

**EPA Response to Public Comments Received on the
Draft Scopes of the Risk Evaluations under the
Toxic Substances Control Act (TSCA) for:**

**Asbestos Part 2: Supplemental Evaluation Including Legacy Uses
and Associated Disposals of Asbestos**

June 2022

**Summary of Public Comments Received on the Draft Scope of the Risk Evaluation for
Asbestos
Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals of Asbestos
under the Toxic Substances Control Act (TSCA)**

In this document, the U.S. Environmental Protection Agency (EPA) is responding to comments received during the public comment period following announcement of the draft scope for the Risk Evaluation for Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposals under the Toxic Substances Control Act (TSCA) on December 29, 2021.

Comments were received during a 45-day public comment period, including a 15-day extension, following the announcement of the draft scope document for the Risk Evaluation for Asbestos Part 2 (86 FR 74088 [December 29, 2021]). During the comment period, the public was invited to submit comments on EPA’s draft scope document, including additional data or information relevant to the chemical substance or that otherwise could be useful to the Agency in finalizing the scope of the risk evaluation. To the extent that comments provided information on conditions of use, as well as other elements of the draft scope document, those comments and other submitted information (*e.g.*, relevant studies and assessments) were used to inform revisions to the draft scope document and may be considered in subsequent phases of the risk evaluation process.

EPA created a new docket for Part 2 of the Risk Evaluation for Asbestos to receive specific information relevant to Part 2. The Agency received comments submissions from 38 different entities. Of those submissions, nine were to request an extension of the public comment period. EPA granted a 15-day extension to the initial 45-day public comment period (87 FR 7833, February 10, 2022). The table below presents the commenters and corresponding docket number submissions in ascending order but does not include extension request docket numbers.

Comments addressed the overall risk evaluation process (*e.g.*, the overall approach to the scope documents and risk evaluation process; including collection, consideration, and systematic review of relevant information); the specific elements of the scope documents (*e.g.*, hazard, exposure, potentially exposed or susceptible subpopulations [PESS]); and information specific to the chemical substances (*e.g.*, relevant studies, assessments, conditions of use [COUs]).

Commenter Name/Organization	Docket Number^a
AIHA	EPA-HQ-OPPT-2021-0254-0014
Michelle Luker	EPA-HQ-OPPT-2021-0254-0015
International Association of Fire Fighters (IAFF)	EPA-HQ-OPPT-2021-0254-0016
American College of Occupational and Environmental Medicine (ACOEM)	EPA-HQ-OPPT-2021-0254-0017
Brooke T. Mossman	EPA-HQ-OPPT-2021-0254-0018
Barry Castleman	EPA-HQ-OPPT-2021-0254-0019
W.R. Grace & Co.	EPA-HQ-OPPT-2021-0254-0020

Commenter Name/Organization	Docket Number^a
Richard Lemen	EPA-HQ-OPPT-2021-0254-0021
Michael Robb	EPA-HQ-OPPT-2021-0254-0022
Terrence Spear	EPA-HQ-OPPT-2021-0254-0023
Andrew Oberta	EPA-HQ-OPPT-2021-0254-0024
Vanderbilt Minerals, LLC	EPA-HQ-OPPT-2021-0254-0025
American Association for Justice (AAJ)	EPA-HQ-OPPT-2021-0254-0026
Asbestos Disease Awareness Organization (ADAO)	EPA-HQ-OPPT-2021-0254-0027
American Water Works Association (AWWA)	EPA-HQ-OPPT-2021-0254-0028
North America's Building Trades Unions (NABTU)	EPA-HQ-OPPT-2021-0254-0029
Steven Markowitz	EPA-HQ-OPPT-2021-0254-0030
American Federation of Labor and Congress of Industrial Organizations (AFL-CIO)	EPA-HQ-OPPT-2021-0254-0031
Industrial Minerals Association – North America (IMA-NA)	EPA-HQ-OPPT-2021-0254-0032
Utility Solid Waste Activities Group (USWAG)	EPA-HQ-OPPT-2021-0254-0033
Industrial Minerals Association - North America (IMA-NA)	EPA-HQ-OPPT-2021-0254-0034
U.S. Chamber of Commerce (US CoC)	EPA-HQ-OPPT-2021-0254-0035
ASTM International (ASTM)	EPA-HQ-OPPT-2021-0254-0036
Hughes Hubbard & Reed LLP (HH&R LLP)	EPA-HQ-OPPT-2021-0254-0037
National Tribal Toxics Council (NTTC)	EPA-HQ-OPPT-2021-0254-0038
Resilient Floor Covering Institute (RFCI)	EPA-HQ-OPPT-2021-0254-0039
National Association of Manufacturers (NAM)	EPA-HQ-OPPT-2021-0254-0040
American Chemistry Council (ACC)	EPA-HQ-OPPT-2021-0254-0041
Environmental Information Association (EIA)	EPA-HQ-OPPT-2021-0254-0042
^a Extension request dockets not included in table.	

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1 Overall Risk Evaluation Process

1.1 Approach to Scope Document

Comment: Two commenters expressed concern that the draft scoping document does not recognize the impact of the upcoming asbestos TSCA section 8(a) reporting and recordkeeping rule on the Part 2 evaluation. EPA is required to promulgate this rule under a settlement agreement with ADAO. The final scoping document should clarify how EPA will use the reports it receives under the rule in conducting Part 2 (EPA-HQ-OPPT-2021-0254-0027; EPA-HQ-OPPT-2021-0254-0027).

Response: EPA will consider reasonably available information, including any such information received from the TSCA section 8(a) reporting and recordkeeping rule, in Part 2 of the Risk Evaluation. EPA has clarified in the final scope that relevant information may be obtained from the TSCA section 8(a) reporting and recordkeeping rule.

Comment: Technical and content errors must be addressed. Throughout the “Draft Scope” a number of technical and content errors must be corrected to ensure the integrity of the Agency’s work product (EPA-HQ-OPPT-2021-0254-0025).

Response: EPA has addressed specific errors that were raised and has additionally conducted a comprehensive review of the document to identify and correct any technical and typographical errors.

Comment: EPA needs to establish an educational program for building inspectors and realtors regarding Zonolite attic insulation so that homeowners and future homeowners are made aware of the hazards (EPA-HQ-OPPT-2021-0254-0023).

Response: At this point in the risk evaluation process, EPA’s objective is to identify the scope of Part 2 of the Risk Evaluation for Asbestos to be conducted. EPA will then conduct the risk evaluation to determine whether asbestos presents an unreasonable risk under of injury to health or the environment, without consideration of costs or other non-risk factors, under the conditions of use within the scope of Part 2 of the Risk Evaluation for Asbestos. If unreasonable risks are found to be presented, risk management rulemaking will be conducted to mitigate the unreasonable risks, in accordance with TSCA section 6. This commenter’s recommendations are relevant to the risk management stage, not the current scoping phase, and the commenter is encouraged to submit those comments during any future risk management rulemaking following the risk evaluation.

Comment: The EPA’s scoping and risk evaluation process is vital to successful TSCA implementation, and the NAM appreciates the opportunity to comment. The NAM supports the critical efforts to improve public health and analysis of legacy uses and disposal of minerals the agency identifies as posing risk. As the EPA reviews this draft scope, we support strong science-based assessments and encourage the EPA to remain focused on the TSCA Section 202 definition of asbestos as, “...asbestiform varieties of – (A) chrysotile (serpentine), (B) crocidolite (riebeckite), (C) amosite (cummingtonite-grunerite), (D) anthophyllite, (E) tremolite, or (F) actinolite.” Further, to maximize all available federal resources, we recommend the EPA consider collaborating directly with the scientists and experts at the United States Geological Survey [USGS], given their deep institutional knowledge regarding the entire mineralogical universe, raw material extraction and downstream supply chains. The scientific and technical expertise housed at the USGS is critical to achieving a science-driven, robust risk assessment here and with any future mineral reviews (EPA-HQ-OPPT-2021-0254-0040).

Response: EPA conducts the risk evaluation according to requirements set forth in TSCA, and in the case of asbestos, must take into account relevant court rulings. EPA appreciates the value of reaching out to scientific and disciplinary experts when it is necessary to do so. Consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with USGS and other relevant Federal agencies for the purpose of achieving the maximum enforcement of TSCA while avoiding the imposition of duplicative requirements. Consultation with other relevant federal agencies is also required during the risk evaluation process under EPA’s implementing regulations at 40 CFR 702.39.

Comment: EPA’s discretionary expansion of the Draft Scope beyond legacy uses and associated disposal of the chemical asbestos as defined by EPA will significantly tax agency resources and prevent EPA from meeting its deadline for completing Part 2 of the Risk Evaluation for Asbestos (EPA-HQ-OPPT-2021-0254-0034).

Response: EPA is committed to meeting the deadline to complete Part 2 of the Risk Evaluation by the deadline.

Comment: The proposed expansion in the Draft Scope ignores the ruling by Judge Chen in the United States District Court in the Northern District of California that EPA lacks sufficient information to inform its modeling and conduct a risk evaluation on asbestos in small or trace amounts as an impurity, in asbestos-containing articles, or with respect to processors (EPA-HQ-OPPT-2021-0254-0034).

Response: EPA is fully aware of the referenced court ruling and is proceeding with a separate rulemaking in accordance with the ruling.

Comment: EPA references “talc” in Draft Scope. EPA should take administrative notice that the majority of commercial talc deposits are not colocated geologically with asbestos. The premise that talc is “implicated as a potential source of asbestos exposure” is based on speculation. The theoretical potential that this could occur should not be used to “implicate” all talc as being co-located geologically with asbestos any more than it implicates any of the dozens of other minerals that may be co-located geologically with asbestos. Talc deposits have several very distinct geologic settings, many of which are not associated with serpentine or amphibole group minerals at all, let alone the six regulated varieties of asbestos or asbestiform varieties of the serpentine and amphibole mineral groups. These deposits represent the majority of commercially produced talc. EPA should take administrative notice that the majority of commercial talc deposits are not colocated geologically with asbestos. EPA’s Draft Scope needs to focus exclusively on the six regulated varieties of asbestos (EPA-HQ-OPPT-2021-0254-0034).

Response: EPA has not assumed that all talc is colocated with asbestos. Rather, EPA has indicated that the consideration of talc as a source of asbestos exposure will be informed by information obtained and evaluated in the systematic review process. Where reasonably available information indicates that there is a condition of use for asbestos-containing talc, EPA intends to evaluate risks from that condition of use.

Comment: It is imperative that EPA include all relevant data in its analyses, including data that may contradict any calculations of unreasonable risks (EPA-HQ-OPPT-2021-0254-0034).

Response: EPA considers reasonably available information identified in the comprehensive systematic review process and information and comments received from stakeholders during the risk evaluation process. EPA clearly describes the inclusion criteria for information in systematic review using the

Population, Exposure, Comparator, and Outcome (PECO) statements detailed in the [Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances Version 1.0 \(TSCA SR Protocol\)](#). The direction of effect is not a factor considered in the inclusion/exclusion criteria, nor is it a part of the study quality considerations.

Comment: On page 7 in the List of Abbreviations & Acronyms, Libby Amphibole Asbestos is listed as “LLA” but it should be “LAA” (EPA-HQ-OPPT-2021-0254-0015).

Response: This typographical error has been corrected in the final scope document.

Comment: The Part 2 Draft Scope Document disregards TSCA’s mandatory timeframes. Part 1 of the Asbestos Risk Evaluation is now complete. The limited purpose Part 2, by EPA’s repeated admission in the past, is to address the *Safer Chemicals* ruling and evaluate legacy uses and associated disposals for the asbestos forms of the six mineral types in the TSCA definition of asbestos. Nothing in the *Safer Chemicals* ruling requires EPA to modify the definition of asbestos that is and has been under review or expand the number of chemicals under review or add on-going conditions of use of other chemicals to the risk evaluation. The court directed EPA to consider only a chemical’s legacy uses and associated (future) disposals as conditions of use (EPA-HQ-OPPT-2021-0254-0032).

Response: EPA disagrees that the considerations of Part 2 of the Risk Evaluation have expanded inappropriately; the agency will focus evaluation of risk and exposure associated with legacy uses and associated disposals of asbestos as well as COUs for asbestos-containing talc, which do not inappropriately overlap with considerations in Part 1.

1.2 Potentially Exposed or Susceptible Subpopulations

Comment: There is a specific request that EPA add “college/university employees and students” to its list of “Potentially Exposed or Susceptible Subpopulation” groups in Section 2.5 of its Scoping Document (EPA-HQ-OPPT-2021-0254-0022).

Response: EPA will detail the PESS considered in the risk evaluation after completing its full evaluation, synthesis, and integration of the exposure literature. EPA plans to analyze all reasonably available information in order to determine whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., workers, ONUs) and whether some human receptor groups may have higher exposure via identified pathways due to unique characteristics (e.g., activities, duration, location of exposure) when compared with the general population.

1.3 Conditions of Use

Comment: In the Part 2 document EPA seems to have ignored the vast amount of asbestos and asbestos containing materials that exist in all manner of buildings and structures. As an example, materials like very friable ACM (asbestos containing material) fireproofing and pipe insulation exist in enormous quantities that have never been accurately estimated by the agency or likely by those that own/operate these buildings and structures. These and many other common ACMs are encountered by the US workforce every day. The EPA cannot ignore this neglected inventory. Question: How does EPA intend to obtain a reliable estimate of the number of commercial buildings/structures, government buildings (such as GSA [General Services Administration], DOD [Department of Defense], DOE (Department of Energy) and many others including those owned and managed by state/local agencies) and homes (multi-family and single family) in the US that contain ACM and asbestos including all known common

ACMs in these structures and facilities? This should include these considerations: The types/uses and extent of all regulated ACM categories friable and nonfriable materials; the physical conditions of these materials and the extent of damage for assessed buildings and structures; these should be estimated within acceptable, statistically valid methods (EPA-HQ-OPPT-2021-0254-0042).

Response: Information submitted by the commenter will be considered through the systematic review process outlined in Appendix A of the scope document. Suggestions on analysis approaches will be considered for feasibility and applied where/when appropriate. EPA cannot provide details on its analyses before systematic review of reasonably available information is completed. At the time of this response, the systematic review remains in progress. Part 2 of the Risk Evaluation will include a detailed description of analytical approaches, reasonably available data, methodologies, and how they were used to inform the assessment. As documented in the analysis plan of the scope document, the exposure estimates will be based on exposure scenarios developed from the COUs. There will be opportunities to comment during the draft risk evaluation public comment period. EPA acknowledges that exposures (and any subsequent risks) vary due to differences among individuals, populations, spatial and temporal scales, and other factors. When building an exposure scenario for identified conditions of use, EPA considers the spatial and temporal relevance of reasonable available information, including information regarding fiber releases or personal exposure information. Exposures to materials such as fireproofing and pipe insulation, as mentioned by the commenter, will be considered as part of the evaluation of demolition, remodeling, and construction activities. EPA will use the best available scientific data to determine the number of commercial buildings/structures that contain asbestos from the reasonably available information identified.

Comment: Will EPA look at both friable and non-friable ACM in these structures? (EPA-HQ-OPPT-2021-0254-0042).

Response: EPA has conducted a comprehensive literature search method to identify all reasonably available information. In addition to information identified during the literature search, EPA considers information submitted by the public during the risk evaluation process. If technical reports are reasonably available from industry that include relevant information for Part 2 of the Risk Evaluation for Asbestos, EPA would consider that information. During the demolition or renovation of a structure containing ACMs, it is possible that both friable and non-friable asbestos will be damaged resulting in significant airborne asbestos concentrations. Therefore, EPA expects to investigate exposure to friable asbestos as well as asbestos fibers from scenarios where non-friable asbestos is damaged, such as during demolition or renovation of structures.

Comment: Of particular interest to USWAG is the inclusion of asbestos-containing arc chutes and pipe wrap as conditions of use (COUs) in the Draft Scope. As USWAG acknowledged in comments submitted to EPA in connection with the asbestos significant new use rule (SNUR) proposed in June 2018 (83 Fed. Reg. 26922), legacy asbestos-containing products (specifically, arc chutes and pipeline wrap) may be present in connection with electric and gas utility operations. Also as indicated in those 2018 comments, USWAG does not have any information suggesting that asbestos-containing arc chutes or pipeline wrap are still being manufactured (including imported) or processed. This is consistent with EPA's explanation of the term "legacy uses" as used within the context of the Draft Scope. In evaluating risk associated with the use of asbestos-containing arc chutes and pipe wrap (for arc chutes, in the industrial/commercial context; for pipe wrap, in both the industrial/commercial and the consumer contexts), it is critical that EPA understand the role that these items play in electric and gas utility operations, as well as the controls that are implemented in connection with such use. This information

will form the foundation from which EPA can consider potential exposure to asbestos from these materials (EPA-HQ-OPPT-2021-0254-0033).

Response: As indicated in Table 2-2 in the draft scope, arc chutes and pipeline wrap have been identified as COUs included in the scope of Part 2 of the Risk Evaluation for Asbestos. Table 2-2 also indicates that there is not ongoing manufacture of arc chutes and pipeline wrap as manufacture and processing are not listed. Further, EPA has the discretion to refine further the COUs included in the scope of the risk evaluation and the analyses to be conducted based upon the reasonably available information identified and reviewed. This can include the addition of COUs and/or technical analyses as well as the exclusion of activities that EPA determines not to be conditions of use, based upon further literature review. Any refinements that are warranted will be presented in the draft risk evaluation that will be made available for public comment and peer review.

Comment: If EPA does evaluate LAA and its winchite and richterite constituents, it should confirm that the conditions of use to be addressed in the risk evaluation do not include mining or processing of LAA, as the risks of those uses, as well as risk management, have already been thoroughly addressed in remediation proceedings over several years (EPA-HQ-OPPT-2021-0254-0020).

Response: Given the asbestos mine in Libby, Montana, closed in 1990, EPA believes that mining or processing of LAA is not a condition of use that warrants consideration in Part 2 of the Risk Evaluation for Asbestos. The evaluation of LAA will involve evaluation of legacy uses and associated disposals related to asbestos-containing building materials.

Comment: EPA should only evaluate credible exposure scenarios using plausible estimates of exposure frequency and duration, and the most relevant airborne asbestos data for each Conditions of Use (COU). EPA should limit the scope of the risk evaluation to reasonable, realistic conditions of use. Exposure scenarios in the first 10 risk evaluations, including the Asbestos Part 1 risk evaluation, were often unrealistic and overly conservative. The Asbestos Part 2 risk evaluation should include reasonable, realistic exposure scenarios expected under the conditions of use (EPA-HQ-OPPT-2021-0254-0034; EPA-HQ-OPPT-2021-0254-0041).

Response: TSCA section 6(b)(4)(A) requires EPA to conduct risk evaluations to determine whether a chemical substance presents unreasonable risk of injury to health or the environment under the conditions of use. TSCA section 3(4) defines “conditions of use” as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” Thus, Part 2 of the Risk Evaluation will cover, in part, intended, known, or reasonably foreseen “legacy” uses and associated disposals of asbestos. EPA plans to evaluate credible exposure scenarios using plausible estimates of exposure frequency and duration, as well as the most relevant airborne asbestos data for each condition of use, dependent upon consideration and evaluation of reasonably available information and the best available science.

Comment: Elemental composition (and in the case of iron, oxidation state), surface properties, and surface area are also critical determinants of asbestos toxicity. EPA should consider potential influences on the potential for a given fiber type to cause adverse health effects when assessing COUs (EPA-HQ-OPPT-2021-0254-0034).

Response: Mineral information, such as elemental composition, surface properties, and surface area, is currently being collected thru the systematic review process for asbestos. EPA intends to extract,

evaluate, and take into consideration such information during the risk evaluation process for Asbestos Part 2, where appropriate.

Comment: Since 2017, in comments oral and written to EPA, I have asked for EPA to find out who in the US is importing 50 tons/year of asbestos yarn and thread from Mexico. EPA can access Customs records and identify the US importer(s) and track down what happens with all that asbestos – what occupational, environmental, and consumer exposures are occurring? (EPA-HQ-OPPT-2021-0254-0019).

Response: Asbestos imports were assessed in Part 1 of the asbestos risk evaluation, and therefore, will not be covered in Part 2.

Comment: EPA should thoroughly evaluate existing regulations related to Asbestos to inform the conditions of use in scope of the risk evaluation (EPA-HQ-OPPT-2021-0254-0041).

Response: EPA has taken under consideration existing statutes and regulations in the development of the COUs in the draft scope. Appendix D in the final scope document includes details on the regulatory history of asbestos, including federal and state laws and regulations and international laws and regulations. Although some COUs are subject to other statutes and regulations, they may remain as legacy uses that should still be considered in the risk evaluation. For example, while the Consumer Product Safety Commission (CPSC) has banned the sale of many asbestos-containing consumer products, products sold prior to the ban may still remain in use.

Comment: Asbestos may contaminate certain personal care products (e.g., talcum powder, makeup) intended for use as drugs or cosmetics. EPA has determined that asbestos that may contaminate personal care products intended for use as drugs or cosmetics falls outside TSCA’s definition of “chemical substance.” Under TSCA section 3(2)(B)(vi), the definition of “chemical substance” does not include any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act [FFDCA]) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. Activities and releases associated with such personal care products use are therefore not ‘conditions of use’ (defined as circumstances associated with ‘a chemical substance,’ TSCA section 3(4)) and will not be evaluated during risk evaluation (EPA-HQ-OPPT-2021-0254-0034).

Response: EPA confirms that “drugs” and “cosmetics,” as defined in the FFDCA, will not be considered as COUs in Part 2 of the Risk Evaluation for Asbestos.

Comment: “Conditions of use” is a very awkward term to describe likely human exposures due to legacy existence of asbestos. Legacy asbestos materials will not be “used” for any purpose with the exception of uncommon re-use of consumer products. A better term would be “conditions of disturbance,” since most legacy exposures will result from intended or unintended disturbance of existing asbestos-containing materials. This suggestion may depart from the customary EPA approach to control of toxic substances, but that seems less important than describing the work of the risk evaluation more accurately {EPA-HQ-OPPT-2021-0254-0030}.

Response: EPA uses the term “conditions of use” to conform with the statutory language. TSCA section 6(b) requires EPA to conduct risk evaluations to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use for that chemical. TSCA section 3 defines the term “conditions of use” to mean “the circumstances, as determined by the

Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.” EPA considers the term to encompass activities that involve existing asbestos-containing materials.

Comment: EPA identified many products potentially containing asbestos in the scoping document, and there are many other sources of such information available on the internet (see, for example, https://inspectapedia.com/hazmat/Asbestos_Products.php). Materials most likely to be encountered by construction workers include the following (this list was reportedly once available from EPA Region 6, but we were unable to locate the primary source and also added to from discussions with the building trades unions (https://inspectapedia.com/hazmat/EPA-Sample-List-of-Asbestos_Containing_Materials.pdf) (EPA-HQ-OPPT-2021-0254-0029).

Response: EPA will review the suggested information sources and add them to the ongoing systematic review process.

Comment: Table 2-2 appears to be missing joint compound, a major use of asbestos in the past (EPA-HQ-OPPT-2021-0254-0030)].

Response: EPA will assess legacy joint compound as a component of the wallboard/sheetrock to which it has been applied. This is because any significant disturbance of installed wallboard (e.g., cutting, sanding, removal, demolition) will almost always disturb joint compound that had been applied to that wallboard’s seams and fasteners, patches, etc. EPA is amending the description of wallboard in Table 2-2 of the final scope to note the inclusion of the associated wallboard joint compound.

Comment: In Section 2.6 of the Draft Scope, EPA notes that conceptual models have not been developed for potential exposures to asbestos via talc COUs due to the preliminary nature of the information that EPA is reviewing. For reasons IMA-NA previously has addressed in detail, the Draft Scope must restrict conditions of use of talc exclusively where talc is conclusively known to be co-located geologically with the six regulated varieties of asbestos. These need to be documented through reasonably available information. As EPA has not developed conceptual models for potential exposure to asbestos via talc COUs, and IMA-NA and others have not had the opportunity to address them in the comment process on the Draft Scope, talc should not be included as a potential exposure to the six currently regulated varieties of asbestos (EPA-HQ-OPPT-2021-0254-0034).

Response: TSCA section 6(b)(4)(A) requires EPA to conduct risk evaluations to determine whether a chemical substance presents unreasonable risk of injury to health or the environment under the conditions of use. TSCA section 3(4) defines “conditions of use” as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” Where reasonably available information indicates that there are conditions of use for asbestos-containing talc, EPA will evaluate risks from that condition of use. EPA will not be evaluating talc exposures and risks as talc is a separate chemical. If appropriate, EPA will develop conceptual models for asbestos-containing talc and present them in the draft risk evaluation that will be made available for public comment and peer review.

1.4 Physical-Chemical Properties and Fate

Comment: Incorrect CAS [Chemical Abstract Service] numbers have been used in the Draft Scope. The draft scope must contemplate only the asbestiform varieties of the minerals identified; in many instances

the CAS numbers for non-asbestiform minerals are used (EPA-HQ-OPPT-2021-0254-0025; EPA-HQ-OPPT-2021-0254-0034).

Response: EPA is aware of the different CAS Registry Numbers (CASRNs) between the asbestiform and non-asbestiform fiber types. The final scope document has been revised to include CASRNs corresponding to the asbestiform fiber types; literature searches were reviewed to ensure the results reflect the appropriate CASRNs.

Comment: All of the studies on which this heat map (page 146) is based refer to chrysotile, not talc. Refer to the hyperlink to which the HAWC directs the reader, located at <https://hawcprd.epa.gov/summary/visual/assessment/100500280/TSCA-Fate-Literature-Inventory-Heat-Maps-Talc/> (EPA-HQ-OPPT-2021-0254-0025).

Response: The diagram represents the number of studies identified in the literature search that were tagged for talc- or magnesium-silicate. These studies have been selected for data extraction and evaluation to capture any relevant information related to the environmental fate of asbestos fibers that might co-occur with talc.

Comment: Table_Apx B-1 Physical and Chemical Properties of Asbestos declares distinct physical and chemical properties “asbestos.” It is incorrect to declare a single value for such properties for “asbestos” because “asbestos” is a set of six distinct mineral species, each with its own unique range of values for the identified physical and chemical properties (EPA-HQ-OPPT-2021-0254-0025).

Response: EPA agrees with the comment and the table has been removed from the final scope document. The physical-chemical properties of each individual asbestos fiber type are now listed in Table_Apx B1 to Table_Apx B6 in the final scope document.

1.5 Exposure

Comment: The only exposure data that should be given serious consideration are those involving asbestos in air, as inhalation is the route of exposure of concern with respect to potential for health risks. There is far too much attention paid to the dermal and oral routes of exposure to asbestos in the Draft Scope Part 2 document. There are few, if any, studies that document risk to humans from such exposure. By contrast, the documentation of harm from inhalational exposures to airborne asbestos is vast. Given the limited magnitude and substantial uncertainty that will attend results of attempts (via modeling or otherwise) to estimate the additional risk imposed by dermal and oral exposures, very limited time and effort should be made to pursue these routes of exposures in the Part 2 risk evaluation (EPA-HQ-OPPT-2021-0254-0030; EPA-HQ-OPPT-2021-0254-0034).

Response: Although inhalation is the most significant exposure pathway, EPA must consider the “weight of the scientific evidence” as defined in the Code of Federal Regulations as, “a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance” per 40 CFR 702.33. Thus, EPA plans to assess all relevant pathways, routes, and receptors, as identified in the industrial, commercial, and consumer conceptual models (Fig 2-12 and Fig 2-13).

Comment: The current evaluation states that EPA will not make risk determinations based on assumptions about use of PPE [personal protective equipment] or control technologies. Draft scope does

not describe how RE will assess likely residual exposure levels given the extensive set of existing measures that are implemented by law and shape modern actual exposure to workers and others. Presumably, the agency analysis will base the exposure analyses on exposure data that reflects current practice. Occupational exposures must reflect real world exposure scenarios. EPA's approach to the question of occupational exposure is inconsistent with industrial hygiene policy and incompatible with the longstanding approach taken by NIOSH [National Institute for Occupational Safety and Health] and OSHA [Occupational Safety and Health Association]. EPA should consider existing regulatory controls which are in place to effectively address any potential risk associated with legacy uses of asbestos vinyl floor tile in occupations and commercial settings; activities which would subject workers to exposure to asbestos are subject to OSHA standards (EPA-HQ-OPPT-2021-0254-0028).

Response: EPA generally intends not to make risk determinations based on assumptions about the use of PPE. However, EPA plans to develop exposure scenarios with and without the use of added PPE or enhanced engineering controls, as applicable and appropriate, to inform any potential risk management required subsequent to an unreasonable risk determination. OSHA recommends employers use the hierarchy of controls to address hazardous exposures in the workplace. The hierarchy of controls strategy outlines, in descending order of priority, the use of elimination, substitution, engineering controls, administrative controls, and lastly PPE. EPA plans to identify the engineering controls and PPE relevant to occupational exposure scenarios based on reasonably available information on control technology and effectiveness. Further, to better inform any potential risk management, EPA plans to assess in the risk evaluation worker exposure pre- and post-implementation of engineering controls (e.g., local exhaust ventilation) and with and without the use of PPE (e.g., respirators) when characterizing risk.

Comment: The EPA scoping document does not mention the hazard of take-home exposures arising from workers bringing in asbestos-contaminated clothing home for laundering, bringing home contaminated tools or supplies, and contaminating the interiors of family vehicles. NABTU urges EPA to include consideration of take-home exposures in their exposure assessment. For reference, see <https://www.cdc.gov/niosh/docket/archive/docket071.html> and <https://www.cdc.gov/niosh/docs/95-123/default.html> (EPA-HQ-OPPT-2021-0254-0029).

Response: The frequency and magnitude of take-home exposure is dependent on several factors, including personal hygiene, amount of the chemical on skin or clothing, and scenario parameters from the systematic review process that are applicable to current working and indoor environments. Take-home scenarios may include abatement workers, or construction work involving cutting, sanding, drilling of asbestos-containing materials that may result in the transport of asbestos fibers by the worker to their residence or other indoor environments (i.e., vehicles). Current take-home scenarios would not include miners or manufacturing/production of asbestos containing products because these are not COUs for Part 2. EPA plans to identify take-home exposure concentration information through the systematic review process for COUs and conduct analyses on take-home exposures, if appropriate.

Comment:

- To give EPA a more complete understanding of our diverse, complex and important industry, we are attaching The Construction Chart Book: The U.S. Construction Industry and Its Workers, 6th edition. The Chart Book provides much more information about how construction workers are organized, employed, and vulnerable than we could convey in these comments. In particular, as made clear in the Chart Book, a huge percentage of workers in this industry are classified not as wage and hour employees, but as “self-employed” independent contractors. Figure 1 illustrates how construction workers are classified based on 2021 data. Self-employed workers

work in various trades, and have exposures that may be similar or more extreme than the exposures described in our tables. In part because these workers are not protected under the OSH Act, EPA's Asbestos Worker Protection rule (40 CFR Part 763, Subpart G), workers compensation insurance, or normal employment laws, they are likely to be even more vulnerable to unsafe work practices than wage and hour employees. While OSHA may not have authority to protect this important segment of the construction industry, EPA does and it should act to make sure they are protected. Finally, in Attachment 5, we are providing descriptions of various construction trades to help complete the picture of the construction workplace and common construction tasks. The Bureau of Labor Statistics (BLS) also provides brief occupational descriptions on its occupation profiles, available at:

https://www.bls.gov/oes/current/naics2_23.htm (EPA-HQ-OPPT-2021-0254-0029).

- EPA must consider all conditions of use for in-place asbestos. EPA must consider all foreseeable conditions of use in the scope of the evaluation. Foreseeable uses must include the potential for non-friable asbestos to be disturbed or degraded. Where asbestos is known to be friable, it is common for an employer to simply label a room or area with a warning about asbestos without abating non-friable asbestos and allowing workers to become exposed if the friability of the asbestos changes. Most employers in the U.S. have no plan for regularly assessing the condition and friability of in-place asbestos, as it is known to create and worsen exposures. Workers are often exposed to asbestos when they are instructed to perform tasks near or on in-place asbestos. These tasks include not only the use of asbestos-containing products or the demolition or renovation of in-place asbestos, but other routine tasks by non-users which disturb in-place asbestos, which can be the bulk of exposures. This may include situations such as general maintenance of asbestos-containing materials causing degradation over time, power and hand tool work near asbestos causing disturbances, and cleaning, polishing, scrubbing, and routine care of asbestos-containing materials causing disturbances and degradation. EPA must consider these real-world scenarios, when determining the risk asbestos poses to workers and unions are willing to provide examples of workplace scenarios their members encounter (EPA-HQ-OPPT-2021-0254-0031).

Response: Part 2 of the Risk Evaluation for Asbestos will include an evaluation of industrial, commercial, and consumer legacy asbestos uses. Legacy asbestos uses are uses for which manufacture (including import), processing, and distribution no longer occur, but for which the uses are still known, intended, or reasonably foreseen to occur. EPA will evaluate the risks associated with the identified COUs provided in the final scope document. For example, demolition, repair, and maintenance scenarios that disturb or degrade non-friable asbestos that EPA concludes are reasonably foreseen to occur will be assessed as they have a high potential for exposure. The risk evaluation will consider all relevant occupational and consumer exposures, including exposures to bystanders and occupational non-users, and take into account the best available science when determining risk. Workers are intended to be evaluated as a PESS, as noted in the scope document. Regarding signage and employers' management of asbestos hazards, EPA generally intends not to make risk determinations based on assumptions about the use of PPE. All appropriate risk management options will be considered to mitigate unreasonable risks found in the risk evaluation. TSCA technical analyses related to worker exposure and risk will be presented in Part 2 of the Risk Evaluation and supplemental documents, and drafts of such documents will be made available for public comment. When undertaking unreasonable risk determinations as part of TSCA risk evaluations, EPA does not believe it is appropriate to assume as a general matter that an applicable OSHA requirement or industry practice is sufficient to address the risk, applicable to all potentially exposed workers, or consistently and always properly applied. Mitigation scenarios included in the EPA risk evaluation (e.g., scenarios considering use of various PPE) likely represent what is happening already in some facilities. However, the Agency cannot assume

that all facilities have adopted these practices for the purposes of making the TSCA risk determination. Additionally, self-employed individuals and public sector workers who are not covered by a State Plan are not covered by OSHA requirements.

Comment:

- Will EPA conduct studies to determine the effectiveness of disposal techniques for asbestos that are part of existing regulations? Suggestion: While the asbestos NESHAP [National Emission Standards for Hazardous Air Pollutants] regulations on waste disposal are fairly straightforward for many stakeholders (§61.150), there are many circumstances where ACM is interred in landfills not licensed to accept these wastes. Further, many illegal dump sites have been found by property owners and State/Local programs. The agency should consult their own CERCLA [Comprehensive Environmental Response, Compensation, and Liability Act] staff to gather the many pages of data they have generated in this work. The designated State/Local programs should also be compelled to contribute their data and known cleanup work to better ascertain how this pollution can affect workers and the public. Currently, this is not a consideration in the Part 2 document and it is an oversight to not study these issues (EPA-HQ-OPPT-2021-0254-0042).
- Will the agency look at both friable and non-friable ACM in these structures? Will EPA work to determine the effectiveness of abatement, handling and disposal regulations in protecting not only abatement workers, but also bystanders, nearby populations and others? Further, will EPA seek to determine the number of undocumented abatement operations – those where EPA and local authorities are not notified – and the potential exposures resulting from these operations? (EPA-HQ-OPPT-2021-0254-0042).

Response: EPA will consider reasonably available information when conducting Part 2 of the Risk Evaluation for Asbestos. As noted in the COU table in the final scoping document (Table 2-2), EPA will consider exposure from disposal of asbestos-containing materials such as demolition debris. Potential risk mitigation practices will be considered during the risk management phase, as the risk evaluation is intended to identify when a chemical substance presents unreasonable risk to human health or the environment under the conditions of use.

Comment: EPA's scoping document, on page 44, refers to the National Emission Standards for Hazardous Air Pollutants (NESHAPS) as a source of data for asbestos releases into the air, but that this and other sources pertain primarily to industrial facilities. EPA goes on to say that, for data on asbestos releases from other sources, such as construction and demolition activities, EPA "...will consider other information sources (e.g., the peer-reviewed literature...)." It is not clear whether EPA intends to obtain asbestos release data from NESHAPS enforcement activities, such as when building owners or managers fail to inform employers of the presence of asbestos prior to demolition, or where employers disregard requirements under NESHAPS. NABTU suggests that EPA try to obtain data from states on asbestos releases during demolition projects under NESHAPS as well as data on NESHAPS violations to augment other data sources (EPA-HQ-OPPT-2021-0254-0029).

Response: As stated in the final scope document, EPA expects to consider NESHAP data in conducting the exposure assessment component of the risk evaluation for asbestos.

Comment: Accordingly, in this context, we would like to bring ASTM D22.07 methodology to the agency's attention as a complement to the AHERA, NESHAP and other laws and regulations (EPA-HQ-OPPT-2021-0254-0036).

Response: EPA considers the quality of analytical and sampling methodology during the systematic review process for reasonably available information.

Comment: Exposure Assessments – 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 (EPA-HQ-OPPT-2021-0254-0014).

Response: EPA plans to complete a full, comprehensive occupational exposure assessment for all industrial and commercial COUs provided in Table 2-2 of the final scope document.

Comment: 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” (https://online-ams.aiha.org/amsssa/ecssashop.show_product_detail?p_product_serno=887&p_mode=detail) It is also recommended 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. The risk assessment should fully incorporate all contaminant sources, fate and transport, exposure point sources, exposure routes, and potentially exposed populations. The conceptual models presented in the draft scopedo not fully illustrate these concepts and are not comprehensive. (EPA-HQ-OPPT-2021-0254-0014).

Response: EPA will consider the principles outlined in the AIHA publication mentioned. EPA described the COUs identified and intended to be evaluated in Part 2 of the Risk Evaluation. The scope document also describes the relevant exposure routes that will be considered. EPA intends to conduct a comprehensive assessment that will be based upon reasonably available information identified through the systematic review process and provided by public commenters. The full details of the exposure assessment will be described in the draft risk evaluation that will be made available for public comment.

Comment: Exposure Assessments – EPA needs to provide justification for their case-by-case selection criteria for ONUs [occupational non-users]. 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 (EPA-HQ-OPPT-2021-0254-0014).

Response: EPA plans to provide justification for the selection of ONUs for each scenario identified in the draft risk evaluation that will be made available for public comment and peer review.

Comment: The IAFF has documented in previous comments to the EPA that part of the firefighting occupation requires entering burning buildings, extinguishing fires, and then opening walls and ceilings during overhaul to check for fire extension. All three tasks expose fire fighters to asbestos fibers. These activities are daily occurrences and result in frequent exposures to legacy asbestos. Our members’ exposure to asbestos does not stop once we leave a fire. These fibers can remain on a fire fighter’s turnout gear and equipment and spread to the apparatus cabs and fire stations. Fire fighters can inhale large amounts of these microscopic fibers and unknowingly increase their risk of developing an asbestos-related disease like Mesothelioma, Lung Cancer, and Asbestosis, to name a few. Asbestos exposure for fire fighters is almost a daily occurrence. In order to protect our members, it is essential for the EPA to understand our exposures and fully evaluate the risk asbestos has on the public and evaluate fire fighters as a susceptible sub-population (EPA-HQ-OPPT-2021-0254-0016).

Response: EPA plans to consider exposure to asbestos-containing building materials during firefighting or other disaster response activities in Part 2 of the Risk Evaluation. EPA intends to include firefighters as a PESS, and the extent and type of analyses conducted will be dependent upon reasonably available information.

Comment: In Europe, asbestos diaphragms are not allowed, Best Available Technology is required: “In terms of production techniques, only monopolar/bipolar membrane and asbestos-free diaphragm techniques are BAT.” Other techniques were not to be used after Dec. 11, 2017 (EU Euro Chlor att.). Non-asbestos diaphragms are commercially available and pay for themselves in improved performance; Castleman has submitted evidence to EPA from De Nora in 2016 showing available diaphragms. The data disclosed to EPA on worker asbestos exposure in the diaphragm areas of their plants by ACC was incomplete and selected (EPA-HQ-OPPT-2021-0254-0019).

Response: Asbestos diaphragms were assessed in Part 1 of the asbestos risk evaluation, and therefore, will not be covered in Part 2.

Comment: The EPA should assess exposure in current and legacy uses in the context of commonly used control measures and clearly define childhood exposures (EPA-HQ-OPPT-2021-0254-0035).

Response: EPA plans to evaluate consumer and bystander as well as general population exposure scenarios for do-it-yourself (DIY) activities in which children could be exposed. EPA will apply age group appropriate factors to the scenarios and commonly used control measures when, and if, appropriate. EPA generally intends not to make risk determinations based on assumptions about the use of PPE. However, EPA plans to develop exposure scenarios with and without the use of PPE and control measures to inform any potential risk management required subsequent to an unreasonable risk determination. Control measures are related to risk mitigation and risk management considerations and are therefore most appropriately considered in that phase of TSCA.

Comment:

- Asbestos is widely distributed in consumer products, ranging from children’s toys to home and hobby products to commercial construction materials. It is NTTC’s [National Tribal Toxics Council] position that Native Americans are, and will continue to be, disproportionately affected by legacy asbestos exposure and, therefore, we have great interest in the ensuing risk evaluation. In the Draft Scope, there was no mention of how multiple exposures and/or susceptibilities will be considered, combined, and aggregated when determining risk. NTTC is concerned that the risks Native Americans face from exposure to legacy asbestos will not be evaluated unless all these factors are considered by EPA and that any resulting risk management decisions will not be protective of this vulnerable population. Due to unique exposure pathways, cumulative exposure from multiple stressors, behavioral, biological, and environmental factors that increase susceptibility, and as a subsistence population, Native Americans should be considered as a vulnerable group in the context of environmental justice, as well. Limited access to health care, for example, may lead to delayed diagnosis, which may contribute in part to the health disparities discussed above, as could the practice of tribal lifeways, life on tribal lands, socio-economic factors, intergenerational trauma, and epigenetic changes (EPA-HQ-OPPT-2021-0254-0038).
- Health disparities between American Indian/Alaska Native people (AI/AN) and the non-Hispanic White (NHW) population are well-documented but frequently not considered by EPA. In Section 2.4.2 of the Draft Scope, EPA lists the health hazards of asbestos exposure it may consider in the risk evaluation and these include mesothelioma, lung, ovarian, and laryngeal cancer. NTTC notes that Alaska Natives, as well as American Indians in the Northern and Southern Plains,

experience disproportionately higher lung cancer incidence rates compared to NHWs (53% higher lung cancer incidence rate for Alaska Native people¹) and lung cancer tends to be diagnosed at a younger age among AI/ANs than among NHWs (23% vs 16%). For the period of 2012-2016, lung cancer was the leading cause of cancer death for AN/AIs (EPA-HQ-OPPT-2021-0254-0038).

Response: EPA plans to include tribal and indigenous native populations as PESS, informed by reasonably available information. The information and references provided by the commenter will be added to ongoing EPA's systematic review process to determine its relevance and reliability and use in the draft risk evaluation analysis. Tribal and indigenous native population activities, patterns of use, and susceptibilities are part of the PESS plan and factors to be considered when building exposure scenarios and compiling factors. TSCA section 6(b)(4)(F) requires EPA, as part of the risk evaluation, to describe whether aggregate or sentinel exposures are considered. Aggregate analysis is defined as the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (40 CFR 702.33). However, aggregate analysis may not be possible if individual sources or contributions into the overall total exposure cannot be identified. Part 2 of the Risk Evaluation will contain detailed descriptions of the approaches, scenarios, models, factors used, and supporting evidence. The public comment period for the draft risk evaluation will be an optimal time to provide feedback and additional relevant information.

Comment: Asbestos has not been used in the domestic manufacture of vinyl floor tiles for approximately four decades. Historically, some types of resilient floor tiles were manufactured with asbestos-containing fibers. Resilient floor tiles were sometimes installed with asphaltic cutback adhesives which could contain asbestos. Asbestos has not been used in the domestic manufacture of resilient floor tiles, sheet vinyl flooring, or asphaltic cutback adhesives since the mid-1980s. Given the significant time that has passed since asbestos-containing vinyl flooring was last manufactured in the United States, exposure to asbestos from flooring products can be expected to be steadily decreasing as the amount of these products in use is steadily diminishing. EPA should focus its risk evaluation on actual ongoing uses of legacy asbestos flooring products. EPA should avoid any anecdotal, hypothetical, or otherwise unsupported information regarding the continued use of asbestos vinyl flooring products and should tailor its risk evaluation to actual use of legacy asbestos flooring products and actual associated exposures (EPA-HQ-OPPT-2021-0254-0039).

Response: EPA plans to evaluate all legacy uses and associated disposals of asbestos—including disposal from demolition, use in remodeling of old structures, and use of asbestos-containing vinyl flooring. Estimations on the prevalence of asbestos in flooring taken into account in technical analyses for exposure will be based upon the best available science. EPA plans to evaluate all potential legacy uses of asbestos, including demolition or remodeling of old structures.

Comment: The draft scope does not describe how the Agency will compile data on drinking water exposure or how it would assess that exposure. SDWA [Safe Drinking Water Act] requires periodic review and based on health risks and compliance data with primary standards. EPA has conducted 3 reviews and not identified a need to set new drinking water standards. Actually, observed occurrence data would be informative as the scoping document appears to imply a reliance on modeled occurrence. AWWA strongly recommends collaborating with drinking water program staff so that evaluation is consistent (EPA-HQ-OPPT-2021-0254-0028).

Response: EPA will consider reasonably available information on drinking water exposure, including any relevant data from the Toxics Release Inventory (TRI), the Chemical Data Reporting (CDR) rule,

discharge monitoring report (DMR), and modeling. EPA's approach to assessing drinking water exposure would involve estimating drinking water that has not gone through drinking water treatment and is meant to address exposure to populations and groups that are upstream. Monitoring data from drinking water and regular household tap water downstream from drink water processing plants may also be used in addition to drinking water modeling. In accordance with TSCA section 9(b), EPA will coordinate actions taken under TSCA with actions taken under other federal laws administered by EPA, including SDWA.

Comment: EPA should utilize and collect data to perform a comprehensive risk assessment in our infrastructure, buildings, and schools. In the scoping document, EPA states it plans to utilize several key data sources when performing the risk evaluation, including previously completed EPA surveys conducted in the 1980s. We strongly support EPA using their previous work, and the work of other agencies such as OSHA, NIOSH and ATSDR [Agency for Toxic Substances and Disease Registry]. The EPA's previous work to estimate the risk of asbestos was conducted approximately 40 years ago, and there has not been a comprehensive examination of where asbestos remains in the United States, nor the condition of the in-place asbestos. The last time worker exposures to asbestos were assessed was in 1994, when OSHA issued their current asbestos regulation. EPA must utilize their previous work, and work of other agencies such as OSHA, NIOSH and ATSDR, as a model to re-evaluate the risk asbestos currently poses to all potentially susceptible subpopulations. EPA should evaluate their needs in order to perform a comprehensive assessment and should require inspection, assessment and reporting to determine locations and condition of asbestos, exposure levels, and the use and effectiveness of control measures. Under TSCA, the EPA has the authority to "reasonably generate, obtain, and synthesize" information to accurately evaluate risks. This should include inspections of commercial buildings or industrial facilities and occupational exposure monitoring data to the agency and develop a thorough model of asbestos exposures in the workplace. Currently, OSHA only has exposure monitoring data they collected during inspections and employers only provide their records when asked by the agency. (EPA should also ask for these data). Moreover, there is no requirement for safe removal of asbestos from commercial buildings or industrial facilities. Given the large volumes of asbestos that remain in place, and the continuing deterioration of these materials, it is appropriate to require certain facilities to remove asbestos that is in place, and to use specific protocols to do the removal so that more workers are not exposed (EPA-HQ-OPPT-2021-0254-0031).

Response: EPA is considering reasonably available information identified through systematic review methods, as outlined in Appendix A of the final scope document, to determine the key data sources related to asbestos exposure. Also, EPA plans to consider information submitted through public comment and may perform supplemental targeted searches of peer-reviewed or gray literature to better understand certain conditions of use to further develop exposure scenarios. Consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with relevant Federal agencies for the purpose of achieving the maximum enforcement of TSCA while avoiding the imposition of duplicative requirements. Consultation with other relevant federal agencies is also required during the risk evaluation process under EPA's implementing regulations at 40 CFR 702.39. These consultations provide an opportunity to inquire about relevant, reasonably available information. EPA will also consider any information received from the rule for reporting and recordkeeping requirements for asbestos under the Toxic Substances Control Act (TSCA) (proposed rule 87 FR 27060, 5/6/2022) to the extent that the information is reasonably available for consideration in the risk evaluation. The risk evaluation will present analyses and conclusions related to the finding of unreasonable or no unreasonable risk based. Considerations related to risk mitigation would take place in the risk management phase that occurs subsequent to finalization of the risk evaluation.

Comment: Age at first asbestos exposure may be a useful consideration in discussion of “potentially exposed or susceptible subpopulations,” particularly in addressing the length of expected lifetime risk of disease for people first exposed as children. It is also a determinant of risk among people first exposed to asbestos as adults (e.g., workers), but, given uncertainty and an incomplete consensus on its importance relative to other aspects of exposure or dose (intensity, duration, frequency at different ages) for adults, it would not be useful to include considerations of age at first exposure in estimating risks that adults (workers, ONU’s, consumers) have for asbestos-related diseases. In addition, given the nature of legacy-associated activities, most adults who perform such activities will likely start as young adults, so there is likely to be little age variation to impact risk determination (EPA-HQ-OPPT-2021-0254-0030).

Response: EPA plans to evaluate exposure for various age groups as consumers, bystanders, or general population when appropriate for the scenario based upon the best available science.

Comment: Many consumers who perform do-it-yourself renovation and construction activities will have exposures that are comparable, or even worse, than workers or workplace ONU’s. This likelihood should be acknowledged in the proposed risk evaluation (EPA-HQ-OPPT-2021-0254-0030).

Response: EPA plans to evaluate exposures from DIY scenarios. These scenarios may use elements from occupational scenarios that apply to DIY activities with the modifications that are appropriate for general population and consumers regarding duration, location of exposure, and other factors.

Comment: EPA’s draft scoping document provides reasonably comprehensive information on the work activities and types of materials that are likely associated with employee exposures to asbestos. To assist EPA further, NABTU is providing more detailed information on the construction industry occupations most likely to involve exposure to asbestos and the characteristics of the construction workforce. Construction occupations most likely to involve exposures to asbestos include: Boilermakers, Bricklayers, Building inspectors, Carpenters, Cement masons (primarily bystander exposure), Demolition workers, Drywallers, Electricians, Elevator constructors, Floor covering workers, Glaziers, Grinders, Hod carriers, Insulators, Ironworkers, Laborers, Maintenance workers, Operating engineers, Painters, Pipefitters, Plasterers, Plumbers, Pointers, Cleaners, Caulkers, Roofers, Sheet metal workers, Steamfitters, Tile setters, and Welders (Adapted from https://www.atsdr.cdc.gov/csem/asbestos/who_is_at_risk.html with input from the building trade unions). Attachment 4 provides information about the number of employees in the construction industry by occupation, most of which reflect the asbestos-related occupations listed above (EPA-HQ-OPPT-2021-0254-0029).

Response: EPA will consider the information provided for risk evaluation.

Comment: Occupational non-users can have significant exposures to asbestos. EPA must consider that occupational non-users of asbestos face unreasonable risks from asbestos exposures, and often can have the greatest risks of exposures in the workplace. Occupational non-users, also known in industrial hygiene as bystanders, are workers who are working near a hazard producing task, but because they are not performing the task directly, their exposures are ignored. They could either be helpers or not involved at all with the asbestos disturbing task. If the hazard is not controlled at the source of generation, then these workers can be exposed to high levels of the toxic substance. One example are janitorial workers who sweep asbestos-containing dust and clean asbestos-work areas. Additionally, these workers often are not provided adequate asbestos-specific training to recognize the hazard nor are provided similar protections to the worker performing the task. Toxic substances can also be carried away from the source to other areas of the workplace or outside the workplace. This type of exposure

can be limited through regulatory measures such as designated and demarcated work-areas and housekeeping requirements. However, it does not eliminate all risk, especially for a substance such as asbestos that has no safe exposure limit and has dire consequences for other workers and other members of the public when transferred onto clothing and other materials. These contributing factors can result in occupational non-users facing unreasonable risks from all types of workplace hazards, including asbestos and must be considered by EPA (EPA-HQ-OPPT-2021-0254-0031).

Response: EPA plans to evaluate exposure to ONUs; i.e., workers who do not directly handle the chemical but perform work in an area where the chemical is present. The Conceptual Model for Legacy Industrial and Commercial Activities and Uses, as well as Appendix F of the final scope, identifies all conditions of use where EPA intends to assess exposures to ONUs. Consistent with the statutory requirements of TSCA section 6(a), EPA will propose risk management action to address any unreasonable risk determined to be presented in Part 2 of the Risk Evaluation. EPA will undertake a separate public notice and comment period as part of the TSCA section 6(a) risk management rulemaking for asbestos and will consider such public comments and any additional information before finalizing the rulemaking. EPA would encourage this commenter to submit comments on risk management approaches during the public comment period.

Comment: Hazards (Effects): 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 elongate mineral particles (EMPs) 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 (EPA-HQ-OPPT-2021-0254-0014).

Response: EPA will use reasonably available information, in a fit-for-purpose approach, to develop a risk evaluation that relies on the best available science and is based on the weight of the scientific evidence.

Comment: On page 11, the draft scope states “Occupational exposure: EPA plans to evaluate exposures to workers and occupational non-users (ONUs) via the inhalation, dermal, and oral route associated with the use and disposal of asbestos, to include any implicated conditions of use (COUs) for talc containing asbestos. EPA plans to analyze dermal exposure for workers and ONUs to fibers that deposit on surfaces.” The Agency must be more precise when using the term “fiber” (EPA-HQ-OPPT-2021-0254-0025).

Response: Changed language from “fibers” to “asbestos fibers.”

Comment: On page 47, the draft scope states “Also, workers and ONUs may be exposed to asbestos in liquid or solid form through dermal and oral routes, as asbestos can be used/transported in liquid or solid form.” Asbestos cannot exist in liquid form (EPA-HQ-OPPT-2021-0254-0025).

Response: Changed language to “asbestos suspended in liquid” rather than “asbestos in liquid form.”

Comment: In Table 2-14. MSHA regularly test for airborne asbestos fibers in mine atmospheres and find none, even when there is amphibole with an aspect ratio of 3:1 existing as elongate mineral particles longer than 5 micrometers in length. Exposure monitoring data from the referenced “U.S. OSHA Chemical Exposure Health Data (CEHD) program data” does not appear to be readily available. Can assistance be provided in accessing this data? The specific identify of the publication titled “EPA 1984 Analysis of Fiber Release from Asbestos Products“ is unclear. Is it the document located at

<https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=9101PBZ6.PDF>? If so, this is presented as a draft document. It is inappropriate to base policy in a draft document from 1984? (EPA-HQ-OPPT-2021-0254-0025).

Response: To access the OSHA CEHD data please see <https://www.osha.gov/opengov/health-samples>. The Analysis of Fiber Release from Asbestos Products is titled as a “draft final report”; although this is a draft report, EPA evaluates the data within the report following the systematic review process outlined in Appendix A and in the Draft TSCA Systematic Review Protocol.. The document can be found in the EPA docket: <https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0159-5917>.

Comment:

- Regarding “Table_Apx A-1. Hazards Title and Abstract and Full-Text PECO Criteria for Asbestos Part 2”, in “Relevant Forms” under the “Exposure” it states, “Exposure based on measured or estimated concentrations of asbestos.” Measured or estimated concentrations based on phase contrast microscopy are not accurate. Phase contrast microscopy cannot be used to quantify airborne asbestos concentrations because it is incapable of discerning elemental composition and habit of crystallization (both necessary to determine if a mineral is asbestos). Further, phase contrast microscopy cannot resolve particles with a diameter below 0.25 microns and will therefore underestimate the exposure to such thin airborne asbestos particulates (EPA-HQ-OPPT-2021-0254-0025).
- 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 microscopy (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 (EPA-HQ-OPPT-2021-0254-0014).
- Table_Apx E-1. Summary of NIOSH HHEs with Monitoring for Asbestos identifies a *Sampling and Analytical Methodology*: number of NIOSH studies. NIOSH has at times incorrectly characterized various elongate mineral particles as asbestos as a result of the application of phase contrast microscopy. Phase contrast microscopy cannot be used to determine if an EMP is asbestos. All these studies need to be evaluated to ensure proper techniques in microscopy (EPA Method 600-93 for bulk materials and NIOSH Methods 7400 plus NIOSH Method 7402) have been used (EPA-HQ-OPPT-2021-0254-0025).
- With regard to “Table_Apx E-2. Summary of Industry Sectors with Asbestos Monitoring Samples Available from OSHA Inspections Conducted between 2010 and 2020” The Agency must ensure that OSHA used the differential counting techniques described by Crane. If such were not the case, that particulates characterized may not be one of the 6 asbestiform minerals regulated as asbestos (EPA-HQ-OPPT-2021-0254-0025).

Response: As discussed extensively in Part 1 of the Risk Evaluation of Asbestos and EPA’s Response to Public Comments, there are limitations to using PCM, recognizing there could be an overestimation of fiber counts. However, the majority of members of the Science Advisory Committee on Chemicals (SACC) did not find this limitation to be prohibitive to use in risk assessment. Furthermore, the majority

of studies with monitoring data use PCM, and if TEM data is sparse, then EPA's ability to conduct quantitative analyses based on TEM data would be limited. EPA will employ statistical and analytical methods that are consistent with the methods used in Part 1, as appropriate. EPA will carefully consider the appropriateness of use PCM and/or TEM measurements in quantitative analyses. Furthermore, the measurement methods referenced have specific applications. EPA will consider measurement methods used in the studies listed in Table_Apx E-1 during systematic review and will provide details supporting the quality evaluation conducted for each study with the draft risk evaluation. EPA will also provide details of the technical analysis in the risk evaluation, including limitations and uncertainties of the evidence. The draft risk evaluation will be made available for public comment and peer review.

Comment: "Table_Apx A-4" gives the following example metrics "Metrics (e.g., mg/kg/day or mg/m³ for worker exposures, kg/site/day for releases)." Typically, airborne asbestos concentrations are characterized in terms of asbestiform fibers per unit volume of atmosphere (e.g., fibers per cubic centimeter) rather than mass per unit volume of atmosphere (EPA-HQ-OPPT-2021-0254-0025).

Response: The example metrics were changed to "fibers/kg/day" and "fibers/cm³" for worker exposures.

Comment: "Table_Apx A-5" specific to "Occupational Exposures," it states, "For solids, bulk and dust particle size characterization data." This should instead state "For solids, bulk, and dust particle size characterization data, dust particle shape characterization data, dust particle habit of characterization data, dust particle elemental composition data, dust particle surface activity data, dust particle surface area data, and other potential dust particle data that may be causal of asbestos-related disease" (EPA-HQ-OPPT-2021-0254-0025).

Response: Changed language from "particle size characterization data" to "particle characterization data (e.g., size, shape, composition)."

Comment: In the scoping document, EPA appropriately identifies OSHA enforcement sampling data and NIOSH publications as sources of occupational exposure data for asbestos. However, NABTU notes that most of the NIOSH studies identified in the scoping document are fairly old and data contained in those reports might not reflect current exposure potentials, particularly given that asbestos-containing materials can become more friable as they age. For this reason, we strongly urge EPA to work with OSHA to obtain more recent exposure information for construction operations. A summary of OSHA's asbestos exposure data to 2015 is provided in Attachment 3 to these comments. These data show that exposures above OSHA's PEL [permissible exposure limit] have continued to occur in recent years and are more prevalent in construction than in other major industry group, except mining. NABTU also notes that overexposures are identified despite the relatively small numbers of samples taken in recent years. For more detailed exposure data, see <https://www.osha.gov/opengov/health-samples> (EPA-HQ-OPPT-2021-0254-0029).

Response: Any information submitted will be considered through the systematic review process outlined in Appendix A and in the Draft TSCA Systematic Review Protocol. EPA also notes that, consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with OSHA and other relevant Federal agencies for the purpose of achieving the maximum enforcement of TSCA while avoiding the imposition of duplicative requirements. Consultation with other relevant federal agencies is also required during the risk evaluation process under EPA's implementing regulations at 40 CFR 702.39

1.6 Human Hazard

Comment: Multiple commenters provided perspective on the potential for differing potency factors for each fiber type and the appropriateness of deriving a single or distinct IURs. Fiber dimensions are critical determinants of asbestos toxicity.

- The six asbestos fiber types differ in their potency and to have unique and independent hazard profiles, EPA should calculate different Inhalation Unit Risks (IURs) for each fiber type separately as well as each fiber type should have an independent hazard evaluation (EPA-HQ-OPPT-2021-0254-0014; EPA-HQ-OPPT-2021-0254-0018; EPA-HQ-OPPT-2021-0254-0034).
- Separate quantitative estimates of risk for each type of cancer caused by asbestos is unnecessary. EPA should evaluate all health hazards caused by asbestos, including all cancers known to be associated with asbestos exposure. EPA's suggested list of asbestos-induced cancers omits gastro-intestinal cancers – a series of cancer that have been associated with exposure to asbestos. We believe, however, that any effort to quantify each cancer risk separately is unnecessary and would increase the uncertainties in the risk estimates so that they no longer add meaningfully to an understanding of asbestos risks. There is not adequate epidemiology to quantify each type of cancer risk (and certainly not to quantify each type of cancer risk fiber-by-fiber) and, besides, the scientific literature clearly demonstrates that mesothelioma is the most sensitive endpoint for asbestos-induced disease. Thus, quantifying the risk of mesothelioma will provide the best evidence of what type of risk management regulations EPA should propose. Efforts to further quantify the risk of each cancer associated with asbestos exposure will only delay forward progress on getting risk management regulations in place. Likewise, asbestos is not known to cause dermal effects. While asbestos fibers on the hands, in hair, on clothing, or elsewhere can pose an ingestion risk if swallowed, asbestos is not known to be absorbed through the skin. EPA should not waste time trying to quantify this route of exposure (EPA-HQ-OPPT-2021-0254-0026).
- EPA should make a determination about the hazards of all asbestos fibers. Part 2 of the Risk Evaluation of asbestos should follow EPA's revised approach under TSCA and make a final risk determination for asbestos based on the "whole chemical." This means EPA's Part 2 of the Risk Evaluation should look at the risks posed by all asbestos fibers. EPA should not revive the discredited fiber-by-fiber approach it proposed in 2008. Any such analysis would be meaningless since most building products and other legacy asbestos contains mixed fibers. There is not adequate data to distinguish among fibers and to characterize the fiber specific exposures, and hence risk, for amphiboles in the epidemiologic literature. Any effort to complete a fiber specific risk evaluation for amphibole creates too much uncertainty to be useful. The Science Advisory Board was correct in 2008 when it concluded that such an approach was scientifically inappropriate (EPA-HQ-OPPT-2021-0254-0026).
- Distinct and separate risk evaluations must be performed for each of the different types of asbestos. Each of the six minerals currently regulated as asbestos have widely recognized differences in their degree of toxicity, as well as their physical properties and elemental composition. To treat them as a single substance will result in the underestimation of risk for some forms and the overestimation of risk for others (EPA-HQ-OPPT-2021-0254-0025).

Response: EPA expects that the reasonably available epidemiologic literature will provide information that represents combined fiber exposures. Similarly, EPA expects that the exposure information that is reasonably available will be based upon combined fiber exposures. To the extent that is the case upon ultimate review, a combined fiber approach to consider hazards and risks could be most appropriate. A separate risk evaluation for each fiber type is not warranted or required under TSCA as the designation was 'asbestos' and not each fiber type as a distinct chemical substance. Further, development of a

single IUR for asbestos was recommended by the majority of the SACC upon review of Part 1 of the Risk Evaluation for Asbestos. Any limitations or uncertainties related to the technical approach taken will be clearly described in the draft risk evaluation that will be made available for public comment. EPA acknowledges that inhalation exposures to asbestos have been the primary concern, and health effects related to dermal exposures may be limited.

Comment: The EPA should explicitly state the limitations of any dose-response modeling for asbestos (EPA-HQ-OPPT-2021-0254-0035).

Response: EPA will identify and describe limitations in the evidence and analyses that are included in Part 2 of the Risk Evaluation, a draft of which will be made available for public comment and peer review.

Comment: In section 2.7.3.2, Human Health Hazards, item 6, EPA indicates that it “believes there will be sufficient reasonably available data to conduct dose-response analysis and/or benchmark dose modeling for the inhalation route of exposure.” However, the references cited (U.S. EPA, 2014; and U.S, 1988) pertain to “Libby Amphibole Asbestos” and chrysotile. They are not relevant for other forms of asbestos (riebeckite asbestos, cummingtonite-grunerite asbestos, anthophyllite asbestos, tremolite asbestos and actinolite asbestos) or winchite and richterite. Dose response analyses from “Libby Amphibole Asbestos” and chrysotile are not applicable for these other forms of asbestos, winchite and richterite due to known differences in their respective inhalation unit risk factors (EPA-HQ-OPPT-2021-0254-0025).

Response: EPA cited these references as support for the expectation that there will be sufficient information available to conduct a dose-response analysis. In review of the Part 1 of the Risk Evaluation for Asbestos, the SACC recommended derivation of one IUR inclusive of all fiber types. EPA has intended to follow this guidance and believes this is a scientifically sound approach. However, EPA is still reviewing the reasonably available information and will present technical analyses in the draft risk evaluation that will be made available for public comment and peer review.

Comment: Asbestosis, lung cancer, and mesothelioma are the only diseases for which conclusive evidence of a causal relationship with asbestos exposure exists. EPA should limit the evaluation to these health endpoints (EPA-HQ-OPPT-2021-0254-0034).

Response: EPA is required to conduct its evaluations in a manner that is consistent with the best available science using reasonably available information. Thus, EPA will collect a comprehensive body of evidence and screen according to the PECO criteria described in the scope document. EPA will build on existing evaluations and analyses, when they are reasonably available and appropriate.

Comment: Inclusion of all recognized asbestos-related diseases (ARD’s) in the risk evaluation will be a strength of the exercise, since it will most accurately portray the total risk due to legacy asbestos exposures. Using a single disease such as mesothelioma as a proxy for all ARD’s will not only fail to yield a full picture of legacy-associated risk but will prevent EPA from fulfilling its obligation to assess the impact of asbestos on “potentially exposed or susceptible subpopulations” (PESS), which includes smokers whose risk of lung cancer, not mesothelioma, is jointly impacted by exposure to asbestos (EPA-HQ-OPPT-2021-0254-0030; EPA-HQ-OPPT-2021-0254-0027).

Response: EPA agrees that it will be important to consider a broad range of health effects that are associated with exposure to asbestos. The health effects that EPA expects to evaluate in the Risk Evaluation for Asbestos Part 2 are described in the scope document.

Comment: I will ask again, why 14 years later, does EPA still need to conduct additional risk analysis on asbestos? Such risk analysis is readily available from multiple National and International collaborating agencies, like the World Health Organization (WHO), the International Agency for Research on Cancer and others concluding “All forms of asbestos, including Chrysotile, are carcinogenic to humans.” In 1999, the European Union directed member states to cease using all types of asbestos, including chrysotile, by 2005. In 2006, the WHO called for a worldwide ban on all asbestos use. In the U.S., as early in 1976, the U.S. National Institute for Occupational Safety and Health (NIOSH) recognized the science was sufficient to call upon the Occupational Safety and Health Administration (OSHA), through its Congressionally mandated function, that “only a ban can assure protection against carcinogenic effects of asbestos” (EPA-HQ-OPPT-2021-0254-0021).

Response: In 2016, EPA designated asbestos as one of the first 10 chemical substances to undergo the TSCA risk evaluation process. Accordingly, EPA is conducting a risk evaluation to determine whether asbestos presents unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, under the conditions of use. EPA published Part 1 of the risk evaluation, focused on chrysotile asbestos, in December 2020. EPA is currently conducting Part 2 of the risk evaluation, which includes legacy uses and associated disposals of asbestos. EPA must rely upon the best available science when conducting TSCA risk evaluations and may consider existing evaluations if they are reasonably available and appropriate. Any unreasonable risk found to be presented through the risk evaluation must be addressed through TSCA section 6(a) risk management rulemaking. Under TSCA section 6(a), EPA must apply one or more listed risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal “to the extent necessary” in order to address the unreasonable risk.

Comment: The draft scoping document identifies many of the legacy conditions of use that are sources of current asbestos exposure (see pp. 26-20) but provides virtually no information on the nature and extent of this exposure and the magnitude of the health risk it may pose. The final scoping document must provide a richer picture of the prevalence of legacy asbestos throughout the United States and the many ways in which people may be at risk (EPA-HQ-OPPT-2021-0254-0027).

Response: A key component of the risk evaluation is the analysis of exposure expected to result from the relevant COUs. This will include consideration of the reasonably available information on the presence of legacy asbestos in buildings, which will inform appropriate exposure scenarios. In the scope document, Section 2.7 of the final scope document describes the approach that EPA expects to use for these analyses. These technical analyses will be present in the draft risk evaluation for public comment.

Comment: Evidence indicates that asbestos is carcinogenic via a threshold mode of action. EPA should assume a threshold mode of action when deriving IURs (EPA-HQ-OPPT-2021-0254-0034).

Response: EPA will evaluate the reasonably available information and determine what quantitative approaches are most appropriate for Part 2 of the Risk Evaluation. In Part 1 of the Risk Evaluation for Asbestos, EPA employed a linear no-threshold model for risk, and this approach was supported by the SACC. EPA will consider the appropriateness of employing this approach and alternative approaches in Part 2 of the Risk Evaluation.

1.7 Risk Determination

Comment: “we have concerns about the inclusion of talc per se, an inclusion that risks “muddying the waters.” We recognize that amphibole asbestos can be co-located geologically with talc, and that talc from some mines can be importantly contaminated by amphiboles; sufficient exposure to such talc would almost certainly pose risks similar to those of other asbestos exposures. But it is the asbestos, not the talc, that is the causal agent. The importance of this distinction is made clear by current legal disputes concerning cosmetic talc. We hope that EPA will not enter those disputes. As part of the proposed rule, we encourage EPA to focus on the contaminating asbestos in talc, and not the talc itself” (EPA-HQ-OPPT-2021-0254-0017).

Response: EPA does not intend to evaluate the risks attributable to talc exposure and will focus solely on the risks related to asbestos exposure. In the scenarios where talc is expected to be a source of asbestos exposure (COUs for asbestos-containing talc), the health risks and exposures in Part 2 of the Risk Evaluation will be specific to asbestos.

1.8 Information Considered

Comment: Omission of legacy exposures to asbestos was an unfortunate omission from the EPA’s Asbestos Risk Evaluation, Part I. Since population exposures to legacy uses of asbestos are likely to be far more common than population exposures to current or new uses of asbestos in production or commerce, it is essential that the completion of the Risk Evaluation Part 2 be timely, efficient, and accurate, so that risk management can be accomplished as soon as possible (EPA-HQ-OPPT-2021-0254-0030).

Response: EPA is working expeditiously to complete Part 2 of the Risk Evaluation for Asbestos. EPA has entered into a consent decree to complete the final risk evaluation by December 1, 2024.

Comment: The EPA’s scoping and risk evaluation process is vital to successful TSCA implementation, and the NAM appreciates the opportunity to comment. The NAM supports the critical efforts to improve public health and analysis of legacy uses and disposal of minerals the agency identifies as posing risk. As the EPA reviews this draft scope, we support strong science-based assessments and encourage the EPA to remain focused on the TSCA Section 202 definition of asbestos as, “...asbestiform varieties of – (A) chrysotile (serpentine), (B) crocidolite (riebeckite), (C) amosite (cummingtonite-grunerite), (D) anthophyllite, (E) tremolite, or (F) actinolite.” Further, to maximize all available federal resources, we recommend the EPA consider collaborating directly with the scientists and experts at the United States Geological Survey, given their deep institutional knowledge regarding the entire mineralogical universe, raw material extraction and downstream supply chains. The scientific and technical expertise housed at the USGS is critical to achieving a science-driven, robust risk assessment here and with any future mineral reviews (EPA-HQ-OPPT-2021-0254-0040).

Response: EPA conducts risk evaluations according to requirements set forth in TSCA, and in the case of asbestos, must take into account relevant court rulings. EPA will consider reaching out to scientific and disciplinary experts when it is necessary to do so. Consistent with TSCA section 9(d), EPA will consult and coordinate TSCA activities with USGS and other relevant Federal agencies for the purpose of achieving the maximum enforcement of TSCA while avoiding the imposition of duplicative requirements. Consultation with other relevant federal agencies is also required during the risk evaluation process under EPA’s implementing regulations at 40 CFR 702.39.

Comment: This first paper, published in the New England Journal of Medicine by Landrigan and Leinen (myself), July 10, 2019. In this paper we identify areas that should be of concern to EPA in their review of “Asbestos Part 2: Supplemental Evaluation Including Legacy Uses and Associated Disposal of Asbestos; Draft Scope of the Risk Evaluation to Be Conducted Under the Toxic Substances Control Act; Notice of Availability and Request for Comments.” The paper states “Most asbestos-related deaths in the United States today are caused either by cancers of long latency that resulted from exposures decades ago or by more recent exposures to asbestos installed long ago in the form of insulation, pipe wrapping, roofing tiles, and siding in thousands of office buildings, schools, and homes. The populations at greatest risk for exposure to legacy asbestos are firefighters, maintenance workers, and people employed in the construction and demolition industries.” “The dominant legally permitted use of asbestos today is by the chemical-manufacturing industry in the production of chlorine and caustic soda in chloralkali plants. Asbestos is also allowed in sheet gaskets, oil-field brake blocks, and aftermarket brake pads and brake linings for trucks and buses.” It is extremely important that EPA look beyond chrysotile asbestos in conducting their Asbestos Part 2 evaluation. Though, chrysotile is now the principal form of new asbestos used in the United States it is clearly not the only fiber type found in legacy asbestos, which includes differing varieties of amphiboles (EPA-HQ-OPPT-2021-0254-0021).

Response: EPA will consider the suggested reference for background context and will also evaluate the study in the systematic review process. As stated in other responses, herein, EPA expects to consider firefighters and workers as PESS. EPA agrees with the commenter’s identified COUs but notes that COUs evaluated in Part 1 of the Risk Evaluation for Asbestos will not be duplicated in Part 2. Part 2 of the Risk Evaluation for Asbestos will consider chrysotile as well as other asbestiform asbestos fiber types including crocidolite, amosite, anthophyllite, tremolite, actinolite, and Libby Amphibole Asbestos (LAA).

Comment: I would like to submit several papers of historical context. It has been quite hard to obtain with a reasonable degree of certainty the number of asbestos-related deaths in the United States. In past papers I have written, I referred to a number generated by the Environmental Working Group (EWG), citing around 12,000-15,000 asbestos-related disease deaths per year, though newer analysis, as reported by the American Public Health Association (APHA), places this number much higher nearing 40,000 deaths per year. This newer analysis is from The Institute for Health Metrics and Evaluation (IHME), at the University of Washington, study on the Global Burden of Disease (GBD), as presented by Dr. Jukka Takala of the International Commission on Occupational Health (ICOH). Dr. Takala reported that U.S. asbestos-related death accounted for a total of 39,275 annual deaths, broken into the following disease categories: Lung cancer = 34,270; Mesothelioma = 3,161; Ovary = 787; Larynx = 443; Asbestosis+ Chronic = 613. In 2019, this total number had increased to 40,7649 and will most likely continue to increase annually (EPA-HQ-OPPT-2021-0254-0021).

Response: EPA will review the suggested information through the TSCA systematic review screening and evaluation process.

Comment: If EPA were to evaluate LAA, it should not build on scientific weakness in the IRIS LAA Assessment. The draft scope document says that EPA will “build from” the 2014 IRIS assessment of LAA as appropriate. If EPA does evaluate LAA and its winchite and richterite constituents in this risk evaluation, it should consider that IRIS assessment carefully in light of numerous weaknesses in that assessment. EPA should freshly evaluate controversial choices made in that IRIS assessment as well as evaluate a comprehensive body of evidence based on its reliability and evidence (EPA-HQ-OPPT-2021-0254-0020; EPA-HQ-OPPT-2021-0254-0035).

Response: EPA will identify, review, and comprehensively evaluate the reasonably available information, including technical resources, in developing Part 2 of the Risk Evaluation.

Comment: Table_Apx A-9. Gray Literature Sources that Yielded Results for Asbestos should also include MSHA [Mine Safety and Health Administration] and its workplace exposure monitoring data for asbestos titled “Mine Data Retrieval System” located at <https://www.msha.gov/mine-data-retrieval-system> (EPA-HQ-OPPT-2021-0254-0025).

Response: The MSHA database has been included as a Gray Literature Source in Table_Apx A-9.

1.9 Systematic Review

Comment: Understanding the likely magnitude of human exposures to legacy asbestos-containing materials is the cornerstone of a useful risk evaluation process. While there is much peer-reviewed published literature, there is also an enormous amount of unpublished data that are relevant to decision-making in the proposed exercise. I note that Appendix A.3.4 (Gray Literature Searches) (p. 91) only contains government sources. The Draft Scope does not describe any attempt to proactively obtain, evaluate and use the large number of unpublished asbestos exposure studies or reports that have been conducted or issued by industry, exposure assessment firms, or other parties in connection with their obligation of industry under OSHA, routine private sector monitoring, or litigation. Given the restrictions on use of asbestos during the past 50 years and the enormous amount of litigation in relation to asbestos products, there are a large number of studies, including high quality studies, that EPA should obtain to include in the Risk Evaluation Part 2 (EPA-HQ-OPPT-2021-0254-0030).

Response: EPA is using the process described in the Draft TSCA Systematic Review Protocol to guide the process of searching for and screening reasonably available information, including information already in EPA’s possession, for use and inclusion in the risk evaluation. EPA is applying these systematic review methods to collect reasonably available information regarding hazards, exposures, PESS, and conditions of use that will help inform Part 2 of the Risk Evaluation. EPA has completed and presents searches of publicly available literature and the title and abstract and full-text screening of the resultant studies. Additionally, EPA will consider any materials or references suggest by public commenters according to the inclusion criteria described in the Draft Systematic Review Protocol.

Comment: IMA-NA has real concerns with how the literature search was executed, particularly for literature relating to the physical and chemical properties of asbestos. EPA appears to have too tightly constrained its literature search to include only the chemistry literature that may be present on asbestos as a “chemical substance.” This ignores the wealth of information that would exist if EPA had considered asbestos as a mineral, which is fundamentally what asbestos is (EPA-HQ-OPPT-2021-0254-0034).

Response: The implemented literature search process included a comprehensive set of key words to capture as much of the literature for a given discipline as possible. The literature search is designed to be broad and inclusive of the substance “asbestos” and relevant fiber types. EPA has reviewed the search terms and has not identified terms to add. EPA does note, however, that even with a comprehensive literature search, some important studies may be missed. Therefore, targeted literature searching for topics not anticipated at the beginning of the risk evaluation process might be needed and is an important aspect of the systematic review process. Also, EPA plans to consider information submitted through public comment and may perform supplemental targeted searches of peer-reviewed or gray literature during the development of the risk evaluation.

Comment: Hazards (Effects): 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). For a risk assessor, the epidemiological information remains the most important source for asbestos dose-response analysis (Wylie, Korchevskiy, 2022). 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, Case, 2012). AIHA recommends that EPA perform a meta-analysis of all available credible data, which will provide statistically significant slope factors for carcinogenic risk assessment (EPA-HQ-OPPT-2021-0254-0014).

Response: For the assessment of human health risks, EPA will rely upon epidemiologic evidence that is reasonably available and evaluate each of the identified studies. The quantitative information from each study meeting inclusion and quality criteria will be used to inform the risk assessment.

Comment: EPA should use the Systematic Review Protocol in its revised final form. EPA should use its updated systematic review protocol for this risk evaluation, but only after responding to comments by the public and the Scientific Advisory Committee on Chemicals (EPA-HQ-OPPT-2021-0254-0020).

Response: EPA has used updated systematic review methods in the development of the scope document for Part 2 of the Risk Evaluation for Asbestos and is continuing to apply the updated methods as it moves into the risk evaluation work. EPA has carefully considered comments from the public, the National Academies of Science, Engineering, and Medicine (NASEM), and the SACC on the Draft TSCA Systematic Review Protocol. Given the court-ordered deadline for Part 2 of the Risk Evaluation, EPA is not able to pause work on the risk evaluation while the TSCA Systematic Review Protocol is finalized.

Comment: Review of EPA Approach – Address Epidemiology/NASES Comments on the TSCA Process from Part 1: Chrysotile Asbestos --> 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 Part 2 of the Risk Evaluation should demonstrate how the agency intends to incorporate methodological revisions as a result of the NASEM review (EPA-HQ-OPPT-2021-0254-0014).

Response: EPA has implemented updated systematic review methods for Part 2 of the Risk Evaluation for Asbestos but is doing so in a way that builds from Part 1, as appropriate. For example, elements of the literature search from Part 1 are pertinent to Part 2. Also, specific study quality evaluation criteria developed in Part 1 are relevant for Part 2. To meet statutory deadlines, Given the court-ordered

deadline for Part 2 of the Risk Evaluation, EPA is not able to pause work on the risk evaluation while the TSCA Systematic Review Protocol is finalized.

1.10 Definition of Asbestos

Comment: Several public commenters offered perspectives and concerns related to the definition of asbestos described in the draft scope document.

- In the Draft Scope, the Agency states: “For the purposes of scoping and risk evaluation, EPA has adopted the definition of asbestos as defined by TSCA Title II (added to TSCA in 1986), Section 202 as the ‘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. However, given that Part 2 of the risk evaluation will focus on legacy asbestos uses and associated disposals, a unique consideration is the collocation of asbestos geologically with commercially mined substances. In particular, Libby Amphibole Asbestos (LAA) is known to be present with a silicate, mica-like mineral called vermiculite, extracted from an open pit mine near Libby, Montana, until its closure in 1990 (U.S., 1988). Vermiculite was widely used in building materials that will be an important focus of the evaluation of legacy uses of asbestos. Thus, LAA (and its tremolite, winchite, and richterite constituents) will be considered in Part 2 of the Risk Evaluation. To identify these substances, EPA has used the following CAS Registry Numbers (CASRNs): 1332-21-4 (asbestos; this is the only asbestos on the TSCA Inventory), 12001-29- 5 (chrysotile), 12001-28-4 (crocidolite), 12172-73-5 (amosite), 17068-78-9 (anthophyllite), 14567-73-8 (tremolite), 12172-67-7 (actinolite), 1318-09-8 (LAA), 12425-92-2 (winchite), and 17068-76-7 (richterite).” EPA should take administrative notice that not all vermiculite should be expected to be collocated geologically with asbestos. EPA’s Draft Scope needs to focus exclusively on the six regulated varieties of asbestos. The vermiculite mine in Libby, Montana, is unique geologically and EPA should treat it as such in the Draft Scope” (EPA-HQ-OPPT-2021-0254-0034).
- Reasonably available information: In searching for reasonably available information to conduct the subsequent risk assessments, the Draft Scope should apply only the correct definition of “asbestos” as defined by the Toxic Substances Control Act (TSCA), Title II, Section 202, as the “asbestiform varieties of six fiber types – chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite.” Draft Scope at 9. For clarity, the correct CAS Registry numbers at issue are as follows: chrysotile (CASRN 12001-29-5), crocidolite (CASRN 12001-28-4), amosite (CASRN 12172-73-5), anthophyllite asbestos (CASRN 77536-67-5), tremolite asbestos (CASRN 77536-68-6) and actinolite asbestos (CASRN 77536-68-4). These are the chemical substances that EPA designated as one of the first ten chemical substances for initial risk evaluation under the updated TSCA statute under the rubric of “asbestos.” See 81 FR 91927, et seq., December 19, 2016. As such, the search terms for reasonably available information should not include: Libby Amphibole Asbestos (LAA) (CASRN 1318-09-8), (and its [non-asbestiform] tremolite (CASRN 14567-73-8), winchite (CASRN 12425-92-2) and richterite (CASRN 17068-76-7) components). As previously mentioned, the asbestiform variety of tremolite, i.e., tremolite asbestos (CASRN 77536-68-6), an amphibole mineral, ostensibly is one of the constituents of LAA and also one of the six currently regulated asbestiform varieties of asbestos. Consequently, it is appropriately included in searches for reasonably available information in the Draft Scope. EPA must revise the tables (page 34 of draft scope) that misidentified the non-asbestiform analogs to reflect data for the three intended currently regulated varieties of asbestos and delete the table that references LAA as being outside the Draft Scope (EPA-HQ-OPPT-2021-0254-0034).

- Winchite and richterite crystallize in more than one habit, and should not be included in this risk assessment. While each of these minerals may crystallize in the asbestiform habit, neither meets the EPA definition of asbestos, as set forth in TSCA, statutorily rendering them outside the jurisdiction of the Draft Scope (EPA-HQ-OPPT-2021-0254-0025).
- *Comment:* EPA must include all forms of asbestos in its risk evaluation; asbestiform varieties including chrysotile, crocidolite, amosite, anthophyllite, tremolite, and Libby Amphibole Asbestos (EPA-HQ-OPPT-2021-0254-0025; EPA-HQ-OPPT-2021-0254-0026; EPA-HQ-OPPT-2021-0254-0027; EPA-HQ-OPPT-2021-0254-0030; EPA-HQ-OPPT-2021-0254-0031; EPA-HQ-OPPT-2021-0254-0032; EPA-HQ-OPPT-2021-0254-0034; EPA-HQ-OPPT-2021-0254-0035; EPA-HQ-OPPT-2021-0254-0041).
- The Draft Scope should consider conditions of use that relate solely to the six regulated varieties of asbestos. Legacy uses of asbestos and associated disposals should be readily identifiable because the sources of the six regulated varieties of asbestos should be readily identifiable, as should their uses, because of the unique characteristics of asbestos that made them commercially viable. The associated disposals of the six regulated varieties of asbestos should be readily identifiable for the same reason. EPA should focus like a laser on these conditions of use. The conditions of use for talc and vermiculite should become moot as they should not be included in the Draft Scope (EPA-HQ-OPPT-2021-0254-0034).
- Procedurally, adding these chemical substances for evaluation more than midway through EPA's risk evaluation of asbestos violates the prioritization procedures of TSCA (EPA-HQ-OPPT-2021-0254-0034; EPA-HQ-OPPT-2021-0254-0020).

Response: EPA recognizes that draft scope was unclear on the applied definition of asbestos and inclusion of Libby Amphibole Asbestos for Part 2 of the Risk Evaluation for Asbestos and understands how this raised procedural and administrative concerns. EPA has revised the description of asbestos to be considered in Part 2 of the Risk Evaluation, clarifying that EPA initially adopted the AHERA Title II definition for Part 1 of the Risk Evaluation for Asbestos which was appropriate given the focus on chrysotile asbestos and ongoing uses of asbestos. It is EPA's judgement that it is necessary and appropriate to include Libby Amphibole Asbestos (with tremolite, winchite, and richterite constituents) in Part 2 of the Risk Evaluation because of the consideration of legacy uses, primarily for asbestos-containing building materials, where vermiculite from the Libby, MT mine had widespread use. Additionally, the final scope is consistent with the identification of "asbestos" as the chemical substance subject to the risk evaluation in the December 2016 notice designating the first ten chemical substances subject to risk evaluations under TSCA (81 FR 91927).

Winchite and richterite will not be considered beyond Libby Amphibole Asbestos

The literature search conducted aligns with EPA's scope and inclusion of asbestos fibers, which has been revised for clarity in the Final Scope. The CASRNs have been corrected in the final scope and the literature searches were updated with the CASRNs for the asbestiform varieties of each fiber. Due to the comprehensive nature of EPA's literature search methods, no new studies were identified with the corrected CASRNs.

EPA must conduct a risk evaluation to determine whether a chemical substance presents unreasonable risk under the conditions of use. Conditions of use are defined as the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. When evaluating the conditions of use in the risk evaluation, exposures to asbestos will be determined based on reasonably available information. EPA must integrate and assess available information on exposures for the conditions of use

for the chemical substance. EPA is focusing on relevant conditions of use and associated exposures in Part 2 of the Risk Evaluation and does not believe that any conditions of use that have been identified are “moot.” EPA has provided clarification on the extent to which talc is considered, noting that the applicable COUs will be those for asbestos-containing talc.