



[EPA-HQ-OPPT-2023-0309; FRL-9347-05-OCSPP]

Letter Peer Review; White Paper: Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2; Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public comment on the document entitled: “White Paper: Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2 - Supplemental Evaluation including Legacy Uses and Associated Disposals of Asbestos” and related charge questions. EPA will be soliciting comments from expert *ad hoc* reviewers on the quantitative approach described in this white paper. The white paper describes the systematic review considerations and criteria for identifying studies for dose-response analysis; includes an evaluation and comparison of existing cancer IURs and the non-cancer point of departure (POD) with the results of the new systematic review; and a proposal for a cancer IUR and non-cancer POD for use in the Part 2 risk evaluation for asbestos. In addition to the final charge questions and white paper, public comments received by the date specified in this document will be provided to the peer reviewers for consideration. The letter peer review is expected to begin October 25, 2023, and end November 24, 2023. Feedback from the letter peer review will be considered by EPA in the development of the Part 2 risk evaluation for asbestos, a draft of which will be released subsequently, along with a separate response document.

DATES: Comments must be received on or before [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit written comments, identified by docket identification (ID) number EPA-HQ-OPPT-2023-0309, through <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be

Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional information on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Contact the Peer Review Leader (PRL), Tamue Gibson, Mission Support Division, Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-7642 or call the main office number:(202) 564-8450; email address: gibson.tamue@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. What action is the Agency taking?

EPA is announcing the availability of and soliciting public comment on the document entitled: “Quantitative Approach to the Human Health Assessment for the Risk Evaluation for Asbestos Part 2: Supplemental Evaluation including Legacy Uses and Associated Disposals of Asbestos.”

B. What is the Agency's authority for taking this action?

Section 6(b) of the Toxic Substances Control Act (TSCA) (15 U.S.C. 2605(b)), requires that EPA conduct risk evaluations on existing chemical substances and identifies the minimum components EPA must include in all chemical substance risk evaluations. The risk evaluation must not consider costs or other non-risk factors (15 U.S.C. 2605(b)(4)(F)(iii)). The specific risk evaluation process is set out in 40 CFR part 702 and summarized on EPA's website at <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca>.

C. Does this action apply to me?

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, and disposal of chemical substances and mixtures, and/or those interested in the assessment of risks involving chemical substances

regulated under TSCA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

D. What should I consider as I submit my comments to EPA?

1. Submitting Confidential Business Information (CBI).

Do not submit CBI or other sensitive information to EPA through <https://www.regulations.gov> or email. If your comments contain any information that you consider to be CBI or otherwise protected, please contact the PRL listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting that information.

2. Tips for preparing comments.

When preparing and submitting your comments, see Tips for Effective Comments at <https://www.epa.gov/dockets>.

III. Request for Comment

EPA is seeking public comment on both the white paper and the draft charge questions for the letter peer review. Both documents are available in EPA Docket ID No. EPA-HQ-OPPT-2023-0309 at <https://www.regulations.gov> and may also be accessed through EPA's website at <https://www.epa.gov/tsca-peer-review>. As additional background materials become available, EPA will include those additional background documents (e.g., reviewers participating in this letter peer review) in the docket and on the website.

III. Letter Peer Review

A. What is the purpose of this Letter Peer Review?

The focus of this Letter Peer Review is to review the quantitative approach to assessing cancer and non-cancer human health hazards. Feedback from this review will be considered in the development of Part 2 of the risk evaluation for asbestos.

B. Why did EPA develop these documents?

Asbestos was identified as one of the first 10 chemicals for risk evaluation under TSCA in December 2016. For the purposes of the risk evaluation for asbestos under TSCA section 6(a),

EPA initially adopted the TSCA Title II (added to TSCA in 1986), section 202 definition; which is “asbestiform varieties of six fiber types – chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite.” The latter five fiber types are amphibole varieties. EPA initially focused its risk evaluation on chrysotile asbestos, as described in the Problem Formulation for the Risk Evaluation for Asbestos, as this is the only fiber type with ongoing use, meaning current manufacture, processing, or distribution in commerce. Following release of the decision to exclude legacy uses from the risk evaluation, EPA was legally challenged by Safer Chemicals, Healthy Families, and in late 2019, the court in *Safer Chemicals, Healthy Families v. EPA*, 943 F.3d 397 (9th Cir. 2019) held that EPA’s Risk Evaluation Rule (82 FR 33726, July 20, 2017 (FRL-9964-38)), should not have excluded “legacy uses” (i.e., uses without ongoing or prospective manufacturing, processing, or distribution) or “associated disposals” (i.e., future disposal of legacy uses) from the definition of conditions of use, although the court upheld EPA’s exclusion of “legacy disposals” (i.e., past disposal). Due to the court ruling, in the March 2020 Draft Risk Evaluation for Asbestos, EPA had signaled the inclusion of other fiber types, in addition to chrysotile, as well as consideration of legacy uses and associated disposal for the asbestos risk evaluation in a supplemental scope document and supplemental risk evaluation when these activities are known, intended, or reasonably foreseen. This was supported by both public comment and the Science Advisory Committee on Chemicals (SACC) during the SACC Peer Review meeting on June 8-11, 2020. The Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos was finalized in December 2020 and specified a Part 2 scope document and risk evaluation would be forthcoming. The Final Scope of the Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos took into consideration public comment and was released in June 2022.

In the final scope document for the Part 2 Risk Evaluation, EPA articulated the plan for the human health analysis to continue to focus on epidemiologic studies, given the robust evidence base and decades worth of evidence examining the relationship between exposure to

asbestos and health effects. However, unlike the analysis in Part 1 that was focused on inhalation exposures and cancer, the analysis for human health in Part 2 also considers non-cancer effects and other routes of exposure. EPA has applied systematic review approach methods, as described in the Final Scope of the Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos and the Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances to identify the reasonably available information to be considered in the Part 2 Risk Evaluation. EPA has continued to screen and evaluate the epidemiologic evidence following the finalization of the final scope document in order to determine the specific technical and quantitative analyses that may be warranted.

As anticipated, numerous epidemiology studies were identified, particularly for inhalation exposures with more limited information for oral and dermal exposure routes, examining asbestos and cancer and non-cancer effects. Because the human health hazards are well-established, it was recognized that streamlined identification of epidemiology studies that could inform dose-response would be both efficient and scientifically appropriate. Thus, EPA employed a fit-for-purpose objective and transparent approach to efficiently identify and evaluate the relevant information. In addition, EPA considered the reasonably available information in the context of the existing EPA assessments and the quantitative risk values those assessments established. Specifically, EPA considered the Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos (2020) and a chrysotile-specific inhalation unit risk (IUR) of 0.16 per fiber/cubic centimeter (cc), the Integrated Risk information System (IRIS) Libby Amphibole Assessment (2017) and a Libby amphibole-specific IUR of 0.17 per fiber/cc and (Reference Concentration (RfC) for Inhalation Exposure of 9×10^{-5} milligram per cubic meter (mg/m³), and the IRIS Asbestos Assessment (1988) and a mixed-fiber IUR of 0.23 per fiber/milliliter (mL)). Based on evaluation and consideration of the totality of the information, EPA has developed a quantitative approach to assessing cancer and non-cancer human health hazards for Part 2 of the

Risk Evaluation for Asbestos.

EPA is soliciting comments through letter peer review on the quantitative approach employed to identify the dose-response relevant information, the evaluation of the epidemiologic cohorts and data for dose-response assessment, analysis of the existing IURs and RfC and their potential suitability for application in the Part 2 Risk Evaluation, and the selection of an IUR and point of departure. EPA has prepared these technical details in the document entitled: “White Paper: Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2 - Supplemental Evaluation including Legacy Uses and Associated Disposals of Asbestos, which will be distributed for a letter peer-review that is expected to begin October 25, 2023, and end November 24, 2023. Feedback from the letter peer review will be considered by EPA in the development of the Part 2 risk evaluation for asbestos, a draft of which will be released subsequently, along with a separate response document.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: July 27, 2023.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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