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EPN Comments on the Draft TSCA Risk Evaluation for Diisononyl Phthalate (DINP)
Docket No. EPA-HQ-OPPT-2018-0436
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The Environmental Protection Network (EPN) harnesses the expertise of more than 650 former Environmental Protection Agency (EPA) career staff and confirmation-level appointees from Democratic and Republican administrations to provide the unique perspective of former regulators and scientists with decades of historical knowledge and subject matter expertise.

Background

Diisononyl phthalate (DINP) is one of seven members of a subclass of phthalates that EPA had identified in its 2014 Workplan as high-priority substances for review. After the Lautenberg Act of 2016 was passed, creating the Existing Chemicals Review Program, the agency selected a number of chemicals from that 2014 Workplan when assembling the first two lists of high priority chemicals to review in the new program. Five phthalates included in the 2014 Workplan were placed on the second list (butyl benzyl phthalate (BBP), dibutyl phthalate (DBP), dicyclohexyl phthalate (DCHP), diethylhexyl phthalate (DEHP) and diisobutyl phthalate (DIBP)). Two additional phthalates from the 2014 Workplan, diisodecyl phthalate (DIDP) and DINP, were not included on that second list. However, in May 2019, EPA received and later granted manufacturers' requests to conduct risk evaluations on these two chemicals. In late July, 2024, the TSCA Science Advisory Committee on Chemicals (SACC) conducted a peer review of the draft risk evaluation for DIDP and its support documents along with several draft DINP support documents (physical chemical properties, fate and transport in the environment, environmental hazards for terrestrial and aquatic species, human health non-cancer hazards, and human health cancer hazards), but not a draft DINP risk evaluation. The drafting of risk evaluations for the other five phthalates is underway as is the development of a cumulative risk assessment for six of the seven compounds (DIDP is excluded). The five draft risk evaluations and draft cumulative risk assessment are expected to be available for public review and comment in early 2025.

The focus of the current request for review and comment is the draft risk evaluation for DINP. A cautionary note is warranted. This draft DINP risk evaluation is based upon the draft DINP support documents (e.g., the human health and ecological hazard assessments) and the exposure methods used in the draft DIDP risk evaluation that were the subject of peer review by the SACC in July-August 2024. The agency has stated that it expects that the methods employed to determine exposure estimates in the DIDP evaluation will be similar to those used across all of the individual phthalate assessments, with each incorporating chemical-specific empirical and/or modeled exposure/data. Hazard values will vary across the seven chemicals, resulting in different risk profiles for each. Given this reliance on a common approach, one should expect that the final DIDP and DINP risk evaluations could both be quite different from the draft versions, depending upon what changes EPA makes in response to the SACC review. The final SACC report was made available on October 2, 2024. This should allow commenters on this draft risk evaluation to have sufficient time to consider the SACC review when preparing their reviews.

The focus of this public comment request is to solicit feedback regarding DINP-specific exposure analyses and the integration of these analyses with previously peer-reviewed information. As noted above, a number

of the DINP technical support documents have undergone public comment and external peer review by the SACC.

Input on the following is of particular interest to the EPA:
Section 3. Releases and Concentrations of DINP in the Environment,
Section 4. Human Health Risk Assessment and
Section 5. Environmental Risk Assessment of the draft risk evaluation for DINP Draft Environmental Release and Occupational Exposure Assessment for DINP;
Draft Consumer and Indoor Exposure Assessment for DINP;
Draft Environmental Media and General Population Screening for DINP;
Draft Environmental Exposure Assessment for DINP;
Whether high-pressure spray applications of DINP-containing adhesives and sealants and paints and coatings are currently in use in industrial settings, or may be used in the future due to changing industrial practices.

EPN Comments

General Comment

Ordinarily, EPN would develop its own set of comments on the matter for which the agency is seeking public review and comment. In this case, however, given its active engagement in the SACC peer review of the DIDP and DINP documents, we have one overarching recommendation: EPA should review the SACC peer review report carefully and heed all of the recommendations that SACC has offered. Its effort was expansive and in-depth, and the report provides wise guidance that will improve the scientific analyses immeasurably and lead to robust high-quality science-based risk evaluations for all seven of the phthalates under review[1].

Additional comments

Executive Summary

EPA stated that it did not include assessment of exposures from COUs not directly attributable to uses subject to TSCA in making its preliminary risk determinations, but may consider their impact when conducting the cumulative risk assessment (CRA). This choice is inconsistent with recent policy changes in which the agency purportedly modified its approach to aggregate exposure assessment to include these sources. Taking these non-TSCA sources into account NOW, as per policy, might make a difference in determining whether or not a COU constitutes an unreasonable risk. This is the time to do this assessment, not just later in the CRA.

Section 3 of the draft risk evaluation: Releases and Concentrations of DINP in the Environment

As EPA points out, when this document was drafted, no empirical DINP release data were available in relevant agency databases, such as the Discharge Monitoring Report, the National Emissions Inventory or

[1] Science Advisory Committee on Chemicals (SACC). 2024. Science Advisory Committee on Chemicals (SACC). Meeting Minutes and Final Report for the "Draft Risk Evaluation for Di-isodecyl Phthalate (DIDP) and Draft Hazard Assessments for Di-isononyl Phthalate (DINP)." October 2, 2024. Washington, DC. Available at https://www.regulations.gov/document/EPA-HQ-OPPT-2024-0073-0098.

the Toxics Release Inventory and, thus, were not available for use in the draft evaluation. The agency resorted to modeling the releases associated with each of the assessed exposure scenarios (industrial, commercial and consumer releases to the environment and down-the-drain consumer uses). EPA offered a weight-of-the-evidence level of confidence for each scenario, selecting from the following confidence descriptors: robust, moderate, slight, or indeterminate. Overwhelmingly, EPA concluded that modeled data had data quality ratings of medium. As a result, for releases that used Generic Scenarios/Emission Scenario Documents (Gss/ESDs), the weight of scientific conclusion was generally deemed moderate, when used in tandem with Monte Carlo modeling. We believe that these ratings are overly generous, and should be re-rated as "slight," until such time as the analyses of relevant empirical data are conducted and compared to the modeling outputs, a necessary step before declaring the risk evaluation adequately revised.