

January 24, 2024

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Michal Freedhoff, Ph.D.
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Re: OPPT Peer review approach for Asbestos and TCEP

Dear Deputy Administrator McCabe and Assistant Administrator Freedhoff,

As you know, the [Environmental Protection Network](https://www.epn.org/) (EPN) harnesses the expertise of more than 600 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.

Today we are writing to you about EPA's peer review practices as they relate to the TSCA Asbestos Part 2 and the Tris(2-chloroethyl) phosphate (TCEP) risk evaluations.

EPN is pleased to see the progress to date on developing the risk evaluation for Asbestos Part 2. Asbestos fibers are a human carcinogen and are an important, high risk environmental pollutant with interests that cut across several other agency programs. As a result, this risk evaluation can serve as an important foundation not only for actions under TSCA, but also the drinking water and air programs and Superfund sites. Therefore, it is critical that EPA make sure all pertinent science has been evaluated and evaluated appropriately. That's where peer review plays an important role and why it is critical that peer review be conducted with rigor.

We are concerned that the peer review for the Asbestos Part 2 risk evaluation is cutting corners. The letter review approach utilized in the review of EPA's White Paper on Quantitative Human Health Approach to be Applied in the Risk Evaluation of Asbestos Part 2 ("Asbestos Part 2 White Paper"), with no plans for peer review of the full draft risk evaluation by the Science Advisory Committee on Chemicals (SACC) once completed, goes against sound scientific processes and jeopardizes the integrity of the science and decisions that will be informed by that science.

EPN had similar concerns when we learned of EPA's plans to conduct only a letter peer review of the draft TCEP risk evaluation. TCEP is the first of the high-priority chemicals selected for risk evaluation during the second round of prioritization in 2019 to have a draft risk evaluation released for peer review and public comment. It is a data-rich chemical possessing a toxicity profile of many endpoints of serious concern (e.g.

neurotoxicity, reproductive and developmental toxicity, carcinogenicity) and a large variety of exposure scenarios that impact every life stage. Many of the approaches being used in the hazard and exposure assessments for TCEP are new to the TSCA program. For all of these reasons, the peer review for TCEP should be carried out in a public, collaborative setting.

The EPA Peer Review Handbook and OMB Peer Review Bulletin provide robust frameworks for conducting peer review, including how it is to be conducted. Serious thought must be given to selecting the appropriate type of peer review to be carried out for a particular scientific product. These frameworks recognize that complex and novel assessments with far-reaching impacts on regulation and policy must receive the highest level of peer review—a transparent panel review process with collaboration among the reviewers, interaction with the public, and a consensus report synthesizing the reviewers’ range of perspectives. External peer review by independent experts under this approach helps to assure that agency assessments and management decisions are based on the best available science and reflect the highest level of robust scientific integrity.

Questionable peer reviews will negatively impact EPA, as seen with the recent letter peer review of the Asbestos Part 2 White Paper. The reviewers were divided on a fundamental issue — the choice of cancer potency factors for the six asbestos fibers — that might have been resolved through a collaborative panel review process. Several of the reviewers criticized the lack of transparency and prohibition of interaction between them. They emphasized that a letter review was inadequate for a substance as important and complex as legacy asbestos.

Risk evaluations for high-profile, high-priority substances, with high risk potential and complex data sets and questions, should always be subjected to publicly-staged, collaborative peer reviews. One might have made a valid argument to conduct a letter review on the Asbestos Part 2 White Paper as an initial step in a more comprehensive process for the entire draft evaluation that includes a publicly-staged collaborative peer review. But it appears that no peer review at all is planned for the draft Part 2 evaluation. This will deprive EPA and the public of further independent scientific input not only on the choice of cancer potency factors but on numerous other major issues as well. The same adverse consequences will also impact the TCEP risk evaluation.

Draft risk evaluations that introduce the use of new approaches for the first time should also be subjected to a publicly-staged collaborative peer review, like a SACC review, so that the integrity, relevance, and application of the new approaches can be robustly discussed. EPA’s current choice of doing only a letter peer review of the TCEP draft risk evaluation is therefore insufficient.

Until the Existing Chemical Review program matures to the point where a standard operating procedure has been defined and all stakeholders know what to expect, EPA has an obligation to subject its products to a robust collaborative public peer review. In the end, this will save time and resources, because the agency won’t have to “do it again,” as happened with the first 10 risk evaluations, and it will provide a sounder foundation for the follow-up risk management rulemakings necessary under TSCA.

In closing, we recommend that EPA reexamine its peer review mechanisms for Asbestos Part 2 and TCEP and convene full SACC panel peer review processes for both evaluations. As always, we are happy to discuss this with you further.

Sincerely,

A handwritten signature in cursive script that reads "Michelle Roos".

Michelle Roos
Executive Director
Environmental Protection Network

cc: H. Christopher Frey, EPA Science Advisor
Maureen Gwinn, EPA Chief Scientist
Elissa Reaves, Director, Office of Pollution Prevention and Toxics