Risk Evaluation and Risk Management for Asbestos, Part 1: Chrysotile Asbestos under TSCA Section 6

Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Public Webinar
February 3, 2021

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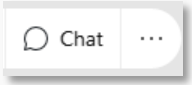
  - Use the chat in the lower right corner of your screen 

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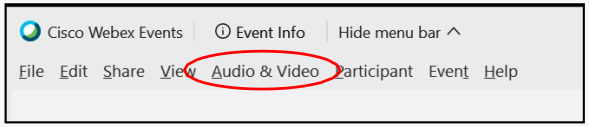
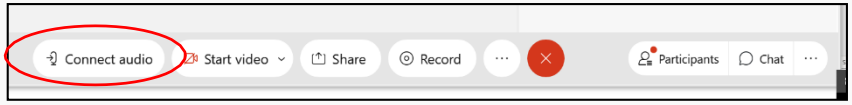




Agenda

3:00 – 3:05 pm	Introductory Remarks *Tanya Mottley – Division Director, Existing Chemicals Risk Management Division*
3:05 – 3:45 pm	Background on Risk Evaluation and Unreasonable Risk Findings for Asbestos, Part 1: Chrysotile Asbestos Risk Management Requirements under TSCA; Types of Information to Inform Risk Management; and Principles for Transparency during Risk Management *Alie Muneer – Physical Scientist, Risk Management Branch 3, Existing Chemicals Risk Management Division*
3:45 – 5:30 pm	Public comments

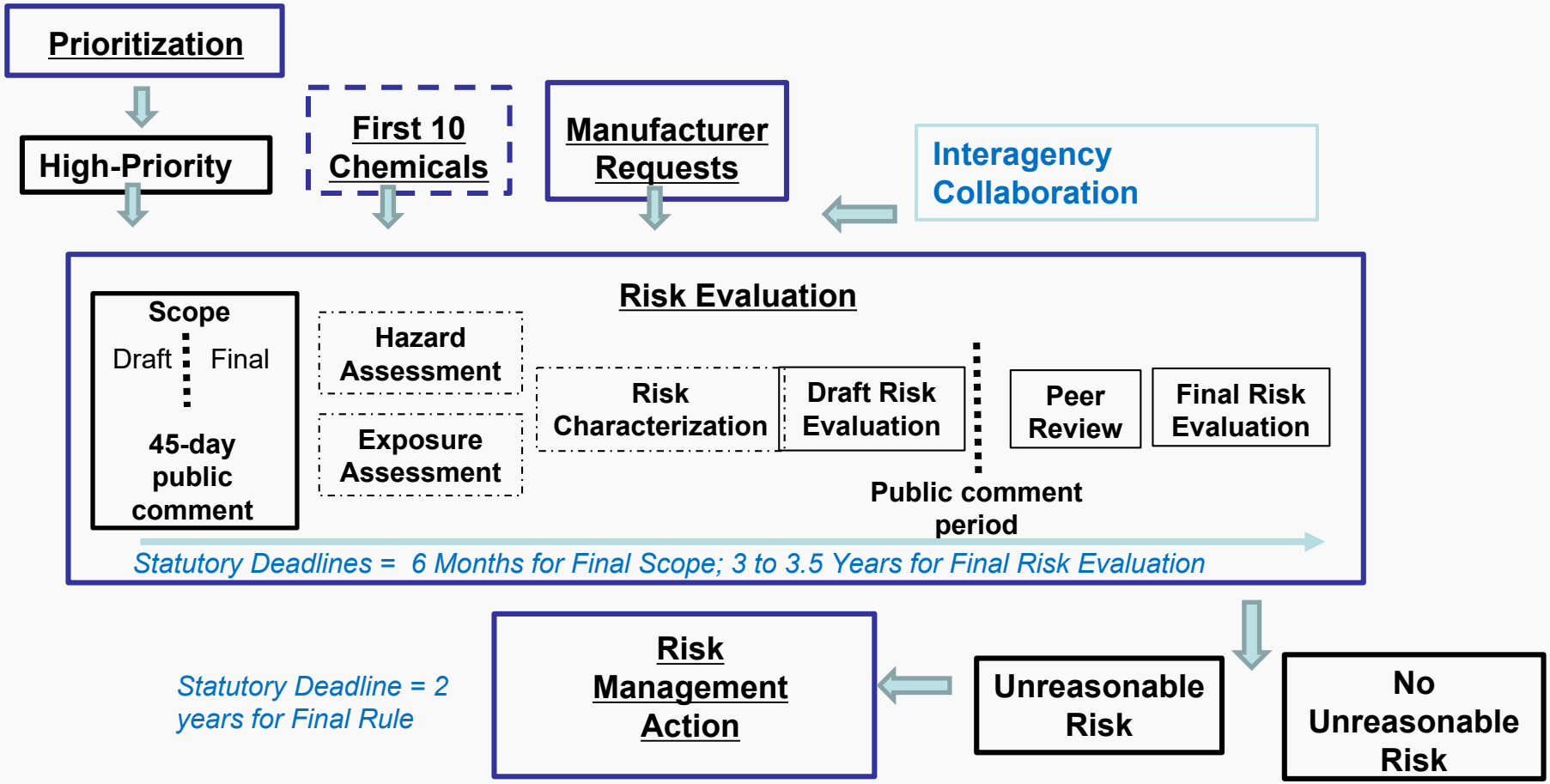
Outline

- Background on Risk Evaluations
- Findings from the Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos
- Overview of Part 2 of the Risk Evaluation
- Risk Management Requirements under TSCA
- Types of Information to Inform Risk Management
- Principles for Transparency During Risk Management
- Additional Information

Risk Evaluation Statutory Requirements

- EPA must evaluate the risks presented by a chemical under the conditions of use and determine if the chemical presents an unreasonable risk of injury to health or the environment under the conditions of use
  - Without consideration of cost or other non-risk factors
  - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation
- TSCA requires a risk evaluation be completed within 3-3.5 years

Risk Evaluation Process and Timeline



Overview of Risk Evaluation for Asbestos, Part 1: Chrysotile Asbestos

- Final risk evaluation for Part 1 published December 30, 2020
- There are six categories of use: 1) Asbestos diaphragms; 2) Sheet gaskets; 3) Oilfield brake blocks; 4) Aftermarket automotive brakes/linings; 5) Other vehicle friction products; and 6) Other gaskets
  - Final risk evaluation follows a series of risk evaluation activities
  - Draft risk evaluation: April 2020; Problem Formulation: May 2018; Scope Document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation for Part 1:
  - 111 public comments received on the draft risk evaluation (comment period closed June 2, 2020)
  - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (June 8-11, 2020)
- The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0501, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0736, at www.regulations.gov

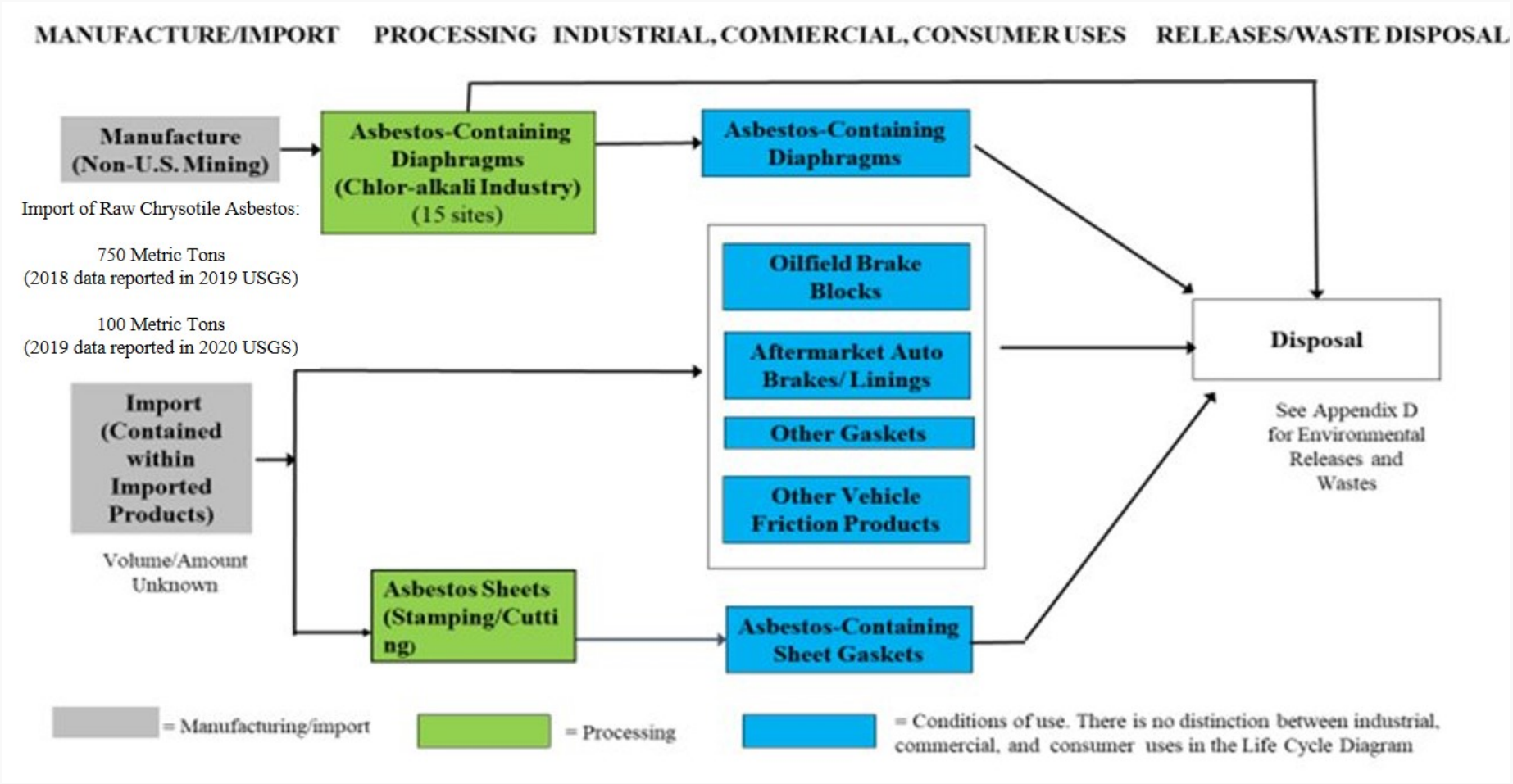
Overview of Part 2 of the Asbestos Risk Evaluation

- Following the November 2019 decision of the Ninth Circuit Court in *Safer Chemicals Healthy Families v. EPA*, the Agency will also evaluate formerly termed "legacy uses" and associated disposals for asbestos (Part 2 of the Risk Evaluation)
- Part 2 of the Risk Evaluation will begin with a draft scope document that will be made available for public comment in mid-2021
- This will be followed by a final scope document, a draft risk evaluation document for public comment, and then a final risk evaluation document
- Part 2 will consider "legacy uses" and associated disposals for all six fiber types of asbestos described in the TSCA Title II definition (chrysotile, crocidolite, amosite, anthophyllite, tremolite or actinolite)
- "Legacy uses" and associated disposals are conditions of use for which manufacture (including import), processing and distribution no longer occur but where use and disposal are still known, intended, or reasonably foreseen to occur (e.g., in situ building materials)

General Information on Asbestos, Part 1: Chrysotile Asbestos

- Chrysotile asbestos is a hydrated magnesium silicate mineral once used extensively in products due to its fiber strength and heat resistance
  - Relatively few uses of chrysotile asbestos remain in the United States
- Chrysotile asbestos is no longer mined in the United States and is only imported in raw form for use in asbestos containing diaphragms (chlor-alkali)
  - Chrysotile-containing articles are no longer manufactured domestically and are only imported
- The total aggregate production volume (import only) of raw chrysotile asbestos was 750 metric tons in 2018 and 100 metric tons in 2019
- Chrysotile asbestos use categories include asbestos-containing diaphragms (chlor-alkali industry), sheet gaskets, oilfield brake blocks, aftermarket automotive brakes/linings, other vehicle friction products, and other gaskets

Chrysotile Asbestos Life Cycle Diagram



Conditions of Use

- There are six categories of use:
    1) Asbestos diaphragms
    2) Sheet gaskets
    3) Oilfield brake blocks
    4) Aftermarket automotive brakes/linings
    5) Other vehicle friction products
    6) Other gaskets

Determinations of No Unreasonable Risk

- Among the six categories of conditions of use identified for chrysotile asbestos, EPA determined that none present an unreasonable risk to the environment
- Among the six categories of conditions of use identified for chrysotile asbestos, EPA determined that certain conditions of use of chrysotile asbestos do not present an unreasonable risk of injury to health:
  - Import of chrysotile asbestos and chrysotile asbestos-containing products
  - Distribution of chrysotile asbestos-containing products
  - Use of chrysotile asbestos brakes for a specialized, large NASA transport plane
  - Disposal of chrysotile asbestos-containing sheet gaskets processed and/or used in the industrial setting and asbestos-containing brakes for a specialized, large NASA transport plane
- These determinations are considered final agency actions and are issued by order pursuant to TSCA section 6(i)(1)

Unreasonable Risk Determinations

- Among the six categories of conditions of use identified for chrysotile asbestos, EPA determined that certain conditions of use of chrysotile asbestos present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
  - Processing and Industrial Use of Chrysotile Asbestos Diaphragms in the Chlor-alkali Industry
  - Processing and Industrial Use of Chrysotile Asbestos-Containing Sheet Gaskets in Chemical Production
  - Industrial Use and Disposal of Chrysotile Asbestos-Containing Brake Blocks in Oil Industry
  - Commercial Use, Consumer Use and Disposal of Aftermarket Automotive Chrysotile Asbestos-Containing Brakes/Linings
  - Commercial Use and Disposal of Other Chrysotile Asbestos-Containing Vehicle Friction Products
  - Commercial Use, Consumer Use and Disposal of Other Chrysotile Asbestos-Containing Gaskets
- EPA's risk evaluation identified unreasonable risks for cancer from chronic inhalation exposure to chrysotile asbestos to workers, occupational non-users (ONUs), consumers and bystanders.

Basis for Unreasonable Risk Determination: Workers, ONUs, Consumers and Bystanders

- The unreasonable risk determinations are based on the following health hazards for workers and ONUs during occupational exposures, and consumers and bystanders during do-it-yourself scenarios of chrysotile asbestos:
  - Cancer effects from chronic inhalation
  - Non-cancer effects from chronic inhalation
- Personal Protective Equipment (PPE) (*only applies to workers):
  - Many conditions of use presented an unreasonable risk to workers due to chronic inhalation exposures in industrial/commercial settings
  - EPA does not assume ONUs to be using PPE to reduce exposures to asbestos

Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- EPA must issue a TSCA section 6(a) rule following risk evaluation to address all identified unreasonable risks within two years:
  - Proposed rule one year after risk evaluation
  - Final rule two years after risk evaluation
- Specific requirements on consideration of alternatives, selecting among options and statement of effects apply to risk management rules
- Input from stakeholders is critical to the process

TSCA Section 6(a) Regulatory Options

- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce
- Prohibit, limit or otherwise restrict manufacture, processing or distribution in commerce for particular use or for use above a set concentration
- Require minimum warnings and instructions with respect to use, distribution, and/or disposal
- Require recordkeeping, monitoring or testing
- Prohibit or regulate manner or method of commercial use
- Prohibit or regulate manner or method of disposal by certain persons
- Direct manufacturers/processors to give notice of the unreasonable risk determination to distributors, users, and the public and replace or repurchase

TSCA Section 6(a) Regulatory Options

- TSCA provides authority to regulate entities including:
  - Distributors
  - Manufacturers and processors (e.g., formulators)
  - Commercial users (workplaces and workers)
  - Entities disposing of chemicals for commercial purposes

Examples of Regulatory Options

- Provide a prominent label securely attached to import container or product with specific directions, limitations, and precautions, or that describes the health endpoints
- Prohibit importing, processing, and distribution for particular conditions of use with unreasonable risks
- Mandate specific engineering controls and PPE at occupational sites
- Require importers, processors, and distributors to maintain ordinary business records and to provide downstream notification to help ensure regulatory information reaches all users in the supply chain
- Set an occupational air exposure limit, for example, establish an Existing Chemical Exposure Limit (ECEL) , and require monitoring of exposures in occupational settings
- Mandate administrative controls and system requirements at occupational sites
- Require a hazard communication program to educate workers on label directions, warnings, etc.

TSCA Section 6(c)

In promulgating any rule under TSCA section 6(a), EPA must consider and publish a statement of effects of the rule based on reasonably available information with respect to:

- The effects and magnitude of exposure to human health
- The effects and magnitude of exposure to environment
- The benefits of the chemical for various uses
- The reasonably ascertainable economic consequences of the rule, including consideration of:
  - The likely effect on the national economy, small business, technological innovation, the environment, and public health
  - The costs and benefits of the proposed and final regulatory action and one or more primary regulatory alternatives
  - The cost effectiveness of the proposed regulatory action and 1 or more primary regulatory alternatives

Executive Orders Relevant to 6(a) Rulemakings

- EO 12866: Regulatory Planning and Review
- EO 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations
- EO 13045: Protection of Children from Environmental Health & Safety Risks
- EO 13132: Federalism
- EO 13175: Consultation and Coordination with Indian Tribal Governments
- EO 13211: Actions that Significantly Affect Energy Supply, Distribution, or Use
- EO 13272: Proper Consideration of Small Entities in Agency Rulemaking
- EO 13771: Reducing Regulation and Controlling Regulatory Costs

Types of Information to Inform Risk Management

- Suggestions on effective methods EPA can use to address the unreasonable risks
- Input on protective regulatory approaches
- Information related to controlling exposures, including current work practices, engineering, and administrative controls
- Information on essential uses, and the impacts if the chemical were not available
- Identification of uses that have been phased out, or can be phased out, and thus are no longer needed
- Any information on substitute chemicals that are safe and effective alternatives
- Suggestions on how EPA can further improve its regulatory processes or be more transparent

Principles for Transparency During Risk Management

- Transparent, proactive, and meaningful engagement
- One-on-one meetings, public webinars, and required consultations with state and local governments, Tribes, environmental justice communities, and small businesses
- Extensive dialogue will help people understand the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input from stakeholders on potential risk management approaches, their effectiveness, and impacts those approaches might have on businesses, workers, and consumers
- Input can help the agency develop regulations that are practical and protective

Coordination and Engagement

- In developing risk management approaches, EPA:
  - Consults with stakeholders to learn about condition of use, existing engineering controls, PPE, available alternatives, or other programs to tailor effective risk management solutions
  - Conducts site visits to obtain detailed information on existing practices in chemical manufacturing, processing, and use
  - Develops an extensive network among all stakeholders to ensure regulatory approaches are fully informed and based on current conditions

Opportunities for Engagement

- One-on-one meetings
- Webinars providing overviews of final risk evaluations and unreasonable risk determinations
  - Other chemicals following their final risk evaluations
- Consultations seeking targeted feedback, with:
  - States and local governments
  - Tribes
  - Small businesses
  - Environmental justice organizations and communities

Additional Information

- General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act
- Current Chemical Risk Management Activities: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/current-chemical-risk-management-activities
- Asbestos, Part 1: Chrysotile Asbestos: Alie Muneer (muneer.alie@epa.gov, 202-564-6369)
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)

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