The Washington State Department of Ecology (hereinafter "DoE") is soliciting comments on the draft scope of its Phthalates Action Plan. DoE has identified two central goals for the action plan, as follows:

- *Develop and make actionable recommendations that will **reduce human exposure** and **reduce environmental contamination**—focusing on **source reduction**.*
- *Focus on the potential for exposure in **sensitive and overburdened populations**, and the potential for exposure in **sensitive species and habitats**.*

These comments are intended to address specific aspects of each goal, with respect to high molecular weight (HMW) phthalates, e.g. di-isononyl phthalate (DINP) and di-isodecyl phthalate (DIDP).

Background

According to the draft scope of the Phthalates Action Plan, DoE intends to develop recommendations for ortho-phthalates as a chemical class. Considering the clear and significant differences in the physical, chemical and biological properties of phthalates, developing recommendations for ortho-phthalates as a class likely cannot be done in a scientifically-defensible manner.

In addition, the chemical class approach fails to account for the fact that different phthalates are used in distinctly different applications, which is necessary when developing source reduction plans. For example, eliminating phthalate use in cosmetics will have no impact on exposures to high molecular weight phthalates, none of which are, or have ever been used in these applications. For this reason, we continue to emphasize that phthalates should be treated as distinct categories.[1]

Comments on the central goals for the action plan

Source reduction:

Phthalates differ significantly in terms of physico-chemical properties and the type of applications in which they can be used. Hence, any attempt at phthalate source reduction must first identify which phthalates are of concern before mapping out their specific exposure and use patterns. For example,[2] the diet accounts for >95% of exposure to DINP in children and adults, and >65% for infants and toddlers. With respect to DIDP, diet accounts for >90% of exposure across the population. In other words, restricting use of these phthalates in certain applications will have limited to no impact on reducing human exposures.

Reduce human exposure:

The US Centers for Disease Control (CDC) has tracked total exposures to HMW phthalates in the US population, through the National Health and Nutrition Examination Survey (NHANES), since 2005.[3] These exposures take into account all sources and routes (e.g. diet and/or skin contact with articles

[1] Phthalates are generally divided into two categories. Low molecular weight (LMW) phthalates and high molecular weight (HMW) phthalates. LMW phthalates (e.g. BBP or DBP) have 3-6 carbon atoms in the longest linear alkyl chain, while HMW phthalates (e.g. DINP and DIDP) have ≥7 carbon atoms in the longest linear alkyl chain. Just the same way ethanol (C_2) has a distinctly different toxicological property compared to methanol (C_1), despite sharing the exact same functional group but only differing by a single carbon atom, LMW phthalates and HMW phthalates do not share the same physico-chemical and toxicological properties.

[2] CHAP (cpsc.gov)

[3] NHANES - National Health and Nutrition Examination Survey Homepage (cdc.gov)

containing HMW phthalates). Below is a summary of average general population exposures to DINP and DIDP.

Table 1: CDC NHANES Average general population exposures to HMW phthalates (ppb)

PHTHALATE	05-'06	07-'08	09-'10	11-'12	13-'14	15-'16
DINP	2.6	2.7	6.2	10	9.4	4.1
DIDP	1.2	1.4	1.4	1.4	1.3	0.73

As shown in table 1, average exposures to the highest consumed HMW phthalates, by tonnage, is in the very low ppb range. These low levels of exposure is what informs the consistent finding among regulatory authorities of a lack of human risk with HMW phthalates. The European Union has published three extensive risk evaluation reports on HMW phthalates. In all cases, no risk was associated with exposure to DINP or DIDP in all existing uses.[4] [5]

In 2020, Environment and Climate Change Canada (ECCC) published screening assessments of several phthalates, including the HMW phthalates DINP, DIDP, DIUP and DTDP.[6] The assessment took into account all possible applications of use (e.g. diet, toys, childcare articles, building and construction products, automotive applications, etc.) and all subpopulations (e.g. infants, toddlers, children, and adults). In general, ECCC concluded that "*most phthalates [including all HMW phthalates] don't pose a risk to health or the environment at current levels of exposure*".[7]

Despite the fact that the diet accounts for the majority of human exposures to HMW phthalates, no dietary risk evaluation published to date has identified any human health concerns.[8] [9] [10] [11] [12]

Reduce environmental contamination:

Assessments show there is little to no environmental impact from HMW phthalates.

Lack of adverse environmental effects: The environmental impacts of HMW phthalates to soil, sediment and aquatic organisms have been studied extensively. Overall, it is well established that HMW phthalates are not acutely or chronically toxic to environmental organisms.[13] The 2003 European Union report on DINP concluded that the substance posed no concern to "*the aquatic compartment, the terrestrial compartment, the atmosphere, microorganisms in the sewage treatment plant as well as for secondary poisoning."*

Fate and disposition: The physico-chemical properties of HMW phthalates dictate their fate and disposition in the environment. The 2020 ECCC screening report of DINP, DIDP, and DIUP included a fugacity model to predict fate of phthalates in environmental media. Based on their high hydrophobicity, high partition coefficient (log kow >8.0) and low vapor pressure, the models predict that >85% of HMW phthalates released in air and >80% released in water preferentially partition to soil and sediment. 100% of phthalates released to soil remains in the soil compartment. As such, we can reach the following conclusions:

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[4] EU Risk Assessment Report (europa.eu)
[5] Microsoft Word - 20130816_ECHA review DINP and DIDP_clean.doc (europa.eu)
[6] Phthalates - Canada.ca
[7] Canada Gazette, Part 1, Volume 154, Number 49: GOVERNMENT NOTICES
[8] FAQ: phthalates in plastic food contact materials | EFSA (europa.eu)
[9] Microsoft Word - phthalates statement 04-11.docx (food.gov.uk)
[10] https://www.fsai.ie/publications_TDS_2012-2014/
[11] https://www.foodstandards.gov.au/publications/Documents/Survey%20of%20plasticisers%20in%20Australian%20foods.pdf
[12] https://www.mpi.govt.nz/dmsdocument/21871/loggedIn
[13] 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.

a. HMW phthalates are unlikely to remain in the air (half-life <2 days for DINP)
b. Due to low mobility, HMW phthalates are unlikely to leach through soil to ground water
c. While HMW phthalates may preferentially partition to organic matter in soil and sediment, they do not persist in these media (readily biodegradable).

Focus on exposure potential in sensitive and overburdened populations:

The CDC NHANES database now stratifies exposure data by age,[14] sex, and race.[15] We reviewed the 90th, 95th and 99th percentiles for DINP exposures for the 2017/2018 cohort. There was no statistically significant difference across any of the three categories ($p < 0.0005$). The same results were obtained for DIDP, with the exception of the 90th and 95th, but not the 99th percentile, for 3-5 year olds vs. the rest of the population. Considering the significantly low exposures to DIDP (9 ppb for 3-5 year olds at the 99th percentile), this sole statistical difference is unlikely to be biologically meaningful.
Overall, it can be concluded from this data that no age range, sex or racial group is disproportionately exposed to HMW phthalates, based on the CDC NHANES 2017/2018 data.

Sensitive species and habitats:

As noted previously, HMW phthalates are not acutely or chronically toxic to environmental species or habitats.

Conclusion

Overall, we commend the DoE for its efforts in safeguarding public and environmental health from exposures to hazardous chemicals. However, we believe that the current broad evaluation of phthalates as a chemical class is not the most efficient approach. We recommend that DoE narrow its focus to any specific phthalates of concern.

Thank you for the opportunity to share our observations. Please contact me with any questions at eileen_conneely@americanchemistry.com or at 202-249-6711.

Sincerely,

Eileen Conneely

Eileen Conneely
Senior Director, Chemical Products & Technology Division

[14] 3-5 years, 6-11 years, 15-45 years (women of reproductive age), >65 years old.
[15] White (non-Hispanic), Mexican American, Black (non-Hispanic), Hispanic, other (including multiracial)