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EPN Comments on the Draft Scopes for the Risk Evaluations of Di-isodecyl Phthalate (DIDP) and Di-isononyl Phthalate (DINP)
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The Environmental Protection Network (EPN) is an organization comprised of almost 550 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of EPA, human health, and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide insights into regulations and policies proposed by the current administration that have a serious impact on public health and environmental protections.

EPN appreciates the opportunity to provide comments on the recently-released draft scopes of the risk evaluations to be conducted under the Toxic Substances Control ACt (TSCA) of Di-isodecyl Phthalate (DIDP) and Di-isononyl Phthalate (DINP). While the agency published separate notices in the Federal Register for each chemical, EPN is providing its comments in a single document, for reasons that should become clear as they are presented.

DIDP and DINP Should Be Evaluated Together in a Combined Assessment

A strong argument can be made that coincident exposure to DIDP and DINP will occur in many of the conditions of use (COUs) identified for assessment in the risk evaluations of these two chemicals; therefore, in those instances where co-occurrence is anticipated, a combined assessment should be undertaken. EPN continues to argue that these two chemicals should also be assessed in combination with the five phthalates EPA has designated as high-priority substances as a "category" under TSCA and for which risk evaluations also are being conducted at the present time.

Our argument is based upon several factors:

1) The two Manufacturer's Requests were submitted on behalf of the same party (ExxonMobil); therefore, one would expect coincident exposure in the requesting party's settings as well as others downstream from manufacture.

   The agency claimed in its Response to Comments document on its proposal to grant these two manufacturer's requests that Section 6 (b)(4)(C) of TSCA prohibits it from assessing anything more than the chemical(s) specifically listed in a specific request, seemingly hiding behind their interpretation of the phrase "in a form and manner." Splitting of requests by the same party into two risk evaluations on two closely-related chemicals is disingenuous at best.

   TSCA Section 6 (b)(4)(C) states:

   > (C) REQUIREMENT—The Administrator shall conduct

> and publish risk evaluations, in accordance with the rule promulgated under subparagraph (B), for a chemical substance—
> '(i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and
> '(ii) subject to subparagraph (E), that a manufacturer of the chemical substance has requested, i*n a form and manner* (emphasis added) and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

Scrutiny of each of the paragraphs and subparagraphs cited above does not reveal any prohibition on the part of the agency to assess chemicals as a category or in combination. In fact, manufacturers may also submit requests for categories of chemical substances, and such requests must include an explanation of why the category is appropriate under 15 U.S.C. 2625(c). One might argue that this would have been the more principled approach for the requesters to take.

Furthermore, examination of the text of the July 17, 2017, Federal Register notice announcing the final risk evaluation rule promulgated under subparagraph (B), Section III. H. 1. b. of the supplementary information addresses categories of chemical substances, stating that "TSCA provides EPA with authority to take action on categories of chemical substances," and "Although the rule most often references 'chemical substances,' EPA includes a clear statement in the final regulation that nothing in the rule shall be construed as a limitation on EPA's authority to take action with respect to categories of chemical substances, and that, where appropriate, EPA can evaluate categories of chemical substances." This policy continues the approach affirmed in the original TSCA as exemplified by the first Section 4 test order ever issued on the chlorinated benzenes as a category.

2) The COUs to be assessed for each chemical overlap to an overwhelming degree, with the expectation that many of the exposures to the chemicals will be on a "both," rather than "either-or" basis.

3) There is known potential for overlap of toxicity endpoints of concern that may impact human health and the environment. Previous assessments have identified developmental, reproductive, and systemic toxicity as potential human health hazards for both chemicals.

No environmental hazards were identified in the manufacturer submission for either DIDP or DINP, but that may be due to a lack of adequate data to judge potential environmental impact on a broad, representative range of ecological targets rather than an actual lack of hazard or risk. Our review of the few reference citations cited in the submission led us to conclude that the available data are too limited to make sweeping statements of "no concern."

Establishment of a robust profile of the potential for environmental impacts should be pursued through the agency's use of its enhanced testing authorities under Section 4 of the "new" TSCA.

EPA should issue a testing order NOW to ensure that adequate data are available for inclusion in the draft and final risk evaluations for these chemicals.

4) Combined assessments of this group of chemicals already have been recommended and/or implemented, for example, as described in the 2008 NAS report *Phthalates and Cumulative Risk Assessment: The Task Ahead*[1] and in the Consumer Product Safety Commission's (CPSC) July 2014 report of the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives.[2]

5) Combined assessment is supported by the agency's own opinion as articulated in its Phthalate Action Plan,[3] which includes its Risk Management Considerations:

> Phthalates are used in products that are subject to rules under EPA, FDA, and the CPSC. People may be exposed to phthalates from a variety of product uses, as well as from industrial releases and environmental exposures; *these exposure pathways should be assessed together to appropriately characterize exposures and avoid underestimating risk* (emphasis added). The assessment of combined exposure is important to determine the potential impacts of these chemicals. *Focusing individually on these phthalates would likely underestimate their impact since they appear to produce similar adverse effects* (emphasis added). Also, many phthalates are interchangeable in their uses as plasticizers for flexible PVC products, so restrictions on one could simply shift use to another of similar toxicity. Given this cumulative impact, the management of the risk from combined exposure requires a coordinated approach by all three agencies and, as appropriate, additional federal agencies. Therefore, EPA intends to work closely with CPSC and FDA to address the range of exposures.

The Political Motivation of Considering the Risks of Use in PVC for Children's Toys and Childcare Articles as a COU in the Risk Evaluations

Both manufacturer's requests included *Use in PVC for children's toys and childcare articles* on their proposed list of uses to be evaluated under the risk evaluations for both DIDP and DINP. Surprisingly, EPA accepted this COU for review, listing it under Consumer Uses: Category: Packaging, paper, plastic, hobby products; Subcategory: Toys, playground, and sporting equipment.

What is surprising about including this COU in this instance? Over and over again, one sees text in the risk evaluation documents already developed under the TSCA Section 6 (b) Existing Chemicals

[1] NRC. 2008. National Research Council Committee on the Health Risks of Phthalates. *Phthalates and Cumulative Risk Assessment: The Task Ahead*. The National Academies Press. Washington, DC. Available at http://www.nap.edu/catalog/12528.html.

[2] CPSC. 2014. Consumer Product Safety Commission's July 2014 report of the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives. Available at https://www.cpsc.gov/s3fs-public/CHAP-REPORT-With-Appendices.pdf

[3] U.S. EPA. 2012. Phthalates Action Plan Revised 03/14/2012. Available at https://www.epa.gov/sites/production/files/2015-09/documents/phthalates_actionplan_revised_2012-03-14.pdf

Risk Evaluation program that speaks to narrowing the scopes of the TSCA assessments, passing off responsibility to other agency programs or other federal agencies, and ignoring the exposures known or anticipated to occur to the substance of interest outside of the COUs selected for evaluation.

For instance, a typical example appears in in the Trichloroethylene risk evaluation:

> Risk to the General Population: General population exposures to TCE may occur from industrial and/or commercial uses; industrial releases to air, water or land; and other conditions of use. As part of the problem formulation for TCE, EPA found those exposure pathways are covered under the jurisdiction of other environmental statutes, administered by EPA, which adequately assess and effectively manage those exposures, i.e., CAA, SDWA, CWA, and RCRA. EPA believes this TSCA risk evaluation should focus on those exposure pathways associated with TSCA conditions of use that are not subject to the regulatory regimes discussed above because those pathways are likely to represent the greatest areas of concern to EPA. Therefore, EPA did not evaluate hazards or exposures to the general population in this risk evaluation, and there is no risk determination for the general population (U.S. EPA, 2018d).

The Methylene Chloride risk evaluation is somewhat more expansive. In addition to the standard discussion of referral to other in-house programs for regulatory action, it also speaks to the EPA Administrator's ability to refer an issue to another federal agency if/when this other agency is in a better position to handle the matter.

In this case, both DIDP and DINP have already been subjected to regulatory action by the CPSC. In 2014, CPSC imposed, then, in 2017, lifted an interim prohibition on DIDP in children's toys and childcare articles, while DINP restrictions continue to exist. DIDP now may be used in children's toys and childcare articles without restriction, unless there were restrictions established within a specific state prior to April 22, 2016, which is the case in California. California has, in fact, included both chemicals on its Proposition 65 list, (DIDP for developmental and reproductive toxicity, DINP for cancer), along with their respective Safe Harbor Levels.

So what is to be gained if EPA assesses the potential for risk of DIDP or DINP exposure in PVC for children's toys and childcare articles as a COU? The answer is preemption. The preemption clause in TSCA applies to state restrictions on chemicals. This means if EPA makes a finding (either of unreasonable or no unreasonable risk) on a specific use in its assessment of a chemical substance, a state would not be able to restrict that use of the chemical, although state actions taken prior to April 22, 2016, are preserved. Thus, once EPA begins review, "pause preemption" begins. States can take no new actions on a chemical for any COU under EPA review. Once EPA issues its final risk evaluation, if EPA finds the chemical does not present an unreasonable risk, final preemption would apply; any action a state may have taken after April 22, 2016, would be deemed null and void unless it meets certain criteria. If EPA finds the chemical does present an unreasonable risk, states could

again impose new restrictions while EPA develops its requisite regulation, but these could be subject to reversal or modification if they don't meet the criteria.

So, what's the bottom line here? 1) EPA generally narrows the scope of the TSCA risk evaluation to exclude situations it says are better dealt with under other laws and regulatory schemes. 2) But, in this case, it retains review of PVC for children's toys and childcare articles as a COU, even though CPSC has already conducted assessments and made regulatory decisions on this use. Why? 3) To preserve the preemption option for the manufacturer requestors. No new restrictions would be allowed by any states unless they meet the criteria, one of which is that they cannot be more restrictive than the federal ruling.

Information Provided in Manufacturer's Requests

The manufacturer's requests for risk evaluation for both DIDP and DINP summarize the information which must accompany a request in order for it to be considered for action by the agency, citing the rule governing the development of risk evaluations under TSCA.[4] To quote, "The request must also include a list of *all* (emphasis added) the existing information that is relevant to whether the chemical substance, under the circumstances identified by the manufacturer(s), presents an unreasonable risk of injury to health or the environment."

A quick scan of APPENDIX C—the REFERENCE LIST in both the DIDP and DINP requests—reveals missing sources EPN would consider relevant to the two risk evaluations. A key publication that is missing from the Independent Party/Authoritative Assessments category is NRC. 2008. National Research Council Committee on the Health Risks of Phthalates. *Phthalates and Cumulative Risk Assessment: The Task Ahead*. The National Academies Press. Washington, DC. Available at http://www.nap.edu/catalog/12528.html.

A second reference missing in this category is the most recent update of the World Health Organization International Programme on Chemical Safety's 2002 *Global Assessment of the State-of-the-science of Endocrine Disruptors*. It can be cited as WHO/UNEP. 2012. State of the Science of Endocrine Disrupting Chemicals. An assessment of the state of the science of endocrine disruptors prepared by a group of experts for the United Nations Environment Programme (UNEP) and WHO. Geneva, Switzerland. Available at: https://www.who.int/ceh/publications/endocrine/en/

[4] Environmental Protection Agency; Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,749 (July 20, 2017)(codified at 40 C.F.R. Pt. 702.37).