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

Docket Number: EPA-HQ-OPPT-2018-0435
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-2018-0435 (Di-isodecyl Phthalate (DIDP); 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 DIDP. After careful review, the Agency determined that all of these comments are substantively or procedurally relevant. All comments received are identified by docket identification (ID) number EPA-HQ-OPPT-2018-0435 and are available at https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0435-0003.

1. Comment submitting additional scientific research

An anonymous commenter (EPA-HQ-OPPT-2018-0435-0006) submitted a publication[1] including information about the negative developmental reproductive toxicity of DIDP.

[1] 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."

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 DIDP.

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

A commenter (EPA-HQ-OPPT-2018-0435-0007) 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 important in determining which conditions of use are included in the scope of a risk evaluation; EPA also solicits public comment on draft risk evaluations and engages in public peer review processes.

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." If EPA makes an unreasonable risk determination, the Agency will move to risk management.

TSCA section 6(c)(2) requires EPA to consider the reasonably ascertainable economic consequences of a rulemaking (occurring during the risk management process), including: the likely effect of a rule on the national economy, small business, technological innovation, the environment, and public health; the costs and benefits of a proposed and final rule and of the one or more primary alternative regulatory actions that EPA considered; and the cost effectiveness of a 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-2018-0435-0008) urged EPA to treat DIDP (together with di-isononyl phthalate (DINP) and the five phthalates EPA proposed to 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 DIDP (CASRNs 26761-40-0 and 68515-49-1), 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 provision of TSCA addressing aggregate exposures does not require EPA to conduct cumulative risk evaluations; it requires EPA to describe whether aggregate or sentinel exposure were considered, and the basis for that consideration (TSCA section 6(b)(4)(F)(ii)). The Agency identified other phthalates for prioritization on March 21, 2019 (including benzyl butyl phthalate (BBP), CASRN 85-68-7; dibutyl phthalate (DBP), CASRN 84-74-2; dicyclohexyl phthalate (DCHP), CASRN 84-61-7; di(2-ethylhexyl)phthalate (DEHP), CASRN 117-81-7; and diisobutyl phthalate (DIBP), CASRN 84-69-5), but these actions are 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-2018-0435-0009) 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 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 DIDP.

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.
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> 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 DIDP 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 conducts literature searches and stakeholder outreach during the risk evaluation process to ensure that all reasonably available information is considered during the risk evaluation. 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"). The Agency has determined that there is sufficient information (both submitted by the manufacturer request and publicly available) to conduct a risk evaluation of DIDP.

The Agency appreciates the information about the prior petition to FDA and will refer to the petition and its literature search for ortho-phthalates (including DIDP) during the risk evaluation.