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February 11, 2022

Michael S. Regan
Administrator
United States Environmental Protection Agency

AIHA Comments on EPA's Draft Scope of the Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos

Docket Number: EPA-HQ-OPPT-2021-0254

Dear Administrator Regan:

AIHA, the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety, appreciates the opportunity to provide feedback on EPA's draft scope of the Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos. Below are our comments, which we hope you find useful.

Review of EPA Approach – Address Epidemiology/NASES Comments on the TSCA Process from Part 1: Chrysotile Asbestos

The EPA's draft scope of the Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos makes numerous references to the Risk Evaluation for Asbestos Part 1: Chrysotile Asbestos, published in December 2020. The Part 2 risk evaluation for asbestos draft protocol states the following: "The draft protocol is based on a revised, generic approach to systematic review accounting for comments from prior Science Advisory Committee on Chemicals (SACC) reviews of chemical risk evaluations and more recent recommendations from the National Academies of Sciences (NAS), Engineering, and Medicine (NASEM)." The revised, generic approach to systematic review described in Part 2 is currently in development.

The new revised TSCA Systematic Review Protocol was developed because the NASEM, in their published consensus study report dated February 2021, concluded that the protocol used for the first ten chemical risk evaluations under the Lautenberg Act, including Part 1 of the Risk Evaluation for Asbestos, did not meet the criteria of "comprehensive, workable,

objective, and transparent."[1] The Part 1 Risk Evaluation contains significant deficiencies related to the exposure assessment such that exposures calculated are unsupported; there is no indication that these deficiencies will be addressed before Part 2. Chrysotile asbestos is a major part of legacy exposure to asbestos. Therefore, the scope of the Risk Evaluation should be based upon an improved evaluation for chrysotile asbestos made in Part 1 of the assessment.

EPA states that it used Part 1 "to inform the development of this draft scope document, EPA leveraged the data and information sources identified for Part 1 of the Risk Evaluation for Asbestos." (Draft Scope, Part 2, p 10). It is premature to move forward with Part 2 of the Asbestos Risk Evaluation before the completion of the revised systematic review and before Part 1 is revised to provide a comprehensive, workable, objective, and transparent risk evaluation that meets the standard of care established by the new systematic review process. To continue with Part 2, which incorporates a flawed Part 1 Asbestos Risk Evaluation, is inefficient and would not be consistent with EPA's stated goal of meeting statutory obligations, being guided by the best available science, ensuring the integrity of Federal decision-making, and protecting human health and the environment.[2] Furthermore, the scope for the Part 2 Risk Evaluation should demonstrate how the agency intends to incorporate methodological revisions as a result of the NASEM review.

Exposure Assessments

Exposure assessment is an essential part of risk evaluation and especially critical for the characterization of health risks from legacy exposure to asbestos. AIHA recommends that EPA include in the scope of the risk evaluation for asbestos the requirement to complete a full, comprehensive occupational exposure assessment for its Part 2 Risk Evaluation. AIHA recommends that EPA rely on the exposure assessment for legacy asbestos on the principles outlined in the AIHA publication "A Strategy for Assessing and Managing Occupational Exposures."[3] EPA must conduct a risk assessment that fully incorporates all contaminant sources, fate and transport, exposure point sources, exposure routes, and potentially exposed populations. The conceptual models presented in the draft scope do not fully illustrate these concepts and are not comprehensive. For example, EPA should better define the populations potentially exposed to legacy asbestos and determine the list of relevant occupations (e.g., mining, milling, and manufacturing) and non-occupationally exposed populations in schools (e.g., students, teachers, custodial and maintenance staff), take-home exposures and others that do not appear in the conceptual models.

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[1] National Academies of Sciences, Engineering, and Medicine; Division on Earth and Life Studies; Board on Environmental Studies and Toxicology; Committee to Review EPA's TSCA Systematic Review Guidance Document: The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations (2021). ISBN 978-0-309-68386-9 | DOI 10.17226/25952

[2] United States Environmental Protection Agency. News Releases from Headquarter, Chemical Safety and Pollution Prevention (OCSPP). EPA Commits to Strengthening Science Used in Chemical Risk Evaluations. February 16, 2021.

[3] https://online-ams.aiha.org/amsssa/ecssashop.show_product_detail?p_product_serno=887&p_mode=detail

Furthermore, ambiguity exists in the scope for assessment of occupational non-users (ONUs). EPA needs to provide justification for their case-by-case selection criteria for ONUs. Without this type of specific occupational and non-occupational exposure information, there is an opportunity to miss a significant population with legacy asbestos exposure and exposure pathways, thereby underestimating risk.

Hazards (Effects)

The estimation of hazards and quantification of risk from the exposure to legacy-related elongate mineral particles (EMPs) (asbestiform and non-asbestiform) in the framework of TSCA is important for the community of occupational and environmental health professionals. EPA should propose the evaluation of risk to various exposure groups based on a methodology that can be considered for ongoing legacy uses and disposal in diverse contexts. For example, risk assessments at workplaces where exposure to EMP is still possible, as well as for retrospective exposure and risk assessment. It is critical for the EPA methodology to be scientifically solid and advanced, using the most recent data, approaches, and models.

From this position, AIHA recommends that EPA rely on the scientific achievements in the area of asbestos risk assessment when human health hazards are evaluated. In particular, it is critical for the assessment to have a solid toxicological base. However, in the draft scope, the prioritization of the relevant human health hazard was apparently not performed efficiently. For example, the current document quotes "ADME, PBPK, cancer, cardiovascular, developmental, endocrine, gastrointestinal, hematological and immune, hepatic, mortality, musculoskeletal, neurological, nutritional and metabolic ocular and sensory, renal, reproductive, respiratory, skin and connective tissue". (p. 46 and elsewhere). It demonstrates that the toxicologically-based hazard identification for asbestos was apparently not exercised systematically, and instead some irrelevant list of health effects was proposed. Without correction of this list, repeated numerous times throughout the document, the risk evaluation for asbestos will be significantly flawed.

It should be noted that the asbestos-related bibliography during the last several decades amassed significant facts about toxicity and carcinogenicity of elongate mineral particles being a function of their various physical and chemical characteristics, including mineralogical type, habit, and dimensions (Wylie et al., 2020).[4] While all asbestos fibers are carcinogenic, the difference between various mineral types of elongate mineral particles in

[4] Wylie AG, Korchevskiy A, Segrave A, Duane A. 2020. Modeling mesotheliomarisk factors from amphibole fiber dimensionality: mineralogical and epidemiological perspective. J Appl Toxicol. 40(4): 515–524.

their ability to cause toxic effects is very significant, by a factor of several orders of magnitude (Hodgson, Darnton, 2000, Berman, Crump, 2008a, Berman, Crump, 2008b).[5 6 7] Recently, the European Chemical Agency (ECHA) in its assessment of asbestos risk, confirmed the significant variability of cancer potency for various mineral types of asbestos.[8] However, EPA noted in the scope document that "[I]t is anticipated that the exposures resulting from the relevant condition of uses will be for a mixture of asbestos fibers. Thus, EPA plans to evaluate the hazard for a mixture of asbestos fibers and not for individual fiber types." (p. 65). This approach is not adequate. Despite a significant part of the exposure to asbestos indeed being constituted from a mixture of various types of asbestos, the composition of this mixture can be evaluated, and characteristics of the elongate particles assessed. Ignoring the difference between mineral types of fibers would be a significant step back in the practice of EPA that previously evaluated Libby amphibole asbestos risk and chrysotile asbestos risk separately and at different levels of carcinogenic potency. [9 10] Therefore, AIHA recommends that EPA estimate risk by various mineral types, habits, and dimensions of elongate mineral particles and apply the potency factors to different exposure mixtures according to the knowledge about typical compositions of such mixtures. The attempts to calculate potency factors for the elongate mineral particles without consideration of their characteristics will be detrimental to asbestos toxicology and will lead to establishing a unit risk for asbestos that will be too high for some types of fibers but too low for others, potentially compromising the safety of workers and populations (Korchevskiy et al., 2020).[11]

The habit and dimensions of asbestos fibers are also issues that should be addressed by the EPA assessment. The differentiation of toxicological characteristics for asbestiform and non-asbestiform particles belonging to the same mineral types is a very significant issue. While the EPA scope defines asbestos in terms of "asbestiform varieties of six fiber types" (p. 9), it is unclear what criteria will be used by EPA in distinguishing asbestiform vs. non-asbestiform varieties of particles. In particular, talc can be contaminated by asbestiform and non-asbestiform varieties of elongate mineral particles that significantly affect the difference in carcinogenicity (Wild, 2006).[12] There is an extensive bibliography characterizing non-asbestiform elongate mineral particles (like cleavage fragments),

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[5] Hodgson J, Darnton A. 2000. The quantitative risks of mesothelioma and lung cancer in relation to asbestos exposure. Ann Occup Hygiene. 44(8):565–601. https://pubmed.ncbi.nlm.nih.gov/11108782/.

[6] Berman DW, Crump KS. 2008a. Update of potency factors for asbestos-related lung cancer and mesothelioma. Crit Rev Toxicol. 38(1): 1–47.

[7] Berman DW, Crump KS. 2008b. A meta-analysis of asbestos-related cancer risk that addresses fiber size and mineral type. Crit Rev Toxicol. 38(1):49–73.

[8] European Chemical Agency (ECHA), 2021. ECHA Scientific report for evaluation of limit values for asbestos at the workplace. 4605fc92-18a2-ae48-f977-4dffdecfec11 (europa.eu).

[9] U.S. EPA, 2017. Toxicological review of Libby amphibole asbestos. EPA/635/R-11/002F.

[10] U.S. EPA, 2020. Risk evaluation for asbestos. Past I. Chrysotile asbestos. EPA-740-R1-8012.

[11] Korchevskiy A, Rasmuson JO, Rasmuson EJ, Strode RD. Inhalation unit risk (IUR) of asbestos based on available science. Inhal Toxicol. 2020 Aug;32(9-10):372-374. doi: 10.1080/08958378.2020.1829210. Epub 2020 Oct 9. PMID: 33032452.

[12] Wild P. Lung cancer risk and talc not containing asbestiform fibres: a review of the epidemiological evidence. *Occup Environ Med*. 2006;63(1):4-9. doi:10.1136/oem.2005.020750

arguing that their carcinogenicity is much lower than for asbestiform fibers (Mossman, 2008, Garabrant, Pastula, 2018).[13] [14] EPA should define the approach to evaluate risk from talcum powder and commercial talc based on the presence of asbestiform asbestos, and not just any variety of amphibole particles that are abundant in rocks and soil.

The EPA also should address the issue of fiber dimensions as a variable impacting the level of carcinogenic potency. The methodology of a dimensionality-based risk assessment was developed by Berman, Crump in 2008.[15] It was established that long, thin fibers are more carcinogenic than a short, thick variety. Recently, this theory was reinforced by several peer-reviewed publications (Wylie et al., 2020, Korchevskiy, Wylie, 2022).[16] [17]

AIHA recommends that EPA rely on an extended pool of epidemiological literature when performing benchmark dose modeling for elongate mineral particles (p. 64). While the data from animal studies can be useful for asbestos toxicology, the utilization of dose-response models from in vivo and in vitro experiments is limited by significant differences in respiratory systems of animals and humans, as well as other factors, including the biopersistence of EMPs that is difficult to observe in animal experiments (Berman, Crump, 2003, Saffiotti, 2005).[18] [19] For a risk assessor, the epidemiological information remains the most important source for asbestos dose-response analysis (Wylie, Korchevskiy, 2022).[20] There are several dozen full-scale epidemiological studies on asbestos-exposure cohorts that should be considered. While applying quality criteria to the published epidemiological data to be used in the risk evaluation for asbestos, EPA should avoid an over-reliance on a single study that was demonstrated to bias the quantitative estimations of risk (Berman,

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[13] Mossman BT. 2008. Assessment of the pathogenic potential of asbestiform vs. nonasbestiform particulates (cleavage fragments) in in vitro (cell or organ culture) models and bioassays. Regul Toxicol Pharmacol. 52(1):S200–S203.
[14] Garabrant DH, Pastula ST. 2018. A comparison of asbestos fiber potency and elongate mineral particle (EMP) potency for mesothelioma in humans. Toxicol Appl Pharmacol. 361:127–136.
[15] Berman DW, Crump KS. 2008b. A meta-analysis of asbestos-related cancer risk that addresses fiber size and mineral type. Crit Rev Toxicol. 38(1):49–73.
[16] Wylie AG, Korchevskiy A, Segrave A, Duane A. 2020. Modeling mesothelioma risk factors from amphibole fiber dimensionality: mineralogical and epidemiological perspective. J Appl Toxicol. 40(4): 515–524.
[17] Korchevskiy AA, Wylie AG. Dimensional characteristics of the major types of amphibole mineral particles and the implications for carcinogenic risk assessment. Inhal Toxicol. 2022 Jan 10:1-15. doi: 10.1080/08958378.2021.2024304. Epub ahead of print. PMID: 35001771.
[18] Berman, D.W., Crump, K.S., 2003. Final Draft: Technical support document for a protocol to assess asbestos-related risk. EPA #9345.4-06. Document Display | NEPIS | US EPA.
[19] Saffiotti, U., 2005. Mesothelioma carcinogenesis: in vivo models. In: Pass, H.I., Vogelzang, N.J., Carbone, M., editors. Malignant Mesothelioma: advances in pathogenesis, diagnosis, and translational therapies. New York, NY, Springer, p. 605. ISBN:0387229493.
[20] Wylie, A., Korchevskiy, A (2022): Letter to the Editor: Epidemiology holds a key to the validation of toxicological models for elongate mineral particles, Current Research in Toxicology, Volume 3, 100062, ISSN 2666-027X, https://doi.org/10.1016/j.crtox.2021.100062.

Case, 2012).[21] AIHA recommends that EPA perform a meta-analysis of all available credible data, which will provide statistically significant slope factors for carcinogenic risk assessment.

We are willing to assist EPA in selecting the best methodologies for hazard identification and dose-response assessment suitable for legacy asbestos risk evaluation.

Measurement/Metrics/Laboratory Issues

The Draft Scope for Part 2 has not included any discussion about the issues related to asbestos measurements and metrics. EPA should demonstrate an understanding of potential discrepancies in available exposure data related to different methods of laboratory analysis for asbestos. The various analytical methods used to analyze for asbestos in airborne samples vary in their abilities to differentiate between asbestos and other fiber types and in the rules they employ for counting. In the Scope, it should be outlined how EPA will deal with data derived using different analytical methodologies and with historical asbestos measurements in comparison to current approaches. In particular, it should be noted that the occupational exposure limit for asbestos in the United States currently is based on phase-contrast microcopy (PCM) criteria. Using electron microscopy (TEM or SEM) methods for the determination of asbestos concentrations without adjustment for the visibility of fibers for PCM methods can make the results incomparable with epidemiological data or established exposure standards. At the same time, EPA should avoid unbiased exclusion of the historical asbestos exposure information because of the difference in laboratory methods. On the contrary, it is recommended to use robust statistical methods to standardize historical data according to available parallel measurements or theoretical assumptions.

Conclusion and Next Steps

AIHA thanks you for the opportunity to provide feedback on EPA's draft scope of the Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos. If you have any questions on these comments or other matters, please contact Mark Ames at mames@aiha.org or (703) 846-0730.

Sincerely,

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Chief Executive Officer
AIHA

[21] D. Wayne Berman, Bruce W. Case, Overreliance on a Single Study: There is no Real Evidence that Applying Quality Criteria to Exposure in Asbestos Epidemiology Affects the Estimated Risk, *The Annals of Occupational Hygiene*, Volume 56, Issue 8, October 2012, Pages 869–878, https://doi.org/10.1093/annhyg/mes027

About AIHA

AIHA is the association for scientists and professionals committed to preserving and ensuring occupational and environmental health and safety in the workplace and community. Founded in 1939, we support our members with our expertise, networks, comprehensive education programs, and other products and services that help them maintain the highest professional and competency standards. More than half of AIHA's nearly 8,500 members are Certified Industrial Hygienists, and many hold other professional designations. AIHA serves as a resource for those employed across the public and private sectors as well as to the communities in which they work. For more information, please visit www.aiha.org.