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EPA Proposes to Determine That TCEP, as a Whole Chemical Substance, Presents Unreasonable Risk to Human Health and the Environment

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On December 15, 2023, the U.S. Environmental Protection Agency (EPA) announced the availability of and solicited public comment on its draft risk evaluation for tris(2-chloroethyl) phosphate (TCEP) and related draft charge questions. 88 Fed. Reg. 86894. EPA states on its website that it reviewed the exposures and hazards of TCEP uses and made risk findings on TCEP. EPA considered relevant risk-related factors, including, but not limited to: the hazards and exposure, magnitude of risk, exposed population, severity of the hazard, and uncertainties, as part of its unreasonable risk determination. EPA proposes to determine that TCEP, as a whole chemical substance, presents unreasonable risk to human health and the environment. Comments on the draft risk evaluation are due **February 13, 2024**.

EPA states in its December 14, 2023, press release that this is the first draft risk evaluation it has released for the 20 high-priority substances prioritized in 2019. EPA notes that it has incorporated improvements to the risk evaluation process announced in 2021 into the risk evaluation, including an assessment of exposure to potentially exposed and susceptible subpopulations such as workers, children, and subsistence fishers.

According to EPA's web page on the TCEP risk evaluation, the primary use for TCEP is as a flame retardant and plasticizer in polymers used in aerospace equipment and products, and as a flame retardant in paint and coating manufacturing. EPA states that information from the 2016 Chemical Data Reporting (CDR) for TCEP indicates the reported production volume was 39,682 pounds per year. EPA notes that while no companies reported the manufacture (including import) of TCEP in the United States from 2016 to 2020, the reporting threshold for TCEP in CDR is 25,000 pounds, "and some manufacturing could be occurring below that threshold."

In the final scope of the risk evaluation, EPA identified conditions of use associated with the importing; processing; distribution in commerce; industrial, commercial, and consumer uses; and disposal of TCEP, for example:

- As a flame retardant in paint and coating manufacturing, polymers, and articles;
- In industrial and commercial aircraft interiors and aerospace products;
- For laboratory chemicals; and

- In commercial and consumer products, including paints and coatings, fabric and textile products, foam seating, and construction materials.

EPA assessed the impact of TCEP on workers, occupational non-users, consumers, and the general population. EPA states that it identified health risks, including neurological effects, reproductive effects, developmental effects, kidney effects, and cancer from exposure to TCEP. EPA assessed the impact of TCEP on aquatic and terrestrial species and found that TCEP poses unreasonable risk to aquatic species like fish and aquatic invertebrates.

Questions for Comment

In its *Federal Register* notice, EPA states that it seeks comment on the following issues:

- The list of considerations EPA used to arrive at the human health hazard confidence levels and the specific confidence levels chosen for individual human health hazard outcomes (neurotoxicity, reproductive/developmental effects, kidney effects, and cancer) in the TCEP risk evaluation.
- Whether the approach used to estimate anaerobic degradation in the absence of data is appropriate for assessing anaerobic degradation in sediment.
- Use of the model Web-based Interspecies Correlation Estimation (Web-ICE) to predict acute toxicity hazard values for aquatic species not represented in the available studies. EPA notes that this is the first time it has used Web-ICE in a Toxic Substances Control Act (TSCA) risk evaluation. EPA states that it used these predictions with available empirical data to create a Species Sensitivity Distribution (SSD). The SSD was used to calculate a hazardous concentration for five percent of species (HC_{05}). EPA is also using a data-driven way of accounting for uncertainty for environmental hazard and solicits comment on its characterization of this uncertainty, specifically its use of the lower bound of the 95 percent confidence interval of the hazardous HC_{05}.
- Human health hazard benchmark dose modeling of animal toxicity data for TCEP.
- The list of considerations EPA used to arrive at the human health hazard confidence levels and the specific confidence levels chosen for individual human health hazard outcomes (neurotoxicity, reproductive/developmental effects, kidney effects, and cancer) to quantitatively evaluate risk from TCEP.

- Use of several approaches for estimating exposures to humans and environmental receptors:

    - The use of the Verner 2008 Multi-compartment model, used to assess TCEP exposure to infants through human milk for the first time in a TSCA risk evaluation;

    - The use of the Verner 2008 Multi-compartment model and associated uncertainties in extrapolating from the inhalation to oral routes of exposure; and

    - The use of the American Meteorological Society/Environmental Protection Agency

Regulatory Model (AERMOD) to estimate air deposition of TCEP. EPA states that it has used AERMOD in previous TSCA risk evaluations; its use in estimating air deposition is novel for TSCA risk evaluations, however.

- Approach for modeling drinking water contamination from wells near municipal solid waste landfills, a new approach for TSCA risk evaluations.

Peer Review

EPA states that it will be submitting the draft risk evaluation and public comments to peer reviewers who will consider the approach and methodologies used. According to EPA, the letter peer review will include review of the analysis of physical-chemical properties, the fate of TCEP in the environment, releases of TCEP to the environment, environmental hazard and risk characterization for terrestrial and aquatic species, and human health hazard and risk characterization for workers, consumers, and the general population. EPA expects the letter peer review to begin on **March 13, 2024**, and end on **April 12, 2024**. EPA will hold a preparatory virtual public meeting on **March 5, 2024**, for reviewers and the public to comment on and ask questions regarding the scope and clarity of the draft charge questions. EPA states that it will consider feedback from the letter peer review in developing the final TCEP risk evaluation.

Commentary

The Acta Group (Acta®) was not surprised by EPA's determination that TCEP as a "whole chemical" substance presents an unreasonable risk. This is consistent with EPA's current policies and its intent to formalize those policies in the proposed framework rule. For more explanation of this, please see our commentary dated October 30, 2023. We are, however, a bit surprised that EPA designated TCEP as a high-priority substance (HPS), thereby requiring EPA to perform a risk evaluation. We agree with EPA that this substance has hazard concerns that warrant such a designation. Our surprise stems from the diminishing exposure potential to TCEP, given that it is under several prohibitions at the state level in the United States, the federal level from EPA's proposed significant new use rule (SNUR), and in many countries and regions around the world, noting that many of these bans predated EPA's HPS designation.

EPA essentially confirmed the benefits of all the regulatory activity on TCEP. For example, It noted that "the most recent updated 2020 CDR data showed that no company reported the manufacture (including import) of TCEP in the United States from 2016 to 2020." Further, EPA also obtained import volume information from Descartes Datamyne, a commercial searchable trade database, that reported an import volume of 593 pounds of TCEP in 2020, the most recent year available. We note this for two reasons. First, EPA continually expresses concern about not being able to complete its work under TSCA because of significant staffing and resource shortages, yet it may have spent considerable resources over the past several years in contractor fees and in EPA employee review time developing the draft risk evaluation for TCEP. Second, experts in the field of genotoxicity and carcinogenicity cautioned more than 20 years ago about the wisdom of "[p]utting huge amounts of money into minuscule hypothetical risks [because it] damages public health by diverting resources and distracting the public from major risks." We share this caution, and it seems to apply here.

Acta notes that we have cautioned readers in the past that even if a chemical substance is not part of their supply chain, they should nevertheless be aware of EPA's activities on all existing chemical substances undergoing TSCA risk evaluations. We have stated this because once issued in final, EPA's risk evaluations set precedent, be it bad or good. Below, we have provided a few examples

from the draft risk evaluation for TCEP that raise questions about the integrity of EPA's risk evaluations. We begin with EPA's conclusions on the carcinogenicity of TCEP. Thereafter, we discuss EPA's updated approach and methodology for evidence integration that includes apparent causality determinations. Finally, we discuss EPA's continued approach of using novel models in its draft risk evaluations that have not undergone independent peer review by the TSCA Science Advisory Committee on Chemicals (SACC) prior to application in a risk evaluation to ensure they are fit-for-purpose.

First, EPA concluded that TCEP is "likely to be carcinogenic to humans …. This conclusion is based on clear evidence of *renal tubule adenomas and carcinomas in rats* …." [Emphasis added.] In comparison, the International Agency for Research on Cancer (IARC) concluded TCEP "is *not classifiable as to its carcinogenicity to humans (Group 3)*." [Emphasis in original.] We note that IARC reviewed the same studies that EPA reviewed (*i.e.*, NTP 1991). Further, the U.S. National Toxicology Program (NTP) concluded the following about the carcinogenicity studies it performed on TCEP and published in 1991: "Under the conditions of these 2-year gavage studies, there was *clear evidence of carcinogenic activity* [asterisk omitted] for male and female F344/N rats receiving tris(2-chloroethyl) phosphate as shown by increased incidences of renal tubule adenomas." [Emphasis in original.] We note that NTP reported the incidence of renal tubule carcinoma in one male rat in the control group and one male rat in the high-dose group. NTP did not identify renal tubule carcinomas in the low-dose male rats nor in any of the control or treated female rats. We note this because it illustrates a concern that we previously raised about EPA lowering the "scientific rigor of its risk evaluations." For discussion, see our memorandum dated October 30, 2023.

Second, EPA updated its approach and methodology for human health hazard in the draft risk evaluation for TCEP. EPA summarized this in part as follows:

> EPA conducted dose-response analysis for the health outcome categories that received a judgment of *likely* ("evidence indicates that TCEP exposure likely causes [health effect]") during evidence integration.

EPA then applied this approach across endpoints in the draft risk evaluation for TCEP. For example, EPA's evidence integration for developmental toxicity found that "human evidence is *indeterminate* for developmental effects," that "[a]nimal studies show *moderate* evidence for developmental effects," and that "supporting mechanistic data [for developmental toxicity are] … *slight*." Based on these determinations, EPA stated:

> Overall, EPA concluded that evidence indicates that TCEP ***likely causes developmental toxicity in humans*** under relevant exposure circumstances [emphasis added].

We understand that as a matter of science policy considering effects reported in rodent studies as relevant to humans is appropriate when assessing potential hazards and risks, particularly in the absence of information to inform human relevance. After all, it is a health protective approach to consider humans as sensitive or more sensitive than the most sensitive species for a particular endpoint when conducting a risk assessment, again when information on human relevance is lacking, which is most often the case. Our concern with EPA's updated approach to evidence integration is that it draws a conclusion on causality based on a scant evaluation of the available data. This lapse goes well beyond EPA's not complying with the scientific standards under TSCA Section 26 or potential implications to the regulated community from risk management actions under TSCA Section

6. This updated approach may have more far-reaching implications, such as inviting a host of legal causes of action such as product liability concerns based solely on EPA's specific conclusory statement that TCEP "likely causes developmental toxicity in humans."

Finally, we note that EPA applied new models in the draft risk evaluation for TCEP. For example, EPA used for the first time in a TSCA risk evaluation, Web-ICE to predict acute toxicity values in aquatic species not evaluated in experimental studies. These predictions were then used with empirical data to generate SSDs. Though we applaud EPA's commitment to advancing new approach methodologies (NAM), such as Web-ICE, we question EPA's application of these new models in a risk evaluation, without first having the new models peer reviewed by the TSCA SACC to ensure they are appropriate for use in risk evaluations.

Acta encourages interested parties to review EPA's draft risk evaluation for TCEP and to provide comments as appropriate. This may seem like an inconsequential assessment, given the regulatory restrictions on a substance with limited commercial applicability. It may also, however, be the very reason why EPA incorporated its updated and/or new approaches and methodologies into this draft risk evaluation. This is not the first time EPA has updated approaches based on questionable scientific support. For more explanation, see our memorandum dated August 22, 2022. It is, however, the first time EPA has included consequential updates in a draft risk evaluation that will be subject to a letter peer review rather than peer review by the TSCA SACC.

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