Di-isononyl Phthalate (DINP); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA)
Response to Comments

Docket Number: EPA-HQ-OPPT-2018-0436
December 2, 2019

Overview

Under 40 CFR 702.37(e)(3), EPA is required to assess whether the circumstances identified in a manufacturer request for a risk evaluation constitute conditions of use (as defined under TSCA section (3)(4) and implementing regulations (40 CFR 702.33)), and whether those conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will also assess what, if any, additional conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance, and conduct these assessments based on the same considerations applied in the same manner as it would for a risk evaluation for a high-priority substance in the EPA-initiated risk evaluation process. No later than 60 business days after receiving a manufacturer request for risk evaluation that EPA has determined to be facially complete (meeting the criteria set forth in 40 CFR 702.37(e)(1)), EPA is required to submit for publication the receipt of the request in the Federal Register, open a public docket for the request (which must contain the manufacturer request and EPA's possible additional conditions of use), and provide no less than 45 calendar days for public comment.

This document includes EPA's responses to comments received during the public comment period (August 19, 2019 to October 3, 2019) for docket number EPA-HQ-OPPT-2018-0436 (Di-isononyl Phthalate (DINP); Manufacturer Request for Risk Evaluation Under the Toxic Substances Control Act (TSCA)). During the public comment period, the public submitted comments and information relevant to the requested risk evaluation.

The Agency received four public comments related to the manufacturer request for risk evaluation for DINP. After careful review, the Agency determined that all of these comments are substantively or procedurally relevant to the proposed rule. All comments received are identified by docket identification (ID) number EPA-HQ-OPPT-2018-0436 and are available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0436-0003.

1. Comment submitting additional scientific research

A commenter (EPA-HQ-OPPT-2018-0435-0006) submitted six publications[1] including information about the negative developmental reproductive toxicity of DINP.

Response: The Federal Register Notice opening the public comment period requested the public submit comments and information relevant to the requested risk evaluation, in particular the identification of any information not included in the request that the commenters believe would be needed to conduct a risk evaluation. The Agency will consider this study during the risk evaluation of DINP.

2. Comment recommending that the Agency engage with a broad array of stakeholders

A commenter (EPA-HQ-OPPT-2018-0435-008) suggested that EPA should engage a broad array of downstream users in any discussion or negotiations relevant to decision-making on potential regulatory actions, since moves by industry to replace chemicals pose significant burdens and costs to the manufacturing cycle.

Response: The Agency engages and works with a variety of stakeholders throughout the risk evaluation and risk management processes, including industry, federal, state, and local partners, and academia, among others. Input from stakeholders is particularly important in determining which conditions of use are included in the scope of a risk evaluation.

As required under TSCA section 6(b)(4), EPA conducts risk evaluations ". . . to determine whether a chemical substance [or category of chemical substances] presents an unreasonable risk of injury to health or the environment, *without consideration of costs or other non-risk factors*, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use." However, TSCA section 6(c)(2) requires EPA to consider the reasonably ascertainable economic consequences of the rule, including: the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of the proposed and final rule and of the one or more primary alternative regulatory actions that EPA considered; and the cost effectiveness of the proposed rule and of the one or more primary alternative regulatory actions that EPA considered. Therefore, the burden and costs to the manufacturing cycle will be considered, as appropriate, as part of the risk management of a chemical substance (or category of chemicals substances).

3. Comment noting a cumulative risk assessment of phthalates

A commenter (EPA-HQ-OPPT-2018-0435-0009) urged EPA to treat DINP (together with di-isononyl phthalate (DIDP) and the five phthalates EPA proposed designate as high-priority substances) as a "category" under TSCA, and to consider a cumulative risk assessment of all seven phthalates.

Should EPA proceed in conducting a risk evaluation of DIDP and DINP, the commenter noted that the Agency should include all known or reasonably foreseen conditions of use, as a failure to do so will underestimate risk (especially to potentially exposed or susceptible sub-populations). Additionally, the commenter noted that the Agency needs to determine the completeness of the database search provided in the manufacturer request, suggesting that the reference list in the request does not include all relevant information.

Response: This manufacturer request for evaluation was made specifically for DINP (CASRNs 28553-12-0 and 68515-48-0), not other chemicals or other phthalates. Since EPA's authority to conduct a manufacturer-requested risk evaluation is tied to the "chemical substance . . . that a manufacturer of the chemical substance has requested . . .be subjected to a risk evaluation," (TSCA section 6(b)(4)(C)), EPA cannot add additional phthalates to the scope of the risk evaluation, since this goes beyond the actual request for risk evaluation made by a manufacturer. The Agency may identify other phthalates for prioritization, but such action would be separate from this request.

4. Comment asserting that the manufacturer request does not include all relevant information under §702.37(b)(4)

A commenter (EPA-HQ-OPPT-2018-0435-010) asserted that the manufacturer request should not have been found facially complete as it does not meet the regulatory requirement in §702.37(b)(4) that a request "include a list of all the existing information" relevant to the risk evaluation. The comment suggests that the manufacturer only provided publicly available information, and that other files and documents within the manufacturer's possession (or known or reasonably ascertainable to them) were not submitted.

The commenter stated that the manufacturer request included the use of DINP in polyvinyl chloride in children's toys as a condition of use, which is formally restricted and forbidden by federal law, to undermine the Consumer Product Commission's (CPSC) prohibition.

The commenter also noted that relying on voluntary requests for information is limited, biased, and/or leads to incomplete information, and that the Agency must identify any information gaps, exercising regulatory authority under TSCA sections 8(c) and 8(d) to obtain "reasonably available information."

Finally, the commenter indicated that they had filed a food additive petition with the Food and Drug Administration (FDA) regarding ortho-phthalates. The commenter suggested that EPA should consider the petition and its literature search when preparing a risk evaluation for DINP.

Response: While the commenter emphasized that the manufacturer did not "include a list of *all the existing information* that is relevant to whether the chemical substance presents an unreasonable risk of injury to health or the environment . . . ."(per §702.37(b)(4)), the submitting manufacturers provided a signed certification (per requirements outlined under §702.37(b)(7)), that all information in the request is accurate and complete, including the following:

> I have either identified or am submitting all information *in my possession, control, and a description of all other data known to or reasonably ascertainable by me as required for this request under this part*. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information in this request and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

40 C.F.R. §702.37(b)(7)(C) (emphasis added)

EPA does not have evidence to support the assertion by the commenter that the submitting manufacturers for DINP did not submit all information in their possession, control, and a description of all other data known to or reasonably ascertainable by them.

In addition to voluntary requests for information, EPA will conduct literature searches and stakeholder outreach during the risk evaluation process, identify any remaining data gaps, and consider the exercise of information-collection authorities at that time. EPA recognizes the requirement to consider "reasonably available information" when conducting risk evaluations ("information that EPA possesses or can reasonably generate, obtain, and synthesize for use in

risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation").

5. Comment asserting that DINP should not include use in children's toys

A commenter (EPA-HQ-OPPT-2018-0435-010) asserted that the manufacturer request for DINP asks EPA to include in its risk evaluation a use that is formally restricted and forbidden by federal law. The commenter stated that the request "asks EPA to include as a "condition of use" the use of DINP in polyvinyl chloride (PVC) "for children's toys and childcare articles," but this use is already legally restricted by the CPSC."

Response: EPA appreciates this information and will consider this comment during the TSCA risk evaluation phase for DINP.

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[1] Boberg, J., Christiansen, M.A., Kledal, T.S., Vinggaard, A.M., Dalgaard, M., Nellemann, C., Hass, U. (2011). "Reproductive and Behaviorial Effects of diisononyl phthalate (DINP) in perinatally Exposed Rats."

Lioy, P.J., Hauser, R., Gennings, C., Koch, H.M., Mirkes, P.E., Schwetz, B.A., Kortenkamp, A. (2015, May 6). "Assessment pf Phthalates/Phthalate Alternatives in Children's Toys and Childcare Articles: Review of the Report Including Conclusions and Recommendation of the Chronic Hazard Advisory Panel of the Consumer Product Safety Commission."

Furr, J.R., Lambright, C.S., Wilson, V.S., Foster, P.M., Gray, Jr, L.E. (2014, May 5). "A Short-term In Vivo Screen Using Fetal Testosterone Production, a Key Event in the Phthalate Adverse Outcome Pathway, to Predict Disruption of Sexual Differentiation."

Gray, Jr, L.E., Ostby, J, Furr, J., Price, M., Rao, Veeramachaneni, R.D.N., Parks, L. (2000, July 24). Perinatal Exposure to the Phthalates EHP, BBP, and DINP, But Not DEP, DMP, or DOTP, Alters Sexual Differentiation of the Male Rat."

Hannas, B.R., Lambright, C.S., Furr, J., Howdeshell, K.L., Wilson, V.S., Gray, L.E. (2011, June 1). "Dose-Response Assessment of Fetal Testosterone Production and Gene Expression Levels in Rat Testes Following In Utero Exposure to Diethylhexyl Phthalate, Diisobutyl Phthalate, Diisoheptyl Phthalate, and Diisononyl Phthalate."

Hannas, B.R., Lambright, C.S., Furr, J., Evans, N., Foster, P.M.D., Gray, L.E., Wilson, V.S. (2011, November 22). "Genomic Biomarkers of Phthalate-Induced Male Reproductive Developmental Toxicity: A Targeted RT-PCR Array Approach for Defining Relative Potency."