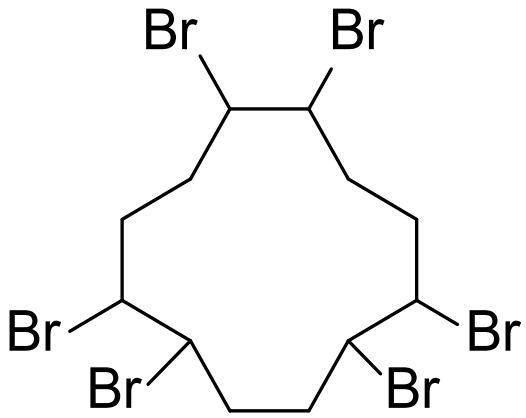
United States
Environmental Protection Agency

EPA Document #740R22001
June 2022
Office of Chemical Safety and
Pollution Prevention

Nontechnical Summary of the Risk Evaluation for

Cyclic Aliphatic Bromide Cluster (HBCD)

CASRN: 25637-99-4
CASRN: 3194-55-6
CASRN: 3194-57-8



June 2022

BACKGROUND

- The primary use for cyclic aliphatic bromide cluster chemicals, including hexabromocyclododecane (HBCD), has been as a flame retardant in expanded polystyrene and extruded polystyrene in insulation foam used for construction; however, EPA identified other uses including use as a component of solder and use in automobile replacement parts.
- The manufacturing (including import) and use of HBCD has rapidly declined in the United States and globally over the past 10 years due to international regulation and the availability of substitutes. Annual production volumes were consistently 10-50 million lbs from 2007 to 2011. From 2012 to 2015, production fell to 1-10 million lbs/year. Additional communications with industry representatives indicate that, as of 2018, domestic manufacture of HBCD had ceased and there are currently no U.S. manufacturers of the chemical.

ACTION

- EPA is releasing a final revision to the risk determination with an order withdrawing the TSCA section 6(i)(1) order previously included in the September 2020 risk evaluation on HBCD. EPA has determined that HBCD presents an unreasonable risk to health and the environment under its conditions of use. For this chemical, commercial and consumer conditions of use were combined.
- This final risk evaluation, which includes the 2020 risk evaluation and a 2022 revised unreasonable risk determination, is conducted pursuant to the Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which requires EPA to prioritize and evaluate the safety of existing chemicals to determine whether a chemical presents an unreasonable risk of injury to health or the environment under the conditions of use. If a chemical is determined to present an unreasonable risk, then EPA must regulate the substance to address the unreasonable risk.
- The 2020 risk evaluation, supplemental materials, 2022 revised unreasonable risk determination and corresponding response to public comments can be found in docket EPA-HQ-OPPT-2019-0237 on www.regulations.gov.
- HBCD was selected in 2016 as one of the first 10 chemicals for risk evaluation under section 6 of TSCA.
- Public comments and external scientific peer review informed the development of the HBCD final risk evaluation. EPA published the revised unreasonable risk determination in June 2022, the HBCD risk evaluation in September 2020, the HBCD draft risk evaluation in June 2019, the HBCD problem formulation document in May 2018, and the scope document in June 2017.

KEY POINTS

- Risk conclusions for the environment are based upon both aquatic and terrestrial organisms of numerous species from different families. Adverse effects on aquatic species included reduced growth of aquatic plants (algae), reduced growth and delayed embryo development in fish, reduced growth and survival for pelagic (water flea) and benthic (California blackworm) invertebrates. Adverse effects in terrestrial soil organisms included effects on reproduction and mortality in earthworms chronically exposed to HBCD.
- Risk conclusions from human health effects were based on the most robust and sensitive acute (offspring loss) and chronic thyroid hormone effects) endpoints. Thyroid hormone

changes (both acute and chronic) are considered the primary effect resulting from HBCD exposure, as they are associated with all the other observed downstream endpoints.

- In the revised unreasonable risk determination for HBCD, EPA is making an unreasonable risk determination for HBCD as a whole chemical substance, rather than a condition of use-specific approach. The whole chemical approach is appropriate for HBCD because there are benchmark exceedances for multiple conditions of use for both health and the environment, HBCD is a persistent, bioaccumulative and toxic substance, and the health effects associated with HBCD exposures are irreversible.
- After evaluating 12 conditions of use of HBCD, EPA determined that HBCD presents an unreasonable risk of injury to health and the environment under its conditions of use.
- In addition, EPA is revising the assumption that workers always or properly use personal protective equipment (PPE). Although EPA does not question public comments received regarding the occupational safety practices often followed by industry. Information on the use of PPE as a means of mitigating risk will be considered during the risk management phase.
- By removing the assumption that all workers always and appropriately wear PPE, four of the six conditions of use driving the unreasonable risk to the environment in the 2020 HBCD risk evaluation now also drive unreasonable risk based on health risks to workers, an identified potentially exposed or susceptible subpopulation (PESS). The four conditions of use affected by this change are: import, processing the chemical as a formulation, mixture, or reaction product; processing the chemical into articles; recycling.
- Overall, six conditions of use of the 12 evaluated drive the HBCD whole chemical unreasonable risk determination due to risks identified for both health and the environment: import, processing the chemical as a formulation, mixture, or reaction product; processing the chemical into articles; recycling; commercial installation of building/construction materials; and disposal (demolition).
- The use of consumer articles and products containing HBCD or where these items were distributed in commerce do not drive the unreasonable risk presented by HBCD.
- Exposures from ambient air, surface water, biosolids, or sediments for the general population from all conditions of use do not drive the unreasonable risk presented by HBCD. Similarly, exposures to the general population via drinking water based on an assessment of the physical-chemical properties and fate of HBCD in the environment as well as the absence of any HBCD measured in water samples do not drive the unreasonable risk presented by HBCD.
- The risk evaluation includes uses of HBCD that are no longer manufactured, processed, or distributed for use in products and the disposal of those products, otherwise known as "legacy uses" and "associated disposal," respectively. Because of the court ruling in *Safer Chemicals Healthy Families v. U.S. Environmental Protection,* as well as public and peer review comments, EPA made additional assessments on these uses: general population exposure to HBCD in dust and indoor air released from HBCD-containing products, and articles that are still in use but for which the manufacture, processing, and distribution for such use has ceased.
- EPA released the draft risk evaluation for HBCD in June 2019 for a 60-day public comment period. Additionally, EPA held a peer review meeting of the Science Advisory Committee on Chemicals (SACC) on the draft risk evaluation of HBCD on July 29-August 2, 2019. The report of the SACC on HBCD is in the docket (EPA-HQ-OPPT-2019-0237). Along with the

final risk evaluation, EPA released a document that provides a response to public and peer review comments.

- EPA is releasing a final revision to the unreasonable risk determination with an order withdrawing the TSCA section 6(i)(1) order previously included in the September 2020 risk evaluation. EPA is also releasing a document with response to public comments received on the draft revised risk determination on HBCD published in December 2021.

NEXT STEPS

EPA has issued the final risk evaluation (2020 risk evaluation and a 2022 revised risk determination) for HBCD, meeting the requirements set forth in TSCA section 6(b) for chemical risk evaluations. EPA is now initiating the process to address the unreasonable risk identified. Following the issuance of the final risk evaluation, EPA will address, by rule, the unreasonable risk identified.

SUMMARY OF UNREASONABLE RISK DETERMINATION

EPA has determined that HBCD present an unreasonable risk of injury to health and the environment under the conditions of use. EPA's unreasonable risk determination for HBCD is driven by risks associated with the following conditions of use, considered singularly or in combination with other exposures:

- Manufacturing - Import
- Processing: Incorporated into a Formulation, Mixture, or Reaction Products
- Processing: Incorporation into Article
- Processing: Recycling (of XPS and EPS foam, resin, and panels containing HBCD
- Commercial/Consumer Use[1]: Building/Construction Materials (Installation)
- Disposal (Demolition)

EPA will initiate TSCA section 6(a) risk management actions on these conditions of use as required under TSCA section 6(c)(1).

[1] Note: Commercial and consumer use was assessed as part of the same exposure scenario, but risks were quantified separately and commercial use is a driver for unreasonable risk while consumer use is not.