can be derived. In its risk evaluation of DINP,[20] 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.[21] 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 related to exposure, either to fish, game or vegetation.[22]

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.

[18] 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

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

[20] EU Risk Assessment Report (europa.eu)

[21] See footnote 15.

[22] See footnotes 15, 16 & 19. 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.