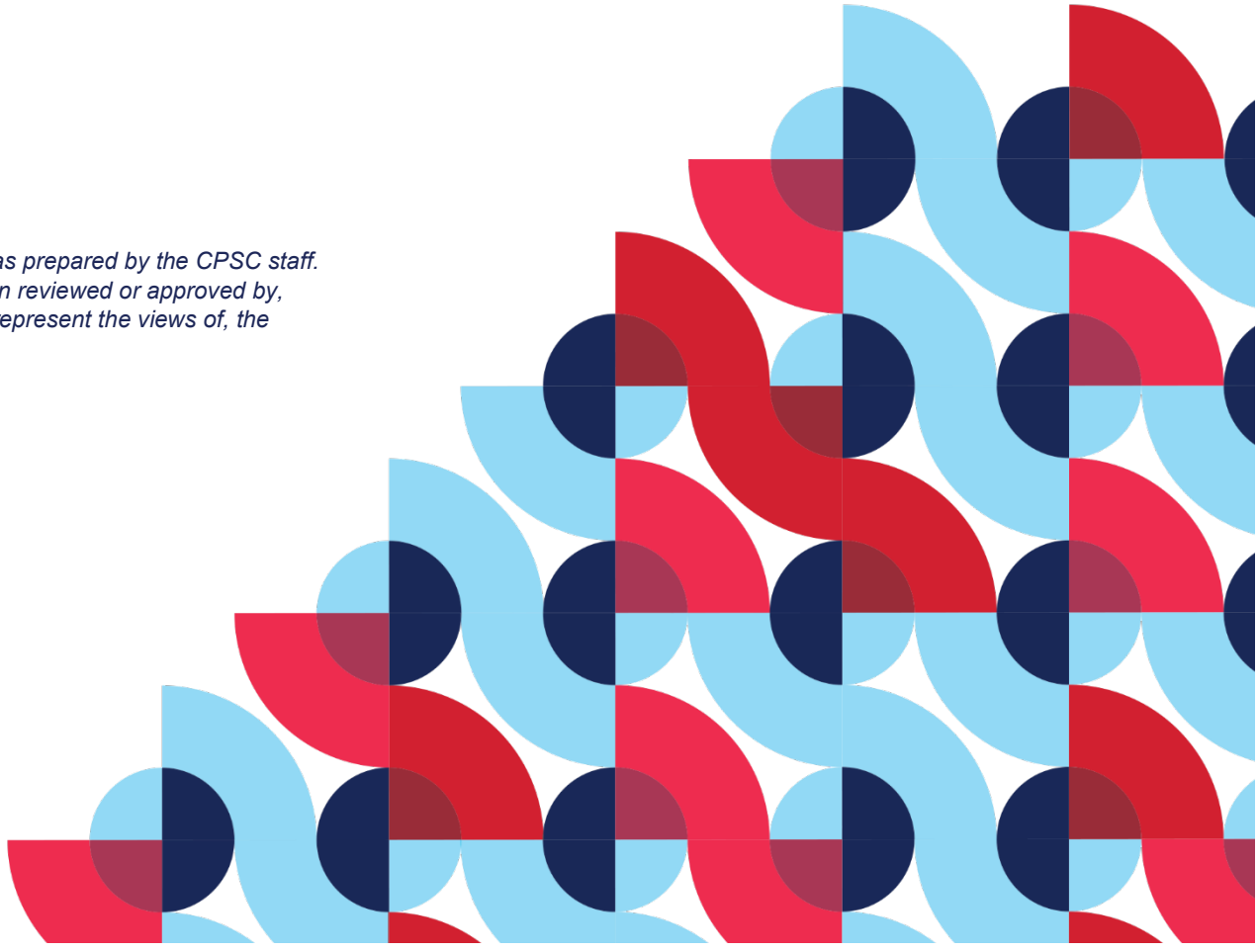
United States
Consumer Product Safety Commission

Organohalogen Flame Retardant Scope Document: Polyhalogenated Diphenyl Ether Subclass

December 2023

This report was prepared by the CPSC staff. It has not been reviewed or approved by, and may not represent the views of, the Commission.



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1. Executive Summary

This scope document addresses the polyhalogenated diphenyl ether (PHDE) subclass, one of 14 subclasses of organohalogen flame retardants (OFR). OFRs contain a carbon-halogen bond and are one of the main categories of flame retardants (FRs). FRs are substances that alter the normal degradation or combustion processes of materials. They are incorporated into materials or used on surfaces to reduce or eliminate the tendency to ignite when exposed to heat or flame for a short amount of time.

Informed by initial review of the market and use research, evidence maps, and availability of physicochemical data for the PHDE subclass and its analogs, as well as the Criteria for Scoping Determination described in this document, Consumer Product Safety Commission (CPSC or Commission) staff concludes, at the time of writing, that the PHDE subclass has sufficient data to proceed with risk assessment. Next steps, as resources are available, involve completing the hazard, dose-response, and exposure assessments before drafting the class-based risk assessment.

2. Introduction

This document contains the results of scoping efforts by CPSC staff to characterize readily available information on the chemistry, uses, human toxicity, exposure, and human health risk of members of the PHDE subclass of OFRs. This document is one of the scope documents that CPSC staff are producing to address each of 14 OFR chemical subclasses.

The primary question answered by the scope documents is:

> *Can a risk assessment for this subclass be completed based on a combination of existing data and estimation (modeling) approaches?*

To answer this question, the scope document developed for each subclass outlines the criteria for determining sufficiency for hazard assessments and exposure assessments, describes the data available, and provides the scoping determination. If the answer to the question above is yes for that subclass, the scope document describes (i) CPSC staff's interpretation of available data through evidence maps and estimation approaches and (ii) the analysis plan and conceptual model that CPSC staff plans to follow to complete this assessment. These subclasses will then be prioritized for risk assessments.

If the answer is no, then the scope document for that particular subclass describes (i) CPSC staff's interpretation of available data through evidence maps and estimation approaches and (ii) key data gaps. These subclasses will be temporarily deprioritized for risk assessments.

For additional details on how the information contained in all scope documents was compiled, refer to the following CPSC companion documents:[1]

[1] Project documents, including CPSC staff reports, contractor reports, and key references may be found on the CPSC Organohalogen Flame Retardant Chemicals Assessment website

- Development of a Flame Retardant and an Organohalogen Flame Retardant Chemical Inventory
- Market and Use Report: Characterizing OFR Chemistries, Sources, and Uses in the U.S. and International Markets, Volumes 1 and 2 (Appendices)
- Literature Survey Guide: Approaches Taken to Develop Evidence Maps from Readily Available Databases, Completed Assessments, and Literature Reviews

3. Background

In 2015, several organizations and individuals petitioned CPSC (Petition HP 15-1) to ban the use of additive OFRs, as a class, in durable infant or toddler products, children's toys, childcare articles, or other children's products (other than car seats), residential upholstered furniture, mattresses and mattress pads, and the plastic casings of electronic devices. In 2017, the Commission voted to grant the petition to direct staff to convene a Chronic Hazard Advisory Panel (CHAP),[2] and to complete a scoping and feasibility study in cooperation with the National Academy of Sciences, Engineering, and Medicine (NASEM).

NASEM established a committee of experts to address the charge and published the Committee's report, "A Class Approach to Hazard Assessment of Organohalogen Flame Retardants," in May 2019 (NASEM, 2019). The Committee first decided to determine whether the chemicals of interest can be defined as a single class or as subclasses, based on structure, physicochemical properties, biology, or a combination of characteristics. The Committee stated that if a class approach is viable, then the hazard assessment approach would be to survey the literature to determine availability of all types of toxicity data (human, animal, in vitro, other relevant studies) for all relevant toxicity end points. Then, if relevant data are available on any chemical of interest for a given end point, the plan would be to extract, evaluate, and integrate the data to reach a decision about potential hazards that can be applied to the entire class or subclass. A key conclusion of the Committee is that OFRs cannot be treated as a single class. Rather, the Committee identified 14 subclasses of OFRs, based on chemical structure, physicochemical properties of the chemicals, and predicted biological activity.

In fiscal year 2020 (FY 2020), CPSC staff developed a process for assessing the risks of OFRs in consumer products. A staff report to the Commission (Staff Plan) (CPSC, 2020) builds on the recommendations from the NASEM committee and outlines options and recommendations for proceeding with the project in FY 2021 and beyond (subject to availability of resources). In brief, the Staff Plan outlined work that initially would establish procedures for class-based risk assessment of each OFR subclass, refine the chemicals and analogs for multiple OFR subclasses, identify data sources, and determine available toxicity, chemical use, and exposure information. Staff subsequently initiated several activities, largely through contractors and interagency collaborations, to begin work on the project.

(https://www.cpsc.gov/Business--Manufacturing/Organohalogen-Flame-Retardant-Chemicals-Assessment) or Docket No. CPSC-2015-0022 (https://www.regulations.gov/docket/CPSC-2015-0022).

[2] CHAP review would occur prior to finalizing any subclass risk assessment if carcinogenicity, mutagenicity, or reproductive/developmental toxicity were chosen as relevant endpoints.

4. Approach

4.1. Criteria for Scoping Determination

CPSC staff will determine whether a subclass has sufficient data to proceed, at this time, with risk assessment based on data availability. In this context, data availability among subclass members and among identified analog chemicals is characterized as "no data," "some data," or "data rich" for both hazard information and exposure information, with definitions of each category provided below.

4.1.1. Hazard

The criteria for sufficiency for hazard assessment for the subclass are:

- At least one data rich chemical among the subclass chemicals or analog chemicals, and
- Multiple chemicals with some data among subclass chemicals or analog chemicals with empirical short-term toxicity and other data (availability of modeled physicochemical and toxicity data can contribute to the determination).
- Only a minority of the substances in the subclass are "no data" substances.

The data availability categories are defined using the literature survey results as follows:

- Chemicals with no data:
    - No empirical data for physicochemical characteristics, and
    - No empirical data for toxicity, and
    - No or limited predicted/modeled physicochemical or toxicity data.
- Chemicals with some data (i.e., chemicals that are neither data rich nor have no data):
    - Some physicochemical data (may include empirical or modeled), and
    - No to limited traditional chronic/subchronic animal toxicity studies, and
    - Some short-term toxicity, in vitro, high-throughput, or other nonanimal data.
- Chemicals that are data rich:
    - Near complete empirical physicochemical data, and
    - Multiple traditional animal toxicity studies (i.e., acute, systemic repeated dose toxicity, or reproductive/developmental), and
    - Multiple short-term in vivo toxicity studies, and in vitro, high-throughput, or other nonanimal data, and
    - Available empirical data likely support derivation of a quantitative toxicity reference value(s).
    - Modeled toxicity data, if such data demonstrate close agreement with available empirical data, are acceptable to support this category, but such data are not required.
    - Availability of human data supports this category but is not required.

In addition to evaluating the amount and breadth of available data for each chemical in a subclass, CPSC staff plans to consider the availability of similar types of data for multiple

subclass members (e.g., similar subchronic/chronic studies, similar endpoints evaluated, and similar short-term toxicity studies, in vitro assays, or mechanistic data). CPSC staff plans to consider consistency in data availability across members of a subclass.

4.1.2. Exposure

The criteria for sufficiency for exposure assessment for the subclass are:

- At least one data rich chemical among the subclass chemicals for which average daily doses for human populations have been reported or can be estimated, and
- Multiple subclass chemicals with some data from environmental monitoring, biomonitoring, product testing, or any toxicokinetic studies (availability of modeled physicochemical, emissions, migration, occurrence, or disposition data can contribute to the determination).
- Note that subclass members classified as “no data” chemicals do not have sufficient information for exposure assessment.

The data availability categories are defined using the literature survey and market and use research results as follows:

- Chemicals with no data:
    - No market and use information indicating use as a flame retardant.
- Chemicals with some data (i.e., chemicals that are neither data rich nor have no data):
    - Some evidence (per market and use information) that it has been, currently is, or could be used as a flame retardant, and
    - Some physicochemical data (may include empirical or modeled), or
    - At least one experimental environmental monitoring, biomonitoring, product testing, or toxicokinetic study, or comparable modeling studies that provide information on estimated occurrence, emissions, or disposition, or
    - Existing or de novo modeled estimates of physicochemical properties, emissions, migration, occurrence, or disposition.
- Chemicals that are data rich:
    - Evidence (per market and use information) that it has been, currently is, or could be used as a flame retardant, and
    - Near complete empirical physicochemical data, and
    - Multiple environmental monitoring, biomonitoring, product testing, or toxicokinetic studies, and
    - Available empirical data support estimates of quantitative average daily dose(s) for human exposure, and
    - Modeled exposure data (emissions, occurrence, disposition), if such data demonstrate close agreement with empirical data, are acceptable to support this category, but such data are not required.

4.2. Inventory

The NASEM committee, as part of its consideration of class approaches to hazard assessment, created an inventory of 161 OFRs and identified more than 1,000 analog chemicals (i.e., chemicals with similar functional, structural, and predicted biological activity) across 14 chemical subclasses. Subsequently, CPSC staff, in collaboration with the U.S. Environmental Protection Agency (EPA), refined a Quantitative-Structure-Use-Relationship (QSUR) model to predict the probability of whether a chemical is a flame retardant or an OFR. These efforts, in combination with market and use research, led to a manuscript, "Development of a Flame Retardant and an Organohalogen Flame Retardant Chemical Inventory," published in *Nature Scientific Data* (Bevington et al., 2022). This work identified additional OFR chemicals, resulting in an expanded inventory of 488 OFRs in 14 subclasses.

The OFR inventory completed by CPSC staff should not be considered a fixed and final list of all possible OFR chemicals. This project, including the market and use research and literature survey work, has used established identifiers for each chemical, such as CAS RN®,[3] DTXSID,[4] INCHIKEY,[5] PUBCHEM ID,[6] and SMILES,[7] as well as chemical names and common synonyms. However, even with identifiers that should uniquely describe chemicals, there are a few cases in the inventory of the same chemical identified in different ways. CPSC staff also acknowledges that some identifiers correspond to mixtures.[8] To the extent that information on chemicals would be located using different identifiers, CPSC staff will maintain separate listings; however, once staff confirms that multiple records apply to a single chemical (or mixture), analyses of the chemical will consider the combined data for that chemical regardless of the identifiers.

CPSC staff also notes that the inventory may be modified through the course of the project as staff continues analyses of chemicals in each subclass and considers additional information. The result of additional analyses could be the removal or addition of chemicals to the inventory.

4.3. Market and Use Research

The OFR market and use research was intended to collect relevant information and data to (1) characterize each OFR subclass, (2) identify uses of chemicals in each OFR subclass, and (3) identify trends associated with each OFR subclass. CPSC staff sought information about production or consumption of OFR chemicals and identified uses in consumer products and other market information. CPSC staff also sought information on regulatory actions, including current and proposed laws, policies, and regulations related to OFR chemicals at the international, federal, state, and local levels of government. Detailed descriptions of the

[3] CAS RN®, or CAS Registry Number®, is a unique identification number for individual chemical substances assigned by CAS, a division of the American Chemical Society.
[4] DTXSID, or DSSTox substance identifier, is an alphanumeric identifier for individual chemical substances used in the U.S. Environmental Protection Agency's CompTox Chemicals Dashboard.
[5] INCHIKEY, stands for International Chemical Identifier and is a unique 27-character identifier.
[6] PUBCHEM ID is a unique identifier specific to the National Library of Medicine's PUBCHEM database.
[7] Simplified molecular-input line-entry system (SMILES) describes the structure of a chemical in a way that can be used by a computer.
[8] See, for example, CAS RN 85535-84-8, which refers to a group of halogenated aliphatic chain chemicals with chain length from 10 to 13 carbons. Chemical names associated with this CAS RN include short chain chlorinated paraffins; alkanes, C10-13, chloro; and chlorinated paraffins, C10-13.

approach and process are found in Volume 1 of the Market and Use Profile (see Appendix: Supporting Files) completed under a CPSC-sponsored contract. Briefly, the market and use research captured information from targeted scientific literature and gray literature, and from readily available data sources in other formats. Data sources included national chemical inventories, other government data, such as from required reporting of production and waste information for specified chemicals or other types of curated databases, and certain commercial sources.

4.3.1. Targeted Literature Search

Section 3.2.6 of the Market and Use Report explains the methodology used for the targeted literature search completed for the OFR market and use research. The targeted searches for literature related to the flame-retardant market identified sources of relevant material from databases, websites, or other online information repositories, and broader searches of internet-based sources using standard search tools such as Google Scholar and selected searches of commercial online literature databases (e.g., Dialog/ProQuest). Specifically, the contractor executed searches of 140 literature databases using the Dialog/ProQuest platform.[9]

Following a review of the source title and abstract, the contractor rated each identified source for relevance on a scale of 1 to 5, 5 being the most relevant. The contractor then obtained PDF copies of as many of the sources identified as possible, with priority given to those sources rated higher for relevance. Among all 255 sources obtained, the contractor prioritized the review of 187 complete sources.

For each PDF reviewed, the contractor highlighted information on topics of interest for the study, such as manufacturing or import activity, use of chemicals in products, lifecycle considerations, and regulatory or other trends. The report further identified all OFR chemicals discussed in the source, and where available, captured the CAS RN for each chemical and any synonyms, abbreviations, and trade names. From the 187 sources extracted and reviewed, the contractor made over 2,200 OFR identifications (for 488 unique OFRs). The summary of sources reviewed is provided in the Data Source Synthesis Excel workbook of the supplemental Market and Use Profile Supporting Files, referenced by OFR subclass.

4.3.2. Other Data Sources

The OFR Market and Use Report contains information collected from inventories and registries from the United States, Canada, Mexico, the EU, Japan, and China. In the United States, the Toxic Substances Control Act (TSCA) inventory was used to identify if an OFR substance was designated as active or inactive. In addition to determining whether OFR substances appear as active substances on the TSCA chemical inventory, the contractor conducted a detailed analysis of U.S. production and import activity using data available from the EPA Chemical Data Reporting (CDR) program, and the manufacturing, processing, and waste management trends of OFR substances from the Toxic Release Inventory (TRI), as reported by industrial and federal facilities.

[9] For a list of data sources searched using Dialog/ProQuest, see Exhibit 3-32 of the Market and Use Report Volume 1.

To determine whether individual OFR chemicals are used in consumer and/or children's products, the contractor reviewed information available from the EPA's CDR and the Interstate Chemicals Clearinghouse High Priority Chemicals Data System (HPCDS). European data on OFR substances in products could not be reviewed in entirety in time for the publication of the report.

In addition, the contractor made efforts to identify OFR chemicals on several chemical business to business (B2B) or e-Commerce sites, using automated techniques to "scrape" data on OFRs from these sites. From Buyersguide.com and Chemnet.com, the contractor obtained the identity, country, and website of OFR suppliers. From Alibaba.com, they obtained the name and website of the OFR suppliers, as well as some data on quantities available and pricing.

4.4. Literature Survey

The OFR literature survey was intended to gather readily available toxicity, exposure, and risk information to characterize the types and amounts of data available for chemicals (and analogs) within a class. CPSC staff defined data sources for the literature survey effort as toxicity, exposure, and chemistry databases; completed toxicity, exposure, or risk assessments; and completed literature reviews. Sources identified in the literature survey were screened to confirm utility and identify the type of data, but the actual data were not evaluated or extracted.

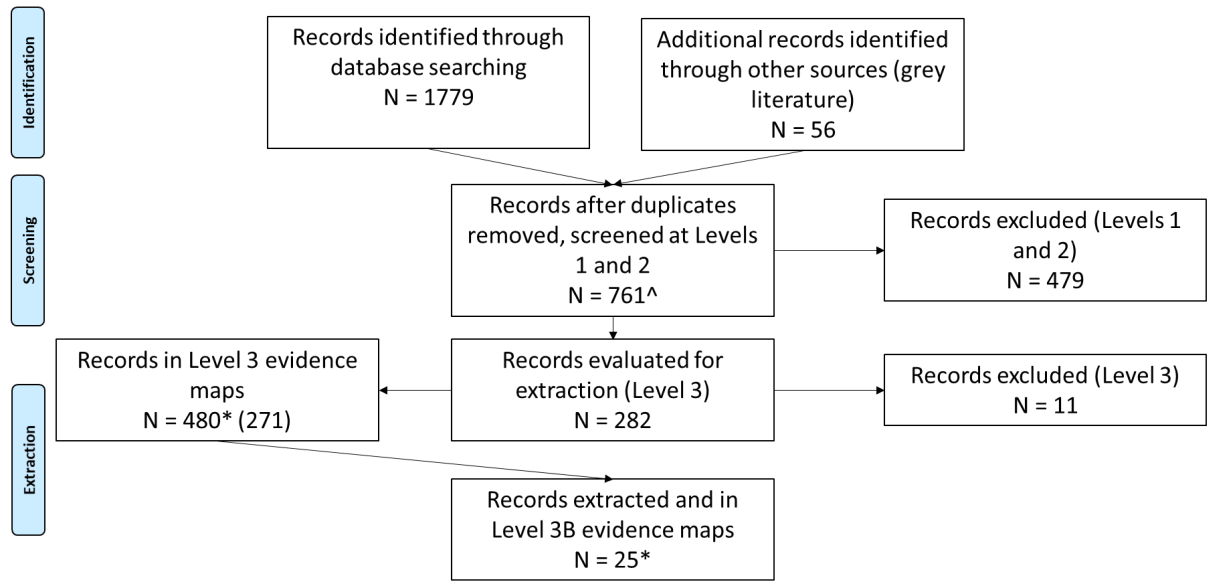
Detailed descriptions of the literature survey approach and process are found in the Literature Survey Guide and accompanying documentation. These documents were developed by University of Cincinnati (UC) Risk Science Center staff as part of work performed under a CPSC-sponsored contract (UC, 2022a; UC, 2022b). Development of the evidence maps followed a multilevel process to screen data sources initially identified in a defined search.

Briefly, for peer-reviewed and gray literature, **Level 1** screening was used to confirm that the reference might contain information about at least one OFR chemical and that the reference was relevant to the PECO statement.[10] **Level 2** screening identified the OFR subclasses included in each reference and tagged the references for the types of data (hazard, exposure, risk). **Level 3** identified the specific OFR or analog chemicals in each reference and extracted more specific information about the types of hazard data, exposure data, or risk assessment information presented for each chemical. Finally, **Level 3B** tagging was performed on a subset of toxicity assessments, toxicity literature reviews, risk assessments, and exposure literature reviews selected from Level 3 to identify even more specific information for the chemicals in these references.

Similarly, data from databases were tagged for type of data using a database logic developed to provide consistency across different data sources. Finally, the tagged information was organized into evidence maps by OFR subclass and specific chemicals. Figure 4-1 shows the numbers of records initially identified and the number of records screened or extracted at each level.

[10] PECO refers to population (P), exposure (E), comparator (C), and outcomes (O) of interest, and generally describes the scope of a literature search and subsequent analyses.

Figure 4-1. Literature Flow Diagram



Notes:
^Removal of duplicates within the subclass.
*PHDE evidence maps contain additional references that were identified in the literature search for the other subclasses. Number in parentheses is the number of references identified by searching for the PHDE subclass only, excluding the references identified by searching other subclasses.

5. Scoping for PHDEs

5.1. PHDE Subclass Chemistry

The PHDE subclass, also commonly referred to as polybrominated diphenyl ethers (PBDEs), generally consists of chemicals containing two halogenated rings connected by an ether functional group. Commercial class members are not single substances, but are mixtures of PBDE congeners (related compounds). For example, congener #209 primarily consists of deca-BDE and non-BDE. Chemicals in this subclass are organized by the number of bromines present. Deca-BDE is the only fully brominated member of this subclass. There are 209 possible PBDE congeners. CPSC staff considered 223 chemicals that could be part of this subclass including unique chemical identifiers for mixtures and congeners.

Table 5-1 lists 53 individual chemicals which were prioritized for literature survey because they were commonly reported congeners (IEc 2022). The market-use survey later identified 102 PHDE chemicals with some market-use information. That is why the market-use section summarizes information for 102 PHDE chemicals and the literature survey section summarizes information for 53 PHDE chemicals. CPSC staff will consider interrelationships of chemical substances within this class due to the close structural similarities.

Table 5-1. List of Chemicals in PHDE Subclass

	CAS RN	Chemical Name	Abbreviation /Synonyms	SMILES
1	1163-19-5	2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl ether	deca-BDE BDE-209	BrC1=C(Br)C(Br)=C(OC2=C(Br)C(Br)=C(Br)C(Br)=C2Br)C(Br)=C1Br
2	117948-63-7	2,2',3,4,4',6,6'-Heptabromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=C(Br)C(Br)=C(Br)C=C2Br)C(Br)=C1
3	117964-21-3	2,2′,3,3′,4,4′,6,6′-Octabromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=C(Br)C(Br)=C(Br)C=C2Br)C(Br)=C1Br
4	147217-75-2	2,2',4-Tribromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=CC=CC=C2Br)C=C1
5	147217-78-5	2',3,4-Tribromodiphenyl ether	NA	BrC1=CC=C(OC2=C(Br)C=CC=C2)C=C1Br
6	182346-21-0	2,2',3,4,4'-Pentabromodiphenyl ether	NA	BrC1=CC=C(OC2=C(Br)C(Br)=C(Br)C=C2)C(Br)=C1
7	182677-30-1	2,2',3,4,4',5'-Hexabromodiphenyl ether	NA	BrC1=CC=C(OC2=CC(Br)=C(Br)C=C2Br)C(Br)=C1Br
8	189084-57-9	1,3-Dibromo-2-(2,4-dibromophenoxy)benzene	NA	BrC1=CC(Br)=C(OC2=C(Br)C=CC=C2Br)C=C1
9	189084-61-5	2,3',4,4'-Tetrabromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=CC(Br)=C(Br)C=C2)C=C1
10	189084-62-6	2,3',4',6-Tetrabromodiphenyl ether	NA	BrC1=CC=CC(Br)=C1OC1=CC(Br)=C(Br)C=C1
11	189084-63-7	1,3,5-Tribromo-2-(4-bromophenoxy)benzene	NA	BrC1=CC=C(OC2=C(Br)C=C(Br)C=C2Br)C=C1
12	189084-64-8	2,2',4,4',6-Pentabromodiphenyl ether	NA	BrC1=CC=C(OC2=C(Br)C=C(Br)C=C2Br)C(Br)=C1
13	189084-67-1	1,2,3,4,5-Pentabromo-6-(2,4-dibromophenoxy)benzene	NA	BrC1=CC(Br)=C(OC2=C(Br)C(Br)=C(Br)C(Br)=C2Br)C=C1
14	207122-15-4	2,2',4,4',5,6'-Hexabromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=CC(Br)=C(Br)C=C2Br)C(Br)=C1
15	207122-16-5	2,2',3,4,4',5',6-Heptabromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=C(Br)C=C(Br)C(Br)=C2Br)C=C1Br
16	243982-82-3	2,2',4,5'-Tetrabromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=C(Br)C=CC(Br)=C2)C=C1
17	243982-83-4	1,2,3-Tribromo-4-(2,4,6-tribromophenoxy)benzene	BDE-140	BrC1=CC(Br)=C(OC2=C(Br)C(Br)=C(Br)C=C2)C(Br)=C1
18	32534-81-9	Pentabromodiphenyl ether	penta-BDE	mixture

	CAS RN	Chemical Name	Abbreviation /Synonyms	SMILES
19	32536-52-0	Octabromodiphenyl ether	octa-BDE	mixture
20	32577-34-7	Benzene, pentabromo(2,3-dibromopropoxy)-	NA	BrCC(Br)COC1=C(Br)C(Br)=C(Br)C(Br)=C1Br
21	337513-55-0	1,2,4-Tribromo-5-(2-bromophenoxy)benzene	BDE-48	BrC1=CC(Br)=C(Br)C=C1OC1=C(Br)C=CC=C1
22	337513-72-1	1,2,3,4,5-Pentabromo-6-(2,4,5-tribromophenoxy)benzene	NA	BrC1=CC(Br)=C(Br)C=C1OC1=C(Br)C(Br)=C(Br)C(Br)=C1Br
23	35854-94-5	2,2',4,4',6,6'-Hexabromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=C(Br)C=C(Br)C=C2Br)C(Br)=C1
24	36065-30-2	1,3,5-Tribromo-2-(2,3-dibromo-2-methylpropoxy)benzene	NA	CC(Br)(CBr)COC1=C(Br)C=C(Br)C=C1Br
25	36483-60-0	Hexabromodiphenyl ether	hexa-BDE	mixture
26	366791-32-4	1,2,3-Tribromo-5-(3,4-dibromophenoxy)benzene	NA	BrC1=CC(OC2=CC(Br)=C(Br)C=C2)=CC(Br)=C1Br
27	40088-47-9	Tetrabromodiphenyl ether	tetra-BDE	mixture
28	41318-75-6	2,4,4'-Tribromodiphenyl ether	NA	BrC1=CC=C(OC2=C(Br)C=C(Br)C=C2)C=C1
29	41424-36-6*	1,3,5-Tribromo-2-methoxy-4-methylbenzene	NA	COC1=C(Br)C(C)=C(Br)C=C1Br
30	437701-78-5	2,2',3,3',4,5,5',6,6'-Nonobromodiphenyl ether	NA	BrC1=CC(Br)=C(Br)C(OC2=C(Br)C(Br)=C(Br)C(Br)=C2Br)=C1Br
31	437701-79-6	2,2′,3,3′,4,4′,5,6,6′-Nonabromodiphenyl ether	NA	BrC1=CC(Br)=C(Br)C(Br)=C1OC1=C(Br)C(Br)=C(Br)C(Br)=C1Br
32	446254-18-8	1,2-Dibromo-3-(2,4-dibromophenoxy)benzene	BDE-42	BrC1=CC=C(OC2=C(Br)C(Br)=CC=C2)C(Br)=C1
33	446254-42-8	1,2,4-Tribromo-5-(4-bromophenoxy)benzene	BDE-74	BrC1=CC=C(OC2=CC(Br)=C(Br)C=C2Br)C=C1
34	446254-64-4	1,2,4-Tribromo-5-(2,3-dibromophenoxy)benzene	BDE-97	BrC1=CC(Br)=C(OC2=CC=CC(Br)=C2Br)C=C1Br
35	446254-66-6	1,2,4-Tribromo-5-(2,6-dibromophenoxy)benzene	BDE-102	BrC1=CC(Br)=C(OC2=C(Br)C=CC=C2Br)C=C1Br
36	446254-80-4	1,2,4-Tribromo-5-(3,4-dibromophenoxy)benzene	NA	BrC1=CC(Br)=C(Br)C=C1OC1=CC(Br)=C(Br)C=C1
37	446254-96-2	1,2,3,5-Tetrabromo-4-(2,4-dibromophenoxy)benzene	NA	BrC1=CC(Br)=C(OC2=C(Br)C(Br)=C(Br)C=C2Br)C=C1
38	446255-00-1	1,2,3,5-Tetrabromo-4-(2,5-dibromophenoxy)benzene	BDE-144	BrC1=CC(OC2=C(Br)C=C(Br)C(Br)=C2Br)=C(Br)C=C1

	CAS RN	Chemical Name	Abbreviation /Synonyms	SMILES
39	446255-19-2	1,2,3,5-Tetrabromo-4-(2,3,4-tribromophenoxy)benzene	BDE-171	BrC1=CC(Br)=C(OC2=C(Br)C(Br)=C(Br)C=C2)C(Br)=C1Br
40	446255-22-7	1,2,3,5-Tetrabromo-4-(2,3,5-tribromophenoxy)benzene	BDE-175	BrC1=CC(OC2=C(Br)C=C(Br)C(Br)=C2Br)=C(Br)C(Br)=C1
41	446255-26-1	1,2,3,4-Tetrabromo-5-(2,4,5-tribromophenoxy)benzene	BDE-180	BrC1=CC(Br)=C(OC2=CC(Br)=C(Br)C(Br)=C2Br)C=C1Br
42	446255-30-7	2,3,3',4,4',5',6-Heptabromodiphenyl ether	NA	BrC1=CC(OC2=C(Br)C(Br)=C(Br)C=C2Br)=CC(Br)=C1Br
43	446255-39-6	2,2′,3,3′,4,4′,5,6′-Octabromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=CC(Br)=C(Br)C(Br)=C2Br)C(Br)=C1Br
44	446255-50-1	1,2,3,5-Tetrabromo-4-(2,3,5,6-tetrabromophenoxy)benzene	BDE-201	BrC1=CC(Br)=C(OC2=C(Br)C(Br)=CC(Br)=C2Br)C(Br)=C1Br
45	51892-26-3**	2,4-Dichlorodiphenyl ether	NA	ClC1=CC(Cl)=C(OC2=CC=CC=C2)C=C1
46	5436-43-1	2,2',4,4'-Tetrabromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=CC=C(Br)C=C2Br)C=C1
47	58965-66-5	Perbromo-1,4-diphenoxybenzene	NA	BrC1=C(Br)C(Br)=C(OC2=C(Br)C(Br)=C(OC3=C(Br)C(Br)=C(Br)C(Br)=C3Br)C(Br)=C2Br)C(Br)=C1Br
48	60348-60-9	2,2',4,4',5-Pentabromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=C(Br)C=C(Br)C(Br)=C2)C=C1
49	63936-56-1	Nonabromodiphenyl ether	nona-BDE	mixture
50	68631-49-2	2,2',4,4',5,5'-Hexabromodiphenyl ether	NA	BrC1=CC(Br)=C(OC2=CC(Br)=C(Br)C=C2Br)C=C1Br
51	68928-80-3	Heptabromodiphenyl ether	hepta-BDE	mixture
52	79755-43-4	3,5-Dibromo-2-(2,4-dibromophenoxy)phenol	NA	OC1=C(OC2=C(Br)C=C(Br)C=C2)C(Br)=CC(Br)=C1
53	85446-17-9	1,1'-Oxybis(2,3,4,5-tetrabromobenzene)	NA	BrC1=C(Br)C(Br)=C(Br)C(OC2=CC(Br)=C(Br)C(Br)=C2Br)=C1

SMILES = simplified molecular-input line-entry system. NA = not available or not found.

* While finalizing this scope document, CPSC staff decided to move this chemical from the PHDE subclass to the Polyhalogenated Benzene Aliphatics and Functionalized (PHBzAF) subclass

** While finalizing this scope document, CPSC staff determined that this chemical is not likely an OFR. These two changes will reduce the number of chemicals in this subclass by two.

5.1.1. Physicochemical Property Summaries

The information collected to date led CPSC staff to find that experimental physicochemical data on PHDE chemicals are limited. Fifteen PHDE subclass members have experimental data and 209 PHDE members have predicted data. Well-studied chemicals in this subclass include 2,2',4,4'-Tetrabromodiphenyl ether, 2,2',4,4',5-Pentabromodiphenyl ether, 2,2',4,4',5,6'-Hexabromodiphenyl ether, and 2,2',3,4,4',5',6-Heptabromodiphenyl ether. From this data set, studied PHDEs have boiling points ranging from 130°C to 400°C, and vapor pressures from

$1.0E^{-12}$ to $2.0E^{-5}$ mm Hg. Data show that the chemicals have low water solubility values and high octanol/water partition coefficient (K_{ow}) values, which are commonly expressed as log K_{ow}, ranging from 5.0 to 10.

5.2. Market and Use Summary for PHDEs

The OFR Market and Use Report, completed in March 2022, includes 223 PHDE chemicals.

- One-hundred-two PHDE chemicals had market and use information and 121 chemicals had no market and use information.
- According to EPA data, 11 PHDE chemicals were identified to be on the EPA TSCA Chemical Substance (active) Inventory, no PHDE chemicals were identified on the TSCA (inactive) inventory, one was on the CDR, and one was on the TRI program list.
- One PHDE chemical was identified in the Interstate Chemicals Clearinghouse (IC2) HPCDS.
- Forty-five PHDE chemicals were identified in the targeted literature search.
- Eighty-two PHDE chemicals had patent data.

5.2.1. PHDEs Used in Commerce

The Market and Use Report summarizes data from a variety of sources including U.S. and international chemical registries, scientific literature, patents, and chemical databases. To determine whether individual OFRs are currently in commerce, have been used in the past, or may be used in the future, these registries, patent data, and literature were reviewed in detail under a CPSC-sponsored contract and data were compiled from four main types of sources. Chemicals that have been in commerce appear on the (1) TSCA inventory, (2) international inventories, (3) in literature, or (4) in patent data. Table 52 lists the 102 PHDEs that are known to be or have been used in commerce, according to data available from these sources.

Among the 102 PHDE chemicals used in commerce, 11 can be found in the TSCA inventory. All 11 chemicals are in the TSCA active inventory and no PHDEs are on the TSCA inactive inventory. In Table 52, PHDE chemicals found on the TSCA inventory are identified as “Active” or “Not found,” accordingly.

Five other international registries were reviewed: EU REACH (2021), CANADA DSL (2021), MEXICO INSQ (2009), JAPAN CSCL (2021), AND CHINA IECSC (2013).[11] Forty-seven PHDE chemicals appear on one or more of these international inventories. In Table 5-2, the number of international registries for the identified PHDE chemicals is listed in the “International Inventories” column.

Forty-five PHDE chemicals were identified in the literature through a targeted literature search.[12] In Table 5-2, the numeric value listed in the “Literature Cites” column is the number of sources from the targeted literature search that referenced the chemical.

[11] EU REACH = European Union Registration, Evaluation, Authorisation, and Restriction of Chemicals; INSQ = Inventario Nacional de Sustancias Químicas; CSCL = Chemical Substances Control Law; IECSC = Inventory of Existing Chemical Substances Produced or Imported in China.
[12] For additional detail on the methodology used for the targeted literature search, see Section 4.3.1, Targeted Literature Search, in this scope document.

Eighty-two PHDE chemicals were mentioned in patents. The total count of patents is provided for each chemical in Table 5-2, returned from a search of the associated Compound Identifier (CID) in PubChem. For those chemicals that were not associated with a CID, "No CID" is reported in the "Patents" column.

Table 5-2. PHDE Chemicals Used in Commerce

CAS Number	Chemical Name	TSCA	International Inventories	Literature Cites	Patents
101-55-3	p-Bromodiphenyl ether	Active	2	3	1,653
103173-66-6	1,1'-Oxybis(3,5-dibromobenzene)	Not found	1	0	3
1163-19-5	Decabromodiphenyl ether	Active	4	47	28,604
116995-32-5	1,2,4,5-Tetrabromo-3-(2,4,6-tribromophenoxy)benzene	Not found	1	0	28,604
116995-33-6	BDE-147	Not found	1	0	0
117948-63-7	Benzene, 1,2,3,5-tetrabromo-4-(2,4,6-tribromophenoxy)-	Not found	1	1	8
117964-21-3	BDE-197	Not found	Not found	6	8
147217-71-8	1-Bromo-2-(4-bromophenoxy)benzene	Not found	1	0	34
147217-72-9	BDE-6	Not found	1	0	34
147217-73-0	BDE-19	Not found	1	0	6
147217-74-1	1,2-Dibromo-3-(2-bromophenoxy)benzene	Not found	1	0	0
147217-75-2	2,2',4-Tribromodiphenyl ether	Not found	1	3	0
147217-76-3	BDE-20	Not found	1	0	10
147217-77-4	2,4-Dibromo-1-(3-bromophenoxy)benzene	Not found	1	0	0
147217-78-5	2',3,4-Tribromodiphenyl ether	Not found	1	0	0
147217-79-6	1,3-Dibromo-5-(3-bromophenoxy)benzene	Not found	1	0	161
147217-80-9	BDE-35	Not found	1	0	0
147217-81-0	BDE-37	Not found	1	0	0
155999-95-4	2,4,6-Tribromodiphenyl ether	Not found	1	0	6
171977-44-9	2,4-Dibromo-1-phenoxybenzene	Not found	1	0	8
182346-21-0	2,2',3,4,4'-Pentabromodiphenyl ether	Not found	Not found	8	49
182677-28-7	1,1'-Oxybis(2,3,4-tribromobenzene)	Not found	Not found	0	49
182677-30-1	2,2',3,4,4',5'-Hexabromodiphenyl ether	Not found	Not found	4	45
189084-60-4	BDE-32	Not found	Not found	1	4

CAS Number	Chemical Name	TSCA	International Inventories	Literature Cites	Patents
189084-61-5	2,3',4,4'-Tetrabromodiphenyl ether	Not found	Not found	9	0
189084-62-6	2,3',4',6-Tetrabromodiphenyl ether	Not found	Not found	4	17
189084-63-7	BDE-75	Not found	Not found	0	19
189084-64-8	2,2',4,4',6-Pentabromodiphenyl ether	Not found	Not found	22	3
189084-65-9	1,2,3,4,5-Pentabromo-6-phenoxybenzene	Not found	1	0	93
189084-66-0	2,3',4,4',6-Pentabromodiphenyl ether	Not found	Not found	3	2,615
189084-67-1	1,2,3,4,5-Pentabromo-6-(2,4-dibromophenoxy)benzene	Not found	Not found	0	18
189084-68-2	2,3,3',4,4',5,6-Heptabromodiphenyl ether	Not found	Not found	2	0
2050-47-7	4,4'-Dibromodiphenyl ether	Active	2	2	1,470
207122-15-4	2,2',4,4',5,6'-Hexabromodiphenyl ether	Not found	1	15	104
207122-16-5	2,2',3,4,4',5',6-Heptabromodiphenyl ether	Not found	1	16	104
243982-82-3	2,2',4,5'-Tetrabromodiphenyl ether	Not found	Not found	3	41
243982-83-4	BDE-140	Not found	Not found	0	41
32534-81-9	Pentabromodiphenyl ether	Active	3	19	No CID
32536-52-0	Octabromodiphenyl ether	Active	2	21	No CID
32577-34-7	Benzene, pentabromo(2,3-dibromopropoxy)-	Not found	Not found	0	4,858
337513-67-4	BDE-21	Not found	Not found	0	16
337513-68-5	BDE-41	Not found	Not found	0	43
337513-72-1	BDE-203	Not found	Not found	3	0
337513-75-4	1,4-Dibromo-2-(3-bromophenoxy)benzene	Not found	Not found	0	2,500
337513-82-3	BDE-57	Not found	Not found	0	188
35854-94-5	2,2',4,4',6,6'-Hexabromodiphenyl ether	Not found	1	1	73
36065-30-2	1,3,5-Tribromo-2-(2,3-dibromo-2-methylpropoxy)benzene	Not found	Not found	0	73
36483-60-0	Hexabromodiphenyl ether	Active	3	3	No CID
366791-32-4	1,2,3-Tribromo-5-(3,4-dibromophenoxy)benzene	Not found	Not found	1	6

CAS Number	Chemical Name	TSCA	International Inventories	Literature Cites	Patents
38463-82-0	1,3,5-Tribromo-2-(2,3-dibromophenoxy)benzene	Not found	Not found	0	1
40088-47-9	Tetrabromodiphenyl ether	Active	3	2	0
405237-85-6	1,2,3,4-Tetrabromo-5-(3,4-dibromophenoxy)benzene	Not found	Not found	1	9
405237-86-7	1,2,3,4,5-Pentabromo-6-(2,5-dibromophenoxy)benzene	Not found	Not found	0	9
41318-75-6	2,4,4'-Tribromodiphenyl ether	Not found	1	13	0
41424-36-6	1,3,5-Tribromo-2-methoxy-4-methylbenzene	Not found	1	0	31
437701-78-5	2,2',3,3',4,5,5',6,6'-Nonabromodiphenyl ether	Not found	Not found	2	8
437701-79-6	BDE-207	Not found	Not found	5	8
442690-45-1	BDE-182	Not found	Not found	0	7
446254-15-5	BDE-22	Not found	Not found	0	7
446254-16-6	BDE-23	Not found	Not found	0	1
446254-25-7	BDE-53	Not found	Not found	0	5
446254-27-9	1,2,3-Tribromo-4-(3-bromophenoxy)benzene	Not found	Not found	0	50
446254-32-6	BDE-61	Not found	Not found	2	731
446254-33-7	BDE-62	Not found	Not found	0	212
446254-40-6	BDE-72	Not found	Not found	0	10
446254-81-5	BDE-121	Not found	Not found	0	1
446254-82-6	BDE-122	Not found	Not found	0	2
446254-96-2	1,2,3,5-Tetrabromo-4-(2,4-dibromophenoxy)benzene	Not found	Not found	0	1
446254-98-4	BDE-142	Not found	Not found	1	0
446254-99-5	BDE-143	Not found	Not found	0	384
446255-03-4	BDE-148	Not found	Not found	1	0
446255-04-5	BDE-149	Not found	Not found	0	307
446255-22-7	BDE-175	Not found	1	0	0
446255-30-7	1,2,3,5-Tetrabromo-4-(3,4,5-tribromophenoxy)benzene	Not found	Not found	1	0
446255-34-1	BDE-193	Not found	Not found	0	8
446255-39-6	BDE-196	Not found	Not found	6	1,956
446255-42-1	BDE-198	Not found	Not found	0	18
446255-50-1	BDE-201	Not found	Not found	2	1

CAS Number	Chemical Name	TSCA	International Inventories	Literature Cites	Patents
446255-54-5	2,2',3,4,4',5,6,6'-Octabromodiphenyl ether	Not found	Not found	0	2
446255-56-7	PBDE 205	Not found	Not found	1	2
46438-88-4	1,3-Dibromo-5-phenoxybenzene	Not found	Not found	0	4
49690-94-0	Tribromodiphenyl ether	Active	2	0	161
51452-87-0	BDE-4	Not found	1	0	373
51892-26-3	2,4-Dichlorodiphenyl ether	Not found	Not found	2	373
51930-04-2	Benzene, 1,3-dibromo-2-phenoxy-	Not found	1	0	128
53563-56-7	Diphenyl ether, dibromo-	Not found	1	0	69
5436-43-1	2,2',4,4'-Tetrabromodiphenyl ether	Not found	1	22	214
58965-66-5	Perbromo-1,4-diphenoxybenzene	Active	3	5	47
60348-60-9	2,2',4,4',5-Pentabromodiphenyl ether	Not found	1	23	143
63387-28-0	1,2,3,4,5-Pentabromo-6-(2,3,4,5-tetrabromophenoxy)benzene	Not found	Not found	4	232
63936-56-1	Nonabromodiphenyl ether	Active	2	3	232
65075-08-3	1,4-Dibromo-2-(4-bromophenoxy)benzene	Not found	1	0	0
67797-09-5	BDE-202	Not found	Not found	1	1
68631-49-2	2,2',4,4',5,5'-Hexabromodiphenyl ether	Not found	1	21	89
6876-00-2	PBDE 002	Not found	1	0	393
68928-80-3	Diphenyl ether, heptabromo derivative	Active	2	5	111
6903-63-5	1,1'-Oxybis(3-bromobenzene)	Not found	1	0	95
7025-06-1	Benzene, bromophenoxy-	Not found	1	0	936
79755-43-4	3,5-Dibromo-2-(2,4-dibromophenoxy)phenol	Not found	Not found	0	51
83694-71-7	1-Bromo-3-(4-bromophenoxy)benzene	Not found	1	0	56
85446-17-9	1,1'-Oxybis(2,3,4,5-tetrabromobenzene)	Not found	Not found	0	4,858
93703-48-1	BDE-77	Not found	1	2	20

Table 5-2 shows that information indicating PHDE chemicals are used in commerce is available from thousands of patents, numerous literature sources, and multiple chemical inventories.

5.2.2. PHDEs Used in Consumer Products

The Market and Use Report identified the use of PHDEs in consumer products, including children's products. To determine whether individual OFR chemicals are used in consumer and/or children's products, a CPSC-sponsored contractor reviewed the information available from the EPA's CDR,[13] the European Chemicals Agency's (ECHA) Substances of Concern in articles as such or in complex objects (Products) (SCIP) database, and the IC2's HPCDS. Data on the uses and applications of PHDE chemicals were also found in the literature.

Targeted Literature Search. In the literature, several sources report the results of product testing, and these indicate PHDEs have been found in a variety of consumer and/or children's products.

The following PHDE chemicals were identified from the targeted literature search to have been used in consumer and children's products, and example uses are provided below:

CAS No. 101-55-3: interior car foam, other interior car materials, curtains, assembly boards, IT devices, upholstered furniture, upholstered furniture, upholstered foams, mattresses, and circuit boards.

CAS No. 1163-19-5: sofas, chairs, mattresses, car seats, pillows, electronics, textiles, children's toys, building insulation, electronic enclosures, tent fabrics, construction materials, flooring, food contact articles, carpets, thermal cups, hair clips, combs, kitchen utensils, textile back coatings, and fibers.

CAS No. 117948-63-7: furniture, electronics, textiles, children's toys, car interior foam, other car interior materials, and curtains.

CAS No. 117964-21-3: car interior foam, other car interior materials, curtains, children's toys.

CAS No. 147217-75-2: upholstered furniture, electrical and electronic equipment, car interior foam, other car interior materials, and curtains.

CAS No. 182346-21-0: children's toys, construction materials, electrical and electronic devices, flooring, fabric, upholstery, curtains, insulation, assembly boards, IT devices, mattresses, circuit boards, car interior foam, and other car interior materials.

CAS No. 182677-30-1: household/office furniture/furnishings, baby care, home appliances, clothing, toys/games, electrical supplies, building products, communication equipment, computing devices, camping gear, IT devices, upholstered furniture, mattresses, circuit boards, car interior foam, other car interior materials, and curtains.

CAS No. 189084-60-4: insulation, assembly boards, IT devices, upholstered furniture, upholstery foams, mattresses, and circuit boards.

CAS No. 189084-61-5: children's toys, construction materials, electrical and electronic devices, flooring, fabric, upholstery, household/office furniture/furnishings, baby care, home appliances,

[13] Data from the review of EPA's CDR for consumer products was generally incomplete, especially for children's products, and therefore are not summarized below however they are available in Section 3.2.5.1 in Volume I of the Market and Use Report.

clothing, toys/games, electrical supplies, communication equipment, computing devices, camping gear, curtains, car interior foam, and other car interior materials.

CAS No. 189084-62-6: upholstered furniture, electrical and electronic equipment, car interior foam, other car interior materials, and curtains.

CAS No. 189084-64-8: furniture, textiles, and children's toys, construction materials, electrical and electronic devices/equipment, flooring, upholstery, household/office furniture/furnishings, baby care, home appliances, clothing, toys/games, electrical supplies, communications equipment, computing devices, camping gear, curtains, paper and textile adhesives, polyurethane and polystyrene foam, plastics, wires, baby mattresses, diaper-changing mats, feeding chairs, baths, aprons, assembly boards, and kitchen utensils.

CAS No. 189084-66-0: car interior foam, other car interior materials, and curtains.

CAS No. 189084-68-2: household/office furniture/furnishings, baby care, home appliances, clothing, toys/games, electrical supplies, building products, communication equipment, computing devices, camping gear, insulation, assembly boards, IT devices, upholstered furniture, upholstery foams, mattresses, and circuit boards.

CAS No. 2050-47-7: car interior foam, other car interior materials, and curtains.

CAS No. 207122-15-4: furniture, textiles, children's toys, construction materials, electrical and electronic devices, flooring, upholstery, household/office furniture/furnishings, baby care, home appliances, clothing, communication equipment, computing devices, camping gear, curtains, electronic casings, paper, textile adhesives, polyurethane and polystyrene foam, plastics, car interior foam, other car interior materials, and kitchen utensils.

CAS No. 207122-16-5: furniture, textiles, children's toys, construction materials, electrical and electronic devices, flooring, upholstery, household/office furniture/furnishings, baby care, home appliances, clothing, toys/games, electrical and electronic equipment, communication equipment, computing devices, camping gear, carpets, curtains, electronic equipment casings, paper and textile adhesives, polyurethane and polystyrene foam, car interior foam, other car interior materials, and kitchen utensils.

CAS No. 243982-82-3: furniture, electronics, textiles, children's toys, children's car seats, car interior foam, other car interior materials, and curtains.

CAS No. 32534-81-9: crib mattresses using polyurethane foam, furniture, electronics, textiles, children's toys, baby products, building materials, paper, textile adhesives, nursing pillows, strollers, baby carriers, car seats, and changing table pads.

CAS No. 32536-52-0: electronic appliances, furniture and upholstery, car interiors, and raw materials for electronics, electronics, textiles, and children's toys, foam plastic building insulation, electronic enclosures, thermal cups, combs, headdresses, paper, textile adhesives, polyurethane and polystyrene foam.

CAS No. 366791-32-4: car interior foam, other car interior materials, and curtains.

CAS No. 405237-85-6: car interior foam, other car interior materials, and curtains.

CAS No. 41318-75-6: furniture, electronics, textiles, children's toys, construction materials, flooring, upholstery, carpets, curtains, children's car seats, car interior foam, other car interior materials, and kitchen utensils.

CAS No. 437701-78-5: electronics, building materials, paper and textile adhesives, polyurethane and polystyrene foam, and plastics.

CAS No. 437701-79-6: electronics, building materials, paper and textile adhesives, polyurethane and polystyrene foam, plastics, car interior foam, other car interior materials, and curtains.

CAS No. 446255-30-7: car interior foam, other car interior materials, and curtains.

CAS No. 446255-39-6: car interior foam, other car interior materials, children's toys, and curtains.

CAS No. 446255-50-1: electronics, building materials, paper and textile adhesives, polyurethane and polystyrene foam, and plastics.

CAS No. 51892-26-3: car interior foam, other car interior materials, and curtains.

CAS No. 5436-43-1: electronics, textiles, children's toys, construction materials, electrical and electronic devices, flooring, upholstery, household/office furniture/furnishings, baby care, home appliances, clothing, toys/games, electrical supplies, communication equipment, computing devices, camping gear, curtains, carpets, electronic casings, paper and textile adhesives, polyurethane and polystyrene foam, children's car seats, mattresses, car interior foam, other car interior materials, and kitchen utensils.

CAS No. 58965-66-5: curtains, polyester, wire, and cable.

CAS No. 60348-60-9: electronic appliances, furniture and upholstery, car interiors, sofas, chairs, mattresses, car seats, pillows, furniture, electronics, textiles, children's toys, foam, plastics, building insulation, electronic enclosures, construction materials, textiles, paper and textile adhesives, polyurethane and polystyrene foam, baby mattresses, diaper-changing mats, feeding chairs, baths, aprons, car interior foam, other car interior materials, curtains, and kitchen utensils.

CAS No. 63387-28-0: car interior foam, other car interior materials, and curtains.

CAS No. 68631-49-2: furniture, electronics, textiles, children's toys, construction materials, electrical and electronic devices, flooring, upholstery, household/office furniture/furnishings, baby care, home appliances, clothing, toys/games, electrical supplies, communication equipment, computing devices, camping gear, carpets, curtains, car interior foam, other car interior materials, and kitchen utensils.

CAS No. 68928-80-3: clothes hangers.

CAS No. 93703-48-1: car interior foam, other car interior materials, and curtains.

HPCDS. Using the HPCDS reporting tool, private industry reports the use of chemicals of concern in products intended for use by children that are sold in select states.[14] From 2012 to 2020, 1,093 reports were submitted to HPCDS identifying the use of OFR chemicals from seven subclasses in children's products sold in two U.S. states, Washington and Oregon. Seventeen percent, or 186 reports, documented the use of PHDE chemicals in children's products.

Table 5-3 shows information on the total report count, the uses, and the concentration of a common PHDE chemical (decabromodiphenyl ether, 1163-19-5) reported to be used in children's products. Approximately half of the reported uses of the substance (91 reports) was for use as a chemical flame retardant. Of the 186 reported uses of this PHDE in children's products, most chemicals were reportedly used in trace amounts, although 10 reports identified the use of PHDEs in children's products in concentrations greater than 1,000 ppm (0.1%), a threshold CPSC staff considers above the level of contaminant.[15] There were eight reported uses of this PHDE in concentrations greater than 0.1% that were expressly for use as a chemical flame retardant in a children's product.

Table 5-3. Number of Children's Products with Reported Use as Flame Retardants for a Select PHDE Chemical

PHDE	Total Report Count	Flame Retardant Use	Concentration >0.1%	Concentration >0.1% + FR Use
1163-19-5	186	91	10	8

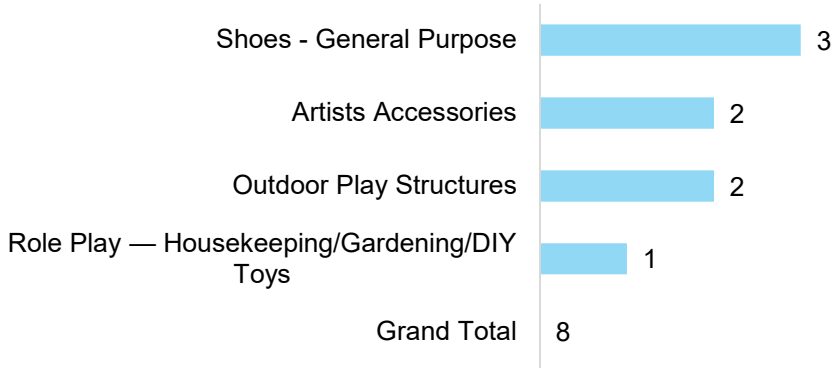
Source: HPCDS, Interstate Chemicals Clearinghouse.

As shown in Figure 5-1, the eight reported applications for which this PHDE is used as a chemical flame retardant (in concentrations greater than 0.1%) were general purpose shoes, outdoor play structures, artist accessories, and role play housekeeping, gardening, and do-it-yourself toys. (See Exhibit 3-28 in the Market and Use Report, Volume 1.)

[14] At this time, CPSC staff is unable to determine if information reported to the HPCDS for Washington and Oregon are representative. Presumably, the number of reports would go up substantially if information for all 50 states were available; however, it is not known whether the chemicals identified and types of children's products would also change.

[15] This amount corresponds with information on candidate list substances in articles in which importers and producers have to submit notification to the European Chemicals Agency (ECHA) if a substance is present in a concentration above 0.1% weight by weight (Introduction to Information on Candidate List substances in articles ECHA [echa.europa.eu]). CPSC staff rationale is that it should consider 0.1% or below to represent a contamination level given that concentrations of these chemicals when used intentionally as flame retardants are typically much higher.

Figure 5-1. Children's Products That Contain PHDE Chemical Flame Retardants



Source: HPCDS, Interstate Chemicals Clearinghouse.

Among children's products identified to contain PHDE chemical FRs in a concentration greater than 0.1%, these high priority chemicals are reportedly found in synthetic polymers (e.g., synthetic rubber, plastics, foams) and in textiles (e.g., synthetic fibers and blends), in concentrations greater than 1,000 ppm. (See Table 5-4.)

Table 5-4. Component Parts That Contain PHDE Chemicals, at a Concentration Equal to or Greater than 1,000 ppm, when Used as Flame Retardant in a Children's Product (2012–2020)

Chemical (CAS RN)	Chemical Name	Synthetic Polymers (Synthetic Rubber, Plastics, Foams, Etc.)	Textiles (Synthetic Fibers and Blends)
1163-19-5	Decabromodiphenyl ether	X	X

SCIP. ECHA maintains a database of information through the REACH regulation, which was enacted in 2007 to improve the protection of human health from risks posed by chemicals. REACH applies to consumer products as well as to the chemicals industry. The REACH regulation requires suppliers of articles (products) containing potentially hazardous chemicals, including OFRs, to communicate down the supply chain and to consumers sufficient information to allow for the safe use of those products that contain them. Any supplier of an article containing a substance of very high concern (SVHC) in a concentration above 0.1% weight by weight (w/w) on the EU market is required to submit information on that article to ECHA. This information is commonly referred to as a "SCIP notification." From data available from the European Union, SCIP notifications have supported the development of the SCIP database.

The SCIP database is an important tool of the REACH framework and helps ensure that information regarding the use of hazardous substances in products is more readily and efficiently shared within the supply chain, and that certain information regarding the use of hazardous substances in products is also available to the public.

Table 5-5 shows that at least one PHDE chemical was included in the SCIP database. (See Exhibit 3-30 in the Market and Use Report, Volume 1.)

Table 5-5. PHDE Chemicals Included in SCIP Database

CAS RN	Substance Name	EC No.	Number of Search Results Returned
1163-19-5	Decabromodiphenyl ether	214-604-9	32,563

As of May 2023, there were 32,563 search results for Deca-BDE (CAS RN 1163-19-5) in the SCIP database. Articles that contain this candidate list substance can be found in over 15 article categories that can be used to help identify articles based on function and use. According to SCIP data, Deca-BDE can be found in vehicles, machinery and appliances, optical instruments, and miscellaneous manufactured articles such as toys, games and sports accessories. However, because SCIP data were first released in September 2021, they could not be reviewed in time for publication of the Market and Use Report.

CDR. According to data available from the EPA's CDR, PHDE chemicals have been used in a variety of product use categories for many years. (See Table 5-6.) This table presents both commercial and consumer product uses of PHDE chemicals because CPSC needs to know the range of product uses for these chemicals during the scoping phase.[16]

EPA changed the names of some product use categories between 2006 and 2012, and again in 2016, and so Table 5-6 presents the names of product use categories of PHDE chemicals in the three reporting periods.[17] To handle small changes in product use category names over these periods, staff used a more generic or general name to be inclusive. The designated general product use category names help maintain consistency over the period displayed in the table below without distorting product use.

According to the CDR, the most common uses of PHDE chemicals are in fabric, textile, and leather products; and in adhesives and sealants, although PHDEs are reported to be used in a variety of other products as well.

[16] In the global economy, supply chains are complex, and reporters to the CDR do not know (or cannot reasonably ascertain) the end use of a product. Therefore, CPSC is reviewing all product use categories of OFR chemicals reported to the CDR, but may exclude certain categories later, if there is sufficient evidence showing that these chemical substances can be found exclusively in commercial products.
[17] For the 2006, 2012, and 2016 reporting periods, chemical-specific product use reporting was only required for the principal reporting year (PRY), the latest completed calendar year preceding the submission period. Therefore, 2006 data are from PRY 2005, 2012 data are from PRY 2011, and 2016 data from PRY 2015.

Table 5-6. Report Counts of Commercial and Consumer Product Uses of PHDE Chemicals

Product Use Category	2006	2012	2016	Total
Adhesives and sealants	1	3	NR	**4**
Building/construction materials – Wood and engineered wood products	NR	2	NR	**2**
Electrical and electronic products	1	2	NR	**3**
Fabric, textile, and leather products not covered elsewhere	1	4	2	**7**
Floor coverings	NR	2	NR	**2**
Plastic and rubber products not covered elsewhere	1	1	1	**3**
Product description not identified	1	NR	NR	**1**
Grand Total	**5**	**14**	**3**	**22**

Notes: Data listed as "Product description not identified" may be interpreted as one of any of the other product categories reported for PHDEs, generally. NR = not reported or not available.

In addition, the CDR provides an opportunity for firms that report the use of a chemical substance to identify if the substance could be used in children's products. However, the CDR should not be considered a complete source for identifying the use of OFR chemical substances in children's products.[18] In 2006, the use of PHDE chemicals in children's products was considered by reporting firms to be confidential business information (CBI) and the product category use of PHDE chemicals was also considered CBI. In 2012, the use of PHDE chemicals in children's products was reported to the CDR to be used in fabric, textile, and leather products not covered elsewhere. In 2016, the use of PHDE chemicals was not reported.

5.2.3. Regulatory History and Trends for PHDEs

OFRs have received considerable regulatory attention from governmental jurisdictions in the United States and around the world; however, the scope and applicability of these regulatory actions varies significantly. This section discusses legislative action taken in the United States at the state level and in Europe through ECHA.

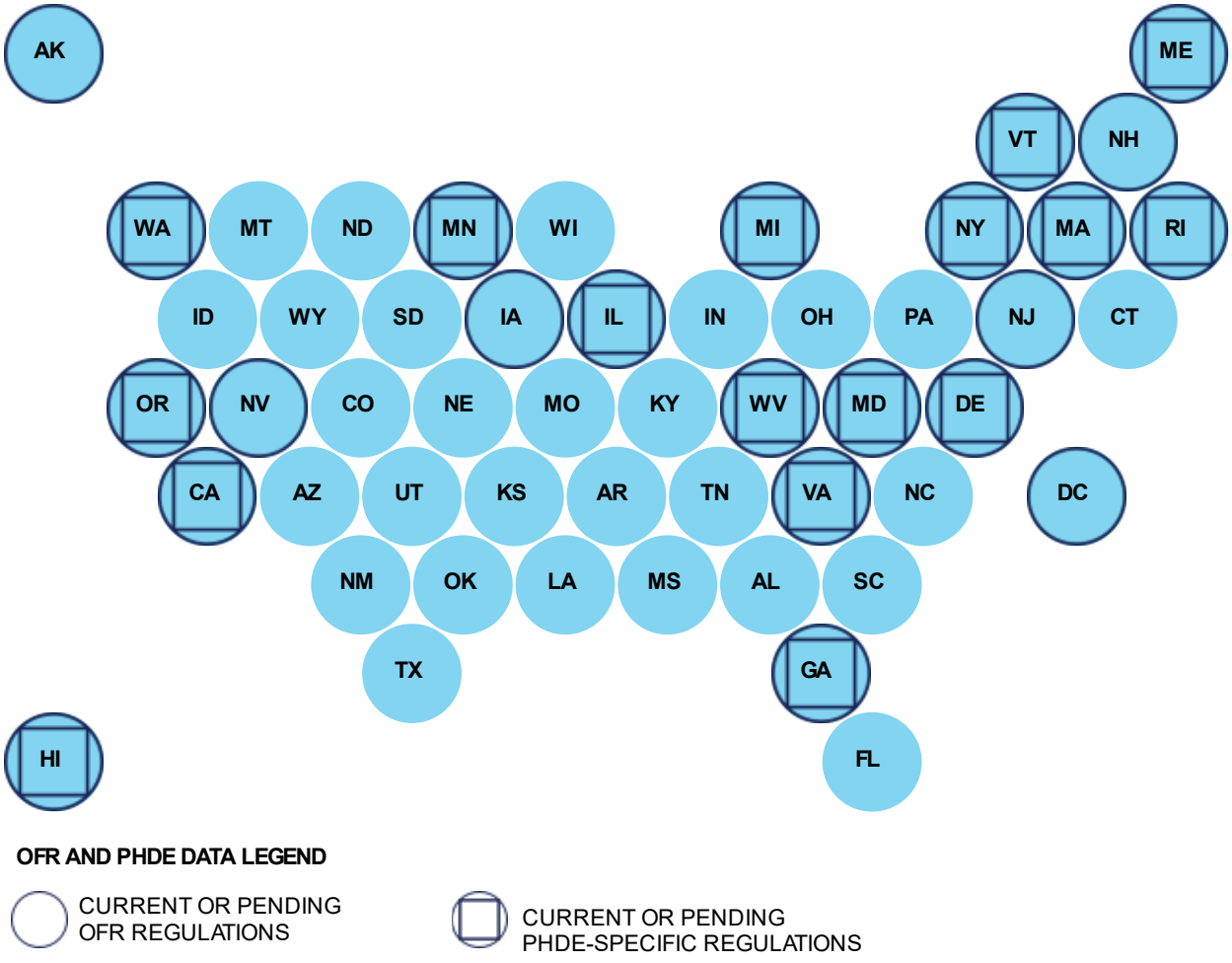
The Market and Use Report provides greater detail of legislative action taken in the United States, as well as action taken by other nations. Volume 2, Appendix R of the Market and Use Report provides detailed fact sheets describing specific pieces of legislation enacted or under consideration since 1986 in 21 U.S. states and the District of Columbia, at the U.S. federal level, and by Canada, the EU, and Japan.[19]

According to the Market and Use Report, 22 states and the District of Columbia have current or pending OFR chemicals regulations. State regulation of OFRs has tended to focus primarily on

[18] The CDR rule provides reporting exemptions for chemical substances in articles, byproducts, impurities, non-isolated intermediates, certain polymers, research and development, and those produced by small manufacturers and small importers. 40 C.F.R. §§ 704.5 and 711.6. The CDR rule also exempts chemical substances manufactured in quantities of less than 2,500 pounds. Id. at § 711.15.
[19] As part of work performed under the CPSC-sponsored contract, CPSC staff also sought to identify legislation developed in China related to OFRs. The literature review suggests China imposes some restrictions on OFRs, which is discussed more generally in Section 4.1.3 of Volume 1 of the Market and Use Report.

the use of these chemicals in children's products, upholstered furniture, and mattresses. (See Market and Use Report Volume 1, section 4.1.2.4 Summary of U.S. Regulatory Trends.) Among areas that have regulated the use of OFRs, 17 states currently regulate the use of PHDEs specifically, or have regulations pending. In the map below, states that regulate OFRs are shown with a circle border and states that regulate PHDEs specifically are shown with a square border. For more information on the state regulation of OFRs and PHDEs, see Volume 2 of the Market and Use Report, Appendix R.

Figure 5-2. U.S. States That Regulate the Use of OFR and PHDE Chemical Flame Retardants



The sharing of data reported to states helps to improve the effectiveness of enacted legislation on potentially hazardous OFR chemicals and to address information asymmetries in the market. Increasingly, state legislation compels reporting and allows for reciprocal data-sharing agreements with trade associations, the IC2, or other independent third parties. Reported data are also shared with the public. According to data compiled in the Market and Use Report (see

Appendix R of Volume 2), eight states and the District of Columbia have reporting or data-sharing requirements for OFR chemicals.

5.3. Literature Survey Results: Evidence Maps of Toxicity Data

The toxicity evidence map descriptions below are high-level observations of the Level 2, 3, and 3B literature surveys in the designated spreadsheet files.[20] The database counts indicate either the number of sources within the database (if available) or the number of entries in the database (if no information on source is available) after attempts were made to remove duplicates. The unit for PDF counts is the individual PDF file. Level 3B tagging was performed on a subset of 25 toxicity assessments, toxicity literature reviews, and risk assessments selected from Level 3 to identify even more specific information for the chemicals in these references. Note that most of the Level 3B data are from database data, and only a subset of the PDF data sources is tagged at Level 3B.

The general observations from the Level 2, 3, and 3B reviews are:

- All PHDE members and analogs had at least one toxicity data source.
- The majority of PHDE members and analogs can be considered data rich.
- The remaining PHDE members and analogs have some data.
- Due to the similarity of chemicals within this class, the *QSAR, Read-across, Analog* category (QSAR = quantitative structure activity relationships) has data covering almost the entire subclass.

5.3.1. Summary of Level 2

The "Integrated" tab of the evidence map contains summed Level 2 toxicity data counts across both PDF and database data.[21]

The literature survey identified integrated data sources (sum of databases and PDFs) for all 53 PHDE members and for 37 of 39 analogs. The PHDE members with the most data sources were 2,2',4,4'-tetrabromodiphenyl ether; 2,2',4,4'-tetrabromodiphenyl ether; 2,2',4,4',5-pentabromodiphenyl ether; and 2,2',4,4',5,5'-hexabromodiphenyl ether. Table 5-7 summarizes how many PHDE members and analogs had different degrees of data source abundance.

[20] See evidence map files on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.
[21] See evidence map file "PHDE Level 2 Evidence Maps 12.5.22, Tab: Integrated" on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.

Table 5-7. Distribution of Toxicity Data Source Abundance Levels at Level 2

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 2 Toxicity Data Sources	
	PHDE Chemicals (n = 53)	Analog Chemicals (n = 39)
21+	18	1
6–20	14	3
1–5	21	33
0	0	0

5.3.2. Summary of Levels 3 and 3B

The "TOX_Integrated" tabs from each file contain Level 3 and Level 3B toxicity data counts across all toxicity databases and PDFs.[22] The Level 3B tabs were divided into A, B, and C to keep the spreadsheets manageable. Integrated Level 3B counts report the sum of data sources from databases and selected PDFs (i.e., not all PDFs identified at Level 3 were reviewed at Level 3B). The integrated counts indicate the number of data sources per chemical from databases and PDFs identified and classified into seven toxicity data type categories. At Level 3B, reviewers tagged the data sources from each category with subcategories to provide additional details of specific data types. Tables 5-8 and 5-9 summarize how many PHDE members and analogs had different degrees of Level 3 toxicity data source abundance.

Table 5-8. Distribution of Toxicity Data Source Abundance Levels at Level 3 – Chemicals

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 3 Toxicity Data Sources						
	PHDE Chemicals (n = 53)						
	Animal Toxicity or Accepted Alternative	Human Toxicity	Human, Animal, or Modeled Toxicokinetics (ADME)	Experimental Mechanistic	QSAR, Read-Across, Analog	Qualitative Hazard Characterization	Quantitative Hazard Characterization
21+	10	7	14	12	38	5	10
6–20	3	7	11	3	13	4	2
1–5	15	12	12	12	1	18	15
0	25	27	16	26	1	26	26

[22] See evidence map file "PHDE Level 3 Evidence Maps 12.5.22, Tab: TOX Integrated" and "PHDE Level 3B Evidence Maps 12.5.22, Tab: TOX Integrated" on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.

Table 5-9. Distribution of Toxicity Data Source Abundance Levels at Level 3 – Analogs

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 3 Toxicity Data Sources						
	PHDE Analogs (n = 39)						
	Animal Toxicity or Accepted Alternative	Human Toxicity	Human, Animal, or Modeled Toxicokinetics (ADME)	Experimental Mechanistic	QSAR, Read-Across, Analog	Qualitative Hazard Characterization	Quantitative Hazard Characterization
21+	1	0	2	3	16	0	1
6–20	2	4	11	1	9	2	1
1–5	11	9	11	15	11	11	11
0	25	26	15	20	3	26	26

Animal Toxicity or Accepted Alternative data sources were available for 28 PHDE members and 14 analogs at Level 3 review. Twenty-seven PHDE members and eight analogs had data in the databases and PDFs at Level 3B review. Level 3B reviews provided additional detail for nine subcategories: Acute Toxicity, Systemic or Repeated Dose Toxicity, Neurotoxicity, Carcinogenicity, Mutagenicity/Genotoxicity, Reproductive Toxicity/Developmental Toxicity, Irritation, Sensitization, and Endocrine Disruption. CPSC staff observed the following:

- PHDE members decabromodiphenyl ether and pentabromodiphenyl ether had data sources in all subcategories.
- PHDE member octabromodiphenyl ether had data sources for all subcategories except Carcinogenicity.
- PHDE member 2,2',4,4'-tetrabromodiphenyl ether, and 2,2',4,4',5-pentabromodiphenyl ether had data sources for all subcategories except Carcinogenicity, Irritation, and Sensitization.
- Systemic or Repeated Dose Toxicity was the subcategory with data sources for the most PHDE members (n = 25) and analogs (n = 4).

Human Toxicity data sources were available for 26 PHDE members and 13 analogs at Level 3 review. Twenty-six PHDE members and four analogs had data in the databases and PDFs at Level 3B review. Level 3B reviews provided additional detail for the same nine subcategories used for *Animal Toxicity or Accepted Alternative* above. CPSC staff observed the following:

- No data sources were reported for any PHDE members or analogs under the subcategories Acute Toxicity or Irritation.
- PHDE members 2,2',4,4'-tetrabromodiphenyl ether; 2,4,4'-tribromodiphenyl ether; 2,2',4,4',5-pentabromodiphenyl ether; decabromodiphenyl ether; and 2,2',4,4',6-pentabromodiphenyl ether had the highest number of hits (n = 14 to 17).
- The subcategories with data sources for the most chemicals were Neurotoxicity and Reproductive Toxicity/Developmental Toxicity (each with 21 PHDE members and one analog) and Endocrine Disruption (n = 20 members and four analogs).

Human, Animal, or Modeled Toxicokinetics (ADME [absorption, distribution, metabolism, and excretion]*)* data sources were available for 37 PHDE members and 24 analogs at Level 3 review. Thirty-seven PHDE members and 12 analogs had data in the databases and PDFs at Level 3B review. Level 3B reviews provided additional detail on seven subcategories: Human Absorption, Distribution, Excretion; Animal Absorption, Distribution, Excretion; Human Metabolism; Animal Metabolism; In Vitro; Chemical or Class-Specific PBPK [physiologically based pharmacokinetic] Model; and Chemical- or Class-Specific QSAR for an ADME Parameter. CPSC staff observed the following:

- PHDE members 2,2',4,4',5-pentabromodiphenyl ether; 2,2',4,4'-tetrabromodiphenyl ether; and decabromodiphenyl ether had data sources in all subcategories except Chemical- or Class-Specific PBPK Model.
- PHDE member 2,2',4,4',5,5'-hexabromodiphenyl ether had data sources in all subcategories except human metabolism.
- PHDE members 2,2',4,4',5,6'-hexabromodiphenyl ether and 2,2',3,4,4',5',6-heptabromodiphenyl ether had data sources in all subcategories except Chemical- or Class-Specific QSAR for an ADME Parameter.
- The subcategories with the most data sources and for the most chemicals were Human Absorption, Distribution, Excretion and Animal Absorption, Distribution, Excretion, with data sources identified for 32 PHDE members and seven analogs.

Experimental Mechanistic data sources were available for 27 PHDE members and 19 analogs at Level 3 review. Thirty-six PHDE members and seven analogs had data in the databases and PDFs at Level 3B review.[23] This category had two subcategories at Level 3B review separating those data sources that make a connection to a mode of action (MOA) and a potential health effect from those that do not.[24] CPSC staff observed the following:

[23] See "TOX_DB" and "TOX_PDF" tabs of evidence map file on the CPSC Organohalogen Flame Retardant Chemicals Assessment website. The 3B data counts for Experimental Mechanistic data are presented only in the "TOX_DB" and "TOX_PDF" tabs and not in the "TOX_Integrated" tab, because PubChem Bioassay data did not contain enough information to distinguish between the Level 3B tags for mechanistic data.

[24] Many database sources could not be tagged for Level 3B because it was not clear whether a connection was made to MOA.

- Eighteen PHDE members and one analog had PDF sources in both subcategories.
- Nine PHDE members had database sources in both subcategories. Some of these hit counts were large, with hundreds or thousands of data sources per chemical per subcategory.

QSAR, Read-Across, Analog data sources were available for all 53 PHDE members and 36 of 39 analogs at Level 3 review. All 53 PHDE members and 37 analogs had data in the databases and PDFs at Level 3B review. Level 3B reviews provided additional detail across the same nine subcategories used for *Animal Toxicity or Accepted Alternative* above. CPSC staff observed the following:

- Three PHDE members [decabromodiphenyl ether; 2,2',4,4'-tetrabromodiphenyl ether; and 1,1'-oxybis(2,3,4,5-tetrabromobenzene)] and four analogs had data sources in all subcategories except Neurotoxicity.
- All 53 PHDE members and 37 analogs had data sources under the Endocrine Disruption subcategory.
- The subcategory Mutagenicity/Genotoxicity had data sources for all PHDE members except for two and for all analogs except for four.
- The subcategories Neurotoxicity and Sensitization had data sources for the fewest PHDE members (n = 10 and 15, respectively) and analogs (zero and six, respectively).
- Of the remaining subcategories, at least one data source was available for the majority of PHDE members per subcategory.

Qualitative Hazard Characterization data sources were available for 27 PHDE members and 13 analogs at Level 3 review. Nineteen PHDE members and nine analogs had data in the databases and PDFs at Level 3B review. This category was separated into the same nine subcategories used for *Animal Toxicity or Accepted Alternative* above. CPSC staff observed the following:

- PHDE member pentabromodiphenyl ether had data sources for each of the nine subcategories.
- PHDE members octabromodiphenyl ether; tetrabromodiphenyl ether; and diphenyl ether, heptabromo derivative and analogs tetrabromodiphenyl ether and heptabromodiphenyl ether had data sources for all subcategories except Endocrine Disruption.
- PHDE member decabromodiphenyl ether had data sources for all subcategories except Neurotoxicity.
- Endocrine Disruption is the subcategory with data sources for the most PHDE members.

Quantitative Hazard Characterization data sources were available for 27 PHDE members and 13 analogs at Level 3 review. Twenty-five PHDE members and five analogs had data in the databases and PDFs at Level 3B review. At Level 3B review, this category was further divided into seven subcategories: Acute Toxicity, Systemic or Repeated Dose Toxicity, Neurotoxicity, Carcinogenicity, Reproductive Toxicity/Developmental Toxicity, Sensitization, and Endocrine Disruption. CPSC staff observed the following:

- The subcategory Sensitization had no data sources for any PHDE members or analogs.
- PHDE member decabromodiphenyl ether had data sources for all subcategories except Sensitization and had the only data sources (n = 14) under the subcategory Carcinogenicity.
- PHDE members pentabromodiphenyl ether; 2,2',4,4'-tetrabromodiphenyl ether; and 2,2',4,4',5-pentabromodiphenyl ether had data sources available in all subcategories except Carcinogenicity and Sensitization.
- Subcategories Systemic or Repeated Dose Toxicity and Reproductive Toxicity/Developmental Toxicity had data sources for the most PHDE members.

5.4. Literature Survey Results: Evidence Maps of Exposure Data

The exposure evidence maps below describe high-level observations of the Level 2, 3, and 3B literature surveys in the indicated spreadsheet files.[25] Level 3B tagging was performed on a subset of 25 toxicity exposure literature reviews selected from Level 3 to identify even more specific information for the chemicals in these references. The database counts indicate the number of entries in the Multimedia Monitoring Database (MMDB). The unit for PDF counts is the individual PDF file. PHDE analogs were not included in the exposure evidence map analyses because exposure to the analogs is outside the scope of the current project.

The general observations from the Level 2, 3, and 3B reviews are:

- Several PHDE members had exposure data available in multiple categories.
- There are several data-rich PHDE members with exposure data. The most data-rich PHDE members for exposure information appear to include:
    - decabromodiphenyl ether
    - 2,2',4,4',6-Pentabromodiphenyl ether
    - 2,2',4,4',5,6'-Hexabromodiphenyl ether
    - 2,2',3,4,4',5',6-Heptabromodiphenyl ether
    - 2,2',4,4'-Tetrabromodiphenyl ether
    - 2,2',4,4',5-Pentabromodiphenyl ether
    - 2,2',4,4',5,5'-Hexabromodiphenyl ether

[25] Exposure evidence map files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.

5.4.1. Summary of Level 2

The MMDB database and PDF searches identified exposure data sources for all 53 PHDE members.[26] The PHDE members with the most data sources were 2,2',4,4'-tetrabromodiphenyl ether; decabromodiphenyl ether; 2,2',4,4',5-pentabromodiphenyl ether; and 2,2',4,4',5,5'-hexabromodiphenyl ether. Table 5-10 summarizes how many PHDE members had different degrees of data source abundance. The PDFs provided more total data sources and covered more PHDE members than the database.

Table 5-10. Distribution of Exposure Data Source Abundance Levels at Level 2

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 2 Exposure Data Sources
	PHDE Chemicals (n = 53)
21+	24
6–20	11
1–5	8
0	10

5.4.2. Summary of Levels 3 and 3B

The "EXP_Integrated" tabs from each file contains Level 3 and 3B exposure data counts.[27] The Level 3 integrated counts indicate the number of data sources per chemical from the MMDB database and identified PDFs. Level 3 counts were classified into six exposure data type categories. Integrated Level 3B counts, report the sum of data sources from MMDB and selected PDFs. At Level 3B, reviewers tagged the data sources to subcategories to provide additional details of specific data types. Table 5-11 summarizes how many PHDE members had different degrees of Level 3 exposure data source abundance.

[26] Exposure evidence map files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.
[27] Exposure evidence map files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.

Table 5-11. Distribution of Exposure Data Source Abundance Levels at Level 3

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 3 Exposure Data Sources					
	PHDE Chemicals (n = 53)					
	Environmental Monitoring	Biomonitoring/ Personal Monitoring	Source Characterization	Epidemiology – Population Group	Modeled Concentrations	Modeled Human Dose
21+	21	16	14	5	0	9
6–20	8	6	14	6	8	11
1–5	6	12	8	10	13	11
0	18	19	17	32	32	22

Environmental Monitoring data sources were available for 35 PHDE members at Level 3 review, and 32 PHDE members had more in-depth data in the targeted Level 3B review. This category was separated into six subcategories for Level 3B review: Indoor/Personal Air, Indoor Dust, Outdoor Air, Food/Dietary, Soil, and Drinking Water. CPSC staff observed the following:

- Thirteen PHDE members had data sources in all of the subcategories.
- Subcategories Soil, Indoor Dust, and Outdoor Dust had data sources for the highest numbers of PHDE members (n = 30, 25, and 25, respectively).

Biomonitoring/Personal Monitoring data sources were available for 34 PHDE members at Level 3 review and 33 PHDE members had more in-depth data in the targeted Level 3B review. This category was separated into five subcategories for Level 3B review: Blood/Serum, Urine, Breast Milk/Lipids, Skin/Dermal, and Human (Other). CPSC staff observed the following:

- Subcategory Urine had no data sources for any PHDE members.
- The remaining subcategories Blood/Serum, Breast Milk/Lipids, Skin/Dermal, Human (Other) had data sources for 31, 28, 26, and 22 PHDE members, respectively.
- Seventeen PHDE members had data sources in all of the subcategories except Urine.
- Several of the PDHE members had data source counts in the hundreds for the Blood/Serum and Breast Milk/Lipids subcategories.

Source Characterization data sources were available for 36 PHDE members at Level 3 review, and 35 PHDE members had data in the targeted Level 3B review. This category was separated into four subcategories for Level 3B review: Product Testing: Content Only, Product Testing: Emission/Migration Data, Nonexperimental Product or Chemical-Specific Modeling Inputs, and Other Qualitative or Quantitative Description of Product Use or Class/Chemical. CPSC staff observed the following:

- Ten PHDE members had data sources for all four subcategories.
- Subcategory Nonexperimental Product or Chemical-Specific Modeling Inputs had data sources for the most PHDE members (n = 35).

Environmental Epidemiology[28] data sources were available for 21 PHDE members at Level 3 review and 18 PHDE members had data in the more targeted Level 3B review. This category was separated into three subcategories for Level 3B review: Children; Adult, Non-Occupational; and Other, Specify (with Suggestions). CPSC staff observed the following:

- Subcategory Other, Specify (with Suggestions) had no data sources for any PHDE members.
- Subcategory Children had data sources for 18 PHDE members, and Adult, Non-Occupational had data sources for three PHDE members. The data source counts were low (n = 1 or 2 per chemical per subcategory).

Modeled Concentrations data sources for 21 PHDE members were identified at Level 3 review and 13 PHDE members had data sources in the more targeted Level 3B review. This category was separated into three subcategories for Level 3B review: Indoor Concentration, Outdoor Concentration, and Dietary/Food. CPSC staff observed the following:

- Twelve PHDE members had data sources for all three subcategories. Each of these PHDE members had one data source per subcategory.
- One PHDE member (BDE-197) had one data source each in subcategories Outdoor Concentration and Dietary/Food.

Modeled Human Dose data sources were available for 31 PHDE members at Level 3 review and 23 PHDE members had data in the more targeted Level 3B review. The subcategories were Children; Adult, Non-occupational; and Other, Specify (with Suggestions).

- The subcategory Other, Specify (with Suggestions) had no hits for any PHDE members.
- Fifteen PHDE members each had one to eight data sources for the remaining subcategories Children and Adult, Non-occupational.
- Subcategories Children and Adult, Non-occupational had data sources for 15 and 23 PHDE members, respectively.

[28] The category *Environmental Epidemiology* here was identified as "*Epidemiology – POP Group*" in the "EXP_Integrated_C" tab of the Excel file, which can be found on the CPSC Organohalogen Flame Retardant Chemicals Assessment website). The change was made in this document for clarity.

5.5. Literature Survey Results: Summary of Existing Human Health Risk Assessments

None of the "Database" (DB) tabs at Levels 2, 3, or 3B reported risk assessment data sources. Therefore, the Integrated and PDF data counts for Human Health Risk Assessments are identical at all levels. In the files that reported PDF data sources, human health risk assessments were included in the tabs for spreadsheets displaying toxicity data sources.

5.5.1. Summary of Level 2

The "Integrated" tab contains summed Level 2 risk data counts from PDF sources.[29] No risk data were found in the databases. Twenty-five PHDE members and three analogs had PDF data sources for risk at Level 2 review. Table 5-12 summarizes how many PHDE members had different degrees of data source abundance. PHDE members 2,2',4,4'-tetrabromodiphenyl ether; decabromodiphenyl ether; 2,2',4,4',5-pentabromodiphenyl ether; and 2,2',4,4',5,5'-hexabromodiphenyl ether had the highest numbers of human health risk assessments available.

Table 5-12. Distribution of Human Health Risk Data Sources Abundance Levels at Level 2

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 2 Risk Data Sources	
	PHDE Chemicals (n = 53)	Analog Chemicals (n = 39)
21+	7	0
6–20	2	0
1–5	16	3
0	28	36

5.5.2. Summary of Levels 3 and 3B

The "Integrated" tab for the Level 3 file contains the *Human Health Risk Assessment* counts from PDF data sources.[30] The "TOX_PDF" tab for Level 3B contains the *Human Health Risk Assessment* counts from 25 PDFs that were selected for 3B extraction. The counts indicate the number of PDFs identified per chemical for each Noncancer and Cancer risk assessment. Table 5-13 summarizes how many PHDE members and analogs had different degrees of Level 3 human health risk data source abundance.

Human Health Risk Assessment data were available for 25 PHDE members and 11 analogs at Level 3 review. Twenty-two PHDE members and two analogs had data in the 25 selected PDFs at Level 3B review. The subcategories used were Noncancer Risk and Cancer Risk, with 25 Noncancer Risk and nine Cancer Risk assessments identified. Staff noted the following observations:

[29] Risk evidence map files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022

[30] Risk evidence map files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website or Docket No. CPSC-2015-0022.

- PHDE member decabromodiphenyl ether had seven Noncancer Risk and two Cancer Risk data sources. This chemical was the only one with data sources under the Cancer subcategory.
- Twenty-two PHDE members had data sources under the Noncancer Risk subcategory. Four of these PHDE members had six or seven sources; the remaining 20 each had one to three sources.
- Two analogs had Noncancer Risk data sources, each with only one source.

Table 5-13. Distribution of Human Health Risk Data Sources Abundance Levels at Level 3

Distribution of Number of Data Sources Available for Each Chemical	Number of Chemicals with Level 3 Risk Data Sources	
	PHDE Chemicals (n = 53)	Analog Chemicals (n = 39)
21+	7	0
6–20	2	1
1–5	16	10
0	28	28

5.6. Literature Survey Results: Key References

Among the literature survey results are several references from authoritative sources. These references include a toxicological profile by the Agency for Toxic Substances and Disease Registry, technical reports from the National Toxicology Program, EPA assessments and evaluations, Health Canada assessments, European Union risk assessment reports, International Agency for Research on Cancer evaluations, and Organisation for Economic Co-operation and Development assessments. Each of these references addressed one or more PHDEs. These reports included 18 specific PHDEs,[31] of which 12 were the subject of multiple technical reports and assessments. Fourteen of these chemicals are among the PHDEs most frequently noted in the Market and Use Report as found in consumer products, as well as in the literature survey results generally. These reports suggest the existence of data about these chemicals, including hazard and potential exposures, and may be useful references for CPSC staff evaluations of these and other PHDEs.

6. Scoping Determination and Next Steps

6.1. Scoping Determination

Informed by initial review of the market and use research, evidence maps, and availability of physicochemical data for the PHDE subclass and its analogs, and the criteria described in

[31] The 18 PHDEs included in one or more key references are (by CAS RN): 101-55-3; 5436-43-1; 40088-47-9; 32534-81-9; 36483-60-0; 68928-80-3; 32536-52-0; 63936-56-1; 1163-19-5; 60348-60-9; 68631-49-2; 2050-47-7; 49690-94-0; 189084-64-8; 59080-40-9; 36355-01-8; 27858-07-7; 13654-09-6.

Section 4.1, Criteria for Scoping Determination, CPSC staff concludes, at the time of writing, that **the PHDE subclass has sufficient data to proceed with risk assessment**.

The criteria for sufficiency for hazard assessment for the subclass require that the subclass and analogs must have at least one data rich chemical, multiple chemicals with some data, and a minority of chemicals that are "no data" substances.

CPSC staff concludes that the subclass includes up to nine data rich PHDE chemicals and that a majority of PHDE chemicals and some analogs have some data. The evidence maps show that many PHDE chemicals have data in the Animal Toxicity or Accepted Alternative category, including among acute, systemic, or repeated dose toxicity, or reproductive/developmental studies. In addition, a majority of PHDE chemicals and some analogs have data in the human toxicity, toxicokinetics, experimental, mechanistic, and QSAR categories, all of which may be used to support further analyses, including performing read-across analyses for predictions among class members with less available data.

The criteria for sufficiency for exposure assessment for the subclass require that the subclass must have at least one data rich chemical and multiple chemicals with some data.

CPSC staff concludes that the subclass includes up to 23 data rich chemicals and that a majority of chemicals have some data. In addition, according to available data sources as many as 102 PHDE chemicals have market information for use in commerce.

Following the determination that the PHDE subclass has sufficient data to proceed with risk assessment, the sections below outline the next steps that CPSC staff plans to take, resources permitting. Below, CPSC staff provides analysis plans to complete a class-based risk assessment. The first analysis plan describes how CPSC staff will consider data in the development of a class-based hazard identification and dose-response assessment for select endpoints. The second analysis plan describes how CPSC staff will consider data in a class-based human exposure assessment. The last step of both analysis plans is identical in that CPSC staff will consider how to combine class-based human exposure estimates with class-based toxicity reference values in a class-based risk assessment.

6.2. Next Steps for Class-Based Hazard Assessment

6.2.1. Analysis Plan

CPSC staff plans to actively work on the remaining list of activities outlined below. These activities can be worked on concurrently, as resources are available. Before completing a hazard analysis, CPSC staff expects to consider and analyze data that could inform hazard identification and dose-response as follows, if resources are available:

1. CPSC staff, in coordination with the Division of Translational Toxicology (DTT) at the National Institute of Environmental Health Sciences, is working on a comprehensive literature search. Available toxicity information from PHDE class members and analogs will be further summarized and integrated after this search is complete. Staff will refine the list of data rich PHDEs, data rich PHDE analogs, PHDEs with some toxicity information, and PHDEs with no toxicity information after the search.

2. CPSC staff plans to complete a systematic evidence map that will be based on a scoping review in coordination with DTT. This evidence map will include a wide range of toxicity data (e.g., animal, human, mechanistic, QSAR, read-across, new approach methodologies [NAMs][32]) from a comprehensive literature search.
3. CPSC staff will refine the NAS analog list and characterize analog substances for the PHDE class that are both chemically and toxicologically similar and have any amount of empirical toxicity information. Analog substances that are both data poor and not sufficiently similar to PHDE class members will be deprioritized. CPSC staff's initial survey shows that empirical toxicity data are available for four analogs and empirical toxicokinetic data are available for one analog.
4. CPSC staff will estimate major metabolites of PHDE class members by interpreting results from the major metabolite prediction tools, such as GLORYx and the OECD QSAR toolbox, and comparing these results with data presented in the literature. CPSC staff will consider predicted and measured metabolites to inform class-based approaches for hazard identification.
5. CPSC staff plans to use a read-across approach that incorporates multiple types of data (i.e., animal, human, mechanistic, QSAR, read-across). Data rich PHDE class members and analogs with available toxicity data can be used to read-across to PHDE class members with insufficient data to estimate toxicity reference values for one or more endpoints of concern. The initial CPSC literature survey suggests that toxicity endpoints that are likely higher priority for the PHDE class are thyroid, liver toxicity, male and female reproductive toxicity, developmental neurotoxicity, neurotoxicity, immunotoxicity, and carcinogenicity. Toxicity endpoints that are likely lower priority for the PHDE class are acute toxicity, irritation and sensitization.
6. CPSC staff will identify a smaller number of endpoint(s) and studies that are candidates for identifying points of departure (POD) and generating toxicity reference values for multiple PHDE class members. PODs may be developed using a wide range of toxicity studies (e.g., animal, human, NAM, QSAR, read-across). CPSC staff will identify studies with a range of reported doses and associated contextual information when developing dose-response information. Benchmark dose modeling will be used as appropriate.
7. CPSC staff will compare these values with toxicity reference values developed by other organizations for PHDE class members.
8. CPSC staff will explore the variability and uncertainty associated with dose-response values for PHDE chemicals within the class.
9. CPSC staff will use information developed in a class-based hazard assessment and dose-response assessment to support a class-based risk assessment for PHDEs.

[32] New approach methodologies (NAM or NAMs) refer broadly to any technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment that avoids the use of intact animals. NAM studies may include studies using human or animal cells and tissues (i.e., in vitro assays, ex vivo studies), toxicity testing using alternative animal species, such as zebrafish and nematodes, and a variety of computational modeling approaches.

6.2.2. Initial Human Health Hazard Observations for Class-Based Assessment of PHDEs

The primary objective of completing a literature survey for a subclass of OFRs is to array available information and determine whether a class-based assessment is possible. CPSC staff considers class-based exposure assessment possible for any class if data on consumer uses and physicochemical properties are available. However, CPSC staff considers class-based hazard assessment as highly data dependent. Thus, whether a class-based risk assessment is possible depends on the availability of different types of human hazard data. When sufficient human health hazard data were identified from the literature survey, this section of the scope document includes initial observations informed by review of select data sources.

PHDEs are thought to target a broad group of systems.[33] Evidence is strongest for effects on the thyroid, liver, male reproductive system (including the developing system), and developing nervous system (ATSDR, 2017; EFSA, 2011), as described further below. The female reproductive system, adult nervous system, and the developing and adult immune systems may also be targets. Where data are available, generally similar effects have been seen for the better-studied congeners, BDE 47,[34] BDE 99, BDE 153, and BDE 209. NASEM (2019) built on the 2017 report and concluded that, because the data are concordant for the well-studied members of the subclass, a designation of potentially hazardous can be applied to the entire subclass.

Despite the general similarity of effects, potency varies substantially across congeners. For example, ATSDR (2017) and EFSA (2011) distinguish between congeners with greater or lesser numbers of bromine. In particular, deca-BDE is less toxic than the lower brominated PHDEs, a finding that has been attributed to the lower oral absorption of deca-BDE (ATSDR, 2017). ATSDR (2017) and Health Canada (2004, 2012) have used a class-based approach for developing Toxicity Reference Values (TRVs) for this group of chemicals, with ATSDR separating “lower brominated PBDEs” from deca-BDE. EFSA (2011) also noted substantial differences in the elimination kinetics between rodents and humans, with the result that similar external doses of BDE-47, -99 and -153 will result in higher internal doses in the human body than in the rodent. Because of this, EFSA (2011) recommended that body burden is a more appropriate metric than daily dose for these chemicals, although this is not a uniform approach across all organizations. In contrast, the half-life in rodents and humans for deca-BDE is sufficiently similar that external dose is an appropriate metric (EFSA, 2011).

Several systematic reviews have evaluated specific potential effects of PBDEs. Gibson et al. (2018) reviewed the epidemiological evidence of an association between prenatal exposure to PBDEs and neurological effects in infants and children and concluded that the majority of studies support an adverse effect on neurodevelopment. NASEM (2017) conducted a

[33] The class is defined as PHDEs, but all but one of the OFRs in this class are brominated, and all of the data summarized in this section are on the brominated compounds. Therefore, this summary will use the term PBDEs, or BDE to refer to individual congeners.

[34] The full names for these congeners are as follows: BDE 47 = 2,2',4,4'-tetrabromodiphenyl ether; BDE 99 = 2,2',4,4',5-pentabromodiphenyl ether; BDE 153 = 2,2',4,4',5,5'-hexabromodiphenyl ether; BDE 209 = 2,2',3,3',4,4',5,5',6,6'-decabromodiphenyl ether. Some toxicity studies and assessments were on individual congeners, whereas others were on mixtures of congeners with the same degree of bromination.

systematic review of PBDEs and developmental neurotoxicity and concluded that BDE-47 is a potential hazard to human health based on effects on intelligence, with conclusions for other congeners equivalent to or weaker than the ones for BDE-47.

Lam et al. (2017) conducted a systematic review and meta-analysis of the effect of developmental exposure to PBDEs and IQ or attention deficit hyperactivity disorder (ADHD). They concluded that there was “moderate” quality of evidence for both endpoints, and “sufficient” evidence for an effect on IQ, but “limited” evidence for an effect on ADHD. Dorman et al. (2018) conducted a systematic review and meta-analysis of the animal data related to neurotoxicity of PBDEs. They found a significant adverse effect on learning for one endpoint, but for most endpoints there were unexplained inconsistencies across studies and no consistent evidence of a dose-response relationship. In a systematic review and meta-analysis, Zhang et al. (2020) found that deca-BDE, BDE 99, and DE 71 (a commercial mixture) had male reproductive effects in rodents.

The development of TRVs for lower brominated PBDEs has focused on male reproductive effects (ATSDR, 2017), neurodevelopmental effects (Health Canada, 2004; EFSA, 2011), and liver effects (US EPA, 1987a, 1987b). Hardy et al. (2009) conducted an extensive review of the literature in the context of a critical evaluation of the Viberg et al. (2003) and related studies that form the basis of several assessments based on neurodevelopmental effects. Hardy et al., concluded that there were deficiencies in several animal studies of developmental neurotoxicity including the ones that have been used as the basis for the PBDE TRVs, that preclude relying on these studies for the development of TRVs. Critical consideration of these studies will be an important part of the development of a class-based assessment, although it is noted that the overall evidence for developmental neurotoxicity is strong, based on animal and human data, and supported by at least some mechanistic data. There is less consistency in TRVs for deca-BDE, with assessments based on changes in serum glucose and altered insulin homeostasis and pancreatic toxicity (ATSDR, 2017), liver effects (ECHA, 2002), or neurobehavioral effects (US EPA, 2008a; EFSA, 2011). The critical effect for penta-BDE (US EPA, 1987a) and octa-BDE (US EPA, 1987b) was in the liver, whereas more recent assessments for BDE-47 (US EPA, 2008b), BDE-99 (US EPA, 2008c), BDE-153 (US EPA, 2008d), and BDE-209 (US EPA, 2008a) were all based on neurobehavioral effects.

Cancer data on PBDEs are limited to studies of deca-BDE that observed liver tumors in rats and mice, and thyroid tumors in mice. IARC (1999) considered deca-DBE not classifiable as to its carcinogenicity in humans, and EPA (2008a) considered there to be *suggestive evidence* as to the carcinogenic potential of deca-BDE. EPA noted an apparent absence of genotoxic potential.

Although no formal MOA evaluation of the tumors was located, mechanistic evidence suggests that the liver and thyroid tumors may occur via a MOA not relevant to humans, or to which humans are much less sensitive than rodents. BDE-209 caused hepatic carcinogenicity and induction of cytochrome P450 enzymes typical of activation of the CAR/PXR (constitutive active receptor/Pregnane X receptor) receptors (EFSA, 2011). These chemicals are tumor promotors in the rodent liver, but only after prolonged high exposure; many scientists do not consider this pathway to be relevant to humans based on quantitative and qualitative differences from rodents (Felter et al., 2018). BDE 209 has been reported to increase the expression of metabolic enzymes in the liver, leading to increased turnover of thyroid hormones (EFSA,

2011). This MOA is well understood to lead to thyroid tumors in rodents. However, due to differences in thyroid hormone homeostasis between rodents and humans, this MOA can lead to goiter and neurodevelopmental toxicity in humans, but not thyroid tumors in humans (Dellarco et al., 2006).

Studies have investigated the binding of PBDEs to a variety of nuclear receptors and activation of receptor pathways, including thyroid hormone receptor, estrogen receptor, androgen receptor, progesterone receptor, and aryl hydrocarbon receptor pathways (Ren et al., 2013). Inconsistencies have been noted, but results indicate that PBDEs interact with several types of nuclear receptors, and reproductive and developmental toxicities may result from PBDEs acting through nuclear receptor-mediated signal transduction pathways (Ren et al., 2013). Binding geometry is critical, which could lead to qualitative or quantitative differences among congeners with the same level of bromination. NASEM (2019) noted that the ether aromatic diphenyl chemotype is associated with inhibition of aromatase, a cytochrome P450 enzyme associated with steroidogenesis.

6.3. Next Steps for Class-Based Exposure Assessment

6.3.1. Analysis Plan

CPSC staff plans to actively work on the remaining list of activities outlined below. These activities can be worked on concurrently, as resources are available. Before completing a hazard analysis, CPSC staff expects to consider and analyze data that could inform hazard identification and dose-response as follows, as resources permit:

1. CPSC staff, in coordination with DTT staff, is working on a comprehensive literature search. Available exposure information from PHDE class members will be further summarized and integrated after this search is complete. Staff will refine the list of data-rich PHDEs, PHDEs with some exposure and use information, and PHDEs with no exposure and use information after the search.
2. Using the market and use research, CPSC staff expects to compile a list of PHDE chemicals that have been or could be used in consumer products. While 122 of the 223 chemicals had some market-use information, 36 PHDE chemicals had more market and use information that could be used to inform analyses for PHDE chemicals with less information. CPSC staff will characterize uses for PHDEs according to available information and consider temporal trends when developing exposure scenarios.
3. CPSC staff will characterize the uses identified in the market and use research and combine this information with likely exposure pathways and populations exposed to define unique combinations of exposure scenarios for chemical substances within the class. Depending on available information, CPSC may be able to quantify exposure scenarios for between 36 and 122 PHDE subclass members.
4. Exposure pathways with likely higher potential for PHDE class members include dietary ingestion, drinking water ingestion, contact exposures with consumer products and articles, indoor dust ingestion, and inhalation of indoor air. Exposure pathways with likely lower potential for PHDE class members include inhalation of ambient air and soil ingestion. CPSC staff will review available environmental monitoring data to determine a range of potential concentrations to which people could be exposed. There are

36 chemicals in the class with source characterization data, 35 chemicals in the class with environmental monitoring data, and 35 chemicals in the class with both types of data.

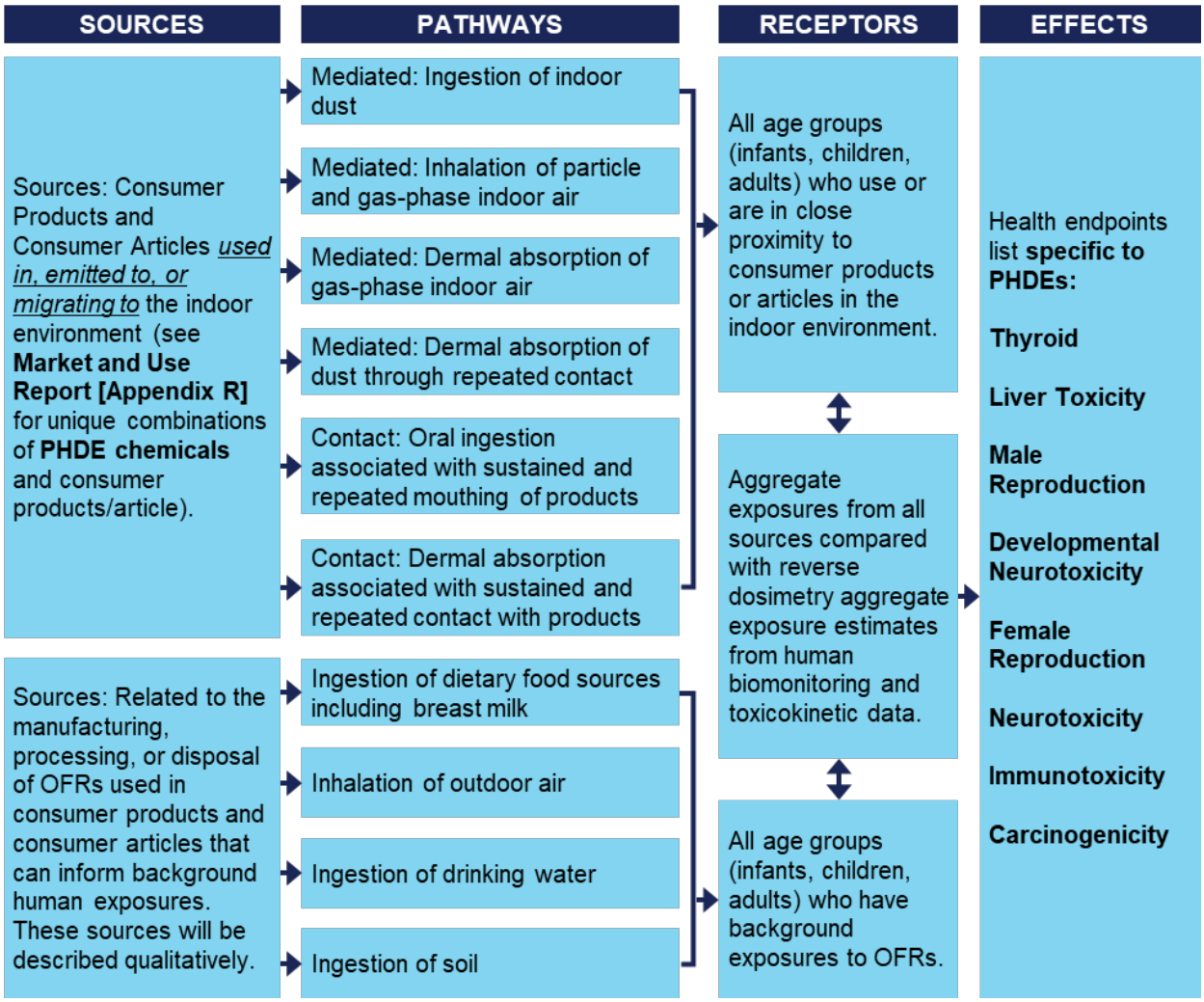
5. CPSC staff plans to review measurement techniques and analytical methods and assess how they have changed over time with regard to identification and quantification of PHDE chemicals. Lack of detection in older studies may be due to older analytical methods with higher detection limits, whereas presence in newer studies may be due to newer analytical methods with lower detection limits. CPSC staff plans to evaluate reported methods and how they influence likely distributions of OFRs in different environmental media or biological matrices.
6. CPSC staff will explore the connection between consumer product sources and reported levels in environmental media by estimating environmental concentrations for a range of uses and determining whether these estimates fall within the range of reported environmental monitoring data. CPSC staff plans to consider indoor exposure modeling, modeling approaches specific to semi-volatile organic compounds (SVOCs), and product testing measurement techniques that characterize emissions or migration of OFRs from products into the indoor environment. When environmental monitoring is not available for comparison, CPSC staff will estimate environmental concentrations for the range of reported uses. There are 18 chemicals in the class with source characterization data and no corresponding environmental monitoring data.
7. CPSC staff will explore the connection between reported or estimated environmental concentrations and reported exposures from human biomonitoring data. First, doses will be estimated using reported or estimated environmental concentrations and population specific exposure factors and activity patterns. Second, doses will be estimated using reported human biomonitoring data and reported or estimated toxicokinetic data. There are 33 PHDE class members with both environmental monitoring data and human biomonitoring data.
8. CPSC staff plans to use multiple approaches to estimate exposures and doses for multiple age groups and populations. CPSC staff plans to develop both deterministic and probabilistic estimates of dose, as data allow. CPSC staff will explore the variability and uncertainty associated with exposure and dose estimates for the population groups included in the human exposure assessment.
9. CPSC staff will use information developed in a class-based exposure assessment to support a class-based risk assessment for PHDEs.

6.3.2. Conceptual Exposure Model

A conceptual exposure model visually represents connections between sources, pathways, receptors, and health effects. Figure 6-1 shows the conceptual exposure model for the PHDE subclass. Sources are grouped into (i) those that can be related back to consumer products and (ii) all other sources that can inform background exposures. These sources will be part of a generic background exposure scenario. Each product/source will be part of an exposure scenario and quantified. Exposure pathways similarly are grouped into pathways related to emission or migration from consumer products and pathways related to occurrence in non-consumer product-related media. Receptors include human populations of all age groups for

which human biomonitoring data will be used to inform ranges of aggregate exposures from all sources. Finally, human health effects most likely to be considered for PHDEs are listed.

Figure 6-1. PHDE Conceptual Exposure Model



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8. Appendix: Supporting Files

The following supporting files are available on the CPSC Organohalogen Flame Retardant Chemicals Assessment website. They can also be found on Docket No. CPSC-2015-0022.

Literature Survey Guide: Approaches Taken to Develop Evidence Maps from Readily Available Databases, Completed Assessments, and Literature Reviews

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