

EPN Comments on Asbestos Part 2 Supplemental Evaluation Including Legacy Uses and Associated Disposals; Draft Risk Evaluation Under the Toxic Substances Control Act Docket No: EPA-HQ-OPPT-2021-0254 June 17, 2024

The <u>Environmental Protection Network</u> (EPN) harnesses the expertise of more than 650 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.

EPN concurs with EPA's preliminary determination that asbestos as a whole chemical, including all forms of asbestos, and disturbing and handling asbestos associated with legacy uses pose an unreasonable risk to human health. We agree with the nine COUs identified by EPA that contribute to unreasonable human health risk for people who handle asbestos products, exposed workers taking asbestos home, non-professional do-it-yourselfers (DIY), and the general population within the vicinity of activities releasing asbestos to the environment. We also agree with EPA's preliminary determination that the remaining seven conditions of use do not contribute to the unreasonable risk. We provide comments below on key issues in the Part 2 risk evaluation.

Worker Exposures

EPN supports EPA's assumption that in all exposure scenarios, workers are not complying with existing federal regulations (i.e., the Asbestos Hazard Emergency Response Act (AHERA), Asbestos National Emission Standards for Hazardous Air Pollutants (NESHAPs), and Occupational Safety and Health Administration (OSHA) standards). EPA's high-end estimates cover situations where those requirements do not apply. EPA's risk evaluation is rightly focused on situations where workers, including self-employed persons hired to perform home renovation work, may not be subject to existing asbestos regulatory requirements, do not follow work practices to reduce asbestos exposure, or may not be aware that asbestos is present at the worksite.

Making unreasonable risk determinations without assuming personal protective equipment (PPE) is justified because unreasonable risk may exist for subpopulations of workers that may be highly exposed for the following reasons: (1) they are not covered by OSHA standards; (2) their employers are out of compliance with OSHA standards; (3) many of OSHA's chemical-specific permissible exposure limits (PELs) were largely adopted in the 1970s and are described currently by OSHA as being "outdated and inadequate for ensuring protection of worker health"; and/or (4) EPA finds unreasonable risk for purposes of TSCA, despite OSHA requirements.

Take-Home Exposures

Although current OSHA regulations prohibit taking contaminated clothing home, EPN agrees that EPA should account for workers who may not follow these guidelines. We support EPA's estimates of take-home

exposures for each occupational exposure scenario based on the resuspension of asbestos fibers during laundry preparation and inhalation by the clothes handler and bystanders.

Talc Exposures

EPA included potential exposures to imported talc products that may contain asbestos (i.e., fillers, putties, and crayons with talc-containing asbestos) in the occupational and consumer exposure assessments. For the consumer use of children's toys, EPA used exposure information based on crayons but did not find that use contributed to the unreasonable risk for consumers or bystanders. However, EPA noted that they were unable to determine if the use of mineral kits contributes to unreasonable risk. While EPA did not have data indicating import of these products is ongoing, the agency is planning to incorporate any relevant talc information gathered from public comments on this draft risk evaluation and the one-time asbestos reporting rule under TSCA Section 8(a) into the final Part 2 evaluation. EPN is concerned that the one-time asbestos report will not provide accurate information on asbestos-containing articles because the countries of origin are not likely to test for asbestos or notify US importers of its presence.

Environmental Risk Assessment

EPN agrees with EPA's preliminary determination that there is no risk of injury to the environment from asbestos that would contribute to the unreasonable risk determination for asbestos. EPA estimated air, water, and land releases of asbestos using appropriate methods and information sources. The agency then evaluated the potential risk to aquatic species via water and sediment and the risk to terrestrial species via inhalation. While the agency found that air emissions of legacy asbestos at construction sites pose risk to the general population, the limited uptake of asbestos fibers in the environment by animals and plants resulted in only limited adverse hazard effects that did not add to the unreasonable risk determination.

Human Health Assessment

Section 5.3.1 Risk Characterization Approach

The document states that "Non-cancer risks from exposure in occupational settings are assessed by first determining the benchmark [margins of exposure (MOE)], then calculating the scenario-specific MOE using Equation 5-2, where human exposure is defined by the average daily concentration (ADC). The calculated MOE is then compared to the benchmark MOE. If the numerical value of the MOE is less than the benchmark MOE, this is a starting point to determine if there are unreasonable non-cancer risks." Equation 5-2 is shown below:

$$MOE_{chronic} = \frac{Non-cancer Hazard Value (POD)}{Human Exposure}$$

Where:

MOE = Margin of Exposure Non-cancer Hazard Value (POD) = point of departure Human Exposure = Concentration (f/cc) Table 5-20 defines the following terms:

Benchmark MOE = 300 for the most sensitive and robust endpoint Benchmark MOE = (UFS) × (UFH) × (UFD)^b = $10 \times 10 \times 3$

The values defined as MOEs are, in reality, a combination (multiplication) of the Uncertainty Factors used by EPA to calculate the Libby Amphibole Reference Concentration (RfC). Additionally, the document states that "Chronic cancer risks from exposure in occupational settings are assessed by calculating the Excess Lifetime Cancer Risk (ELCR) using Equation 5-3, where the exposure concentration is assumed to be equal to an 8-hour TWA concentration, developed separately for each occupational use scenario. This COU-specific 8-hour TWA may be based upon measured or modeled data, depending upon which are available for that COU. The calculated ELCR is then compared to the benchmark ELCR. If the calculated ELCR is greater than the benchmark ELCR, this is a starting point to determine if there are unreasonable cancer risks."

When assessing cancer risk associated with a measured or modeled air concentration in an occupational setting, the cancer risk is calculated using Equation 5-3 and then compared to a benchmark cancer risk (e.g., *de minimus* risk of 1×10^4).

The limited oral exposure information available to evaluate the health effects of ingesting low concentrations of respirable fibers in mucus was inconclusive. We understand that dermal exposure was not assessed because the size and lack of solubility of asbestos fibers are thought to prevent systemic dermal penetration and absorption. We hope that other commenters on this draft Part 2 evaluation will identify additional relevant studies on oral or dermal exposures that would be of value to EPA in crafting a more robust assessment for these two routes of exposure.

Aggregate Risk

EPA defines aggregate exposure as "the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (40 CFR 702.33)." In this instance, given the lack of adequate data to determine if risk may result from exposure to asbestos via the oral or dermal route, EPA's aggregate analyses focused on inhalation-only, cross-COU/exposure scenario risk determinations.

EPA goes on to say, "If the individual estimates in the aggregation result in risk for a particular COU or exposure scenario, this value is omitted from aggregation calculations, but the possibility of that specific COU/activity occurring is described." This sentence is somewhat confusing, but EPN interpreted it to mean that if any single exposure scenario reflects an unacceptable risk on its own, that scenario should not be included in an aggregate analysis. If this is the correct interpretation, EPN believes that this was a misguided decision and could lead to a significant underestimation of risk to some populations from exposure to the "whole chemical," particularly those in the Potentially Exposed or Susceptible Subpopulation (PESS) category. The key to a robust and more credible aggregate assessment is to include *ALL* COUs/exposure scenarios with a reasonable probability of co-occurrence in representative (sub) populations such as PESS *without regard to their individual risk status*. An interesting and more realistic array of outcomes is likely. Therefore, we recommend that the agency, when doing aggregate risk analyses, include all COUs in order to provide valuable total risk information for the public. Greater transparency is obligatory.

One mode of analysis would be to identify and aggregate only "on-their-own, no-risk" scenarios, as the agency appears to have done in this case. If, in combination, the group is determined to be an unreasonable risk, it should prompt the relabelling of each "no-risk" scenario as "unreasonable." If this combination did not reach the unreasonable risk threshold, they would likely remain "no-risk" based upon only that one combination. But examining just one combination is inadequate—and potentially deceptive. It is not clear from the discussion in section 5.1.5 Aggregate Exposure Scenarios how many different combinations of exposures were sampled to test the hypothesis that for the "no-risk" scenarios, central tendency estimates are more likely to co-occur than high-end estimates. EPA also claimed that a significant number of occupational and non-occupational COUs exceed benchmarks alone at central tendency and/or high-end exposures. However, EPA did not present statistics, probabilities, or frequencies for populations engaging in activities represented in the aggregate analysis scenarios but identified activities that exceed benchmarks when they co-occur to support their conclusions. We sense that more and broader sampling should be incorporated into this analysis. Furthermore, there is no summarization of how many, if any, "no-risk" scenarios, when combined with other no-risk scenarios then became, in combination, "unreasonable risk" scenarios.

The second mode of analysis would be to identify and aggregate *all* scenarios with a reasonable probability of co-occurrence in representative (sub) populations such as PESS *without regard to their individual risk status*. An aggregate analysis of reasonably expected combinations composed of both unreasonable and no-risk scenarios would not water down the previously determined unreasonable risk scenarios; it actually would increase the total level of risk. It would demonstrate the inextricable link between the no-risk scenario(s) and the unreasonable risk scenarios previously determined "no-risk" as scenarios of concern.

Single Unreasonable Risk Determination

EPN agrees with EPA's single unreasonable risk determination for asbestos as a chemical substance that includes both the COUs evaluated in the 2020 Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos and the COUs evaluated in the draft Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals. We concur that a single unreasonable risk determination is appropriate because EPA has thoroughly documented: 1) the benchmark exceedances for multiple conditions of use spanning most aspects of the asbestos life cycle and 2) the risk of severe health effects associated with chronic inhalation exposures from all of these conditions of use.