

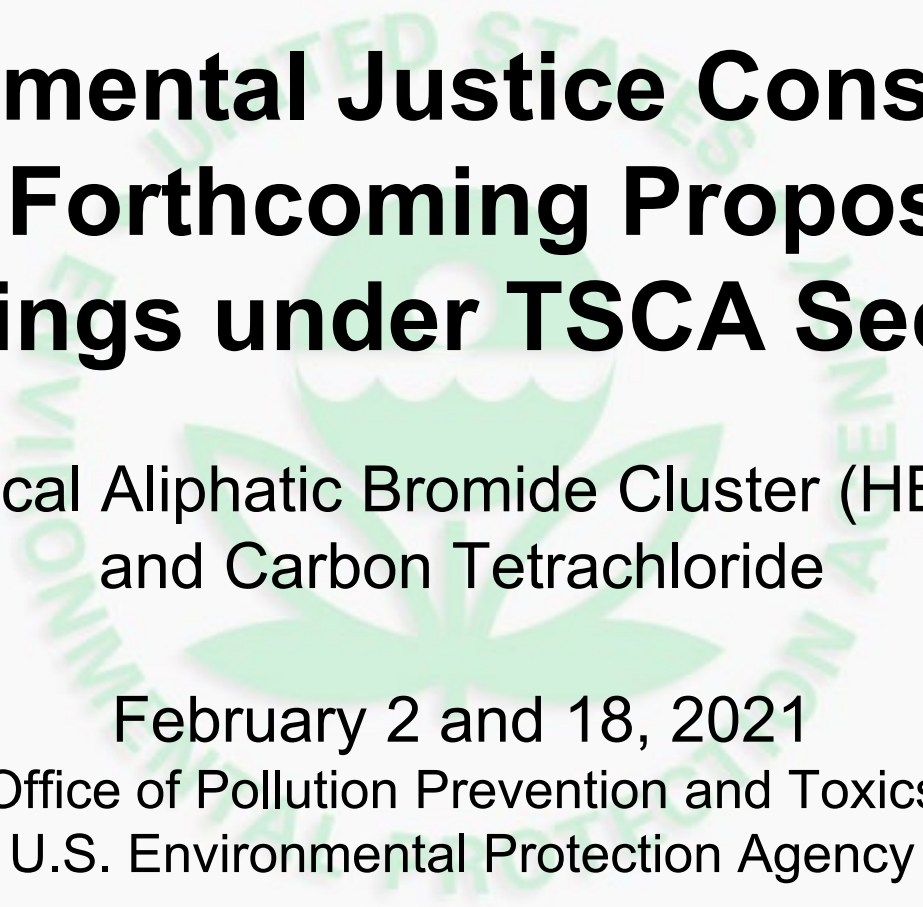


Environmental Justice Consultation on Forthcoming Proposed Rulemakings under TSCA Section 6(a)

Cyclical Aliphatic Bromide Cluster (HBCD)
and Carbon Tetrachloride

February 2 and 18, 2021

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





Today's Consultation

- Welcome
- Purpose of today's consultation
- Risk management under TSCA section 6(a)
- Proposed rulemaking for cyclical aliphatic bromide cluster (HBCD)
 - Comments and discussion
- Proposed rulemaking for carbon tetrachloride
 - Comments and discussion
- Next Steps: Comments due by April 2, 2021



E.O. 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

- The purpose of E.O. 12898 is to focus federal attention on the environmental and human health effects of federal actions on minority and low-income populations with the goal of achieving environmental protection for all communities.
- Under E.O. 12898, EPA is seeking input from stakeholders interested in environmental justice issues during this consultation and encourages participation and comments to inform EPA's upcoming proposed regulation.



Risk Management under TSCA Section 6(a)



Risk Management Requirements

- Under TSCA, EPA is required to take action to address chemicals that pose unreasonable risks to human health or the environment
- Following a determination of unreasonable risk, EPA must issue a TSCA section 6(a) rule so that the chemical no longer presents an unreasonable risk, within two years:
 - Proposed rule one year after risk evaluation
 - Final rule two years after risk evaluation
- Specific requirements regarding consideration of alternatives depending on the options selected, and a statement of effects for each risk management rule
- Your input 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)

- TSCA provides EPA with authority to address unreasonable risks in occupational settings, and to regulate entities including:
 - Manufacturers and processors (e.g., formulators)
 - Distributors
 - Commercial users (workplaces and workers)
 - Entities disposing of chemicals for commercial purposes
- Cannot directly regulate consumer users
 - Under TSCA, EPA has authority to regulate at the manufacturing, processing and distribution levels in the supply chain to eliminate or restrict the availability of chemicals and chemical-containing products for consumer use
 - These authorities allow the EPA to regulate at key points in the supply chain to effectively address unreasonable risks to consumers



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 about the findings in the risk evaluations, the risk management process required by TSCA, and the options available for managing unreasonable risks
- Seeking input 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



Your Comments

- Please provide specific comments on:
 - Do you have any concerns about these uses of HBCD or carbon tetrachloride, particularly regarding uses in environmental justice communities?
 - How would these rulemakings impact environmental justice communities?
 - Other thoughts on the rulemaking?



Your Advice for EPA

- Please provide specific examples of:
 - Any experience with use of HBCD or carbon tetrachloride
 - Any experience with regulations of HBCD or carbon tetrachloride
 - Any risk management experience with specific conditions of use of HBCD or carbon tetrachloride



Cyclical Aliphatic Bromide Cluster (HBCD)



HBCD Topics

- Background on risk evaluation and findings
- Focused discussion on specific conditions of use
- Consultation comments
- Your advice for EPA



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](https://www.regulations.gov/docket/EPA-HQ-OPPT-2019-0237), with additional materials supporting the risk evaluation process in docket [EPA-HQ-OPPT-2016-0735](https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0735), on www.regulations.gov



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 repackaging
- 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



Examples of Regulatory Options

- Prohibit manufacturing, processing and distribution of the chemical
- Prohibit manufacturing, processing and distribution for particular conditions of use with unreasonable risks
- Mandate specific engineering controls, ventilation requirements, and personal protective equipment (PPE) at occupational sites
- Provide a prominent label securely attached to each container with specific directions, limitations, and precautions, or that describe the health endpoints



Examples of Regulatory Options

- Require manufacturers, processors, and distributors to maintain ordinary business records
- Require manufacturers, 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)
- Restrict distribution of a chemical or product only to certain users, under a limited access program that could require training and certification



Examples of Regulatory Options

- 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



Your Comments

- Please provide specific examples of:
 - Any experience with use of HBCD
 - Any experience with regulation of HBCD
 - Any risk management experience with specific conditions of use of HBCD
- Please provide specific comments:
 - Do you have any concerns about these uses of HBCD, particularly regarding uses in environmental justice communities?
 - How would these rulemakings impact environmental justice communities?
 - Other thoughts on the rulemaking?



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), <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/final-risk-evaluation-cyclic-aliphatic-bromide-cluster#findings>
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)



Carbon Tetrachloride

U.S. Environmental Protection Agency



Carbon Tetrachloride

- Background on risk evaluation and findings for carbon tetrachloride
- Focused discussion on specific conditions of use
- Consultation comments
- Your advice for EPA



Overview of Risk Evaluation for Carbon Tetrachloride

- Final risk evaluation published November 3, 2020
 - 15 conditions of use were evaluated
 - Final risk evaluation follows a series of risk evaluation activities
 - Carbon Tetrachloride (CCl₄) draft risk evaluation: January 2020; CCl₄ problem formulation: May 2018; CCl₄ scope document: June 2017
- Public comments and external scientific peer review informed the final risk evaluation
 - 19 public comments received on the draft risk evaluation (comment period closed March 27, 2020)
 - Peer review: EPA's Science Advisory Committee on Chemicals (SACC) met to review the draft evaluation (February 2020)
- The final risk evaluation and supplemental materials are in docket [EPA-HQ-OPPT-2019-0499](#), with additional materials supporting the risk evaluation process in docket [EPA-HQ-OPPT-2016-0733](#), on www.regulations.gov



Unreasonable Risk Determinations

- EPA determined that 13 of the 15 conditions of use of CCl_4 present an unreasonable risk of injury to health
- EPA's determinations are based on unreasonable risks of injury to:
 - Workers and occupational non-users (ONUs) during occupational exposures
- EPA's risk evaluation identified unreasonable risks for non-cancer (liver toxicity) and cancer adverse effects from chronic inhalation and dermal exposure to CCl_4



Manufacturing, Processing, Industrial, Commercial, and Disposal Uses that Present an Unreasonable Risk

- Domestic manufacture
- Import
- Processing: as a reactant in the production of hydrochlorofluorocarbon, hydrofluorocarbon, hydrofluoroolefin, and perchloroethylene
- Processing: incorporation into formulation, mixture or reaction products – Petrochemicals-derived manufacturing, agricultural products manufacturing, and other basic organic and inorganic chemical manufacturing
- Processing: repackaging for use in laboratory chemicals
- Processing: recycling
- Industrial and commercial use as an industrial processing aid in the manufacture of petrochemicals-derived products and agricultural products



Manufacturing, Processing, Industrial, Commercial, and Disposal Uses that Present an Unreasonable Risk (cont'd)

- Industrial and commercial use as an additive
- Industrial and commercial use in other basic organic and inorganic chemical manufacturing (manufacturing of chlorinated compounds used in solvents for cleaning and degreasing, adhesives and sealants, paints and coatings, asphalt, and elimination of nitrogen trichloride in the production of chlorine and caustic)
- Industrial and commercial use in metal recovery
- Industrial and commercial use in specialty uses for the Department of Defense
- Industrial and commercial use as a laboratory chemical
- Disposal



Basis for Unreasonable Risk Determination: Workers and ONUs

- The unreasonable risk determinations for workers and ONUs are based on the following health hazards during occupational exposures of CCl_4 :
 - Cancer effects (liver, adrenal, and brain tumors) from dermal exposures and chronic inhalation
 - Liver effects from chronic inhalation
- Personal Protective Equipment (PPE):
 - The OSHA Carbon Tetrachloride Standard sets a PEL of 10 ppm
 - Many conditions of use presented an unreasonable risk to workers even with use of gloves with a PF of 20
 - No unreasonable risk to workers due to acute and chronic inhalation exposures assuming use of respirators with APF of 50 in industrial/commercial settings
 - EPA does not assume ONUs use PPE because they do not handle the chemical



Examples of Regulatory Options

- Set a concentration for a particular use, for example, product formulations cannot contain more than a certain percentage by weight
- Provide a prominent label securely attached to each container with specific directions, limitations, and precautions, or that describe the health endpoints
- Prohibit manufacturing, processing and distribution for particular conditions of use with unreasonable risks
- Mandate specific engineering controls, ventilation requirements, and personal protective equipment (PPE) at occupational sites



Examples of Regulatory Options

- Require manufacturers, processors, and distributors to maintain ordinary business records
- Require manufacturers, 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)
- Restrict distribution of a chemical or product only to certain users, under a limited access program that could require training and certification



Your Comments

- Please provide specific examples of:
 - Any experience with use of carbon tetrachloride
 - Any experience with regulation of carbon tetrachloride
 - Any risk management experience with specific conditions of use of carbon tetrachloride
- Please provide specific comments:
 - Do you have any concerns about these uses of carbon tetrachloride, particularly regarding uses in environmental justice communities?
 - How would these rulemakings impact environmental justice communities?
 - Other thoughts on the rulemaking?



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>
- Carbon Tetrachloride: Claudia Menasche (menasche.claudia@epa.gov, 202-564-3391), <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-management-carbon-tetrachloride>
- General risk management outreach: Douglas Parsons (parsons.douglas@epa.gov, 202-564-0341)



Next Steps

- Please submit written comments by **April 2, 2021** to:
 - Amanda Hauff hauff.amanda@epa.gov;
 - Claudia Menashe Menasche.Claudia@epa.gov;
and
 - Sue Slotnick Slotnick.Sue@epa.gov.