5. UNREASONABLE RISK DETERMINATION

TSCA section 6(b)(4) requires EPA to conduct a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by EPA as relevant to this Risk Evaluation, under the conditions of use.

EPA has determined that HBCD presents an unreasonable risk of injury to health and the environment under the conditions of use. This determination is based on the information in previous sections of this Risk Evaluation, the appendices and supporting documents of Cyclic Aliphatic Bromide Cluster (HBCD), in accordance with TSCA section 6(b), as well as TSCA's best available science (TSCA section 26(h)) and weight of scientific evidence standards (TSCA section 26(i)), and relevant implementing regulations in 40 CFR part 702.

The full list of conditions of use evaluated for the HBCD TSCA risk evaluation is included in Table 1-8 of the risk evaluation: https://www.epa.gov/sites/default/files/2020-09/documents/1._risk_evaluation_for_cyclic_aliphatic_bromide_cluster_hbcd_casrn25637-99-4_casrn_3194-5_casrn_3194-57-8.pdf. 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 risk management for HBCD by applying one or more of the requirements under TSCA section 6(a) to the extent necessary so that HBCD no longer presents an unreasonable risk. Under TSCA section 6(a), EPA is not limited to regulating the specific activities found to drive unreasonable risk and may select from among a suite of risk management options related to manufacture, processing, distribution in commerce, commercial use, and disposal in order to address the unreasonable risk. For instance, EPA may regulate upstream activities (*e.g.*, processing, distribution in commerce) in order to address downstream activities driving unreasonable risk (*e.g.*, use) even if the upstream activities are not unreasonable risk drivers.

[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.

5.1 Background

5.1.1 Background on Policy Changes Relating to the Whole Chemical Risk Determination and Assumption of PPE Use by Workers

From June 2020 to January 2021, EPA published risk evaluations on the first ten chemical substances, including for HBCD in September 2020. The risk evaluations included individual unreasonable risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present an unreasonable risk were issued by order under TSCA section 6(i)(1).

In accordance with Executive Order 13990 ("Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis") and other Administration priorities (Refs. 1, 2, 3, and 4), EPA reviewed the risk evaluations for the first ten chemical substances to ensure that they meet the requirements of TSCA, including conducting decision-making in a manner that is consistent with the best available science and weight of the scientific evidence.

As a result of this review, EPA announced plans to revise specific aspects of certain of the first ten risk evaluations in order to ensure that the risk evaluations appropriately identify unreasonable risks and thereby can help ensure the protection of health and the environment (https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations). To that end, EPA has reconsidered two key aspects of the risk determinations for HBCD published in September 2020. First, EPA has determined that the appropriate approach to these determinations is to make an unreasonable risk determination for HBCD as a whole chemical substance, rather than making unreasonable risk determinations separately on each individual condition of use evaluated in the risk evaluation. Second, EPA has determined that the risk determination shall explicitly state that it does not rely on assumptions regarding the use of personal protective equipment (PPE) in making the unreasonable risk determination under TSCA section 6; rather, the use of PPE will be considered during risk management. Further discussion of the rationale for the whole chemical approach is found in the Federal Register Notice in the docket accompanying this revised HBCD unreasonable risk determination and further discussion of the decision to not rely on assumptions regarding the use of PPE is provided in the Federal Register Notice and in Section 5.2.1.3 below. With respect to the HBCD risk evaluation, EPA did not amend, nor does a whole chemical approach require amending, the underlying scientific analysis of the risk evaluation in the risk characterization section of the risk evaluation.

With regard to the specific circumstances of HBCD, as further explained below, EPA has determined that a whole chemical approach is appropriate for HBCD in ordered to protect health and the environment. The whole chemical approach is appropriate for HBCD because there are benchmark exceedances for multiple conditions of use (spanning across most aspects of the chemical lifecycle–from manufacturing (import), processing, commercial use, and disposal) for both health and the environment, HBCD is a persistent, bioaccumulative and toxic substance, and the health effects associated with HBCD exposures are irreversible. Because these chemical-specific properties cut across the conditions of use within the scope of the risk evaluation and a

substantial amount of the conditions of use drive the unreasonable risk , it is therefore appropriate for the Agency to make a determination that the whole chemical presents an unreasonable risk. As explained in the Federal Register Notice, the revisions to the unreasonable risk determination (Section 5 of the risk evaluation) follow the issuance of a draft revision to the TSCA HBCD unreasonable risk determination (86 FR 74082, December 29, 2021) (Ref. 5) and the receipt of public comment. A response to comments document is also being issued with this final revised unreasonable risk determination for HBCD. As noted in the Federal Register Notice, the revisions to the unreasonable risk determination are based on the existing risk characterization section of the risk evaluation (Section 4 of this Risk Evaluation) and do not involve additional technical or scientific analysis. The discussion of the issues in this revision to the risk determination supersedes any conflicting statements in the prior HBCD risk evaluation and the response to comments document (Summary of External Peer Review and Public Comments and Disposition for Cyclic Aliphatic Bromide Cluster (HBCD), September 2020). In addition, as discussed below in Section 5.2.1.3, in making this risk determination, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. EPA is revising the assumption for HBCD that workers always or properly use PPE, although it does not question the public comments received regarding the occupational safety practices often followed by industry respondents. EPA also views the peer reviewed hazard and exposure assessments and associated risk characterization as robust and upholding the standards of best available science and weight of the scientific evidence, per TSCA sections 26(h) and (i).

5.1.2 Background on Unreasonable Risk Determination

In each Risk Evaluation under TSCA section 6(b), EPA determines whether a chemical substance presents an unreasonable risk of injury to health or the environment, under the conditions of use. The unreasonable risk determination does not consider costs or other nonrisk factors. In making the unreasonable risk determination, EPA considers relevant risk-related factors, including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any potentially exposed or susceptible subpopulations (PESS)); the severity of hazard (including the nature of the hazard, the irreversibility of the hazard); and uncertainties. EPA takes into consideration the Agency's confidence in the data used in the risk estimate. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization. This approach is in keeping with the Agency's final rule, *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017).[2]

[2] This risk determination is being issued under TSCA section 6(b) and the terms used, such as unreasonable risk, and the considerations discussed are specific to TSCA. Other EPA programs have different statutory authorities and mandates and may involve risk considerations other than those discussed here.

This section describes the revised unreasonable risk determination for HBCD, under the conditions of use in the scope of the Risk Evaluation for the cyclic aliphatic bromide cluster chemicals. EPA evaluated two of the three chemicals in the cluster: CASRN 25637-99-4 and CASRN 3194-55-6. In this document, the use of "HBCD" refers to either or both chemicals. No conditions of use were identified for the third chemical, CASRN 3194-57-8. This revised unreasonable risk determination is based on the risk estimates in the final Risk Evaluation, which may differ from the risk estimates in the draft Risk Evaluation due to peer review and public comments.

5.2 Unreasonable Risk to Human Health

5.2.1 Human Health

EPA's HBCD risk evaluation identified non-cancer adverse effects from acute and chronic inhalation and dermal exposures to HBCD. The most sensitive and robust endpoint for acute exposure is offspring loss, and for chronic exposure, it is thyroid effects. Risks were estimated for all human receptors following both acute and chronic exposure for representative endpoints from every hazard domain carried through to dose-response analysis. The health risk estimates for all conditions of use are in Tables 4-14 through 4-24 of this Risk Evaluation.

EPA accounted for PESS in risk estimation by providing risk conclusions based on the most sensitive receptor or lifestage (*i.e.,* female workers of reproductive age for occupational risk, the youngest relevant lifestage for general population and consumer risk) and consideration of high end exposures (Section 4.5.2 and Table 4-11 of this Risk Evaluation).

EPA evaluated exposures to workers, occupational non-users (ONUs)[3], consumer users, and the general population using reasonably available monitoring and modeling data for inhalation, dermal, and ingestion exposures, as applicable. The description of the data used for human health exposure is in Section 4.2 of this Risk Evaluation. Uncertainties in the analysis are discussed in Section 4.3.2 of this Risk Evaluation and are considered in the unreasonable risk determination. These uncertainties include EPA not being able to model the potential effects of bioaccumulation in human tissues over time, EPA not being able to quantify ONU exposure due to lack of adequate data or relevant models, and uncertainty surrounding estimated fish ingestion exposure because this is highly dependent on the selected value for the Bioaccumulation Factor (BAF).

EPA quantitatively evaluated inhalation, ingestion and dermal exposures to the general population via exposure to indoor and ambient air; dermal contact with soil and dust; and oral exposures via ingestion of food, breast milk, soil, dust and fish. While HBCD is released to surface water, EPA determined during problem formulation that no further analysis beyond what was presented in the problem formulation document would be done for the drinking water exposure pathway in this Risk Evaluation. While this exposure pathway remains in the scope of this Risk Evaluation, EPA does not find the unreasonable risk determination for HBCD to be

[3] ONUs are workers who do not directly handle HBCD but perform work in an area where HBCD is present. (Executive Summary of this Risk Evaluation).

driven by general population exposure to HBCD in drinking water, based on a qualitative assessment of the physical chemical properties and fate of HBCD in the environment as well as the absence of any detection of HBCD in monitored water samples (Section 2.3.5.3 of the Problem Formulation; Section 4.2.3.1 of this Risk Evaluation).

5.2.1.1 Non-Cancer Risk Estimates

The risk estimates of non-cancer effects (expressed as margins of exposure or MOEs) refer to adverse health effects associated with health endpoints other than cancer, including to the body's organ systems, such as thyroid effects, liver effects, and reproductive/developmental effects. The MOE is the point of departure (POD) (an approximation of the no-observed adverse effect level (NOAEL) or benchmark dose level (BMDL)) and the corresponding human equivalent concentration (HEC) for a specific health endpoint divided by the exposure concentration for the specific scenario of concern. Section 3.2.5 presents the PODs for acute and chronic non-cancer effects for HBCD and Section 4.2 presents the MOEs for acute and chronic non-cancer effects.

The MOEs are compared to a benchmark MOE. The benchmark MOE accounts for the total uncertainty in a POD, including, as appropriate: (1) the variation in sensitivity among the members of the human population (*i.e.*, intrahuman/intraspecies variability); (2) the uncertainty in extrapolating animal data to humans (*i.e.*, interspecies variability); (3) the uncertainty in extrapolating from data obtained in a study with less-than-lifetime exposure to lifetime exposure (*i.e.*, extrapolating from subchronic to chronic exposure); and (4) the uncertainty in extrapolating from a lowest observed adverse effect level (LOAEL) rather than from a NOAEL. A lower benchmark MOE (*e.g.*, 30) indicates greater certainty in the data (because fewer of the default uncertainty factors (UFs) relevant to a given POD as described above were applied). A higher benchmark MOE (*e.g.*, 1000) would indicate more uncertainty for specific endpoints and scenarios. However, these are often not the only uncertainties in a risk evaluation. The benchmark MOE for the most robust and sensitive acute non-cancer risks for HBCD is 100 (accounting for intraspecies and interspecies variability). The benchmark MOE for the most robust and sensitive chronic non-cancer risks for HBCD is 300 (accounting for interspecies and intraspecies variability as well as subchronic to chronic extrapolation). Additional information regarding the benchmark MOE is in Section 3.2.6. of this Risk Evaluation.

5.2.1.2 Cancer Risk Estimates

Usually, EPA determines cancer risk estimates to represent the incremental increase in probability of an individual in an exposed population developing cancer over a lifetime (excess lifetime cancer risk (ELCR)) following exposure to the chemical. EPA did not evaluate cancer risk from exposure to HBCD because there is indeterminate evidence to make a conclusion of genotoxicity of HBCD and therefore inadequate information to assess the carcinogenic potential of HBCD. The only experimental animal study to examine cancer endpoints concluded that HBCD was not carcinogenic, however, this study was only available as an incomplete report (Kurokawa et al. 1984). Therefore, according to the U.S. EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA 2005), there is "inadequate information to assess the carcinogenic potential" of HBCD. Despite the limited evidence, it is unlikely that the results of any potential additional studies would significantly alter the conclusions about the hazard due to the mixed results and the negative incomplete report. As a result, this hazard was not carried forward for dose-response analysis or risk estimation (Section 3.2.4.2 of this Risk Evaluation).

5.2.1.3 Determining Unreasonable Risk of Injury to Health

Calculated non-cancer risk estimates (MOEs) can provide a risk profile of HBCD by presenting a range of estimates for different health effects for different conditions of use. A calculated MOE that is less than the benchmark MOE supports a determination of unreasonable risk of injury to health, based on noncancer effects.These calculated risk estimates alone are not bright-line indicators of unreasonable risk. Whether EPA makes a determination of unreasonable risk for the chemical substance depends upon other risk-related factors, such as the endpoint under consideration, the reversibility of effect, exposure-related considerations (*e.g.*, duration, magnitude, or frequency of exposure, or population exposed), and the confidence in the information used to inform the hazard and exposure values.

In the HBCD risk characterization, offspring loss was identified as the most robust and sensitive endpoint for non-cancer adverse effects from acute exposures for all conditions of use. For chronic exposures, thyroid effects were identified as the most robust and sensitive endpoint for noncancer adverse effects for all conditions of use. However, additional risks associated with other adverse effects (*e.g.,* liver effects, reproductive effects, and other developmental effects) were also identified for acute and chronic exposures. The HBCD unreasonable risk determination uses offspring loss and thyroid effects as driving endpoints.

When making a determination of unreasonable risk for the chemical substance, the Agency has a higher degree of confidence where uncertainty is low. For example, EPA has high confidence in the hazard and exposure characterizations when the basis for characterizations is measured or monitoring data or a robust model and the hazards identified for risk estimation are relevant for conditions of use. This Risk Evaluation discusses the major assumptions and key uncertainties by major topic: physical-chemical properties and toxicokinetics, hazard, occupational exposure, general population/consumer exposure, and historical production volumes and activities. For the human health risk estimation, key assumptions and uncertainties are related to the toxicokinetics of HBCD, including high-end assumptions about dermal absorption and uncertainty whether

existing UFs sufficiently account for bioaccumulation in human tissues. Additional sources of uncertainty related to human health hazard include the application of adult rodent thyroid hormone changes to humans in a developmental context and the absence of reliable dose-response information for developmental neurotoxicity endpoints. Important assumptions and key sources of uncertainty in the risk characterization are described in more detail in Section 4.3.2 of this Risk Evaluation.

When determining the unreasonable risk for a chemical substance, EPA considers the central tendency and high-end exposure levels in occupational settings and in environmental media. Risk estimates based on high-end exposure level scenarios (*e.g.*, 95th percentile) are generally intended to cover individuals or sub-populations with greater exposure (*i.e.,* PESS) as well as to capture individuals with sentinel exposure, and risk estimates at the central tendency exposure levels are generally estimates of average or typical exposure (Section 4.4. of this Risk Evaluation).

As shown in Section 4 of this Risk Evaluation, when characterizing the risk to human health from occupational exposures during risk evaluation under TSCA, EPA believes it is appropriate to evaluate the levels of risk present in baseline scenarios where PPE is not assumed to be used by workers. It should be noted that, in some cases, baseline conditions may reflect certain mitigation measures, such as engineering controls, in instances where exposure estimates are based on monitoring data at facilities that have engineering controls in place. This approach considers the risk to potentially exposed or susceptible subpopulations of workers who may not be covered by Occupational Safety and Health Administration (OSHA) standards, such as self-employed individuals and public sector workers who are not covered by a State Plan. In addition, EPA risk evaluations may characterize the levels of risk present in scenarios considering applicable OSHA requirements (*e.g.*, chemical-specific PELs and/or chemical-specific health standards with PELs and additional ancillary provisions), as well as scenarios considering industry or sector best practices for industrial hygiene that are clearly articulated to the Agency. EPA's evaluation of risk under scenarios that, for example, incorporate use of engineering or administrative controls, or personal protective equipment, serves to inform its risk management efforts. By characterizing risks using scenarios that reflect different levels of mitigation, EPA's risk evaluations can help inform potential risk management actions by providing information that could be used to tailor risk mitigation appropriately to address worker exposures where the Agency has found unreasonable risk. In particular, EPA can use the information developed during its risk evaluation to determine whether alignment of EPA's risk management requirements with existing OSHA requirements or industry best practices will adequately address unreasonable risk as required by TSCA.

When undertaking unreasonable risk determinations as part of TSCA risk evaluations, EPA cannot assume as a general matter than an applicable OSHA requirement or industry practice is consistently and always properly applied. Mitigation scenarios included in the HBCD risk evaluation (*e.g.*, scenarios considering use of various personal protective equipment (PPE)) likely represent what is happening already in some facilities. However, the Agency cannot assume that all facilities will have adopted these practices for the purposes of making the TSCA risk determination.

Therefore, EPA conducts baseline assessments of risk and makes its determination of unreasonable risk from a baseline scenario that is not based on an assumption of compliance with OSHA standards, including any applicable exposure limits or requirements for use of respiratory protection or other PPE. Making unreasonable risk determinations based on the baseline scenario should not be viewed as an indication that EPA believes there are no occupational safety protections in place at any location, or that there is widespread non-compliance with applicable OSHA standards. Rather, it reflects EPA's recognition that unreasonable risk may exist for subpopulations of workers that may be highly exposed because they are not covered by OSHA standards, such as self-employed individuals and public sector workers who are not covered by a State Plan, or because their employer is out of compliance with OSHA standards, or because EPA finds unreasonable risk for purposes of TSCA notwithstanding existing OSHA requirements.

The revised unreasonable risk determination for HBCD is based on the peer reviewed risk characterization (Section 4 of this Risk Evaluation), which was developed according to TSCA section 26(h) requirements to make science-driven decisions, consistent with best available science. Changing the risk determination to a whole chemical approach does not impact the underlying data and analysis presented in the risk characterization of the risk evaluation. Section 4.5.2 and Table 4-27 of this Risk Evaluation summarize the risk estimates with and without PPE, and informed the revised unreasonable risk determination.

5.3 Unreasonable Risk to the Environment

EPA's Risk Evaluation identified adverse effects resulting from acute and chronic exposures to HBCD for both aquatic and terrestrial organisms for all conditions of use, as summarized in Section 3.1. The environmental hazard threshold is calculated for both aquatic and terrestrial organisms. The hazard threshold for aquatic organisms takes into account an assessment factor that represents uncertainties explained in Section 3.1.5, therefore allowing a concentration of concern (COC) to be derived. Limitations in data availability regarding HBCD toxicity to terrestrial organisms do not allow for an assessment factor to be used to derive a COC, therefore the hazard threshold is based on reported hazard effect concentrations reported by key studies summarized in Section 3.1.5. The description of the data used for environmental exposure is in Section 2.3. The environmental concentration is determined based on the levels of the chemical released to the environment (*e.g.*, surface water, sediment, soil, biota) under the conditions of use, based on the fate properties, release potential, and reasonably available environmental monitoring data. Section 4.1. provides more detail regarding the risk quotient derivations for HBCD.

EPA calculated a risk quotient (RQ) to compare environmental concentrations against an effect level. The environmental risk quotient from exposure to HBCD via water (*e.g.*, surface water and sediment) and air (*e.g.*, soil) releases are characterized in Section 4.1 (Table 4-3 through Table 4-7). Uncertainties in the analysis are discussed in Section 4.3 and considered in the risk determination below, including the fact that despite HBCD being a PBT, exposure to HBCD across and within media types were not aggregated to estimate risk (as explained in Section 4.1.3), therefore environmental risk may be underestimated for aquatic and terrestrial organisms.

5.3.1 Determining Unreasonable Risk of Injury to the Environment

Calculated risk quotients (RQs) can provide a risk profile by presenting a range of estimates for different environmental hazard effects for different conditions of use. An RQ equal to 1 indicates that the exposures are the same as the concentration that causes effects. An RQ less than 1, when the exposure is less than the effect concentration, generally indicates that there is not risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance. An RQ greater than 1, when the exposure is greater than the effect concentration, generally indicates that there is risk of injury to the environment that would support a determination of unreasonable risk for the chemical substance. Consistent with EPA's human health evaluations, the RQ is not treated as a bright line and other risk-based factors may be considered (*e.g.*, confidence in the hazard and exposure characterization, duration, magnitude, uncertainty) for purposes of making an unreasonable risk determination.

EPA evaluated the effects of exposure to HBCD on aquatic and terrestrial organisms. HBCD is a persistent, bioaccumulative, and toxic (PBT) substance. EPA found that there were exceedances of benchmarks for pelagic and benthic aquatic organisms (Section 4.5.1.1 of this Risk Evaluation). There were no exceedances of benchmarks for terrestrial organisms (Section 4.5.1.2 of this Risk Evaluation). In the HBCD risk characterization, delayed hatching and reduced growth of offspring were identified as the most robust and sensitive endpoints for pelagic organisms due to acute and chronic exposures of HBCD, respectively. EPA evaluated algae risk separately from the categorization of an acute or chronic exposure, and risk of reduced algae growth was evaluated. The most robust and sensitive endpoint identified for benthic organisms due to chronic HBCD exposure was reduced reproduction. EPA also identified reduced reproduction and survival of soil organisms due to chronic exposure to HBCD as being the most robust and sensitive endpoint. EPA provides estimates for environmental risk in Section 4.5.1 of this Risk Evaluation.

EPA may make an unreasonable risk determination when the risk affects organisms that are identified as being relevant (Section 3.1 of this Risk Evaluation). Based on the available hazard data for aquatic and terrestrial organisms, EPA based environmental risk for conditions of use on predicted media-specific HBCD concentrations. Although EPA acknowledges that due to the physical-chemical properties of HBCD that dietary exposure is likely, HBCD release information cannot be directly used to extrapolate tissue concentrations of prey of either aquatic or terrestrial organisms; monitoring data was primarily used for the trophic transfer estimation of HBCD (Section 3.1.3 of this Risk Evaluation), and that is used to evaluate the potential for HBCD to undergo trophic transfer due to all activities and releases that likely contribute to HBCD background exposures. Due to the lack of HBCD hazard information regarding terrestrial organism exposure, terrestrial organism risk resulting from HBCD exposure is limited to that for soil organisms (*e.g.*, earthworms), and EPA acknowledges this uncertainty (Section 4.3.1 of this Risk Evaluation).

When making a determination of unreasonable risk, EPA has a higher degree of confidence where uncertainty is low. For example, EPA has high confidence in the hazard and exposure characterizations when the basis for the characterizations is measured or monitoring data or a

robust model and the hazards identified for risk estimation are relevant for conditions of use. Where EPA has made assumptions in the scientific evaluation, the degree to which these assumptions are conservative (i.e., more protective) is also a consideration. Additionally, EPA considers the central tendency and high-end scenarios when determining the unreasonable risk. High-end risk estimates (*e.g.*, 90th percentile) are generally intended to cover organisms or populations with greater exposure (those inhabiting ecosystems near industries) and central tendency risk estimates are generally estimates of average or typical exposure.

EPA considered uncertainties in its determination of unreasonable risk for HBCD. Key assumptions and uncertainties in the environmental risk estimation are related to data used for the characterization of environmental exposure (*e.g.,* model input parameters, inability to directly relate monitoring sites to conditions of use) and environmental hazard (*e.g.,* selection of representative organisms, allometric-scaling to estimate hazard thresholds for other organisms). Additionally, the reasonably available environmental monitoring data was limited temporally and geographically. Assumptions and key sources of uncertainty in the risk characterization are detailed in Section 4.3.1. of this Risk Evaluation.

5.4 Additional Information regarding the Basis for the Unreasonable Risk Determination

Tables 5-1 and 5-2 summarize the basis for the revised determination of unreasonable risk of injury to health and the environment presented by HBCD. In both tables, a checkmark indicates the type of effect and the exposure route to the population evaluated for each condition of use that drive the unreasonable risk determination for HBCD. As explained in Section 5.1, for the revised unreasonable risk determination, EPA considered the effects on human health and the environment of exposure to HBCD at the central tendency and high-end, the exposures from the condition of use, the risk estimates, and the uncertainties in the analysis. See Sections 4.5.1 and 4.5.2 of this Risk Evaluation for a summary of risk estimates.

Table 5-1. Supporting Bases for the Revised Unreasonable Risk Determination for Human Health[4]

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk			
					Acute Non-cancer		Chronic Non-cancer	
					High End	Central Tendency	High End	Central Tendency
Manufacture	Import	Import	Worker	Inhalation and Dermal	✓	✓	✓	✓
Processing	Incorporated into formulation, mixture or reaction product	Flame retardants used in custom compounding of resin (*e.g.*, compounding in XPS masterbatch) and in solder paste	Worker	Inhalation and Dermal	✓	✓	✓	✓
Processing	Processing – incorporation into article	Flame retardants used in plastics product manufacturing (manufacture of XPS and EPS foam; manufacture of structural insulated panels (SIPS) and automobile replacement parts from XPS and EPS foam)	Worker	Inhalation and Dermal	✓	✓	✓	✓
Processing	Recycling	Recycling of XPS and EPS foam, resin, panels containing HBCD	Worker	Inhalation			✓	

[4] The checkmarks indicate the type of effect and the exposure route to the population evaluated for each condition of use that support the revised unreasonable risk determination for HBCD. This table is based on Table 4-27 of this Risk Evaluation.

Life Cycle Stage	Category [a]	Subcategory [b]	Population	Exposure Route	Human Health Risk			
					Acute Non-cancer		Chronic Non-cancer	
					High End	Central Tendency	High End	Central Tendency
Commercial/ consumer use	Building/ construction materials	Plastic articles (hard): construction and building materials covering large surface areas (*e.g.*, XPS/EPS foam insulation in residential, public and commercial buildings, and other structures) and solder paste	Worker & ONU	Inhalation and Dermal			✓	
Disposal	Disposal	Land disposal (*e.g.*, EPS and XPS foam insulation)	Worker & ONU	Inhalation			✓	

[a] These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent additional information regarding all conditions of use of HBCD.

[b] These subcategories reflect more specific information regarding the conditions of use of HBCD.

Table 5-2. Supporting Bases for the Revised Unreasonable Risk Determination for the Environment[5]

Life Cycle Stage	Category[a]	Subcategory[b]	Population	Exposure Route	Environmental Risk			
					Acute		Chronic	
					High End	Central Tendency	High End	Central Tendency
Manufacture	Import	Import	Aquatic Organisms	Surface Water and Sediment	✓	✓	✓	✓
Processing	Incorporated into formulation, mixture or reaction product	Flame retardants used in custom compounding of resin (*e.g.*, compounding in XPS masterbatch) and in solder paste	Aquatic Organisms	Surface Water and Sediment	✓	✓	✓	

[5] The checkmarks indicate the type of effect and the exposure route to the population evaluated for each condition of use that support the revised unreasonable risk determination for HBCD. This table is based on Table 4-26 of this Risk Evaluation.

Life Cycle Stage	Category[a]	Subcategory[b]	Population	Exposure Route	Environmental Risk			
					Acute		Chronic	
					High End	Central Tendency	High End	Central Tendency
Processing	Processing – incorporation into article	Flame retardants used in plastics product manufacturing (manufacture of XPS and EPS foam; manufacture of structural insulated panels (SIPS) and automobile replacement parts from XPS and EPS foam)	Aquatic Organisms	Surface Water and Sediment	✓	✓	✓	✓
Processing	Recycling	Recycling of XPS and EPS foam, resin, panels containing HBCD	Aquatic Organisms	Surface Water and Sediment	✓	✓	✓	
Commercial/consumer use	Building/ construction materials	Plastic articles (hard): construction and building materials covering large surface areas (*e.g.*, XPS/EPS foam insulation in residential, public and commercial buildings, and other structures) and solder paste	Aquatic Organisms	Surface Water and Sediment	✓	✓		
Disposal	Disposal	Land disposal (*e.g.*, EPS and XPS foam insulation)	Aquatic Organisms	Surface Water	✓	✓	✓	

[a] These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes, and broadly represent additional information regarding all conditions of use of HBCD.

[b] These subcategories reflect more specific information regarding the conditions of use of HBCD.

5.5 Order Withdrawing TSCA Section 6(i)(1) Order

The September 2020 risk evaluation for HBCD included individual risk determinations for each condition of use evaluated. The determinations that particular conditions of use did not present unreasonable risk were issued by order under TSCA section 6(i)(1). Section 5.4.1 of the September 2020 risk evaluation stated: "This subsection of the final Risk Evaluation… constitutes the order required under TSCA section 6(i)(1), and the 'no unreasonable risk' determinations in this subsection are considered to be final agency action effective on the date of issuance of this order."

In this revised risk determination, EPA has determined that HBCD as a whole chemical substance presents an unreasonable risk of injury to health and the environment under the conditions of use. This revised risk determination supersedes the no unreasonable risk determinations in the September 2020 risk evaluation that were premised on a condition-of-use-specific approach to determining unreasonable risk. This subsection of the revised risk determination also constitutes an order withdrawing the TSCA section 6(i)(1) order in the September 2020 risk evaluation. EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the to the extent permitted by law and supported by reasoned explanation. *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *see also Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). Further explanation and justification for this action can be found in the Federal Register Notice announcing the availability of the draft revised risk determination for HBCD, 86 Fed. Reg. 74082 (Dec. 29, 2021) (Ref. 5), and in the Federal Register Notice accompanying this revised risk determination.

5.6 References

1. Executive Order 13985. Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. *Federal Register* (86 FR 7009, January 25, 2021).

2. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. *Federal Register* (86 FR 7037, of January 25, 2021).

3. Executive Order 14008. Tackling the Climate Crisis at Home and Abroad. *Federal Register* (86 FR 7619, February 1, 2021).

4. Presidential Memorandum. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking. *Federal Register* (86 FR 8845, February 10, 2021).

5. Notice. Cyclic Aliphatic Bromide Cluster (HBCD); Draft Revision to Toxic Substances Control Act (TSCA) Risk Determination; Notice of Availability and Request for Comment. *Federal Register* (86 FR 74082, December 29, 2021).