Cyclic Aliphatic Bromide Cluster (HBCD): Risk Evaluation and Risk Management under TSCA Section 6

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

Public Webinar
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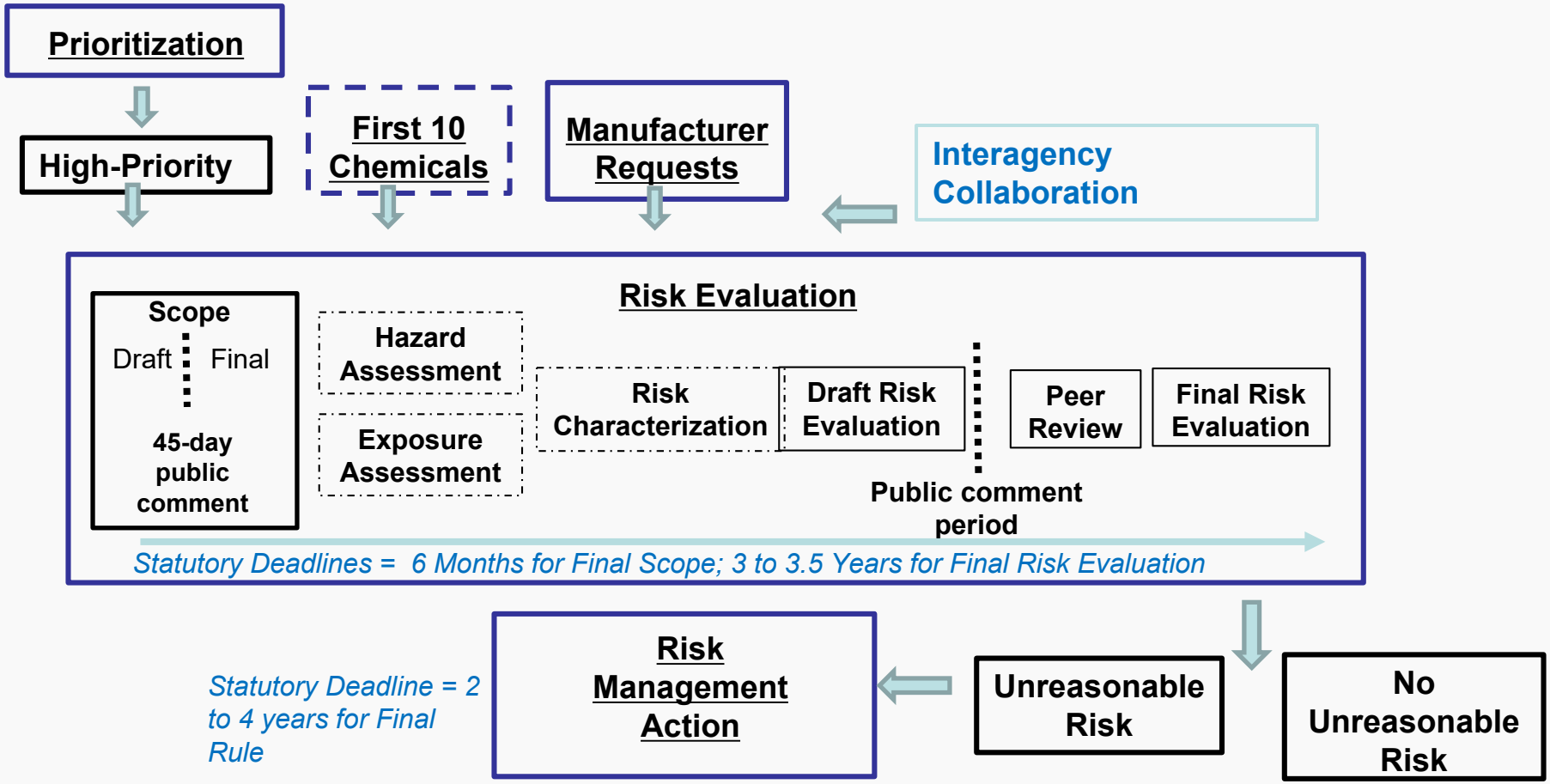
Agenda

- Background on Risk Evaluations
- Findings from Risk Evaluation for HBCD
- 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 to 3.5 years

Risk Evaluation Process and Timeline



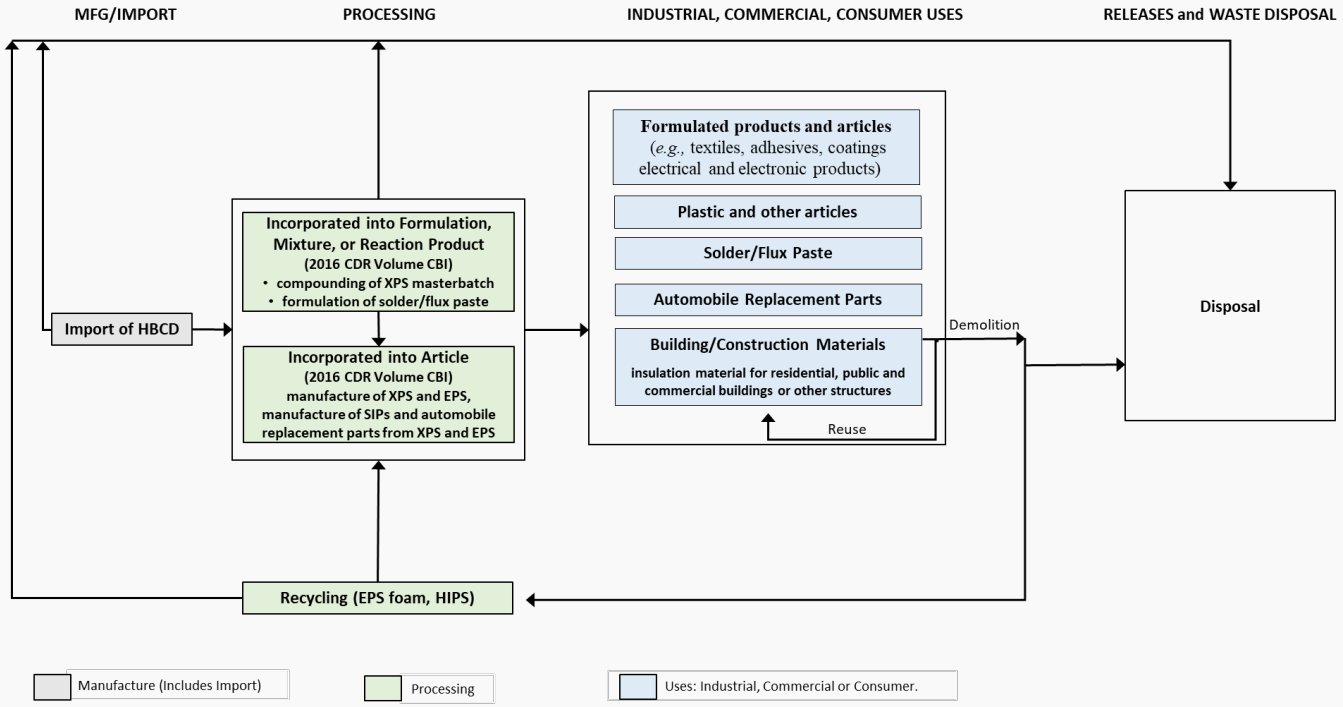
Overview of Risk Evaluation for HBCD

- Final risk evaluation published September 25, 2020
  - 12 conditions of use were evaluated
  - Final risk evaluation follows a series of risk evaluation activities
  - HBCD draft risk evaluation: June 2019; HBCD problem formulation: May 2018; HBCD scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
  - 24 public comments received on the draft risk evaluation (comment period closed August 30, 2019)
  - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (July-August 2019)
- The final risk evaluation and supplemental materials are in docket EPA-HQ-OPPT-2019-0237, with additional materials supporting the risk evaluation process in docket EPA-HQ-OPPT-2016-0735, on www.regulations.gov

General Information on HBCD

- HBCD is a white, odorless, non-volatile solid
- The total aggregate production volume was 25 to 150 million pounds between 2012 and 2015
  - HBCD is no longer manufactured in the United States
- EPA identified conditions of use during various life cycle stages of HBCD, including import, processing, distribution in commerce, use (commercial and consumer), and disposal
- HBCD has been used primarily as a flame retardant added to polystyrene to make insulation boards for buildings
  - Small amounts are incorporated into solder paste and replacement automobile parts

HBCD Life Cycle Diagram



Determinations of No Unreasonable Risk

- EPA determined that six of the 12 conditions of use of HBCD do not present an unreasonable risk of injury to health or the environment:
  - Recycling of electronics waste
  - Distribution in commerce
  - Commercial and consumer use of automobile replacement parts
  - Commercial and consumer use of minor products
  - Consumer use of articles from recycled plastic
  - Disposal of minor products

- These determinations are considered final agency actions and are issued by order pursuant to TSCA section 6(i)(1)

Conditions of Use that Present an Unreasonable Risk

EPA determined that six conditions of use of HBCD present an unreasonable risk of injury to the environment and human health.

Risk to the Environment

- Import
- Processing: incorporation into formulation
- Processing into articles
- Recycling of insulation boards
- Commercial use of insulation boards
- Disposal (demolition) of insulation boards

Risk to Human health (occupational exposure)*

- Commercial use of insulation boards
- Disposal (demolition) of insulation boards

*These two conditions of use present unreasonable risk to both the environment and human health

Basis for Unreasonable Risk Determination: Environment

- EPA determined unreasonable risks of injury to aquatic organisms exposed to HBCD in surface water and sediment
- The unreasonable risk determinations are based on the most sensitive endpoints:
  - Reduced growth
  - Reduced reproduction
- EPA evaluated risk at a low stream flow (meaning higher concentration of HBCD) and at a higher stream flow (meaning lower concentration of HBCD)

Basis for Unreasonable Risk Determination: Workers and Occupational Non-Users (ONUs)

- For workers and ONUs, EPA identified unreasonable risks from chronic inhalation exposure to HBCD
- The determinations are based on the most sensitive endpoint: thyroid hormone effects
- EPA used high-end risk estimates; estimates at the central tendency do not exceed benchmarks
- Personal protective equipment (PPE):
  - EPA assumes construction and demolition workers do not use respirators
  - EPA assumes ONUs have the same exposure to HBCD as workers and do not use respirators

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 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 (includes import), 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

- Cannot directly regulate consumer users
  - Can advise or recommend, but can regulate at the manufacturing, processing or distribution level in the supply chain for consumer use

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
- Require importers, processors and distributors 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)

Examples of Regulatory Options

- Require monitoring of exposures in occupational settings
- Require a hazard communication program to educate workers on label directions, warnings, etc.
- Redesign import containers to prevent release to the environment
- Require engineering controls or equipment to contain releases to outside air from facilities that import, process, or recycle
- Require work practices that reduce dust emissions at construction and demolition sites
- Prohibit or regulate manner of commercial disposal

TSCA Section 6(c)

- In promulgating any rule under 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

Complex Consumer and Durable Goods—Section 6(c)(2)

- EPA shall exempt replacement parts for complex durable goods and complex consumer goods designed prior to publication of the risk management rule from section 6(a) unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation, to the general population or to an identified potentially exposed or susceptible subpopulation
- "Complex consumer goods" means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace
- "Complex durable goods" means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use

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 avoiding release to the environment, 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, personal protection equipment (PPE), available alternatives, or other programs to tailor effective risk management solutions
  - Conducts (virtual if possible) site visits to obtain detailed information on existing practices in chemical manufacturing, processing, use, and disposal
  - 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
- HBCD: Sue Slotnick (slotnick.sue@epa.gov, 202-566-1973)
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)