



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2023-0309; FRL-9347-04-OCSPP]

Letter Peer Review; 2023 White Paper on the Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2; Request for Nominations of Expert Reviewers

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or “Agency”) is seeking public nominations of scientific and technical experts to review the “2023 White Paper on the Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2.” The white paper will be released for public review and comment in late July 2023 and subsequently submitted for letter peer review. EPA currently anticipates selecting approximately 10-15 expert reviewers and plans to make a list of candidates under consideration as prospective letter reviewers for this review available for public comment by early August 2023.

DATES: Submit your nominations to EPA on or before **[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Submit your nominations via email to the Designated Federal Official (DFO) listed under FOR FURTHER INFORMATION CONTACT. Do not use email to submit any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Contact the DFO, Tamue Gibson, Office of Program Support (7602M), Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-7642 or call the Science Advisory Committee on Chemicals (SACC) main office number: (202) 564-8450; email address: gibson.tamue@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. What action is the Agency taking?

The Agency is seeking public nominations of scientific and technical experts that the EPA can consider for service as peer reviewers for the review of the “2023 White Paper on the Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2.” EPA will be soliciting comments from the reviewers on the quantitative approach to assessing cancer and non-cancer human health hazards for Part 2 of the risk evaluation for asbestos.

This document provides instructions for submitting nominations of scientific and technical experts that EPA can consider as prospective candidates to serve as peer reviewers. EPA will publish a separate document in the Federal Register in late July 2023 to announce the availability of the white paper and solicit public comments.

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

TSCA section 6(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 (15 U.S.C. 2605(b)). 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: <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 nominations to EPA?

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

II. Nominations for Peer Reviewers

A. Why is EPA seeking nominations for peer reviewers?

As part of a broader process for developing a pool of candidates for peer reviews, EPA is asking the public and stakeholder communities for nominations of scientific and technical experts that EPA can consider as prospective candidates to serve as peer reviewers. Any interested person or organization may nominate qualified individuals for consideration as prospective candidates for this review by following the instructions provided in this document. Individuals may also self-nominate.

Those who are selected from the pool of prospective candidates will be asked to review the white paper for asbestos and to help finalize the letter review report.

B. What expertise is sought for this peer review?

Individuals nominated for this peer review, should have expertise in one or more of the following areas: Asbestos epidemiology; epidemiology and biostatistics; asbestos exposure measurement; and application of epidemiology in risk assessment. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this review.

C. How do I make a nomination?

By the deadline indicated under **DATES**, submit your nomination to the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Each nomination should include the following information: Contact information for the person making the nomination; name, affiliation, and contact information for the nominee; and the disciplinary and specific areas of

expertise of the nominee.

D. Will ad hoc reviewers be subjected to an ethics review?

Peer reviewers are subject to the provisions of the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR part 2635, conflict of interest statutes in title 18 of the United States Code and related regulations. In anticipation of this requirement, prospective candidates will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks, and bonds, and where applicable, sources of research support. EPA will evaluate the candidates' financial disclosure forms to assess whether there are financial conflicts of interest, appearance of a loss of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service.

E. How will EPA select the letter peer reviewers?

The selection of scientists and technical experts to serve as peer reviewers is based on the expertise needed to address the Agency's charge to the reviewers. No interested scientists or technical experts shall be ineligible to serve by reason of their membership on an advisory committee to a federal department or agency or their employment by a federal department or agency, except EPA. Other factors considered during the selection process include availability of the prospective candidate to fully participate in the Letter Review, absence of any conflicts of interest or appearance of loss of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of loss of impartiality, lack of independence, and bias may result in non-selection, the absence of such concerns does not assure that a candidate will be selected to serve as a peer reviewer.

Numerous qualified candidates are often identified for the review. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific

perspectives across reviewers. The Agency will consider all nominations of prospective candidates for service as peer reviewers that are received on or before the date listed in the **DATES** section of this document. However, the final selection of peer reviewers is a discretionary function of the Agency. At this time, EPA anticipates selecting 10-15 reviewers in the review of the designated topic.

EPA plans to make a list of candidates under consideration as prospective peer reviewers for this review available for public comment by early August 2023. The list will be available in the docket at: <http://www.regulations.gov> (docket ID number EPA-HQ-OPPT-2023-0309). You may also subscribe to the following listserv for alerts regarding this and other peer review related activities:

https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_T_101.

III. Letter Review

A. What is the purpose of this Letter Review?

The focus of this Letter 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.

In addition, EPA intends to publish a separate document, in late July 2023, in the Federal Register to announce the availability of and solicit public comment on the white paper, at which time EPA will provide instructions for submitting written comments

B. Why did EPA develop these documents?

Asbestos was identified as one of the First 10 Chemicals for risk evaluation under the Toxic Substances Control Act (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 this 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), 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 SACC during the SACC Peer Review (virtual) meeting, 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 was released in June 2022, taking into consideration public comment.

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 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, a wealth of epidemiologic evidence was 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 epidemiologic studies that could inform dose-response would be beneficial. 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: 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 for Inhalation Exposure (RfC) 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 White Paper on the Quantitative Human Health Approach to be Applied in the Risk Evaluation for Asbestos Part 2, for peer-review. Part 2 of the Risk Evaluation will be released for public comment, anticipated later in 2023 or early 2024, pursuant to TSCA Section 6.

C. How can I access the documents submitted for review to the Peer Reviewers?

EPA is planning to release the white paper mentioned above and all background documents, related supporting materials, and draft charge questions by early August 2023. At that time, EPA will publish a separate document in the Federal Register to announce the availability of and solicit public comment on the white paper and provide instructions for submitting written comments. These materials will also be available in the docket at: <https://www.regulations.gov> (docket ID number EPA-HQ-OPPT-2023-0309) and <https://www.epa.gov/tsca-peer-review>. In addition, as additional background materials become available, EPA will include those additional background documents (e.g., reviewers participating in this letter review) in the docket and on the website.

Authority: 15 U.S.C. 2625(o).

Dated: June 16, 2023.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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