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Problem Formulation of the Risk Evaluation for Asbestos

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDIX TABLES

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ABBREVIATIONS

ABPO	1989 Asbestos Ban and Phase Out Rule
ACC	American Chemistry Council
ACGIH TLV	American Conference of Governmental Industrial Hygienists Threshold Limit Value
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
ChV	Chronic Value
COC	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
HTS	Harmonized Tariff Schedule
IARC	International Agency for Research on Cancer
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IRIS	Integrated Risk Information System
lb	Pound
LOEC	Lowest Observable Effect Concentration
MAP	Model Accreditation Plan
MCLG	Maximum Contaminant Level Goal
µm	Micrometers
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 for Occupational Safety and Health
NOEC	No Observable Effect Concentration
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
ONU	Occupational Non-User
OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBPK	Physiologically Based Pharmacokinetic
PECO	Population, Exposure, Comparator and Outcome
PEL	Permissible Exposure Level
PESO	Pathways/Processes, Exposure, Setting and Outcomes
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
RESO	Receptors, Exposure, Setting/Scenario and Outcomes
RfC	Reference Concentration
RIA	Regulatory Impact Analysis
SDS	Safety Data Sheet
SDWA	Safe Drinking Water Act
TCCR	Transparent, Clear, Consistent, and Reasonable
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TURA	Toxics Use Reduction Act
TWA	Time Weighted Average
UCMR 3	Unregulated Contaminant Monitoring Rule 3
U.S.	United States
USGS	United States Geological Survey
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 and in June 2017, EPA published the Scope of the Risk Evaluation for Asbestos. As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for asbestos. Comments received on this problem formulation document will inform development of the draft risk evaluation.

This problem formulation document refines the conditions of use, exposures and hazards presented in the scope of the risk evaluation for asbestos and presents refined conceptual models and analysis plans that describe how EPA expects to evaluate the risk for asbestos.

For the purposes of scoping, problem formulation 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 CASRN on the TSCA Inventory. However, other CASRNs are 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 2017, the United States imported approximately 300 metric tons of raw asbestos, all of it comprised of chrysotile asbestos.

EPA has identified the ongoing use of chrysotile asbestos in: industrial processes in the chlor-alkali industry, asbestos sheet gaskets for use in equipment used in the manufacture of titanium dioxide and asbestos brake blocks in oilfield equipment and aftermarket asbestos brake linings. In addition, certain asbestos containing products can be imported into the U.S., but the amounts are not known. These products are mostly used in industrial processes (e.g. cement products) but could also be used by consumers, and include woven products and automotive brakes and linings.

In the case of asbestos, legacy uses, associated disposals, and legacy disposals will be excluded from the problem formulation and risk evaluation, as they were in the Scope document. 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 generally interprets the mandates under section TSCA § 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.

During scoping and problem formulation EPA reviewed the existing EPA IRIS health assessments to ascertain the established health hazards and any known toxicity values. EPA had previously, in the IRIS assessments, identified asbestos as a carcinogen causing both lung cancer and mesothelioma from inhalation exposures and derived a unit risk to address both cancers. No toxicity values or unit risks have yet been estimated for other cancers that have been identified by the International Agency for Research on Cancer (IARC) and others. Given the well-established carcinogenicity of asbestos for lung cancer and mesothelioma, EPA has decided to limit the scope of its systematic review to these two specific cancers with the goal of updating, or reaffirming, the existing unit risk. No clear association was found for drinking water asbestos exposure and cancer. Dermal exposures may cause non-cancerous skin lesions. Since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, which are the basis of the 1988 cancer unit risk, exposures from the oral and dermal routes will not be assessed. These inhalation hazards will be evaluated based on the specific exposure scenarios identified for workers, consumers and the general population where applicable.

Most of the ongoing uses of asbestos pertain to industrial and commercial uses. Exposures to workers, consumers and the general population, as well as environmental receptors may occur from industrial releases and use of asbestos-containing products. Only environmental releases of friable asbestos are reported in the Toxics Release Inventory. 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.

The revised conceptual models presented in this problem formulation identify conditions of use; exposure pathways (e.g., media); exposure routes (inhalation); potentially exposed or susceptible subpopulations; and hazards EPA expects to consider in the risk evaluation. The initial conceptual models provided in the scope document were revised during problem formulation based on evaluation of reasonably available information for physical and chemical properties, fate, exposures, hazards, and conditions of use and based upon consideration of other statutory and regulatory authorities.

EPA's overall objectives in the risk evaluation process are to conduct timely, relevant, high-quality, and scientifically credible risk evaluations within the statutory deadlines, and to evaluate the conditions of use that raise greatest potential for risk 82 FR 33726, 33728 (July 20, 2017).

1 INTRODUCTION

This document presents for comment the problem formulation of the risk evaluation to be conducted for asbestos under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA), the Nation's primary chemicals management law, on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

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, within 6 months after the initiation of a risk evaluation. The scope documents for all first 10 chemical substances were issued on June 22, 2017. The first 10 Problem Formulation documents are a refinement of what was presented in the first 10 scope documents. TSCA § 6(b)(4)(D) does not distinguish between scoping and problem formulation, and requires EPA to issue scope documents that include information about the chemical substance, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that the Administrator expects to consider in the risk evaluation. In the future, EPA expects scoping and problem formulation to be completed prior to the issuance of scope documents and intends to issue scope documents that include problem formulation.

As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for asbestos. Comments received on this problem formulation document will inform development of the draft risk evaluation.

The Agency defines problem formulation as the analytical phase of the risk assessment in which "the purpose of the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined" [see Section 2.2 of the *Framework for Human Health Risk Assessment to Inform Decision Making*, (U.S. EPA, 2014a)]. The outcome of problem formulation is a conceptual model(s) and an analysis plan. The conceptual model describes the linkages between stressors and adverse human health and environmental effects, including the stressor(s), exposure pathway(s), exposed life stage(s) and population(s), and endpoint(s) that will be addressed in the risk evaluation (U.S. EPA, 2014a). The analysis plan follows the development of the conceptual model(s) and is intended to describe the approach for conducting the risk evaluation, including its design, methods and key inputs and intended outputs as described in the EPA Human Health Risk Assessment Framework (U.S. EPA, 2014a). The problem formulation documents refine the initial conceptual models and analysis plans that were provided in the scope documents.

First, EPA has removed from the risk evaluation any activities and exposure pathways and hazards that EPA has concluded do not warrant inclusion in the risk evaluation. For example, for some activities that

were listed as "conditions of use" in the scope document, EPA has insufficient information following the further investigations during problem formulation to find they are circumstances under which the chemical is actually "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

Second, EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA) – and which EPA does not expect to include in the risk evaluation.

As a general matter, EPA believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes.[1] EPA does not expect to include any such excluded pathways as further explained below in the problem formulation. The provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes.

Third, EPA identified any conditions of use, hazards, or exposure pathways which were included in the scope document and that EPA expects to include in the risk evaluation but which EPA does not expect to further analyze in the risk evaluation. EPA expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis and therefore plans to conduct no further analysis on those conditions of use, hazards or exposure pathways in order to focus the Agency's resources on more extensive or quantitative analyses. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without comprehensive or quantitative risk evaluations. 82 FR 33726, 33734, 33739 (July 20, 2017).

EPA received comments on the published scope document for asbestos and has considered the comments specific to asbestos in this problem formulation document. EPA is soliciting public comment on this problem formulation document and when the draft risk evaluation is issued the Agency intends to respond to comments that are submitted. In its draft risk evaluation, EPA may revise the conclusions and approaches contained in this problem formulation, including the conditions of use and pathways covered and the conceptual models and analysis plans, based on comments received.

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 evaluated and considered the impact of at

[1] As explained in the final rule for chemical risk evaluation procedures, "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, and consequently merit an unreasonable risk determination [82FR 33726, 33729] (July 20, 2017).

least some 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. Consideration of the nexus between these existing regulations and TSCA conditions of use may additionally be made as detailed/specific conditions of use and exposure scenarios are developed in conducting the analysis phase 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; including adding the Department of Transportation regulations on asbestos since the scope document.

State Laws and Regulations

Asbestos is subject to statutes or regulations implemented by state agencies or departments. A summary of state laws, regulations and implementing authorities is provided in Appendix A-2 (updated since the scope document).

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 the scope and problem formulation documents for the risk evaluation. Table 1-1 shows the assessments that have been conducted. Since publication of the Scope document in June 2017 EPA has added documents to Table 1-1 that supported the 1988 Asbestos Ban and Phase Out rule (54 FR 29460) which were consulted for background information on uses, exposures, and risk assessment, as well as the ecological risk assessment conducted at the Libby Asbestos Superfund Site.

In addition to using this information, EPA intends to conduct a full review of the relevant data/information collected in the initial comprehensive search (see *Asbestos (CASRN 1332-21-4) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0736) following the literature search and screening strategies documented in the *Strategy for Conducting Literature Searches for Asbestos: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0736). This will ensure that EPA considers data/information that has been made available since these assessments were conducted.

Table 1-1. Assessment History of Asbestos

Authoring Organization	Assessment
EPA assessments	
EPA, Integrated Risk Information System (IRIS)	IRIS Assessment on Asbestos (1988b)
EPA, Integrated Risk Information System (IRIS)	IRIS Assessment on Libby Amphibole Asbestos (2014c)

Authoring Organization	Assessment
EPA, Region 8	Site-Wide Baseline Ecological Risk Assessment, Libby Asbestos Superfund Site, Libby Montana (U.S. EPA, 2014b)
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)
EPA, Final Rule (40 CFR Part 763)	Asbestos; Manufacture, Importation, Processing and Distribution in Commerce Prohibitions (1988)
EPA, Asbestos Modeling Study	Final Report; Asbestos Modeling Study (U.S. EPA, 1988a)
EPA, Asbestos Exposure Assessment	Revised Report to support ABPO rule (1988)
EPA, Nonoccupational Exposure Report	Revised Draft Report, Nonoccupational Asbestos Exposure (Versar, 1987)
EPA, Airborne Asbestos Health Assessment Update	Support document for NESHAP review (1986)
Other U.S.-based organizations	
National Institute for 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)

1.3 Data and Information Collection

EPA/OPPT generally applies a systematic process and workflow that includes: (1) data collection; (2) data evaluation; and (3) data integration of the scientific information used in risk evaluations 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. Additional information that may be considered and was not part of the initial comprehensive bibliographies will be documented in the Draft Risk Evaluation for asbestos.

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 and human exposures, including potentially exposed or susceptible subpopulations; and, ecological and 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. For most disciplines, 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 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 susceptibility; and ecological hazard). However, within each data set, there are two broad categories or data tags: (1) o*n-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. O*ff-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). The scope document provided 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 *off-topic* 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.

1.4 Data Screening during Problem Formulation

EPA/OPPT is in the process of completing the full text screening of the on-topic references identified in the *Asbestos (CASRN: 1332-21-4) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0736). The screening process at the full-text level is described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). Appendix D provides the inclusion and exclusion criteria applied at the full text screening. The eligibility criteria are guided by the analytical considerations in the revised conceptual models and analysis plan, as discussed in the problem formulation document. Thus, it is expected the number of data/information sources entering evaluation is reduced to those that are relevant to address the technical approach and issues described in the analysis plan of this document.

Following the screening process, the quality of the included studies will be assessed using the evaluation strategies that are described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2 PROBLEM FORMULATION

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 included in the scope document a life cycle diagram and conceptual models that describe the actual or potential relationships between asbestos and human and ecological receptors. During the problem formulation, EPA revised the conceptual models based on further data gathering and analysis, as presented in this problem formulation document. An updated 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.

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" (IARC, 2012). 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 CASRN on the TSCA Inventory. However, other CASRNs are 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. EPA received public comment on the definition and fiber types of asbestos used in the Scope document and adjusted Table 2-1 to clarify the fiber types and size included in the definition. EPA will continue to use the TSCA Title II definition of asbestos in the risk evaluation.

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 United States Geological Survey (USGS) estimated that 300 metric tons of asbestos were imported into the U.S. in 2017, 57% less than 702 metric tons in 2016, and 22% less than 386 metric tons in 2015 (USGS, 2018). It is used wholly by the chlor-alkali industry.

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) (Virta, 2011).

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. These tetrahedrons occur as sheets $[Si_4O_{10}]$ in chrysotile (U.S. EPA, 2014a). 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.

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 (Virta, 2011).

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

	Chrysotile	Amosite	Crocidolite	Asbestiform Tremolite	Asbestiform Anthophyllite	Asbestiform Actinolite
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

	Chrysotile	Amosite	Crocidolite	Asbestiform Tremolite	Asbestiform Anthophyllite	Asbestiform Actinolite
Color	Usually white to grayish green; may have tan coloration	Yellowish gray to dark brown	Cobalt blue to lavender blue	Gray-white, green, yellow, blue	Grayish white, also brown-gray or green	Greenish
Luster	Silky	Vitreous to pearly	Silky to dull	Silky	Vitreous to pearly	Silky
Surface area [b, c] (m^2/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
Fiber size, median true diameter (µm)[d]	0.06	0.26	0.09	No data	No data	No data
Fiber size, median true length (µm)[d]	0.55	2.53	1.16	No data	No data	No data
Resistance to: Acids Bases	 Weak, undergoes fairly rapid attack Very good	 Fair, slowly attacked Good	 Good Good	 Good Good	 Very good Very good	 Fair 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

	Chrysotile	Amosite	Crocidolite	Asbestiform Tremolite	Asbestiform Anthophyllite	Asbestiform Actinolite
[a] Badollet (1951). [b] Hodgson (1986). [c] Addison et al. (1966). [d] Hwang (1983)						

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

In the scope documents EPA identified, based on reasonably available information, the conditions of use for the subject chemical. 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-2016-0736-0085). 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) (U.S. EPA, 2017b), 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 and verifying conditions of use. The information and input received from the public and stakeholder meetings was incorporated into this document to the extent appropriate, as indicated in Table 2-2. Thus, EPA believes the identified manufacture, processing, distribution, use and disposal activities identified in this document constitute the intended, known, and reasonably foreseen activities associated with the subject chemical, based on reasonably available information.

2.2.2 Identification of Conditions of Use

To determine the current conditions of use of asbestos and inversely, activities that do not qualify as conditions of use, EPA conducted extensive research and outreach. This included EPA's review of published literature and online databases including the most recent data available from EPA's Chemical Data Reporting program (CDR), Safety Data Sheets (SDSs), the United States Geological Survey's Mineral Commodities Summary and Minerals Yearbook, the U.S. International Trade Commission's Dataweb and government and commercial trade databases. EPA also reviewed company websites of potential manufacturers, importers, distributors, retailers, or other users of asbestos. EPA also received comments on the *Scope of the Risk Evaluation for Asbestos* (EPA-HQ-OPPT-2016-0736-0086) that were used to determine the conditions of use. In addition, prior to the June 2017 publication of the scope document, EPA 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 Scope document (EPA-HQ-OPPT-2016-0736-0086) identified uses of asbestos and described them in terms of product categories. In an 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 June 2017 when the Scope document was published:

- 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

EPA has removed from the risk evaluation any activities that EPA has concluded do not constitute conditions of use – for example, because EPA has insufficient information to find certain activities are circumstances under which the chemical is actually "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of." EPA has also identified any conditions of use that EPA does not expect to include in the risk evaluation. As explained in the final rule for Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, TSCA section 6(b)(4)(D) requires EPA to identify "the hazards, exposures, conditions of use and the potentially exposed or susceptible subpopulations that the Agency expects to consider in a risk evaluation," suggesting that EPA may exclude certain activities that EPA has determined to be conditions of use on a case-by-case basis (82 FR 33736, 33729; July 20, 2017). For example, EPA may exclude conditions of use that the Agency has sufficient basis to conclude would present only de minimis exposures or otherwise insignificant risks (such as use in a closed system that effectively precludes exposure or use as an intermediate).

The activities that EPA no longer believes are conditions of use or that were otherwise excluded during problem formulation are described in Section 2.2.2.1. The conditions of use included in the scope of the risk evaluation are summarized in Section 2.2.2.2.

2.2.2.1 Categories Determined Not to be Conditions of Use During Problem Formulation

During problem formulation, the conditions of use of asbestos identified in the Scope document were further refined upon determination that EPA has insufficient information to find certain activities to be "conditions of use." After further investigation of the current conditions of use – circumstances under which the chemical is "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of" – EPA determined there is a lack of sufficient evidence of the import, processing, or distribution of asbestos in adhesives and sealants, roof and non-roof coatings, and building materials other than asbestos cement products. EPA had originally identified an asbestos-containing adhesive for use as a mirror adhesive but later determined after contacting the supplier that it is no longer sold. EPA also identified during the scoping process a domestic company that appeared to manufacture and sell asbestos-containing roof and non-roof coatings, but after contacting the company, determined that the information available on their website was outdated and those products were no longer manufactured and sold in the United States.

Based on data available to EPA, general and some specified building materials and other unspecified activities have been removed from consideration from the original scope during problem formulation, as depicted in Table 2-2. EPA does not expect to consider or evaluate any such products or associated hazards or exposures in the applicable risk evaluation because the use of asbestos in these products is not intended, known, or reasonably foreseen in the United States. Therefore, the asbestos-containing products listed in Table 2-2 are not included in the Life Cycle Diagram, Figure 2-1.

Table 2-2. Categories Determined Not to be Conditions of Use During Problem Formulation

Activity	Product Category	Example
No Known, Intended, or Reasonably Foreseen Use	Adhesives and Sealants	Mirror adhesive
	Roof and Non-Roof Coatings	Roofs/Foundations; Mastics
	Building Materials, Other	Articles not specified, including building materials other than asbestos cement products

Legacy Use – Excluded from Scope (and Problem Formulation) of the Risk Evaluation

EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations 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 life cycle. Consistent with this rationale, EPA has excluded certain uses from the scope of the risk evaluation, as identified below.

During 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. Many asbestos products fall into this category. These materials were installed in the past, and there is no evidence to suggest that manufacturing, processing, or distribution for such activities is intended, known, or reasonably foreseen; EPA received no public comments providing information to indicate otherwise. Legacy asbestos-containing products excluded from the scope of the risk evaluation include:

- Asbestos arc chutes
- Asbestos pipeline wrap
- Asbestos separators in fuel cells and batteries
- Asbestos-reinforced plastics
- Beater-add gaskets
- Extruded sealant tape
- Filler for acetylene cylinders
- High-grade electrical paper
- Millboard
- Missile liner
- Roofing felt
- Vinyl-asbestos floor tile

Upon further investigation during problem formulation, EPA has determined that seven asbestos product categories (asbestos packings, asbestos protective clothing, automatic transmission friction components, clutch facings, asbestos-cement flat sheet, asbestos-cement shingles, and corrugated asbestos-cement sheet) that were listed as legacy uses in the Scope document fall under broader categories that EPA has identified as conditions of use (other gaskets and packing, woven products, automotive friction materials and asbestos cement products). Therefore, EPA has removed these seven product categories from the above list because it is reasonably foreseen that these products could be considered under the risk evaluation as specific products in broader categories of conditions of use.

The manufacture, processing, and distribution for a number of additional uses of asbestos were banned 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[2]

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 mined near Libby, MT and extensively distributed throughout the United States during the 20th century. Vermiculite from Libby, MT had a range of commercial applications, the most common of which included packing material, attic and wall insulation, various garden and agricultural products, and various cement and building products. Although vermiculite contaminated with the Libby Amphibole remains in buildings as an insulating material it is no longer manufactured, processed or distributed for use in the United States and therefore is not considered a condition of use of asbestos for the purpose of risk evaluation under TSCA.

2.2.2.2 Categories of Conditions of Use Included in the Scope of Risk Evaluation

Table 2-3 summarizes the conditions of use for asbestos that EPA expects to consider in the risk evaluation. Using the 2016 CDR, EPA identified industrial processing or use activities, industrial function categories and commercial and consumer use product categories. For risk evaluations, EPA intends to consider the conditions of use for each life cycle stage and assess relevant potential sources of release and human exposure associated with that life cycle stage (see Figure 2-1).

Reporting of asbestos in the 2016 Chemical Data Reporting (CDR) [3,4] period was limited (U.S. EPA, 2016b). 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).

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

[2] Defined by 40 CFR 763.163 as "commercial uses of asbestos not identified in §763.165 the manufacture, importation or processing of which would be initiated for the first time after August 25, 1989."

[3] 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 some chemical substances, including asbestos, subject to certain TSCA actions (U.S. EPA, 2017a).

[4] For purposes of the CDR, 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, 2016c)

currently imported into the United States is chrysotile, all of which originated from Brazil in 2017 (USGS, 2018). USGS reports that in 2017, the United States imported approximately 300 metric tons of raw asbestos, the total of which they state is used in the chlor-alkali industry (USGS, 2018). In 2016, the United States imported approximately 702 metric tons of raw asbestos (USGS, 2018). Other import data presented in the USGS report are difficult to interpret with respect to volumes because most of the asbestos-containing 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. EPA continues to work with its federal partners such as USGS and Customs and Border Protection to better define import information on asbestos-containing products in support of conducting the risk evaluation.

Table 2-3 provides a listing of the conditions of use of asbestos intended, known, or reasonably foreseen to be considered under the TSCA risk evaluation for asbestos. The conditions of use identified in the Scope document have been refined as part of the problem formulation process. Table 2-3 reflects the updated list of conditions of use, identified by asbestos product category, and provides examples for how each product is used. Information provided in Table 2-3 is also reflected the Life Cycle Diagram, Figure 2-1.

Table 2-3. Categories of Conditions of Use Included in the Scope of the Risk Evaluation

Activity	Product Category	Example
Known, Intended, or Reasonably Foreseen Use	Asbestos Diaphragms	Chlor-alkali Industry
	Sheet Gaskets	Chemical Manufacturing
	Oilfield Brake Blocks	Oil Industry
	Aftermarket Automotive Brakes/Linings	Passenger Vehicles
	Other Vehicle Friction Products	Non-passenger Vehicles
	Asbestos Cement Products	Cement pipe
	Other Gaskets and Packing	Equipment Seals
	Woven Products	Imported Textiles

Most of the asbestos-containing products listed in the categories in Table 2-3 are primarily associated with industrial and commercial use. It is important to note that the import volume of products containing asbestos is not known.

2.2.2.3 Overview of Conditions of Use and Life Cycle Diagram

The life cycle diagram provided in Figure 2-1 depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, distribution, use (industrial, commercial, consumer) and disposal. Additions or changes to the conditions of use based on additional information gathered or analyzed during problem formulation are described in Sections 2.2.2.1 and 2.2.2.2. The activities that EPA determined are out of scope during problem formulation are not included in the life cycle diagram.

Use categories include the following: "industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. "Consumer use" means the use of a chemical or a

mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use (U.S. EPA, 2017a).

To understand conditions of use relative to one another and associated potential exposures under those conditions of use, the life cycle diagram includes the production volume associated with each stage of the life cycle, as reported in the 2016 CDR reporting (U.S. EPA, 2017a) when the volume was not claimed confidential business information (CBI). However, in the case of asbestos, reported USGS production volume was used since the CDR production volume was claimed CBI.

Descriptions of the industrial, commercial and consumer use categories included in the life cycle diagram are summarized below. The descriptions provide a brief overview of the use category; Appendix B contains more detailed descriptions (e.g., process descriptions, worker activities) for each manufacture, processing, distribution, use and disposal category.

Figure 2-1 depicts the life cycle diagram of asbestos from manufacture to the point of disposal. Activities related to distribution (e.g., loading, unloading) will be considered throughout the asbestos life cycle, rather than using a single distribution scenario.

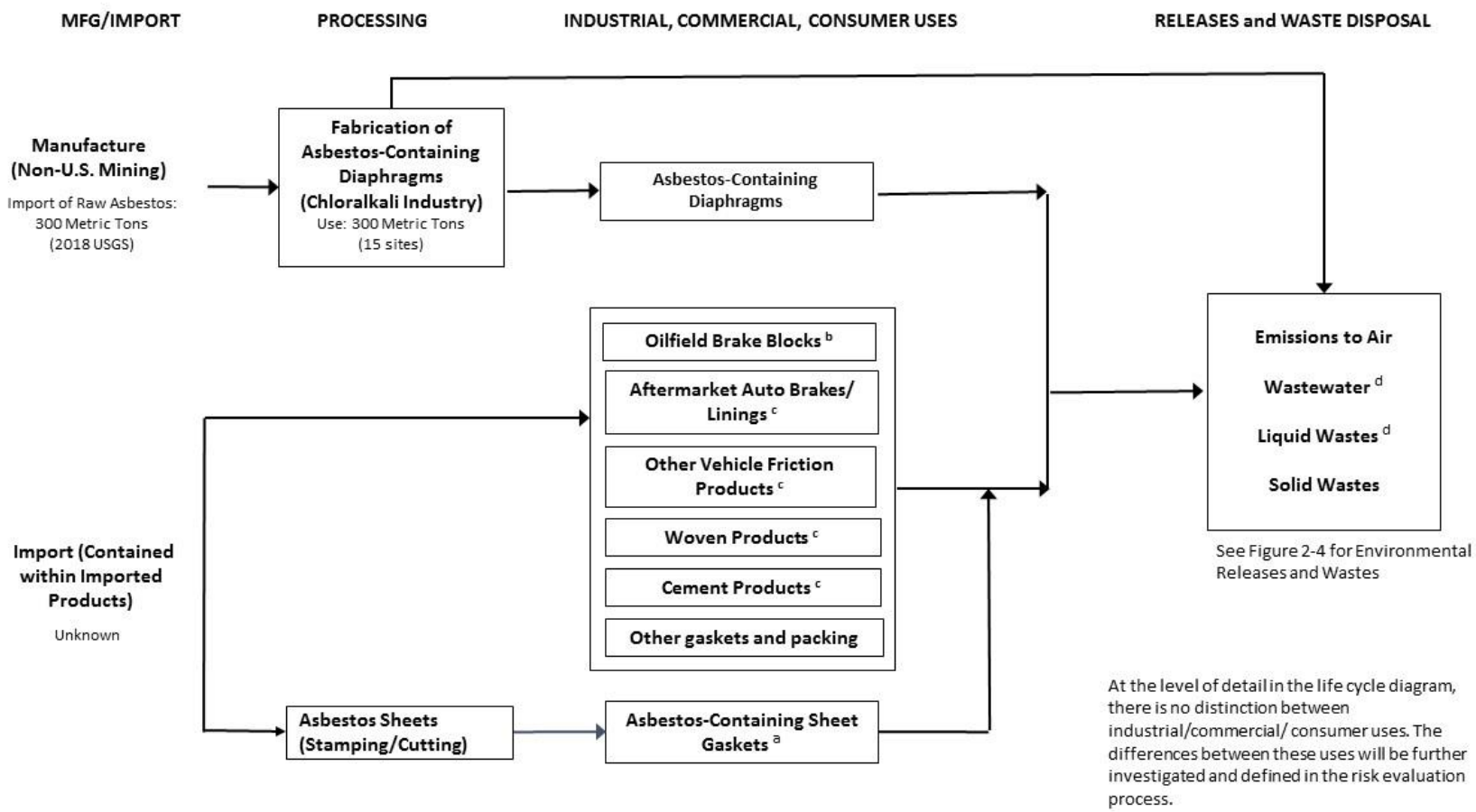

Figure 2-1. Asbestos Life Cycle Diagram

The life cycle diagram depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer), distribution and disposal. The import volume shown is from 2018 USGS. 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] Oilfield brake blocks identified via industry response during problem formulation.

[c] Data is very limited for these uses.

[d] Wastewater: combination of water and organic liquid, where the organic content is less than 50 percent. Liquid Wastes: combination of water and organic liquid, where the organic content is greater than 50 percent

EPA is aware of the use of raw imported chrysotile asbestos in the chlor-alkali industry, the use of imported asbestos-containing sheet gaskets in the manufacture of titanium dioxide, the use of imported asbestos-containing brake blocks in the oil industry, and other imported asbestos-containing products that could be used either in industrial or consumer settings.

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) (USGS, 2017). During a meeting with EPA in January 2017, industry representatives stated that in the United States, there are three companies (Olin Corporation, Occidental Chemical and Axial/Westlake Corporation) who own a total of 15 chlor-alkali plants that continue to fabricate and use asbestos (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 continues to evaluate how representative the processes witnessed at these two facilities are of processes at other plants when evaluating this use in the analysis phase of the risk evaluation. EPA held a conference call with Axial/Westlake on April 11, 2017 to discuss their use of asbestos diaphragms at their Plaquemine, LA plant (EPA-HQ-OPPT-2016-0736-0070). EPA also had follow-up meetings with Occidental Chemical on September 6, 2017, (EPA-HQ-OPPT-2016-0736-0116) and Olin Chemical on September 14, 2017 (EPA-HQ-OPPT-2016-0736-0117) to better understand the use, processes (including personal protective equipment and engineering controls used) and disposal methods followed for asbestos diaphragms.

Sheet Gaskets

During the public comment period, one chemical production company, Chemours, notified EPA of their current use of imported gaskets from China (Comment ID (EPA-HQ-OPPT-2016-0736-0067). 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. On October 30, 2017, EPA met with both the commenter, Chemours, and their gasket supplier, Branham Corporation, who provided EPA with additional information on the fabrication and use of the gaskets (EPA-HQ-OPPT-2016-0736-0119). Branham imports rubberized sheets of the asbestos-containing material from a manufacturer in China and then fabricates (by cutting to specific sizes) the gaskets from the sheet material. Chemours informed EPA during the meeting that asbestos-containing gaskets are optimal because they are resistant to cyclical high temperatures and immense pressure. During the manufacture of titanium dioxide, temperatures can exceed 1850 degrees Fahrenheit and pressures can be greater than 50 pounds per square inch.

Brake Blocks in Oilfields

During problem formulation, EPA contacted a domestic brake blocks manufacturing company to confirm that asbestos brake blocks are still used in oilfield equipment within the United States (https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0118 EPA-HQ-OPPT-2016-0736-0118). Although the company no longer fabricates brake blocks using asbestos, the company did confirm that they import asbestos-containing brake blocks on behalf of some clients for use in the oilfield industry. It is unclear how widespread the continued use of asbestos brake blocks is for use in oilfield equipment, but EPA understands from interactions with industry that the use of asbestos brake blocks has decreased significantly over time and continues to decline. EPA continues to investigate the use of this product.

Asbestos Containing Products for Commercial and Consumer Use

EPA found limited evidence of asbestos-containing products currently used in the United States. In the scope document, certain asbestos-containing products, such as cement products, aftermarket brake linings, other vehicle friction materials, and other gaskets and packing were identified in the *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Asbestos* (Docket: EPA-HQ-OPPT-2016-0736-0005) (U.S. EPA, 2017b) . During problem formulation, EPA consulted with USGS staff on what uses of asbestos they consider to be ongoing based on their professional judgement after reviewing government and commercial trade databases. USGS believes that the asbestos-containing products that continue to be imported include raw chrysotile asbestos (for use in chlor-alkali diaphragms), asbestos brake linings (automotive brakes/linings, other vehicle friction products), knitted fabrics (woven products), asbestos rubber sheets (i.e., sheet gaskets) and asbestos cement products. USGS and EPA believe that other asbestos imports listed by harmonized tariff schedule (HTS) code in government and commercial trade databases are likely misreported and are not ongoing current conditions of use.

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 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 asbestos.

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 ecological receptors EPA expects to consider in the risk evaluation. EPA has identified and considered environmental fate data as reported in several assessments in developing the scope and problem formulation for asbestos (WHO, 2014; IARC, 2012; ATSDR, 2001).

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 (IARC, 2012; ATSDR, 2001). Asbestos fibers can be found in soils, sediments, lofted in air and windblown dust, surface water, ground water and biota (IARC, 2012; ATSDR, 2001). Small asbestos fibers (<1 µm) remain suspended in air and water for a significant period of time and may be transported over long distances (ATSDR, 2001). Chrysotile asbestos forms stable suspensions in water and degrades to some extent in acidic conditions, however the silicate structure remains intact (IARC, 2012). 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.) (WHO, 2014).

Asbestos may be released to the environment through industrial or commercial activities, such as processing raw asbestos, fabricating/processing asbestos containing products, or the lofting of friable asbestos during use, disturbance and disposal of asbestos containing products. Systematic literature review is currently underway to determine if any new information may inform the development of the risk evaluation.

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, and estimations based on empirical data and/or assumptions and models.

A source of information that EPA considered 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, asbestos (friable) is a TRI-reportable substance effective January 1, 1987.

EPA's TRI data contains information about asbestos releases to air and water and disposal to land from industrial facilities in covered sectors in the United States. For TRI reporting, facilities in covered sectors 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.[5] Facilities are required to report if they are in a covered industrial code and manufacture (including import) or process more than 25,000 pounds of friable asbestos, or if they otherwise use more than 10,000 pounds of friable asbestos.

Table 2-4 provides production-related waste management data for friable asbestos reported by industrial facilities in covered sectors to the TRI program for 2015. In 2015, 36 facilities reported a total of approximately 25 million pounds of friable asbestos waste managed. Of this total, zero pounds were recovered for energy, approximately 188,000 pounds were treated, and nearly 25 million pounds were disposed of or otherwise released into the environment. It was determined during problem formulation that the 875 pounds of recycled material reported to TRI for 2015 was in error (error correction pending).

Table 2-4. Summary of Asbestos TRI Production-Related Waste Managed in 2015 (lbs)

Number of Facilities	Recycling	Energy Recovery	Treatment	Releases [a,b,c]	Total Production Related Waste
36	875	0	188,437	25,360,853	25,550,164

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] Does not include releases due to one-time event not associated with production such as remedial actions or earthquakes.
[c] Counts all releases including release quantities transferred and release quantities disposed of by a receiving facility reporting to TRI.

Table 2-5 provides a summary of asbestos TRI releases to the environment in 2015. There were zero pounds of friable asbestos reported as released to water via surface water discharges, and a total of 314

[5] According to 53FR4519 (VII)C(5), "The listing for asbestos is qualified by the term "friable." This term refers to a physical characteristic of asbestos. EPA interprets "friable" as being crumbled, pulverized, or reducible to a powder with hand pressure. Again, only manufacturing, processing, or use of asbestos in the friable form triggers reporting. Similarly, supplier notification applies only to distribution of friable asbestos."

pounds of air releases from collective fugitive and stack air emissions. The vast majority of friable asbestos was disposed of to landfills from both Resource Conservation and Recovery Act (RCRA) Subtitle C landfills and to landfills other than RCRA Subtitle C.

Table 2-5. Summary of Asbestos TRI Releases to the Environment in 2015 (lbs)

	Number of Facilities	Air Releases		Water Releases	Land Disposal			Other Releases [a]	Total On- and Off-Site Disposal or Other Releases [b, c]
		Stack Air Releases [d]	Fugitive Air Releases [e]		Class I Under-ground Injection	RCRA Subtitle C Landfills	All other Land Disposal [a]		
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.
[d] Point source (stack) air emissions are releases to air that occur through confined air streams, such as stacks, ducts or pipes.
[e] Fugitive air emissions are emissions that do not occur through a confined air stream, which may include equipment leaks, releases from building ventilation systems, and evaporative losses from surface impoundments and spills.

While production-related waste managed shown in Table 2-4 excludes any quantities reported as catastrophic or one-time releases (TRI section 8 data), release quantities shown in Table 2-5 include both production-related and non-routine quantities (TRI section 5 and 6 data) for 2015. As a result, release quantities may differ slightly and may further reflect differences in TRI calculation methods for reported release range estimates (U.S. EPA, 2017d).

From TRI data available using TRI Explorer, Table 2-6 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, total on-site and off-site disposal or other releases of friable asbestos have risen from 8.8 million pounds to nearly 25.6 million pounds, respectively. As previously noted, the vast majority of the total on-site and off-site disposal or other releases of friable asbestos are released to land. Release quantities to other media sources such as air are of much smaller magnitude. 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 treatment and disposal sector, followed by the petroleum and other chemical and electric sectors.

Table 2-6. Total On- and Off-site Disposal or Other Releases of Friable Asbestos (lbs) (2009-2015), based on TRI Data

Year	Total On- and Off-site Disposal or Other Releases (lbs)
2009	8,757,577
2010	13,015,169
2011	12,492,732
2012	16,018,091

Year	Total On- and Off-site Disposal or Other Releases (lbs)
2013	16,641,975
2014	17,521,650
2015	25,568,291

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.

In addition to TRI data, EPA has also received release information from industry that will be used in the risk evaluation (see Section 2.6.1.3).

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 (0.0001 fibers/ml) than in rural areas (0.00001 fibers/ml) (ATSDR, 2001).

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 (ATSDR, 2001).

Available data (although over 30 years old) indicate asbestos has been detected in many different freshwater fishes and mussels from bodies of water contaminated with asbestos (U.S. EPA, 1980b; Shugar, 1979).

Asbestos fibers have been measured in U.S. municipal sewage sludges, with asbestos fiber content up to 10% of ashed sludge by volume (ATSDR, 2001). Biosolids in the U.S. may be disposed of by land application, land filling, or incineration. However, in the most recent EPA biosolids review, asbestos was not detected (see Section 2.5.3.2).

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 the revised conceptual model, Figure 2-4, in conducting the risk evaluation for asbestos.

The physical chemical properties of asbestos indicate that fibers can settle over time into sediments from surface water. The larger the fiber, the faster it will settle.

Compliance monitoring data, available for 2006-2011 shows 214 systems (3.7% of 5,785 systems) had detects greater than the minimum reporting level (MRL) of 0.2 MFL but only 8 systems had detects of asbestos greater than the MCL of 7 MFL (https://www.epa.gov/dwsixyearreview/six-year-review-3-

compliance- monitoring-data-2006-2011). Data from 1998-2005 showed 268 systems (3.2% of 8278 systems) had detects ≥ the MRL of 0.2 MFL but only 14 (0.169%) systems had detects of asbestos greater than the MCL of 7 MFL (https://www.epa.gov/dwsixyearreview/six-year-review-2-drinking-water-standards).

A source of information that EPA expects to consider in evaluating surface water releases are data reported in EPA's Discharge Monitoring Report (DMR) Pollutant Loading Tool (https://cfpub.epa.gov/dmr/) to identify facilities that discharge asbestos to surface water. Information was obtained from the DMR Pollutant loading tool accessed on December 1, 2017. Facilities were identified using "EZ Search" which identifies facilities that submit Discharge Monitoring Reports (DMRs). Searches were conducted for the two most current (and complete) years in the tool: 2015 and 2016. Only one DMR facility was identified in 2014 and 2015 and this facility was a mining facility and may be related to legacy mining use runoff. Asbestos has not been mined or otherwise produced in the United States since 2002. EPA did not consider legacy releases or releases based on naturally occurring background levels in this assessment.

2.3.5 Human Exposures

EPA plans to analyze occupational, consumer and general population exposures. Subpopulations, including potentially exposed and susceptible subpopulations, within these exposed groups will also be considered.

The physical condition of asbestos is an important factor when considering the potential human pathways of exposure. Several of the asbestos-containing products identified as conditions of use of asbestos (refer to Section 2.2.2.2) are not friable as intact products; 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 (see discussion in Section 2.4.2).

2.3.5.1 Occupational Exposures

Exposure pathways and exposure routes are listed for worker activities under the various conditions of use described in Section 2.2. In addition, occupational non-users (ONU), who do not directly handle asbestos but perform work in an area where the chemical is present are listed. Engineering controls and/or personal protective equipment may impact occupational exposure levels.

EPA considers inhalation of asbestos fibers to be the most likely asbestos exposure pathway for workers and occupational non-users during the conditions of use included in Sections 2.2.2.2 and 2.2.2.3. These include the fabrication of asbestos-containing diaphragms in the chlor-alkali industry, use of asbestos-containing gaskets in the production of titanium dioxide, and the use of asbestos containing brake blocks in the oil industry. Workers and occupational non-users may also be exposed to asbestos containing products (e.g., friction products, cement products, other gaskets and packing, woven products) that may become friable during use or handling. EPA will only evaluate the inhalation route of exposure (see Section 2.4.2 for discussion).

Workers and occupational non-users may be exposed to asbestos when performing activities associated with conditions of use described in Section 2.2.2.3 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., oilfield equipment maintenance);
- Processing and using imported sheet gaskets;
- Cutting cement pipes;
- Changing asbestos-containing automotive brakes;
- Handling, transporting and disposing waste containing asbestos in chlor-alkali plants and other industrial facilities handling asbestos.

Key data that inform occupational exposure assessment 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 https://www.osha.gov/oshstats/index.html. 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 (the data were received [October 25th, 2017] and are being evaluated). 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 https://www.cdc.gov/niosh/hhe/ . In addition, occupational monitoring information was received from companies in the chlor-alkali and sheet gasket industries; some of this data has been claimed CBI. 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). The NIOSH Recommended Exposure Limit (REL) (NIOSH, 2007) and the American Conference of Governmental Industrial Hygienists Threshold Limit Value (ACGIH TLV) (ACGIH, 1994) are also 0.1 f/cc (respirable fibers), with the REL duration of 100 minutes. Both the PEL and REL are based on phase contrast microscopy (PCM) (which would not include fibers with diameters less than approximately 0.25 µm).

2.3.5.2 Consumer Exposures

Through further investigation of the list of products available for purchase on the internet as depicted in Section 3 of the *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Asbestos* document EPA-HQ-OPPT-2016-0736-0005, (U.S. EPA, 2017b), EPA has determined that asbestos-containing consumer products are likely imported only, not produced in the United States, and are limited to aftermarket friction materials. Available data suggest woven products could also be imported and used by consumers in the United States.

Exposure routes for consumers using asbestos-containing products may include inhalation of particulates resulting from use, and there is the possibility that clothing contaminated from asbestos through product use or manipulation could result in exposures to asbestos. EPA will only evaluate the inhalation route of exposure (see Section 2.4.2 for discussion).

2.3.5.3 General Population Exposures

Asbestos is a naturally occurring mineral and is therefore present in the environment. Thus, the general population may be exposed to low levels of naturally occurring asbestos (ATSDR, 2001). Asbestos fibers may potentially be released during processing or use of asbestos in industry and use of imported

asbestos containing products (see Section 2.3.2 and the public docket EPA-HQ-OPPT-2016-0736). As explained in Section 2.3.2, only friable asbestos above a specified threshold is required to be reported to the Toxics Release Inventory. Therefore, other sources of air releases will be consulted in the risk evaluation. For example, EPA will evaluate the data that has been submitted by the chlor-alkali and gasket industries as well as other sources of data.

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires the determination of whether a chemical substance presents an 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." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011).

As part of the Problem Formulation, EPA identified potentially exposed and susceptible subpopulations for further analysis during the development and refinement of the life cycle, conceptual models, exposure scenarios, and analysis plan. 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.

EPA identifies the following as potentially exposed or susceptible subpopulations that EPA expects to consider in the risk evaluation due to their *greater exposure*:

- 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 2.2.2.2 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 analyze 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 (ATSDR, 2001). In the Scope document, fire fighters were also included as a potentially exposed or susceptible subpopulation. However, fire fighters will be exposed to materials that are predominately legacy uses, which will not be evaluated in the risk evaluation.

In summary, in the risk evaluation for asbestos, EPA plans to analyze the following potentially exposed groups of human receptors including: workers, occupational non-users, consumers, bystanders associated with consumer use, and other groups of individuals within the general population who may

experience greater exposure. 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 plans to analyze 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 will be analyzed for every exposure scenario.

2.4.1 Environmental Hazards

EPA identified the following sources of environmental hazard data for asbestos: 45 FR 79318, 1980 ATSDR (2001); U.S. EPA (2014c); U.S. EPA (2014b); WHO (2014); and IARC (2012). In addition, EPA conducted a literature search to identify additional environmental hazard data for asbestos 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). Only the *on-topic* references listed in the Ecological Hazard Literature Search Results were considered as potentially relevant data/information sources for the risk evaluation. Inclusion criteria were used to screen the results of the ECOTOX literature search (as explained in the *Strategy for Conducting Literature Searches for Asbestos: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0736). Data from the screened literature are summarized below (Table 2-7. Ecological Hazard Characterization of Chrysotile Asbestos (CASRN 12001-29-5) as ranges (min-max). EPA plans to review these data/information sources during risk evaluation using the data quality review evaluation metrics and the rating criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

Data were available for aquatic organisms (vertebrates, invertebrates and plants) and terrestrial species (earthworms and plants). For problem formulation, a screening evaluation was conducted using aquatic toxicity studies characterizing the effects of chronic exposure of chrysotile asbestos to aquatic invertebrates and fish, presented in Table 2-7. Ecological Hazard Characterization of Chrysotile Asbestos (CASRN 12001-29-5) Preliminary review of these studies indicates that chronic exposure to waterborne chrysotile asbestos may result in reproductive, growth and sublethal effects to these taxa at a concentration range of 10^4-10^8 fibers/L (i.e., 0.01-100 MFL). A comparison to available monitoring data (see Section 2.6.1.2) preliminarily indicates exposure concentrations may be within the same order of magnitude; hence, EPA will further evaluate this pathway.

Table 2-7. Ecological Hazard Characterization of Chrysotile Asbestos (CASRN 12001-29-5)

Duration	Test Organism	Endpoint	Hazard Value[a]	Unit	Effect Endpoint(s)	References
Aquatic Organisms						
Chronic	Fish	NOEC[b]	0.01-1.5	MFL[e]	Behavioral stress (aberrant swimming, loss of equilibrium); Egg development, hatchability, survival; Growth; Mortality	Belanger (1985); Belanger et al. (1990); Belanger et al. (1986c); Cairns et al. (1990)
		LOEC[c]	1-3			
		ChV[d]	0.1-2.12			
	Aquatic invertebrates	LOEC	0.0001-100	MFL	Reduction in siphoning activity; # of larvae released; Alterations of gill tissues; Fiber accumulation in tissues; Growth; Mortality	Belanger et al. (1986b); Belanger et al. (1986a)
	Aquatic Plant	LOEC	0.5	µg chrysotile/ frond	# of fronds; Root length; Chlorophyll content; Carotenoid content; Biomass of fronds; Protein content; Free sugar; Starch; Photosynthetic pigments; Lipid peroxidation; Cellular hydrogen peroxide levels; Catalase activity; Superoxide Dismutase	Trivedi et al. (2004); Trivedi et al. (2007)
Terrestrial Organisms						
Chronic	Terrestrial Plant	ChV	No observed effects	N/A[f]	Growth	Miller et al. (1980)

[a]Values in the tables are presented as reported by the study authors.
[b]NOEC, No Observable Effect Concentration
[c]LOEC, Lowest Observable Effect Concentration
[d]ChV, Chronic Value; Calculated using the geometric mean of LOEC and NOEC values [as described in U.S. EPA (2013)].
[e]MFL, Million Fibers/Liter
[f]N/A, Not applicable

For additional perspective on understanding the environmental hazard of asbestos materials, EPA/OPPT reviewed other, related documents on asbestos materials not considered under TSCA. For example, EPA Region 8 reviewed the same data identified above for the Libby Superfund Site ecological risk assessment (U.S. EPA, 2014b) and considered it relevant; thus suggesting the experiments/information reasonably describes the aquatic hazard of asbestos. However, Region 8 decided to perform *in situ* studies to specifically evaluate ecological receptor effects following exposure to Libby Amphibole Asbestos (LAA, or LA in the report). During the course of performing these experiments/exposures, Region 8 found them difficult to conduct and quantify, thus highlighting the difficulty of evaluating asbestos/asbestiform fibers in ecological receptors.

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 reviewed. EPA relied heavily on these comprehensive reviews in preparing the scope and problem formulation documents. EPA expects to use these documents as a starting point for identifying key and supporting studies to inform the human health hazard assessment, including dose-response analysis. EPA also expects to consider other studies 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 inhalation exposures to human populations. Only inhalation exposures in humans will be evaluated in the risk evaluation of asbestos. The relevant studies will be evaluated using the data quality criteria in the *Application of Systemic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018).

During scoping and problem formulation EPA reviewed the existing EPA IRIS health assessments to ascertain the established health hazards and any known toxicity values. EPA had previously, in the IRIS assessment on asbestos (1988), identified asbestos as a carcinogen causing both lung cancer and mesothelioma from inhalation exposures and derived a unit risk to address both cancers. No toxicity values or unit risks have yet been estimated for other cancers that have been identified by the International Agency for Research on Cancer (IARC) and other government agencies. Given the well-established carcinogenicity of asbestos for lung cancer and mesothelioma, EPA has decided to limit the scope of its systematic review to these two specific cancers with the goal of updating, or reaffirming, the existing unit risk. Asbestos may cause non-cancer health effects, with quantitative evidence coming from the EPA Toxicological Review of Libby Amphibole Asbestos (U.S. EPA, 2014c). At a Target Risk of 1 cancer per 1,000,000 people (1E-6), the existing EPA general asbestos toxicity value appears to be the clear risk driver compared to the only existing EPA non-cancer toxicity value (RfC) for Libby Amphibole Asbestos (U.S. EPA, 2014c). Because cancer is expected to be the risk driver, in conducting further analysis for the risk evaluation of asbestos, EPA will limit the scope of the risk evaluation to lung cancer and mesothelioma in humans. No clear association was found for drinking water asbestos exposure and cancer (NTP, 2016; IARC, 2012), and dermal exposures may cause non-cancerous skin lesions. Since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, which are the basis of the 1988 cancer unit risk, exposures from the oral and dermal routes will not be assessed. These hazards will be evaluated based on the specific exposure scenarios identified for workers, consumers and the general population where applicable.

2.4.2.1 Cancer Hazard

Many authorities have established that there are causal associations between asbestos exposures and lung cancer and mesotheliomas (NTP, 2016; IARC, 2012; ATSDR, 2001; U.S. EPA, 1988b; IARC, 1987, 1977). EPA also noted in the scope that there is a causal association between exposure to asbestos and cancer of the larynx and cancer of the ovary (IARC, 2012), and that 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). In addition, the scope document reported increases in lung cancer mortality reported in both workers and residents exposed to various asbestos fiber types as well as fiber mixtures (IARC, 2012). 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 (IARC, 2012).

During problem formulation, EPA reviewed the existing EPA IRIS health assessments (U.S. EPA, 2014c, 1988b) to ascertain the established health hazards and any known toxicity values. EPA had previously (U.S. EPA, 1988b, 1986) identified asbestos as a carcinogen causing both lung cancer and mesothelioma and derived a unit risk to address both cancers. The U.S. Institute of Medicine (NRC, 2006) and the International Agency for Research on Cancer (IARC, 2012) have evaluated the evidence for causation of cancers of the pharynx, larynx, esophagus, stomach, colon, and rectum, and IARC has evaluated the evidence for cancer of the ovary. Both the U.S. Institute of Medicine and IARC concluded that asbestos causes cancer of the larynx and IARC concluded that asbestos causes cancer of the ovary. No toxicity values or unit risks have yet been estimated for these other cancers.

2.4.2.2 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 analyze available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to asbestos.

2.5 Conceptual Models

EPA risk assessment guidance (U.S. EPA, 2014a, 1998), defines Problem Formulation as the part of the risk assessment framework that identifies the factors to be considered in the assessment. It draws from the regulatory, decision-making and policy context of the assessment and informs the assessment's technical approach.

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. The initial conceptual models describing the scope of the assessment for asbestos have been refined during problem formulation. The changes to the conceptual models in this problem formulation are described along with the rationales.

In this section EPA outlines those pathways that will be included and further analyzed in the risk evaluation; will be included but will not be further analyzed in risk evaluation; and will not be included in the TSCA risk evaluation and the underlying rationale for these decisions.

EPA determined as part of problem formulation that it is not necessary to conduct further analysis on certain exposure pathways that were identified in the asbestos scope document and that remain in the risk evaluation. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without extensive or quantitative risk evaluations (82 FR 33726, 33734, 33739).

As part of this problem formulation, EPA also identified exposure pathways under other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist, i.e., the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA). OPPT worked closely with the offices within EPA that administer and implement the regulatory programs under these statutes. In some cases, EPA has determined that chemicals present in various media pathways (i.e., air, water, land) fall under the jurisdiction of existing regulatory programs and associated analytical processes carried out under other EPA-administered statutes and have been assessed and effectively managed under those programs. EPA believes that the TSCA risk evaluation should focus on those exposure pathways associated with TSCA uses that are not subject to the regulatory regimes discussed above because these pathways are likely to represent the greatest areas of concern to EPA. As a result, EPA does not expect to include in the risk evaluation certain exposure pathways identified in the asbestos scope document.

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

The revised conceptual model (Figure 2-2) describes the pathways of exposure from industrial and commercial activities and uses of asbestos EPA plans to include in the risk evaluation.

The population most likely to have high exposure to asbestos are workers who come into contact with asbestos while on the job (ATSDR, 2001). As described in Section 2.2.2.2, EPA has confirmed the ongoing industrial and commercial uses of asbestos in the chlor-alkali industry, brake blocks in oil industry, and use of sheet gaskets in titanium dioxide production. These uses, as well as uses in other products (brakes and other friction products, other gaskets, woven products, and cement products) will continue to be investigated during the risk evaluation. All of these uses will be included in the risk evaluation, as indicated in Figure 2-2.

EPA anticipates inhalation of asbestos fibers as being the most likely exposure route for workers and occupational non-users. As discussed in Section 2.4.2, given the well-established carcinogenicity of asbestos for lung cancer and mesothelioma, EPA will only evaluate these two specific cancers in the risk evaluation (and associated systematic review) with the goal of updating, or reaffirming, the existing unit risk.

In the Scope document, worker exposures via oral and dermal pathways were identified as potential routes of exposure. However, since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, exposures from those routes (pathways) will not be included in the risk evaluation.

Workers may be exposed via direct contact with dry or friable asbestos during waste handling, treatment and disposal. This could occur during disposal of asbestos containing articles or wastes. 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.

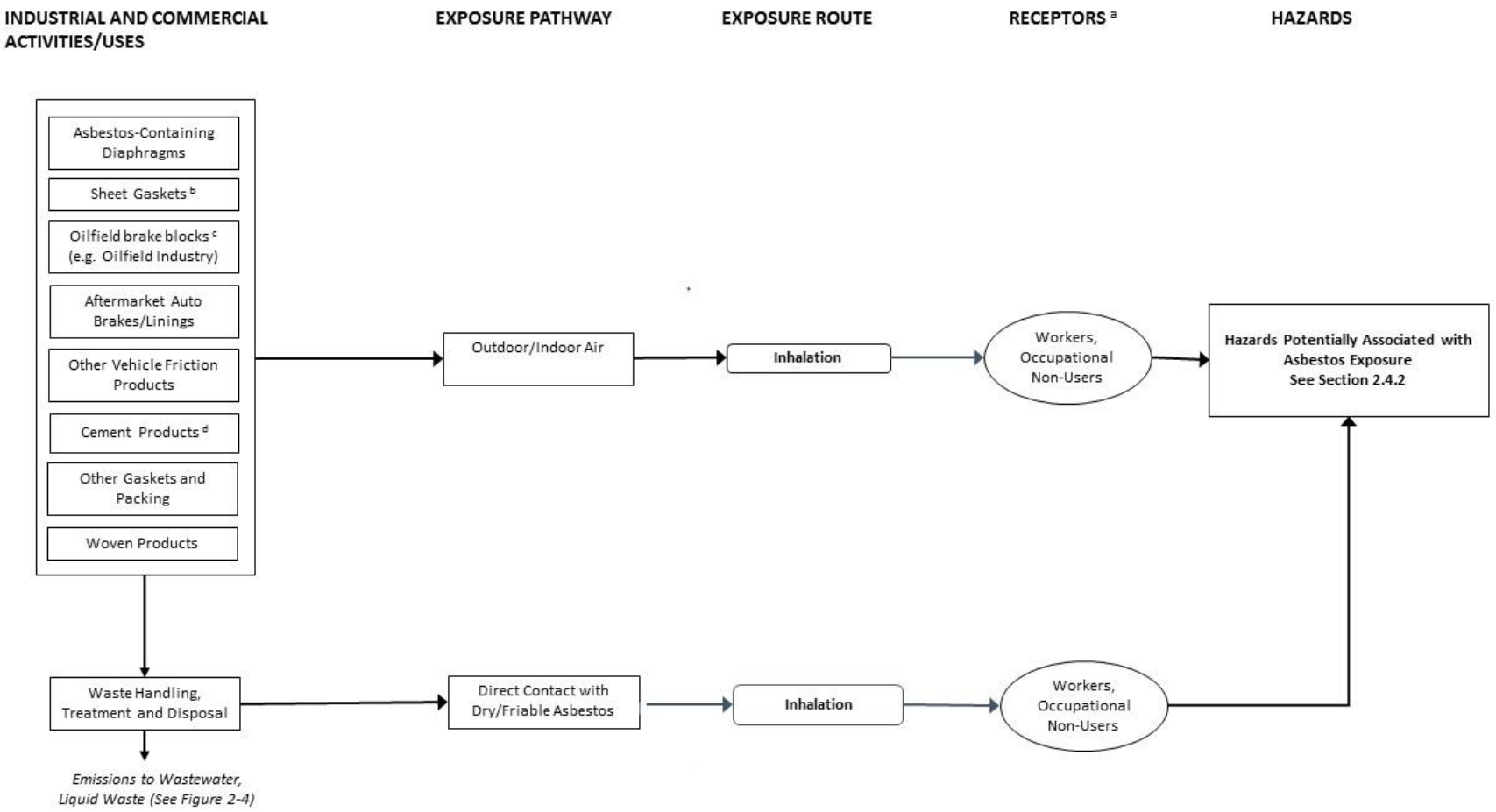

Figure 2-2. Asbestos Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of asbestos.

[a] Receptors include potentially exposed or susceptible subpopulations.
[b] Sheet gaskets were identified during public comment period.
[c] Oilfield brake blocks identified via industry response during problem formulation.
[d] Asbestos cement products identified during problem formulation.

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

Figure 2-3 presents the conceptual model for human populations from potential consumer uses of asbestos. There are very few asbestos-containing products with ongoing uses that were identified and confirmed during problem formulation. EPA identified the import of asbestos-containing automotive brakes and linings and woven products as the only known, intended, or reasonably foreseen asbestos-containing products that may have consumer exposure. These uses are included in Figure 2-3. Consumer exposures will be difficult to evaluate since the quantities of these products that still might be imported into the United States is not known.

Scenarios where consumers could be exposed and may be considered during risk evaluation include: changing asbestos-containing brakes or brake linings or cutting or using asbestos-containing woven products, and handling of asbestos waste that may result from these activities.

EPA anticipates inhalation of asbestos fibers as being the most likely exposure route for consumers. As discussed in Section 2.4.2, given the well-established carcinogenicity of asbestos for lung cancer and mesothelioma, EPA will only evaluate these two specific cancers in the risk evaluation (and associated systematic review) with the goal of updating, or reaffirming, the existing unit risk.

In the Scope document, consumer exposures via oral and dermal pathways were identified as potential routes of exposure. However, since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, exposures from those routes (pathways) will not be included in the risk evaluation.

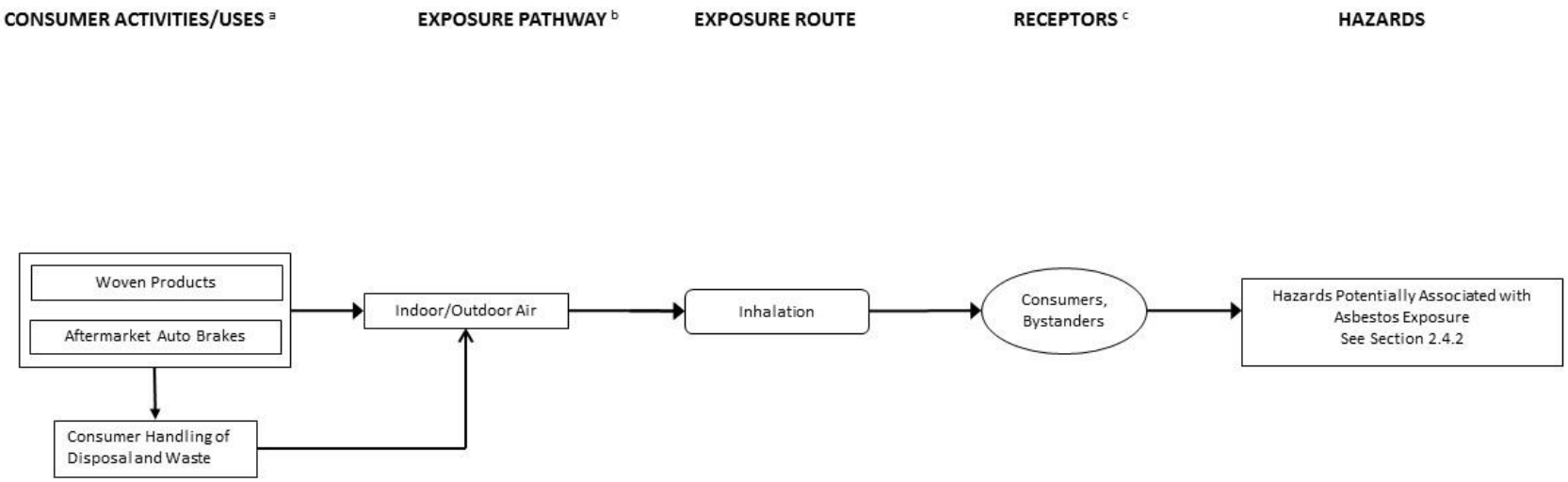

Figure 2-3. Asbestos Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

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

[b] Products may be used during indoor and outdoor activities.

[c] Receptors include potentially exposed and susceptible subpopulations.

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

The revised conceptual model (Figure 2-4) illustrates the expected exposure pathways to human and ecological receptors from environmental releases and waste stream associated with industrial and commercial activities for asbestos. The pathway that EPA plans to include and analyze further in risk evaluation is described in Section 2.5.3.1 and shown in the conceptual model. The pathways that EPA plans to include but not further analyze in risk evaluation are described in Section 2.5.3.2 and the pathways that EPA does not expect to include in risk evaluation are described in Section 2.5.3.3.

2.5.3.1 Pathways That EPA Expects to Include and Further Analyze in Risk Evaluation

EPA plans to further analyze environmental releases from water pathways to aquatic species exposed via contaminated surface water.

No releases to water have been reported to TRI for asbestos (Table 2-4). However, data submitted to EPA from the chlor-alkali industry indicate that water releases may occur from these industries. Based on data submitted to EPA from the chlor-alkali industry, who uses all of the raw asbestos imported into the United States to fabricate asbestos-containing diaphragms, asbestos containing wastes generated in their processes are disposed of according to NESHAP regulations established in 40 CFR 61.150. Asbestos is not regulated as a hazardous waste under RCRA. Asbestos-containing diaphragms used in the chlor-alkali processes may be reused at some of the plants. At the end of the diaphragms' life, water is used to clean and remove the diaphragm from its frame. The wet diaphragm is bagged and landfilled according to NESHAP regulations. Waste water from the washing of the diaphragm and frame is sent to on-site waste water treatment; which may lead to eventual releases to water.

Asbestos-containing gaskets are used in the production of rutile/chlorine based titanium dioxide (TiO2). Based on data submitted to EPA from the asbestos sheet gasket importer/processor, scrap pieces from the gasket cutting process are double bagged and transported to landfills. EPA has been informed that users of asbestos-containing gaskets dispose of spent gaskets primarily via incineration (3 onsite and 1 offsite facility) and RCRA Subtitle C landfill (1 facility). No water releases are anticipated.

Preliminary review of environmental studies indicates that chronic exposure to waterborne chrysotile asbestos may result in reproductive, growth and sublethal effects. Compliance monitoring data, available for 2006-2011 shows 214 systems (or 3.7% of 5,785 systems) with asbestos fiber concentrations greater than the minimum reporting level (MRL) of 0.2 MFL, with asbestos concentrations in 8 systems greater than the MCL of 7 MFL (https://www.epa.gov/dwsixyearreview/six-year-review-3-compliance- monitoring-data-2006-2011). Data from 1998-2005 showed 268 systems (or 3.237% of 8278 systems) had asbestos fiber concentrations greater than or equal to the MRL of 0.2 MFL, with asbestos concentrations in 14 (0.169%) systems greater than the MCL of 7 MFL (https://www.epa.gov/dwsixyearreview/six-year-review-2-drinking-water-standards).

As further explained in Section 2.5.3.2, EPA has not developed CWA section 304(a) recommended water quality criteria for the protection of aquatic life for asbestos and there are no national recommended criteria for this use available for adoption into state water quality standards and available for use in NPDES permits. As a result, this pathway will undergo aquatic life risk evaluation under TSCA (see Section 2.5.3.1).

Therefore, EPA plans to evaluate risks to aquatic species from exposures to asbestos in surface waters.

2.5.3.2 Pathways That EPA Expects to Include in Risk Evaluation but Not Further Analyze

As noted in Section 2.5.3.1 above, there are possible releases from conditions of use (i.e., chlor-alkali plants) to water. Once in water, it will eventually settle into sediments (or possibly biosolids from wastewater treatment plants).

EPA does not expect to perform a full analysis of exposures to asbestos fibers to sediment-dwelling organisms. EPA is still reviewing literature sources identified in the original search that suggest that the asbestos exposure levels in sediments is low and perhaps outdated. Finally, the most important concern for asbestos exposures are via inhalation to humans.

However, EPA does not expect to further analyze general population exposures to asbestos fibers, via inhalation due to lofting of dried asbestos, during or after the land application of biosolids. EPA has identified literature which indicates that asbestos has been detected in biosolids from municipal wastewater treatment. However, it is expected that the concentration of asbestos fibers in biosolids due to current uses of asbestos will be low, and thus the subsequent re-suspension of the asbestos fibers into air following biosolid land application, although possible, will result in exceedingly low airborne concentrations.

2.5.3.3 Pathways That EPA Does Not Expect to Include in the Risk Evaluation

Exposures to receptors (i.e. general population, terrestrial species) may occur from industrial and/or commercial uses, industrial releases to air, water or land, and other conditions of use. As described in Section 2.5, EPA does not expect to include in the risk evaluation pathways under programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist. These pathways are described below.

Air Pathway

The Clean Air Act (CAA) contains a list of hazardous air pollutants (HAP) and provides EPA with the authority to add to that list pollutants that present, or may present, a threat of adverse human health effects or adverse environmental effects. For stationary source categories emitting HAP, the CAA requires issuance of technology-based standards and, if necessary additions or revisions to address developments in practices, processes, and control technologies, and to ensure the standards adequately protect public health and the environment. The CAA thereby provides EPA with comprehensive authority to regulate emissions to ambient air of any hazardous air pollutant.

Asbestos is a HAP. Because stationary source releases of asbestos to ambient air are adequately assessed and any risks effectively managed when under the jurisdiction of the CAA, EPA does not plan to evaluate emission pathways to ambient air from commercial and industrial stationary sources or associated inhalation exposure of the general population or terrestrial species in this TSCA evaluation.

Drinking Water Pathway

EPA has regular analytical processes to identify and evaluate drinking water contaminants of potential regulatory concern for public water systems under the Safe Drinking Water Act (SDWA). Under SDWA, EPA must also review and revise "as appropriate" existing drinking water regulations every 6 years.

EPA has promulgated National Primary Drinking Water Regulations (NPDWRs) for asbestos under the Safe Drinking Water Act. EPA has set an enforceable Maximum Contaminant Level (MCL) as close as

feasible to a health based, non-enforceable Maximum Contaminant Level Goal (MCLG). Feasibility refers to both the ability to treat water to meet the MCL and the ability to monitor water quality at the MCL, SDWA Section 1412(b)(4)(D), and public water systems are required to monitor for the regulated chemical based on a standardized monitoring schedule to ensure compliance with the MCL. The MCL for asbestos in water is 7 million fibers/liter, or 7 MFL.

Hence, because the drinking water exposure pathway for asbestos is currently addressed in the SDWA regulatory analytical process for public water systems, EPA does not expect to include this pathway in the risk evaluation for asbestos under TSCA.

Ambient Water Pathways

EPA develops recommended water quality criteria under section 304(a) of the CWA for pollutants in surface water that are protective of aquatic life or human health designated uses. EPA develops and publishes water quality criteria based on priorities of states and others that reflect the latest scientific knowledge. A subset of these chemicals are identified as "priority pollutants" (103 human health and 27 aquatic life). The CWA requires states adopt numeric criteria for priority pollutants for which EPA has published recommended criteria under section 304(a), the discharge or presence of which in the affected waters could reasonably be expected to interfere with designated uses adopted by the state. When states adopt criteria that EPA approves as part of state's regulatory water quality standards, exposure is considered when state permit writers determine if permit limits are needed and at what level for a specific discharger of a pollutant to ensure protection of the designated uses of the receiving water. Once state adopt criteria as water quality standards, the CWA requires that National Pollutant Discharge Elimination System (NPDES) discharge permits include effluent limits as stringent as necessary to meet standards. CWA section 301(b)(1)(C). This is the process used under the CWA to address risk to human health and aquatic life from exposure to a pollutant in ambient waters.

EPA has identified asbestos as a priority pollutant and EPA has developed recommended water quality criteria for protection of human health for asbestos which are available for adoption into state water quality standards for the protection of human health and are available for use by NPDES permitting authorities in deriving effluent limits to meet state narrative criteria. As such, EPA does not expect to include this pathway in the risk evaluation under TSCA. EPA's Office of Water and Office of Pollution Prevention and Toxics will continue to work together providing understanding and analysis of the CWA water quality criteria development process and to exchange information related to toxicity of chemicals undergoing risk evaluation under TSCA. EPA may update its CWA section 304(a) water quality criteria for asbestos in the future under the CWA.

EPA has not developed CWA section 304(a) recommended water quality criteria for the protection of aquatic life for asbestos, so there are no national recommended criteria for this use available for adoption into state water quality standards and available for use in NPDES permits. As a result, this pathway will undergo aquatic life risk evaluation under TSCA (see Section 2.5.3.1). EPA may publish CWA section 304(a) aquatic life criteria for asbestos in the future if it is identified as a priority under the CWA.

Disposal Pathways

Asbestos is not regulated as a RCRA hazardous waste under RCRA Subtitle C. The general RCRA standard in RCRA section 3004(a) for the technical criteria that govern the management (treatment, storage, and disposal) of hazardous waste are those "necessary to protect human health and the environment." Subtitle C controls cover not only hazardous wastes that are landfilled, but also hazardous wastes that are incinerated (subject to joint control under RCRA Subtitle C and the Clean Air Act

(CAA) hazardous waste combustion MACT) or injected into UIC Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA)).

EPA does not expect to include emissions to ambient air from municipal and industrial waste incineration and energy recovery units in the risk evaluation, as they are regulated under section 129 of the Clean Air Act. An incinerator burning hazardous waste must achieve a destruction and removal efficiency (DRE) of 99.99% for each principal organic hazardous constituent. Furthermore, RCRA provisions for site-specific risk assessments and the Hazardous Waste Combustor maximum achievable control technology (MACT) rule provisions for a Residual Risk and Technology Review together cover risks for RCRA-regulated hazardous wastes and CAA HAPs. Emissions to ambient air from municipal and industrial waste incineration and energy recovery units will not be included in the risk evaluation, as they are regulated under section 129 of the Clean Air Act. CAA section 129 also requires EPA to review and, if necessary, add provisions to ensure the standards adequately protect public health and the environment. Thus, the asbestos combustion by-products from incineration treatment of asbestos wastes (less than 188,437 lbs identified in Table 2-4 under "treatment" which includes incineration, as well as other treatment methods) would be subject to the aforementioned regulations.

EPA does not expect to include on-site releases to land that go to underground injection in its risk evaluation. TRI reporting in 2015 indicated zero pounds of asbestos were released to underground injection to a Class I well. Therefore, disposal of asbestos via underground injection will not result in environmental and general population exposures.

EPA does not expect to include on-site releases to land that go to RCRA Subtitle C hazardous waste landfills or RCRA Subtitle D municipal solid waste (MSW) landfills or exposures of the general population (including susceptible populations) or terrestrial species from such releases in the TSCA risk evaluation. Based on 2015 reporting to TRI, approximately 38% of the land disposals of asbestos occur in Subtitle C landfills (9.7 million lbs) as opposed to all other land disposal (15.8 million pounds). Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Bulk liquids may not be disposed in Subtitle C landfills. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. In addition, landfills have special requirements for handling and securing the asbestos-containing waste regulated under NESHAP to prevent releases of asbestos into the air. NESHAP requires that regulated 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. Landfills have special requirements for handling and securing the asbestos containing waste 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. Finally, asbestos is a fiber that is not likely to be leached out of a landfill. Given these controls, general population exposure to asbestos in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

While permitted and managed by the individual states, municipal solid waste (MSW) landfills are required by federal regulations to implement some of the same requirements as Subtitle C landfills. MSW landfills generally must have a liner system with leachate collection and conduct groundwater

monitoring and corrective action when releases are detected. MSW landfills are also subject to closure and post-closure care requirements, and must have financial assurance for funding of any needed corrective actions. MSW landfills have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 220 lbs per month). EPA does not expect to include on-site releases to land from RCRA Subtitle C hazardous waste landfills or RCRA Subtitle D municipal solid waste landfills or exposures of the general population (including susceptible populations) or terrestrial species in this TSCA evaluation.

Industrial-non-hazardous and construction/demolition waste landfills are primarily regulated under state regulatory programs. States must also implement limited federal regulatory requirements for siting, groundwater monitoring, and corrective action, and a prohibition on open dumping and disposal of bulk liquids. States may establish additional requirements such as for liners, post-closure care and financial assurance, but are not required to do so. Therefore, EPA does not expect to include this pathway in the risk evaluation.

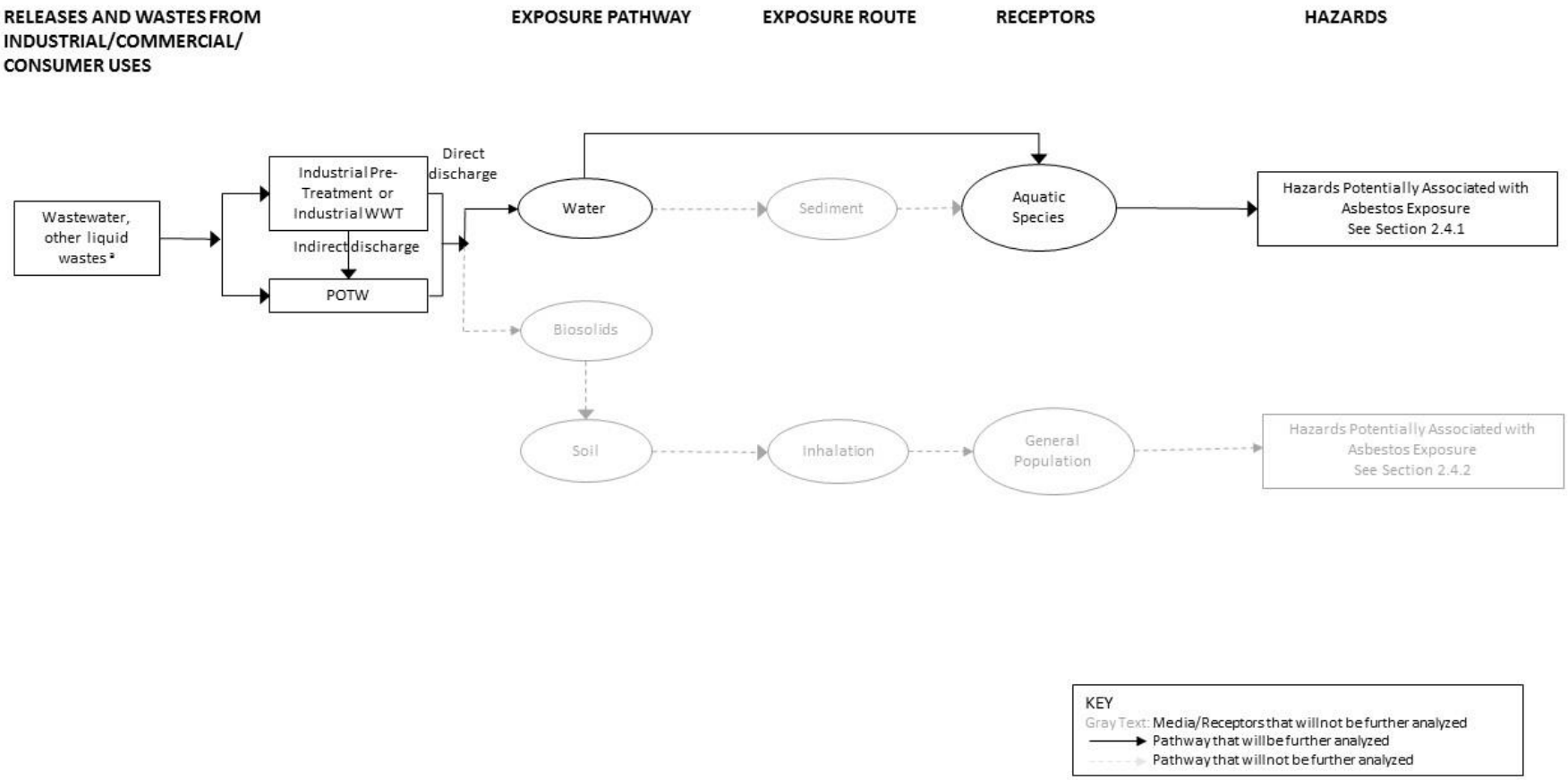

Figure 2-4. Asbestos Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

[a] 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).

2.6 Analysis Plan

The analysis plan presented here elaborates on the initial analysis plan that was published in the *Scope of the Risk Evaluation for Asbestos* (U.S. EPA, 2017c).

The analysis plan is based on the conditions of use of asbestos, as described in Section 2.2 of this problem formulation. EPA is implementing systematic review approaches to identify, select, assess, integrate and summarize the findings of studies supporting the TSCA risk evaluation. The analytical approaches and considerations in the analysis plan are used to frame the scope of the systematic review activities for that assessment. The supplemental document, *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018), provides additional information about criteria and methods that have been and will be applied to the first 10 chemical risk evaluations.

While EPA has conducted a comprehensive search for reasonably available information from public sources as described in the *Scope of the Risk Evaluation for Asbestos* (U.S. EPA, 2017c), 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 during the risk evaluation. EPA will continue to consider new information submitted by the public.

During risk evaluation, EPA will rely on the comprehensive literature results (see *Asbestos (CASRN 1332-21-4) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0736) or supplemental literature searches to address specific questions. Further, EPA may consider any relevant confidential business information (CBI) in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure. The analysis plan is based on EPA's knowledge of asbestos to date which includes partial, but not complete review of identified literature. Should additional data or approaches become available, EPA may refine its analysis plan based on this information.

2.6.1 Exposure

Based on their physical-chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment chemical substances are more likely to be present in some media and less likely to be present in others. Media-specific levels will vary based on the chemical substance of interest. For most chemical substances level(s) can be characterized through a combination of available monitoring data and modeling approaches.

2.6.1.1 Environmental Fate and Environmental Releases

In the scope document, there was a section in the analysis plan pertaining to environmental fate. Most questions originally posed were determined to be not relevant for asbestos, a naturally occurring and solid material, during problem formulation.

As described in Section 2.5, EPA does not expect to further analyze certain releases to environmental media. However, for purposes of developing estimates of occupational exposure, EPA may use release related data collected under selected data sources such as the Toxics Release Inventory (TRI) and National Emissions Inventory (NEI) programs.

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

1) Review reasonably available published literature or information on processes associated with the conditions of use to evaluate the types of releases and wastes generated from ongoing uses.

- EPA has received and continues to receive measured data from some of the industries, and these data will be reviewed and used in the risk evaluation, where appropriate. These documents can be found at:

  September 6, 2017, Asbestos Use Outreach Meeting Between EPA, Occidental Chemical Corporation and the American Chemistry Council (ACC)
  https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0116

  September 14, 2017, Asbestos Use Outreach Meeting Between EPA, Olin Chemical and the American Chemistry Council (ACC)
  https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0117

  October 20, 2017, Asbestos Use Outreach Teleconference Between EPA and American Friction
  https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0118

  October 30, 2017, Asbestos Use Outreach Meeting Between EPA, Chemours, Branham Corp. and the American Chemistry Council (ACC)
  https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0736-0119

2) Review reasonably available release data on asbestos, including measured or estimated release data (e.g., data collected under the TRI and National Emissions Inventory [NEI] programs and Office of Water, and Office of Land and Emergency Management, etc.).
   - The Office of Water provided OPPT with surface water data and a preliminary review shows some samples in receiving waters have reported asbestos concentrations ranging from 1-14 million fibers per liter (MFL).
   - Review site specific treatment information for possible development of site specific release model.
   - Review the release assessment approaches developed for 1988 Asbestos Ban and Phase-Out rule and, if possible, make any needed modifications or updates to models and exposure parameters used in ABPO.

2.6.1.2 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 release water (ecological receptors only).
   - Based on the discussions in Sections 2.2 through 2.5, EPA will be focusing on the possible presence of asbestos in water for aquatic organisms.
2) Review reasonably available information on releases near industrial point sources (e.g. asbestos releases from chlor-alkali manufacture) compare with available monitoring data. Available exposure models will be evaluated and considered alongside available monitoring data to characterize environmental exposures to water for ecological receptors. The following sources of data could be consulted:
   - Some information has been evaluated (OW six-year review as cited above) and others (listed below) will be further analyzed.

- STORET (USGS/EPS) for chemicals in surface water and sediment: https://www.epa.gov/waterdata/storage-and-retrieval-and-water-quality-exchange#portal

3) Review 1989 Asbestos Ban and Phase Out (ABPO) support documents (i.e. exposure assessment, risk assessment documents) to inform approaches for air modeling and general population exposures for asbestos-containing products. Evaluate more recent modeling approaches for and review secondary sources of data (e.g., ATSDR).
4) Evaluate the weight of evidence of environmental occurrence data and modeled estimates.
5) Continue to map or group each condition(s) of use to environmental assessment scenario(s).

2.6.1.3 Occupational Exposures

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

1) Review reasonably available worker exposure monitoring data for specific condition(s) of use (i.e., personal and area samples from chlor-alkali industry, users of asbestos-containing sheet gaskets, OSHA, NIOSH and other data received by EPA and found in published literature).
    - Information provided during meetings with the chlor-alkali industry, written correspondence from the American Chemistry Council (ACC), site visits to chlor-alkali plants will be reviewed and used by EPA in exposure scenarios;
    - Information provided by chemical industry representatives along with an importer/supplier of asbestos-containing sheet gaskets who further fabricate the sheet gaskets for use in equipment for the manufacture of titanium dioxide will be used by EPA in exposure scenarios.
    - Identify additional information on imported asbestos brake blocks used in the oil industry to define exposure scenarios.
    - Received personal monitoring and area sampling from OSHA.
2) Review process information, including use of personal protective equipment and engineering controls, from the chlor-alkali industry and users of asbestos-containing sheet gaskets (an effort currently underway), to better characterize work practices and exposures in occupational settings.
    - Review information on PPE use received from chlor-alkali industry;
    - Review information on PPE use received from gasket fabricators
    - Obtain PPE and exposure data for workers from use of oil brake blocks.
3) For conditions of use where information is limited or not available, review existing exposure models that may be applicable.
    - Review 1988 Asbestos Ban and Phase Out (ABPO) rule support documents to inform approaches for workplace exposure modeling.
    - Evaluate current models and exposure assessment approaches for workplace air modeling (e.g., AERMOD, EFAST).
    - EPA is continuing to review the literature to identify exposure scenarios corresponding to some of the conditions of use, such as other gaskets and packing and woven products. EPA will continue to look for reasonably available information to understand those conditions of use which may inform exposure scenarios. EPA may also need to further research applicable models that may be used to estimate releases for certain conditions of use.
4) Incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios, as appropriate.
5) Evaluate the weight of the evidence of occupational exposure data.

6) Use the Table provided in Appendix C, which maps and groups each condition of use to occupational exposure assessment scenario(s), to develop, adapt, or apply exposure models or empirical data to the risk evaluation.

2.6.1.4 Consumer Exposures

As noted in Section 2.2, the consumer products being considered are imported asbestos-containing woven products and imported asbestos brakes/linings. EPA expects to consider and analyze both consumers using a consumer product and bystanders who are nearby as follows:

1) Define exposure scenarios for consumers by considering sources of exposure (consumer products), exposure pathways, exposure settings, exposure routes, and populations exposed. Considerations for constructing exposure scenarios for consumers include:
    - Given that the consumer exposure scenarios are limited to 2 categories of uses and that very little information has been identified to date on the extent of the uses, EPA will attempt to communicate with identified importers of asbestos-containing products (automotive brakes and woven products) to determine current status of import and use
    - Identify reasonably available data on consumer products or products available for consumer use including the content of asbestos in products
    - Identify information characterizing the use patterns of consumer products containing asbestos including how the product is used, the amount of product used, frequency and duration of use, and room of use
    - Identify the associated exposure setting and route of exposure for consumers
    - Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need be further refined. Populations who may be exposed to products, including potentially exposed and susceptible subpopulations such as children or women of child bearing age, consumers and bystanders of uses of existing asbestos products including subsets of consumers who may use commercially available asbestos-containing products more frequently. For exposure pathways where data are not available, review existing indoor and outdoor exposure models that may be applicable in estimating exposure levels. Determine the applicability of the identified models for use in a quantitative exposure assessment.
2) Use the Table provided in Appendix C, which maps and groups each condition of use to consumer exposure assessment scenario(s), to develop, adapt, or apply exposure models or empirical data to the risk evaluation.
3) Evaluate the weight of evidence of consumer exposure data.

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.
    - Environmental hazard studies were identified using the literature search strategies laid out in the "*Strategy for Conducting Literature Searches for Asbestos: Supplemental Document to the TSCA Scope Document (CASRN 1332-21-4)*". Section 2.4.1 provides a summary of the appropriate environmental hazard data.
    - As discussed in Section 2.5.3.1, only aquatic ecological receptors were identified as being evaluated further for this risk evaluation.
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.
    - There are aquatic (aqueous-only) studies identified, which assess the aquatic hazard of chronic (13-86 days) exposure to chrysotile asbestos. The chronic hazard to fish and aquatic invertebrates exposed to asbestos is possible at concentrations ranging from 10^4-10^8 fibers/L.
3) Derive aquatic concentrations of concern (COC) for acute and, where possible, chronic endpoints.

    The aquatic environmental hazard studies may be used to derive acute and chronic concentrations of concern (COC) for mortality, behavioral, developmental and reproductive or other endpoints determined to be detrimental to environmental populations. Depending on the robustness of the evaluated data for a particular organism (e.g. aquatic invertebrates), environmental hazard values (e.g. ECx/LCx/NOEC/LOEC, etc.) may be derived and used to further understand the hazard characteristics of asbestos to aquatic species.
4) Evaluate the weight-of-evidence of the environmental hazard data.
    - In the risk evaluation, each study will be evaluated based on its overall study confidence. An analysis of the acute and chronic toxicity values derived from the studies may then be used to determine a reliable range of acute and chronic toxicity thresholds to characterize the hazard of asbestos to environmental organisms. EPA expects to consider and evaluate the weight-of-evidence (WOE) of the aquatic (aqueous-only) environmental hazard data by comparing and contrasting different aquatic endpoints in the literature and U.S. EPA WOE guidance document (U.S. EPA, 2016d).
5) Consider the route(s) of exposure, available environmental monitoring data and available approaches to integrate exposure and hazard assessments.
    - The chronic hazard to fish and aquatic invertebrates exposed to asbestos is possible at concentrations ranging from 10^4- 10^8 fibers/L; which is equivalent to 0.01 to 100 MFL (million fibers/Liter). The Office of Water provided OPPT with surface water data and a preliminary review shows some samples in receiving waters have reported asbestos concentrations ranging from 1-14 MFL.

2.6.2.2 Human Health Hazards

Given the well-established carcinogenicity of asbestos for lung cancer and mesothelioma, EPA decided to limit the scope of its systematic review to these two specific cancers with the goal of updating, or reaffirming, the existing cancer unit risk (U.S. EPA, 1988b).

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

1) Included human health studies will be reviewed using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).
    - Studies will be evaluated using specific data evaluation criteria.
    - Study results will be extracted and presented in evidence tables by cancer endpoint.
2) Evaluate the weight of the scientific evidence of human health hazard data.
    - EPA will rely on the weight of the scientific evidence when evaluating and integrating human health hazard data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.
    - Assess dose-response information to refine quantitative unit risk for lung cancer and mesothelioma. Review the appropriate human data identified to update, or reaffirm, the 1988 quantitative estimate of the unit risk of asbestos-related lung cancer and mesothelioma by the inhalation route.
3) In evaluating reasonably available data, EPA will determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.

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) (U.S. EPA, 2000). EPA will also present information in this section consistent with approaches described in the Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726). For instance, in the risk characterization summary, EPA will further carry out the obligations under TSCA section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. EPA will also be guided by EPA's Information Quality Guidelines (U.S. EPA, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA will also identify: (1) Each population addressed by an estimate of applicable risk effects; (2) the expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected; (3) each appropriate upper-bound or lower bound estimate of risk; (4) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) peer reviewed studies known to the

Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

REFERENCES

ACGIH. (1994). 1994-1995 Threshold limit values for chemical substances and physical agents and biological exposure indices. Cincinnati, OH.

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. (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. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/3098571.

Badollet, MS. (1951). Asbestos, a mineral of unparalleled properties. 54: 151-160.

Belanger, SE. (1985) Functional and Pathological Responses of Selected Aquatic Organisms to Chrysotile Asbestos. (Doctoral Dissertation). Virginia Polytechnic Institute and State University, Blacksburg, VA.

Belanger, SE; Cherry, DS; Cairns, J. (1990). Functional and pathological impairment of japanese medaka (oryzias-latipes) by long-term asbestos exposure. Aquat Toxicol. 17: 133-154. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/3585046.

Belanger, SE; Cherry, DS; Cairns J, J. R. (1986a). SEASONAL BEHAVIORAL AND GROWTH CHANGES OF JUVENILE CORBICULA-FLUMINEA EXPOSED TO CHRYSOTILE ASBESTOS. Water Res. 20: 1243-1250. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/3093856.

Belanger, SE; Cherry, DS; Cairns J, J. R. (1986b). UPTAKE OF CHRYSOTILE ASBESTOS FIBERS ALTERS GROWTH AND REPRODUCTION OF ASIATIC CLAMS. Can J Fish Aquat Sci. 43: 43-52.

Belanger, SE; Schurr, K; Allen, DJ; Gohara, AF. (1986c). Effects of chrysotile asbestos on coho salmon and green sunfish: evidence of behavioral and pathological stress. Environ Res. 39: 74-85. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/3584231.

Cairns, J; Cherry, DS; Belanger, SE. (1990). Functional and Pathological Impairment of Japanese Medaka (Oryzias latipes) by Long-term Asbestos Exposure. 17: 133-154. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/3660974.

CalEPA. (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.

Flanagan, DM. (2016). 2015 Minerals yearbook. Asbestos [advance release]. In US Geological Survey 2015 Minerals Yearbook. Reston, VA: U.S. Geological Survey. https://minerals.usgs.gov/minerals/pubs/commodity/asbestos/myb1-2015-asbes.pdf.

Hodgson, AA. (1986). Scientific advances in asbestos, 1967 to 1985. Crowthorne, United Kingdom: Anjalena Publications Ltd.

Hwang, CY. (1983). Size and shape of airborne asbestos fibres in mines and mills. Br J Ind Med. 40: 273-279.

IARC. (1977). IARC monographs on the evaluation of carcinogenic risk of chemicals to man: Asbestos. Lyon, France: World Health Organization. http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono14.pdf.

IARC. (1987). Asbestos and certain asbestos compounds [IARC Monograph]. In Overall evaluations of carcinogenicity: An updating of IARC monographs volumes 1 to 42 (pp. 106-116). Lyon, France. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/3827265C3 - 27,30,384,1656,1893,1898,1919,1923,1924,1927,2214,2537.

IARC. (2012). A review of human carcinogens. Part C: Arsenic, metals, fibres, and dusts [IARC Monograph]. Lyon, France: World Health Organization. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/1104368.

Miller, RW; Honarvar, S; Hunsaker, B. (1980). Effects of drilling fluids on soils and plants: I. Individual fluid components. J Environ Qual. 9: 547-552. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/3655179.

NIOSH. (2007). NIOSH pocket guide to chemical hazards. (DHHS-2005-149. CBRNIAC-CB-112149). Cincinnati, OH. http://www.cdc.gov/niosh/docs/2005-149/.

NIOSH. (2011). Current intelligence bulletin 62: Asbestos fibers and other elongate mineral particles: State of the science and roadmap for research [Revised April 2011] (Revised ed.). (DHHS (NIOSH) Publication No. 2011–159). Atlanta, GA: National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention. https://www.cdc.gov/niosh/docs/2011-159/pdfs/2011-159.pdf.

NRC. (1983). Drinking water and health: Volume 5. Washington, DC: National Academies Press. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/3827172C3 - 2537,2540.

NRC. (2006). Asbestos: Selected cancers. Institute of Medicine (US) Committee on Asbestos: Selected Health Effects. Washington, DC: The National Academies Press. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/2228647C3 - 2537.

NTP. (2016). 14th Report On Carcinogens. Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service. https://ntp.niehs.nih.gov/pubhealth/roc/index-1.html.

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.

Trivedi, AK; Ahmad, I; Musthapa, MS; Ansari, FA. (2007). Environmental contamination of chrysotile asbestos and its toxic effects on antioxidative system of Lemna gibba. Arch Environ Contam Toxicol. 52: 355-362. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/621276.

Trivedi, AK; Ahmad, I; Musthapa, MS; Ansari, FA; Rahman, Q. (2004). Environmental contamination of chrysotile asbestos and its toxic effects on growth and physiological and biochemical parameters of Lemna gibba. Arch Environ Contam Toxicol. 47: 281-289. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/3080106.

U.S. EPA. (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. (1980b). Water Quality Criteria Documents. 45: 79318-79379(ABS).

U.S. EPA. (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. (1986). Airborne asbestos health assessment update. (EPA/600/8-84/003F). Washington DC: U.S. Environmental Protection Agency, Environmental Criteria and Assessment. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/17608.

U.S. EPA. (1988a). Asbestos Modeling Study. Final Report. Report from Versar to EPA. (560/3-88/091). Washington, D.C.: Office of Toxic Substances.

U.S. EPA. (1988b). IRIS summary for asbestos (CASRN 1332-21-4). Washington, DC: U.S. Environmental Protection Agency, Integrated Risk Information System. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/783514.

U.S. EPA. (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. (1998). Guidelines for ecological risk assessment [EPA Report]. (EPA/630/R-95/002F). Washington, DC: U.S. Environmental Protection Agency, Risk Assessment Forum. http://www.epa.gov/raf/publications/guidelines-ecological-risk-assessment.htm.

U.S. EPA. (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. https://www.epa.gov/risk/risk-characterization-handbook.

U.S. EPA. (2002). Guidelines for ensuring and maximizing the quality, objectivity, utility, and integrity, of information disseminated by the Environmental Protection Agency. (EPA/260/R-02/008). Washington, DC: U.S. Environmental Protection Agency, Office of Environmental Information. http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf.

U.S. EPA. (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. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=158363.

U.S. EPA. (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. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=236252.

U.S. EPA. (2013). Interpretive assistance document for assessment of discrete organic chemicals. Sustainable futures summary assessment [EPA Report]. Washington, DC. http://www.epa.gov/sites/production/files/2015-05/documents/05-iad_discretes_june2013.pdf.

U.S. EPA. (2014a). Framework for human health risk assessment to inform decision making. Final [EPA Report]. (EPA/100/R-14/001). Washington, DC: U.S. Environmental Protection, Risk Assessment Forum. http://www2.epa.gov/risk/framework-human-health-risk-assessment-inform-decision-making.

U.S. EPA. (2014b). Site-wide Baseline Ecological Risk Assessment Libby Asbestos Superfund Site. https://www.epa.gov/sites/production/files/2015-01/documents/libby-asbestos-site-wide-bera-1-9-2015.pdf.

U.S. EPA. (2014c). Toxicological review of libby amphibole asbestos: In support of summary information on the Integrated Risk Information System (IRIS) [EPA Report]. (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. (2016a). Asbestos national emissions standard for hazardous air pollutants: Waste disposal and transportation. https://www.epa.gov/asbestos/asbestos-national-emissions-standard-hazardous-air-pollutants-neshap#was.

U.S. EPA. (2016b). Public database 2016 chemical data reporting (May 2017 release). Washington, DC: US Environmental Protection Agency, Office of Pollution Prevention and Toxics. Retrieved from https://www.epa.gov/chemical-data-reporting

U.S. EPA. (2016c). 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. (2016d). Weight of evidence in ecological assessment. (EPA100R16001). Washington, DC: Office of the Science Advisor. https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=335523.

U.S. EPA. (2017a). How to report under chemical data reporting. https://www.epa.gov/chemical-data-reporting/how-report-under-chemical-data-reporting.

U.S. EPA. (2017b). Preliminary information on manufacturing, processing, distribution, use, and disposal: Asbestos. Support document for Docket EPA-HQ-OPPT-2016-0736 [Comment].

Washington, DC: Office of Chemical Safety and Pollution Prevention. https://www.epa.gov/sites/production/files/2017-02/documents/asbestos.pdf.
U.S. EPA. (2017c). Scope of the risk evaluation for Asbestos [EPA Report]. (EPA-740-R1-7008). Washington, DC: U.S. EPA, Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT). https://www.epa.gov/sites/production/files/2017-06/documents/asbestos_scope_06-22-17.pdf.
U.S. EPA. (2017d). Toxics Release Inventory (TRI). Retrieved from https://www.epa.gov/toxics-release-inventory-tri-program/tri-data-and-tools
U.S. EPA. (2018). Application of systematic review in TSCA risk evaluations: DRAFT Version 1.0. (740P18001). Washington, D.C.: U.S. Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.
USGS. (2016). Mineral commodity summaries: Asbestos. https://minerals.usgs.gov/minerals/pubs/commodity/asbestos/mcs-2016-asbes.pdf.
USGS. (2017). Mineral commodity summaries 2017. Washington, DC: U.S. Department of the Interior. https://minerals.usgs.gov/minerals/pubs/mcs/2017/mcs2017.pdf.
USGS. (2018). Mineral commodity summaries 2018. Washington, DC: U.S. Department of the Interior. http://dx.doi.org/10.3133/70194932.
Versar. (1987). Nonoccupational asbestos exposure. Revised Report. Washington, D.C.: U.S. Environmental Protection Agency.
Virta, R. (2011). Asbestos. In Kirk-Othmer Encyclopedia of Chemical Technology. [online]: John Wiley & Sons. http://dx.doi.org/10.1002/0471238961.0119020510151209.a01.pub3.
WHO. (2014). Chrysotile asbestos. Geneva, Switzerland. https://heronet.epa.gov/heronet/index.cfm/reference/download/reference_id/3827263.

APPENDICES

Appendix A REGULATORY HISTORY

A-1 Federal Laws and Regulations

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, record-keeping 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 polychlorinated biphenyls (PCBs), asbestos, radon and lead-based paint. The Frank R. Lautenberg Chemical Safety for the 21st Century Act updated TSCA in 2016 https://www.epa.gov/laws-regulations/summary-toxic-substances-control-act.

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 local education agencies (i.e., school districts) to inspect school buildings 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 school buildings and also 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) in school buildings.

1989 Asbestos: Manufacture, Importation, Processing, and Distribution in Commerce Prohibitions; Final Rule (also known as Asbestos Ban and Phase-out Rule (Remanded), 1989)
40 CFR Part 763, Subpart I
Docket ID: OPTS-62048E; FRL-3269-8

- 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):

- Corrugated paper
- Rollboard
- Commercial paper
- Specialty paper
- 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 (Defined by 40 CFR 763.163 as "commercial uses of asbestos not identified in §763.165 the manufacture, importation or processing of which would be initiated for the first time after August 25, 1989.").

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
15 U.S.C. §2607(f)

- Helped to provide transparency and identify the companies making certain types of asbestos-containing 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 in buildings and other facilities (but excluding residences with 4 or fewer dwelling units single family homes).
- 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 leak-tight 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.

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, time-weighted 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) 16 CFR 1500
Food and Drug Administration (FDA): Prohibits the use of asbestos-containing filters in pharmaceutical manufacturing, processing and packing. 21 CFR 211.72

Mine Safety and Health Administration (MSHA): follows OSHA's safety standards.
Surface Mines 30 CFR part 56, subpart D
Underground Mines 30 CFR part 57, subpart D

Department of Transportation

Prescribes the requirements for shipping manifests and transport vehicle placarding applicable to asbestos 40 CFR part 172.

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. . Thirty-nine (39) states[6] have EPA-approved MAP programs and twelve (12) states[7] 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 or further delegate those oversight responsibilities to local municipal governments. While federal regulations set national asbestos safety standards, states have the authority to impose stricter regulations. As an example, many states extend asbestos federal regulations – such as asbestos remediation by trained and accredited professionals, demolition notification, and asbestos disposal – to ensure safety in single-family homes. Thirty (30) states[8] require firms hired to abate asbestos in single family homes to be licensed by the state. Nine (9) states[9] mandate a combination of notifications to the state, asbestos inspections, or proper removal of asbestos in single family homes. Some states have regulations completely independent of the federal regulations. For example, California and Washington regulate products containing asbestos. Both prohibit use of more than 0.1% 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

Asbestos is listed on California's Candidate Chemical List as a carcinogen. Under California's Propositions 65, businesses are required to warn Californians of the presence and danger of asbestos 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.

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[6] Alabama, Alaska, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Illinois, Indiana, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Texas, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

[7] Connecticut, Colorado, Illinois, Kentucky, Louisiana, Massachusetts, Maine, New Hampshire, Oklahoma, Rhode Island, Texas, and Utah.

[8] California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Utah, Vermont, Virginia, Washington, West Virginia, and Wisconsin.

[9] Colorado, Connecticut, Georgia, Maine, Massachusetts, New York, Oregon, Vermont, and West Virginia.

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 Complete List of TURA Chemicals - March 2016.

Minnesota
Toxic Free Kids Act Minn. Stat. 2010 116.9401 – 116.9407
Asbestos is included on the 2016 Minnesota Chemicals of High Concern List 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 – Air Toxics Air Pollution Control Regulation No. 22
Establishes acceptable ambient air levels for asbestos.

Washington
Better Brakes Law (Effective 2015) *Chapter 70.285 RCW Brake Friction Material*
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.
Requirement to Label Building Materials that Contain Asbestos Chapter 70.310 RCW
Building materials that contain asbestos must be clearly labeled as such by manufacturers, wholesalers, and distributors.

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 proposed a rule to ban asbestos and regulate asbestos-containing products (Prohibition of Asbestos and Asbestos Products Regulations).

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

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 (USGS, 2016).

B-1-1-2 Import

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, all of which originated from Brazil in 2017 (USGS, 2018). USGS reports that in 2017, the United States imported approximately 300 metric tons of raw asbestos, the total of which they state is used in the chlor-alkali industry (USGS, 2018). In 2016, the United States imported approximately 702 metric tons of raw asbestos (USGS, 2017). According to chlor-alkali industry information, chrysotile 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 (raw chrysotile) is used in the chlor-alkali industry for the fabrication of semi-permeable diaphragms, which effectively separate the anode from the cathode chemicals in the production of chorine and sodium hydroxide (caustic soda) (USGS, 2017). 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 semi-permeable 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 m^2 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. In plants where the diaphragm is replaced but the cell is reused, 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. At least one U.S. company imports and distributes non-metallic, asbestos-woven brake blocks used in the drawworks of drilling rigs. According to product specification sheets, 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. 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 *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: Asbestos* public document [Docket: EPA-HQ-OPPT-2016-0736; (U.S. EPA, 2017b)], 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 EPA-HQ-OPPT-2016-0736-0067). 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. EPA learned through stakeholder meetings that these sheet gaskets are imported, processed, then distributed in the United States.

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 or construction worker installing cement pipes). Most available products used commercially contain non-friable asbestos but can become friable during processing and use.

B-1-3-4 Consumer Uses

Remaining asbestos-containing products available for consumer use in the United States include a limited number of imported woven products and imported aftermarket friction products (USGS, 2017). 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 NESHAP-regulated 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-air-pollutants-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, 2016a)(U.S. EPA, 2016a)(U.S. EPA, 2016a). 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 are 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.

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

North American Industrial Classification System (NAICS)	NAICS Description
22	Utilities
23	Construction
31	Manufacturing
32	Manufacturing
33	Manufacturing
42	Wholesale trade

North American Industrial Classification System (NAICS)	NAICS Description
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

Appendix C SUPPORTING TABLE FOR INDUSTRIAL, COMMERCIAL AND CONSUMER ACTIVITIES AND USES FOR CONCEPTUAL MODELS

This appendix provides the rationale for inclusion and exclusion of exposure pathways for industrial, commercial and consumer activities.

Table_Appendix C-1. Preliminary Rationale for Inclusion and Exclusion of Exposure Pathways for Industrial, Commercial and Consumer Activities

Product Category (or Category)	Use Example (or Subcategory)	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population[1]	Proposed for Further Risk Evaluation	Rationale for Further Evaluation / No Further Evaluation
Asbestos Diaphragms	Chlor-alkali Industry	Manufacture of Asbestos Diaphragms	Air	Inhalation	Workers, ONU	Yes	This is the only known use of imported raw asbestos in the U.S. today, and inhalation is the most important exposure route.
				Oral	Workers, ONU	No	Since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, which are the focus of the risk evaluation, exposures from the oral and dermal routes will not be assessed.
				Dermal			
			Solid Contact	Dermal	Workers		
		Chlor-Alkali Industry Use of Asbestos Diaphragms	Air	Inhalation	Workers, ONU	Yes	This is the only known use of imported raw asbestos in the U.S. today; inhalation exposure will be evaluated.
				Oral	Workers, ONU	No	Since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, which are the focus of the risk evaluation, exposures from the oral and dermal routes will not be assessed.
				Dermal			
			Solid Contact	Dermal	Workers		
Sheet Gaskets	Chemical Manufacturing	Processing/Cutting Sheet Gaskets	Air	Inhalation	Workers, ONU	Yes	Asbestos-containing sheet gaskets are cut/processed; inhalation – will be further evaluated.
				Oral	Workers, ONU	No	Since neither oral nor dermal exposures are expected to contribute to the risks of

				Dermal			lung cancer and mesothelioma, which are the focus of the risk evaluation, exposures from the oral and dermal routes will not be assessed.
		Installing and Replacing Sheet Gaskets	Air	Inhalation	Workers, ONU	Yes	The work process described in Comment ID EPA-HQ-OPPT-2016-0736-0067 should be further evaluated.
				Oral	Workers, ONU	No	Since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, which are the focus of the risk evaluation, exposures from the oral and dermal routes will not be assessed
				Dermal			
			Solid Contact	Dermal	Workers		
Industrial Friction Products	Brake Blocks in Oil Industry	Oilfield Well Production	Air	Inhalation	Workers, ONU	Yes	The process of replacing asbestos-containing brake blocks will likely generate friable airborne asbestos and will be further evaluated.
				Oral	Workers, ONU	No	Since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, which are the focus of the risk evaluation, exposures from the oral and dermal routes will not be assessed.
				Dermal			
			Solid Contact	Dermal	Workers		
Aftermarket Automotive Brakes	Passenger and Non-passenger Vehicles	Commercial Brake Servicing and Consumer	Air	Inhalation	Workers, ONU, Consumer	Yes	The process of replacing asbestos-containing brakes will likely generate friable airborne asbestos and will be further evaluated.
				Oral	Workers, ONU, Consumer	No	Since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, which are the focus of the risk evaluation, exposures from the oral and dermal routes will not be assessed.
				Dermal			
			Solid Contact	Dermal	Workers		
Cement Products	Cement pipe	Contracting and Masonry Work	Air	Inhalation	Workers, ONU	Yes	Based on data from USGS, it is possible that asbestos cement pipe is imported and used in the United States. Exposures to workers will be evaluated.
				Oral	Workers, ONU	No	Since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, which are the focus of the risk evaluation, exposures
				Dermal			

			Solid Contact	Dermal	Workers		from the oral and dermal routes will not be assessed.
Woven Products	Imported Textiles	Use of Heat-Resistant Woven Textiles	Air	Inhalation	Workers, ONU, Consumer	Yes	Based on conversations with USGS, knitted fabrics (woven products) containing asbestos continue to be imported into U.S.
				Oral	Workers, ONU, Consumer	No	Since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, which are the focus of the risk evaluation, exposures from the oral and dermal routes will not be assessed.
				Dermal			
			Solid Contact	Dermal	Workers		
Other gaskets and packing	Chemical Manufacturing	Installing and Replacing Gaskets	Air	Inhalation	Workers, ONU	Yes	The work process described in Comment ID EPA-HQ-OPPT-2016-0736-0067 will be further evaluated.
				Oral		No	Since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, which are the focus of the risk evaluation, exposures from the oral and dermal routes will not be assessed.
				Dermal			
			Solid Contact	Dermal	Workers		
Waste Handling, Treatment and Disposal	Disposal of Asbestos Waste	Worker Handling of Wastes	Air	Inhalation	Workers, ONU	Yes	Disposal of asbestos containing articles/wastes are placed in plastic bags for disposal.
			Air	Oral		No	Since neither oral nor dermal exposures are expected to contribute to the risks of lung cancer and mesothelioma, which are the focus of the risk evaluation, exposures from the oral and dermal routes will not be assessed.
			Air	Dermal			
			Solid Contact	Dermal	Workers		
			Liquid Contact	Dermal			

Appendix D INCLUSION AND EXCLUSION CRITERIA FOR FULL TEXT SCREENING

Appendix D contains the eligibility criteria for various data streams informing the TSCA risk evaluation: environmental fate; engineering and occupational exposure; exposure to the general population and consumers; and human health hazard. The criteria are applied to the *on-topic* references that were identified following title and abstract screening of the comprehensive search results published on June 22, 2017.

Systematic reviews typically describe the study eligibility criteria in the form of PECO statements or a modified framework. PECO stands for Population, Exposure, Comparator and Outcome and the approach is used to formulate explicit and detailed criteria about those characteristics in the publication that should be present in order to be eligible for inclusion in the review. EPA/OPPT adopted the PECO approach to guide the inclusion/exclusion decisions during full text screening.

Inclusion and exclusion criteria were also used during the title and abstract screening, and documentation about the criteria can be found in the *Strategy for Conducting Literature Searches* document published in June 2017 along with each of the TSCA Scope documents. The list of *on-topic* references resulting from the title and abstract screening is undergoing full text screening using the criteria in the PECO statements. The overall objective of the screening process is to select the most relevant and highest quality evidence for the TSCA risk evaluation. As a general rule, EPA is excluding non-English data/information sources and will translate on a case by case basis.

The inclusion and exclusion criteria for ecotoxicological data have been documented in the ECOTOX SOPs. The criteria can be found at https://cfpub.epa.gov/ecotox/help.cfm?helptabs=tab4) and in the *Strategy for Conducting Literature Searches* document published along with each of the TSCA Scope documents.

Since full text screening commenced right after the publication of the TSCA Scope document, the criteria were set to be broad to capture relevant information that would support the initial scope. Thus, the inclusion and exclusion criteria for full text screening do not reflect the refinements to the conceptual model and analysis plan resulting from problem formulation. As part of the iterative process, EPA is in the process of refining the results of the full text screening to incorporate the changes in information/data needs to support the revised scope.

These refinements will include changes to the inclusion and exclusion criteria discussed in this appendix to better reflect the revised scope of the risk evaluation and will likely reduce the number of data/information sources that will undergo evaluation.

D-1 Inclusion Criteria for Data Sources Reporting Environmental Fate Data

EPA/OPPT developed a generic Pathways and Processes, Exposure, Setting or Scenario, and Outcomes (PESO) statement to guide the full text screening of environmental fate data sources. Subsequent versions of the PESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental

fate assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PESO statement.

Assessors seek information on various chemical-specific fate endpoints and associated fate processes, environmental media and exposure pathways as part of the process of developing the environmental fate assessment (Table_Apx D-1. Inclusion Criteria for Data Sources Reporting Environmental Fate Data). The PESO statement and information in Table_Apx D-2. Fate Endpoints and Associated Processes, Media and Exposure Pathways Considered in the Development of the Environmental Fate Assessment) will be used when screening the fate data sources to ensure complete coverage of the processes, pathways and data relevant to the fate of the chemical substance of interest.

Since full text screening commenced right after the publication of the TSCA Scope document, the criteria for fate data were set to be broad to capture relevant information that would support the initial scope. Thus, the inclusion and exclusion criteria for full text screening do not reflect the refinements to the conceptual model and analysis plan resulting from problem formulation. As part of the iterative process, EPA is in the process of refining the results of the full text screening to incorporate the changes in information/data needs to support the revised scope.

Table_Apx D-1. Inclusion Criteria for Data Sources Reporting Environmental Fate Data

PESO Element	Evidence
Pathways and **P**rocesses	• Fate will use transport, partitioning and degradation behavior across media to inform exposure pathways in conceptual models • Exposure pathways included in the conceptual models: - Water - Air • Processes associated with the target exposure pathways
Exposure	• Exposures of aquatic organisms to Asbestos • Consumer exposure pathways of humans to Asbestos (Chemical-specific population[s] of interest may be determined by toxicologists or by EPA policy decisions)
Setting or **S**cenario	• All aquatic ecological exposure scenarios for releases of Asbestos to the natural or built environment. • Consumer exposure scenarios of humans to Asbestos (Chemical-specific scenarios will be determined in conjunction with toxicologists and exposure assessors or by EPA policy decisions)

PESO Element	Evidence
Outcomes	• Fate properties which allow assessments of exposure pathways: o Partitioning within and between environmental media (see Pathways)

Table_Apx D-2. Fate Endpoints and Associated Processes, Media and Exposure Pathways Considered in the Development of the Environmental Fate Assessment

Fate Data Endpoint	Associated Process(es)	Associated Media/Exposure Pathways				
		Surface water	Soil, Biosolids	Ground-water	Air	[Indoor environment, anthropogenic materials]
First Tier Environmental Fate Data						
Particle Transport	Mobility	X			X	X
Suspension/Resuspension	Suspension/Resuspension, Mobility	X				
Water and wastewater treatment removal	Wastewater treatment	X				

D-2 Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data

EPA/OPPT developed a generic RESO statement to guide the full text screening of engineering and occupational exposure literature (Table_Apx D-3. Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data for Asbestos). RESO stands for Receptors, Exposure, Setting or Scenario, and Outcomes. Subsequent versions of the RESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria specified in the RESO statement will be eligible for inclusion, considered for evaluation, and possibly included in the environmental release and occupational exposure assessments, while those that do not meet these criteria will be excluded.

The RESO statement should be used along with the engineering and occupational exposure data needs table (**Error! Reference source not found.**) when screening the literature.

Since full text screening commenced right after the publication of the TSCA Scope document, the criteria for engineering and occupational exposure data were set to be broad to capture relevant information that would support the initial scope. Thus, the inclusion and exclusion criteria for full text screening do not reflect the refinements to the conceptual model and analysis plan resulting from problem formulation. As part of the iterative process, EPA is in the process of refining the results of the full text screening to incorporate the changes in information/data needs to support the revised scope.

Table_Apx D-3. Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data for Asbestos

RESO Element	Evidence
Receptors	• **Humans:** Workers, including occupational non-users • **Environment:** Aquatic ecological receptors (release estimates input to Exposure) Please refer to the conceptual models for more information about the ecological and human receptors included in the TSCA risk evaluation.
Exposure	• Worker exposure to and relevant environmental releases of asbestos o Inhalation as indicated in the conceptual model o Water and air indicated in the conceptual model Please refer to the conceptual models for more information about the routes and media/pathways included in the TSCA risk evaluation.
Setting or **S**cenario	• Any occupational setting or scenario resulting in worker exposure and relevant environmental releases (includes all manufacturing, processing, use, disposal indicated in Table B-2 below except (state none excluded or list excluded uses)
Outcomes	• Quantitative estimates* of worker exposures and of relevant environmental releases from occupational settings • General information and data related and relevant to the occupational estimates*

* Metrics (e.g., mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering Data Needs (Table_Apx D-4) provides a list of related and relevant general information.
TSCA=Toxic Substances Control Act

Table_Apx D-4. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments

Objective Determined during Scoping	Type of Data
General Engineering Assessment (may apply for either or both Occupational Exposures and / or Environmental Releases)	1. Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (e.g., each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. [Tags: Life cycle description, Life cycle diagram][a] 2. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. [Tags: Production volume, Import volume, Use volume, Percent PV] [a] 3. Description of processes, equipment, unit operations, and material flows and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). [Tags: Process description, Process material flow rate, Annual operating days, Annual batches, Weight fractions (for each of above, manufacture, import, processing, use)] [a] 4. Basic chemical properties relevant for assessing exposures and releases, e.g., molecular weight, normal boiling point, melting point, physical forms, and room temperature vapor pressure. [Tags: Molecular weight, Boiling point, Melting point, Physical form, Vapor pressure, Water solubility] [a] 5. Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site locations. [Tags: Numbers of sites (manufacture, import, processing, use), Site locations] [a]
Occupational Exposures	6. Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. [Tags: Worker activities (manufacture, import, processing, use)] [a] 7. Potential routes of exposure (e.g., inhalation, dermal). [Tags: Routes of exposure (manufacture, import, processing, use)] [a] 8. Physical form of the chemical(s) of interest for each exposure route (e.g., liquid, vapor, mist) and activity. [Tags: Physical form during worker activities (manufacture, import, processing, use)] [a] 9. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). [Tags: PBZ measurements (manufacture, import, processing, use)] [a] 10. Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). [Tags: Area measurements (manufacture, import, processing, use)] [a] 11. For solids, bulk and dust particle size characterization data. [Tags: PSD measurements (manufacture, import, processing, use)] [a] 12. Dermal exposure data. [Tags: Dermal measurements (manufacture, import, processing, use)] 13. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). [Tags: Worker exposure modeling data needs (manufacture, import, processing, use)] [a] 14. Exposure duration (hr/day). [Tags: Worker exposure durations (manufacture, import, processing, use)] [a] 15. Exposure frequency (days/yr). [Tags: Worker exposure frequencies (manufacture, import, processing, use)] [a] 16. Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. [Tags: Numbers of workers exposed (manufacture, import, processing, use)] [a]

Objective Determined during Scoping	Type of Data
	17. Personal protective equipment (PPE) types employed by the industries within scope. [Tags: Worker PPE (manufacture, import, processing, use)] [a] 18. Engineering controls employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates of exposure reductions. [Tags: Engineering controls (manufacture, import, processing, use), Engineering control effectiveness data] [a]
Environmental Releases	19. Description of sources of potential environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. [Tags: Release sources (manufacture, import, processing, use)] [a] 20. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each environmental medium (air, water, land) and treatment and disposal methods (POTW, incineration, landfill), including releases per site and aggregated over all sites (annual release rates, daily release rates) [Tags: Release rates (manufacture, import, processing, use)] [a] 21. Release or emission factors. [Tags: Emission factors (manufacture, import, processing, use)] [a] 22. Number of release days per year. [Tags: Release frequencies (manufacture, import, processing, use)] [a] 23. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). [Tags: Release modeling data needs (manufacture, import, processing, use)] [a] 24. Waste treatment methods and pollution control devices employed by the industries within scope and associated data on release/emission reductions. [Tags: Treatment/ emission controls (manufacture, import, processing, use), Treatment/ emission controls removal/ effectiveness data] [a]

Notes:

[a] These are the tags included in the full text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information.

Abbreviations:

hr=Hour
kg=Kilogram(s)
lb=Pound(s)
yr=Year
PV=Particle volume
PBZ= Personal Breathing Zone
POTW=Publicly owned treatment works
PPE=Personal projection equipment
PSD=Particle size distribution
TWA=Time-weighted average

D-3 Inclusion Criteria for Data Sources Reporting Exposure Data on General Population, Consumers and Ecological Receptors

EPA/OPPT developed PECO statements to guide the full text screening of exposure data/information for human (i.e., general population, consumers, potentially exposure or susceptible subpopulations) and ecological receptors. Subsequent versions of the PECO statements may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PECO statement are eligible for inclusion, considered for evaluation, and possibly included in the exposure assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PECO statement. The asbestos-specific PECO is provided in Table_Apx D-5.

Since full text screening commenced right after the publication of the TSCA Scope document, the criteria for exposure data were set to be broad to capture relevant information that would support the initial scope. Thus, the inclusion and exclusion criteria for full text screening do not reflect the refinements to the conceptual model and analysis plan resulting from problem formulation. As part of the iterative process, EPA is in the process of refining the results of the full text screening to incorporate the changes in information/data needs to support the revised scope.

Asbestos Specific PECO Statement

Population: Asbestos has been detected in indoor and outdoor air as well as in many different freshwater fishes and mussels from bodies of contaminated water. Potentially exposed populations include consumers and bystanders in the home using imported asbestos aftermarket brake pads and friction products (e.g., from do-it-yourself (DIY) replacement of asbestos aftermarket brake pads), and aquatic organisms which may become exposed from asbestos from surface water.

Exposure: Expected primary and lesser exposure sources, pathways, and routes are noted in the table below.

- The sources of asbestos are based on current marketed uses of asbestos only. The use profile of asbestos has changed. Currently asbestos can be found in only certain articles that are readily available for public purchase at common retailers. Asbestos is no longer mined in the U.S. and production of asbestos diaphragms are the only known importer of raw asbestos. Currently marketed articles include asbestos diaphragms, asbestos sheet gaskets, other gaskets (equipment seals), vehicle friction products (non-passenger vehicles), brake blocks for oil drilling, imported asbestos cement products and automotive brakes/linings. Legacy uses and associated/legacy disposals will be excluded from the scope of the risk evaluation. These include asbestos-containing materials remaining in older buildings or parts of older products for which manufacture, processing and distribution in commerce are not currently intended, known or reasonably foreseen.

The pathways of asbestos are based on detection of possible presence in certain environmental and biological media. Human-health-specific pathways include direct inhalation with articles containing asbestos only.

The route of asbestos exposure for humans is inhalation exposure for only currently marketed asbestos articles. Although many of the ongoing uses of asbestos articles are classified as non-friable, it can be made friable due to physical and chemical wear and normal use of asbestos-containing products. While exposures to asbestos can potentially occur via all routes, EPA anticipates that the most likely exposure route is inhalation for adults.

Comparator (Scenario): Is there range/variation across exposure scenarios to help inform a comparison of exposure to individuals or population groups (human or ecological)?

Outcome: Many authorities have established a causal association between asbestos exposure and lung cancer and mesotheliomas and will be used as endpoint for exposure analysis. EPA expects to consider the hazards of asbestos to aquatic organisms (including fish, aquatic invertebrates and aquatic plants) that are potentially exposed under acute and chronic exposure conditions.

Table_Apx D-5. Inclusion Criteria for Data Sources Reporting Asbestos Exposure Data on General Population, Consumers and Ecological Receptors

PECO Element	Evidence
Population	**Human:** Consumers; bystanders experiencing indoor exposures in the home to current regulated uses of asbestos articles (e.g., changing aftermarket asbestos brake pads). Adults are likely to be the only population to work with these articles.
	Ecological: Aquatic organisms (fish, aquatic invertebrates, plants);.
Exposure	**Expected Exposure Sources, Pathways, Routes** Source: Secondary ambient air exposure to industrial activities if applicable (chlor-alkali, sheet gasket manufacturing or commercial use, asbestos, brake blocks for oil well drilling), consumer uses of articles containing asbestos (aftermarket asbestos brakes/linings pads/shoes) that were not categorized as legacy. [Asbestos has not been produced in the US since 2002, but can still be imported. Legacy uses and legacy disposals are excluded from the problem formulation.] Pathway: waste streams described in the problem formulation (e.g., surface water); indoor air from contact with asbestos articles (brakes); Routes: inhalation (indoor)
Comparator (Scenario)	**Human:** Consider only replacement of asbestos aftermarket articles [asbestos brakes/linings and friction products (clutch facings and/or gaskets)] used for consumer use in their garage at home. Inhalation monitoring data for commercial auto worker (i.e., replacing brake pads) may be an applicable conservative surrogate data source for this exposure assuming consumer exposure factors are utilized. The use of other asbestos articles may be more appropriate for occupational settings (use and processing of asbestos woven material, replacing sheet gaskets, workers replacing chloro- alkali diaphragms, replacement of brake blocks for oil well drilling, automotive workers engaged in replacement of auto gaskets, brake blocks for trucks, brake pads and shoes, clutch facings, and other asbestos friction products), which would likely be out of scope for ambient exposures to general population and consumers. However, reference material will also be collected and scenarios identified if considered applicable and reasonable.
	Ecological: Consider narrow use/source specific exposure scenarios for imported asbestos cement products, gasket manufacture, or chloro-alklali plants that release asbestos to surface water.

Outcomes for Exposure Concentration or Dose	**Human:** Chronic air, and water concentration estimates (fibers/cm^3 or fibers/L)
	Ecological: A narrow range of ecological receptors will be considered (range depending on available ecotoxicity data) using surface water concentrations from releases to specific current asbestos releases to surface water (see sources above and in the problem formulation).

D-4 Inclusion Criteria for Data Sources Reporting Human Health Hazards

EPA/OPPT developed an asbestos-specific PECO statement Table_Apx D-6 to guide the full text screening of the human health hazard literature. Subsequent versions of the PECOs may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the criteria specified in the PECO statement will be eligible for inclusion, considered for evaluation, and possibly included in the human health hazard assessment, while those that do not meet these criteria will be excluded according to the exclusion criteria.

In general, the PECO statements were based on (1) information accompanying the TSCA Scope document, and (2) preliminary review of the health effects literature from authoritative sources cited in the TSCA Scope documents. When applicable, these authoritative sources (e.g., IRIS assessments, EPA/OPPT's Work Plan Problem Formulations or risk assessments) will serve as starting points to identify PECO-relevant studies.

Table_Apx D-6. Inclusion Criteria for Data Sources Reporting Human Health Hazards Related to Asbestos Exposure

PECO Element	Papers/Features Included	Papers/Features Excluded
	Human Evidence Streams [b]	
Population	• Any population • The following study designs will be considered: ○ Controlled exposure, cohort, case-control, cross-sectional, case-crossover	• Non-human populations • Study designs other than controlled exposure, cohort, case-control, cross-sectional, case-crossover
Exposure	• Exposure to TSCA-defined asbestos fiber types: ○ Chrysotile, Amosite, Anthophylite, Crocidolite, Tremolite, and Anthophylite (includes studies of mixed asbestos fiber types) [c] • Exposure based on measured or estimated concentrations of asbestos and may be combined with estimates of duration of exposure, such as exposure biomonitoring data (e.g., lung tissue specimens), environmental or occupational-setting monitoring data (e.g., ambient air levels), job title or residence. • Exposure identified as ***or presumed to be*** from inhalation routes	• Route of exposure ***not*** by inhalation, type (i.e., oral, dermal, intraperitoneal, or injection routes) • Non-quantitative measures of exposure • Less than 2 exposure groups present • Not pertaining to one or more of the TSCA-defined asbestos fiber types [c]

PECO Element	Papers/Features Included	Papers/Features Excluded
	• Quantitative measures or estimates of exposure ***only*** • For categorical exposures, a minimum of 2 exposure groups (referent group + 1)	
Comparator	• An internal or external comparison population included, (i.e., non-exposed or exposed to lower levels). • Exposure-response modeling results are presented in sufficient detail (e.g., relative risk models for lung cancer [i.e., SMR, RR, OR], additive models for mesothelioma, potency factors [KL, KM], or regression coefficients presented with variation)	• No comparison group • No exposure-response modeling results
Outcome	• Health Endpoints [d, e]: o Lung cancer o Mesothelioma	• Not pertaining to lung cancer or mesothelioma health effects.
General Considerations	**Papers/Features Included**	**Papers/Features Excluded**
	• Written in English [f] • Reports primary data [a] • Full-text available • Reports both asbestos exposure ***and*** a health outcome • Publication date after 1986 [d]	• Not written in English [f] • Reports secondary data (e.g., review papers) [a] • No full-text available (e.g., only a study description/abstract, out-of-print text) • Reports an asbestos-related exposure ***or*** a health outcome, but not both (e.g. incidence, prevalence report) • Not published after 1986 [d]

[a] Some of the studies that are excluded based on the PECO statement may be considered later during the systematic review process. For asbestos, EPA will evaluate studies related to susceptibility and may evaluate, toxicokinetics and physiologically based pharmacokinetic models after other data (e.g., human dose-response data) are reviewed. EPA may also review other data as needed (e.g., mechanistic data including genotoxicity, review papers).

[b] Animal and mechanistic data are excluded during the full text screening phase of the systematic review process but may be considered later (see footnote *a*).

[c] Papers reporting exposure to "asbestos" generally, not specific fiber type of asbestos, will be included for further consideration.

[d] EPA will review key and supporting studies in the IRIS assessment that were considered in the dose-response assessment for non-cancer and cancer endpoints as well as studies published after the IRIS assessment.

[e] EPA may screen for hazards other than those listed in the scope document if they were identified in the updated literature search that accompanied the scope document.

[f] EPA may translate studies as needed.