

Scope of the Risk Evaluation for Asbestos

June 2017

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Docket

Supporting information can be found in public docket: <u>EPA-HQ-OPPT-2016-0736</u>.

Disclaimer

Reference herein to any specific commercial products, process or service by trade name, trademark, manufacturer or otherwise does not constitute or imply its endorsement, recommendation or favoring by the United States Government.

ABBREVIATIONS

ACC	American Chemistry Council				
AHERA	Asbestos Hazard Emergency Response Act				
ASHAA	Asbestos School Hazard Abatement Act				
ASHARA	Asbestos School Hazard Abatement Reauthorization Act				
ATSDR	Agency for Toxic Substances and Disease Registries				
CAA	Clean Air Act				
CASRN	Chemical Abstract Service Registry Number				
CBI	Confidential Business Information				
CDR	Chemical Data Reporting				
CEPA	Canadian Environmental Protection Act				
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act				
сос	Concentration of Concern				
CPCat	Chemical and Product Categories				
CPID	Consumer Product Information Database				
CPSC	Consumer Product Safety Commission				
CWA	Clean Water Act				
DHHS	Department of Health and Human Services				
EG	Effluent Guideline				
EMP	Elongated Mineral Particle				
EPA	Environmental Protection Agency				
EPCRA	Emergency Planning and Community Right-to-Know Act				
EU	European Union				
FDA	Food and Drug Administration				
f/cc	Fibers per cubic centimeter				
FHSA	Federal Hazardous Substance Act				
g	Gram(s)				
HEPA	High-Efficiency Particulate Air				
IARC	International Agency for Research on Cancer				
lgA	Immunoglobulin A				
lgG	Immunoglobulin G				
IRIS	Integrated Risk Information System				
lb	Pound				
MAP	Model Accreditation Plan				
MCLG	Maximum Contaminant Level Goal				
MFL	Million Fibers per Liter				
mg	Milligram(s)				
MPa	Megapascal				
MSDS	Material Safety Data Sheet				
MSHA	Mine Safety and Health Administration				
mV	Millivolt				
NAICS	North American Industrial Classification System				
ND	Non-detects (value is < analytical detection limit)				
NEI	National Emissions Inventory				
NESHAP	National Emission Standard for Hazardous Air Pollutants				
NIH	National Institutes of Health				

NIOSH	National Institute of Occupational Safety and Health
NOI	Notice of Intent
NPL	National Priorities List
NTP	National Toxicology Program
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
РВРК	Physiologically Based Pharmacokinetic
PEL	Permissible Exposure Level
POD	Point of Departure
POTW	Publicly Owned Treatment Works
PPE	Personal Protective Equipment
ppm	Part(s) per Million
RCRA	Resource Conservation and Recovery Act
PV	Production Volume
QSAR	Quantitative Structure Activity Relationship
RA	Risk Assessment
RIA	Regulatory Impact Analysis
SDS	Safety Data Sheets
SDWA	Safe Drinking Water Act
TCCR	Transparent, Clear, Consistent, and Reasonable (TCCR)
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TURA	Toxics Use Reduction Act
TWA	Time Weighted Average
U.S.	United States
USGS	United States Geological Service
WHO	World Health Organization

EXECUTIVE SUMMARY

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use." In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). Asbestos was one of these chemicals.

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. This document fulfills the TSCA § 6(b)(4)(D) requirement for asbestos.

This document presents the scope of the risk evaluation to be conducted for asbestos. If a hazard, exposure, condition of use or potentially exposed or susceptible subpopulation has not been discussed, EPA, at this point in time, is not intending to include it in the scope of the risk evaluation. As per the rulemaking, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA)*, with respect to conditions of use in conducting a risk evaluation under TSCA, EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion.

In the case of asbestos, legacy uses and associated and legacy disposals will be excluded from the scope of the risk evaluation. These include asbestos-containing materials that remain in older buildings or are part of older products but for which manufacture, processing and distribution in commerce are not currently intended, known or reasonably foreseen. EPA is excluding these activities because EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing or distribution is intended, known to be occurring, or reasonably foreseen, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of conditions of use in that context.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for asbestos. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

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. The general CAS Registry Number (CASRN) of asbestos is 1332-21-4; this is the only asbestos on the TSCA Inventory. However, CASRNs are also available for specific fiber types.

Asbestos has not been mined or otherwise produced in the United States since 2002; therefore, any new asbestos entering this country is imported. In 2016, the United States imported approximately 340 metric tons of raw asbestos.

EPA has identified the ongoing use of chrysotile asbestos in the chlor-alkali industry and the use of asbestos-containing sheet gaskets in the manufacture of titanium dioxide. Other uses that have been identified include asbestos containing products for ongoing commercial and consumer use. For the purposes of this scoping document, the products were placed into use categories that include, "known use," "evidence of use," and "reasonably foreseen use."

The initial conceptual models presented in Section 2 identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed populations, including potentially exposed or susceptible subpopulations; and hazards EPA expects to evaluate based on the inherent hazards of the chemical. It is expected that inhalation will be the primary route of exposure to all populations.

This document presents the occupational scenarios in which workers and occupational non-users may be exposed to asbestos during a variety of conditions of use, such as fabrication of asbestos-containing diaphragms in the chlor-alkali industry and use of imported asbestos-containing products in industrial settings. It also presents the consumer model which indicates that exposures to asbestos-containing products may occur in either indoor or outdoor environments. For asbestos, EPA believes that workers, consumers, and bystanders as well as certain other groups of individuals may experience greater exposures than the general population. EPA will evaluate whether other groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration), or have greater susceptibility than the general population, and should therefore be considered relevant potentially exposed or susceptible subpopulations for purposes of this risk evaluation.

Exposures to the general population may occur from industrial releases. Only environmental releases of friable asbestos are reported in the Toxics Release Inventory. Most of the reported asbestos releases were to landfills. Asbestos fibers are largely chemically inert under environmental conditions. They may undergo minor physical changes, such as changes in fiber length, but do not degrade, react, or dissolve to any appreciable extent in the environment.

Asbestos has been the subject of numerous health hazard and risk assessments, based primarily on data on human populations. Any existing assessments will be a starting point as EPA will conduct a systematic review of the literature, including new literature since the existing assessments, as available in *Asbestos (CASRN 1332-21-4) Bibliography: Supplemental File for the TSCA Scope Document*, <u>EPA-HQ-</u>

<u>OPPT-2016-0736</u>). Many authorities have established that there is causal association between asbestos and lung cancer and mesotheliomas. Causal associations between exposure to asbestos and cancer of the larynx and ovary have also been reported. Non-cancer hazards of asbestos include toxicity to the respiratory system (e.g., asbestosis) and immunotoxicity. These hazards will be evaluated based on the specific exposure scenarios identified.

The initial analysis plan describes EPA's plan for conducting systematic review of readily available information and identification of assessment approaches to be used in conducting the risk evaluation for asbestos. The initial analysis plan will be used to develop the problem formulation and final analysis plan for the risk evaluation of asbestos.

1 INTRODUCTION

This document presents the scope of the risk evaluation to be conducted for asbestos. If a condition of use has not been discussed, EPA, at this point in time, is not intending to include that condition of use in the scope of the risk evaluation. Moreover, during problem formulation EPA may determine that not all conditions of use mentioned in this scope will be included in the risk evaluation. Any condition of use that will not be evaluated will be clearly described in the problem formulation document.

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended the Toxic Substances Control Act (TSCA), the nation's primary chemicals management law, was signed into law. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

TSCA § 6(b)(4) requires the U.S. Environmental Protection Agency (EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use."

In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). These 10 chemical substances were drawn from the 2014 update of EPA's TSCA Work Plan for Chemical Assessments, a list of chemicals that EPA identified in 2012 and updated in 2014 (currently totaling 90 chemicals) for further assessment under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA § 6(b)(4).

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. On February 14, 2017, EPA convened a public meeting to receive input and information to assist the Agency in its efforts to establish the scope of the risk evaluations under development for the ten chemical substances designated in December 2016 for risk evaluations pursuant to TSCA. EPA provided the public an opportunity to identify information, via oral comment or by submission to a public docket, specifically related to the conditions of use for the ten chemical substances. EPA used this information in developing this scope document, which fulfills the TSCA § 6(b)(4)(D) requirement for asbestos.

As per the rulemaking, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA), in conducting a risk evaluation under TSCA EPA will first identify "circumstances" that constitute "conditions of use" for each chemical. While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. Based on legislative history, statutory structure and other evidence of Congressional intent, EPA has determined that certain activities may not generally be considered to be conditions of use. In exercising its discretion, for example, EPA would not generally consider that a single unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's "conditions of use." As a further example, although the definition could be read literally to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA does not generally intend to include such activities in either a chemical substance's prioritization or risk evaluation. In addition, EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacture, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section 6 might reasonably include the use of a chemical substance in insulation where the manufacture, processing or distribution in commerce for that use is prospective or on-going, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses.

Furthermore, in exercising its discretion under section 6(b)(4)(D) to identify the conditions of use that EPA expects to consider in a risk evaluation, EPA believes it is important for the Agency to have the discretion to make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemical substances in commerce present an unreasonable risk. Consequently, EPA may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern meriting an unreasonable risk consideration. For example, EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping, in order to determine which risk evaluation the potential risks from the chemical substance should be addressed in. As an additional example, EPA may, on a case-by-case basis, exclude uses that ePA has sufficient basis to conclude would present only "de minimis" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks.

The situations identified above are examples of the kinds of discretion that EPA will exercise in determining what activities constitute conditions of use, and what conditions of use are to be included in the scope of any given risk evaluation. See the preamble to Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (TSCA) for further discussion of these issues.

To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. The first 10 chemical substances were not subject to the prioritization process that will be used in the future in accordance with amendments to TSCA. EPA expects to collect and screen much of the relevant

information about chemical substances that will be subject to the risk evaluation process during and before prioritization. The volume of data and information about the first 10 chemicals that is available to EPA is extremely large and EPA is still in the process of reviewing it, since the Agency had limited ability to process the information gathered before issuing the scope documents for the first 10 chemicals. As a result of the statutory timeframes, EPA had limited time to process all of the information gathered during scoping for the first 10 chemicals within the time provided in the statute for publication of the scopes after initiation of the risk evaluation process. For these reasons, EPA's initial screenings and designations with regard to applicability of data (e.g., on-topic vs. off-topic information and data) may change as EPA progresses through the risk evaluation process. Likewise, the Conceptual Models and Analysis Plans provided in the first 10 chemical scopes are designated as "Initial" to indicate that EPA expects to further refine them during problem formulation.

The aforementioned time constraints and uncertainty associated with developing the risk evaluation process rule has resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be. In addition, there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents. For these reasons, EPA will publish and take public comment on a problem formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluations for the first 10 chemicals. This problem formulation is expected to be released within approximately 6 months of publication of the scope.

1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to asbestos. EPA compiled this summary from data available from federal, state, international and other government sources, as cited in Appendix A. EPA may evaluate and consider the impact of these existing laws and regulations in the problem formulation step to determine what, if any further analysis might be necessary as part of the risk evaluation.

Federal Laws and Regulations

Asbestos is subject to federal statutes or regulations, other than TSCA, that are implemented by other offices within EPA and/or other federal agencies/departments. A summary of federal laws, regulations and implementing authorities is provided in Appendix A-1.

State Laws and Regulations

Asbestos is subject to state statutes or regulations implemented by state agencies or departments. A summary of state laws, regulations and implementing authorities is provided in Appendix A-2.

Laws and Regulations in Other Countries and International Treaties or Agreements

Asbestos is subject to statutes or regulations in countries other than the United States and/or international treaties and/or agreements. A summary of these laws, regulations, treaties and/or agreements is provided in Appendix A-3.

1.2 Assessment History

EPA has identified assessments conducted by other EPA Programs and other organizations (see Table 1-1). Depending on the source, these assessments may include information on conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations—information useful to EPA in preparing this scope for risk evaluation. Table 1-1 shows the assessments that have been conducted. In addition to using this information, EPA intends to conduct a full review of the data collected (see *Asbestos (CASRN 1332-21-4) Bibliography: Supplemental File for the TSCA Scope Document*, <u>EPA-HQ-OPPT-2016-0736</u>) using the literature search strategy (see *Strategy for Conducting Literature Searches for Asbestos: Supplemental File for the TSCA Scope Document*, <u>EPA-HQ-OPPT-2016-0736</u>) to ensure that EPA is considering information that has been made available since these assessments were conducted.

Authoring Organization	Assessment		
EPA assessments			
EPA, Integrated Risk Information System (IRIS)	IRIS Assessment on Asbestos (1988)		
EPA, Integrated Risk Information System (IRIS)	IRIS Assessment on Libby Amphibole Asbestos (2014)		
EPA, Drinking Water Criteria Document	U.S. EPA Drinking Water Criteria Document for Asbestos (1985)		
EPA, Ambient Water Quality Criteria for Asbestos	Asbestos: Ambient Water Quality Criteria (1980a)		
Other U.Sbased organizations			
National Institutes of Occupational Safety and Health (NIOSH)	Asbestos Fibers and Other Elongate Mineral Particles: State of the Science and Roadmap for Research (2011)		
Agency for Toxic Substances and Disease Registry (ATSDR)	Toxicological Profile for Asbestos (2001)		
National Toxicology Program (NTP)	Report on Carcinogens, Fourteenth Edition (2016)		
CA Office of Environmental Health Hazard Assessment (OEHHA), Pesticide and Environmental Toxicology Section	Public Health Goal for Asbestos in Drinking Water (2003)		
International	·		
International Agency for Research on Cancer (IARC)	IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Arsenic, Metals, Fibres, and Dusts. Asbestos (Chrysotile, Amosite, Crocidolite, Tremolite, Actinolite, and Anthophyllite) (2012)		
World Health Organization (WHO)	World Health Organization (WHO) Chrysotile Asbestos (2014)		

Table 1-1. Assessment History of Asbestos

1.3 Data and Information Collection

EPA/OPPT generally applies a process and workflow that includes: (1) data collection; (2) data evaluation; and (3) data integration of the scientific data used in risk assessments developed under TSCA. Scientific analysis is often iterative in nature as new knowledge is obtained. Hence, EPA/OPPT expects that multiple refinements regarding data collection will occur during the process of risk evaluation.

Data Collection: Data Search

EPA/OPPT conducted chemical-specific searches for data and information on: physical and chemical properties; environmental fate and transport; conditions of use information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations; ecological hazard, human health hazard, including potentially exposed or susceptible subpopulations.

EPA/OPPT designed its initial data search to be broad enough to capture a comprehensive set of sources containing data and/or information potentially relevant to the risk evaluation. Generally, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed literature and gray literature (e.g., publicly-available industry reports, trade association resources, government reports). When available, EPA/OPPT relied on the search strategies from recent assessments, such as EPA Integrated Risk Information System (IRIS) assessments and the National Toxicology Program's (NTP) *Report on Carcinogens,* to identify relevant references and supplemented these searches to identify relevant information published after the end date of the previous search to capture more recent literature. *Strategy for Conducting Literature Searches for Asbestos: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0736) provides details about the data sources and search terms that were used in the initial search.

Data Collection: Data Screening

Following the data search, references were screened and categorized using selection criteria outlined in *Strategy for Conducting Literature Searches for Asbestos: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0736). Titles and abstracts were screened against the criteria as a first step with the goal of identifying a smaller subset of the relevant data to move into the subsequent data extraction and data evaluation steps. Prior to full-text review, EPA/OPPT anticipates refinements to the search and screening strategies, as informed by an evaluation of the performance of the initial title/abstract screening and categorization process.

The categorization scheme (or tagging structure) used for data screening varies by scientific discipline (i.e., physical and chemical properties; environmental fate and transport; chemical use/conditions of use information; human and environmental exposures, including potentially exposed or susceptible subpopulations identified by virtue of greater exposure; human health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater exposure; numan health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazard), but within each data set, there are two broad categories or data tags: (1) on-topic references or (2) off-topic references. On-topic references are those that may contain data and/or information relevant to the risk evaluation. Off-topic references are those that do not appear to contain data or information relevant to the risk evaluation. The Strategy for Conducting Literature Searches for Asbestos: Supplemental File for the TSCA Scope Document (EPA-HQ-OPPT-2016-0736) discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as on-topic or off-topic.

Additional data screening using sub-categories (or sub-tags) was also performed to facilitate further sorting of data/information. For example, identifying references by source type (e.g., published peer-reviewed journal article, government report); data type (e.g., primary data, review article); human health hazard (e.g., liver toxicity, cancer, reproductive toxicity); or chemical-specific and use-specific data or information. These sub-categories are described in the *Strategy for Conducting Literature Searches for Asbestos: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0736) and will be used to organize the different streams of data during the stages of data evaluation and data integration steps of systematic review.

Results of the initial search and categorization results can be found in the *Asbestos (CASRN 1332-21-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0736). This document provides a comprehensive list (bibliography) of the sources of data identified by the initial search and the initial categorization for *on-topic* and *off-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from the *on-topic* to the *offtopic* categories, and vice versa. Moreover, targeted supplemental searches may also be conducted to address specific needs for the analysis phase (e.g., to locate specific data needed for modeling); hence, additional *on-topic* references not initially identified in the initial search may be identified as the systematic review process proceeds.

2 SCOPE OF THE EVALUATION

As required by TSCA, the scope of the risk evaluation identifies the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA is including an initial life cycle diagram and initial conceptual models that describe the actual or potential relationships between asbestos and human and ecological receptors. An initial analysis plan is also included which identifies, to the extent feasible, the approaches and methods that EPA may use to assess exposures, effects (hazards) and risks under the conditions of use of asbestos. As noted previously, EPA intends to refine this analysis plan during the problem formulation phase of risk evaluation.

2.1 Definition, Structure and Physical and Chemical Properties

2.1.1 Definition of Asbestos

Asbestos is a "generic commercial designation for a group of naturally occurring mineral silicate fibers of the serpentine and amphibole series" (<u>IARC, 2012</u>). The Chemical Abstract Service (CAS) definition of asbestos is "a grayish, non-combustible fibrous material. It consists primarily of impure magnesium silicate minerals." The general CAS Registry Number (CASRN) of asbestos is 1332-21-4; this is the only asbestos on the TSCA Inventory. However, CASRNs are also available for specific fiber types.

TSCA Title II (added to TSCA in 1986), Section 202 defines asbestos 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. EPA is using this definition of asbestos for the risk evaluation for asbestos.

The most common form of asbestos used in the United States is chrysotile, which is found in serpentine rock formations (chrysotile content average 5%, with a maximum 50%) (WHO, 2014). Chrysotile was the predominant type of asbestos used in the United States and is currently the only type of raw asbestos imported. The three varieties of amphibole fibers that are the most commonly found are crocidolite, amosite and tremolite. Crocidolite and amosite were the only amphiboles with significant industrial uses in recent years. Tremolite, although having essentially no industrial application, may be found as a contaminant associated with other fibers or in other industrial minerals (e.g., chrysotile and talc) (<u>Virta, 2011</u>).

2.1.2 Structure

As with all silicate minerals, the basic building blocks of asbestos fibers are silicate tetrahedra $[SiO_4]^{4-}$ where four oxygen atoms are covalently bound to the central silicon (Figure 2-1). These tetrahedrons occur as sheets $[Si_4O_{10}]$ in chrysotile (Figure 2-2) (<u>U.S. EPA, 2014</u>).

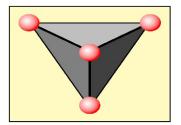


Figure 2-1. Silicon Tetrahedron

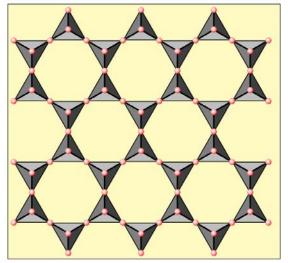


Figure 2-2. Silicate Sheet Structure of Chrysotile

In the case of chrysotile, an octahedral brucite layer having the formula $[Mg_6O_4(OH)_8]$ is intercalated between each silicate tetrahedral sheet.

2.1.3 Physical and Chemical Properties of Asbestos

Physical-chemical properties influence the environmental behavior and the toxic properties of a chemical, thereby informing the potential conditions of use, exposure pathways and routes, and hazards EPA intends to consider. For scope development, EPA considered the measured or estimated physical-chemical properties set forth in Table 2-1.

	Chrysotile	Amosite	Crocidolite	Tremolite	Anthophyllite	Actinolite
CASRN	12001-29-5	12172-73-5	12001-28-4	14567-73-8	17068-78-9	12172-67-7
Essential composition	Mg silicate with some water	Fe, Mg silicate with some water	Na, Fe silicate with some water	Ca, Mg silicate with some water	Mg silicate with some iron	Ca, Mg, Fe silicate with some water
Color	Usually white to grayish green; may	Yellowish gray to dark brown	Cobalt blue to lavender blue	Gray-white, green, yellow, blue	Grayish white, also brown-gray or green	Greenish

Table 2-1. Physical and Chemical Properties of Asbestos Fiber Types ^a

	Chrysotile	Amosite	Crocidolite	Tremolite	Anthophyllite	Actinolite
	have tan coloration					
Luster	Silky	Vitreous to pearly	Silky to dull	Silky	Vitreous to pearly	Silky
Surface area ^{b, c} (m²/g)	13-18	2-9	2-9	2-9	2-9	2-9
Hardness (Mohs)	2.5-4.0	5.5-6.0	4.0	5.5	5.5-6.0	6.0
Specific gravity	2.4-2.6	3.1-3.25	3.2-3.3	2.9-3.2	2.85-3.1	3.0-3.2
Optical properties	Biaxial positive parallel extinction	Biaxial positive parallel extinction	Biaxial oblique extinction	Biaxial negative oblique extinction	Biaxial positive extinction parallel	Biaxial negative extinction inclined
Refractive index	1.53-1.56	1.63-1.73	1.65-1.72	1.60- 1.64	1.61	1.63 weakly pleochroic
Flexibility	High	Fair	Fair to good	Poor, generally brittle	Poor	Poor
Texture	Silky, soft to harsh	Coarse but somewhat pliable	Soft to harsh	Generally harsh	Harsh	Harsh
Spinnability	Very good	Fair	Fair	Poor	Poor	Poor
Tensile strength (MPa)	1,100-4,400	1,500-2,600	1,400-4,600	<500	≤27	≤7
Resistance to: Acids	Weak, undergoes fairly rapid attack	Fair, slowly attacked	Good	Good	Very good	Fair
Bases	Very good	Good	Good	Good	Very good	Fair
Zeta potential (mV)	+13.6 to +54	-20 to -40	-32	NA	NA	NA
Decomposition temperature (°C)	600-850	600-900	400-900	950-1,040	950	NA
^a <u>Badollet (1951)</u> . ^b <u>Hodgson (1986)</u> .						

^c <u>Addison et al. (1966)</u>.

Asbestos fibers are basically chemically inert, and they do not evaporate, dissolve, burn or undergo significant reactions with most chemicals. They are insoluble in water and organic solvents. In acid and neutral aqueous media, magnesium is lost from the outer brucite layer of chrysotile. Amphibole fibers are more resistant to acid attack and all varieties of asbestos are resistant to attack by alkalis (<u>Virta, 2011</u>).

2.2 Conditions of Use

TSCA § 3(4) defines the 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."

2.2.1 Data and Information Sources

As the first step in preparing these scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. As further described in this document, EPA searched a number of available data sources (e.g., Use and Market Profile for Asbestos, EPA-HQ-OPPT-2016-0736). Based on this search, EPA published a preliminary list of information and sources related to chemical conditions of use (see *Preliminary Information on Manufacturing, Processing,* Distribution, Use, and Disposal: Asbestos) (Docket: EPA-HQ-OPPT-2016-0736-0005), prior to a February 2017 public meeting on scoping efforts for risk evaluation convened to solicit comment and input from the public. EPA also convened meetings with companies, industry groups, chemical users and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. The information and input received from the public and stakeholder meetings has been incorporated into this scope document to the extent appropriate, as indicated in Table 2-3. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities identified in these documents constitute the intended, known, and reasonably foreseen activities associated with the subject chemicals, based on reasonably available information. The documents do not, in most cases, specify whether activity under discussion is intended, known, or reasonably foreseen, in part due to the time constraints in preparing these documents.

2.2.2 Identification of Conditions of Use

Reporting of asbestos in the 2016 Chemical Data Reporting (CDR)^{1, 2} period was limited (<u>U.S. EPA,</u> <u>2016a</u>). Only two companies, both from the chlor-alkali industry, reported importing asbestos and the amounts cannot be publicly disclosed due to company claims of confidential business information (CBI).

¹ Manufacturers (including importers) are required to report under CDR if they meet certain production volume thresholds, generally ≥25,000 lbs of a chemical substance at any single site. Reporting is triggered if the annual reporting threshold is met during any of the calendar years since the last principal reporting year. In general, the reporting threshold remains 25,000 lbs per site. However, a reduced reporting threshold (2,500 lbs) now applies to chemical substances subject to certain TSCA actions (U.S. EPA, 2017a).

² For purposes of the scope, manufacture means to manufacture, produce, or import for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances. (40 CFR 711.3) (U.S. EPA, 2016b)

Asbestos has not been mined or otherwise produced in the United States since 2002 (Flanagan, 2016); hence, mining is not included in the scope of the TSCA risk evaluation for asbestos. All asbestos used in this country is imported. According to the U.S. Geological Survey (USGS), the only form of asbestos currently imported into the United States is chrysotile, which primarily originates from Brazil (USGS, 2017). USGS reports that in 2016, the United States imported approximately 340 metric tons (749,572 pounds) of raw asbestos, the total of which they state is used in the chlor-alkali industry (USGS, 2017). Other import data presented in the USGS report are difficult to interpret with regard to volumes because most of the asbestos products reported are described in terms of monetary value and not import volume. Also, the monetary value is associated with a product without reference to amount or type of asbestos present in that product.

In addition to CDR, EPA used supplementary information gathered from meetings with chlor-alkali industry representatives, written correspondence from the American Chemistry Council (ACC), and site visits to two chlor-alkali plants to further understand the typical life cycle of asbestos within this industry. EPA staff also conducted market research to ascertain the availability of asbestos-containing products in the United States.

The uses included in the scope of the risk evaluation are identified in Figure 2-3 and are described in terms of product categories. As part of the effort to understand the current asbestos product market, EPA referred to the *Regulatory Impact Analysis [RIA] of Controls on Asbestos and Asbestos Products (Final Report Volume III)*, which was conducted in support of the 1989 *Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions; Final Rule (40 CFR Part 763)*. The RIA explained that in 1981, asbestos products were distributed into 35 product categories (U.S. EPA, 1989). For scoping, EPA researched the 35 product categories included in the 1989 RIA, and based on the results of this research, developed the following use categories that reflect current knowledge of uses as of 2017:

- Known Use companies and manufacturing processes are identified
- Evidence of Use web sites and/or Safety Data Sheets (SDS) indicate asbestos in products
- Reasonably Foreseen Use indication by USGS that asbestos-containing products are imported to the United States

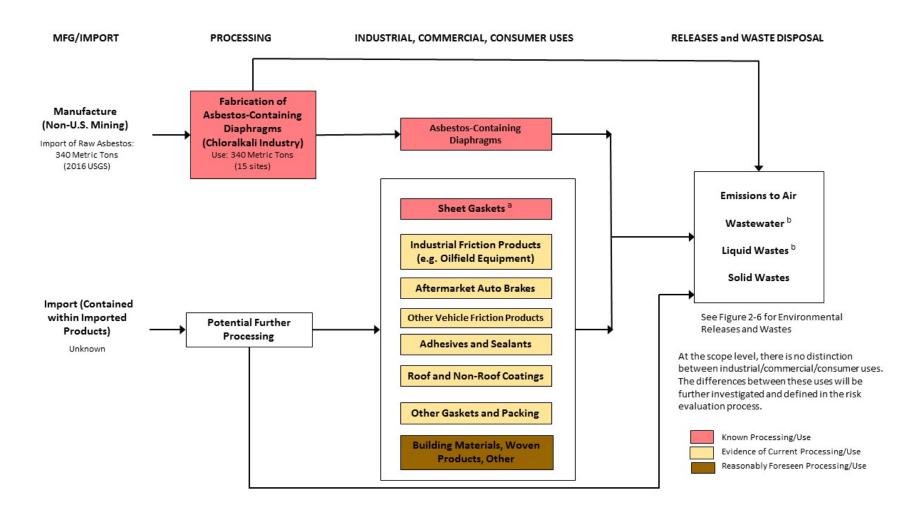


Figure 2-3. Initial Asbestos Life Cycle Diagram

Figure 2-3 depicts the initial life cycle diagram which depicts the conditions of use of asbestos that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial or commercial), distribution and disposal The import volume shown is from 2016 USGS (<u>USGS, 2017</u>). Import volumes of asbestos-containing products are unknown. Activities related to distribution (e.g., loading, unloading, etc.) will be considered throughout the asbestos life cycle, rather than using a single distribution scenario.

^a Sheet gaskets were identified during public comment period.

^b Wastewater: combination of water and organic liquid, where the organic content is ≤ 50%. Liquid Wastes: combination of water and organic liquid, where the organic content is ≥ 50%.

Table 2-2 provides a listing of the known and assumed product use categories identified for asbestos and examples of their use. The import volume of products containing asbestos is not known.

Use Status*	Product Category	Use Example	Reference		
Known Use	Asbestos Diaphragms	Chlor-alkali Industry	<u>U.S. EPA (2017c); Comment ID EPA-HQ-OPPT-</u> 2016-0736-0041; Comment ID <u>EPA-HQ-OPPT-</u> 2016-0736-0063		
	Sheet Gaskets	Chemical Manufacturing	Comment ID EPA-HQ-OPPT-2016-0736-0067		
	Industrial Friction Products Brake Blocks in Oil Industry				
Evidence of UseAftermarket Automotive BrakesEvidence of UseOther Vehicle Friction ProductsAdhesive and SealantsRoof and Non-roof Coatings		Passenger Vehicles			
		Non-passenger Vehicles	Preliminary Use Information		
	Mirror adhesive; tile cement	<u>EPA-HQ-OPPT-2016-0736-0005</u>			
	Roof and Non-roof Coatings	Roofs/Foundations; Mastics			
	Other Gaskets and Packing	Washers			
Reasonably Foreseen Use	Building Materials	Imported Cement			
	Woven Products	Imported Textiles	Preliminary Use Information EPA-HQ-OPPT-2016-0736-0005		
	Other	Articles not specified	<u>LFA-HQ-0FFF-2010-0750-0005</u>		
*Known Use, I	Evidence of Use and Reasonably	Foreseen Use are represen	ted by three different colors in the initial life		

Known Use in the Industrial Sector

cycle diagram.

EPA is aware of the use of raw chrysotile asbestos in the chlor-alkali industry and the use of asbestoscontaining sheet gaskets in the manufacture of titanium dioxide.

Diaphragms in Chlor-alkali Industry

The chlor-alkali industry imports raw chrysotile asbestos for use in semipermeable diaphragms, which separate the anode from the cathode chemicals in the production of chlorine and sodium hydroxide (caustic soda) (<u>USGS, 2017</u>). During a meeting with EPA in January 2017, industry representatives stated that in the United States, there are three companies who own a total of 15 chlor-alkali plants that continue to fabricate and use chrysotile-containing semipermeable diaphragms onsite.

EPA conducted a site visit of two chlor-alkali plants in March 2017 and observed the methods described at the January industry meeting. EPA also learned about the automated process wherein raw imported asbestos is processed and diaphragms are constructed. EPA will further evaluate how representative the processes witnessed at these two facilities are of processes at other plants.

Sheet Gaskets

During the public comment period, one chemical production company notified EPA of the current use of imported gaskets from China (Comment ID <u>EPA-HQ-OPPT-2016-0736-0067</u>).

These sheet gaskets are composed of 80% (minimum) chrysotile asbestos, encapsulated in Styrene Butadiene Rubber, and used to create tight chemical containment seals during the production of titanium dioxide.

Evidence of Use

Asbestos Containing Products for Commercial and Consumer Use

EPA found limited evidence of asbestos-containing products currently produced in the United States. In the <u>Preliminary Information on Manufacturing, Processing, Distribution, Use, and</u> <u>Disposal: Asbestos</u> (Docket: <u>EPA-HQ-OPPT-2016-0736-0005</u>), Table 1 provides a "List of Asbestos-Containing Products Currently Available for Purchase on the internet." Products available from several online retailers and distributers include brake blocks, aftermarket friction products, roof and non-roof coatings, and gaskets, most of which are imported. No public comments were received regarding these uses.

Reasonably Foreseen Use

Cement, textiles, and articles not specified are potentially fabricated or imported into the United States. These products fall into categories that were identified by USGS as having been reported to U.S. Customs and Border Protection as being imported into the United States in 2016. No public comments were received regarding these reasonably foreseen uses.

Legacy Use – Excluded from Scope of the Risk Evaluation

EPA interprets the mandates under section 6(a)-(b) to conduct risk assessments and any corresponding risk management to focus on current and prospective uses, for which manufacture, processing, or distribution in commerce is intended, known or reasonably foreseen, rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context [TSCA section 6(b)(4)(B)]. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. Consistent with this rationale, EPA has excluded certain uses from the scope of the risk evaluation, as identified below.

As part of scoping, EPA identified uses including pre-existing materials currently in place within buildings (e.g., insulation materials, flooring, etc.) and also within pre-existing non-building equipment and vehicles (e.g., brakes, gaskets, other friction products, etc.). Many asbestos products fall into this category. These materials were installed in the past, and there is no current manufacturing, processing, or distribution for these uses. EPA received no public comments providing information that manufacturing, processing, or distribution of these uses is on-going. Legacy uses of asbestos excluded from the scope of the risk evaluation include:

- Asbestos arc chutes
- Asbestos packings
- Asbestos pipeline wrap
- Asbestos protective clothing
- Asbestos separators in fuel cells and batteries
- Asbestos-cement flat sheet
- Asbestos-cement pipe and fittings
- Asbestos-cement shingles

- Asbestos-reinforced plastics
- Automatic transmission friction components
- Beater-add gaskets
- Clutch facings
- Corrugated asbestos-cement sheet
- Extruded sealant tape
- Filler for acetylene cylinders
- High-grade electrical paper
- Millboard
- Missile liner
- Roofing felt
- Vinyl-asbestos floor tile

The manufacture, processing, and distribution for a number of additional uses of asbestos were also banned by rule under TSCA in 1989 as part of the *Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions; Final Rule* (40 CFR Part 763) (also known as Asbestos Ban and Phase-out Rule (Remanded), 1989). The uses of asbestos covered by the ban and thus excluded from the scope of the risk evaluation include:

- Corrugated paper
- Rollboard
- Commercial paper
- Specialty paper
- Flooring felt
- New uses

Another legacy use not included in the scope of this evaluation is Libby Amphibole asbestos, which is a mixture of several mineral fibers such as winchite, richterite, and tremolite found in vermiculite ore near Libby, MT. Although vermiculite contaminated with the Libby Amphibole remains in buildings as an insulating material and therefore presents the potential for human exposure, vermiculite containing the Libby Amphibole is no longer manufactured or processed for use in the United States and therefore is not considered a condition of asbestos use for the purpose of risk evaluation under TSCA.

2.3 Exposures

For TSCA exposure assessments, EPA expects to evaluate exposures and releases to the environment resulting from the conditions of use applicable to asbestos. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including potentially exposed or susceptible subpopulations and ecological receptors. EPA will take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to the chemical substance.

2.3.1 Fate and Transport

Environmental fate includes both transport and transformation processes. Environmental transport is the movement of the chemical within and between environmental media. Transformation occurs

through the degradation or reaction of the chemical with other species in the environment. Hence, knowledge of the environmental fate of the chemical informs the determination of the specific exposure pathways and potential human and environmental receptors EPA expects to consider in the risk evaluation.

EPA has identified and considered the following environmental fate data in developing the scope for asbestos: <u>WHO (2014)</u>, <u>IARC (2012)</u> and <u>ATSDR (2001)</u>.

Asbestos fibers are largely chemically and biologically inert under environmental conditions. They may undergo minor physical changes, such as changes in fiber length or leaching of surface minerals, but do not degrade, react or dissolve to any appreciable extent in the environment (<u>IARC, 2012</u>; <u>ATSDR, 2001</u>). Asbestos fibers can be found in soils, sediments, lofted in air and windblown dust, surface water, ground water and biota (<u>IARC, 2012</u>; <u>ATSDR, 2001</u>). Small asbestos fibers (<1 µm) remain suspended in air and water for a significant period of time and may be transported over long distances (<u>ATSDR, 2001</u>). Chrysotile asbestos forms stable suspensions in water and degrades to some extent in acidic conditions, however the silicate structure remains intact (<u>IARC, 2012</u>). Asbestos fibers will eventually settle to sediments and soil, and movement therein may occur via erosion, runoff or mechanical resuspension (wind-blown dust, vehicle traffic, etc.) (<u>WHO, 2014</u>).

Asbestos may be released to the environment through industrial or commercial activities, such as the fabrication or processing of raw asbestos and asbestos containing products, or the lofting of friable asbestos during use, disturbance and disposal of asbestos containing products.

2.3.2 Releases to the Environment

Releases to the environment from conditions of use (e.g., industrial and commercial processes, commercial or consumer uses resulting in down-the-drain releases) are one component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

A source of information that EPA expects to consider in evaluating exposure are data reported under the Toxics Release Inventory (TRI) program. Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 rule, asbestos is a TRI-reportable substance effective January 1, 1987.

EPA's TRI data contains information about asbestos releases to air, water and land from industrial facilities in the United States. For TRI reporting, facilities are required to report releases or other waste management of only the friable form of asbestos, under the general CASRN 1332-21-4. TRI interprets "friable" under EPCRA Section 313, referring to the physical characteristic of being able to be crumbled, pulverized or reducible to a powder with hand pressure, and "asbestos" to include the six types of asbestos as defined under Title II of TSCA.

Table 2-3 provides production-related waste managed data (also referred to as waste managed) for friable asbestos reported by industrial facilities to the TRI program for 2015. Table 2-4 provides more detailed information on the quantities released to air or water or disposed of on land.

Number of Facilities	Recycling	Energy Recovery	Treatment	Releases ^{a,b}	Total Production Related Waste	
36	875	0	188,437	25,360,853	25,550,164	
Data source: <u>U.S. EPA (2017d)</u> . ^a Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points. ^b Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.						

In 2015, 36 facilities reported a total of approximately 25.6 million pounds of friable asbestos waste managed. Of this total, 875 pounds were recycled, zero pounds were recovered for energy, approximately 188,000 pounds were treated, and nearly 25.4 million pounds were released into the environment. Of these releases, the vast majority were released to land via Resource Conservation and Recovery Act (RCRA) Subtitle C landfills and all other land disposal methods (approximately 25.6 million pounds), whereas 314 pounds were released to air (stack and fugitive air emissions), and zero pounds were released to water (surface water discharges).

Table 2-4. Summary of Asbestos TRI Releases to the Environment in 2015 (lbs)

		Air Releases			Land Releases				
	Number of Facilities	Stack Air Releases	Fugitive Air Releases	Water Releases	Class I Under- ground Injection	RCRA Subtitle C Landfills	All other Land Disposal ^a	Other Releases ^a	Total Releases ^{b, c}
Subtotal		106	208		0	9,718,957	15,849,020		
Totals	36	314		0	25,567,977		0	25,568,292	

Data source: U.S. EPA (2017d).

^a Terminology used in these columns may not match the more detailed data element names used in the TRI public data and analysis access points. ^b These release quantities do include releases due to one-time events not associated with production such as remedial actions or earthquakes. ^c Counts release quantities once at final disposition, accounting for transfers to other TRI reporting facilities that ultimately dispose of the chemical waste.

While production-related waste managed shown in Table 2-3 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), release quantities shown in Table 2-4 include both production-related and non-routine quantities (TRI section 5 and 6 data). As a result, release quantities may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (<u>U.S. EPA, 2017d</u>).

From the most current and updated TRI data available using TRI Explorer, Table 2-5 shows that there has been a relatively large increase in total on-site and off-site disposal or other releases of friable asbestos since 2009 [EPA-HQ-OPPT-2016-0736-0005 (U.S. EPA, 2017b)]. From 2009 to 2015 (with 2015 being the most recent reporting year with available data), total on-site and off-site disposal or other releases of friable asbestos have risen from 8.8 million pounds to 25.6 million pounds, respectively. The vast majority of the total on-site and off-site disposal or other releases of friable asbestos are released to land (by means of RCRA Subtitle C landfills and other disposal landfills). As an example in 2015, 36 industrial facilities reported a total of 25.6 million pounds of on- and off-site disposal or other

releases of friable asbestos, in which 23.1 million pounds were released to land on-site and 2.4 million pounds were disposed of or otherwise released off-site. Release quantities to other media sources such as air and water are of much smaller magnitude. For the same 2015 reporting year, 314 pounds of friable asbestos were released to air (from both fugitive and point source air emissions), and zero pounds were released to water (from surface water discharges). It is important to note that quantities released from surface water discharges have been zero pounds since 2009. The industry accounting for the highest release quantities of friable asbestos is the hazardous waste sector, followed by the petroleum and other chemical and electric sectors.

Year	Total On- and Off-site Disposal or Other Releases (lbs)				
2009	8,757,577.45				
2010	13,015,169.28				
2011	12,492,732.86				
2012	16,018,091.60				
2013	16,641,975.26				
2014	17,521,650.31				
2015	25,568,291.58				

Table 2-5. Total On- and Off-site Disposal or Other Releases of Friable Asbestos (lbs) (2009-2015), based on TRI Data

Other sources of information provide evidence of releases of asbestos, including EPA effluent guidelines (EGs) promulgated under the Clean Water Act (CWA), National Emission Standards for Hazardous Air Pollutants (NESHAPs) promulgated under the Clean Air Act (CAA); or other EPA standards and regulations that set legal limits on the amount of asbestos that can be emitted to a particular media. EPA expects to consider these data in conducting the exposure assessment component of the risk evaluation for asbestos.

2.3.3 Presence in the Environment and Biota

Monitoring studies or a collection of relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Monitoring data were identified in EPA's data search for asbestos.

Presence of asbestos fibers in the air is highly variable, although there typically is a 10-fold higher concentration of asbestos in cities than in rural areas, with rural areas having 0.00001 fibers/mL of asbestos in air (<u>ATSDR, 2001</u>).

In 2001, the U.S. drinking water supplies generally had asbestos concentrations <1 million fibers per liter (MFL), although some locations may contain 10-300 MFL (<u>ATSDR, 2001</u>).

Although there is no information available on the effect of asbestos on the mortality of aquatic organisms, asbestos has been detected in many different freshwater fishes and mussels from bodies of water contaminated with asbestos (U.S. EPA, 1980b; Shugar, 1979).

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use, and disposal of asbestos can result in releases to the environment. EPA expects to consider exposures to the environment and ecological receptors that occur via the exposure pathways or media shown in Figure 2-6 in conducting the risk evaluation for asbestos.

2.3.5 Human Exposures

EPA expects to consider three broad categories of human exposures: occupational exposures, consumer exposures and general population exposures. Subpopulations within these exposure categories will also be considered as described herein.

The condition of asbestos is an important factor when considering the potential human pathways of exposure. Many of the existing and currently ongoing uses of asbestos products identified in the uses section (see Section 2.2.2) are classified as non-friable asbestos building materials; however, non-friable asbestos can be made friable due to physical and chemical wear and normal use of asbestos containing products. Exposures to asbestos can potentially occur via all routes; however, EPA anticipates that the most likely exposure route is inhalation for all of the subpopulations considered (IARC, 2012). However, certain conditions of use may also result in dermal exposure or oral exposure through incidental ingestion of asbestos residue on hand and body; or through fibers that deposit in the upper respiratory tract.

2.3.5.1 Occupational Exposures

EPA expects to consider worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2. In addition, EPA expects to consider exposure to occupational non-users, who do not directly handle the chemical but perform work in an area where the chemical is present. When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personal protective equipment have on occupational exposure levels.

EPA considers inhalation of asbestos fibers to be the most likely asbestos exposure pathway for workers and occupational non-users. Workers and occupational non-users may be exposed to asbestos through inhalation during a variety of conditions of use included in Section 2.2.2, such as fabrication of asbestos-containing diaphragms in the chlor-alkali industry and use of imported asbestos-containing products in industrial and commercial settings. Although less likely exposure routes, dermal and oral exposure is possible when asbestos containing products are used (e.g., friction products) and accidental ingestion due to eating and/or drinking during and immediately after use of asbestos containing products.

Workers and occupational non-users may be exposed to asbestos when performing activities associated with conditions of use described in Section 2.2 including, but not limited to:

- Unloading and transferring raw asbestos to and from storage containers to storage rooms, process equipment or glove boxes in the chlor-alkali industry;
- Using asbestos within process equipment (e.g., fabrication of diaphragms in the chlor-alkali industry);

- Cleaning and maintaining equipment in the chlor-alkali industry;
- Using imported and/or aftermarket asbestos-containing products (e.g., changing brakes on cars or oilfield equipment);
- Applying formulations and products containing asbestos onto substrates (e.g., applying coatings/adhesives/sealants containing asbestos);
- Handling, transporting and disposing waste containing asbestos in chlor-alkali plants.

Key data that inform occupational exposure assessment and which EPA expects to consider include: the OSHA Chemical Exposure Health Data (CEHD) and NIOSH Health Hazard Evaluation (HHE) program data. OSHA data are workplace monitoring data from OSHA inspections. The inspections can be random or targeted, or can be the result of a worker complaint. OSHA data can be obtained through the OSHA Integrated Management Information System (IMIS) at

<u>https://www.osha.gov/oshstats/index.html</u>. Table Apx B-1 in Appendix B provides a summary of industry sectors with asbestos personal monitoring air samples obtained from OSHA inspections conducted between 2011 and 2016. NIOSH HHEs are conducted at the request of employees, union officials, or employers and help inform potential hazards at the workplace. HHEs can be downloaded at <u>https://www.cdc.gov/niosh/hhe/</u>. During the problem formulation, EPA will review these data and evaluate their utility in the risk evaluation.

According to OSHA asbestos standards, the employee permissible exposure limit (PEL) is 0.1 fibers per cubic centimeter (f/cc) as an 8-hour, time-weighted average (TWA) and/or the excursion limit (1.0 f/cc as a 30-minute TWA) (Asbestos General Standard 29 CFR 1910).

Based on these activities, EPA expects to consider inhalation exposure to asbestos fibers and, although unlikely, dermal exposure, including skin contact with solids for workers and occupational non-users. EPA also expects to consider potential worker exposure via oral route such as from incidental ingestion of asbestos residue on hand/body; or through fibers, that deposit in the upper respiratory tract.

2.3.5.2 Consumer Exposures

Asbestos can be found in consumer products and/or commercial products that are readily available for public purchase at common retailers [EPA-HQ-OPPT-2016-0736-0005, Sections 3 and 4, (U.S. EPA, 2017b)] and can therefore result in exposures to consumers. Asbestos-containing consumer products and commercial products available for consumer purchase are provided in Section 2.2.2.

Exposures routes for consumers using asbestos-containing products may include inhalation of particulates and, although unlikely, dermal exposure to products and incidental ingestion due to eating and/or drinking during and immediately after product use. In addition, there is the possibility that clothing contaminated from asbestos through product use or manipulation could result in exposures to asbestos through all routes. While EPA anticipates inhalation of asbestos fibers being the most likely exposure route, certain conditions of use, such as installing or changing asbestos-containing brakes, may also result in dermal exposure.

EPA expects to consider inhalation, dermal and oral exposures to consumers and bystanders associated with the consumer use. These pathways will be further investigated during the problem formulation phase.

2.3.5.3 General Population Exposures

Wastewater/liquid wastes, solid wastes or air emissions of asbestos could result in potential pathways for oral, dermal or inhalation exposure to the general population. EPA will consider each media, route and pathway to estimate general population exposures.

Inhalation

Since asbestos minerals have been identified in the environment, the general population may be exposed to low levels of naturally occurring asbestos (<u>ATSDR, 2001</u>). The general population also may be exposed to releases to the atmosphere during disposal of currently used asbestos containing materials (<u>ATSDR, 2001</u>). Asbestos fibers may also be potentially released during processing or use of asbestos in industry (chlor-alkali) and use of imported asbestos containing products (see Section 2.3.2 and the public docket <u>EPA-HQ-OPPT-2016-0736</u>). In addition, there is the possibility that asbestos-contaminated clothing through product use or manipulation could result in exposures to asbestos.

Based on these potential sources and pathways of exposure, EPA expects to consider inhalation exposures of the general population to air containing asbestos in air that may result from the conditions of use of asbestos.

Oral

The general population may ingest asbestos via contaminated drinking water and contaminated soil. Asbestos does not dissolve in water, but fibers can enter water by being eroded from waste asbestos, from asbestos-containing cement pipes used to carry drinking water (<u>ATSDR, 2001</u>), or from potential industrial releases to water. Asbestos-contaminated soil and dust is a possible pathway of exposure for the general population through intentional soil ingestion or through hand-to-mouth activities in children (<u>ATSDR, 2001</u>).

Based on these potential sources and pathways of exposure, EPA expects to consider oral exposures to the general population that may result from the conditions of use of asbestos.

Dermal

Although it is unlikely, dermal contact to the general population may occur from direct contact to asbestos or indirect exposure to asbestos contaminated dust or soil from asbestos building materials.

A recent article has reported that the annual number of malignant mesothelioma deaths in the United States is increasing, particularly among persons aged ≥85 years, most likely representing exposure from many years ago (Mazurek et al., 2017). However, although malignant mesothelioma deaths decreased in persons aged 35–64 years, the continuing occurrence of mesothelioma deaths among persons aged <55 years suggests ongoing occupational and environmental exposures to asbestos fibers and other causative elongated mineral particles (EMPs) (Mazurek et al., 2017).

Based on these potential sources and pathways of exposure, EPA expects to consider dermal exposures to the general population that may result from the conditions of use of asbestos.

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation

identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers or the elderly."

In this section, EPA addresses the potentially exposed or susceptible subpopulations identified as relevant based on greater exposure. EPA will address the subpopulations identified as relevant based on greater susceptibility in the hazard section.

Of the human receptors identified in the previous sections, EPA identifies the following as potentially exposed or susceptible subpopulations due to their *greater exposure* that EPA expects to consider in the risk evaluation:

- Workers and occupational non-users.
- Consumers and bystanders associated with consumer use. Asbestos has been identified as being used in products available to consumers; however, only some individuals within the general population may use these products. Therefore, those who do use these products are a potentially exposed or susceptible subpopulation due to greater exposure.
- Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, use or disposal sites).

In developing exposure scenarios, EPA will evaluate available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006).

The population most likely to have high exposure to asbestos are workers who come into contact with asbestos while on the job (<u>ATSDR, 2001</u>). Other groups who may experience greater exposures may include:

- Fire fighters may also be exposed to asbestos remaining in building materials, particularly during the overhaul phase, during or after fighting a fire (<u>EPA-HQ-OPPT-2016-0736</u>) (<u>Pukkala et al., 2014</u>; <u>Markowitz et al., 1991</u>).
- People who live near an asbestos-related industry or site (<u>ATSDR, 2001</u>).
- People who may ingest asbestos in drinking water (<u>ATSDR, 2001</u>).

In summary, in the risk evaluation for asbestos, EPA expects to consider the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use. As described above, EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of asbestos, as described in *Strategy for Conducting Literature Searches for Asbestos: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0736). Based on initial screening, EPA expects to consider the hazards of asbestos identified in this scope document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios. This means that it is unlikely that every hazard identified in the scope will be considered for every exposure scenario.

2.4.1 Environmental Hazards

For scoping purposes, EPA consulted the following sources of environmental hazard data for asbestos: U.S. EPA (2014), WHO (2014), IARC (2012), ATSDR (2001), Shugar (1979), U.S. EPA (1980b). However, EPA also expects to consider other studies (*e.g.*, more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for Asbestos (*Asbestos Bibliography (CASRN 1332-21-4): Supplemental File for the TSCA Scope Document* <u>EPA-HQ-OPPT-2016-0736</u>). It should be noted that the data are limited.

EPA expects to consider the hazards of asbestos to aquatic organisms including fish, aquatic invertebrates and aquatic plants potentially exposed under acute and chronic exposure conditions. EPA expects to consider the hazards of asbestos to terrestrial organisms including soil invertebrates potentially exposed under acute and chronic exposure conditions.

According to U.S. EPA (1980b), no freshwater and saltwater organisms have been tested with any asbestiform mineral and no statement can be made concerning acute or chronic toxicity.

2.4.2 Human Health Hazards

Asbestos has an existing EPA IRIS Assessment and an ATSDR Toxicological Profile; hence, many of the hazards of asbestos have been previously compiled and systematically reviewed. EPA has relied heavily on these comprehensive reviews in preparing this scope. EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for asbestos (*Asbestos (CASRN 1332-21-4*) *Bibliography: Supplemental File for the TSCA Scope Document, EPA-HQ-OPPT-2016-0736*). The preponderance of information in these assessments is based on human populations. EPA expects to consider all potential hazards associated with asbestos. Based on reasonably available information, the following are the hazards that have been identified in previous government documents and that EPA currently expects will likely be the focus of its analysis.

2.4.2.1 Non-Cancer Hazards

Inhalation is considered to be the primary route of asbestos exposure and will be the main focus of this section. Data on non-cancer health effects from oral exposures to asbestos are limited and inconsistent, and studies in animals provide evidence that oral asbestos exposures result in little or no risk for non-carcinogenic effects (ATSDR, 2001). The only reported adverse health effect related to dermal exposure of asbestos was the formation of "warts" or "corns" on the hand due to the

penetration of fibers in to the skin, which disappeared upon removal of the asbestos fibers (<u>ATSDR</u>, <u>2001</u>).

Respiratory System

Following inhalation exposure to asbestos, the following non-cancer adverse effects have been observed in humans: asbestosis (fibrotic lung disease), diffuse pleural thickening, localized pleural thickening (pleural plaques), pleuritis (acute pleural effusion, chronic pleuritic pain) and a decrease in pulmonary function (U.S. EPA, 2014; ATSDR, 2001). In addition, increased mortality from cardiovascular diseases in workers exposed to asbestos have been reported, as well as cor pulmonale, a condition arising from pulmonary hypertension and compensatory hypertrophy of the right ventricle, have been associated with severe cases of asbestosis (ATSDR, 2001). The most significant non-cancer effect in animals was lung fibrosis.

Immunotoxicity

Several studies have demonstrated depressed cell-mediated immunity in workers exhibiting radiological evidence of asbestosis. Increased natural killer cell numbers with impaired cytotoxic potency, alterations in lymphocytes and leukocytes, and increased levels of Immunoglobulin A (IgA) and Immunoglobulin G (IgG) have been reported in asbestos-exposed individuals. Immunological aberrations were minor or absent in asbestos workers without clinical signs of asbestosis. Impaired immunity may contribute to an increased risk for cancer (<u>ATSDR, 2001</u>). Animal studies support adverse immunological effects being caused by asbestos exposure (<u>ATSDR, 2001</u>).

2.4.2.2 Genotoxicity and Cancer Hazards

There is evidence in in vitro, in vivo, human and animal studies that asbestos is genotoxic (<u>ATSDR</u>, <u>2001</u>).

Many authorities have established that there is causal association between asbestos and lung cancer and mesotheliomas (NTP, 2016; IARC, 2012; ATSDR, 2001; U.S. EPA, 1988; IARC, 1987, 1977) as well as a causal association between exposure to asbestos and cancer of the larynx and cancer of the ovary (IARC, 2012). There is also suggestive evidence of a positive association between asbestos and cancer of the pharynx (IARC, 2012; NRC, 2006), stomach (IARC, 2012; ATSDR, 2001) and colorectum (NTP, 2016; IARC, 2012; NRC, 2006; ATSDR, 2001; NRC, 1983; U.S. EPA, 1980a).

Increases in lung cancer mortality have been reported in both workers and residents exposed to various asbestos fiber types as well as fiber mixtures (<u>IARC, 2012</u>).

Mesotheliomas, tumors arising from the thin membranes that line the chest (thoracic) and abdominal cavities and surround internal organs, are relatively rare in the general population, but are often observed in populations of asbestos workers. All types of asbestos fibers have been reported to cause mesothelioma (<u>IARC, 2012</u>).

Mortality studies of asbestos workers have revealed increases in cancer mortality at one or more sites other than the lung, the pleura or the peritoneum. Cancer of the larynx and ovary and gastrointestinal cancers, such as colorectum, pharynx and stomach, have been observed in populations exposed to various types of asbestos (IARC, 2012; NRC, 2006). Some studies have also noted excess deaths from,

or reported cases of, cancers at other sites, such as the kidney and esophagus; however, the evidence is not consistent (<u>IARC, 2012</u>; <u>ATSDR, 2001</u>).

While there are some reports that asbestos in drinking water may lead to higher-than-average death rates from gastrointestinal cancers (<u>ATSDR, 2001</u>), no clear association has been reported between cancer risk and exposure to asbestos in drinking water (<u>NTP, 2016</u>; <u>IARC, 2012</u>).

2.4.2.3 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." In developing the hazard assessment, EPA will evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

Several assessments have identified populations that may potentially be susceptible to adverse health effects associated with asbestos exposure (NTP, 2016; U.S. EPA, 2014; IARC, 2012; ATSDR, 2001). Numerous potential factors may contribute to increased susceptibility to asbestos including age, pre-existing health conditions, genetic makeup and co-exposure to other substances (e.g., tobacco smoke). Individuals exposed at an earlier age might be more susceptible to health effects due to the long-term retention of asbestos fibers in the lung and long latency period for the onset of asbestos-induced respiratory diseases (ATSDR, 2001). Smoking can impair clearance of particles like asbestos fibers from the respiratory track (U.S. EPA, 2014). Smokers who are also exposed to asbestos have increased risk of developing lung cancer than non-smokers, suggesting a synergistic relationship between cigarette smoking and asbestos exposure (NTP, 2016). Individuals with genetic polymorphisms or preexisting respiratory conditions may also experience altered biological response to asbestos) (U.S. EPA, 2014; IARC, 2012).

2.5 Initial Conceptual Models

A conceptual model describes the actual or predicted relationships between the chemical substance and receptors, either human or environmental. These conceptual models are integrated depictions of the conditions of use, exposures (pathways and routes), hazards and receptors. As part of the scope for asbestos, EPA developed three conceptual models, presented here.

2.5.1 Initial Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

Figure 2-4 presents the initial conceptual model for human receptors from industrial and commercial uses of asbestos. EPA expects that workers and occupational non-users may be exposed to asbestos via inhalation and oral routes, and possibly dermal. While EPA anticipates inhalation of asbestos fibers being the most likely exposure route, certain conditions of use, such as a mechanic changing asbestos-containing brakes, may also result in dermal exposure; hence dermal exposures will be considered

further in problem formulation. Oral exposure to asbestos may occur through incidental ingestion of asbestos residue on hand and body; or through fibers that deposit in the upper respiratory tract and are eventually swallowed. When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

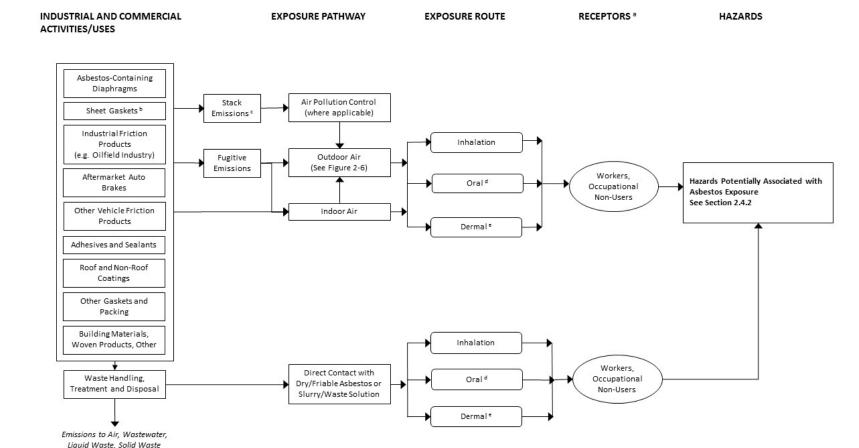


Figure 2-4. Initial Asbestos Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of asbestos.

^a Receptors include potentially exposed or susceptible subpopulations.

^b Sheet gaskets were identified during public comment period.

(See Figure 2-6)

^c Stack air emissions are emissions that occur through stacks, confined vents, ducts, pipes or other confined air streams. Fugitive air emissions are those that are not stack emissions and include fugitive equipment leaks from valves, pump seals, flanges, compressors, sampling connections, open-ended lines; evaporative losses from surface impoundment and spills; and releases from building ventilation systems.

^d Oral exposure may occur through incidental ingestion of asbestos residue on hand/body or through deposits in the upper respiratory tract that are eventually swallowed.

^e Dermal exposure is unlikely due to glove use in the work place.

2.5.2 Initial Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

Figure 2-5 presents the initial conceptual model for human populations from consumer uses of asbestos. It should be noted that asbestos-containing commercial products may be readily available to consumers.

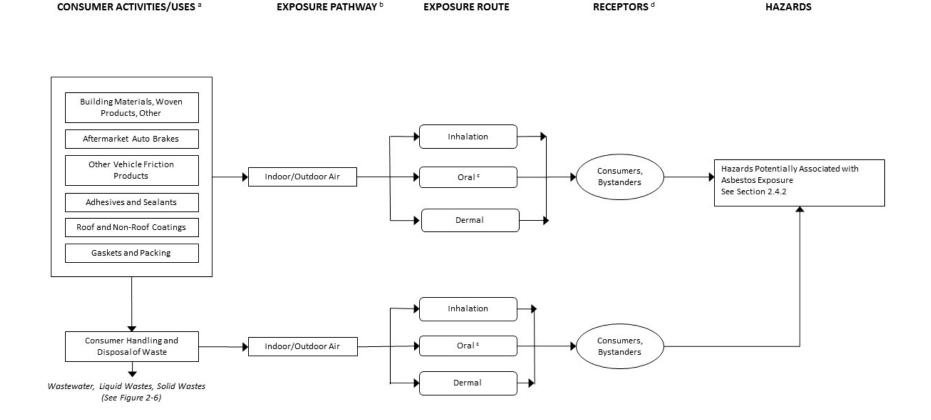


Figure 2-5. Initial Asbestos Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of asbestos.

^a Products may be used in both commercial and consumer applications.

^b Many products may be used during indoor and outdoor activities.

^c Oral exposure may occur through incidental ingestion of asbestos residue on hand/body or through deposits in the upper respiratory tract that are eventually swallowed.

^d Receptors include potentially exposed or susceptible subpopulations.

2.5.3 Initial Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

Figure 2-6 illustrates potential exposure pathways for human and ecological receptors from environmental releases and waste disposal activities.

The initial conceptual models include all possible exposure pathways and routes associated with environmental releases of asbestos. For the risk evaluation, EPA will consider actual releases, environmental fate and transport and influence of other regulations when quantifying exposures.

For some populations (e.g., those living near abandoned mines or landfills that accept asbestoscontaining waste), there is a potential inhalation exposure pathway. Populations living near chlor-alkali (industrial) facilities using asbestos, could experience asbestos exposure via inhalation of outdoor air. Exposure to asbestos-contaminated water, sediment and soil for aquatic and terrestrial life is possible; hence, EPA will evaluate the significance during problem formulation.

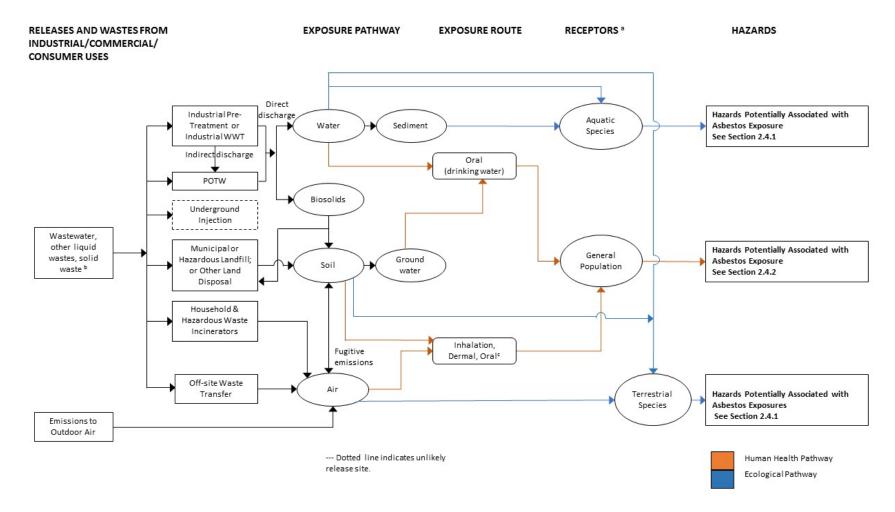


Figure 2-6. Initial Asbestos Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human and environmental receptors from environmental releases and wastes of asbestos.

^a Receptors include potentially exposed or susceptible subpopulations.

^b Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

^c Oral exposure may occur through incidental ingestion of asbestos residue on hand/body, or through deposits in the upper respiratory tract that are eventually swallowed.

2.6 Initial Analysis Plan

The initial analysis plan will be used to develop the eventual problem formulation and final analysis plan for the risk evaluation. While EPA has conducted a search for readily available data and information from public sources as described in Section 1.3, EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for refining conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations.

The analysis plan outlined here is based on the conditions of use of chemical name, as described in Section 2.2 of this scope. The analysis plan may be refined as EPA proceeds with the systematic review of the information in the *Asbestos (CASRN 1332-21-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0736). EPA will be evaluating the weight of the scientific evidence for both hazard and exposure. Consistent with this approach, EPA will also use a systematic review approach. As such, EPA will use explicit, pre-specified criteria and approaches to identify, select, assess, and summarize the findings of studies. This approach will help to ensure that the review is complete, unbiased, reproducible and transparent.

2.6.1 Exposure

2.6.1.1 Environmental Releases

EPA expects to consider and analyze releases to environmental media as follows:

- 1) Review reasonably available published literature or information on processes and activities associated with the conditions of use to evaluate the types of releases and wastes generated.
- 2) Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data collected under the TRI and National Emissions Inventory [NEI] programs).
- 3) Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses, volatility, chemical and physical properties.
- 4) Understand and consider regulatory limits that may inform estimation of environmental releases.
- 5) Review and determine applicability of Organisation for Economic Co-operation and Development (OECD) Emission Scenario Documents and EPA Generic Scenarios for estimation of environmental releases.
- 6) Evaluate the weight of the evidence of environmental release data.
- 7) Map or group each condition(s) of use to a release assessment scenario.

2.6.1.2 Environmental Fate

EPA expects to consider and analyze fate and transport in environmental media as follows:

- 1) Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search.
- 2) Using measured data and/or modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.
- 3) Evaluate the weight of the evidence of environmental fate data.

2.6.1.3 Environmental Exposures

EPA expects to consider the following in developing its Environmental Exposure Assessment of asbestos:

- 1) Review reasonably available environmental and biological monitoring data for all media relevant to environmental exposure.
- 2) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data. Available exposure models will be evaluated and considered alongside available monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: release into the media of interest, fate and transport and characteristics of the environment.
- 3) Review reasonably available biomonitoring data. Consider whether these monitoring data could be used to compare with species or taxa-specific toxicological benchmarks.
- 4) Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation. Review and characterize the spatial and temporal variability, to extent data are available, and characterize exposed aquatic and terrestrial populations.
- 5) Evaluate the weight of evidence of environmental occurrence data and modeled estimates.
- 6) Map or group each condition(s) of use to environmental assessment scenario(s).

2.6.1.4 Occupational Exposures

EPA expects to consider and analyze both worker and occupational non-user exposures as follows:

- Review reasonably available exposure monitoring data for specific condition(s) of use. Exposure data to be reviewed may include workplace monitoring data collected by government agencies such as OSHA and NIOSH, and monitoring data found in published literature (e.g., personal exposure monitoring data (direct measurements) and area monitoring data (indirect measurements).
- 2) Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to asbestos.
- 3) For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.
- 4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.
- 5) Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios.
- 6) Evaluate the weight of the evidence of occupational exposure data.
- 7) Map or group each condition of use to occupational exposure assessment scenario(s).

2.6.1.5 Consumer Exposures

EPA expects to consider and analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

- 1) Review reasonably available consumer product-specific exposure data related to consumer uses/exposures.
- 2) Evaluate the weight of the evidence of consumer exposure data.
- 3) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.

- 4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
- 5) Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with those reported in monitoring data.
- 6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further refined.
- 7) Map or group each condition of use to consumer exposure assessment scenario(s).

2.6.1.6 General Population

EPA expects to consider and analyze general population exposures as follows:

- 1) Review reasonably available environmental and biological monitoring data for media to which general population exposures are expected.
- 2) For exposure pathways where data are not available, review existing exposure models that may be applicable in estimating exposure levels.
- 3) Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling.
- 4) Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.
- 5) Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.
- 6) Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further defined.
- 7) Evaluate the weight of the evidence of general population exposure data.
- 8) Map or group each condition of use to general population exposure assessment scenario(s).

2.6.2 Hazards (Effects)

2.6.2.1 Environmental Hazards

EPA expects to consider and analyze environmental hazards of asbestos as follows:

- 1) Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies).
- 2) Conduct hazard identification (the qualitative process of identifying acute and chronic endpoints) and concentration-response assessment (the quantitative relationship between hazard and exposure) for all identified environmental hazard endpoints.
- 3) Derive concentrations of concern (COC) for all identified ecological endpoints.
- 4) Evaluate the weight of the evidence of environmental hazard data.
- 5) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments.

2.6.2.2 Human Health Hazards

EPA expects to consider and analyze human health hazards as follows:

- 1) Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).
- 2) In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.
- 3) Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for appropriate human health hazard endpoints.
- 4) Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.
- 5) Evaluate the weight of the evidence of human health hazard data.
- 6) Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.

2.6.3 Risk Characterization

Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. EPA will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined in EPA's *Risk Characterization Policy*, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk assessment being characterized. The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (TCCR) *Handbook* (U.S. EPA, 2000). EPA will also present information in this section consistent with approaches described in the Risk Evaluation Framework Rule.

REFERENCES

- Addison, WE; Neal, GH; White, AD. (1966). Amphi-boles—Part IV—Surface properties of amosite and crocido-lite. J Am Chem Soc A: 79-81.
- ATSDR (Agency for Toxic Substances and Disease Registry). (2001). Toxicological profile for asbestos (update). (CIS/03/00067). Atlanta, Georgia: U.S. Department Of Health And Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry.
- <u>Badollet, MS.</u> (1951). Asbestos, a mineral of unparalleled properties. Transactions of the Canadian Institute of Mining & Metallurgy 54: 151-160.
- <u>Cal/EPA</u> (California Environmental Protection Agency). (2003). Public health goal for Asbestos in drinking water. Sacramento, CA: Office of Environmental Health Hazard Assessment, California Environmental Protection Agency.

https://oehha.ca.gov/media/downloads/water/chemicals/phg/ph4asbestos92603 0.pdf

- <u>Flanagan, DM.</u> (2016). 2015 Minerals yearbook. Asbestos [advance release]. Reston, VA: U.S. Geological Survey. <u>https://minerals.usgs.gov/minerals/pubs/commodity/asbestos/myb1-2015-asbes.pdf</u>
- <u>Hodgson, AA.</u> (1986). Scientific advances in asbestos, 1967 to 1985. Crowthorne, United Kingdom: Anjalena Publications Ltd.
- <u>IARC</u> (International Agency for Research on Cancer). (1977). IARC monographs on the evaluation of carcinogenic risk of chemicals to man: Asbestos. Lyon, France: World Health Organization. <u>http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono14.pdf</u>
- <u>IARC</u> (International Agency for Research on Cancer). (1987). Asbestos and certain asbestos compounds [IARC Monograph]. In IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (pp. 106-116). Lyon, France. <u>http://monographs.iarc.fr/ENG/Monographs/suppl7/index.php</u>
- <u>IARC</u> (International Agency for Research on Cancer). (2012). A review of human carcinogens. Part C: Arsenic, metals, fibres, and dusts [IARC Monograph]. Lyon, France: World Health Organization. <u>http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C.pdf</u>
- Markowitz, SB; Garibaldi, K; Lilis, R; Landrigan, PJ. (1991). Asbestos exposure and fire fighting. Ann N Y Acad Sci 643: 573-577.
- Mazurek, JM; Syamlal, G; Wood, JM; Hendricks, SA; Weston, A. (2017). Malignant Mesothelioma Mortality - United States, 1999-2015. MMWR Morb Mortal Wkly Rep 66: 214-218. <u>http://dx.doi.org/10.15585/mmwr.mm6608a3</u>
- NIOSH (National Institute for Occupational Safety and Health). (2011). Asbestos fibers and other elongate mineral particles: State of the science and roadmap for research. Current Intelligence Bulletin 62. (Atlanta, GA). National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.
- <u>NRC</u> (National Research Council). (1983). Drinking Water And Health. Washington, DC: Safe Drinking Water Committee, Board on Toxicology and Environmental Health Hazards, National Research Council, National Academies Press. <u>http://dx.doi.org/10.17226/326</u>
- <u>NRC</u> (National Research Council). (2006). Asbestos: Selected cancers. Institute of Medicine (US) Committee on Asbestos: Selected Health Effects. Washington, DC: The National Academies Press.
- <u>NTP</u> (National Toxicology Program). (2016). 14th Report On Carcinogens. Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service. <u>https://ntp.niehs.nih.gov/pubhealth/roc/index-1.html</u>

- Pukkala, E; Martinsen, JI; Weiderpass, E; Kjaerheim, K; Lynge, E; Tryggvadottir, L; Sparén, P; Demers,
 PA. (2014). Cancer incidence among firefighters: 45 years of follow-up in five Nordic countries.
 Occup Environ Med 71: 398-404. <u>http://dx.doi.org/10.1136/oemed-2013-101803</u>
- Shugar, S. (1979). Effects of asbestos in the Canadian environment. Volume 40 of Canada NRC Environmental Quality Report. (NRCC No 16452). Ottawa, Canada: National Research Council of Canada.
- U.S. EPA (U.S. Environmental Protection Agency). Asbestos national emissions standard for hazardous air pollutants: Waste disposal and transportation. <u>https://www.epa.gov/asbestos/asbestos-national-emissions-standard-hazardous-air-pollutants-neshap#was</u>
- U.S. EPA (U.S. Environmental Protection Agency). (1980a). Ambient water quality criteria for asbestos [EPA Report]. (EPA/440/5-80/022). Washington, DC. http://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=00001LP6.txt
- U.S. EPA (U.S. Environmental Protection Agency). (1980b). Water Quality Criteria Documents. In Federal Register (pp. 79318-79379).
- U.S. EPA (U.S. Environmental Protection Agency). (1985). Drinking water criteria document for asbestos. (600/X-84/199-1). Cincinnati, OH: Environmental Criteria and Assessment Office, U.S. Environmental Protection Agency.
- U.S. EPA (U.S. Environmental Protection Agency). (1988). IRIS summary for asbestos (CASRN 1332-21-4). Washington, DC: Integrated Risk Information System. http://www.epa.gov/iris/subst/0371.htm
- U.S. EPA (U.S. Environmental Protection Agency). (1989). Regulatory impact analysis of controls on asbestos and asbestos products: Final report: Volume III. (5601989ICF001). Washington, DC: Office of Toxic Substances, U.S. Environmental Protection Agency.
- U.S. EPA (U.S. Environmental Protection Agency). (2000). Science policy council handbook: Risk characterization (pp. 1-189). (EPA/100/B-00/002). Washington, D.C.: U.S. Environmental Protection Agency, Science Policy Council. <u>https://www.epa.gov/risk/risk-characterizationhandbook</u>
- U.S. EPA (U.S. Environmental Protection Agency). (2006). A framework for assessing health risk of environmental exposures to children (pp. 1-145). (EPA/600/R-05/093F). Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. <u>http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363</u>
- U.S. EPA (U.S. Environmental Protection Agency). (2011). Exposure factors handbook: 2011 edition (final) [EPA Report]. (EPA/600/R-090/052F). Washington, DC: U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. <u>http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=236252</u>
- U.S. EPA (U.S. Environmental Protection Agency). (2014). Toxicological review of libby amphibole asbestos. In Support of Summary Information on the Integrated Risk Information System (IRIS). (EPA/635/R-11/002F). Washington, DC: Integrated Risk Information System, National Center for Environmental Assessment, Office of Research and Development.

https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/1026tr.pdf

- U.S. EPA (U.S. Environmental Protection Agency). (2016a). Public database 2016 chemical data reporting (May 2017 release). Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics. Retrieved from <u>https://www.epa.gov/chemical-data-reporting</u>
- <u>U.S. EPA</u> (U.S. Environmental Protection Agency). (2016b). TSCA Chemical Data Reporting. Fact Sheet: Importers. Washington, DC: Office of Pollution Prevention and Toxics.

https://www.epa.gov/sites/production/files/2015-12/documents/cdr fact sheet importers final dec2015 0.pdf

- U.S. EPA (U.S. Environmental Protection Agency). (2017a). How to report under chemical data reporting. <u>https://www.epa.gov/chemical-data-reporting/how-report-under-chemical-data-reporting</u>
- U.S. EPA (U.S. Environmental Protection Agency). (2017b). Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Asbestos. Support document for Docket EPA-HQ-OPPT-2016-0736. Washington, DC: Office of Chemical Safety and Pollution Prevention. <u>https://www.epa.gov/sites/production/files/2017-02/documents/asbestos.pdf</u>
- U.S. EPA (U.S. Environmental Protection Agency). (2017c). Public meeting on risk evaluation scoping efforts under TSCA for 10 chemical substances - Background material & presentation [Website]. <u>https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/public-meeting-risk-</u> evaluation-scoping-efforts-under-0
- <u>U.S. EPA</u> (U.S. Environmental Protection Agency). (2017d). Toxics Release Inventory (TRI). Retrieved from <u>https://www.epa.gov/toxics-release-inventory-tri-program/tri-data-and-tools</u>
- <u>USGS</u> (U.S. Geological Survey). (2016). Mineral commodity summaries: Asbestos. <u>https://minerals.usgs.gov/minerals/pubs/commodity/asbestos/mcs-2016-asbes.pdf</u>
- <u>USGS</u> (U.S. Geological Survey). (2017). Mineral Commodity Summaries 2017. Washington, DC: U.S. Department of the Interior. <u>https://minerals.usgs.gov/minerals/pubs/mcs/2017/mcs2017.pdf</u>
- <u>Virta, R.</u> (2011). Asbestos. Kirk-Othmer Encyclopedia of Chemical Technology. [online]: John Wiley & Sons. <u>http://dx.doi.org/10.1002/0471238961.0119020510151209.a01.pub3</u>
- <u>WHO</u> (World Health Organization). (2014). Chrysotile asbestos. Geneva, Switzerland. <u>http://www.who.int/ipcs/assessment/public_health/chrysotile_asbestos_summary.pdf</u>

Appendix A REGULATORY HISTORY

A-1 Federal Laws and Regulations

Asbestos is subject to federal and State laws and regulations in the United States.

The federal laws and regulations applicable to asbestos are listed along with the regulating agencies below. States also regulate asbestos through state laws and regulations, which are also listed within this section.

Toxics Substances Control Act (TSCA), 1976

15 U.S.C. §2601 et seq

The Toxic Substances Control Act of 1976 provides EPA with authority to require reporting, recordkeeping and testing requirements, and restrictions relating to chemical substances and/or mixtures. Certain substances are generally excluded from TSCA, including, among others, food, drugs, cosmetics and pesticides.

TSCA addresses the production, importation, use and disposal of specific chemicals including <u>polychlorinated biphenyls (PCBs)</u>, <u>asbestos</u>, <u>radon</u> and <u>lead-based paint</u>. The Frank R. Lautenberg Chemical Safety for the 21st Century Act updated TSCA in 2016 <u>https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act</u>.

Asbestos Hazard Emergency Response Act (AHERA), 1986

TSCA Subchapter II: Asbestos Hazard Emergency Response 15 U.S.C. §2641-2656

- Defines asbestos as the asbestiform varieties of chrysotile (serpentine), crocidolite (riebeckite), amosite (cummingtonite-grunerite), anthophyllite, tremolite or actinolite.
- Requires schools to inspect for asbestos and submit asbestos management plans to appropriate state; management plans must be publicly available and inspectors must be trained and accredited.
- Tasked EPA to develop an asbestos Model Accreditation Plan (MAP) for states to establish training requirements for asbestos professionals who do work in schools and public and commercial buildings.

Asbestos-Containing Materials in Schools Rule (per AHERA), 1987

40 CFR Part 763, Subpart E

 Requires local education agencies to use trained and accredited asbestos professionals to identify and manage asbestos-containing building material and perform asbestos response actions (abatements).

1989 Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions; Final Rule (also known as Asbestos Ban and Phase-out Rule (Remanded), 1989) <u>40 CFR Part 763, Subpart I</u>

- EPA issued a final rule under Section 6 of Toxic Substances Control Act (TSCA) banning most asbestos-containing products.
- In 1991, this rule was vacated and remanded by the Fifth Circuit Court of Appeals. As a result, most of the original ban on the manufacture, importation, processing or distribution in commerce for the majority of the asbestos-containing products originally covered in the 1989 final rule was overturned. The following products remain banned by rule under the Toxic Substances Control Act (TSCA):
 - o Corrugated paper
 - o Rollboard
 - o Commercial paper
 - o Specialty paper
 - o Flooring felt

In addition, the regulation continues to ban the use of asbestos in products that have not historically contained asbestos, otherwise referred to as "new uses" of asbestos.

Other EPA Regulations:

Asbestos Worker Protection Rule, 2000 40 CFR Part 763, Subpart G

• Extends OSHA standards to public employees in states that do not have an OSHA approved worker protection plan (about half the country).

Asbestos Information Act, 1988

<u>15 U.S.C. §2607(f)</u>

• Helped to provide transparency and identify the companies making certain types of asbestoscontaining products by requiring manufacturers to report production to the EPA.

Asbestos School Hazard Abatement Act (ASHAA), 1984 and Asbestos School Hazard Abatement Reauthorization Act (ASHARA), 1990

20 U.S.C. 4011 et seq. and Docket ID: OPTS-62048E; FRL-3269-8

• Provided funding for and established an asbestos abatement loan and grant program for school districts and ASHARA further tasked EPA to update the MAP asbestos worker training requirements.

Emergency Planning and Community Right-to-Know Act (EPCRA), 1986 42 U.S.C. Chapter 116

- Under Section 313, Toxics Release Inventory (TRI), requires reporting of environmental releases of friable asbestos at a concentration level of 0.1%.
- Friable asbestos is designated as a hazardous substance subject to an Emergency Release Notification at 40 CFR §355.40 with a reportable quantity of 1 pound.

Clean Air Act, 1970

42 U.S.C. §7401 et seq.

• Asbestos is identified as a Hazardous Air Pollutant.

Asbestos National Emission Standard for Hazardous Air Pollutants (NESHAP), 1973 40 CFR Part 61, Subpart M of the Clean Air Act

- Specifies demolition and renovation work practices involving asbestos.
- Requires building owner/operator notify appropriate state agency of potential asbestos hazard prior to demolition/renovation.
- Banned spray-applied surfacing asbestos-containing material for fireproofing/insulating purposes in certain applications.
- Requires that asbestos-containing waste material from regulated activities be sealed in a leaktight container while wet, labeled, and disposed of properly in a landfill qualified to receive asbestos waste.

Clean Water Act (CWA), 1972

33 U.S.C. §1251 et seq

- Toxic pollutant subject to effluent limitations per Section 1317.
- Recommend ambient water quality criteria for asbestos be the same as the drinking water Maximum Contaminant Levels of 7 million fibers/L (longer than 10um) (EPA, 2002).

Safe Drinking Water Act (SDWA), 1974

42 U.S.C. §300f

• Asbestos Maximum Contaminant Level Goals (MCLG) 7 million fibers/L (longer than 10um).

Resource Conservation and Recovery Act (RCRA), 1976

42 U.S.C. §6901 et seq.

40 CFR 239-282

• Asbestos is subject to solid waste regulation when discarded; NOT considered a hazardous waste.

Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), 1980 42 U.S.C. §9601 et seq.

40 CFR Part 302.4 - Designation of Hazardous Substances and Reportable Quantities

- 13 Superfund sites containing asbestos, nine of which are on the National Priorities List (NPL)
- Reportable quantity of friable asbestos is one pound.

Other Federal Agencies:

Occupational Safety and Health Administration (OSHA):

Public Law 91-596 Occupational Safety and Health Act, 1970

Employee permissible exposure limit (PEL) is 0.1 fibers per cubic centimeter (f/cc) as an 8-hour, timeweighted average (TWA) and/or the excursion limit (1.0 f/cc as a 30-minute TWA).

- Asbestos General Standard 29 CFR 1910
- Asbestos Shipyard Standard 29 CFR 1915
- Asbestos Construction Standard 29 CFR 1926

Consumer Product Safety Commission (CPSC): Banned several consumer products. Federal Hazardous Substances Act (FHSA) <u>16 CFR 1500</u>

Food and Drug Administration (FDA): Prohibits the use of asbestos-containing filters in pharmaceutical manufacturing, processing and packing. <u>21 CFR 211.72</u>

Mine Safety and Health Administration (MSHA): follows OSHA's safety standards.

Surface Mines <u>30 CFR part 56, subpart D</u> Underground Mines <u>30 CFR part 57, subpart D</u> Non-regulatory information of note:

• NIOSH conducts related research and monitors asbestos exposure through workplace activities in an effort to reduce illness and ensure worker health and safety.

A-2 State Laws and Regulations

Pursuant to AHERA, states have adopted through state regulation the EPA's Model Accreditation Plan (MAP) for asbestos abatement professionals who do work in schools and public and commercial buildings. Some states have also applied to and received a waiver from EPA to oversee implementation of the Asbestos-Containing Materials in Schools Rule pursuant to AHERA. States also implement regulations pursuant to the Asbestos NESHAP regulations. While federal regulations set national asbestos safety standards, states have the authority to impose stricter regulations. Some states have regulations independent of the federal regulations. For example, California and Washington regulate products containing asbestos. Both prohibit use of more than 0.01% of asbestos in brake pads and require laboratory testing and labeling.

Below is a list of state regulations that are independent of the federal AHERA and NESHAP requirements that states implement. This may not be an exhaustive list.

California

<u>Asbestos</u> is listed on <u>California's Candidate Chemical List</u> as a carcinogen. Under <u>California's</u> <u>Propositions 65</u>, businesses are required to warn Californians of the presence and danger of <u>asbestos</u> in products, home, workplace and environment.

California Brake Friction Material Requirements (Effective 2017)

Division 4.5, California Code of Regulations, Title 22 Chapter 30

Sale of any motor vehicle brake friction materials containing more than 0.1% asbestiform fibers by weight is prohibited. All brake pads for sale in the state of California must be laboratory tested, certified and labeled by the manufacturer.

Massachusetts

Massachusetts Toxics Use Reduction Act (TURA)

Requires companies in Massachusetts to provide annual pollution reports and to evaluate and implement pollution prevention plans. Asbestos is included on the <u>Complete List of TURA Chemicals -</u> <u>March 2016</u>.

Minnesota

Toxic Free Kids Act <u>Minn. Stat. 2010 116.9401 – 116.9407</u> Asbestos is included on the <u>2016 Minnesota Chemicals of High Concern List</u> as a known carcinogen.

New Jersey

New Jersey Right to Know Hazardous Substances

The state of New Jersey identifies hazardous chemicals and products. Asbestos is listed as a known carcinogen and talc containing asbestos is identified on the Right to Know Hazardous Substances list.

Rhode Island

Rhode Island Air Resources – <u>Air Toxics Air Pollution Control Regulation No. 22</u> Establishes acceptable ambient air levels for asbestos.

Washington

Better Brakes Law (Effective 2015) <u>Chapter 70.285 RCW Brake Friction Material</u> Prohibits the sale of brake pads containing more than 0.1% asbestiform fibers (by weight) in the state of Washington and requires manufacturer certification and package/product labelling. <u>Requirement to Label Building Materials that Contain Asbestos (Effective 2014)</u> Requires product warning label on "any building material naturally containing more than 0.1% asbestos" and "any building material that has any amount of asbestos added to it." <u>http://www.ecy.wa.gov/programs/air/AOP_Permits/asbestos_label.html</u>

A-3 International Laws and Regulations

Asbestos is also regulated internationally. Nearly 60 nations have some sort of asbestos ban. The European Union (EU) will prohibit the use of asbestos in the chlor-alkali industry by 2025 (*Regulation* (EC) No 1907/2006 of the European Parliament and of the Council, 18 December 2006).

Canada has announced its plan to propose a rule to ban asbestos, to be published December 2017; see Notice of Intent (NOI) to develop regulations respecting asbestos published December 17, 2016 in Canada Gazette, Part I <u>http://canadagazette.gc.ca/rp-pr/p1/2016/2016-12-17/html/notice-avis-</u> <u>eng.php#nl3</u>; and mandatory survey notice under section 71 of the Canadian Environmental Protection Act (CEPA) published December 17, 2016 in Canada Gazette, Part I <u>http://www.gazette.gc.ca/rp-</u> <u>pr/p1/2016/2016-12-17/html/notice-avis-eng.php#nl2</u>.

In addition, the Rotterdam Convention is considering <u>adding chrysotile to Annex III</u> at its <u>2017 meeting</u>, and the World Health Organization (WHO) has a global campaign to eliminate asbestos-related diseases (<u>WHO Resolution 60.26</u>).

Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for asbestos.

B-1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities for consideration.

B-1-1 Manufacture and Import

B-1-1-1 Manufacturing

As a naturally occurring mineral, asbestos is manufactured by mining, but asbestos has not been mined (or manufactured) in the United States since 2002 (<u>USGS, 2016</u>).

B-1-1-2 Import

The USGS published the Mineral Commodity Summaries in January 2017. According to this document, 100% of raw asbestos imported to the United States in 2016 was for use by the chlor-alkali industry, which uses chrysotile asbestos to fabricate semi-permeable diaphragms for use in the chlorine and caustic soda production process (USGS, 2017). According to chlor-alkali industry information, chrysotile-containing asbestos used in the fabrication of diaphragms is imported in sealed containers, with the asbestos in 40-50 kg sealed bags made of dust-proof, woven plastic. Typically, they indicated that 20 bags are placed on a pallet at the point of shipment and the pallet is covered completely by a heavyweight wrap – durable and similar in thickness to a drum liner. The pallets are placed in a shipping container, which gets sealed with a heavy-duty bolt-type seal. At the port of entry, the shipping container is marked and transported to a chlor-alkali facility where the pallets and bags are removed.

B-1-2 Processing

B-1-2-1 Chlor-Alkali Industry

Asbestos (chrysotile-containing) is used in the chlor-alkali industry during the fabrication of semipermeable diaphragms, which effectively separate the anode from the cathode chemicals in the production of chorine and sodium hydroxide (caustic soda) (<u>USGS, 2017</u>). The information in this section was described by industry representatives to EPA in a January 2017 meeting, provided to EPA by the American Chemistry Council (ACC) in written communication, or observed during March 2017 EPA visits to chlor-alkali plants. The information provided below is primarily based on information provided by either the chlor-alkali industry or ACC and is meant to represent typical practices.

Chlor-alkali industry representatives have stated that in the United States, there are three companies who own a total of 15 chlor-alkali plants that continue to fabricate and use asbestos-containing semipermeable diaphragms onsite. From its entry into a port in the United States to its ultimate disposal, the management of asbestos in the chlor-alkali industry is typically managed in a closely controlled process. The ACC reports that engineering controls, personal protective equipment (PPE), employee training, medical surveillance and personal monitoring are all used to monitor and mitigate worker exposures.

After arriving at the plant, the shipping container is inspected and damaged containers are rejected. According to industry, where containers are damaged, port/warehouse remediation activities are managed in conformance with OSHA's asbestos standard for general industry (29 CFR 1910.1001). Once the container is opened, the bags are inspected. If broken bags or loose asbestos is evident, the area is controlled to prevent accidental exposure, the bags are repaired, and the area is barricaded and treated as an area requiring cleanup. Plastic-wrapped pallets are labeled per OSHA's hazard communication and asbestos standards. Any loose asbestos from punctured bags inside the container is cleaned up using high-efficiency particulate air-filtered (HEPA-filtered) vacuum cleaners or wetted with water and cleaned up before unloading proceeds. Damaged bags are placed in appropriately labeled, heavy-duty plastic bags or appropriately repaired. Individuals not involved in cleanup are prohibited from entering the area until cleanup is complete. When moving the asbestos bags into storage locations, care is taken to ensure that bags are not punctured, and personnel moving the bags wear specific PPE, including respirators and protective clothing. Storage areas are isolated, enclosed and labeled. They are secure and inspected on a regular basis. Any area or surface with evidence of asbestos is HEPA-vacuumed or wetted and cleaned up by employees wearing PPE.

To create these asbestos-containing diaphragm cells, sealed bags of asbestos are placed inside a glove box (at some plants) before being opened. They are then opened and the asbestos is transferred to a mixing tank via a closed system maintained under vacuum. At other plants, this process is fully automated and enclosed; where asbestos bags are placed into a machine, opened and transferred to mixing tanks. Empty bags are placed into closed and labeled waste containers, either through a port in the glove box or during the automated process. The raw asbestos used to create a diaphragm is mixed with a liquid solution of weak caustic soda and salt. A resultant chrysotile asbestos slurry is created and asbestos is no longer likely to become airborne. Modifiers (e.g., Halar[®], Teflon[®]) are added to the slurry and then co-deposited in the diaphragm and heated. The modifiers fuse to the asbestos. The amount of asbestos used for each are added to the slurry, which is then co-deposited in the diaphragm and heated. The modifiers fuse to the asbestos. The amount of asbestos used for each diaphragm is in the range of 50-250 lbs (depending on cell size) and a typical plant will use about 5-25 tons of raw asbestos per year. Industry representatives stated during meetings with EPA that a standard-sized manufacturing cell will have a surface area of 70 m² and each cell will typically have 20 chrysotile asbestos diaphragms within it, although cell size can vary.

The chlor-alkali chemical production process involves the separation of the sodium and chloride atoms of salt in saltwater (brine) via electricity to produce sodium hydroxide (caustic soda), hydrogen and chlorine. Specifically, brine is passed through an electric current and sodium hydroxide, hydrogen and chlorine are formed. This reaction occurs in an electrolytic cell. The cell contains two compartments separated by a semi-permeable diaphragm, which is made mostly of chrysotile asbestos. The diaphragm prevents the reaction of the caustic soda with the chlorine and allows for the separation of both materials for further processing.

The cell will typically operate for 1-3 years before it must be replaced due to a loss of conductivity. Many factors can determine the life of a cell, including the brine quality and the size of the cell. When the diaphragm cell is replaced, the asbestos is hydro-blasted out (remaining in a wet state) in a cleaning bay. The excess water used during this process is filtered prior to discharge to the facility's wastewater collection and treatment system. The filtered waste is to be sealed into containers that are sent to a landfill that accepts asbestos-containing waste per federal and state asbestos disposal regulations.

B-1-3 Uses

B-1-3-1 Oil Industry

At least one company in the United States sells asbestos-containing brake blocks in the oil industry. The brake of a drawworks hoisting machine is an essential component of a rotary drilling rig, as the machine is used to hoist or lower thousands of pounds of weight in large operations. A company sells asbestos-containing "Silverline 'SP' Brake Blocks", which are non-metallic, asbestos-woven brake blocks used in the drawworks of drilling rigs. According to the product specification sheets, these asbestos-containing brake blocks are most often used on large drilling drawworks and contain wire in the backing only for added strength, and they are more resistant than full-metallic blocks, with good flexibility and a favorable coefficient of friction block (<u>Stewart & Stevenson - product specs sheet</u>). The asbestos allows for heat dissipation and the woven structure provides firmness and controlled density of the brake block. Workers in the oilfield industry operate a drilling rig's brakes in an outdoor environment, and must periodically replace spent brake blocks.

B-1-3-2 Use of Sheet Gaskets in Titanium Dioxide Production

In the <u>Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Asbestos</u> public document (Docket: <u>EPA-HQ-OPPT-2016-0736</u>), Table 1 depicts a "List of Asbestos-Containing Products Currently Available for Purchase on the internet." On page 11 of the preliminary information document, EPA lists useful types of information. During the public comment period, one chemical production company notified EPA of the current use of imported gaskets from China (Comment ID <u>EPA-HQ-OPPT-2016-0736-0067</u>). According to the comment, these sheet gaskets are composed of 80% (minimum) chrysotile asbestos, fully encapsulated in Styrene Butadiene Rubber, and used to create tight chemical containment seals during the production of titanium dioxide.

B-1-3-3 Commercial Uses

Chrysotile asbestos has several unique properties, including low electrical conductivity, high tensile strength, high friction coefficient and high heat resistance (Virta, 2011). These properties make asbestos ideal for use in friction materials (brakes), insulation (sound, heat and electrical) and building materials (cement pipes, roofing compounds, adhesives, flooring) over the past century. However, due to health concerns and consumer preference, most products used commercially in the United States are now asbestos-free. Although most domestically manufactured products are asbestos-free, it is possible that imported asbestos-containing products could go into aftermarket sales and be used commercially (e.g., a mechanic installing new brakes, roofer applying coatings, construction worker using sealants/adhesives). Most available products used commercially contain non-friable asbestos.

B-1-3-4 Consumer Uses

Remaining asbestos-containing products available for consumer use in the United States include a limited number of roof and non-roof coatings, adhesives, sealants, gaskets and imported aftermarket friction products. USGS import data suggests other asbestos-containing products (e.g., asbestos-containing building materials; woven materials) are manufactured outside the United States and imported for domestic use (USGS, 2016). These same products could also be used commercially. EPA

staff conducted an online search using various search terms to determine any currently available asbestos-containing products in the United States. The products found were either advertised as containing asbestos or the associated Safety Data Sheet (SDS) listed asbestos as a product constituent. Additionally, the EPA reviewed databases (EPA CPCat, U.S. Department of Health and Human Services [DHHS] Household Products Database and DeLima Associates Consumer Product Information Database [CPID]) that list manufacturers/distributers/retailers of asbestos-containing products. Some companies found are no longer in business or have been rebranded and absorbed by another company. In researching these companies' products and their SDSs, EPA found little evidence of continued asbestos use. Consumer activities using these products would likely be limited to small-scale do-it-yourself projects.

B-1-4 Disposal

Asbestos NESHAP minimizes asbestos release during renovation/demolition by requiring NESHAPregulated asbestos-containing waste material be sealed in a leak-tight container while wet, labeled and disposed of properly in a landfill qualified to receive asbestos waste.

https://www.epa.gov/asbestos/asbestos-national-emissions-standard-hazardous-airpollutants-neshap#was. Transport and Disposal of Asbestos Waste (Appendix D to Subpart E of 40 CFR Part 763)

Landfills have special requirements for handling and securing the asbestos-containing waste regulated under NESHAP to prevent releases of asbestos into the air. Transportation vehicles that move the waste from the point of generation to the asbestos landfill have special labeling requirements and waste shipment recordkeeping requirements (U.S. EPA). Specific waste management practices are controlled at the state level.

B-2 Occupational Exposure Data

Data that inform occupational exposure assessment and which EPA expects to consider as part of the occupational exposure assessment is the Occupational Safety and Health Administration (OSHA) Chemical Exposure Health Data (CEHD), which are monitoring data collected during OSHA inspections. According to OSHA asbestos standards, the employee permissible exposure limit (PEL) is 0.1 fibers per cubic centimeter (f/cc) as an 8-hour, time-weighted average (TWA) and/or the excursion limit (1.0 f/cc as a 30-minute TWA) (Asbestos General Standard 29 CFR 1910).

A preliminary summary of OSHA's monitoring data from 2011 to 2016 is presented in Table_Apx B-1. These data represent actual exposure levels of asbestos at specific workplaces encompassing several industry sectors and conditions of use.

North American Industrial Classification System (NAICS)	NAICS Description
22	Utilities
23	Construction
31	Manufacturing
32	Manufacturing
33	Manufacturing
42	Wholesale trade
44	Retail trade
45	Retail trade
48	Transportation and warehousing
49	Transportation and warehousing
52	Finance and insurance
53	Real estate rental and leasing
54	Professional, scientific and technical services
56	Administrative and support and waste management and remediation services
61	Educational services
62	Health care and social assistance
71	Arts, entertainment and recreation
72	Accommodation and food services
92	Public administration

Table_Apx B-1. Summary of Industry Sectors with Asbestos Personal Monitoring Air SamplesObtained from OSHA Inspections Conducted Between 2011 and 2016