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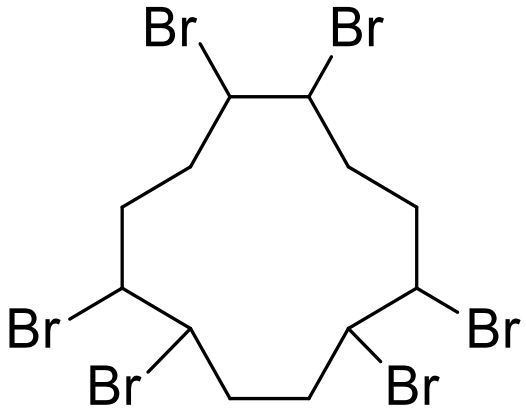
Office of Chemical Safety and
Pollution Prevention

United States
Environmental Protection Agency

Problem Formulation for Cyclic Aliphatic Bromides Cluster (HBCD)



CASRN	NAME
25637-99-4	Hexabromocyclododecane
3194-55-6	1,2,5,6,9,10-Hexabromocyclododecane
3194-57-8	1,2,5,6-Tetrabromocyclooctane

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ABBREVIATIONS

°C	Degrees Celsius
atm	Atmosphere(s)
BAF	Bioaccumulation Factor
BCF	Bioconcentration Factor
C&D	Construction and Demolition
CAA	Clean Air Act
CASRN	Chemical Abstracts Service Registry Number
CBI	Confidential Business Information
CCL	Candidate Contaminant List
CDR	Chemical Data Reporting
cm^3	Cubic Centimeter(s)
COC	Concentration of Concern
CPSC	Consumer Product Safety Commission
EC	European Commission
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EPCRA	Emergency Planning and Community Right-to-Know Act
EPS	Expanded Polystyrene
EPS-IA	Expanded Polystyrene Industry Alliance
ESD	Emission Scenario Document
g	Gram(s)
HAP	Hazardous Air Pollutant
HBCD	Hexabromocyclododecane
HIPS	High Impact Polystyrene
HPV	High Production Volume
IRIS	Integrated Risk Information System
kg	Kilogram(s)
K_{oa}	Octanol:Air Partition Coefficient
L	Liter(s)
lb	Pound
LCD	Liquid-Crystal Display
LOAEL	Lowest Observed Adverse Effect Level
LOEC	Lowest Observed Effect Concentration
Log K_{oc}	Logarithmic Organic Carbon:Water Partition Coefficient
Log K_{ow}	Logarithmic Octanol:Water Partition Coefficient
m^3	Cubic Meter(s)
MATC	Maximum Acceptable Toxicant Concentration
µg	Microgram(s)
mmHg	Millimeter(s) of Mercury
MSW	Municipal Solid Waste
MSWLF	Municipal Solid Waste Landfills
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
NIOSH	National Institute of Occupational Safety and Health
NOEC	No Observed Effect Concentration
OCSPP	Office of Chemical Safety and Pollution Prevention
OECD	Organisation for Economic Co-operation and Development

OPPT	Office of Pollution Prevention and Toxics
OSHA	Occupational Safety and Health Administration
PBPK	Physiologically Based Pharmacokinetic
PEC	Predicted Environmental Concentration
PESS	Potentially Exposed or Susceptible Subpopulation
POD	Point of Departure
POP	Persistent Organic Pollutant
POTW	Publicly Owned Treatment Works
ppm	Part(s) per Million
PQL	Practical Quantitation Limit
SDS	Safety Data Sheet
SIPS	Structural Insulated Panels
SNUR	Significant New Use Rule
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
TURA	Toxics Use Reduction Act
U.S.	United States
UNEP	United Nations Environment Programme
WEEE	Waste Electrical and Electronic Equipment
WSDE	Washington State Department of Ecology
WWTP	Wastewater Treatment Plant
XPS	Extruded Polystyrene
XPSA	Extruded Polystyrene Association

EXECUTIVE SUMMARY

TSCA § 6(b)(4) requires the United States Environmental Protection Agency (U.S. EPA) to establish a risk evaluation process. In performing risk evaluations for existing chemicals, EPA is directed to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator under the conditions of use." In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). The cyclic aliphatic bromide cluster (HBCD) was one of these chemicals.

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider. In June 2017, EPA published the Scope of the Risk Evaluation for HBCD. As explained in the Scope Document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for further scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for HBCD. Comments received on this problem formulation document will inform development of the draft risk evaluation.

This problem formulation document refines the conditions of use, exposures and hazards presented in the scope of the risk evaluation for HBCD and presents refined conceptual models and analysis plans that describe how EPA expects to analyze the risk associated with the conditions of use of HBCD.

The cyclic aliphatic bromide cluster chemicals, including HBCD (Chemical Abstracts Service Registry Number [CASRN] 25637-99-4), 1,2,5,6,9,10-hexabromocyclododecane (1,2,5,6,9,10-HBCD; CASRN 3194-55-6 are flame retardants. Uses for 1,2,5,6-tetrabromocyclooctane have not been identified. For the purposes of this problem formulation document, the use of "HBCD" refers to either CASRN 25637-99-4 or 3194-55-6, or both.

The primary use of HBCD is as a flame retardant in expanded polystyrene (EPS) foam and extruded polystyrene (XPS) foam in the building and construction industry for thermal insulation boards and foam insulation panels. HBCD also has limited use in replacement parts for automobiles. Past uses of HBCD have included use in HIPS (high impact polystyrene) and textiles. Information gathered from research, industry and consumer product organizations, however, has led EPA to conclude that those past uses are not ongoing; there is no longer manufacture, processing or distribution of HBCD for HIPS or textiles; and therefore, those uses are not included in the scope of the risk evaluation of HBCD.

With the listing of HBCD as a persistent organic pollutant under the Stockholm Convention in 2013, industry began to phase out manufacture and use of HBCD. In recent years, domestic manufacture of HBCD has ceased. Some HBCD was imported in 2017 and EPA believes that a small amount of import of HBCD may be ongoing. Use of stockpiles and exportation from the United States was completed at the end of 2017, and is further discussed in Section 2.2.2 of the Problem Formulation. EPA concludes that the import and processing of HBCD for use in EPS and XPS in buildings may be ongoing.

The conditions of use of EPS and XPS building insulation are within the scope of the evaluation and are anticipated to continue to contribute to exposures in indoor environments. In indoor environments, there

may also be exposures resulting from legacy uses of HBCD in articles (textiles, electronics and electrical products) containing HBCD. These exposures are expected to decline over time as use of these articles is phased out. The time scales for this are dependent on the age of the products, their useful service lives and time lines for replacement.

While environmental exposures are expected to decline as importing and processing of the chemical are phased out, based on past production volumes (millions of pounds per year) and the only recent cessation of domestic manufacturing, reductions in environmental concentrations will occur gradually over a period of time for this persistent and bioaccumulative compound.

This document presents the potential exposures that may result from the conditions of use of HBCD. Exposures to workers, consumers and/or the general population may occur from industrial, commercial, and consumer uses of HBCD and releases to air, water or land. Workers and occupational non-users may be exposed to HBCD during conditions of use such as import, processing, distribution, repackaging and recycling. Consumers and bystanders may also be exposed to HBCD via inhalation of particulates, dermal contact with HBCD in articles and oral exposure via ingestion of settled dust. Exposures to the general population may occur from industrial releases related to the import, processing, distribution and use of HBCD. For HBCD, EPA considers workers, occupational non-users, consumers, and bystanders and certain other groups of individuals who may experience greater exposures than the general population due to proximity to conditions of use to be potentially exposed or susceptible subpopulations. EPA will evaluate whether groups of individuals within the general population may be exposed via pathways that are distinct from the general population due to unique characteristics (e.g., life stage, behaviors, activities, duration) that increase exposure, and whether groups of individuals have heightened susceptibility, and should therefore be considered potentially exposed or susceptible subpopulations for purposes of the risk evaluation.

For aquatic ecological receptors, sediment-dwelling benthic species are expected to be exposed to HBCD. Exposures to pelagic species are also expected from HBCD present in surface water. Trophic magnification may result in greater exposure following bioaccumulation. It is expected that aquatic and terrestrial species will be exposed to HBCD through the dietary exposure pathway. EPA will consider which aquatic and terrestrial species are related via the food chain.

HBCD has been the subject of several prior health hazard, ecological hazard and risk assessments. Human health hazards of HBCD have been reviewed previously and include toxicity following acute (e.g., potential neurological effects, clinical signs of toxicity, and death at high-doses), and chronic (liver toxicity, thyroid toxicity, reproductive/developmental toxicity, neurotoxicity, immunotoxicity) exposures, and sensitization/irritation, all of which EPA expects to evaluate in the scope of the TSCA risk evaluation. HBCD hazards to fish, aquatic plants, sediment invertebrates and terrestrial organisms have also previously been assessed. If additional hazard concerns are identified during the systematic review of the literature, these will also be considered. These hazards will be evaluated based on the specific exposure scenarios identified.

The revised conceptual models presented in this problem formulation identify conditions of use; exposure pathways (e.g., media); exposure routes (e.g., inhalation, dermal, oral); potentially exposed or susceptible subpopulations; and hazards EPA expects to consider in the risk evaluation. The initial conceptual models provided in the HBCD Scope Document (U.S. EPA, 2017d) were revised during problem formulation based on evaluation of reasonably available information for physical-chemical

properties, fate, exposures, hazards and conditions of use and based upon consideration of other statutory and regulatory authorities. In each problem formulation document for the first 10 chemical substances, EPA also refined the activities, hazards, and exposure pathways that will be included in and excluded from the risk evaluation.

EPA's overall objectives in the risk evaluation process are to conduct timely, relevant, high-quality, and scientifically credible risk evaluations within the statutory deadlines, and to evaluate the conditions of use that raise the greatest potential for risk. 82 FR 33726, 33728 (July 20, 2017).

1 INTRODUCTION

This document presents for comment the problem formulation of the risk evaluation to be conducted for HBCD under the Frank R. Lautenberg Chemical Safety for the 21st Century Act. The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA), the Nation's primary chemicals management law, on June 22, 2016. The new law includes statutory requirements and deadlines for actions related to conducting risk evaluations of existing chemicals.

In December of 2016, EPA published a list of 10 chemical substances that are the subject of the Agency's initial chemical risk evaluations (81 FR 91927), as required by TSCA § 6(b)(2)(A). These 10 chemical substances were drawn from the 2014 update of EPA's TSCA Work Plan for Chemical Assessments, a list of chemicals that EPA identified in 2012 and updated in 2014 (currently totaling 90 chemicals) for further assessment under TSCA. EPA's designation of the first 10 chemical substances constituted the initiation of the risk evaluation process for each of these chemical substances, pursuant to the requirements of TSCA § 6(b)(4).

TSCA § 6(b)(4)(D) requires that EPA publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations that the Administrator expects to consider, within 6 months after the initiation of a risk evaluation. The scope documents for all first 10 chemical substances were issued on June 22, 2017. The first 10 problem formulation documents are a refinement of what was presented in the first 10 scope documents. TSCA § 6(b)(4)(D) does not distinguish between scoping and problem formulation, and requires EPA to issue scope documents that include information about the chemical substance, such as the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that the Administrator expects to consider in the risk evaluation. In the future, EPA expects scoping and problem formulation to be completed prior to the issuance of scope documents and intends to issue scope documents that include problem formulation.

As explained in the scope document, because there was insufficient time for EPA to provide an opportunity for comment on a draft of the scope, as EPA intends to do for future scope documents, EPA is publishing and taking public comment on a problem formulation document to refine the current scope, as an additional interim step prior to publication of the draft risk evaluation for HBCD. Comments received on this problem formulation document will inform development of the draft risk evaluation.

The Agency defines problem formulation as the analytical phase of the risk assessment in which "the purpose for the assessment is articulated, the problem is defined and a plan for analyzing and characterizing risk is determined" [see Section 2.2 of the Framework for Human Health Risk Assessment to Inform Decision Making (U.S. EPA, 2014c)]. The outcome of problem formulation is a conceptual model(s) and an analysis plan. The conceptual model describes the linkages between stressors and adverse human health effects, including the stressor(s), exposure pathway(s), exposed life stage(s) and population(s), and endpoint(s) that will be addressed in the risk evaluation (U.S. EPA, 2014c). The analysis plan follows the development of the conceptual model(s) and is intended to describe the approach for conducting the risk evaluation, including its design, methods and key inputs and intended outputs as described in the EPA Human Health Risk Assessment Framework (U.S. EPA, 2014c). The problem formulation documents refine the initial conceptual models and analysis plans that were provided in the scope documents.

First, EPA has removed from the risk evaluation any activities and exposure pathways that EPA has concluded do not warrant inclusion in the risk evaluation. For example, for some activities which were listed as "conditions of use" in the scope document, EPA has insufficient information following the further investigations during problem formulation to find they are circumstances under which the chemical is "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." Other activities, for example, may have been determined to be legacy use, associated disposal, or legacy disposal during problem formulation. EPA does not expect to consider or evaluate any such activities or associated hazards or exposures in the applicable risk evaluation – that is to say, EPA does not expect to determine whether these activities, hazards or exposures present unreasonable risk.

Second, EPA also identified certain exposure pathways that are under the purview of regulatory programs and associated analytical processes carried out under other EPA-administered environmental statutes – namely, the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA), and the Resource Conservation and Recovery Act (RCRA) – and which EPA does not expect to include in the risk evaluation.

As a general matter, EPA believes that certain programs under other Federal environmental laws adequately assess and effectively manage the risks for the covered exposure pathways. To use Agency resources efficiently under the TSCA program, to avoid duplicating efforts taken pursuant to other Agency programs, to maximize scientific and analytical efforts, and to meet the three-year statutory deadline, EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA, by excluding, on a case-by-case basis, certain exposure pathways that fall under the jurisdiction of other EPA-administered statutes.[1] EPA does not expect to include any such excluded pathways as further explained below in the risk evaluation. The provisions of various EPA-administered environmental statutes and their implementing regulations represent the judgment of Congress and the Administrator, respectively, as to the degree of health and environmental risk reduction that is sufficient under the various environmental statutes.

Third, EPA identified any conditions of use, hazards, or exposure pathways which were included in the scope document and that EPA expects to include in the risk evaluation but which EPA does not expect to further analyze in the risk evaluation. EPA expects to be able to reach conclusions about particular conditions of use, hazards or exposure pathways without further analysis and therefore plans to conduct no further analysis on those conditions of use, hazards or exposure pathways in order to focus the Agency's resources on more extensive or quantitative analyses. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without comprehensive or quantitative risk evaluations. 82 FR 33726, 33734, 33739 (July 20, 2017).

EPA received comments on the published scope document for HBCD and has considered the comments specific to HBCD in this problem formulation document. EPA is soliciting public comment on this problem formulation document and when the draft risk evaluation is issued, the Agency intends to

[1] As explained in the final rule for chemical risk evaluation procedures, "EPA may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination". [82 FR 33726, 33729 (July 20, 2017)].

respond to comments that are submitted. In its draft risk evaluation, EPA may revise the conclusions and approaches contained in this problem formulation, including the conditions of use and pathways covered and the conceptual models and analysis plans, based on comments received.

1.1 Regulatory History

EPA conducted a search of existing domestic and international laws, regulations and assessments pertaining to HBCD. EPA compiled this summary from data available from federal, state, international and other government sources, as cited in Appendix A. EPA evaluated and considered the impact of these existing laws and regulations (e.g. regulations on landfill disposal, design and operations) in the problem formulation step to determine what, if any further analysis might be necessary as part of the risk evaluation. Consideration of the nexus between these existing regulations and TSCA uses may additionally be made as detailed/specific conditions of use and exposure scenarios are developed in conducting the analysis phase of the risk evaluation.

Federal Laws and Regulations

HBCD is subject to federal statutes or regulations, other than TSCA, that are implemented by other offices within EPA and/or other federal agencies/departments. A summary of federal laws, regulations and implementing authorities is provided in Appendix A.1.

State Laws and Regulations

HBCD is subject to state statutes or regulations implemented by state agencies or departments. A summary of state laws, regulations and implementing authorities is provided in Appendix A.2.

Laws and Regulations in Other Countries and International Treaties or Agreements

HBCD is subject to statutes or regulations in countries other than the United States and/or international treaties and/or agreements. A summary of these laws, regulations, treaties and/or agreements is provided in Appendix A.3.

1.2 Assessment History

EPA has identified assessments conducted by other EPA Programs and other organizations (see Table 1-1). Depending on the source, these assessments may include information on conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations. Table 1-1 shows the assessments that have been conducted.

In addition to using this information, EPA intends to conduct a full review of the relevant data/information collected in the initial comprehensive search (see *HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0735) following the literature search and screening strategies documented in the *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0735). This will ensure that EPA considers information that has been made available since these evaluations were conducted.

A Problem Formulation and Initial Assessment (PFIA) for the Cyclic Aliphatic Bromides Cluster was published in 2015 (U.S. EPA, 2015c); however, a draft risk assessment was not completed. As part of the scope, EPA developed an initial life cycle diagram and initial conceptual models for HBCD that re-considered reasonably available information.

Table 1-1. Assessment History of HBCD

Authoring Organization	Assessment
EPA assessments	
EPA, Office of Chemical Safety and Pollution Prevention (OCSPP), Office of Pollution Prevention and Toxics (OPPT)	Initial Risk Based Prioritization of High Production Volume Chemicals. Chemical/Category: Hexabromocyclododecane (HBCD) (U.S. EPA, 2008)
EPA, OCSPP, OPPT	Hexabromocyclododecane (HBCD) Action Plan (U.S. EPA, 2010)
EPA, OCSPP, OPPT	Flame Retardant Alternatives for Hexabromocyclododecane (HBCD) (U.S. EPA, 2014a)
EPA, OCSPP, OPPT	Toxic Chemical Work Plan Problem Formulation and Initial Assessment for HBCD, Cyclic Aliphatic Bromides Cluster (U.S. EPA, 2015c)
Other U.S.-based organizations	
Consumer Product Safety Commission (CPSC)	CPSC Staff Exposure and Risk Assessment of Flame Retardant Chemicals in Residential Upholstered Furniture (CPSC, 2001)
National Research Council	National Academy of Sciences Report: Toxicological Risks of Selected Flame Retardant Chemicals (NRC, 2000)
International	
Organisation for Economic Co-operation and Development (OECD), Screening Information Data Set (SIDS)	OECD SIDS Initial Assessment Profile (SIAP) (OECD, 2007b)
European Commission (EC), European Chemicals Bureau	European Union Risk Assessment Report, Hexabromocyclododecane CASRN 25637-99-4. EINECS No: 247-148-4 (EINECS, 2008)
United Nations Environment Programme (UNEP); Stockholm Convention on Persistent Organic Pollutants (POPs)	Hexabromocyclododecane Draft Risk Profile (UNEP, 2010) Hexabromocyclododecane Risk Management Evaluation (2011) (UNEP, 2011)

Authoring Organization	Assessment
Environment Canada and Health Canada	Draft Screening Assessment of Hexabromocyclododecane (Environment Canada, 2011)
Australian Government Department of Health, National Industrial Chemicals Notification and Assessment Scheme (NICNAS)	Priority Existing Chemical Assessment Report, Hexabromocyclododecane (NICNAS, 2012b)

1.3 Data and Information Collection

EPA/OPPT generally applies a systematic review process and workflow that includes: (1) data collection; (2) data evaluation; and (3) data integration of the scientific data used in risk assessments developed under TSCA. Scientific analysis is often iterative in nature as new knowledge is obtained. Hence, EPA/OPPT expects that multiple refinements regarding data collection will occur during the process of risk evaluation. Additional information that may be considered and was not part of the comprehensive bibliographies will be documented in the Draft Risk Evaluation for HBCD.

Data Collection: Data Search

EPA/OPPT conducted chemical-specific searches for information on: physical and chemical properties; environmental fate and transport; conditions of use information; environmental and human exposures, including potentially exposed or susceptible subpopulations; and ecological hazard and human health hazard, including potentially exposed or susceptible subpopulations.

EPA/OPPT designed its initial data search to be broad enough to capture a comprehensive set of sources containing data and/or information potentially relevant to the risk evaluation. Generally, the search was not limited by date and was conducted on a wide range of data sources, including but not limited to: peer-reviewed literature and gray literature (e.g., publicly-available industry reports, trade association resources, government reports). When available, EPA/OPPT relied on the search strategies from recent assessments, such as EPA Integrated Risk Information System (IRIS) assessments and the National Toxicology Program's (NTP) *Report on Carcinogens*, to identify relevant references and supplemented these searches to identify relevant information published after the end date of the previous search to capture more recent literature. *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0735) provides details about the data sources and search terms that were used in the literature search.

Data Collection: Data Screening

Following the data search, references were screened and categorized using selection criteria outlined in *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0735, (U.S. EPA, 2017f)). Titles and abstracts were screened against the criteria as a first step with the goal of identifying a smaller subset of the relevant data to move into the subsequent data extraction and data evaluation steps. Prior to full-text review, EPA/OPPT anticipates refinements to the search and screening strategies, as informed by an evaluation of the performance of the initial title/abstract screening and categorization process.

The categorization scheme (or tagging structure) used for data screening varies by scientific discipline (i.e., physical and chemical properties; environmental fate and transport; chemical use/conditions of use

information; environmental exposures, human exposures, including potentially exposed or susceptible subpopulations identified by virtue of greater exposure; human health hazard, including potentially exposed or susceptible subpopulations identified by virtue of greater susceptibility; and ecological hazard). However, within each data set, there are two broad categories or data tags: (1) o*n-topic* references or (2) *off-topic* references. *On-topic* references are those that may contain data and/or information relevant to the risk evaluation. O*ff-topic* references are those that do not appear to contain data or information relevant to the risk evaluation. The supplemental document, *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0735, (U.S. EPA, 2017f)) discusses the inclusion and exclusion criteria that EPA/OPPT used to categorize references as *on-topic* or *off-topic*.

Additional data screening using sub-categories (or sub-tags) was also performed to facilitate further sorting of data/information - for example, identifying references by source type (e.g., published peer-reviewed journal article, government report); data type (e.g., primary data, review article); human health hazard (e.g., liver toxicity, cancer, reproductive toxicity); or chemical-specific and use-specific data or information. These sub-categories are described in *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0735, (U.S. EPA, 2017f)) and will be used to organize the different streams of data during the stages of data evaluation and data integration steps of systematic review.

Results of the initial search and categorization results can be found in the *HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0735). This document provides a comprehensive list (bibliography) of the sources of data identified by the initial search and the initial categorization for *on-topic* references and *off-topic* references. Because systematic review is an iterative process, EPA/OPPT expects that some references may move from the *on-topic* to the *off-topic* categories, and vice versa. Moreover, targeted supplemental searches may also be conducted to address specific needs for the analysis phase (e.g., to locate specific data needed for modeling); hence, additional *on-topic* references not initially identified in the initial search may be identified as the systematic review process proceeds.

1.4 Data Screening During Problem Formulation

EPA/OPPT is in the process of completing the full text screening of the *on-topic* references identified in the *HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document*. The screening process at the full-text level is described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). Appendix E provides the inclusion and exclusion criteria applied at the full text screening. The eligibility criteria are guided by the analytical considerations in the revised conceptual models and analysis plan, as discussed in the problem formulation document. Thus, it is expected that the number of data/information sources entering evaluation is reduced to those that are relevant to address the technical approach and issues described in the analysis plan of this document.

Following the screening process, the quality of the included data/information sources will be assessed using the evaluation strategies that are described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

2 PROBLEM FORMULATION

As required by TSCA, the scope of the risk evaluation identifies the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Administrator expects to consider. To communicate and visually convey the relationships between these components, EPA included in the scope document a life cycle diagram and conceptual models that describe the actual or potential relationships between HBCD and human and ecological receptors. During the problem formulation, EPA revised the conceptual models based on further data gathering and analysis, as presented in this problem formulation document. An updated analysis plan is also included which identifies, to the extent feasible, the approaches and methods that EPA may use to assess exposures, effects (hazards) and risks under the conditions of use for HBCD.

2.1 Physical and Chemical Properties

Physical-chemical properties influence the environmental behavior and the toxic properties of a chemical, thereby informing the potential conditions of use, exposure pathways and routes and hazards that EPA intends to consider. For scope development, EPA considered the measured or estimated physical-chemical properties set forth in Table 2-1 and EPA found no additional information during problem formulation that would change these values.

HBCD is a white odorless non-volatile solid that is used as a flame retardant. Technical HBCD is often characterized as a mixture of mainly three diastereomers, which differ only in the spatial disposition of the atoms. Commercial-grade HBCD may contain some impurities, such as tetrabromocyclododecene or other isomeric HBCDs (UNEP, 2010), which are not separately included in this scope. The density of HBCD is greater than that of water (2.24 g/cm^3 at 20°C). It has low water solubility (66 µg/L at 20°C) and a log octanol:water partition coefficient (log K_{ow}) of 5.62.

Table 2-1. Physical and Chemical Properties of HBCD

Property	Value [a]	References
Molecular formula	$C_{12}H_{18}Br_6$	
Molecular weight	641.7 g/mole	
Physical form	White solid; odorless	EINECS (2008)
Melting point	Ranges from approximately: 172-184°C to 201-205°C	EINECS (2008)
Boiling point	>190°C (decomposes)	EINECS (2008)
Density	2.24 g/cm^3	EINECS (2008)
Vapor pressure	4.7E-07 mmHg at 21°C	EINECS (2008)
Vapor density	Not readily available	EINECS (2008)
Water solubility	66 µg/L at 20°C	EINECS (2008)
Octanol:water partition coefficient (log K_{ow})	5.625 at 25°C	EINECS (2008)
Henry's Law constant	7.4E-06 atm-m^3/mole (estimated)	U.S. EPA (2012b)
Flash point	Not readily available	EINECS (2008)

Property	Value [a]	References
Autoflammability	Decomposes at >190°C	EINECS (2008)
Viscosity	Not readily available	EINECS (2008)
Refractive index	Not readily available	EINECS (2008)
Dielectric constant	Not readily available	EINECS (2008)
[a] Measured unless otherwise noted.		

2.2 Conditions of Use

TSCA § 3(4) defines the conditions of use as ‘‘the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.’’

2.2.1 Data and Information Sources

In the scope documents, EPA identified, based on reasonably available information, the conditions of use for the subject chemicals. EPA searched a number of available data sources (e.g., *Use and Market Profile for HBCD,* EPA-HQ-OPPT-2016-0735). Based on this search, EPA published a preliminary list of information and sources related to chemical conditions of use (see *Preliminary Information on Manufacturing, Processing, Distribution, Use, and Disposal: HBCD,* EPA-HQ-OPPT-2016-0735-0003) prior to a February 2017 public meeting on scoping efforts for risk evaluation convened to solicit comment and input from the public. EPA also convened meetings with companies, industry groups, chemical users and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. The information and input received from the public, stakeholder meetings and the additional contacts was incorporated into this problem formulation to the extent appropriate. Thus, EPA believes the manufacture, processing, distribution, use and disposal activities constitute the intended, known, and reasonably foreseen activities associated with the subject chemical, based on reasonably available information.

2.2.2 Identification of Conditions of Use

To determine the conditions of use of HBCD and inversely, activities that do not qualify as conditions of use, EPA conducted extensive research and outreach. This included EPA’s review of published literature and online databases including the most recent data available from: U.S. Consumer Product Safety Commission (CPSC), CPSC staff exposure and risk assessment of flame retardant chemicals in residential upholstered furniture, 2001; National Institute of Health’s (NIH) Household Product Database; EPA’s Chemical/Product Categorical Data (CPcat) database; the most recent data available from EPA’s Chemical Data Reporting program (CDR); Safety Data Sheets (SDSs); European Chemical Agency (ECHA) reports; United Nations Environment Program (UNEP) reports. EPA also conducted online research by reviewing company websites of potential manufacturers, importers, distributors, retailers, or other users of HBCD and queried government and commercial trade databases. EPA also received comments (EPA-HQ-OPPT-2016-0735) on the *Scope of the Risk Evaluation for HBCD* (U.S. EPA, 2017e)that were used to determine the current conditions of use. In addition, EPA convened meetings and personal communications with companies, industry groups, chemical users, states, environmental groups, federal agencies, and other stakeholders to aid in identifying conditions of use and verifying conditions of use identified by EPA. Those meetings included a February 14, 2017 public meeting with such entities (EPA-HQ-OPPT-2016-0735) in addition to meeting with: Adhesives and

Sealants Council, American Chemistry Council, Alliance of Automobile Manufacturers, Association of Global Automakers, Motor and Equipment Manufacturers Association, Business and Institutional Furniture Manufacturer's Association, Consumer Specialty Products Association, Duke University Faculty, Design Chain, Eagle Performance Products, Ecology Center, EPS Industry Alliance, Green Policy Institute, Motor & Equipment Manufacturers Association, National Council of Textile Organizations, Plastics Industry Association, XPS Association, and others.

EPA has removed from the risk evaluation any activities that EPA concluded do not constitute conditions of use – for example, because EPA has insufficient information to find certain activities are circumstances under which the chemical is actually "intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." EPA has also identified any conditions of use that EPA does not expect to include in the risk evaluation. As explained in the final rule for Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, TSCA section 6(b)(4)(D) requires EPA to identify "the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider" in a risk evaluation, suggesting that EPA may exclude certain activities that EPA has determined to be conditions of use on a case-by-case basis. (82 FR 33736, 33729; July 20, 2017). For example, EPA may exclude conditions of use that the Agency has sufficient basis to conclude would present only de minimis exposures or otherwise insignificant risks (such as use in a closed system that effectively precludes exposure or use as an intermediate).

The activities that EPA no longer believes are conditions of use or were otherwise excluded during problem formulation are described in Section 2.2.2.1. The conditions of use included in the scope of the risk evaluation are summarized in Section 2.2.2.2.

2.2.2.1 Categories and Subcategories Determined not to be Conditions of Use or Otherwise Excluded During Problem Formulation

Domestic Manufacture of HBCD

Domestic manufacture of HBCD has ceased. Domestic manufacture of HBCD is not intended, known, or reasonably foreseen and is therefore not considered a condition of use under which EPA will evaluate HBCD.

U.S. manufacturers have indicated complete replacement of HBCD in their product lines (U.S. EPA, 2017g) and that use of stockpiles and exportation was completed in 2017. Communication with Chemtura (Lanxess Solutions, US) indicates that the company has not manufactured HBCD since 2015, and that there are currently no U.S. manufacturers of the chemical (LANXESS, 2017b). The company does not intend to manufacture, import, or export HBCD in the future and has no existing stockpiles (LANXESS, 2017a). Albemarle Corporation, another historic manufacturer of HBCD, indicated that they stopped manufacturing HBCD flame retardants around 2016 and do not intend to resume the manufacture of HBCD-based flame retardants. In 2017, Albemarle exported its entire inventory of approximately 57 metric tons (MT) of HBCD to Mexico and Turkey for use in construction (EPS/XPS) applications (Albemarle, 2017b). Albemarle does not intend to import HBCD in the future (Albemarle, 2017a).

Domestic Manufacture of EPS Resin and XPS Masterbatch
In the past, the process for making insulation with HBCD included an intermediate step of resin manufacture. A small group of EPS and XPS resin manufacturers purchased HBCD (domestically manufactured or imported) and combined it with polystyrene and other ingredients to produce resin. Separate facilities used the resin to make foam insulation products for construction. Domestic manufacturers of EPS and XPS resin have phased out the use of HBCD due to international bans and the availability of alternative flame retardants. The EPS Industry Alliance (EPS-IA) which represents all major North American manufacturers (including Canada and Mexico) of EPS resin, reports that its members have phased out of the use of HBCD in the production of EPS resins (Public comment, EPA-HQ-OPPT-2016-0735-0026). Similar to the EPS resin industry, major producers of XPS masterbatch have fully transitioned out of using HBCD (XPSA, 2017a) .

Use in High Impact Polystyrene (HIPS)
Use of HBCD in High Impact Polystyrene (HIPs) appears to have ceased and EPA does not believe this use is intended, known, or reasonably foreseen. Therefore, use of HBCD in HIPS is not considered a condition of use under which EPA will evaluate HBCD.

HBCD was used as a flame retardant in HIPS in electronic components. The most recent information showing use, in both the United States and Europe, of HBCD as a flame retardant in HIPS for electrical and electronic appliances, such as audio-visual equipment, refrigerator lining and some wire and cable applications was based on a 2009 data source (ECHA, 2009b; Morose, 2006a). Use in television sets at that time was the predominant application of HIPS (Weil and Levchik, 2009). EPA's recent research and outreach did not yield data showing current use of HBCD in HIPS for electrical and electronic appliances (Design Chain Associates, 2017).

The Australian Department of Health and Aging reported in 2012 that minimal amounts of HBCD were imported into Australia already incorporated into various articles, such as inkjet printers, projectors, scanners, ventilation units for offices, compact fluorescent lights and liquid-crystal display (LCD) digital audiovisual systems (NICNAS, 2012a). Similar current uses of HBCD in electronic articles or import of those articles into the U.S. have not been found.

The use of HBCD in electronic equipment is legacy and therefore disposal of HBCD containing HIPS is also considered legacy (associated disposal). Electronic products (which may or may not contain HBCD) can be recycled and HIPS materials constitute more than half the plastic materials recovered from household electronics (Borchardt, 2006). However, no information was identified that confirms use of HBCD in recycled HIPS for the purposes of flame retardancy. EPA, therefore, does not believe that this use is intended, known, or reasonably foreseen and is not a condition of use for HBCD. Nor is there information that the recycling (i.e., processing) of HIPS containing HBCD is done to retrieve the HBCD or to otherwise use the flame retardant properties of HBCD. Therefore, EPA believes the manufacturing, processing, or distribution in commerce for use of HBCD as a flame retardant in HIPS is not intended, known, or reasonably foreseen and is not a condition of use of HBCD.

Use in Textiles
In the United States, HBCD was historically used as a flame retardant in the back coating of textiles. Use in this application was quite small; in 2005, manufacturers reported only 1% of HBCD was used in textiles in the United States and only for commercial, not consumer use (U.S. EPA, 2012e).

Use in Consumer Textiles: EPA found that a small amount of HBCD was being used in consumer textiles, i.e., floor mats, headliners and possibly other interior fabrics in motor vehicles made or imported to the United States in 2011 (U.S. EPA, 2012e). Based on this information and the CDR reporting in 2005, EPA finalized a SNUR in 2015 (U.S. EPA, 2015b) which requires persons who intend to manufacture (including import) or process HBCD for use in consumer textiles (other than for use in motor vehicles) to notify EPA at least 90 days before commencing that activity. EPA has received no notifications since the rule became effective in late 2012, and therefore does not expect HBCD to be used in such consumer textiles. Articles containing HBCD that were manufactured prior to the effective date of the SNUR might continue to be in service.

Information from industry indicates that HBCD is no longer used in textiles in motor vehicles (Alliance of Automobile Manufacturers, 2018) and EPA does not believe the use is intended, known, or reasonably foreseen. Therefore, use in textiles in motor vehicles is not a condition of use under which EPA will evaluate HBCD.

From June 2012 to March 2017, the use of HBCD in children's clothing and blankets was self-reported 44 times by manufacturers and retailers to Washington State under state law (Public comment, EPA-HQ-OPPT-2016-0735-0022). The forty-four reports are associated with consumer textiles which are expected to have been covered by the SNUR (U.S. EPA, 2015b); and therefore may reflect textiles produced prior to 2015. The textile products were reported with practical quantitation levels (PQL) of less than 100 parts per million (ppm). EPA further assessed the data and concluded that none of the products appear to contain intentionally-added HBCD.

Information gathered from research, industry and consumer product organizations has led EPA to believe that HBCD is no longer used in consumer textiles. Current use in consumer textiles has not been confirmed and EPA does not believe it is known, intended, or reasonably foreseen. Therefore, use in consumer textiles is not a condition of use under which EPA will evaluate HBCD.

Use in Commercial Textiles: EPA received information in 2011 from a group of textile formulators that the end uses of HBCD-containing textiles are for military, institutional and aviation applications, such as durable carpet tiles for hospitals or prisons (U.S. EPA, 2012e; Friddle, 2011). By 2017, HBCD use in these textile applications appeared to be phasing out (Friddle, 2017). The U.S. Department of Defense found no direct use of HBCD (Underwood, 2017). According to the National Council of Textile Organizations, HBCD has not been used in textiles for more than a decade (Poole, 2017). Current use in commercial textiles could not been confirmed, but EPA concludes that based on the information above, HBCD use in these textiles is not intended, known, or reasonably foreseen. Therefore, use in commercial textiles is not a condition of use under which EPA will evaluate HBCD.

Use in Adhesives

Use of HBCD in adhesives was one of several minor uses included in the HBCD Scope Document, however further research could not confirm current use in adhesives. During Problem Formulation, EPA found that the Henkel company manufactured a pressure sensitive adhesive containing HBCD for use in flexible air duct core under the product name Aquence AV 7584 Black, according to the company's website and product Safety Data Sheet (Henkel Corp, 2017). However, as of January 2018 (Pierson, 2018), EPA has learned that the company will no longer use HBCD in their product line and does not have a current supply of HBCD to draw from. EPA could find no evidence of ongoing manufacture,

processing or distribution of adhesives using HBCD. Therefore, adhesives are not included as a condition of use for which EPA will evaluate HBCD.

Use in Automotive Sector
Use of HBCD in the automotive sector was not reported in the 2012/2016 CDR or 2006 IUR datasets.

EPA received a public comment from the Global Automakers Association stating that "our members have not identified any ongoing uses [of HBCD] in the manufacture of new vehicles. However, [HBCD] has been and currently is being used in the manufacture of replacement parts only – replacement parts designed prior to the date of the publication of the EPA HBCD Scoping Document" (Public comment, EPA-HQ-OPPT-2016-0735-0027).

The Motor and Equipment Manufacturers Association reports that HBCD "is not used during the manufacturing process of any automotive components. Information from our members submitted in 2015 also indicated it had nearly phased out completely the use of HBCD. Our data indicates HBCD is phased out" (Public comment, EPA-HQ-OPPT-2016-0735-0014).

In a public comment on the Use Document, however, the Alliance of Automotive Manufacturers wrote: "Our members have indicated to us that this chemical is not used during the auto manufacturing process. HBCD has been aggressively phased out by the auto industry over the past several years. However, the chemical may still be used by some automakers as a flame retardant in coatings of certain components (e.g., dashboards and headliners) and in solder paste in interior components (e.g., circuits). This chemical may also be present in adhesives and foams." (Public comment, EPA-HQ-OPPT-2016-0735-0015). Specifics on these uses by non-member companies could not be verified.

Based on the information provided above, EPA concludes that use of HBCD in the manufacture of new automobiles is not occurring (U.S. EPA, 2017c, 2012d, 2006b). Therefore, the use of HBCD in manufacture of new automobiles is not intended, known, or reasonably foreseen and therefore is not a condition of use under which EPA will evaluate HBCD. Automotive replacement parts, however, are considered a condition of use and will be included within the scope of the risk evaluation based on the information provided above.

Other Uses
In order to determine whether other uses exist and to what extent, EPA reviewed state databases, product testing results and information from foreign countries, in addition to the literature search and contacts with industry groups.

Detections of HBCD in children's products reported by industry to Washington State Department of Ecology (WSDE) include three products listed as "toy/games variety pack" and one entry for a baby car/booster seat. The HBCD was found in surface coatings and polymers. One toy product and the car seat were reported to have practical quantitation limits (PQLs) of "equal to or greater than 100 but less than 5000 ppm." As this data is self-reported to the WSDE state database, more specific information regarding the contaminant test methodologies, tested components, or prevalence of HBCD in the products information could not be verified. The WSDE tested for flame retardants in a set of 169 general and consumer products purchased between August 2012 and August 2013 from local stores in the south Puget Sound area and online retailers. HBCD was detected in two of the products: in the polystyrene of a child's bean bag chair at a concentration of 0.06%, and in the plastic of a protective work glove at

4.4% (WSDE, 2014). WSDE noted in a 2015 report to the Washington state legislature that these test results showed HBCD at percent levels but concluded: "TBBPA and HBCD were not detected in children's products and furniture at levels consistent with use as a flame retardant in products tested by Ecology" (https://fortress.wa.gov/ecy/publications/documents/1404047.pdf). EPA followed up with the supplier of the Carbon X brand of work glove that WSDE had tested in 2012-2013. The company provided documentation that HBCD is not used in four varieties of the Carbon X work glove (Mechanix Wear, 2018). EPA concludes that other uses are not intended, known, or reasonably foreseen and are not considered conditions of use under which EPA will evaluate HBCD.

EPA has concluded that legacy uses of HBCD include adhesives, textiles (including upholstery fabric, floor mats and headliners in automobiles, and commercial uses) and electronics and electrical products.

EPA has concluded that the following are not conditions of use: coatings, solder, children's products including toys and car seats; furniture (such as bean bag chairs).

Beyond the uses identified in the Scope of the Risk Evaluation for HBCD, EPA has received no additional information identifying additional current conditions of use for HBCD from public comment and stakeholder meetings.

Table 2-2. Categories and Subcategories Determined not to be Conditions of Use or Otherwise Excluded During Problem Formulation

Life Cycle Stage	Category[a]	Subcategory[b]	References
Manufacture	Domestic manufacture	Domestic manufacture	U.S. EPA (2016b)
Processing	Processing as a reactant/ intermediate	Intermediate for all other basic inorganic chemical manufacturing	U.S. EPA (2016b)
	Processing - incorporated into formulation, mixture or reaction product	Flame retardants used in plastic material and resin manufacturing (e.g., manufacture of EPS resin beads)	Use Document, EPA-HQ-OPPT-2016-0735-0003; EINECS (2008); Market Profile, EPA-HQ-OPPT-2016-0735.
	Processing - incorporated into formulation, mixture or reaction product	Flame retardants used in paints and coatings manufacturing (e.g., micronisation and formulation of polymer-based dispersions for textile coatings).	Use Document, EPA-HQ-OPPT-2016-0735-0003; Market Profile, EPA-HQ-OPPT-2016-0735; EINECS (2008)
	Processing - incorporated into formulation, mixture or reaction product	Flame retardants used in adhesive manufacturing (e.g., manufacture of solder paste and other adhesives)	Public Comment, EPA-HQ-OPPT-2016-0735-0008; Public Comment, EPA-HQ-OPPT-2016-0735-0015
	Incorporated into article	Flame retardants used in plastics product manufacturing	Use Document, EPA-HQ-OPPT-2016-0735-0003; Market Profile, EPA-HQ-

Life Cycle Stage	Category[a]	Subcategory[b]	References
		(manufacture of HIPS; manufacture of electronics articles)[d]	OPPT-2016-0735; U.S. EPA (2014b)
	Incorporated into article	Flame retardants used in textiles, apparel and leather manufacturing (e.g., coatings used at textile and fabric finishing mills, fabric coating mills and carpet and rug mills)[d]	Use Document, EPA-HQ-OPPT-2016-0735-0003; U.S. EPA (2014b)
	Incorporated into article	Flame retardants used in transportation equipment manufacturing (e.g., manufacture of interior components in automobiles, including fabrics, coatings, solder paste, adhesives and foams) [d]	Use Document, EPA-HQ-OPPT-2016-0735-0003; Market Profile, EPA-HQ-OPPT-2016-0735; Public Comment, EPA-HQ-OPPT-2016-0735-0015
Processing	Recycling	Recycling of Products and Articles Containing HBCD for applications that do not have intentional flame retardancy	
Commercial/consumer Use	Electrical and electronic products	Plastic articles (soft) (e.g., wire and cable)	Use Document, EPA-HQ-OPPT-2016-0735-0003; Market Profile, EPA-HQ-OPPT-2016-0735; U.S. EPA (2016b)
		Plastic articles (hard) (e.g., distribution boxes, audio-visual equipment; refrigerator lining; computers; Inkjet printers/scanners)	Use Document, EPA-HQ-OPPT-2016-0735-0003; Market Profile, EPA-HQ-OPPT-2016-0735; U.S. EPA (2016b)
	Adhesives	Adhesives (e.g., ductwork)	(Henkel Corp, 2017), (Pierson, 2018).
	Floor coverings	Fabrics, textiles and apparel (e.g., carpets and rugs)	Use Document, EPA-HQ-OPPT-2016-0735-0003
	Furniture and furnishings	Fabrics, textiles and apparel: Furniture and furnishings, including furniture coverings (e.g., institutional furniture)	Use Document, EPA-HQ-OPPT-2016-0735-0003;

Life Cycle Stage	Category[a]	Subcategory[b]	References
	Fabric, textile and leather products [d]	Fabrics, textiles and apparel (e.g., interior fabrics for automobiles)	Use Document, EPA-HQ-OPPT-2016-0735-0003; Market Profile, EPA-HQ-OPPT-2016-0735
	Fabric, textile and leather products [d]	Textile finishing and impregnating/surface treatment products (e.g., other textile products)	Use Document, EPA-HQ-OPPT-2016-0735-0003; Public Comment, EPA-HQ-OPPT-2016-0735-0022; Public Comment, EPA-HQ-OPPT-2016-0735-0008;
Commercial/consumer Use	Other uses[e]	Other (e.g., toys and games, car seats, toys and toy vehicles)	Use Document, EPA-HQ-OPPT-2016-0735-0003; Market Profile, EPA-HQ-OPPT-2016-0735; Public Comment, EPA-HQ-OPPT-2016-0735-0022; Public Comment, EPA-HQ-OPPT-2016-0735-0008; Public Comment, EPA-HQ-OPPT-2016-0735-0015; EPA-HQ-OPPT-2016-0735-0015; WSDE (2017).

Note: This table presents categories and subcategories of activities that are based on the 2016 CDR industrial function category and industrial sector descriptions and the OECD product and article category descriptions for the HBCD uses identified. Clarification on the subcategories of use from the listed data sources are provided in parentheses.

[a] These categories of activities appear in the Life Cycle Diagram, reflect CDR codes and broadly represent activities in industrial and/or consumer settings.

[b] These subcategories reflect more specific uses of HBCD.

[c] 2015 SNUR; (U.S. EPA, 2015a), EPA requires 90-day notification before manufacture or processing of HBCD in consumer textiles, except those used in motor vehicles.

[d] Historically have been used.

[e] Other uses in EPA's Market Report 2017 (U.S. EPA, 2017g) were identified from foreign studies and product testing results, reporting by manufacturers to the state of Washington, and other sources. For the uses in other countries, it is uncertain whether similar U.S. products contain HBCD. In some of the articles, HBCD is present but may not have been intentionally used.

2.2.2.2 Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Table 2-3 summarizes each life cycle stage and the corresponding categories and subcategories of conditions of use for HBCD that EPA expects to consider in the risk evaluation. Using the 2016 CDR, EPA identified industrial processing or use activities, industrial function categories and commercial use product categories. EPA identified the subcategories by supplementing CDR data with other published literature and information obtained through stakeholder consultations. For risk evaluations, EPA intends to consider each life cycle stage (and corresponding use categories and subcategories) and assess relevant potential sources of release and human exposure associated with that life cycle stage.

Automotive Replacement Parts
EPA received a public comment from the Global Automakers Association stating that HBCD is no longer used in new automobile manufacturing and is only present in replacement parts manufactured prior to date of the EPA HBCD Scoping Document (Public comment, EPA-HQ-OPPT-2016-0735-0027). Major automobile manufacturers have phased out use of HBCD in U.S. production but continue to use it in a few replacement parts, according to information provided to EPA by the Alliance of Automotive Manufacturers since publication of the HBCD Scope Document. Manufacturers identified three replacement parts containing HBCD, these are absorbers (front roof rail energy) and two types of insulator panels (Alliance of Automobile Manufacturers, 2018). EPA assumes that HBCD in these replacement parts is incorporated into EPS and XPS based on CDR reporting that showed the vast majority of use of HBCD was for EPS and XPS. For the risk evaluation, EPA will try to obtain more specific information on the three replacement parts, including whether they are domestically manufactured or imported, what materials incorporate the HBCD, and volumes used.

Expanded Polystyrene (EPS) and Extruded Polystyrene (XPS) Foam
"Building/Construction Materials" include products containing HBCD as a flame retardant primarily in XPS and EPS foam insulation products that are used for the construction of residential, public, commercial or other structures (UNEP, 2010; Weil and Levchik, 2009).

Use in EPS and XPS foam had accounted for 95% of all HBCD applications in the past decade (U.S. EPA, 2014a; UNEP, 2010). Based on information from market reports (U.S. EPA, 2017g), HBCD is used primarily in construction materials, which may include structural insulated panels (SIPS). The building and construction industry uses EPS and XPS foam thermal insulation boards and laminates for sheathing products. EPS foam prevents freezing, provides a stable fill material and creates high-strength composites in construction applications. XPS foam board is used mainly for roofing applications and architectural molding. HBCD is used in both types of foams because it is highly effective at levels less than 1% and, therefore, maintains the insulation properties of EPS and XPS foam (Morose, 2006a). EPS foam boards contain approximately 0.5% HBCD by weight in the final product and XPS foam boards contain 0.5-1% HBCD by weight (Public comment, EPA-HQ-OPPT-2016-0735-0017) (XPSA, 2017b; U.S. EPA, 2014a; Morose, 2006b).

According to the EPS-IA, an estimated 80-85% of EPS rigid foam insulation manufactured in the United States is molded from EPS resins supplied by EPS-IA member companies, none of which use HBCD (EPS Industry Alliance, 2017).

The XPS Association (XPSA) stated that its members, which are the major producers of XPS resin, supply the resin for more than 95% of the XPS foam insulation products manufactured for the North American market and that the remaining small percentage is probably made using imported resin (XPSA, 2017a). An intermediate step in manufacture of XPS foam insulation, compounding of masterbatch, in which HBCD, resins, and other chemicals are processed is described in Appendix B.

Some companies reuse EPS and XPS insulation. See discussion below in Recycling of EPS and XPS foam.

EPA is including the use of HBCD in XPS and EPS insulation using imported HBCD in the risk evaluation. There is a potential for import of HBCD for use in the manufacture of EPS and XPS foam insulation. Taking into account the high percentage of HBCD production volume dedicated to these two

uses in previous years and the fact that smaller EPS and XPS manufacturers may be currently using imported HBCD resin, EPA is including the processing and use of HBCD in XPS and EPS insulation and import of HBCD resin in the risk evaluation.

Recycling of EPS and XPS foam

To date, little is known by EPA about the recycling of EPS and XPS products containing HBCD. Schlummer et al. (Schlummer et al., 2017) notes that EPS and XPS foam in construction insulation materials are rarely recycled for numerous reasons, including that insulation waste is typically not separated from mixed waste stream and most insulation containing HBCD is still in place. Schlummer et al. (Schlummer et al., 2017) describe technologies available only on a small scale to separate HBCD from insulation panels and recycle polystyrene.

Reuse and recycling is available in the United States for consumers through removal of insulation during re-roofing projects. Two companies were identified that directly reuse (e.g., reuse without reforming) and recycle (e.g., melting and inserting into the manufacturing process) XPS and EPS foam insulation.

- Green Insulation Group: http://www.greeninsulationgroup.com/products/
- Nationwide Foam Recycling: http://nationwidefoam.com/what-you-can-recycle.cfm

Nationwide Foam Recycling, which is owned by Conigliaro Industries, Inc., indicate that their plant recycles all EPS insulation and reuses all XPS insulation (U.S. EPA, 2017g). Once processed, their recycled EPS roofing insulation is taken to polystyrene product manufacturers, notably picture frame manufacturers, mostly in China but also in domestic markets. The company also delivers recycled roofing material to other local EPS recycling plants that may use different processes. Nationwide Foam Recycling processes 90,000 pounds/year of EPS standard packaging and 10,000 pounds/year of EPS roofing material and estimated that 10-20% of EPS roofing material is recycled nationally. The company also reuses XPS roofing material due the special equipment needed to recycle XPS and indicated that XPS is rarely recycled in the United States. It was estimated that the majority (>50%) of XPS roofing material is sent to landfills or waste energy plants. Processing estimates for XPS material were not provided by the company.

Disposal of Existing HBCD Products

Despite industry indicating that production of HBCD products is declining, there is a large of amount of HBCD products still in use, particularly in construction materials. Eventually, buildings constructed with HBCD-containing products will be either demolished or remodeled and the HBCD containing products will need to be removed and either reused, disposed of or recycled.

Summary of Conditions of Use Included in the Risk Evaluation

Based on the information described in this section, EPA plans to analyze HBCD importation; incorporation into formulation, mixture or reaction product (e.g. compounding of masterbatch XPS); incorporation into articles (e.g. manufacture of EPS and XPS and the manufacture of structural insulated panels from EPS and XPS); disposal; recycling; and the industrial, commercial and consumer use of EPS and XPS in construction materials (e.g. insulation boards).

Table 2-3. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation

Life Cycle Stage	Category[a]	Subcategory[b]	References
Manufacture	Import	Import	U.S. EPA (2016b)
Processing	Processing - incorporated into formulation, mixture or reaction product	Flame retardants used in custom compounding of resin (e.g., compounding in XPS masterbatch)	EINECS (2008)
	Incorporated 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)	Use Document, EPA-HQ-OPPT-2016-0735-0003; Market Profile, EPA-HQ-OPPT-2016-0735; U.S. EPA (2014a) (Alliance of Automobile Manufacturers, 2018).
	Recycling	Recycling of XPS and EPS foam, resin, panels containing HBCD	Use Document, EPA-HQ-OPPT-2016-0735-0003
Distribution	Distribution	Distribution	
Commercial/consumer Use	Building/construction materials	Plastic articles (hard): construction and building materials covering large surface areas (e.g., EPS/XPS foam insulation in residential, public and commercial buildings, and other structures)	Use Document, EPA-HQ-OPPT-2016-0735-0003; U.S. EPA (2016b); U.S. EPA (2014a)
	Other	Automobile replacement parts	(Alliance of Automobile Manufacturers, 2018)
Disposal	Disposal	Other land disposal (e.g. Construction and Demolition Waste)	EINECS (2008)

Note: This table presents categories and subcategories of conditions of use that are based on the 2016 CDR industrial function category and industrial sector descriptions and the OECD product and article category descriptions for the HBCD uses identified. Clarification on the subcategories of use from the listed data sources are provided in parentheses.

[a] These categories of conditions of use appear in the Life Cycle Diagram, reflect CDR codes and broadly represent conditions of use of HBCD in industrial and/or consumer settings.

[b] These subcategories reflect more specific uses of HBCD.

2.2.2.3 Overview of Conditions of Use and Lifecycle Diagram

The life cycle diagram provided in Figure 2-1 depicts the conditions of use that are considered within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, and consumer), distribution and disposal. Additions or changes to the conditions of use based on additional information gathered or analyzed during problem formulation are described in Sections 2.2.2.1 and 2.2.2.2. The activities that EPA determined are out of scope during problem formulation are not included in the life cycle diagram. The information is grouped according to Chemical Data Reporting (CDR) processing codes and use categories (including functional use codes for industrial uses and product categories for industrial, commercial and consumer uses), in combination with other data sources (e.g., published literature and consultation with stakeholders) to provide an overview of conditions of use. EPA notes that some subcategories of use may be grouped under multiple CDR categories.

Use categories include the following: "industrial use" means use at a site at which one or more chemicals or mixtures are manufactured (including imported) or processed. "Commercial use" means the use of a chemical or a mixture containing a chemical (including as part of an article) in a commercial enterprise providing saleable goods or services. "Consumer use" means the use of a chemical or a mixture containing a chemical (including as part of an article, such as furniture or clothing) when sold to or made available to consumers for their use (U.S. EPA, 2016b).

To understand conditions of use relative to one another and associated potential exposures under those conditions of use, the life cycle diagram includes the production volume associated with each stage of the life cycle, as reported in the 2016 CDR reporting (U.S. EPA, 2016b). However, the life cycle diagram for HBCD does not include specific production volumes because the information was claimed as confidential business information (CBI).

The 2016 CDR reporting data for HBCD are provided in Table 2-4 from EPA's CDR database (U.S. EPA, 2016b). This information has not changed from that provided in the HBCD Scope Document.

Table 2-4. Production Volume of HBCD in CDR Reporting Period (2012 to 2015)[a]

Reporting Year		2012	2013	2014	2015
Total Aggregate Production Volume (lbs)	CASRN 25637-99-4	1-10 million	1-10 million	1-10 million	1-10 million
	CASRN 3194-55-6	10-50 million	10-50 million	1-10 million	1-10 million

[a] The CDR data for the 2016 reporting period is available via ChemView (https://java.epa.gov/chemview) (U.S. EPA, 2016b). Because of an ongoing CBI substantiation process required by amended TSCA, the CDR data available in the HBCD Scope Document is more specific than currently in ChemView.

HBCD Production Volume (Manufacture and Import)

Data reported for the CDR period for 2016 for HBCD indicate that between 1 and 10 million lbs of each CASRN were manufactured in or imported into the United States in 2015; the national production volume is CBI (U.S. EPA, 2016b). For both CASRNs, site-specific production volumes for the 2015 reporting year were withheld as TSCA CBI. Six firms comprised of nine sites are identified by the 2016 CDR as manufacturers or importers of HBCD: Chemtura Corporation, Albemarle Corporation, Dow Chemical Company, Campine NV, BASF Corporation, and Styropek USA, Inc (U.S. EPA, 2016b).

Current Status of Domestic Manufacture of HBCD

Industry has indicated complete replacement of HBCD in their product lines (U.S. EPA, 2017g) and that use of stockpiles and exportation was completed in 2017, as discussed in Section 2.2.2.1.

Current Status of Importation of HBCD

The companies that previously reported HBCD import volumes to CDR have stated to EPA that they permanently stopped the activity in 2016 or 2017. The Dow Chemical Company imported 19 metric tons (MT) of HBCD in 2016 and roughly 48 MT in 2017. Dow possessed roughly 41 MT of HBCD in stockpiles as of September 2017, which the company then used to produce XPS foam. By November 2017, Dow had stopped using HBCD at all of its plants and had no intention of importing HBCD in the future. (Dow Chemical Company, 2017).

Similarly, Campine NV indicated in a correspondence with EPA that they had ceased importation of HBCD in 2016 (Campine, 2017). BASF has indicated in a correspondence with EPA (BASF, 2017) that the company ceased importing HBCD in 2016 and currently has no stockpiles. ICL-IP[2] previously manufactured an HBCD-containing flame retardant marketed as FR-1206. However, this product has been discontinued, and ICL-IP has reportedly ceased production of products containing HBCD (Additives for Polymers, 2015). Styropek also indicated in its correspondences with EPA that the company phased out HBCD as a flame retardant in 2016.

Although there are a number of possible source countries for importation of HBCD to the United States, under the Stockholm Convention on Persistent Organic Pollutants (POPs), 171 of the 188 Parties (countries) have agreed to ban the production, use, import, and export of HBCD, consistent with the obligations of that Convention (SCCH, 2018a, b) . The Convention does include a process by which a party can apply for a time limited exemption to continue production and/or use of a listed chemical, however, that exemption is limited to the specific use(s) identified in the Convention. In accordance with Article 4, specific exemptions expire five years after the date of entry into force of the Convention with respect to that particular chemical, unless an additional five-year extension in granted by the Conference of the Parties (SCCH, 2018b). For HBCD, the specific uses for which a Party can register a production or use exemption is limited to use "in EPS and XPS in buildings." According to the *Register of Specific Exemptions* for the Convention, there are currently three Parties registered for production for those uses and six Parties registered for use. The United States is not a Party to the Convention (SCCH, 2018c).

Descriptions of the industrial, commercial and consumer use categories identified from the 2016 CDR (U.S. EPA, 2016b) and included in the life cycle diagram are summarized in Section 2.2.2.2. The descriptions provide a brief overview of the use category; Appendix B contains more detailed descriptions (e.g., process descriptions, worker activities, process flow diagrams, equipment illustrations) for each manufacture, processing, use and disposal category. The descriptions provided below are primarily based on the corresponding industrial function category and/or commercial and consumer product category descriptions from the 2016 CDR and can be found in EPA's Instructions for Reporting 2016 TSCA Chemical Data Reporting (U.S. EPA, 2016a).

Figure 2-1 depicts the life cycle diagram of HBCD from manufacture to the point of disposal. Activities related to distribution (e.g., loading, unloading) will be considered throughout the HBCD life cycle, rather than using a single distribution scenario.

[2] ICL-IP did not report to the 2016 CDR.

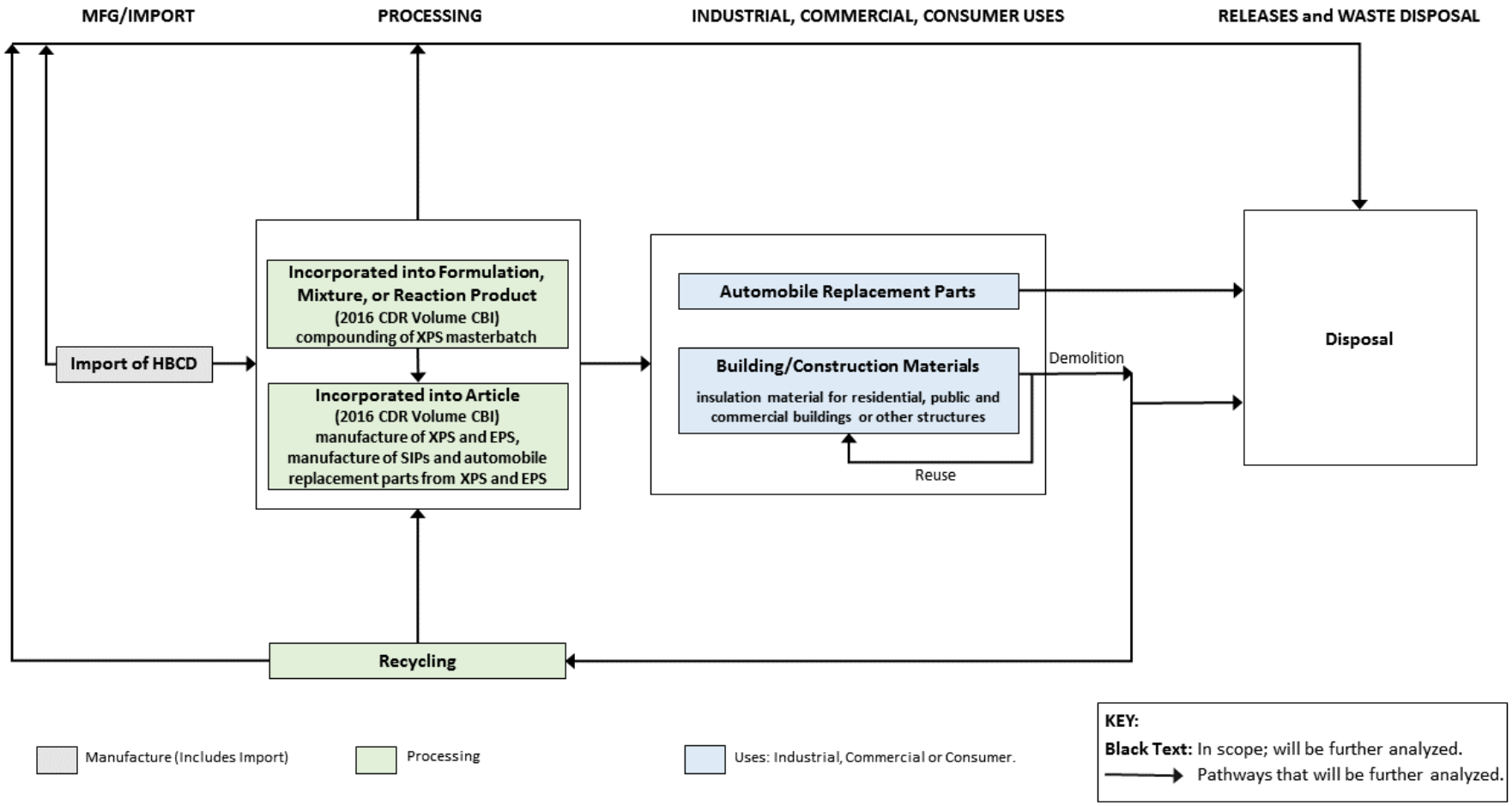

Figure 2-1. HBCD Life Cycle Diagram

The life cycle diagram depicts the conditions of use that are within the scope of the risk evaluation during various life cycle stages including manufacturing, processing, use (industrial, commercial, consumer), distribution and disposal. Activities related to distribution (e.g., loading, unloading) will be considered throughout the HBCD life cycle, rather than using a single distribution scenario.

2.3 Exposures

For TSCA exposure assessments, EPA expects to analyze exposures and releases to the environment resulting from the conditions of use applicable to HBCD. Post-release pathways and routes will be described to characterize the relationship or connection between the conditions of use of the chemical and the exposure to human receptors, including potentially exposed or susceptible subpopulations and ecological receptors. EPA will take into account, where relevant, the duration, intensity (concentration), frequency and number of exposures in characterizing exposures to HBCD.

2.3.1 Fate and Transport

Environmental fate includes both transport and transformation processes. Environmental transport is the movement of the chemical within and between environmental media. Transformation occurs through the degradation or reaction of the chemical with other species in the environment. Hence, knowledge of the environmental fate of the chemical informs the determination of the specific exposure pathways and potential human and environmental receptors EPA expects to analyze in the risk evaluation. Table 2-5 provides environmental fate data that EPA identified and considered in developing the scope for HBCD. This information has not changed from that provided in the HBCD Scope Document.

During problem formulation, EPA/OPPT considered volatilization during wastewater treatment, volatilization from lakes and rivers, biodegradation rates, organic carbon: water partition coefficient (log K_{OC}) and bioaccumulation potential when making changes to the conceptual models as described in Section 2.5. Systematic literature review is currently underway, so model results and basic principles were used to support the fate data used in problem formulation.

The environmental fate information on HBCD presented in Table 2-5 is based on information published in a number of publications (U.S. EPA, 2015c, 2014a; NICNAS, 2012b; EC/HC, 2011; EINECS, 2008; U.S. EPA, 2008; OECD, 2007a).

Table 2-5. Environmental Fate Characteristics of HBCD

Property or Endpoint	Value [a]	References
Direct photodegradation	Does not undergo direct photolysis (estimated)	U.S. EPA (2015c)
Indirect photodegradation	2.1 days (air)	U.S. EPA (2015c)
Hydrolysis half-life	Does not undergo hydrolysis	U.S. EPA (2015c)
Biodegradation half life	0% in 28 days (aerobic in wastewater, OECD 301D) $t_{1/2}$ = 63 days (aerobic soil, OECD 307) $t_{1/2}$ = 7 days (anaerobic soil, OECD 308) $t_{1/2}$ = 11-32 days (aerobic sediment, OECD 308) $t_{1/2}$ = 1.1-1.5 days (anaerobic sediment, OECD 308) $t_{1/2}$ = 0.66 days (anaerobic in sludge)	U.S. EPA (2015c)
Bioconcentration factor (BCF)	8,974-18,100 (fish)	U.S. EPA (2015c)
Bioaccumulation factor (BAF)	3,556,000 (estimated)	U.S. EPA (2012b)

Property or Endpoint	Value [a]	References
Organic carbon:water partition coefficient (log K_{OC})	4.9	U.S. EPA (2015c)
[a] Measured unless otherwise noted. Based on literature review described in (U.S. EPA, 2015c), Problem formulation document https://www.epa.gov/sites/production/files/2015-09/documents/hbcd_problem_formulation.pdf.		

HBCD is persistent in environmental media. HBCD is expected to be stable to hydrolysis and direct photolysis. Measured aerobic biodegradation half-lives are on the order of months. Anaerobic biodegradation may be more rapid but in anaerobic conditions, degradation is also slow with half-lives on the order of days. HBCD is expected to sorb to particulates and sediments and has limited mobility in soil. Low water solubility (66 µg/l), organic carbon:water partitioning (log K_{OC} = 4.9) and limited potential for aerobic and anaerobic biodegradation ($t_{½}$ of up to months) suggest that HBCD in wastewater treatment plants (WWTPs) will associate with biosolids which may subsequently be land applied.

HBCD has a low vapor pressure and Henry's law constant so is expected to have limited volatilization from soils and water surfaces. However, in air, HBCD is expected to occur primarily associated with particulates and exposure from dust and atmospheric particulates is likely. HBCD may undergo long-range transport and particulate bound HBCD will be removed from the atmosphere by wet or dry deposition, resulting in widespread occurrence in soil and water.

HBCD is highly bioaccumulative with BCF values of 8,974-18,100 indicating that consumption of animal products from aquatic and terrestrial species (fish, meat, and dairy) may result in exposure from bioaccumulation and trophic magnification. HBCD's estimated upper trophic level bioaccumulation factor (BAF) is 3,556,000 indicating very high bioaccumulation potential. The model prediction was obtained using the default settings of the EPI Suite™ (U.S. EPA, 2012c) BCFBAF module.

2.3.2 Releases to the Environment

Releases to the environment from conditions of use (e.g., industrial and commercial processes, commercial or consumer uses resulting in down-the-drain releases) are one component of potential exposure and may be derived from reported data that are obtained through direct measurement, calculations based on empirical data and/or assumptions and models.

A source of information that EPA expects to consider in the risk evaluation in evaluating exposure are data reported under the Toxics Release Inventory (TRI) program, however, TRI data are not yet available for HBCD. Under the Emergency Planning and Community Right-to-Know Act (EPCRA) Section 313 rule, HBCD is a TRI-reportable substance effective November 30, 2016. HBCD is reportable beginning with the 2017 calendar year and has been assigned a 100-pound reporting threshold. The first reporting forms from facilities are due by July 1, 2018.

There may be releases of HBCD from industrial sites to wastewater treatment plants (WWTP), surface water, air and landfill (U.S. EPA, 2015c). Sawing of EPS or XPS foam during commercial and consumer use results in release of HBCD to the environment and emissions of HBCD from EPS and XPS foam and wear of these products result in release of HBCD during their service life (U.S. EPA, 2015c). Disposal of EPS and XPS foam may result in releases to the environment as a result of demolition of buildings or material that is left on or in the soil (U.S. EPA, 2015c).

Articles that contain HBCD may release HBCD to the environment during use or through recycling and disposal. Examples of HBCD releases that are more recently being explored in the literature include release of HBCD from building materials through demolition (Duan et al., 2016) and sorption of suspended particles to clothing and transport down the drain during washing of textiles (Saini et al., 2016).

EPA expects to review these data in conducting the exposure assessment component of the risk evaluation for HBCD.

2.3.3 Presence in the Environment and Biota

Monitoring studies or a collection of relevant and reliable monitoring studies provide(s) information that can be used in an exposure assessment. Monitoring studies that measure environmental concentrations or concentrations of chemical substances in biota provide evidence of exposure.

Monitoring and biomonitoring data were identified in EPA's data search for HBCD.

Environment

HBCD has been widely detected in both the environment and biota. When considering monitoring studies reported in risk assessments completed to date and monitoring studies reported to open literature, there are hundreds of studies that have reported HBCD in various media ([*HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0735]; (NICNAS, 2012b; EC/HC, 2011; EINECS, 2008).

HBCD has been detected in a wide variety of environmental media. Based on review of previously completed assessments and EPA's problem formulation (U.S. EPA, 2015c), HBCD is expected to be present at relatively higher levels in sediment, soil and indoor dust. HBCD is also expected to be present in ambient air, indoor air and surface water at relatively lower levels. Physical-chemical properties influence the fate and transport of HBCD between media. For example, EPA expects to consider partitioning of HBCD to sediment within the water column and to suspended particles and dust in indoor environments (Law et al., 2014). HBCD has also been detected in remote areas as a result of long range transport and in very close proximity to industrial sources and many sampling locations in between (Law et al., 2014).

EPA plans to evaluate and review available environmental monitoring data in the risk evaluation.

Biota

HBCD has the potential to both persist ($T_{½}$ of months or longer in some media) and bioaccumulate (BCF = 9000 - 18,000) in the environment (UNEP, 2010). Once HBCD is present in the environment, it is available for uptake by a variety of species, including humans. HBCD has been detected in human milk, adipose tissue, blood and hair. HBCD has been detected in invertebrates, fish, birds, mammals and plants. HBCD is also present in edible fish, plants, milk and other food sources, and there are existing studies that quantify potential dietary exposures (NICNAS, 2012b; EC/HC, 2011; EINECS, 2008).

EPA plans to review available biomonitoring data in the risk evaluation.

2.3.4 Environmental Exposures

The manufacturing, processing, distribution, use and disposal of HBCD can result in releases to the environment.

Environmental exposures are informed by releases into the environment, overall persistence, degradation, and bioaccumulation within the environment, and partitioning across different media. EPA will evaluate exposures to aquatic and terrestrial organisms in aquatic and terrestrial environments. EPA will evaluate food-chain relationships where appropriate.

2.3.5 Human Exposures

EPA plans to analyze occupational, consumer and general population exposures. Subpopulations, including potentially exposed and susceptible subpopulations, within these exposed groups will also be considered.

2.3.5.1 Occupational Exposures

EPA plans to analyze worker activities where there is a potential for exposure under the various conditions of use described in Section 2.2.2. In addition, EPA may analyze exposure to occupational non-users (i.e. workers, who do not directly handle the chemical but perform work in an area where the chemical is present) depending on available information. When data and information are available to support the analysis, EPA also expects to consider the effect(s) that engineering controls and/or personal protective equipment have on occupational exposure levels.

EPA anticipates inhalation of dust and other respirable particles (for example, particulate generated by hot wire cutting of EPS or XPS foam) as the most important HBCD exposure pathway for workers and occupational non-users (U.S. EPA, 2015c; NICNAS, 2012b; ECHA, 2009c; EINECS, 2008) however, dermal exposure, may also occur when performing certain work activities.

Workers and occupational non-users may be exposed to HBCD when performing activities associated with the conditions of use described in Section 2.2.2, including, but not limited to:

- Repackaging or unloading containers of HBCD powder or pellets.
- Handling, transporting and disposing waste containing HBCD.
- Cutting EPS or XPS foam (e.g., at constructions sites).

Based on these activities, EPA expects to analyze inhalation exposure to particulates and dermal exposure, including skin contact with particulates for workers and may also do so in the case of occupational non-users depending on available information. EPA also expects to consider potential worker exposure via the oral route such as from incidental ingestion of HBCD particulates that deposit in the upper respiratory tract from inhalation exposure.

Occupational exposure limits for HBCD have not been established by the Occupational Safety and Health Administration (OSHA), the American Conference of Government Industrial Hygienists (ACGIH), or the National Institute of Occupational Safety and Health (NIOSH). https://www.ncbi.nlm.nih.gov/books/NBK225635/

2.3.5.2 Consumer Exposures

Exposure routes for consumers using HBCD-containing products and bystanders (non-product users that are incidentally exposed to the product or article, (U.S. EPA, 2017a)) may include inhalation of suspended particulates, dermal exposure due to contact with articles, and ingestion of settled dust and mouthing of articles.

Consumer exposure to articles containing HBCD is somewhat different from consumer exposure to a product where the chemical is consumed during its use and then discarded (for example, a can of spray paint). HBCD is incorporated into articles that may be present during the entire useful life of the article in microenvironments where consumers may be continually exposed until the article is disposed. HBCD-containing articles (e.g., insulation, electronics products, plastic based products and textiles) have relatively long service lives in comparison to other consumer products that are quickly used and discarded. Indoor environments with elevated levels of HBCD in indoor air and dust may contain some combination of articles containing HBCD.

The primary on-going consumer use of HBCD is within EPS and XPS insulation. In the 2015 Problem Formulation and Initial Assessment of HBCD (U.S. EPA, 2015c), EPA did not anticipate evaluating EPS and XPS insulation as a stand-alone scenario and instead planned to analyze indoor exposures from all sources of reported indoor air and dust concentrations. EPA will further analyze the source contribution of EPS and XPS insulation to levels of HBCD in indoor air and dust. EPA will also assess on-going uses of HBCD within automobile replacement parts. EPA plans to analyze uses of recycled articles back into EPS and XPS insulation. EPA does not expect to consider recycled articles, where those articles do not have intended flame retardant applications.

Inhalation and Oral

Consumer exposure to HBCD may include inhalation and ingestion exposure related to emissions of HBCD from articles. Indoor air and indoor dust concentrations may vary based on the source strength of emissions associated with the presence of articles. Emission from articles will vary based on the surface area of the article present in the building, the weight fraction of HBCD within the article and building characteristics such as air exchange and inter-zonal air flow. Based on the relatively high octanol: air partition coefficient (K_{oa}) and relatively low vapor pressure, HBCD emitted to indoor air is likely to partition to suspended particles and settle to indoor dust rather than be emitted in its vapor phase. EPA expects to further analyze ingestion of dust and inhalation of dust associated with conditions of use of HBCD.

Dermal

Consumer exposure to HBCD may include dermal exposure related to direct skin contact with articles containing HBCD. However, there are several factors to be considered and this is likely a relatively minor pathway compared to dermal contact with dust. The contact duration, solubility and diffusivity of HBCD within different articles, and contact surface area of skin all influence potential exposures (EINECS, 2008). EPA expects to consider dermal exposure associated with use of HBCD in EPS and XPS during installation and removal, contact with dust, and with recycled use applications.

There may be some consumers who may have greater exposure potential to HBCD such as:

- Children or adults who spend time in microenvironments with elevated dust or indoor air concentrations due to presence of multiple article which contain elevated levels of HBCD.
- Children or adults who have elevated dermal contact with EPS/XPS insulation containing HBCD.

EPA expects to analyze inhalation, dermal and oral exposures to consumers and bystanders associated with the conditions of use by consumers.

2.3.5.3 General Population Exposures

Wastewater/liquid wastes, solid wastes or air emissions of HBCD could result in potential pathways for oral, dermal or inhalation exposure to the general population.

Inhalation

There is the potential for inhalation exposure to HBCD by breathing ambient air and indoor air. Ambient air concentrations may vary by proximity to an industrial source, while indoor air concentrations are discussed in the consumer exposure section. Based on the relatively high K_{oa} and relatively low vapor pressure, HBCD is expected to be present primarily in suspended particles in the air rather than in the vapor phase.

Based on these potential sources and pathways of exposure, EPA expects to analyze inhalation exposures of the general population to air/particulates containing HBCD that may result from the conditions of use of HBCD.

Oral

The general population may ingest HBCD via several exposure pathways.

There is potential for oral exposure to HBCD by ingestion of dust and soil; drinking water and breast milk; and edible aquatic and terrestrial biota (e.g., from fishing, hunting, gathering and farming). There is a wide range of dust and soil monitoring data available. Dust concentrations vary widely across different microenvironments and within microenvironments and are generally reported in the ng/g or µg/g range (U.S. EPA, 2015c). Existing exposure assessments outside of the United States have quantified dietary exposure from a variety of food sources and compared these values to other pathways (Environment Canada, 2011; EINECS, 2008).

EPA does not expect to further analyze exposures from drinking water sources. Exposures from drinking water containing HBCD are possible, but are likely to be relatively lower than other oral exposure pathways (Environment Canada, 2011; EINECS, 2008). Drinking water monitoring data is generally unavailable. There are existing data on HBCD concentrations in surface water which are relatively low, below 1 µg/L. The physical-chemical and fate properties of HBCD, such as high sorption, low water solubility, and high K_{OC} indicate that concentrations of HBCD in drinking water would be expected to be low prior to treatment. When sediment monitoring data is used with assumptions about K_{OC}, organic content and density of water and sediment, surface water concentrations can be estimated and are generally below the highest levels reported in surface water (ECHA, 2016). These same physical-chemical properties indicate that drinking water treatment processes would further reduce HBCD concentrations in drinking water. Overall, the contribution to exposure to HBCD via drinking water is expected to be low compared to other exposures.

Based on these potential sources and pathways of exposure, EPA expects to analyze oral exposures to the general population that may result from the conditions of use of HBCD.

Dermal

There is potential for dermal exposure to HBCD through contact with dust and soil containing HBCD. Dermal exposure is likely to vary based on the contact time with the material, the concentration of HBCD and properties of HBCD that influence dermal absorption (EINECS, 2008).

Based on these potential sources and pathways of exposure, EPA expects to analyze dermal exposures to the general population that may result from the conditions of use of HBCD.

2.3.5.4 Potentially Exposed or Susceptible Subpopulations

TSCA requires EPA to determine whether a chemical substance presents an unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation." TSCA §3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." General population is "the total of individuals inhabiting an area or making up a whole group" and refers here to the U.S. general population (U.S. EPA, 2011).

As part of the Problem Formulation, EPA identified potentially exposed and susceptible subpopulations for further analysis during the development and refinement of the life cycle, conceptual models, exposure scenarios, and analysis plan. In this section, EPA addresses the potentially exposed or susceptible subpopulations identified as relevant based on greater exposure. EPA will address the subpopulations identified as relevant based on greater susceptibility in the hazard section.

Of the human receptors identified in the previous sections, EPA identifies the following as potentially exposed or susceptible subpopulations due to their *greater exposure* that EPA expects to consider in the risk evaluation:

- Workers and occupational non-users.
- Consumers and bystanders associated with consumer use. HBCD has been identified as being used in products available to consumers; however, only some individuals within the general population may use these products. Therefore, those who do use these products are a potentially exposed or susceptible subpopulation due to greater exposure.
- Other groups of individuals within the general population who may experience greater exposures due to their proximity to conditions of use identified in Section 2.2 that result in releases to the environment and subsequent exposures (e.g., individuals who live or work near manufacturing, processing, distribution, use or disposal sites).

There are some reasonably likely exposure scenarios where greater exposure from multiple sources may occur. There may be some individuals who have greater potential for exposure to HBCD such as:

- Children who spend time in microenvironments with elevated dust concentrations.
- Breast-fed infants where concentrations of breast milk containing HBCD are elevated.
- Children or adults who ingest soil or sediment in environments where HBCD concentrations are elevated.
- Children or adults who consume edible aquatic biota or terrestrial biota containing elevated levels of HBCD.

In developing exposure scenarios, EPA will analyze available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or lifestage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population (U.S. EPA, 2006a).

In summary, in the risk evaluation for HBCD, EPA plans to analyze the following potentially exposed groups of human receptors: workers, occupational non-users, consumers, bystanders associated with consumer use. As described above, EPA may also identify additional potentially exposed or susceptible subpopulations that will be considered based on greater exposure.

2.4 Hazards (Effects)

For scoping, EPA conducted comprehensive searches for data on hazards of HBCD, as described in *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0735) (U.S. EPA, 2017f). Based on initial screening, EPA plans to analyze the hazards of HBCD identified in this problem formulation document. However, when conducting the risk evaluation, the relevance of each hazard within the context of a specific exposure scenario will be judged for appropriateness. For example, hazards that occur only as a result of chronic exposures may not be applicable for acute exposure scenarios. This means that it is unlikely that every identified hazard will be analyzed for every exposure scenario.

2.4.1 Environmental Hazards

For scoping purposes, EPA consulted the sources of environmental hazard data for HBCD found in Table 2-6. However, EPA also expects to consider other studies (e.g., more recently published, alternative test data) that have been published since these reviews, as identified in the literature search conducted by the Agency for HBCD [*HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0735]. Only the on-topic references listed in the Ecological Hazard Literature Search Results were considered as potentially relevant data/information sources for the risk evaluation. Inclusion criteria were used to screen the results of the ECOTOX literature search (as explained in the *Strategy for Conducting Literature Searches for HBCD: Supplemental File for the TSCA Scope Document* (EPA-HQ-OPPT-2016-0735) (U.S. EPA, 2017f). Data from the screened literature are summarized below (Table 2-6)as ranges (min-max). EPA plans to review these data/information sources during risk evaluation using the data quality review evaluation metrics and the rating criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

Table 2-6. Summary of Aquatic and Sediment Environmental Hazard Information for HBCD

Test Organism	Duration	Endpoint	Hazard Value	Effect Type	Units	Reference
Aquatic Organisms						
Fish	Acute	LC_{50}	0.0025 - >100	mortality	mg/L	(WILDLIFE INTERNATIONAL LTD, 1997), (Calmbacher, 1978)
	Chronic	NOEC	0.0037 - <500	growth and reproduction	mg/L	(Zhang et al., 2008; Drottar and Krueger, 2000)
		LOEC	0.1	DNA damage	mg/L	(Zhang et al., 2008)
		MATC	>0.032	Larvae malformations	mg/L	(Hong et al., 2014)
Invertebrates	Acute	EC_{50}	>0.0032 - 146	immobility	mg/L	(Wildlife Intl LTD, 1997; BASF, 1990)
	Chronic	NOEC	0.0031	growth and reproduction	mg/L	(Drottar and Krueger, 1998)
		LOEC	0.0056 – 0.1	Growth; gill degeneration	mg/L	(Smolarz and Berger, 2009; Drottar and Krueger, 1998)
		MATC	0.0042	growth	mg/L	(Drottar and Krueger, 1998)
Plants	Chronic	EC_{50}	0.009 - >500	Growth;	mg/L	(Walsh et al., 1987);
		MATC	0.01		mg/L	(BASF CORP, 1990)
Amphipod		NOEC	100 – 1,000	No effect mentioned in Thomas paper	mg/kg dwt	(Thomas et al., 2003a, b) for both ends of range
		LOEC	500	Survival	mg/kg dwt	(Thomas et al., 2003a, b)
Oligochaetes		NOEC	3.1	population	mg/kg dwt	(Oetken et al., 2001)
		LOEC	28.7	population	mg/kg dwt	(Oetken et al., 2001)
		MATC	15.4 (normalized)	population	mg/kg dwt	(Oetken et al., 2001)
Terrestrial Organisms						
Avian	Chronic	LOEC	125	reduction in hatchability	µg/L	(MOEJ, 2009)
			15	reduced chick survival	mg/L	
			2.1		mg/kg/day	
			5		mg/L	
		LOEC	164.3	reduced corticosterone response in male nestling kestrels, reduced flying activities in juvenile males, delayed response time to predator avoidance in juvenile females	ng/g wet weight of egg	(Kobiliris, 2010)
Earthworm	Chronic	EC_{10}	21	reproduction	mg/kg/dwt.	(Aufderheide et al., 2003)
		NOEC	128			
Plants	Chronic	NOEC	>5,000	Not reported	mg/kg/dwt	(Porch et al., 2002)

EPA expects to analyze the hazards of HBCD to aquatic organisms including fish, aquatic invertebrates, aquatic plants and sediment invertebrates exposed to relevant media under acute and chronic exposure conditions. Based on the assessments mentioned above, there was acute toxicity to aquatic invertebrates from HBCD, based on mortality and immobilization. Chronic toxicity to aquatic invertebrates (growth and reproduction) was observed when exposed to HBCD. Chronic toxicity was observed in sediment dwelling organisms based on reduced survivability when exposed to HBCD.

EPA expects to analyze the hazards of HBCD to terrestrial organisms including soil invertebrates and avian species exposed to relevant media under acute and chronic exposure conditions. Based on previous assessments, chronic toxicity to terrestrial invertebrates (reproduction) was observed when exposed to HBCD. Also, toxicity to avian species was observed, based on reduced hatchability and survival, when exposed to HBCD.

2.4.2 Human Health Hazards

The human health hazard of HBCD has been examined in several publications (U.S. EPA, 2016c, 2014a, d; NICNAS, 2012b; Environment Canada, 2011; EINECS, 2008; U.S. EPA, 2008; OECD, 2007b). EPA expects to consider potential human health hazards associated with HBCD. Based on reasonably available information, the following sections describe the hazards EPA expects to further analyze.

HBCD does not have an existing EPA IRIS Assessment; however, as part of a coordinated agency effort, in the TRI Technical Review of HBCD (U.S. EPA, 2016c), the TSCA Work Plan Problem Formulation and Initial Assessment, (U.S. EPA, 2015c), and *Preliminary Materials for the IRIS Toxicological Review of HBCD* (U.S. EPA, 2014d), non-cancer health hazards of HBCD were compiled and reviewed, including: acute toxicity, liver toxicity, thyroid toxicity, reproductive/developmental toxicity, neurotoxicity, immunotoxicity, sensitization and irritation. EPA relied heavily on this comprehensive review in preparing this Problem Formulation. EPA also expects to evaluate other studies (e.g., more recently published, alternative test data) that have been published since these reviews during the analysis phase of the risk evaluation, as identified in the literature search conducted by the Agency for HBCD [*HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0735]. EPA expects to use these previous analyses as a starting point for identifying key and supporting studies to inform the human health hazard assessment, including dose-response analysis. The relevant studies will be evaluated using the data quality criteria in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018).

2.4.2.1 Non-Cancer Hazards

Acute Toxicity

Animal studies have observed potential neurological effects and clinical signs of toxicity including death following high-dose acute administration of HBCD (U.S. EPA, 2015c).

Liver Toxicity

Increased liver weight has been observed in multiple laboratory animal studies, in both sexes, across species and following both adult and developmental exposures. In mice, HBCD exposure induced evidence of inflammatory changes in the liver and hepatic fatty changes (steatosis) in animals with a high-fat diet (U.S. EPA, 2014d).

Thyroid Toxicity
Human epidemiological studies have reported potential effects of HBCD on thyroid hormones. Animal toxicity studies provide stronger evidence of thyroid perturbation associated with HBCD exposure, including altered levels of thyroid hormones, histological changes and increased thyroid weight, with effects observed across multiple lifestages, sexes, species and exposure durations (U.S. EPA, 2014d).

Reproductive/Developmental Toxicity
For female reproductive effects, there is some rodent evidence that HBCD may alter fertility and pregnancy outcomes as well as reduce the number of mature and developing follicles in the ovary; however, effects on reproductive organ weight are inconsistent. The potential for HBCD to affect the female reproductive system has not been investigated in humans. For male reproductive effects, there is some epidemiological support of an association between HBCD exposure and altered serum testosterone and sex hormone binding globulin (SHGB) levels; however, animal studies did not report any effects on male reproductive organ weights, reproductive development, hormone concentrations or spermatogenic measures. There is mixed epidemiological data on developmental toxicity of HBCD, while animal toxicity studies suggest that early life exposure to HBCD at high doses can affect various developmental outcomes, including reduced offspring viability, decrements in pup weight and alterations in eye opening (U.S. EPA, 2014d).

Neurotoxicity
There is an absence of a strong association between HBCD exposure and developmental neurotoxicity in various neuropsychological domains observed in the limited epidemiological studies that are available; however, there is evidence of potential developmental neurotoxicity in rodents. Perinatal HBCD exposure was shown to alter neurodevelopmental milestones while eliciting changes in locomotor activity and executive function that persisted into adulthood. HBCD exposure also appears to affect other neurological endpoints related to changes in auditory sensitivity, dopamine system function and brain weight in multiple studies. Effects on neurodevelopmental endpoints were observed in both sexes and across a wide range of doses and exposure durations. However, there is currently not any substantial evidence to support concern for neurotoxicity when exposure is limited to adulthood (U.S. EPA, 2014d).

Immunotoxicity
The effects of HBCD on both functional and structural immune endpoints have been evaluated in animal models. Overall, immunological effects from HBCD exposure are variable and inconsistent across studies for endpoints such as immune organ weights, hematology or histopathology (U.S. EPA, 2014d), and its relevance to the risk evaluation will require further evaluation.

Sensitization/Irritation
There is limited information available suggesting potential mild irritation and sensitizing potential of HBCD (U.S. EPA, 2015c).

2.4.2.2 Genotoxicity and Cancer Hazards

Available data suggest that HBCD is not genotoxic. Existing assessments have also concluded, based on genotoxicity information and a limited lifetime study, that HBCD is not carcinogenic (NICNAS, 2012b; EINECS, 2008; TemaNord, 2008; OECD, 2007b). Although the current data does not appear to provide sufficient evidence that HBCD is carcinogenic, EPA will further evaluate genotoxicity and other cancer hazards in the risk evaluation as part of a systematic review.

2.4.2.3 Potentially Exposed or Susceptible Subpopulations

TSCA requires that the determination of whether a chemical substance presents an unreasonable risk include consideration of unreasonable risk to "a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation" by EPA. TSCA § 3(12) states that "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." In developing the hazard assessment, EPA will evaluate available data to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

2.5 Conceptual Models

EPA risk assessment guidance (U.S. EPA, 2014c, 1998), defines Problem Formulation as the part of the risk assessment framework that systematically identifies the factors to be considered in the assessment. It draws from the regulatory, decision-making and policy context of the assessment and informs the assessment's technical approach.

A conceptual model describes the actual or predicted relationships between the chemical substance and receptors, either human or environmental. These conceptual models are integrated depictions of the conditions of use, exposures (pathways and routes), hazards and receptors. The initial conceptual models describing the scope of the assessment for HBCD, have been refined during problem formulation. The changes to the conceptual models in this problem formulation are described along with the rationales.

In this section EPA outlines those pathways that will be included and further analyzed in the risk evaluation; will be included but will not be further analyzed in the risk evaluation; and will not be included in the TSCA risk evaluation and the underlying rationale for these decisions.

EPA determined as part of problem formulation that it is not necessary to conduct further analysis on certain exposure pathways that were identified in the HBCD Scope Document and that remain in the risk evaluation. Each risk evaluation will be "fit-for-purpose," meaning not all conditions of use will warrant the same level of evaluation and the Agency may be able to reach some conclusions without extensive or quantitative risk evaluations. 82 FR 33726, 33734, 33739 (July 20, 2017).

As part of this problem formulation, EPA also identified exposure pathways under regulatory programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist, i.e., the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA). OPPT worked closely with the offices within EPA that administer and implement the regulatory programs under these statutes. In some cases, EPA has determined that the chemicals present in various media pathways (i.e., air, water, land) fall under the jurisdiction of existing regulatory programs and associated analytical processes carried out under other EPA-administered statutes and have been assessed and effectively managed under those programs. EPA believes that the TSCA risk evaluation should generally focus on those exposure pathways associated with TSCA conditions of use that are not adequately assessed and effectively managed under the regulatory regimes discussed above because these pathways are likely to represent the greatest areas of risk concern. As a result, EPA does not expect to include in the risk evaluation certain exposure pathways identified in the HBCD Scope Document.

2.5.1 Conceptual Model for Industrial and Commercial Activities and Uses: Potential Exposures and Hazards

The revised conceptual model (Figure 2-2) illustrates the pathways of exposure from industrial and commercial activities and uses of HBCD that EPA plans to evaluate. There are exposures to workers and occupational non-users via the inhalation and oral routes and to workers via the dermal route during processing and use for the conditions of use identified in this problem formulation.

The industrial and commercial activities/uses that EPA expects to consider are those that are conditions of use. As discussed in Section 2.2.2.2, these activities include importation of HBCD; compounding of XPS master batch; manufacture of XPS; manufacture of EPS; manufacture of SIPs; manufacture of automobile replacement parts; and use of XPS, EPS, and SIPs in construction.

EPA expects to further analyze pathways and routes of exposure that may occur during repackaging, processing steps (i.e., plastics compounding; plastics converting and SIP assembly; recycle of EPS), use (i.e., installation/reuse/demolition of EPS/XPS foam) and disposal (i.e., handling of wastes) including:

- Inhalation of dust containing HBCD by workers and occupational non-users. EPA expects this to be an important exposure route for workers and occupational non-users (U.S. EPA, 2015c).
- Dermal exposure to HBCD solids by workers that may occur as a result of handling particulate solids (OECD, 2015; EINECS, 2008).
- Ingestion of HBCD by workers and occupational non-users from ingestion of dust that deposits in the upper respiratory tract and is swallowed.

EPA does not plan to further analyze exposure to liquid. Based on information from the 2016 CDR, all importers reported solid physical forms of HBCD and therefore, worker and non-occupational user exposure to liquid HBCD is not expected.

For each condition of use identified in Table 2-3 a determination was made as to whether or not each unique combination of exposure pathway, route, and receptor will be further analyzed in the risk evaluation. The results of that analysis along with the supporting rationale are presented in Appendix C.

Waste Handling, Treatment and Disposal

Figure 2-2 shows that waste handling, treatment and disposal is expected to lead to the same pathways as other industrial and commercial activities and uses. The path leading from the "Waste Handling, Treatment and Disposal" box to the "Hazards Potentially Associated with Acute and/or Chronic Exposures" box was re-routed to accurately reflect the expected exposure pathways, routes, and receptors associated with these conditions of use of HBCD.

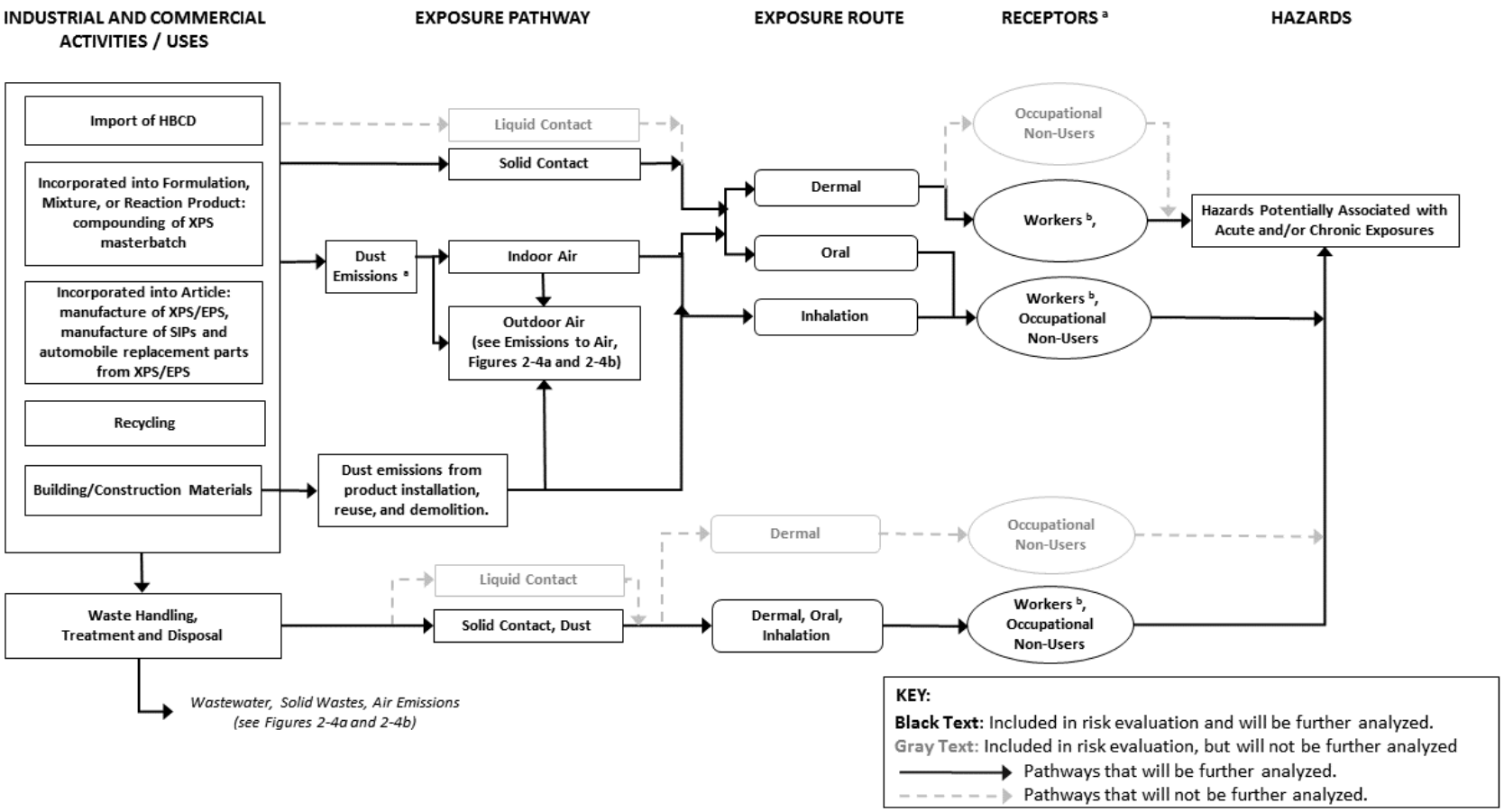

Figure 2-2. HBCD Conceptual Model for Industrial and Commercial Activities and Uses: Worker and Occupational Non-User Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from industrial and commercial activities and uses of HBCD.

[a] Receptors include potentially exposed or susceptible subpopulations (see Section 2.3.5.4).

[b] When data and information are available to support the analysis, EPA also considers the effect that engineering controls and/or personal protective equipment have on occupational exposure levels.

2.5.2 Conceptual Model for Consumer Activities and Uses: Potential Exposures and Hazards

Figure 2-3 presents the conceptual model for human receptors from consumer uses of HBCD. This conceptual model has been modified to indicate the exposure pathways that will and will not be further analyzed. More detailed information can be found in Appendix D.

EPA expects to consider certain conditions of use related to consumer uses. As described in Section 2.2.2.2, these uses include building and construction materials.

HBCD is present in consumer articles, many of which are found in indoor environments such as the home. The service-life of articles will vary based on the type of article (e.g., textile, electronics, structural insulation panel) but are expected to range from months to years. Service-life is defined as the length of time an article or consumer good is used before it is disposed of or recycled. Over this period of time, there is potential for long-term continuous low-level releases which may contribute to levels of HBCD found within indoor dust and air. These articles may be recycled and reintroduced into the indoor environment at the end of their service-life. HBCD within indoor air is expected to be present primarily as a particulate, rather than a vapor. Depending on recycling/reuse patterns and processes for different types of articles, HBCD may continue to be present within articles for another service life of the recycled or reused product.

Figure 2-3 illustrates exposure pathways for consumers from consumer uses of HBCD. EPA expects to analyze pathways and routes of exposure that may occur during use or disposal of building and construction materials or recycled products including:

- Ingestion of suspended or settled dust containing HBCD by consumers and bystanders. Ingestion of suspended dust may occur by inhalation of dust that deposits in the upper respiratory tract and is swallowed. Ingestion of settled dust may occur via hand to mouth behavior.
- Inhalation of suspended dust containing HBCD by consumers and bystanders. EPA expects this to be an important route of exposure.
- Dermal exposure to HBCD solids by consumers that may occur as a result of handling of articles or dermal contact with dust.

The primary route of exposure for consumers to HBCD is via ingestion of suspended or settled dust. This will be evaluated for both EPS/XPS insulation and for replacement automobile parts. Oral exposure related to mouthing of articles is not expected for the primary ongoing use of HBCD in EPS/XPS insulation. Ingestion of dust via hand to mouth behavior may also occur. Younger children (e.g., infants and toddlers) may be susceptible receptors due to higher dust ingestion rates and higher frequency and duration of hand and object to mouth contact, when compared to older children and adults.

Inhalation of suspended dust may also occur from abraded particles or resuspended settled dust and this will be further analyzed.

Dermal exposure to consumers from HBCD containing articles may occur during contact with dust and handling of articles. The potential for HBCD to absorb dermally under different conditions, will be further analyzed during risk evaluation.

The primary routes of exposure resulting from consumer handing of disposal of waste is inhalation and oral ingestion of suspended particulate including dust. Under some conditions such as renovation of a home, it is possible that abraded dust from articles, such as structural insulation panels, could result in elevated levels of dust compared to those typically found in monitoring studies. Renovation and abrasion of dust will be further analyzed during risk evaluation as part of an EPS/XPS exposure scenario rather than as a stand-alone consumer handling and disposal of waste scenario.

EPA does not plan to further analyze liquid contact to HBCD for consumers or bystanders as HBCD is incorporated into articles in the solid form.

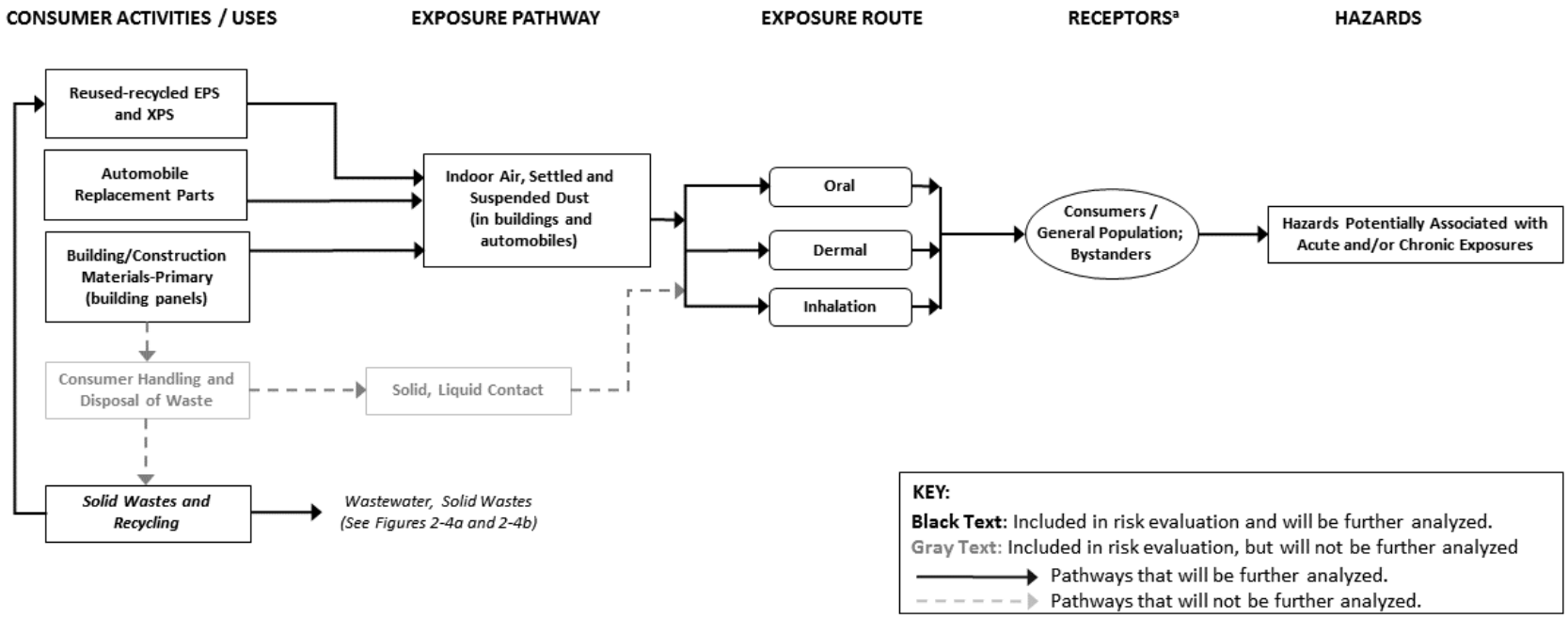

Figure 2-3. HBCD Conceptual Model for Consumer Activities and Uses: Consumer Exposures and Hazards

The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from consumer activities and uses of HBCD.

[a] Receptors include potentially exposed or susceptible subpopulations (see Section 2.3.5.4).

2.5.3 Conceptual Model for Environmental Releases and Wastes: Potential Exposures and Hazards

The revised conceptual models (Figure 2-4a and Figure 2-4b) illustrate the expected exposure pathways to human and ecological receptors from environmental releases and waste streams associated with industrial and commercial activities for HBCD that EPA expects to include in the risk evaluation. The pathways that EPA plans to include and analyze further in the risk evaluation are described in Section 2.5.3.1 and are shown in the conceptual models. The pathways that EPA plan to include in the risk evaluation but not further analyze are described in Section 2.5.3.2 and the pathways that EPA does not expect to include in risk evaluation are described in Section 2.5.3.3.

2.5.3.1 Pathways that EPA Plans to Include and Further Analyze in Risk Evaluation

Pathways that EPA expects to further analyze include:

- Emissions to air: The general population including populations and ecological receptors living near industrial and commercial facilities processing, using or disposing of HBCD may be exposed via inhalation of suspended HBCD particulate in the ambient air from fugitive or stack emissions; and ingestion of HBCD from uptake from the environment into food sources (via indirect deposition into water bodies or soil).
- Releases to surface water (and sediment): The general population including populations living near industrial and commercial facilities processing, using or disposing of HBCD may be exposed by incidental ingestion of surface water and suspended particulates and by ingestion of HBCD from uptake (via direct or indirect deposition into water bodies or soil) from the environment into food sources. Aquatic and terrestrial ecological receptors may also be directly exposed due to proximity to surface water and sediment.
- Biosolid application to soil from wastewater: Ecological receptors and the general population including populations living near industrial and commercial facilities processing, using or disposing of HBCD may be exposed by incidental soil ingestion or uptake from the environment into food sources, particularly for backyard fruit and vegetable gardens near facilities.

HBCD has a relatively low water solubility (66 ug/L) and high log K_{OC} (4.9) and tends to sorb to solids in surface water, groundwater and wastewater. It is resistant to aerobic biodegradation ($t_{½}$= months) and hydrolysis; therefore, it is not degraded during wastewater treatment and will tend to associate with sludge. If land applied, treated biosolids will transfer HBCD to soil where it will be taken up by biota and bioaccumulate in the terrestrial and human food chain. From soil, it may be transported to surface water by runoff and particulate erosion and be taken up by and bioaccumulate in aquatic species. Emissions to air are also expected to occur and a long vapor ($t_{½}$ > days) and particulate phase half-life indicates that long range transport can occur. Deposition to soil and water from air may also lead to HBCD concentrations in soil and water far from the source location.

As HBCD is bioaccumulative (estimated BAF of 3,556,000, see Table 2-5), oral exposure via ingestion of food items such as fish, meat, eggs, dairy products and plants are expected. The primary route of exposure for the general population is expected to be via ingestion of terrestrial biota and aquatic biota. There may be additional oral exposure to young children from ingestion of breast milk and from indoor dust exposure.

As shown in Figure 2-4a, EPA anticipates that the general population living near industrial and commercial facilities processing, using or disposing of HBCD may be exposed via several pathways. As

HBCD is persistent and bioaccumulative, releases to the environment from industrial or commercial activities are expected to result in exposures to human receptors via inhalation, ingestion of water, breast milk and edible aquatic and terrestrial biota (e.g., from fishing, hunting, gathering, farming).

Releases of HBCD to the environment from industrial or commercial activities may also result in exposure to aquatic and terrestrial life via contaminated water, sediment or soil as shown in Figure 2-4b. Trophic magnification may result in greater exposure following bioaccumulation. Based on the potential for bioaccumulation, it is expected that terrestrial species will also be exposed to HBCD via the food chain.

Air Pathways
Particulate-associated HBCD may result in transport and subsequent inhalation exposure. This is not expected to be a primary route of exposure although those living near a facility which release HBCD may experience higher levels of exposure than the general population. Atmospheric transport and off-site deposition may also contribute to low levels of contamination away from the release location which may contribute to environmental bioaccumulation from water and soil.

Water Pathways
Currently, no states or tribes include criteria for HBCD in water quality standards and values are not available for use in NPDES permits. Thus, EPA cannot conclude that risk to human health and aquatic life from exposure to HBCD in ambient waters has been effectively managed. As a result, this pathway will undergo risk evaluation under TSCA. EPA may publish CWA section 304(a) human health or aquatic life criteria for HBCD in the future if it is identified as a priority under the CWA.

Biosolids Pathways
This pathway will undergo risk evaluation under TSCA.

Disposal Pathways
HBCD or HBCD containing articles may be disposed of in construction and demolition waste landfills by commercial and consumer users. Land disposal of HBCD in EPS/XPS building materials (e.g. insulation) is expected to be the primary disposal pathway for these materials and is likely to occur at construction and demolition landfills.

2.5.3.2 Pathways that EPA Plans to Include in the Risk Evaluation but Not Further Analyze

Drinking Water Pathways
Exposures from drinking water containing HBCD are possible, but are likely to be relatively lower than other oral exposure pathways (Environment Canada, 2011; EINECS, 2008). Drinking water monitoring data is generally unavailable. There are existing data on HBCD concentrations in surface water which are relatively low, below 1 µg/L. The physical-chemical and fate properties of HBCD, such as high sorption, low water solubility, and high K_{OC} indicate that concentrations of HBCD in drinking water would be expected to be low prior to treatment. When sediment monitoring data is used with assumptions about K_{OC}, organic content and density of water and sediment, surface water concentrations can be estimated and are generally below the highest levels reported in surface water (ECHA, 2016). These same chemical and fate properties would indicate that drinking water treatment processes would

further reduce HBCD concentrations in finished drinking water. Overall, the contribution to exposure to HBCD via drinking water is expected to be low compared to other exposures.

Direct or indirect discharge of wastewater to surface water may occur and runoff from land application fields may transport HBCD into surface water. Leaching to groundwater is expected to be limited by low water solubility and high sorption potential. HBCD has a relatively low water solubility and will tend to sorb to solids in surface and groundwater. It is expected to be removed by water treatment and exposure to the general population via drinking water is expected to be low. HBCD will tend to sorb to subsurface soils. Reductive de-bromination may result in subsurface degradation with $t_{1/2}$ of months or longer. HBCD may migrate to groundwater but exposure via this pathway may be limited.

2.5.3.3 Pathways that EPA Does Not Expect to Include in the Risk Evaluation

Exposures to receptors (i.e. general population, terrestrial species) may occur from industrial and/or commercial uses, industrial releases to air, water or land, and other conditions of use. As described in Section 2.5, EPA does not expect to include in the risk evaluation pathways under programs of other environmental statutes, administered by EPA, which adequately assess and effectively manage exposures and for which long-standing regulatory and analytical processes already exist. These pathways are described below.

Disposal Pathways

Because HBCD is not classified as a RCRA hazardous waste, wastes are not expected to be sent to Subtitle C incinerators, due to the higher cost of such incineration as compared with MSW or other incinerators; therefore emissions from hazardous waste incinerators will not be included in the risk evaluation. 40 CFR 264.345 specifies performance standards for hazardous waste incinerators. An incinerator burning hazardous waste must achieve a destruction and removal efficiency (DRE) of 99.99% for each principal organic hazardous constituent. Furthermore, RCRA provisions for site-specific risk assessments and the Hazardous Waste Combustor maximum achievable control technology (MACT) rule provisions for a Residual Risk and Technology Review together cover risks for RCRA hazardous wastes.

EPA does not expect to include on-site releases to land that go to underground injection in its risk evaluation. Environmental disposal of HBCD injected into Class I well types are presumed to be managed and prevented from further environmental release by RCRA and SDWA regulations. Therefore, disposal of HBCD via underground injection is not likely to result in environmental and general population exposures.

EPA does not expect to include on-site releases to land that go to RCRA Subtitle C hazardous waste landfills. Design standards for Subtitle C landfills require double liner, double leachate collection and removal systems, leak detection system, run on, runoff, and wind dispersal controls, and a construction quality assurance program. They are also subject to closure and post-closure care requirements including installing and maintaining a final cover, continuing operation of the leachate collection and removal system until leachate is no longer detected, maintaining and monitoring the leak detection and groundwater monitoring system. Subtitle C landfill operators are required to implement an analysis and testing program to ensure adequate knowledge of waste being managed, and to train personnel on routine and emergency operations at the facility. Hazardous waste being disposed in Subtitle C landfills must also meet RCRA waste treatment standards before disposal. Given these controls, general

population exposure to HBCD in groundwater from Subtitle C landfill leachate is not expected to be a significant pathway.

EPA does not expect to include on-site releases to land from RCRA Subtitle D municipal solid waste landfills (MWSLFs), other than for construction and demolition wastes as described in Section 2.3.5.1. While permitted and managed by the individual states, municipal solid waste landfills (MSWLFs) are required by federal regulations to implement many of the same requirements as Subtitle C landfills. MSWLFs must have a liner system with leachate collection and conduct groundwater monitoring and corrective action when releases are detected. MSWLFs are also subject to closure and post-closure care requirements, as well as providing financial assurance for funding of any needed corrective actions. MSWLFs have also been designed to allow for the small amounts of hazardous waste generated by households and very small quantity waste generators (less than 100 kg per month).

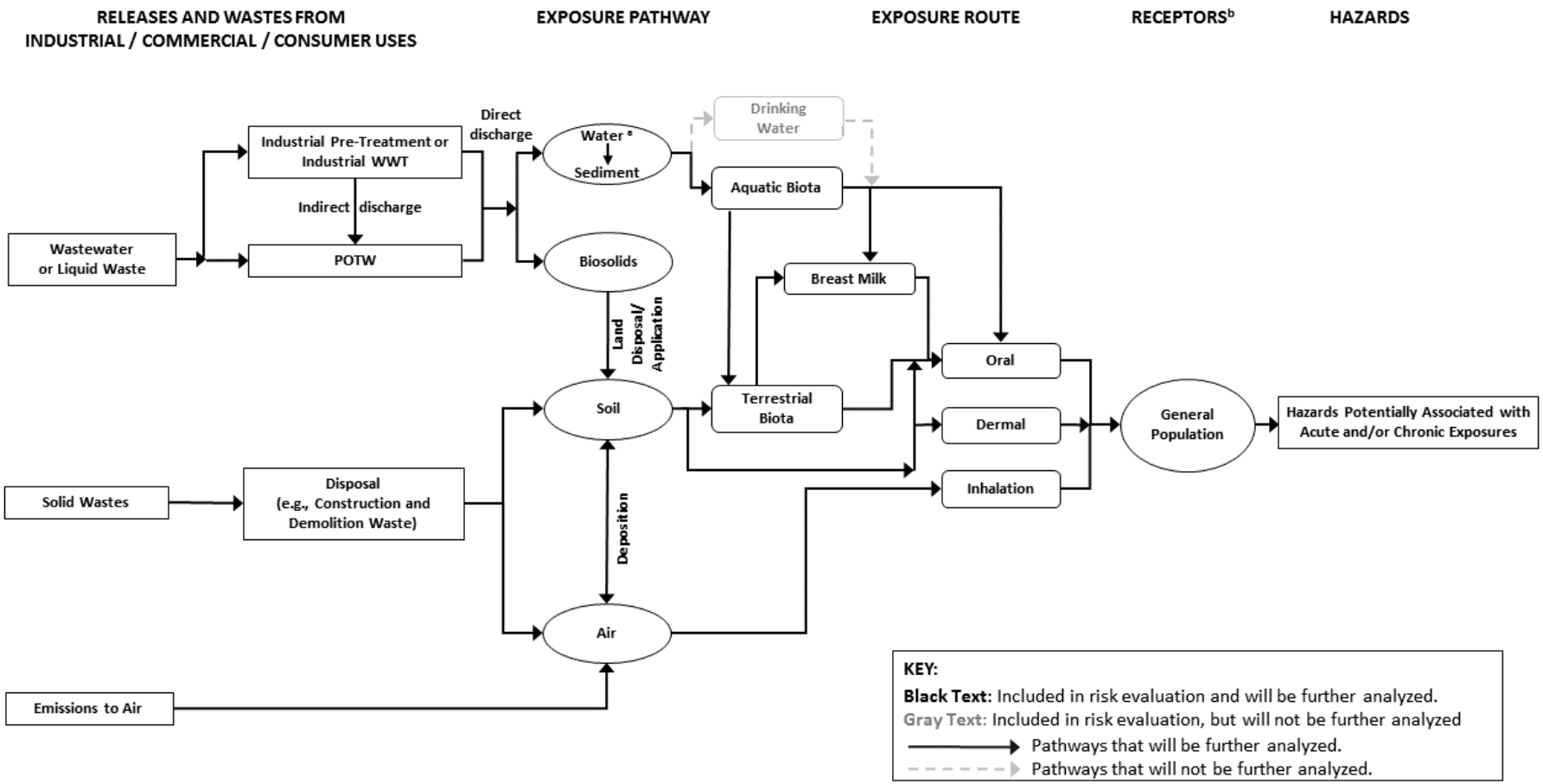

Figure 2-4a. HBCD Conceptual Model for Environmental Releases and Wastes: General Population Exposures and Hazards
The conceptual model presents the exposure pathways, exposure routes and hazards to human receptors from releases and wastes from industrial and commercial uses of HBCD.

[a] Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW (i.e., down the drain). Drinking water will undergo further treatment in drinking water treatment plant. Ground water may also be a source of drinking water.

[b] Receptors include potentially exposed or susceptible subpopulations (see Section 2.3.5.4).

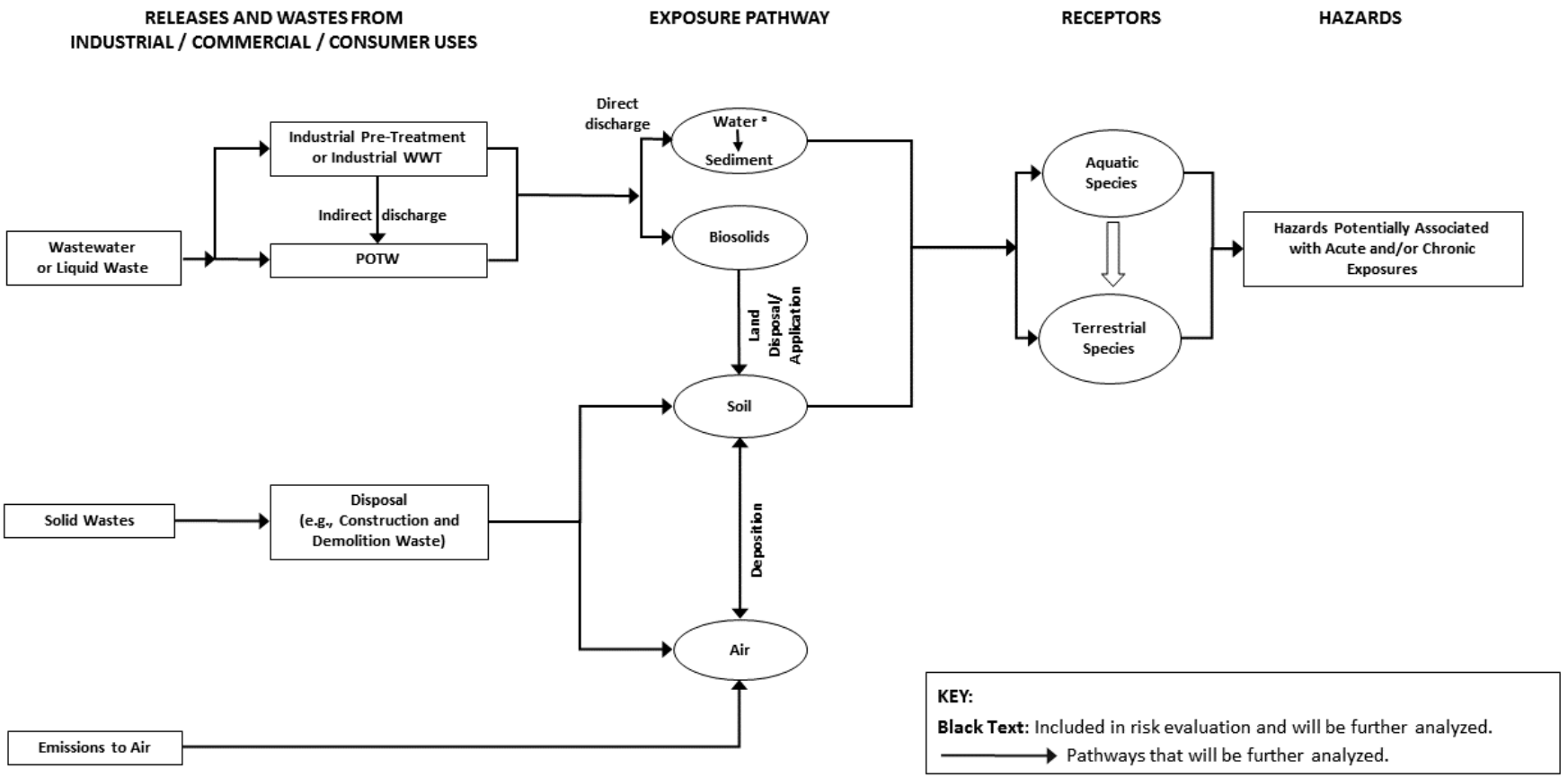

Figure 2-4b. HBCD Conceptual Model for Environmental Releases and Wastes: Ecological Exposures and Hazards

The conceptual model presents the exposure pathways and hazards for environmental receptors from industrial and commercial uses of HBCD.

[a] Industrial wastewater or liquid wastes may be treated on-site and then released to surface water (direct discharge), or pre-treated and released to POTW (indirect discharge). For consumer uses, such wastes may be released directly to POTW (i.e., down the drain).

2.6 Analysis Plan

The analysis plan presented here is a refinement of the initial analysis plan that was published in the Scope of the Risk Evaluation for HBCD (U.S. EPA, 2017e).

The analysis plan is based on the conditions of use of HBCD, as described in Section 2.2 of this problem formulation. EPA is implementing systematic review approach and/or methods to identify, select, assess, integrate and summarize the findings of studies supporting the TSCA risk evaluation. The analytical approaches and considerations in the analysis plan are used to frame the scope of the systematic review activities for this assessment. The supplemental documents, *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018), provides additional information about the criteria, approaches and/or methods that have been and will be applied to the first 10 chemical risk evaluations.

While EPA has conducted a comprehensive search for reasonably available data as described in the Scope of the Risk Evaluation for HBCD (U.S. EPA, 2017e), EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources, that may be relevant for further evaluating conditions of use, exposures, hazards and potentially exposed or susceptible subpopulations during risk evaluation. EPA will continue to consider new information submitted by the public.

During the risk evaluation, EPA will rely on the search results *HBCD (CASRN 25637-99-4, 3194-55-6, 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document*, EPA-HQ-OPPT-2016-0735) or perform supplemental searches to address specific questions. Further, EPA may consider any relevant CBI information in the risk evaluation in a manner that protects the confidentiality of the information from public disclosure. The analysis plan is based on EPA's knowledge of HBCD to date which includes a partial, but not complete review of identified information. Should additional data or approaches become available, EPA may refine its analysis plan based on this information.

2.6.1 Exposure

Based on their physical-chemical properties, expected sources, and transport and transformation within the outdoor and indoor environment chemical substances are more likely to be present in some media and less likely to be present in others. Media-specific levels will vary based on the chemical substance of interest. For some high-priority chemical substances, non-zero background level(s) can be characterized through a combination of available monitoring data and modeling approaches.

Background levels can be used to:

- Better characterize the overall magnitude and distribution of exposures when considered alongside scenario-specific exposures.
- Serve as a comparison or point of reference for scenario-specific exposure estimates.
    - Scenario-specific exposures that are lower than background exposure levels may not need to be further analyzed.
    - Scenario-specific exposures that are approximately the same or higher than background exposure levels warrant further consideration.

For HBCD, EPA plans to analyze background levels for indoor dust, indoor air, ambient air, surface water, sediment, soil, dietary food sources, aquatic biota, and terrestrial biota. EPA has not yet determined the background levels in these media or how they may be used in the risk evaluation.

Exposure scenarios are unique combinations of sources (uses), exposure pathways, and exposed receptors. Draft release/exposure scenarios corresponding to various conditions of use for HBCD are presented in Appendix D. EPA plans to analyze background exposures and scenario-specific exposures.

2.6.1.1 Environmental Releases

EPA expects to analyze releases to environmental media as follows:

1) **Review reasonably available published literature and other reasonably available information on processes and activities associated with the conditions of use to analyze the types of releases and wastes generated.**

   EPA has reviewed some key data sources containing information on processes and activities resulting in releases, and the information found is described in Appendix B. EPA will continue to review data sources identified in Appendix B during risk evaluation using the evaluation strategy for environmental releases and occupational exposure data sources discussed in the *Application of Systematic Review in TSCA Risk Evaluations and Strategy for Assessing Data Quality in TSCA Risk Evaluations* (U.S. EPA, 2018).

   The specific industrial activities that EPA expects to analyze are summarized in Table 2-7 below:

Table 2-7. Summary of Industrial Activities EPA Will Analyze

Life Cycle Stage	Category	Subcategory	Specific Scenarios that EPA will Assess
Manufacture	Import	Repackaging	Import of HBCD as powder or pellets and/or as part of XPS masterbatch, and/or as part of EPS resin beads to a single site and subsequent repackaging of the imported material and its transfer to other sites for the following purposes: 1. The production of XPS master batch at a generic compounding site using the imported HBCD; 2. The production of XPS at a generic site for the manufacture of XPS using the imported HBCD or the imported XPS masterbatch. 3. The production of EPS at a generic site for the manufacture of EPS using the imported EPS resin beads.
Processing	Incorporation into formulation, mixture, or reaction product	Compounding of XPS master batch	The compounding of XPS master batch at a generic site by the processing of imported HBCD

Life Cycle Stage	Category	Subcategory	Specific Scenarios that EPA will Assess
	Incorporation into an article	Manufacture of XPS	The manufacture of XPS at a generic site from the XPS master batch produced at a generic compounding site or the imported HBCD or the imported XPS masterbatch.
		Manufacture of EPS	The manufacture of EPS at a generic site from imported EPS resin beads.
		Manufacture of SIPs and automobile replacement parts from XPS or EPS	The manufacture of SIPs at a generic site.
			The manufacture of replacement automobile parts at a generic site.

EPA will consider using an import volume of up to 100,000 lbs (i.e. the highest CDR reporting threshold) to estimate releases resulting from repackaging of imported product and subsequent processing (i.e., production of XPS master batch, XPS and EPS). EPA will conduct additional data collection to estimate the quantity of the imported HBCD that is used for the manufacture of XPS and EPS, SIPs, and replacement automobile parts.

Furthermore, EPA will further consider whether EPS and XPS, are recycled to produce products that contain HBCD as a flame retardant. If EPA proceeds with the evaluation of any of the recycling processes, then EPA may perform targeted data searches as needed.

2) **Review reasonably available chemical-specific release data, including measured or estimated release data (e.g., data from risk assessments by other environmental agencies).**

There are currently no reported Toxics Release Inventory (TRI) data for HBCD. EPA will review the TRI data for the first reporting year of 2017 when they become available in approximately July 2018. EPA will continue to review relevant data sources as identified in Appendix B during the risk evaluation. EPA will match identified data to applicable conditions of use and identify data gaps where no data are found for particular conditions of use. EPA will assess releases from the specific industrial activities identified above and will compare the results of this assessment with any release data that will reported in the TRI.

Additionally, for conditions of use where no measured data on releases are available, EPA may use a variety of methods including release estimation approaches and assumptions in the Chemical Screening Tool for Occupational Exposures and Releases ChemSTEER (U.S. EPA, 2013).

3) **Review reasonably available measured or estimated release data for surrogate chemicals that have similar uses and physical properties.**

EPA has not identified surrogate chemicals and data that can be used to estimate releases from uses of HBCD. EPA may conduct targeted searches for surrogate data. For example, EPA may search for data on release of chemicals as a result of building demolition and will then evaluate the utility of any such data as surrogate data for release of HBCD due to building demolition.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to the particular risk evaluation.**

This item will be performed after completion of #2 and #3 above. EPA will evaluate relevant data to determine whether the data can be used to develop, adapt or apply models for specific conditions of use (and corresponding release scenarios).

5) **Review and determine applicability of OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios to estimation of environmental releases.**

EPA has identified potentially relevant OECD Emission Scenario Documents (ESDs) and EPA Generic Scenarios (GS) that correspond to some conditions of use; for example, the 2009 ESD on Plastics Additives and the 2011 ESD on Chemical Industry may be useful. EPA will need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed.

EPA Generic Scenarios are available at the following: https://www.epa.gov/tsca-screening-tools/using-predictive-methods-assess-exposure-and-fate-under-tsca#fate.

OECD Emission Scenario Documents are available at the following: http://www.oecd.org/chemicalsafety/risk-assessment/emissionscenariodocuments.htm

EPA was not able to identify release scenarios corresponding to several conditions of use (e.g. recycling, construction and demolition) of products containing HBCD. EPA may conduct industry outreach efforts, or perform supplemental, targeted literature searches to better understand the process steps involved in that condition of use before a release assessment can be made.

6) **Map or group each condition of use to a release assessment scenario(s).**

EPA has identified release scenarios and mapped (i.e. grouped) them to relevant conditions of use as shown in B.2. EPA was not able to identify release scenarios corresponding to some conditions of use (e.g. recycling, construction and demolition). EPA will perform targeted research to understand those uses, which may inform identification of release scenarios. EPA may further refine the mapping/grouping of release scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of evidence of environmental release data.**

EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental release data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.2 Environmental Fate

EPA expects analyze fate and transport in environmental media as follows:

1) **Review reasonably available measured or estimated environmental fate endpoint data collected through the literature search.**

A general overview of persistence and bioaccumulation was presented in the TSCA Work Plan Chemical Problem Formulation and Initial Assessment for HBCD (U.S. EPA, 2015c). Key environmental fate characteristics were included in the Scope of the Risk Evaluation for HBCD (U.S. EPA, 2017e) and in previous assessments of HBCD, including those conducted by the US EPA (U.S. EPA, 2014b, 2008), Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS, 2012b), Environment Canada (Environment Canada, 2011), European Inventory of Existing Commercial Chemical Substances (EINECS, 2008), and the Organization for Economic Cooperation and Development Screening Information Datasets (OECD, 2007b). These information sources will be used as a starting point for the environmental fate assessment. Other sources that will be consulted include those that are identified through the systematic review process. Studies will be evaluated using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018).

If measured values resulting from sufficiently high-quality studies are not available (to be determined through the systematic review process), chemical properties will be estimated using EPI Suite, SPARC, and other chemical parameter estimation models. Estimated fate properties will be reviewed for applicability and quality.

2) **Using measured data and/or modeling, determine the influence of environmental fate endpoints (e.g., persistence, bioaccumulation, partitioning, transport) on exposure pathways and routes of exposure to human and environmental receptors.**

Measured fate data including volatility from water, sorption to organic matter in soil and sediments, aqueous and atmospheric photolysis rates, and aerobic and anaerobic biodegradation rates, along with physical-chemical properties and models such as the EPI Suite™ STP model (which estimates removal in wastewater treatment due to adsorption to sludge and volatilization to air), will be used to characterize the movement of HBCD within and among environmental media and the persistence of HBCD in media.

3) **Evaluate the weight of the evidence of environmental fate data, which include qualitative and quantitative sources of information.**

   EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental fate data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.3 Environmental Exposures

EPA expects to analyze the following in developing its environmental exposure assessment of HBCD:

1) **Review available environmental and biological monitoring data for all media relevant to environmental exposure.**

   For HBCD, environmental media which will be analyzed are sediment, soil, and surface water. In addition, air deposition of HBCD, effluent, landfill leachate, and biosolids may contribute to HBCD levels in sediment, soil, and surface water. Biological media which will be analyzed are targeted species of predatory birds, fish, and invertebrates. Full-text screening is underway, but not yet complete and over 100 monitoring studies have been identified across all media types.

2) **Review reasonably available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.**

   Available environmental exposure models that meet the TSCA Science Standards and that estimate surface water, sediment, and soil concentrations will be analyzed and considered alongside available surface water, sediment, and soil monitoring data to characterize environmental exposures. Modeling approaches to estimate surface water concentrations, sediment concentrations and soil concentrations generally consider the following inputs: direct release into surface water, sediment, or soil, indirect release into surface water, sediment, or soil (i.e., air deposition), fate and transport (partitioning within media) and characteristics of the environment (e.g., river flow, volume of lake, meteorological data).

3) **Review reasonably available biomonitoring data for predatory bird species. Consider whether these data could be used to compare with comparable species or taxa-specific toxicological benchmarks.**

   Predatory bird species that consume fish with elevated levels of HBCD will be analyzed. If species-specific biomonitoring data matches toxicity studies, direct comparisons can be made. EPA will also consider refining data for other species by using body weight of the birds, fish ingestion rate of birds, and typical fish species consumed.

4) **Determine applicability of existing additional contextualizing information for any monitored data or modeled estimates during risk evaluation.**

There have been changes to use patterns of HBCD over the last few years. Monitoring data or modeled estimates will be reviewed to determine how representative they are of ongoing use patterns.

Any studies which relate levels of HBCD in the environment or biota with specific sources or groups of sources will be evaluated.

HBCD has been widely studied with several monitoring studies reporting detected levels in biota and the indoor and outdoor environment. However, many of these monitoring studies do not attempt to describe potential sources or groups of sources that could have resulted in the presence of HBCD in a given media. EPA will evaluate all monitoring studies, and note any monitoring studies that include some description of source attribution.

5) **Group each condition(s) of use to environmental assessment scenario(s).**

Refine and finalize exposure scenarios for environmental receptors by considering unique combinations of sources (use descriptors), exposure pathways including routes, and populations exposed. For HBCD, the following are noteworthy considerations in constructing exposure scenarios for environmental receptors:

- temporal trends in uses and resulting sources of HBCD to the environment over time
- overall persistence in the environment and bioaccumulation into a wide variety of aquatic and terrestrial species
- characterization of background levels in the environment that are not generally attributable to any one use or source
- possible interactions within food-chains and relative contribution of dietary vs. non-dietary sources for predatory animals

6) **Evaluate the weight of evidence of environmental occurrence data and modeled estimates.**

Both environmental occurrence data and modeled estimates will be evaluated by EPA. EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental occurrence data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.4 Occupational Exposures

EPA expects to analyze both worker and occupational non-user exposures as follows:

1) **Review reasonably available exposure monitoring data for specific condition(s) of use.**

No occupational exposure limits have been established or recommended by OSHA or NIOSH. EPA expects to review monitoring data found in published literature including both personal exposure monitoring data (direct exposure) and area monitoring data (indirect exposures). EPA

has identified data sources that contain measured monitoring data and or/estimated data for the various conditions of use (including import and processing of HBCD), for example, HBCD risk assessments published by the European Chemicals Agency, Environment Canada, and Australia's Department of Health. EPA will review these sources and other data sources (as identified in Appendix B) to extract relevant data for consideration and analysis during risk evaluation.

2) **Review reasonably available exposure data for surrogate chemicals that have uses, volatility and chemical and physical properties similar to HBCD.**

   EPA has not identified surrogate chemicals and data that can be used for estimating occupational exposures to HBCD at this time. Based on cursory review of some data sources, EPA does not anticipate a need to identify surrogate data. However, if surrogate data are needed to augment HBCD-specific data, EPA will review literature sources identified and if surrogate data are found, these data will be matched to applicable conditions of use for potentially filling data gaps.

3) **For conditions of use where data are limited or not available, review existing exposure models that may be applicable in estimating exposure levels.**

   EPA has identified potentially relevant OECD ESDs and EPA GS's corresponding to some conditions of use, for example, the 2009 ESD on Plastics Additives and the 2011 ESD on Chemical Industry. EPA will need to critically review these generic scenarios and ESDs to determine their applicability to the conditions of use assessed. EPA was not able to identify release scenarios corresponding to several conditions of use (e.g. recycling, construction and demolition) of products containing HBCD. EPA may conduct industry outreach efforts or perform supplemental, targeted literature searches to better understand the process steps involved in those conditions of use. EPA will consider the applicability of exposure models in the Chemical Screening Tool for Occupational Exposure and Releases [ChemSTEER (U.S. EPA, 2013)] tool that are routinely used for assessing new chemicals to assess inhalation exposures during various conditions of use. EPA may also need to perform targeted research to identify other models that EPA could use to estimate exposures for certain conditions of use.

4) **Review reasonably available data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario.**

   This step will be performed after Steps #2 and #3 are completed. Based on information developed from Steps #2 and #3, EPA will evaluate relevant data to determine whether the data can be used to develop, adapt, or apply models for specific conditions of use (and corresponding exposure scenarios).

5) **Consider and incorporate applicable engineering controls and/or personal protective equipment into exposure scenarios.**

   EPA will review potentially relevant data sources on engineering controls and personal protective equipment as identified in Appendix B to determine their applicability and incorporation into exposure scenarios during risk evaluation.

6) **Map or group each condition of use to occupational exposure assessment scenario(s).**

EPA has identified occupational exposure scenarios and mapped them to relevant conditions of use (see B.2). As presented in the fourth column in Table_Apx C-1. Worker and Occupational Non-User Exposure Conceptual Model Supporting Table, EPA has grouped the scenarios into 8 representative release/exposure scenarios of which 7 will be further analyzed. EPA was not able to identify occupational scenarios corresponding to some conditions of use (e.g. recycling, construction and demolition). EPA may further refine the mapping/grouping of occupational exposure scenarios based on factors (e.g., process equipment and handling, magnitude of production volume used, and exposure/release sources) corresponding to conditions of use as additional information is identified during risk evaluation.

7) **Evaluate the weight of the evidence of occupational exposure data, which may include qualitative and quantitative sources of information.**

EPA will rely on the weight of the scientific evidence when evaluating and integrating occupational data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.5 Consumer Exposures

EPA expects to analyze both consumers using a consumer product and bystanders associated with the consumer using the product as follows:

1) **Group each condition of use to consumer exposure assessment scenario(s).**

Refine and finalize exposure scenarios for consumers by considering unique combinations of sources (ongoing consumer uses), exposure pathways including routes, and exposed populations.

For HBCD, the following are noteworthy considerations in constructing consumer exposure scenarios:

- reasonably available information on sources including the concentration of HBCD in newly made or recycled consumer products and articles including temporal trends associated with such information;
- information characterizing the release potential of HBCD from products and articles into the indoor environment through diffusion from materials to air, physical abrasion, direct transfer to dust, or leaching into sweat, and skin oil;
- populations who may be more greatly exposed to products, including potentially exposed and susceptible subpopulations such as infants, children, pregnant women; and,
- the associated exposure setting and route for exposed populations.

2) **Evaluate the relative potential of indoor exposure pathways based on available data.**

Indoor exposure pathways expected to be relatively higher include dust ingestion and mouthing of products. Indoor exposure pathways expected to be relatively lower include inhalation of indoor air, dermal contact with dust and articles. The data sources associated with these respective pathways have not been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

3) **Review existing indoor exposure models that may be applicable in estimating indoor air, indoor dust concentrations, or indoor dust surface loadings.**

Indoor exposure models that estimate emission and migration of SVOCs into the indoor environment are available. These models generally consider mass transfer as informed by the gas-phase mass transfer coefficient, the solid-phase diffusion coefficient, and the material-air partition coefficient. In addition, direct transfer to surface dust or physical abrasion may influence emissions over time. These properties vary based on physical-chemical properties and properties of the material. OPPT's Indoor Environmental Concentrations in Buildings with Conditioned and Unconditioned Zones (IECCU) model and other similar models can be used to estimate indoor air and dust exposures from indoor sources.

4) **Review reasonably available empirical data that may be used in developing, adapting or applying exposure models to a particular risk evaluation scenario. For example, existing models developed for a chemical assessment may be applicable to another chemical assessment if model parameter data are available.**

To the extent other organizations have already modeled an HBCD consumer exposure scenario that is relevant to OPPT's assessment, EPA will evaluate those modeled estimates. In addition, if other chemicals similar to HBCD have been modeled for similar uses, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

5) **Review reasonably available consumer product-specific sources to determine how those exposure estimates compare with each other and with indoor monitoring data reporting HBCD in specific media (e.g., dust or indoor air).**

The availability of HBCD concentration for various ongoing uses will be evaluated. This data provides the source term for any subsequent indoor modeling. Source attribution between overall indoor air and dust levels and various indoor sources will be analyzed.

6) **Review reasonably available population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further refined.**

For HBCD, exposure scenarios that involve potentially exposed and susceptible subpopulations will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations. For example, children spend different amounts of time in microenvironments throughout the day.

7) **Evaluate the weight of the evidence of consumer exposure estimates based on different approaches.**

EPA will rely on the weight of the scientific evidence when evaluating and integrating data related to consumer exposure. The weight of the evidence may include qualitative and quantitative sources of information. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.1.6 General Population

EPA expects to analyze general population exposures as follows:

1) **Refine and finalize exposure scenarios for general population by considering unique combinations of sources and uses, exposure pathways including routes, and exposed populations.**

For HBCD, the following are noteworthy considerations in constructing exposure scenarios for the general population:

- temporal trends in uses and resulting sources/releases of HBCD to the environment over time;
- overall persistence in the environment and bioaccumulation into a wide variety of aquatic and terrestrial species relevant to human consumption;
- characterization of background levels in the environment that are not generally attributable to any one condition of use or source; and,
- consideration of spatial differences between populations located near industrial point sources and those exposed at lower background levels.
- releases to the environment. For HBCD, TRI releases are expected to be reported for 2017. These releases are not yet linked to a specific lifecycle stage and use. Approaches for estimating exposures from the conditions of use as they relate to the reported TRI emissions will be further explored.

EPA plans to evaluate a variety of data types to determine which types are most appropriate when quantifying exposure scenarios. Environmental monitoring data, biomonitoring data, modeled estimates, experimental data, epidemiological data, and survey-based data can all be used to quantify exposure scenarios. In an effort to associate exposure estimates with sources of exposure and/or conditions of use, EPA will consider source apportionment across exposure scenarios during risk evaluation. EPA anticipates that there will be a wide range in the relative exposure potential of the exposure scenarios identified in Appendix C. Source apportionment characterizes the relative contribution of any of the following: a use/source toward a total media concentration, a media concentration toward a total exposure route, or an exposure route toward a total external or internal dose. This consideration may be qualitative, semi-quantitative, or quantitative, and is dependent upon available data and approaches. For example, EPA may consider the co-location of TSCA industrial facilities with available monitoring data or modeled estimates. EPA may compare modeled estimates for discrete outdoor and indoor sources/uses that apply to unique receptor groups. If available, EPA will compare multiple scenario-specific

and background exposure doses estimated from media-specific concentrations and exposure factors with available biomonitoring data. The forward-calculated and back-calculated exposures could be compared to characterize the relative contribution from defined exposure scenarios.

After refining and finalizing exposure scenarios, EPA will quantify concentrations and/or doses for these scenarios. The number of scenarios will depend on how unique combinations of uses, exposure pathways, and receptors are characterized. The number of scenarios is also dependent upon the available data and approaches to quantify scenarios. When quantifying exposure scenarios, EPA plans to use a tiered approach. First-tier analysis is based on data that is readily available without a significant number of additional inputs or assumptions, and may be qualitative, semi-quantitative, or quantitative. First-tier analyses were conducted during problem formulation and are expected to continue during risk evaluation. The results of first tier analyses inform whether scenarios require more refined analysis. Refined analyses will be iterative, and require careful consideration of variability and uncertainty. Should data become available that summarily alters the overall conclusion of a scenario through iterative tiering, EPA can refine its analysis during risk evaluation.

2) **Review available environmental and biological monitoring data for exposure pathways and media to which general population exposures are expected.**

   General population exposure pathways expected to be relatively higher include: dietary ingestion for lipid rich food sources, soil ingestion, sediment ingestion, and inhalation of suspended particles. General population exposure pathways expected to be relatively lower include: drinking water, dietary ingestion for non-lipid rich food sources, incidental ingestion of surface water and suspended particulates during recreation, and dermal contact with particles. In addition, dust ingestion is an important pathway that will be considered for consumer exposure as well for general population exposure. The data sources associated with these respective pathways have not been comprehensively evaluated, so quantitative comparisons across exposure pathways or in relation to toxicity thresholds are not yet available.

3) **For exposure pathways where empirical data is not available, review existing exposure models that may be applicable in estimating exposure levels.**

   For HBCD, media where exposure models will be considered for general population exposure include models that estimate ambient air concentrations, surface water concentrations, sediment concentrations, soil concentrations, and uptake from aquatic and terrestrial environments into edible aquatic and terrestrial organisms.

4) **Consider and incorporate applicable media-specific regulations into exposure scenarios or modeling approaches.**

5) **Review available exposure modeled estimates. For example, existing models developed for a previous HBCD chemical assessment may be applicable to EPA's assessment. In addition, another chemical's assessment may also be applicable if model parameter data are available.**

To the extent other organizations have already modeled an HBCD general population exposure scenario that is relevant to OPPT's assessment, EPA will evaluate those modeled estimates. In addition, if modeled estimates for other chemicals with similar physical chemical properties and similar uses are available, those modeled estimates will also be evaluated. The underlying parameters and assumptions of the models will also be evaluated.

6) **Review available information on releases to determine how modeled estimates of concentrations near industrial point sources compare with available monitoring data.**

The expected releases from industrial facilities are changing over time. Any modeled concentrations based on recent release estimates will be carefully compared with available monitoring data to determine representativeness.

7) **Review available information about population- or subpopulation-specific exposure factors and activity patterns to determine if potentially exposed or susceptible subpopulations need to be further defined (e.g., early life and/or puberty as a potential critical window of exposure).**

For HBCD, exposure scenarios that involve potentially exposed and susceptible subpopulations will consider age-specific behaviors, activity patterns, and exposure factors unique to those subpopulations. For example, children will have different intake rates for dust, soil, and diet than adults.

8) **Evaluate the weight of the evidence of general population exposure estimates based on different approaches.**

EPA will rely on the weight of the scientific evidence when evaluating and integrating data related to general population exposures. The weight of the evidence may include qualitative and quantitative sources of information. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

2.6.2 Hazards (Effects)

2.6.2.1 Environmental Hazards

EPA will conduct an environmental hazard assessment of HBCD as follows:

1) **Review reasonably available environmental hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; in vitro studies).**

- Environmental hazard data will be evaluated using the ecological toxicity data quality criteria outlined in the *Application of Systematic Review in TSCA Risk Evaluations* document. The study evaluation results will be documented in the risk evaluation phase and data from suitable studies will be extracted and integrated in the risk evaluation process.

- Conduct hazard identification (the qualitative process of identifying acute and chronic endpoints) and concentration-response assessment (the quantitative relationship between hazard and exposure) for all identified environmental hazard endpoints. Suitable environmental hazard data will be reviewed for acute and chronic endpoints for mortality and other effects (e.g. growth, immobility, reproduction, etc.). EPA will evaluate the character of the concentration-response relationship (*i.e.* positive, negative or no response) as part of the review.

2) Derive aquatic and terrestrial concentrations of concern (COC) for acute and, where possible, chronic endpoints.

The aquatic environmental hazard studies may be used to derive acute and chronic concentrations of concern (COC) for mortality, behavioral, developmental and reproductive or other endpoints determined to be detrimental to environmental populations. Depending on the robustness of the evaluated data for a particular organism (*e.g.* aquatic invertebrates), environmental hazard values (e.g. EC_x/LC_x/NOEC/LOEC, etc.) may be derived and used to further understand the hazard characteristics of HBCD to aquatic species.

3) Evaluate the weight of the evidence of environmental hazard data.

EPA will rely on the weight of the scientific evidence when evaluating and integrating environmental hazard data. The data integration strategy will be designed to be fit-for-purpose. EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

4) Consider the route(s) of exposure, available biomonitoring data and available approaches to integrate exposure and hazard assessments.

- Based on the physical-chemical and fate properties (low water solubility and high absorption), EPA plans to consider the aquatic, sediment and terrestrial pathways in the HBCD conceptual model. These organisms are likely to be exposed to HBCD in liquid waste from industrial wastewater treatment facility, municipal and hazardous waste landfills and incineration of municipal hazardous waste pathways. These pathways can result in groundwater and eventually surface water exposure to terrestrial, aquatic and sediment organisms.
- EPA plans to consider benthic and pelagic species in the HBCD conceptual model. HBCD exposure from POTWs can affect these organisms and trophic magnification could result from over exposure following bioaccumulation of HBCD.
- EPA plans to consider soil organisms in the HBCD conceptual model. Land application of biosolids containing HBCD could transfer to soil thus exposing terrestrial organisms.

5) Conduct an ecological risk characterization of HBCD.

EPA plans to conduct a risk characterization of HBCD to determine whether there are risks to the aquatic and/or terrestrial environments from the measured levels of HBCD found in wastewater,

surface water, sediment or soil. The data for environmental monitoring and toxicity will be used in this risk assessment to determine if:

- The acute exposure to levels of HBCD measured in wastewater in the US pose risks for adverse effects in aquatic invertebrates, fish, or plants.
- The chronic exposure to levels of HBCD measured in surface water in the US pose risks for adverse effects in aquatic invertebrates, fish, or plants or terrestrial species.
- The chronic exposure to levels of HBCD measured in sediment in the US pose risks for adverse effects in sediment-dwelling invertebrates.

Environmental risk will be characterized by calculating risk quotients (RQs) (U.S. EPA, 1998; Barnthouse et al., 1982). The COCs derived from aquatic and terrestrial organisms hazard data will be used to calculate RQs. The environmental concentration for each compartment (i.e., wastewater, surface water, sediment, soil) will be based on measured and modeled concentrations of HBCD.

6) Conduct a Persistent, Bioaccumulative, and Toxic (PBT) Assessment of HBCD.

EPA will assess the persistence, bioaccumulation, and toxic (PBT) potential of HBCD in accordance with U.S. EPA Final Water Quality Guidance for Great Lakes System (U.S. EPA, 1995). EPA will assess the available studies collected from the systematic review process relating to bioaccumulation and bioconcentration (BAF/BCF) of HBCD. In addition, EPA will integrate traditional environmental hazard endpoint values (e.g., LC_{50}, LOEC) and exposure concentrations (e.g., surface water concentrations, tissue concentrations) for HBCD with the fate parameters (BAF/BCF/BMF/TMF).

2.6.2.2 Human Health Hazards

EPA expects to analyze human health hazards as follows:

1) Review reasonably available human health hazard data, including data from alternative test methods (e.g., computational toxicology and bioinformatics; high-throughput screening methods; data on categories and read-across; *in vitro* studies; systems biology).

Human health studies will be evaluated using the evaluation strategies laid out in the *Application of Systematic Review in TSCA Risk Evaluations* (U.S. EPA, 2018). For the HBCD risk evaluation, EPA will evaluate information in the *Preliminary Materials for the IRIS Toxicological Review of HBCD* (U.S. EPA, 2014d), *Strategy for Conducting Literature Searches for Cyclic Aliphatic Bromine Cluster (HBCD): Supplemental Document to the TSCA Scope Document*,(U.S. EPA, 2017f, 2002), and studies published after 2015 that were captured in the comprehensive literature search conducted by the agency for HBCD (*Cyclic Aliphatic Bromides Cluster (HBCD) (CASRN: 25637-99-4; 3194-55-6; 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document* (U.S. EPA, 2017b) using OPPT's structured process described in the document, *Application of Systematic Review in TSCA Risk Evaluations*.

Mechanistic data may include analyses of alternative test data such as novel *in vitro* test methods and high throughput screening. The association between acute and chronic exposure scenarios to

the agent and each health outcome will also be integrated. Study results will be extracted and presented in evidence tables or another appropriate format by organ/system.

2) **In evaluating reasonably available data, determine whether particular human receptor groups may have greater susceptibility to the chemical's hazard(s) than the general population.**

Reasonably available human health hazard data will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to HBCD hazard(s). Susceptibility of particular human receptor groups to HBCD will be determined by evaluating information on factors that influence susceptibility.

EPA has reviewed some sources containing hazard information associated with susceptible populations and lifestages such as pregnant women and infants. Pregnancy (i.e., gestation) and childhood are potential susceptible lifestages for HBCD exposure. The document *Cyclic Aliphatic Bromides Cluster (HBCD) (CASRN: 25637-99-4; 3194-55-6; 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document* (U.S. EPA, 2017b) contains a list of studies that will be evaluated to ascertain whether some human receptor groups may have greater susceptibility than the general population to HBCD's hazard(s). Also, EPA/OPPT will further examine the availability of any new chemical-specific information on susceptible populations or the distribution of susceptibility in the general population since the TSCA Work Plan Problem Formulation and Initial Assessment (U.S. EPA, 2015c) and their impact in decreasing or increasing the default uncertainty factors for variability. EPA will review the current state of the literature since the TSCA Work Plan Problem Formulation and Initial Assessment (U.S. EPA, 2015c) in order to potentially quantify these differences for risk evaluation purposes.

3) **Conduct hazard identification (the qualitative process of identifying non-cancer and cancer endpoints) and dose-response assessment (the quantitative relationship between hazard and exposure) for identified human health hazard endpoints.**

Human health hazards from acute and chronic exposures will be identified by evaluating the human and animal data that meet the systematic review data quality criteria described in the *Application of Systematic Review in TSCA Risk Evaluations* document (U.S. EPA, 2018). Data quality evaluation will be performed on key studies identified from the TSCA Work Plan Problem Formulation and Initial Assessment (U.S. EPA, 2015c), *Preliminary Materials for the IRIS Toxicological Review of HBCD* (U.S. EPA, 2014d), *Strategy for Conducting Literature Searches for Cyclic Aliphatic Bromine Cluster (HBCD): Supplemental Document to the TSCA Scope Document*,(U.S. EPA, 2017f, 2002), and studies published after 2015 that were captured in the comprehensive literature search conducted by the agency for HBCD (*Cyclic Aliphatic Bromides Cluster (HBCD) (CASRN: 25637-99-4; 3194-55-6; 3194-57-8) Bibliography: Supplemental File for the TSCA Scope Document;* (U.S. EPA, 2017b). Hazards identified by studies meeting data quality criteria will be grouped by routes of exposure relevant to humans (oral, dermal, inhalation) and by cancer and noncancer endpoints.

Dose-response assessment will be performed in accordance with EPA guidance (U.S. EPA, 2012a, 2011, 1994). Dose-response analyses may be used if the data meet data quality criteria

and if additional information on the identified hazard endpoints are not available or would not alter the analysis.

The cancer mode of action (MOA) determines how cancer risks can be quantitatively evaluated. If cancer hazard is determined to be applicable to HBCD, EPA will evaluate information on genotoxicity and the mode of action for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the U.S. EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005).

4) **Derive points of departure (PODs) where appropriate; conduct benchmark dose modeling depending on the available data. Adjust the PODs as appropriate to conform (e.g., adjust for duration of exposure) to the specific exposure scenarios evaluated.**

Hazard data will be evaluated to determine the type of dose-response modeling that is applicable. Where modeling is feasible, a set of dose-response models that are consistent with a variety of potentially underlying biological processes will be applied to empirically model the dose-response relationships in the range of the observed data consistent with the EPA *Benchmark Dose Technical Guidance Document*. Where dose-response modeling is not feasible, NOAELs or LOAELs will be identified. Non-quantitative data will also be evaluated for contribution to weight of evidence or for evaluation of qualitative endpoints that are not appropriate for dose-response assessment.

EPA will evaluate whether the available PBPK and empirical kinetic models are adequate for route-to-route and interspecies extrapolation of the POD, or for extrapolation of the POD to standard exposure durations (e.g., lifetime continuous exposure). If application of the PBPK model is not possible, oral PODs may be adjusted by $BW^{3/4}$ scaling in accordance with U.S. EPA (2011), and inhalation PODs may be adjusted by exposure duration and chemical properties in accordance with U.S. EPA (1994).

5) **Evaluate the weight of the evidence of human health hazard data.**

EPA will rely on the weight of the scientific evidence when evaluating and integrating human health hazard data. The data integration strategy will be designed to be fit-for-purpose in which EPA will use systematic review methods to assemble the relevant data, evaluate the data for quality and relevance, including strengths and limitations, followed by synthesis and integration of the evidence.

6) **Consider the route(s) of exposure (oral, inhalation, dermal), available route-to-route extrapolation approaches, available biomonitoring data and available approaches to correlate internal and external exposures to integrate exposure and hazard assessment.**

At this stage of review, EPA believes there will be sufficient data to conduct dose-response analysis and/or benchmark dose modeling for the oral route of exposure. EPA will also evaluate any potential human health hazards following dermal and inhalation exposure to HBCD, which could be important for worker, consumer, and general population risk analysis. Available data will be assessed to determine whether or not a point of departure can be identified for the dermal

and inhalation routes. This may include using route-to-route extrapolation methods where appropriate, and depending on the nature of available data.

If sufficient toxicity studies are not identified in the literature search to assess risks from dermal and inhalation exposures, then a route-to-route extrapolation from oral toxicity studies would be needed to assess systemic risks from dermal or inhalation exposures. Without an adequate PBPK model, the approaches described in the EPA guidance document *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)* (U.S. EPA, 2004) could be applied to extrapolate from oral to dermal exposure. These approaches may be able to further inform the relative importance of dermal exposures compared with other routes of exposure. Similar methodology may also be used for assessing inhalation exposures.

2.6.3 Risk Characterization

Risk characterization is an integral component of the risk assessment process for both ecological and human health risks. EPA will derive the risk characterization in accordance with EPA's *Risk Characterization Handbook* (U.S. EPA, 2000). As defined EPA's Risk Characterization Policy, "the risk characterization integrates information from the preceding components of the risk evaluation and synthesizes an overall conclusion about risk that is complete, informative and useful for decision makers." Risk characterization is considered to be a conscious and deliberate process to bring all important considerations about risk, not only the likelihood of the risk but also the strengths and limitations of the assessment, and a description of how others have assessed the risk into an integrated picture.

Risk characterization at EPA assumes different levels of complexity depending on the nature of the risk assessment being characterized. The level of information contained in each risk characterization varies according to the type of assessment for which the characterization is written. Regardless of the level of complexity or information, the risk characterization for TSCA risk evaluations will be prepared in a manner that is transparent, clear, consistent, and reasonable (TCCR) (U.S. EPA, 2000). EPA will also present information in this section consistent with approaches described in the Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726). For instance, in the risk characterization summary, EPA will further carry out the obligations under TSCA section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. EPA will also be guided by EPA's Information Quality Guidelines (U.S, 2002) as it provides guidance for presenting risk information. Consistent with those guidelines, in the risk characterization, EPA will also identify: (1) Each population addressed by an estimate of applicable risk effects; (2) the expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected; (3) each appropriate upper-bound or lower bound estimate of risk; (4) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) peer reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

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APPENDICES

Appendix A REGULATORY HISTORY

The chemical substance, HBCD, is subject to federal and state laws and regulations in the United States. The federal laws and regulations applicable to HBCD are listed along with the regulating agencies below in Table_Apx A-1. States also regulate HBCD through state laws and regulations, which are also listed within this section in Table_Apx A-2.

A.1 Federal Laws and Regulations

Table_Apx A-1. Federal Laws and Regulations

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
Toxic Substances Control Act (TSCA) – Section 5(a)	Once EPA determines that a use of a chemical substance is a significant new use under TSCA section 5(a), persons are required to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use.	In September 2015, EPA promulgated a SNUR to designate manufacture or processing of HBCD for use as a flame retardant in consumer textiles (apart from use in motor vehicles) as a significant new use. Manufacturers (which includes importers) and processors are required to notify EPA 90 days before commencing the activity (80 FR 57293, September 23, 2015).
TSCA – Section 6(b)	EPA is directed to identify and begin risk evaluations on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.	Cyclic Aliphatic Bromide Cluster (HBCD) is on the initial list of chemicals to be evaluated for unreasonable risk under TSCA (81 FR 91927, December 19, 2016).
TSCA – Section 8(a)	The TSCA section 8(a) CDR Rule requires manufacturers (including importers) to give EPA basic exposure-related information on the types, quantities and uses of chemical substances produced domestically and imported into the United States.	HBCD manufacturing (including importing), processing, and use information is reported under the CDR rule (76 FR 50816, August 16, 2011)
TSCA – Section 8(b)	EPA must compile, keep current and publish a list (the TSCA Inventory) of each chemical	HBCD (CASRN 25637-99-4 and CASRN 3194-55-

Statutes/Regulations	Description of Authority/Regulation	Description of Regulation
	substance manufactured, processed or imported into the United States.	6) was on the initial TSCA Inventory and therefore was not subject to EPA's new chemicals review process (60 FR 16309, March 29, 1995).
Emergency Planning and Community Right-to-Know Act (EPCRA) – Section 313	Requires annual reporting from facilities in specific industry sectors that employ 10 or more full-time equivalent employees and that manufacture, process or otherwise use a TRI-listed chemical in quantities above threshold levels.	EPA listed HBCD on the TRI under 81 FR 85440 effective November 28, 2016. The first TRI reporting deadline for HBCD is July 1, 2018.

A.2 State Laws and Regulations

Table_Apx A-2. State Laws and Regulations

State Actions	Description of Action
Classification of HBCD as Chemical of Concern to Children; law requiring reporting by manufacturers	Maine classifies HBCD as a chemical of high concern (Maine 38 M.R.S.A. § 1693-A(1)) Maine requires manufacturers or distributers to report the use of deca BDE and/or hexabromocylododecane, when intentionally added to certain children's products which are sold in the State of Maine. The first reporting deadline was August 31, 2017. (Rule Chapter 889) http://www.maine.gov/dep/safechem/
	Minnesota classifies HBCD as a chemical of high concern (Toxic Free Kids Act Minn. Stat. 2010 116.9401-116.9407)
	Oregon's Toxic-Free Kids Act requires manufacturers of children's products sold in Oregon to report products containing HBCD or other high priority chemicals of concern for children's health if found at or above specific levels in those products. Ultimately, manufacturers are to remove these chemicals from certain products or seek a waiver. Products that fall under this law are those that are marketed to or intended for children. The first deadline for providing notice was January 2018.
	Washington requires manufacturers of children's products sold in Washington to report if their product contains certain chemicals of high concern to children, including HBCD. The law also bans from manufacture or sale, in the state, children's products or residential upholstered furniture containing >1,000 ppm of five flame retardants, including HBCD (Wash. Admin. Code § 173-334-130)

State Actions	Description of Action
Other	In California, HBCD is listed as an initial informational candidate under California's Safer Consumer Products regulations, on the state's Proposition 65 list (Cal. Code Regs, tit. 22, § 69502.3, subd. (a))
	California lists HBCD as a designated priority chemical for biomonitoring. However, California has not yet started biomonitoring HBCD. (California SB 1379)
	The Oregon Department of Environmental Quality lists HBCD as a priority persistent pollutant and publishes use, exposure pathways and release data for HBCD (Oregon SB 737)
	In Massachusetts, HBCD will be reportable under the Toxics Use Reduction Act beginning in reporting year 2018. (300 CMR 41.00)

A.3 International Laws and Regulations

Table_Apx A-3. Regulatory Actions by other Governments and Tribes

Country/Organization	Requirements and Restrictions
Canada	In October 2016, the Regulations Amending the Prohibition of Certain Toxic Substances Regulations, 2012 (the Amendments) were published in the Canada Gazette, Part II: Vol. 150, No. 20 - October 5, 2016 and will come into force in December 2016. The Amendments include controls on HBCD that prohibit HBCD and certain products containing the substance. Time-limited exemptions for certain uses are included to allow industry to phase-out their use of HBCD. (Government of Canada)
European Union	HBCD is listed as a substance of very high concern (SVHC) and it is also listed under Annex XIV (Authorisation list) of European Union's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). After August 21, 2015, only persons with approved authorization applications may continue to use the chemical (European Chemicals Agency)
	The Waste Electrical and Electronic Equipment (WEEE) directive in the European Union requires the separation of plastics containing brominated flame retardants prior to recycling (European Commission WEEE).
Japan	HBCD is subject to mandatory reporting requirements in Japan under the Chemical Substances Control Law (CSCL); specifically, Japan requires type III monitoring for all substances that may interfere with the survival and/or growth of flora and fauna (Ministry of Economy, Trade and Industry Japan).

Country/Organization	Requirements and Restrictions
Stockholm Convention on POPs	In May 2013, HBCD was added to the United Nation's Stockholm Convention list of POPs with specific exemptions for production and use in EPS or XPS in buildings. As required by the convention, Parties that use these exemptions must register with the secretariat and the exemptions, unless extended in accordance with the obligations of the Convention, expire five years from after the date of entry into force of the Convention with respect to the particular chemical (SCCH, 2018b).

Appendix B PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION

This appendix provides information and data found in preliminary data gathering for HBCD.

B.1 Process Information

Process-related information potentially relevant to the risk evaluation may include process diagrams, descriptions and equipment. Such information may inform potential release sources and worker exposure activities.

B.1.1 Manufacture (Including Import)

B.1.1.1 Import

EPA has not identified specific activities related to the import of HBCD at this time. EPA anticipates that imported chemicals are often stored in warehouses prior to distribution for further processing and use. In some cases, the chemicals may be repackaged into differently sized containers, depending on customer demand, and quality control (QC) samples may be taken for analyses.

B.1.2 Processing and Distribution

B.1.2.1 Incorporated into a Formulation, Mixture or Reaction Product

Incorporation into a formulation, mixture or reaction product refers to the process of mixing or blending of several raw materials to obtain a single product or preparation. HBCD may undergo several processing steps and the processing is dependent on its downstream incorporation into articles, which is discussed in the next subsection. EPA identified the following processing activities for HBCD.

Compounding into XPS Masterbatch

HBCD is compounded into an XPS masterbatch prior to being sold to XPS plastic converters, who then convert the XPS into a final article. Compounding likely occurs in a partially open process using extruders. In extruders, blends of polymer, additives and/or masterbatch are mixed either in the hopper or in tumblers and then fed into an extruder comprising one or two screws. These both shear the material and transport it through a heating regime. Volatile emissions may be produced and these are vented at various points in the extruder barrel (OECD, 2004). The compounded masterbatch may be converted into a final extrudate; however, EPA expects that the masterbatch is sent to industrial customers for further processing into a final article. HBCD concentration in the masterbatch is expected to be 50-70% (EINECS, 2008).

B.1.2.2 Incorporated into an Article

Incorporation into an article typically refers to a process in which a chemical becomes an integral component of an article (as defined at 40 CFR 704.3) for distribution in commerce. Exact process operations involved in the incorporation of HBCD-containing formulations or reaction products are dependent on the article. EPA identified the following processing activities that incorporate HBCD and HBCD formulations or reaction products into articles.

EPS resin beads are converted into EPS products by expansion and then molding into rigid closed-cell foam. Once expanded, the beads are fused in a steam heated mold to form a specific shape or can be formed in a billet or block that can be hot-wire cut to its desired shape and size by users (Priddy, 2006).

HBCD powder or granules are incorporated into XPS products by extrusion. The HBCD powder or granules are unloaded into a hopper and fed into an extruder along with polystyrene resin, a blowing agent and other ingredients. A viscous plastic fluid is formed in the extruder and is discharged under pressure through a die onto a moving belt at ambient conditions. The blowing agent vaporizes, causing the polymer to expand into a desired shape or form, most likely continuous sheets (boards) of closed cell insulation. Alternatively, a vacuum is used in addition to the blowing agent to cause polymer expansion. XPS masterbatch is similarly converted into XPS products (NICNAS, 2012b; EINECS, 2008; Suh, 2000).

B.1.2.3 Recycling

As stated in Section 2.2.2, construction insulation materials are rarely recycled for numerous reasons, including that insulation waste is typically not separated from mixed waste stream. However, reuse and recycle does occur in the United States. At the end-of-life, polystyrene insulation boards (i.e., EPS and XPS foam insulation containing HBCD) may still have beneficial value for insulation. The insulation can be removed in whole and reused in the same capacity. Polystyrene insulation may also be demolished, melted and reformed into new insulation materials boards or other applications. Typically, polystyrene insulation containing HBCD can only be recycled into building insulation or other building applications (U.S. EPA, 2014a).

Electronic products (which may or may not contain HBCD) can also be recycled. HIPS materials constitute more than half the plastic materials recovered from household electronics (Borchardt, 2006). No information was identified that further described the processes used in recovering the plastics from electronics and how those plastics are reprocessed into other products.

B.1.3 Uses

B.1.3.1 Building/Construction Materials

A major use of HBCD is in XPS and EPS foam for continuous insulation applications such as in walls and roofs on the exterior of buildings, ceilings and subfloor systems. The materials may be incorporated into building products such as structural insulated panels or insulating concrete forms or used in other below grade or geotechnical applications for foundations or highways or for dimensional stability or strength applications (e.g., insulated cold storage applications) (U.S. EPA, 2017g, 2014a; NICNAS, 2012b).

B.1.4 Disposal

Releases from industrial sites to surface water (via direct discharge or indirect discharge through POTWs), air and landfill are expected during manufacture, processing, use, product usage and disposal of HBCD or products containing HBCD (U.S. EPA, 2014a; NICNAS, 2012b; Environment Canada, 2011; EINECS, 2008).

Demolished building materials are classified as Construction and Demolition (C&D) waste, which may be disposed in municipal solid waste landfills (MSWLFs) or C&D landfills (U.S. EPA, 2014a). XPS foam may also be disposed of via waste energy plants.

B.2 Sources Containing Potentially Relevant Data or Information

Some sources of information and data related to releases and worker exposure were found during the systematic review literature search. Sources of data or information identified in the Analysis Plan Sections 2.6.1.1 and Section 2.6.1.4 are shown in the four tables below. The data sources identified are based on preliminary results to date of the full-text screening step of the systematic review process. Further screening and quality evaluation are on-going. These sources will be reviewed to determine the utility of the data and information in the Risk Evaluation.

Table_Apx B-1. Potentially Relevant Data Sources for Information Related to Process Description

Bibliography	url
NICNAS (2001). Polybrominated flame retardants (PBFRs): Priority existing chemical assessment report no. 20.	NICNAS (2001)
NICNAS (2012). Hexabromocyclododecane: Priority existing chemical assessment report no. 34. Australia.	NICNAS (2012b)
Zhang, H., et al. (2012). "Co-release of hexabromocyclododecane (HBCD) and Nano- and microparticles from thermal cutting of polystyrene foams." Environmental Science and Technology **46**(20): 10990-10996.	Zhang et al. (2012)
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Li, L., et al. (2016). "Long-term emissions of hexabromocyclododecane as a chemical of concern in products in China." Environment International **91**: 291-300.	Li et al. (2016)
OECD (2009). Emission scenario documents on coating industry (paints, lacquers and varnishes). Paris, France.	OECD (2009)
OECD (2015). Emission scenario document on use of adhesives. Paris, France.	OECD (2015)
ToxNet Hazardous Substances Data Bank (2017). HSDB: 1,2,5,6,9,10-Hexabromocyclododecane. Bethesda, MD, National Institute of Health, U.S. National Library of Medicine.	ToxNet Hazardous Substances Data Bank (2017)
ECHA (2008). Risk assessment: hexabromocyclododecane. Helsinki, Finland.	ECHA (2008)
ECHA (2014). Template for third party submission of information on alternatives for applications for authorisation HBCD use in EPS for building applications. Helsinki, Finland.	ECHA (2014)
INEOS Styrenics (2017). Analysis of alternatives: HBCDD use in EPS for building applications. Helsinki, Finland, European Chemicals Agency.	INEOS Styrenics (2017)
ECHA (2017). Hexabromocyclododecane, Part 2. Helsinki, Finland.	ECHA (2017d)
European Flame Retardants Association (2016). Fireaway! the EFRA newsletter.	European Flame Retardants Association (2016)

Table_Apx B-2. Potentially Relevant Data Sources for Measured or Estimated Release Data

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Gorga, M., et al. (2013). "Determination of PBDEs, HBB, PBEB, DBDPE, HBCD, TBBPA and related compounds in sewage sludge from Catalonia (Spain)." Science of the Total Environment **444**: 51-59.	Gorga et al. (2013)
Tomko, G. and K. M. Mcdonald (2013). "Environmental fate of hexabromocyclododecane from a new Canadian electronic recycling facility." Journal of Environmental Management **114**: 324-327.	Tomko and Mcdonald (2013)
Ni, H. G., et al. (2016). "Brominated flame retardant emissions from the open burning of five plastic wastes and implications for environmental exposure in China." Environmental Pollution **214**: 70-76.	Ni et al. (2016)
Li, L., et al. (2016). "Long-term emissions of hexabromocyclododecane as a chemical of concern in products in China." Environment International **91**: 291-300.	Li et al. (2016)
OECD (2015). Emission scenario document on use of adhesives. Paris, France.	OECD (2015)
ECHA (2008). Risk assessment: hexabromocyclododecane. Helsinki, Finland.	ECHA (2008)
ECHA (2017). Chemical safety report: Hexabromocyclododecane and all major diastereoisomers identified. Helsinki, Finland.	ECHA (2017a)
ECHA (2009). Background document for hexabromocyclododecane and all major diastereoisomers identified. Helsinki, Finland.	ECHA (2009a)
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European Flame Retardants Association (EFRA) (2015). Keeping fire in check an introduction to flame retardants used in transport applications. Brussels, Belgium.	European Flame Retardants Association (EFRA) (2015)
European Brominated Flame Retardant Industry Panel (2008). EBFRIP statement RE UBA's publication on brominated flame retardant. Brussels, Belgium.	European Brominated Flame Retardant Industry Panel (2008)

Table_Apx B-3. Potentially Relevant Data Sources for Personal Exposure Monitoring and Area Monitoring Data

Bibliography	url
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Rosenberg, C., et al. (2011). "Exposure to flame retardants in electronics recycling sites." Annals of Occupational Hygiene **55**(6): 658-665.	Rosenberg et al. (2011)
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Velsicol Chem Corp (1978). Industrial hygiene survey, Velsicol Chemical Corporation, El Dorado, Ark Plant, Fire Master 680 Unit and semi-works summary with attachments and cover letter dated 071978. Chicago, IL.	Velsicol Chem Corp (1978)
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Kuo, Y., uY, et al. (2014). "Chemical Composition of Nanoparticles Released from Thermal Cutting of Polystyrene Foams and the Associated Isomerization of Hexabromocyclododecane (HBCD) Diastereomers." Aerosol and Air Quality Research **14**(4): 1114-1120.	Kuo et al. (2014)
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(2008). Summary risk assessment report: Hexabromocyclododecane. Helsinki, Finland, European Chemicals Agency.	2008)
ECHA (2009). Prioritisation and Annex XIV background information: hexbromocyclododecane. Helsinki, Finland.	ECHA (2009d)

Table_Apx B-4. Potentially Relevant Data Sources for Engineering Controls and Personal Protective Equipment

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Rosenberg, C., et al. (2011). "Exposure to flame retardants in electronics recycling sites." Annals of Occupational Hygiene **55**(6): 658-665.	Rosenberg et al. (2011)
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Appendix C SUPPORTING INFORMATION FOR OCCUPATIONAL EXPOSURE CONCEPTUAL MODEL

Table_Apx C-1. Worker and Occupational Non-User Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale
Manufacture	Import	Import	Repackaging of import containers	Liquid	Dermal	Workers	No	According to CDR, all importers reported solid physical forms of HBCD and therefore, exposure to liquid HBCD during repackaging is not likely.
				Solid	Dermal	Workers	Yes	Exposure will only occur in the event the imported material is repackaged. In that case, EPA expects potential exposure as a result of dust generation during repackaging of solid particulates.
				Fugitive Dust	Inhalation	Workers, ONU	Yes	Exposure will only occur in the event the imported material is repackaged.
				Fugitive Dust	Oral	Workers, ONU	Yes	Oral exposure of workers to HBCD may occur through ingestion of dust that deposits in the upper respiratory tract and is swallowed during repackaging.
				Liquid, Solid	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
Processing	Incorporated into formulation, mixture or reaction product	Flame retardants used in custom compounding of purchased resin (e.g., compounding in XPS masterbatch)	Plastics compounding	Solid	Dermal	Workers	Yes	EPA expects potential exposure during the unloading of HBCD.
				Fugitive Dust	Inhalation	Workers, ONU	Yes	EPA anticipates inhalation of dust as a result of generation of dust during the unloading of HBCD as the most important HBCD exposure pathway.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale
				Fugitive Dust	Oral	Workers, ONU	Yes	Oral exposure of workers to HBCD may occur through ingestion of dust that deposits in the upper respiratory tract and is swallowed.
				Solid	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
Processing	Incorporated into articles	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)	Plastics converting; SIP assembly	Solid	Dermal	Workers	Yes	As an additive flame retardant, HBCD is not chemically bonded to the base material (resin) and therefore there may be a potential for release and subsequent exposure during handling.
				Fugitive Dust	Inhalation	Workers, ONU	Yes	
				Fugitive Dust	Oral	Workers, ONU	Yes	Oral exposure of workers to HBCD may occur through ingestion of dust that deposits in the upper respiratory tract and is swallowed.
				Solid	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
Processing	Recycling	Recycling	Recycle of EPS.	Solid	Dermal	Workers	Yes	As an additive flame retardant, HBCD is not chemically bonded to the base material (resin) and therefore there may be a potential for release and subsequent exposure during recycling activities.
				Fugitive	Inhalation	Workers, ONU	Yes	

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale
				Fugitive	Oral	Workers, ONU	Yes	Oral exposure of workers to HBCD may occur through ingestion of dust that deposits in the upper respiratory tract and is swallowed.
				Solid	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
Distribution in Commerce	Distribution	Distribution	Distribution of bulk raw material; Distribution of formulated products	--	--	--	No	Potential for exposure expected only in the event the packaged raw material or formulated products are damaged, resulting in the potential release of HBCD.
Commercial Use	Building/construction materials	Plastic articles (hard): construction and building materials covering large surface areas	Installation/Reuse/Demolition of EPS/XPS foam insulation in residential, public and commercial buildings, and other structures	Solid	Dermal	Workers	Yes	Potential for exposure highly expected because the building/construction materials can be roughly handled during construction use, which could result in the release of HBCD in dust emissions from this activity.
				Fugitive and Installation/ Reuse/Demolition Dust	Inhalation	Workers, ONU	Yes	EPA anticipates inhalation of dust and other respirable particles as the most important HBCD exposure pathway.
				Fugitive and Installation/ Reuse/Demolition Dust	Oral	Workers, ONU	Yes	Oral exposure of workers to HBCD may occur through ingestion of dust that deposits in the upper respiratory tract and is swallowed.
				Solid	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.
	Automobile replacement parts	Automobile replacement parts	Use of automobile replacement parts	Fugitive dust	Dermal, inhalation and oral	Workers	No	Emissions of HBCD from automobile replacement parts are not expected to be significant and the EPS or XPS that comprises these replacement parts is expected to be covered with other material thereby limiting emissions.

Life Cycle Stage	Category	Subcategory	Release / Exposure Scenario	Exposure Pathway	Exposure Route	Receptor / Population	Proposed for Further Analysis	Rationale
Disposal	Waste Handling, Treatment and Disposal	Disposal of HBCD wastes	Worker handling of wastes	Liquid	Dermal	Workers	No	Liquid contact is not assessed due to subcategories of uses that have ceased as discussed in Section 2.2.
				Solid	Dermal	Workers	Yes	Highest potential for exposure for workers/occupational non-users would be to wastes from handling HBCD in powder form (e.g., disposal of raw material packaging, baghouse dust).
				Fugitive Dust	Inhalation	Workers, ONU	Yes	EPA anticipates inhalation of dust as the most important HBCD exposure pathway.
				Fugitive and Settled Dust	Oral	Workers, ONU	Yes	Oral exposure of workers to HBCD may occur through ingestion of dust that deposits in the upper respiratory tract and is swallowed.
				Solid	Dermal	ONU	No	Dermal exposure is expected to be primarily to workers directly involved in working with the chemical.

Appendix D SUPPORTING INFORMATION FOR CONSUMER, GENERAL POPULATION AND ENVIRONMENTAL EXPOSURE CONCEPTUAL MODEL

Table_Apx D-1. Consumer Exposure Conceptual Model Supporting Table

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Proposed for Further Analysis	Rationale
Consumer Use	Building/ construction materials	EPS/XPS foam insulation in residential buildings covering large surface areas- hard plastic article	Long-term emission/mass-transfer, Abrasion, Direct Transfer to Dust	Mouthing	Oral	Consumers (children)	No	Consumers are not likely to be in direct contact and mouth EPS insulation.
Consumer Use; Consumer Reuse and Recyling	Building/ construction materials	EPS/XPS foam insulation in residential buildings covering large surface areas- hard plastic article	Long-term emission/mass-transfer, Abrasion, Direct Transfer to Dust	Suspended particles in Air	Inhalation	Consumers: Adults and Children with EPS insulation in their residence	Yes	Based on HBCD's relatively low vapor pressure and relatively high octanol-air partition coefficient, it is likely to preferentially partition to smaller suspended particles in the air. Note, EPS and XPS will be compared and may be considered together or separately.
			Long-term emission/mass-transfer, Abrasion, Direct Transfer to Dust	Settled Dust	Oral Dermal	Consumers: Adults and Children with EPS insulation in their residence	Yes	Based on HBCD's relatively low vapor pressure and relatively high octanol-air partition coefficient, it is likely to preferentially partition to settled dust from the air, and directly to surface dust on the material.
			Direct contact during installation, renovation, and removal	Abrasion through drilling/sawing Direct contact	Dermal, Inhalation, Oral	Consumers: Adults who install or remove EPS insulation	Yes	Drilling is a common mechanism to attach panels to surfaces. The material may be similarly abraded during renovation and removal. It is expected that adults would perform these activities. EPS insulation is typically in unfinished spaces where children would not spend long amounts of time.

Life Cycle Stage	Category	Subcategory	Release from source	Exposure Pathway	Route	Receptor	Proposed for Further Analysis	Rationale
Consumer Use	Automotive products	Automobile Replacement Parts	Long-term emission/mass-transfer, Abrasion, Direct Transfer to Dust	Suspended particles in Air	Inhalation	Consumers: Adults and Children with replace-ment parts within their automobile	Yes	Based on HBCD's relatively low vapor pressure and relatively high octanol-air partition coefficient, it is likely to preferentially partition to smaller suspended particles in the air. Note, EPS and XPS will be compared and may be considered together or separately.
			Long-term emission/mass-transfer, Abrasion, Direct Transfer to Dust	Settled Dust	Oral Dermal	Consumers: Adults and Children with replace-ment parts in their automobile	Yes	Based on HBCD's relatively low vapor pressure and relatively high octanol-air partition coefficient, it is likely to preferentially partition to settled dust from the air, and directly to surface dust on the material.
Background	All	All	Suspended particles	Indoor Air	Inhalation	Bystander/ Resident	Yes	EPA plans to analyze background levels of HBCD in indoor air.
Background	All	All	Settled Dust	Indoor Dust	Ingestion	Bystander/ Resident	Yes	EPA plans to analyze background levels of HBCD in indoor dust and associated ingestion.
Background	All	All	Settled Dust	Indoor Dust	Dermal	Bystander/ Resident	Yes	EPA plans to analyze background levels of HBCD in indoor dust and associated dermal exposure.

Table_Apx D-2. General Population and Environmental Exposure Conceptual Model Supporting Table

Life Cycle Stage	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale
All	Emissions to Air	Near facility ambient air concentrations	Inhalation; Ingestion of suspended particles	General Population: Adults and Children living near facilities	Yes	EPA believes that release of HBCD to air is probable based on a preliminary review of the literature. TRI data will be available starting in mid-2018. EPA is currently conducting a systematic review of the scientific literature. Based on the results of this review, EPA will either confirm the rationale or reach a different conclusion.
		Indirect deposition to nearby bodies of water and soil catchments	Surface water and sediment (lakes)- Ingestion Soil (catchments)- Ingestion Uptake from environment into food sources- Ingestion	General Population: Adults and Children living near facilities	Yes	Based on HBCD's physical chemical properties, it is likely to be released as a particulate and be deposited to nearby water bodies and soil catchments.
			Surface water and sediment (lakes) Soil (catchments)	Aquatic and Terrestrial Receptors	Yes	
All	Industrial pre-treatment and wastewater treatment-	Direct release into surface water and indirect partitioning to sediment	Surface water and Sediment (rivers)	Aquatic and Terrestrial Receptors	Yes	EPA believes that release of HBCD in wastewater is probable based on a preliminary review of the literature. Its subsequent release through the exposure pathway may result in potential for exposure. TRI data will be available starting in mid-2018. EPA is currently conducting a systematic review of the scientific literature. Based on the results of this review, EPA will either confirm the rationale or reach a different conclusion.

Life Cycle Stage	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale
		Direct release into surface water and partitioning to sediment and bioaccumulation into edible aquatic species	Surface water and Sediment (rivers) Uptake from environment into food sources-Ingestion	General Population: Adults and Children living near facilities	Yes	HBCD has been reported in surface water and sediment concentrations near industrial facilities.
		Biosolids application to soil	Soil ingestion Uptake from environment into food sources-Ingestion	General Population: Adults and Children living near facilities	Yes	HBCD has been detected in biosolids and soil samples.
		Biosolids application to soil	Soil	Terrestrial receptors	Yes	HBCD has been detected in soil samples.
Disposal	Solid and Liquid Wastes sent to Municipal Incinerator	Indirect deposition to nearby bodies of water and soil catchments	Surface water and sediment (lakes)-Ingestion Soil (catchments)-Ingestion Uptake from environment into food sources-Ingestion	General Population: Adults and Children living near facilities	Yes	Municipal incinerators may release HBCD due to incomplete removal during burning.
	Solid and Liquid Wastes sent to Municipal Incinerator	Indirect deposition to nearby bodies of water and soil catchments	Surface water and sediment (lakes) Soil (catchments)	Aquatic and Terrestrial Receptors	Yes	Municipal incinerators may release HBCD due to incomplete removal during burning.

Life Cycle Stage	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale
	Municipal landfill and other land disposal	Leachate to POTW and surface water	Ingestion	General Population: Adults and Children living near facilities	Yes	HBCD has been detected in leachate and HBCD containing materials are sent to landfill as part of disposal.
	Municipal landfill and other land disposal	Leachate to POTW and surface water and partitioning to sediment	Surface water and sediment (rivers)	Aquatic Receptors	Yes	HBCD has been detected in leachate and HBCD containing materials are sent to landfill as part of disposal.
Recycling	Recycling of EPS/XPS materials and emissions to air	Near Facility Ambient Air Concentrations	Inhalation Ingestion of suspended particles	General Population: Adults and Children living near facilities	Yes	EPS/XPS is the primary use HBCD and there is continuing exposure potential near these recycling facilities.
		Indirect deposition to nearby bodies of water and soil catchments	Surface water and sediment (lakes)- Ingestion Soil (catchments)- Ingestion Uptake from environment into food sources- Ingestion	General Population: Adults and Children living near facilities	Yes	EPS/XPS is the primary use of HBCD and there is continuing exposure potential near these recycling facilities.
		Indirect deposition to nearby bodies of water and soil catchments	Surface water and sediment (lakes) Soil (catchments)	Aquatic and Terrestrial Receptors	Yes	EPS/XPS is the primary use HBCD and there is continuing exposure potential near these recycling facilities.

Life Cycle Stage	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale
All	Background	Surface water	Ingestion	General Population: Adults and Children; Aquatic and Terrestrial Receptors	Yes	HBCD has been detected in surface water sampling at locations away from facilities. EPA plans to analyze background levels of HBCD in these media
		Sediment	Ingestion	Aquatic Receptors	Yes	HBCD has been detected in sediment sampling locations not near facilities. EPA plans to analyze background levels of HBCD in these media
		Soil	Ingestion	General Population: Adults and Children; Terrestrial Receptors	Yes	HBCD has been detected in soil sampling locations not near facilities. EPA plans to analyze background levels of HBCD in these media
		Aquatic Biota	n/a	Aquatic Receptors	Yes	HBCD has been detected in aquatic biota. EPA plans to analyze background levels of HBCD in these organisms.
		Terrestrial Biota	n/a	Terrestrial receptors	Yes	HBCD has been detected in aquatic biota. EPA plans to analyze background levels of HBCD in these organisms.
		Indoor Air	Inhalation Ingestion of suspended particles	General Population	Yes	HBCD has been detected in a wide range of indoor air and dust samples. It is likely that the predominant source of exposure is from indoor sources. However, other sources could also contribute. Background indoor dust concentrations will also be analyzed
		Indoor Dust	Ingestion, Dermal	General Population	Yes	
All	Background	Dietary Food Sources	Ingestion	General Population	Yes	HBCD has been detected in a variety of dietary food sources. These background levels will be analyzed.
All	Background	Human Biomonitoring - breast milk	n/a	General Population	Yes	HBCD has been detected in breast milk and this is a source of exposure for nursing infants and helps inform adult exposure intakes.

Life Cycle Stage	Release	Exposure Pathway / Media	Exposure Routes	Receptor / Population	Proposed for Further Analysis	Rationale
All	Background	Human Biomonitoring-serum-blood	n/a	General Population	Yes	HBCD has been detected in human matrices. These measured levels may be considered with toxicokinetics data to compare estimates of dose.

Appendix E INCLUSION AND EXCLUSION CRITERIA FOR FULL TEXT SCREENING

Appendix E contains the eligibility criteria for various data streams informing the TSCA risk evaluation: environmental fate; engineering and occupational exposure; exposure to the general population and consumers; and human health hazard. The criteria are applied to the *on-topic* references that were identified following title and abstract screening of the comprehensive search results published on June 22, 2017.

Systematic reviews typically describe the study eligibility criteria in the form of PECO statements. PECO stands for Population, Exposure, Comparator and Outcome and the approach is used to formulate explicit and detailed criteria about those characteristics in the publication that should be present in order to be eligible for inclusion in the review. EPA/OPPT adopted the PECO approach or variant to guide the inclusion/exclusion decisions during full text screening.

Inclusion and exclusion criteria were also used during the title and abstract screening, and documentation about the criteria can be found in the *Strategy for Conducting Literature Searches* document published in June 2017 along with each of the TSCA scope documents. The list of on-topic references resulting from the title and abstract screening is undergoing full text screening using the criteria in the PECO statements. The overall objective of the screening process is to select the most relevant evidence for the TSCA risk evaluation. As a general rule, EPA is excluding non-English data/information sources and will translate on a case by case basis.

The inclusion and exclusion criteria for ecotoxicological data have been documented in the ECOTOX SOPs. The criteria can be found at https://cfpub.epa.gov/ecotox/help.cfm?helptabs=tab4) and in the *Strategy for Conducting Literature Searches* document published along with each of the TSCA scope documents.

E.1 Inclusion Criteria for Data Sources Reporting Environmental Fate Data

EPA/OPPT developed a generic PESO statement to guide the full text screening of environmental fate data sources. PESO stands for Pathways and Processes, Exposure, Setting or Scenario, and Outcomes. Subsequent versions of the PESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PESO statement are eligible for inclusion, considered for evaluation, and possibly included in the environmental fate assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PESO statement.

Assessors seek information on various chemical-specific fate endpoints and associated fate processes, environmental media and exposure pathways as part of the process of developing the environmental fate assessment (Table_Apx E-2). Those that will be the focus of the environmental fate assessment for HBCD have been indicated in Table_Apx E-2. The PESO statement and information in Table_Apx E-1 will be used when screening the fate data sources to ensure complete coverage of the processes, pathways and data relevant to the fate of the chemical substance of interest.

Table_Apx E-1. Inclusion Criteria for Data Sources Reporting Environmental Fate Data	
PESO Element	**Evidence**
Pathways and **P**rocesses	• Environmental fate, transport, partitioning and degradation behavior across environmental media to inform exposure pathways of the chemical substance of interest • Media of interest may include: – Air – Surface water – Ground water – Soil – Sediment – Biosolids – Other media including anthropogenic materials and media in the indoor environment (e.g., dust) Please refer to the conceptual models for more information about the exposure pathways included in each TSCA risk evaluation.
Exposure	• Environmental exposure of ecological receptors (i.e., aquatic and terrestrial organisms) to the chemical substance of interest and/or its degradation products and metabolites • Environmental exposure of human receptors, including any potentially exposed or susceptible subpopulations, to the substance of interest and/or its degradation products and metabolites Please refer to the conceptual models for more information about the ecological and human receptors included in each TSCA risk evaluation.
Setting or **S**cenario	Any setting or scenario resulting in releases of the chemical substance of interest into the natural or built environment (e.g., buildings including homes or workplaces, or wastewater treatment facilities) that would expose ecological (i.e., aquatic and terrestrial organisms) or human receptors (i.e., general population, and potentially exposed or susceptible subpopulation)
Outcomes	• Fate properties which allow assessments of exposure pathways: ○ Abiotic and biotic degradation rates, mechanisms, pathways, and products ○ Bioaccumulation magnitude and metabolism rates ○ Partitioning within and between environmental media (see Pathways and Processes)

Table_Apx E-2. Fate Endpoints and Associated Processes, Media and Exposure Pathways Considered in the Development of the Environmental Fate Assessment						
Fate Data Endpoint	**Associated Process(es)**	**Associated Media/Exposure Pathways**				
		Surface water, Sediment	**Soil, Biosolids**	**Groundwater**	**Air**	**Indoor environment, anthropogenic materials, other media**
Required Environmental Fate Data						
Abiotic reduction rates or half-lives	Abiotic reduction, Abiotic dehalogenation	X				
Aerobic biodegradation rates or half-lives	Aerobic biodegradation	X	X			
Anaerobic biodegradation rates or half-lives	Anaerobic biodegradation	X	X	X		
Aqueous photolysis (direct and indirect) rates or half-lives	Aqueous photolysis (direct and indirect)	X				
Atmospheric photolysis (direct and indirect) rates or half-lives	Atmospheric photolysis (direct and indirect)				X	X
Bioconcentration factor (BCF), Bioaccumulation factor (BAF)	Bioconcentration, Bioaccumulation	X				
Hydrolysis rates or half-lives	Hydrolysis	X				
K_{AW}, Henry's Law constant, and other volatilization information	Volatilization	X	X		X	X
K_{OC} and other sorption information	Sorption, Mobility	X	X	X		
Optional Environmental Fate Data						
Abiotic transformation products	Hydrolysis, Photolysis	X			X	
Aerobic biotransformation products	Aerobic biodegradation	X	X			
Anaerobic biotransformation products	Anaerobic biodegradation	X	X	X		
Atmospheric deposition information	Atmospheric deposition				X	X
Biomagnification and related information	Trophic magnification	X				

Table_Apx E-2. Fate Endpoints and Associated Processes, Media and Exposure Pathways Considered in the Development of the Environmental Fate Assessment						
Coagulation information	Coagulation, Mobility	X				
Desorption information	Sorption, Mobility	X	X	X		
Incineration removal information	Incineration				X	
Suspension/resuspension information	Suspension/resuspension, Mobility	X				X
Wastewater treatment removal information	Wastewater treatment	X				

E.2 Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data

EPA/OPPT developed a generic RESO statement to guide the full text screening of engineering and occupational exposure literature (Table_Apx E-3). RESO stands for Receptors, Exposure, Setting or Scenario, and Outcomes. Subsequent versions of the RESO statement may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria specified in the RESO statement will be eligible for inclusion, considered for evaluation, and possibly included in the environmental release and occupational exposure assessments, while those that do not meet these criteria will be excluded.

The RESO statement should be used along with the engineering and occupational exposure data needs table (Table_Apx E-4) when screening the literature.

Table_Apx E-3. Inclusion Criteria for Data Sources Reporting Engineering and Occupational Exposure Data

RESO Element	Evidence
Receptors	• **Humans:** Workers, including occupational non-users • **Environment:** Aquatic and possibly terrestrial ecological receptors (release estimates input to Exposure) Please refer to Appendix C and Appendix D for more information about the ecological and human receptors included in each TSCA risk evaluation.

Exposure	• Worker exposure to and relevant environmental releases of the chemical substance of interest
	  ○ Any exposure route (list included: dermal, inhalation, oral) as indicated in the conceptual model
	  ○ Any relevant media/pathway as indicated in the conceptual model
	
	Please refer to the conceptual models for more information about the routes and media/pathways included in each TSCA risk evaluation.

Setting or **S**cenario	• Any occupational setting or scenario resulting in worker exposure and environmental releases (includes all manufacturing, processing, use, disposal indicated in Table_Apx E-4 below.
Outcomes	• Quantitative estimates* of worker exposures and of relevant environmental releases from occupational settings • General information and data related and relevant to the occupational estimates*
* Metrics (e.g., mg/kg/day or mg/m^3 for worker exposures, kg/site/day for releases) are determined by toxicologists for worker exposures and by exposure assessors for releases; also, the Engineering Data Needs (Table_Apx E-4) provides a list of related and relevant general information.	

Table_Apx E-4. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments	
Objective Determined during Scoping	**Type of Data**
General Engineering Assessment (may apply for either or both Occupational Exposures and / or Environmental Releases)	1. Description of the life cycle of the chemical(s) of interest, from manufacture to end-of-life (e.g., each manufacturing, processing, or use step), and material flow between the industrial and commercial life cycle stages. {Tags: Life cycle description, Life cycle diagram}[a] 2. The total annual U.S. volume (lb/yr or kg/yr) of the chemical(s) of interest manufactured, imported, processed, and used; and the share of total annual manufacturing and import volume that is processed or used in each life cycle step. {Tags: Production volume, Import volume, Use volume, Percent PV} [a] 3. Description of processes, equipment, unit operations, and material flows and frequencies (lb/site-day or kg/site-day and days/yr; lb/site-batch and batches/yr) of the chemical(s) of interest during each industrial/ commercial life cycle step. Note: if available, include weight fractions of the chemicals (s) of interest and material flows of all associated primary chemicals (especially water). {Tags: Process description, Process material flow rate, Annual operating days, Annual batches, Weight fractions (for each of above, manufacture, import, processing, use)} [a] 4. Basic chemical properties relevant for assessing exposures and releases, e.g., molecular weight, normal boiling point, melting point, physical forms, and room temperature vapor pressure. {Tags: Molecular weight, Boiling point, Melting point, Physical form, Vapor pressure, Water solubility} [a] 5. Number of sites that manufacture, process, or use the chemical(s) of interest for each industrial/ commercial life cycle step and site locations. {Tags: Numbers of sites (manufacture, import, processing, use), Site locations} [a]
Occupational Exposures	6. Description of worker activities with exposure potential during the manufacture, processing, or use of the chemical(s) of interest in each industrial/commercial life cycle stage. {Tags: Worker activities (manufacture, import, processing, use)} [a] 7. Potential routes of exposure (e.g., inhalation, dermal). {Tags: Routes of exposure (manufacture, import, processing, use)} [a] 8. Physical form of the chemical(s) of interest for each exposure route (e.g., liquid, vapor, mist) and activity. {Tags: Physical form during worker activities (manufacture, import, processing, use)} [a] 9. Breathing zone (personal sample) measurements of occupational exposures to the chemical(s) of interest, measured as time-weighted averages (TWAs), short-term exposures, or peak exposures in each occupational life cycle stage (or in a workplace scenario similar to an occupational life cycle stage). {Tags: PBZ measurements (manufacture, import, processing, use)} [a] 10. Area or stationary measurements of airborne concentrations of the chemical(s) of interest in each occupational setting and life cycle stage (or in a workplace scenario similar to the life cycle stage of interest). {Tags: Area measurements (manufacture, import, processing, use)} [a] 11. For solids, bulk and dust particle size characterization data. {Tags: PSD measurements (manufacture, import, processing, use)} [a] 12. Dermal exposure data. {Tags: Dermal measurements (manufacture, import, processing, use)} 13. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). {Tags: Worker exposure modeling data needs (manufacture, import, processing, use)} [a] 14. Exposure duration (hr/day). {Tags: Worker exposure durations (manufacture, import, processing, use)}[a] 15. Exposure frequency (days/yr). {Tags: Worker exposure frequencies (manufacture, import, processing, use)} [a] 16. Number of workers who potentially handle or have exposure to the chemical(s) of interest in each occupational life cycle stage. {Tags: Numbers of workers exposed (manufacture, import, processing, use)} [a] 17. Personal protective equipment (PPE) types employed by the industries within scope. {Tags: Worker PPE (manufacture, import, processing, use)} [a] 18. Engineering controls employed to reduce occupational exposures in each occupational life cycle stage (or in a workplace scenario similar to the life cycle stage of interest), and associated data or estimates

Table_Apx E-4. Engineering, Environmental Release and Occupational Data Necessary to Develop the Environmental Release and Occupational Exposure Assessments	
Objective Determined during Scoping	**Type of Data**
	of exposure reductions. {Tags: Engineering controls (manufacture, import, processing, use), Engineering control effectiveness data} [a]
Environmental Releases	19. Description of sources of potential relevant environmental releases, including cleaning of residues from process equipment and transport containers, involved during the manufacture, processing, or use of the chemical(s) of interest in each life cycle stage. {Tags: Release sources (manufacture, import, processing, use)} [a] 20. Estimated mass (lb or kg) of the chemical(s) of interest released from industrial and commercial sites to each relevant environmental medium and treatment and relevant disposal methods, including releases per site and aggregated over all sites (annual release rates, daily release rates) {Tags: Release rates (manufacture, import, processing, use)} [a] 21. Relevant release or emission factors. {Tags: Emission factors (manufacture, import, processing, use)} [a] 22. Number of release days per year. {Tags: Release frequencies (manufacture, import, processing, use)} [a] 23. Data needs associated with mathematical modeling (will be determined on a case-by-case basis). {Tags: Release modeling data needs (manufacture, import, processing, use)} [a] 24. Relevant waste treatment methods and pollution control devices employed by the industries within scope and associated data on relevant release/emission reductions. {Tags: Treatment/ emission controls (manufacture, import, processing, use), Treatment/ emission controls removal/ effectiveness data} [a]
Notes: [a] These are the tags included in the full text screening form. The screener makes a selection from these specific tags, which describe more specific types of data or information. **Abbreviations:** hr=Hour kg=Kilogram(s) lb=Pound(s) yr=Year PV=Particle volume PBZ= Personal breathing zone POTW=Publicly owned treatment works PPE=Personal projection equipment PSD=Particle size distribution TWA=Time-weighted average	

E.3 Inclusion Criteria for Data Sources Reporting Exposure Data on General Population, Consumers and Ecological Receptors

EPA/OPPT developed PECO statements to guide the full text screening of exposure data/information for human (i.e., general population, consumers, potentially exposure or susceptible subpopulations) and ecological receptors. Subsequent versions of the PECO statements may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the inclusion criteria in the PECO statement are eligible for inclusion, considered for evaluation, and possibly included in the exposure assessment. On the other hand, data sources are excluded if they do not meet the criteria in the PECO statement. The HBCD-specific PECO is provided in Table_Apx E-5.

Table_Apx E-5. Inclusion Criteria for the Data Sources Reporting HBCD Exposure Data on General Population, Consumers and Ecological Receptors	
PECO Element	**Evidence**
Population	**Human:** Many different human population groups may be exposed to HBCD – including Potentially Exposed or Susceptible Subpopulations (e.g., children, susceptible populations (lifestages, preexisting conditions, genetic factors, pregnant women, women of child bearing age, infants), general population exposures through all relevant media, populations with subsistence diets (fish, plants, mammals, game animals, etc.), near facility populations, consumers and bystanders. EPA will also consider typical and potentially highly exposed groups within these general categories. Examples may include take-home exposures and renovation scenarios. No chemical-specific exclusions are suggested at this time. Human biomonitoring data to be considered.
	Ecological: Aquatic biota (edible and non-edible fish, daphnia, marine mammals), sediment dwelling worms, birds, earthworms. Consider ways to target the species list-for example, edible wildlife and species that have eco data. Many different aquatic and terrestrial species may be exposed to HBCD. No chemical specific exclusions are suggested at this time. Wildlife biomonitoring data to be considered.
Exposure	**Expected Primary Exposure Sources, Pathways, Routes:** • Sources: Manufacturing, Processing, Use, and Disposal of building insulation (extruded polystyrene XPS and expanded polystyrene EPS). Indoor sources/materials that cover a large surface area, are abraded during use, or have high potential for direct contact. • Pathways: dust, soil, food (fish, breastmilk, meat, eggs, dairy), biosolids, sediment, indoor air, outdoor air, media specific background and source attribution to be considered. • Routes of Exposure: oral (dietary ingestion of food, dust ingestion, soil ingestion, indoor air ingestion of particles, mouthing of products/materials. Inhalation (indoor air and outdoor air). Dermal (contact with dust). **Expected Lesser Exposure Sources, Pathways, Routes** • Sources: Manufacturing, Processing, Use, and Disposal of products containing recycled HBCD and associated releases to water, or solid wastes. Indoor sources/materials that are less prevalent and/or contain relatively low concentrations of HBCD. • Pathway: surface water, outdoor air deposition, food (fruits and vegetables), media specific background and source attribution to be considered. • Routes of Exposure: Dermal (contact with soil, contact with products/materials)
Comparator (Scenario)	**Human:** Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
	Ecological: Consider media-specific background exposure scenarios and use/source specific exposure scenarios as well as which receptors are and are not reasonably exposed across the projected exposure scenarios.
Outcomes for Exposure Concentration or Dose	**Human:** Both external potential dose and internal dose based on biomonitoring and reverse dosimetry mg/kg/day will be considered (to compare with a wide range of health effects following acute through chronic exposures).
	Ecological: Surface water concentrations, sediment concentrations, and soil concentrations will be used (to compare with metrics used for ecological toxicity values). Targeted use of wildlife biomonitoring data such as in certain bird species will also be explored.

E.4 Inclusion Criteria for Data Sources Reporting Human Health Hazards

EPA/OPPT developed an HBCD-specific PECO statement (Table_Apx E-6) to guide the full text screening of the human health hazard literature. Subsequent versions of the PECOs may be produced throughout the process of screening and evaluating data for the chemicals undergoing TSCA risk evaluation. Studies that comply with the criteria specified in the PECO statement will be eligible for

inclusion, considered for evaluation, and possibly included in the human health hazard assessment, while those that do not meet these criteria will be excluded according to the exclusion criteria.

In general, the PECO statements were based on (1) information accompanying the TSCA scope document, and (2) preliminary review of the health effects literature from sources cited in the TSCA scope documents. When applicable, these sources (e.g., IRIS assessments, EPA/OPPT's Work Plan Problem Formulations or risk assessments) will serve as starting points to identify PECO-relevant studies.

Table_Apx E-6. Inclusion and Exclusion Criteria for Data Sources Reporting Human Health Hazards Related to Cyclic Aliphatic Bromide Cluster (HBCD Cluster) Exposure [a]

PECO Element	Evidence Stream	Papers/Features Included	Papers/Features Excluded [a]
Population [b]	*Human*	• Any population • All lifestages • All study designs: ○ Controlled exposure, cohort, case-control, cross-sectional, case-crossover	
	Animal	• All standard whole-organism mammalian species, including rat, mouse, hamster, rabbit, guinea pig, monkey, dog • All lifestages	• Wildlife species • Non-mammalian species • Agricultural species/livestock
	Mechanistic	• Human or animal cells (including nonmammalian model systems), tissues, or biochemical reactions (e.g., ligand-binding assays); bioinformatics pathways of disease analysis; or high-throughput screening data.	
Exposure	*Human and Animal*	• Exposure to an administered dose or concentration of HBCD • Exposure is measured as a concentration in an environmental medium (e.g., air, dust, soil, diet) or biological fluid or tissue (e.g., blood, milk, urine, adipose tissue), or administered as a controlled dose • Exposure is in vivo • Exposure identified as ***or presumed to be*** from oral, dermal, and inhalation routes	• Not a chemical specific (study population is not exposed to HBCD) • Exposure is to a mixture only, i.e., simultaneous exposure to other chemicals in addition to HBCD (applies to animal studies only) • Exposure via injection (e.g., intravenous [i.v.])
	Mechanistic	• Exposure based on concentrations of HBCD (individual α-, β-, or y-isomers or the commercial/technical mixtures)	
Comparator	*Human*	• A comparison population [not exposed, exposed to lower levels, exposed below detection] for all endpoints	• No comparison population for endpoints
	Animal and Mechanistic	• Negative controls that are vehicle-only treatment and/or no treatment • No minimum number of dose or concentration groups	• Negative controls ***other than*** vehicle-only treatment or no treatment

Outcome	*Human and Animal*	• Health Endpoints [b]:
		  • Irritation
		  • Sensitization
		  • Liver effects
		  • Endocrine/thyroid effects
		  • Developmental effects
		  • Immune effects
			• No health outcome evaluated (e.g., a study of HBCD exposure levels)

		• Neurological effects • Reproductive effects • Acute toxicity • Other endpoints [d]	
	Mechanistic	• Mechanistic data that supports the characterization of the identified endpoints of interest	
General Considerations		**Papers/Features Included**	**Papers/Features Excluded**
		• Written in English [e] • Reports primary source or meta-analysis. [a] • Full-text available	• Not written in English • Reports a secondary source (e.g., review papers) [a] • No full-text available (e.g., only a study description/abstract, out-of-print text)

[a] Some of the studies that are excluded based on the PECO statement may be considered later during the systematic review process. For HBCD, EPA will evaluate studies related to susceptibility and may evaluate toxicokinetic and physiologically based pharmacokinetic models after other data (e.g., human and animal data identifying adverse health outcomes) are reviewed.

[b] EPA will review studies identified in the *Preliminary Materials for the IRIS Toxicological Review of HBCD* (U.S. EPA, 2014d). Mechanistic data will be considered to support hazard characterization for these endpoints.

[c] Measurement of HBCD includes individual α-, β-, or y-isomer; commercial or technical mixtures of HBCD isomers; CASRN 3194-55-6 (1,2,5,6,9,10-hexabromocyclododecane technical mixtures); CASRN 25637-99-4 (hexabromocyclododecane, all isomers)

[d] EPA may screen for hazards other than those listed in the scope document if they were identified in the updated literature search that accompanied the scope document.

[e] EPA may translate studies as needed.