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EPA Releases Draft Risk Evaluation for DINP for Public Comment

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The U.S. Environmental Protection Agency (EPA) announced on September 3, 2024, the release of the draft risk evaluation for diisononyl phthalate (DINP) under the Toxic Substances Control Act (TSCA) for public comment. 89 Fed. Reg. 71270. EPA states in its August 30, 2024, press release that it preliminarily determined that two industrial uses and one consumer use "significantly contribute to the unreasonable risk of DINP out of the 45 uses evaluated." EPA preliminarily determined that DINP has the potential to cause developmental toxicity and harm the liver and that it could cause cancer at higher levels of exposure. EPA notes that it also preliminarily determined that DINP does not pose unreasonable risk of injury to the general population or pose unreasonable risk to the environment. EPA will host a public webinar on **September 26, 2024, at 2:00 p.m. (EDT)** to provide an overview of the risk evaluation and an opportunity for participants to share comments. Requests to make comments during the webinar were due by September 23, 2024. Comments on the draft risk evaluation are due **November 4, 2024**.

Draft Risk Evaluation for DINP

According to EPA, DINP is used primarily as a plasticizer to manufacture flexible polyvinyl chloride (PVC). It is also used to make building and construction materials; automotive and fuel products; and other commercial and consumer products, including adhesives and sealants, paints and coatings, and electrical and electronic products. EPA notes that there are other DINP uses that are generally excluded from TSCA, such as personal care products, cosmetics, and food contact materials, and states that it did not evaluate risk associated with these uses.

EPA states that workers may be exposed to DINP when making products containing DINP or otherwise using DINP in the workplace. According to EPA, when manufactured or used to make products, DINP can be released into the water, where most of it will end up in the sediment at the bottom of lakes and rivers. If released into the air, it will attach to dust particles and then be deposited onto land or into water. Indoors, DINP has the potential over time to come out of products and adhere to dust particles that could be inhaled or ingested.

EPA preliminarily determined that one consumer use of DINP contributes significantly to unreasonable risk: the use of DINP in floor coverings and construction and building materials covering large surface areas, such as vinyl flooring, in-place wallpaper, and carpet backing.

According to EPA, this use significantly contributes to the unreasonable risk of DINP to infants, toddlers, and preschool children under the age of five to dust containing DINP that migrated from these materials via the air, direct contact, or both.

EPA states that the two worker uses that it preliminarily determined contribute significantly to the unreasonable risk to workers involved unprotected workers using spray adhesives and sealants or paints and coatings that contain DINP with high-pressure sprayers. According to EPA, using these sprayers could create high concentrations of DINP in mist that an unprotected worker could inhale. EPA notes that it was not able to identify products containing DINP that are currently used in high-pressure spray applications "and expects that public comments on this draft will help address this uncertainty."

EPA did not evaluate uses and potential exposure pathways that are not, by statute, covered by TSCA, such as food packaging. EPA notes that past assessments, including the U.S. Consumer Product Safety Commission's (CPSC) risk assessment found that DINP exposure comes primarily from diet for women, infants, toddlers, and children. EPA states that "[i]t is possible that DINP could pose risks to human health through uses or exposure pathways that are not regulated under TSCA." While the draft risk evaluation preliminarily concludes that only three TSCA conditions of use (COU) significantly contribute to the draft unreasonable risk finding for DINP, "this conclusion cannot be extrapolated to form conclusions about uses of DINP that are not subject to TSCA, and that EPA did not evaluate."

Request for Comment

EPA states in the *Federal Register* notice that because many of the DINP technical support documents have undergone public comment and are currently undergoing external peer review, "input on the following is of particular interest":

- Sections 3, 4, and 5 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; and
- 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.

Next Steps

EPA received and granted manufacturer requests for risk evaluations of DINP and diisodecyl phthalate (DIDP) in 2019. As reported in our May 24, 2024, memorandum, EPA released the draft risk evaluation for DIDP in May 2024 and requested peer review on the DINP human health hazard assessment at that time. The Science Advisory Committee on Chemicals (SACC) is currently engaged in peer review of these documents. EPA notes that it has not yet released the report from SACC's July 30 to August 1, 2024, meeting on these draft documents and that the human health hazard assessment in this draft risk evaluation is the same draft version submitted to SACC. EPA plans to release the report from SACC's meeting in **October 2024**.

EPA states that since DINP has the potential to cause effects on the developing male reproductive system, commonly known as phthalate syndrome, it is including DINP in its cumulative risk

assessment, along with five other phthalate chemicals that also have the potential to cause phthalate syndrome. EPA notes that assessments by Health Canada, CPSC, the European Chemicals Agency, the European Food Safety Authority, and the Australian National Industrial Chemicals Notification and Assessment Scheme (now the Australian Industrial Chemicals Introduction Scheme) have reached similar conclusions about the health effects of DINP.

Commentary

Bergeson & Campbell, P.C. (B&C®) is pleased that EPA posted the transcript from the September 13, 2024, TSCA SACC meeting. These deliberations provide some insight into TSCA SACC's scientific opinions for its pending final report. B&C anticipates that readers may be particularly interested in TSCA SACC's comments on EPA's assessment of the carcinogenicity of DINP and its occupational exposure assessment. We discuss each of these areas below with preliminary insight from the TSCA SACC meeting.

EPA's charge questions to TSCA SACC included EPA's preliminary conclusion that "there is too much scientific uncertainty associated with the incidences of [mononuclear cell leukemia] MNCL observed in F344 rats to use quantitatively to estimate human risk from exposure to DINP." EPA requested TSCA SACC's feedback on "the strengths and uncertainties of EPA's decision to focus its cancer assessment on liver tumors."

In response, TSCA SACC agreed generally with EPA's approach. It stated in part that "Overall, … the Agency's decision not to consider MNCL to drive quantitative risk assessment of cancer hazard is well supported by data." TSCA SACC further stated that "Overall, the Agency's decision to focus on liver tumors rather than other types of tumors for cancer risk evaluation is justified."

EPA also charged TSCA SACC with providing comment on EPA's preliminary conclusion that "the weight of scientific evidence supports a peroxisome proliferator activated receptor alpha (PPAR?) [mode of action] MOA for liver tumors in rats and mice" and to discuss the "strengths and uncertainties of available data supporting key events in the PPAR? MOA and the scientific rationale for a threshold approach for cancer dose-response." In response, TSCA SACC also agreed generally with EPA's approach. TSCA SACC stated that EPA's evaluation was "an exceptional example of how this type of analysis should be conducted by the Agency."

TSCA SACC's deliberations on these points suggest that EPA will retain its threshold approach for cancer dose-response in the risk evaluation for DINP when issued in final. We mention this because in the past, EPA has applied a linear low-dose extrapolation for cancer dose-response when it has concluded that "[t]he exact mechanism/mode of action … is not established" or concluded that "[t]here is currently insufficient information to determine the [carcinogenic] MOA …," even when robust evaluations are available. For discussion, see our memorandum dated July 21, 2022.

EPA stated in the draft risk evaluation for DINP that it "determined that the central tendency estimates of worker exposure and risk are most representative for all manufacturing, processing, industrial and commercial COUs — with exception of some industrial COUs for Adhesive and sealant chemicals and Paints and coatings due to the potentially elevated inhalation exposures from pressurized spray operations." EPA stated this same conclusion nearly verbatim in the draft risk evaluation for DIDP.

This represents a departure from EPA's typical evaluations, where its unreasonable risk conclusions are informed by central tendency (CT) and/or high-end (HE) exposure estimates. One member of

TSCA SACC stated that “in the charge questions there were no charge questions that asked about occupational exposure [for the draft risk evaluation for DIDP].” The discussion on this point did not, however, delve into EPA’s use of CT and/or HE exposure estimates. At least one member of the public raised this point in public comments to EPA, noting that “EPA failed to rationally explain why the COUs at issue are better represented by central tendency exposures.” Although EPA does not state it specifically, EPA may have relied upon the low-pressure spray scenario (represented by the CT exposure) instead of the HE exposure, because “[it] did not identify any products containing DINP that are currently used in high-pressure spray applications” that led to the HE exposure levels. Which exposure scenario will ultimately be used to determine whether or not there is risk will likely depend on public comments.

It is unclear how EPA will proceed with its unreasonable risk determinations in the risk evaluations for DIDP and DINP when issued in final. EPA did not publish differing scientific opinions (DSO) for either of these documents, as it has once before on other chemical substances. For discussion, see our memorandum dated July 19, 2024. This suggests that there was general agreement within EPA about its use of the CT exposure estimates for informing most of its unreasonable risk determinations on these substances, but the risk assessment could be improved with additional explanation as to why EPA did so.

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