Response to Comments on the Draft Alternatives Assessment for Decabromodiphenyl Ether (decaBDE) – January, 2014

On July 30, 2012, the U.S. Environmental Protection Agency (EPA)'s Design for the Environment (DfE) program issued a draft alternatives assessment report titled *An Alternatives Assessment for the Flame Retardant Decabromodiphenyl Ether (decaBDE)*. Under its enhanced chemicals management program, the EPA issued an action plan for polybrominated diphenyl ethers (PBDEs). DecaBDE breaks down into PBDE congeners, which are persistent, bioaccumulative, and toxic to humans and the environment. The action plan called for the development of a multi-stakeholder alternatives assessment for decaBDE conducted by DfE. The draft report of this alternatives assessment was posted on the DfE website for public review and a 60-day comment period.

DfE's Alternatives Assessment Program helps industries choose safer chemicals and provides a basis for informed decision-making by developing a detailed comparison of potential human health and environmental effects of chemical alternatives. The alternatives assessment for decaBDE is just one project of DfE's broad work on flame retardant chemicals. DfE has applied its alternatives assessment methodology to other flame retardant chemicals including pentabromodiphenyl ether in polyurethane foam in furniture, tetrabromobisphenol A in printed circuit boards, and is in the process of applying it to hexabromocyclododecane in expanded polystyrene and extruded polystyrene foam.

DfE received comments from fifteen entities on the draft report *An Alternatives Assessment for the Flame Retardant Decabromodiphenyl Ether (decaBDE)* during the comment period, which ran from July 30 to September 30, 2012. The comments submitted illustrated the viewpoints of variety of interests including chemical manufacturers, automotive industry, aerospace industry, electronics industry, and shipping pallet industry. Of the fifteen sets of comments DfE received, most addressed the hazard profiles of specific chemicals. DfE greatly appreciates the effort of those who submitted comments, including those who shared their input less formally.

Below, DfE presents and discusses the comments received on the draft assessment and indicates planned changes to the proposed text of the *Draft Alternatives Assessment for the Flame Retardant Decabromodiphenyl Ether (decaBDE)*. DfE has also made minor editorial and non-substantive technical corrections to the report. EPA received comments on 1) specific chemical hazard assessments, 2) hazard assessments and conclusions in general, and 3) general report content. Please note that the comments have at times been paraphrased, summarized and combined, as appropriate, for efficiency and readability; full versions, as well as the final report, are available on the DfE website at http://www.epa.gov/dfe/pubs/projects/decaBDE/about.htm.

Comments and DfE Responses

I. Comments on the Assessments of Specific Chemicals

A. Aluminum Diethylphosphinate (CASRN 225789-38-8)

Comment: Aluminum diethylphosphinate (CASRN 225789-38-8) is not listed on the non-confidential Toxic Substances Control Act (TSCA) Inventory. EPA should clarify if it is in the premanufacture notice (PMN) process or if it is on the confidential Inventory.

Response: Under TSCA, EPA cannot state whether a substance is on the confidential Inventory or give details on the PMN process if it has been claimed as confidential by the manufacturer. To address this, DfE has added the following statement into Chapters 3 and 4 of the report:

Chemical Alternatives and the Toxic Substances Control Act

EPA's Design for the Environment (DfE) program is administered by the Office of Pollution Prevention and Toxics (OPPT), which is charged with the implementation of the Toxic Substances Control Act (TSCA) and the Pollution Prevention Act (PPA).

Central to the administration of TSCA is the management of the TSCA Inventory. Section 8 (b) of TSCA requires EPA to compile, keep current, and publish a list of each chemical substance that is manufactured or processed in the United States. Companies are required to verify the TSCA status of any substance they wish to manufacture or import for a TSCA-related purpose. For more information, please refer to the TSCA Chemical Substance Inventory website: http://www.epa.gov/opptintr/existingchemicals/pubs/tscainventory/basic.html.

TSCA and DfE Alternatives Assessments

Substances selected for evaluation in a DfE Alternatives Assessment generally fall under the TSCA regulations and therefore must be listed on the TSCA inventory, or be exempt or excluded from reporting before being manufactured in or imported to, or otherwise introduced in commerce in, the United States. For more information see http://www.epa.gov/oppt/newchems/pubs/whofiles.htm.

To be as inclusive as possible, DfE Alternatives Assessments may consider substances that may not have been reviewed under TSCA, and therefore may not be listed on the TSCA inventory. DfE has worked with stakeholders to identify and include chemicals that are of interest and likely to be functional alternatives**,** ***regardless of their TSCA status***. Chemical identities are gathered from the scientific literature and from stakeholders and, for non-confidential substances, appropriate TSCA identities are provided.

Persons are advised that substances, including DfE-identified functional alternatives, may not be introduced into U.S. commerce unless they are in compliance with TSCA. Introducing such substances without adhering to the TSCA provisions may be a violation of applicable law. Those who are considering using a substance discussed in this report should check with the manufacturer or importer about the substance's TSCA status. If you have questions about reportability of substances under TSCA, please contact the OPPT Industrial Chemistry Branch at 202-564-8740.

Comment: The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) report on Exolit OP 1312 (which also contains melamine polyphosphate and zinc borate) is not appropriate for the EPA hazard evaluation of aluminum diethylphosphinate. Please use the

European Chemicals Agency (ECHA) Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) dossier, which has more up to date and reviewed information.

Response: The "Data Quality" entries for studies in the aluminum diethylphosphinate hazard evaluation that are cited to NICNAS, 2005 have been revised to inform readers that the data is reported for a commercial formulation. Data from the ECHA website for the confidential entry has been added to the hazard profile.

Comment: Please find enclosed a study report from TNO, 2010 (please treat as CONFIDENTIAL), which shows that the bioavailability/bioaccessibility of the aluminum from aluminum diethylphosphinate is very low (0.1%). Therefore, concern levels for developmental and neurological should be reconsidered.

Response: Submitted confidential studies were provided and added to the hazard profile for aluminum diethylphosphinate. Although there were no developmental effects reported in the added study at doses up to 1,000 mg/kg-day, an estimated Moderate hazard potential remains for neurodevelopmental toxicity based on the presence of a bioavailable metal species and based on comparison to analogous metal salts. No experimental studies specifically designed to evaluate the neurodevelopmental endpoint were located; therefore, the potential for neurodevelopmental effects cannot be ruled out. The additional submitted study resulted in a change of the reproductive hazard designation from estimated Low to measured Very Low. In the absence of experimental data, the hazard designations for neurological toxicity endpoints are estimated to be Moderate based on comparison to analogous metal salts and EPA professional judgment.

B. Aluminum Hydroxide (CASRN 21645-51-2)

Comment: Acute and chronic toxicity studies done for different soluble and non-soluble aluminum salts during the REACH registration process show no evidence for any acute or chronic toxicity effects for aluminum hydroxide.

Response: The acute and chronic aquatic studies for aluminum hydroxide in the 2010 REACH dossier have been added to the decaBDE alternatives assessment but resulted in no change to the hazard designations. An acute fish toxicity study suggests no effects at saturation (NES). Studies in daphnia and algae reported effect values below the water solubility limit of the test substance; therefore, hazard potential based on potential aquatic toxicity for dissolved aluminum species cannot be ruled out. The available data for other aluminum salts are also not sufficient to dismiss potential hazard of dissolved aluminum from aluminum hydroxide.

Comment: The draft EPA DfE hazard assessment for aluminum hydroxide states that inherent inorganic substances will be assessed as of Very High hazard regarding persistence. If this is truly the case, then these criteria should be revised since they systematically stigmatize chemicals that are inherently harmless by virtue of their insolubility and inertness.

Response: The draft EPA DfE hazard assessment for aluminum hydroxide did not state that inherent inorganic substances will be assessed as Very High hazard for persistence. Chapter 4 of the report describes the assessment methodology as follows:

Chemicals that contain a metal were assigned a High persistence designation in the assessment, as these inorganic moieties are recalcitrant. In this instance, an 'R' footnote was added to the hazard summary table to indicate that the persistence potential was based on the presence of a recalcitrant inorganic moiety...

Additionally, the persistence summary for aluminum hydroxide reads:

HIGH: As an inorganic material, aluminum hydroxide is not expected to biodegrade or oxidize under typical environmental conditions. Aluminum hydroxide does not absorb light at environmentally relevant wavelengths and is not expected to photolyze. No degradation processes for aluminum hydroxide under typical environmental conditions were identified.

A persistence hazard designation of "H^R" has been assigned in Table 4-6.

Chapter 4 describes persistence as a function of the potential rate of removal of a substance under environmental conditions. Not all inorganic chemicals are inert and insoluble. However, insoluble, inert, metal-containing or inorganic compounds will not undergo ultimate removal and are therefore considered recalcitrant. Chemical flame retardants must be stable by design in order to maintain their flame retardant properties throughout the lifetime of the product. Therefore, persistence is not a distinguishing endpoint and high persistence is not a stigmatizing designation.

Comment: Based on the complete absence of systemic effects following oral or inhalation absorption, it is not justified to flag aluminum hydroxide for systemic toxicity.

Response: The hazard designation for repeated dose effects (systemic toxicity) is estimated to have potential for immunotoxicity based on professional judgment and comparison to analogous aluminum compounds; therefore, an estimated Moderate hazard designation was assigned.

Comment: Various aspects of aluminum neurotoxicity have been experimentally provoked only under conditions that are unrelated to real-life exposure situations. Effects elicited only by artificial introduction of metal ions into tissues that they cannot reach via physiological pathways are interesting from an academic and scientific point of view, but must not be the basis for regulatory decisions.

Response: For chronic endpoints, such as neurological toxicity, the hazard designation was based on potency. The evaluation considers the identification of both lowest observed adverse effect levels (LOAELs) and no observed adverse effect levels (NOAELs) when available. Neurological effects (impaired learning in a labyrinth maze test) were reported in a 90-day oral study in rats at a dose of 35 mg Al/kg-day as aluminum hydroxide with citric acid; this value falls within the Moderate hazard designation range. Another experiment in the same study (Bilkei-Gorzo, 1993) was added to the hazard profile and also reported impaired learning in rats at a dose of 300 mg Al/kg-day as aluminum hydroxide (without citric acid added). The LOAEL of 300 mg Al/kg-day falls within the Low hazard designation; however, there is uncertainty because only one dose of 300 mg/kg-day was tested and a NOAEL could not be identified. It is possible that neurological effects may occur at doses that would warrant a Moderate hazard designation. The hazard

designation for the neurotoxicity endpoint will remain Moderate based on available experimental data. The results of the DfE alternatives assessment are not a regulatory action.

C. Ammonium Polyphosphate, APP (CASRN 68333-79-9)

Comment: Ammonium polyphosphate (APP) persistence hazard designation should be changed from Very High to Low or Very Low. The water solubility has been determined from the suspension and would reflect the real solubility in water. The water solubility was determined using only the clear phase of the suspension after centrifugation of the suspension. APP can be hydrolyzed in the same manner as is it condensed. The shorter the APP chain length, the higher the hydrolysis rate. We recommend dividing the ammonium polyphosphates in three groups – APPII, APPI and liquid APP – and assigning persistence qualifications as Low, Low, and Very Low, respectively.

Response: The chemical name APP or ammonium polyphosphate (CASRN 68333-79-9) is used for a range of polyphosphoric chain lengths. This APP assessment is only for the large, high molecular weight (MW), relatively water-insoluble APP substance (with oligomers with a MW <1,000 not expected), as this is the material anticipated to be used as a flame retardant. Please refer to the chemical considerations section of this hazard profile for a more detailed review and supporting reference information.

The persistence designations are based on ultimate degradation according to the DfE Alternatives Assessment Criteria. The large, high MW, relatively water-insoluble APP is expected to have long chain lengths with greater than 50 repeating phosphate units. Hydrolysis is not expected to occur at rates related to a lower persistence designation for this large, inorganic, high MW substance due to its limited water solubility. The Very High persistence hazard designation represents a half-life greater than six months. The persistence hazard summary statement for APP acknowledges the potential for long term inherent degradation by hydrolysis.

As noted in the submitted comment and the assessment, shorter chain lengths have a higher rate of hydrolysis. Lower MW ammonium phosphates including diammonium phosphate (CASRN 7783-28-0) and triphosphoric acid, triammonium salt (CASRN 14728-39-3) are more water soluble and would likely have a higher rate of hydrolysis but this does not apply to the higher MW, insoluble APP evaluated in this assessment.

The information provided for the water solubility studies was added to the APP water solubility entries appear in Table 1 below:

Table 1. Revised Water Solubility Section in APP Hazard Profile

PROPERTY/ENDPOINT	DATA	REFERENCE	DATA QUALITY
Water Solubility (mg/L)	0.5% (w/w) at 25ºC in 10% suspension (Measured)	Clariant, 2011	Reported in chemical datasheet.
	0.5-0.05% max. at 25ºC in 10% suspension (Measured)	Wanjie International Co., 2007	Inadequate. This value likely represents a dispersion and is not an indication of the material's true water solubility.

D. Antimony Trioxide (CASRN 1309-64-4)

Comment: Consider incorporating the dermal irritation study by Gross et al., 1955 that has been used in the Antimony Trioxide Risk Assessment Report (ATO RAR). Also it has been concluded in the ATO RAR that special conditions, namely heat and sweat, are required in addition to high chemical dermal exposure to antimony trioxide in all cases where skin irritation effects were described in the workplace. The skin irritation is a non-specific phenomenon in which poorly soluble fine powders can block the sweat ducts, therefore causing rashes. It is also unclear if antimony trioxide was the only chemical substance to which the above mentioned workers had been exposed. It would be appreciated if the hazard designation for dermal irritation in the present draft report be changed from Moderate to Low.

Response: The dermal irritation study by Gross et al., 1955 was not added to the hazard profile due to the study and reporting limitations noted by EU RAR, 2008. In addition, the conclusions of the ATO RAR – that special conditions contribute to dermal irritation – are noted in the hazard summary statement. The hazard designation will remain Moderate given the evidence for the potential for dermal irritation to workers under possible occupational conditions.

E. Bisphenol A Bis-(diphenyl phosphate), BAPP (CASRN 181028-79-5)

Comment: Clarification requested about the statement in the BAPP endocrine activity summary section "BAPP does not release bisphenol A."

Response: The BAPP endocrine activity summary section as well as the metabolites, degradates and transformation products section were updated to address the potential release of bisphenol A by BAPP:

> *None identified. Degradation of BAPP has been demonstrated in experimental studies (Iwami, 1994; Hogg, 1997; Armstrong and White, 1999); however the degradates have not been identified. Degradation of BAPP by sequential dephosphorylation could produce phenol (CASRN 108-95-2), diphenyl phosphate (CASRN 838-85-7), and bisphenol A (CASRN 80-05-1). The importance of dephosphorylation relative to possible competing pathways has not been demonstrated in a published study. Therefore the hazards of the theoretical degradation products were not considered in this hazard assessment.*

Furthermore, the chemical considerations section was revised to account for the potential of bisphenol A to be present in BAPP commercial formulations as an impurity.

Experimental studies indicate that BAPP is highly persistent and has low water solubility. Therefore, this hazard screening has been updated to more clearly distinguish that BAPP has the potential to release bisphenol A. However, the rates and conditions for this to occur have not been established by experimental studies.

Comment: The experimental bioconcentration factor (BCF) for BAPP is in the Low to Moderate range and the estimated bioaccumulation factor (BAF), 1,100, is just slightly over the High bioaccumulation designation cutoff. Under these circumstances, it would seem EPA may want to consider a Moderate designation and show it in color, indicating that data exists.

Response: BAF and BCF values must be evaluated when determining the overall bioaccumulation hazard designation, as they incorporate metabolism and elimination. The color and font of the hazard designation in the hazard summary table is based on the data used to make the hazard designation. In this case, an estimated BAF value is used. Please note that an additional experimental BCF value (≤100) from a stakeholder's submitted confidential study was added to the BAPP hazard profile. The BAPP bioaccumulation hazard summary section was revised to address the differences between the BCF and BAF values:

> *HIGH: Although measured BCF values for the components of the polymeric mixture result in a Moderate bioaccumulation hazard designation, the overall bioaccumulation designation for BAPP is High based on an estimated BAF value. The estimated BAF of 1,100 for the predominant component of the mixture with a MW <1,000 daltons, suggests that BAPP may bioaccumulate in higher trophic levels.*

F. Brominated Polymers

[The Brominated Polymers group includes the following six substances in the final report:

- *Brominated Epoxy Polymer(s)*(CASRN Confidential)
- *Brominated Epoxy Polymers* (CASRN 68928-70-1)
- *Mixture of Brominated Epoxy Polymer(s) and Bromobenzyl Acrylate* (CASRN Confidential)
- *Brominated Epoxy Resin End-Capped with Tribromophenol* (CASRN 135229-48-0)
- *Brominated Polyacrylate* (CASRN 59447-57-3)
- *Brominated Polystyrene* (CASRN 88497-56-7)

Please note that four brominated polymers included in the draft report have been renamed in the final report. In some instances, chemicals that were presented separately in the draft report are now combined. The name changes for these four chemicals are provided in Table 2 below.]

Table 2. Chemical Name Changes from the Draft Report to the Final Report

PREVIOUS NAME	NEW NAME
Confidential Brominated Epoxy Polymer #1	Brominated Epoxy Polymer(s)
Confidential Brominated Epoxy Polymer #2	
Confidential Brominated Epoxy Polymer Mixture #1	Mixture of Brominated Epoxy Polymer(s) and Bromobenzyl Acrylate
Confidential Brominated Epoxy Polymer Mixture #2	

The following comments were made in regards to the five brominated polymers included in the report.

Comment: EPA inaccurately asserts that exposure to brominated polymers is associated with lung overloading, fibrosis, and cancer. The EPA states that materials of this MW "have potential for adverse effects due to lung overloading as a consequence of dust-forming operations." However, many applications using brominated polymers do not result in any dust generation.

Response: Polymers with an average MW >10,000 have potential for adverse effects due to lung overloading and this potential is considered throughout the chemical's complete lifecycle (EPA, 2010a).

The estimated Moderate hazard designations assigned to chemicals with MW >10,000 in this report were changed to estimated Low hazard designations and footnoted with a more detailed caveat for dust-forming operation scenarios ("[d] This hazard designation would be assigned MODERATE if >5% of the particles are in the respirable range as a result of dust forming operations."). In addition, the language has been revised in Section 4.4.2 of Chapter 4 to reflect that the potential for fibrosis or cancer are not assumed with high MW compounds.

Comment: Five of the hazard profiles have confidential CASRNs and molecular formulas (Polyquel 240, 241, 145, 146, and Emerald Innovation 1000™). It is of no value to a user to hold the CASRN confidential as well as the formula. These five hazard profiles include no information beyond EPA's professional judgment, leaving a potential user unable to make an independent assessment as to the viability of these chemicals for production processes.

Response: Under TSCA, companies may claim confidentiality for proprietary information and DfE must protect these confidentiality claims in its alternatives assessments. As part of its commitment to increase transparency and public access to chemical information, EPA encourages the release of confidential information once intellectual property protections are in place for a chemical. In the final version of the report, the confidential brominated polymer has been changed to the generic name brominated poly(phenylether) to provide readers with a general description of the product's structural identity while honoring the manufacturer's proprietary information.

Comment: The report states the following about the regulatory status of brominated epoxy resin end-capped with tribromophenol (CASRN: 135229-48-0): "Listed on the TSCA Chemical Inventory as EPA Acc. No. 153958 CASRN: 534584-61-7 (ICL Industrial Products, 2009). This chemical is not listed on the non-confidential TSCA Inventory." Searches of databases do not associate either CASRN with the Accession Number provided. EPA should provide further clarification for users to determine if the chemical is a viable candidate for production purposes.

Response: The CASRN 135229-48-0 is not on the TSCA Inventory. The CASRN 534584-61-7 is not listed on the non-confidential Inventory. However, the ICL MSDS for this product states "Listed on the TSCA Chemical Inventory as EPA Acc. No. 153958 CASRN: 534584-61-7." EPA cannot publicly say if a substance is on the Inventory when it is claimed confidential unless there is a public disclosure; in this case, the manufacturer made this disclosure on the MSDS. See also the related comment and response under Aluminum diethylphosphinate.

Comment (for brominated poly(phenyl ether): The good laboratory practice (GLP) chronic daphnid study is complete and will be submitted. Results indicate that this endpoint designation is Low.

Response: A chronic aquatic toxicity study in *Daphnia magna* was submitted and added to the hazard profile. The study indicates a Low hazard designation. However, no test data regarding chronic aquatic toxicity for fish and algae were located, therefore the potential for aquatic toxicity is uncertain in these species. EPA has predicted the behavior of this substance in the environment based upon physical-chemical properties and data on structurally similar chemicals. The notice of commencement for this substance includes pended testing for fish early life stage toxicity and algal toxicity (OPPTS 850.1400, 850.1300 and 850.5400). Pended testing must be submitted only if the manufacturer wishes to be released from this chemical's Consent Order.

Comment: The addition of CASRN 148993-99-1, the CASRN used for PBDS-80 and the other Chemtura products, is requested.

Response: CASRN 148993-99-1 was assessed as an analog to brominated polystyrene (CASRN 88497-56-7). Although CASRN 148993-99-1 is a close structural analog, these two CASRN represent slightly different polymers. CASRN 88497-56-7 has a slightly higher degree of bromination than CASRN 148993-99-1 (Mack, 2004). The difference between the two polymers is minimal and the DfE assessment for CASRN 148993-99-1 is expected to closely resemble the assessment of CASRN 88497-56-7. Some exceptions would result because the experimental values from CASRN 88497-56-7 would be applied as estimated by analogy for CASRN 148993-99-1.

G. Brominated Poly(phenylether) (CASRN Confidential)

Comment: Five of the hazard profiles have confidential CASRNs and molecular formulas (Polyquel 240, 241, 145, 146, and Emerald Innovation 1000™). It is of no value to a user to hold the CASRN confidential as well as the formula. These five hazard profiles include no information beyond EPA's professional judgment, leaving a potential user unable to make an independent assessment as to the viability of these chemicals for production processes.

Response: Under TSCA, companies may claim confidentiality for proprietary information and DfE must protect these confidentiality claims in its alternatives assessments. As part of its commitment to increase transparency and public access to chemical information, EPA encourages the release of confidential information once intellectual property protections are in place for a chemical. In the final version of the report, the confidential brominated polymer has

been changed to the generic name brominated poly(phenylether) to provide readers with a general description of the product's structural identity while honoring the manufacturer's proprietary information.

Comment: Was the confidential analog for the brominated poly(phenylether) BAF endpoint a substance with >1,000 MW? If not, then it is not a suitable analog. In addition, the lowest MW species in our product is well above 1,000 and impurities <1,000 are essentially absent. The EPA polymer exemption allows for up to 25% of species with a MW <1,000 and still be considered a polymer of Low hazard. What analog substances with MW >1,000 have a BAF factor above 100? Above 10?

Response: The confidential nature of this substance limits the detail of response to this comment. The bioaccumulation potential for this compound is uncertain, as stated in the hazard summary and indicated by the estimated designation. However, bioaccumulation potential exists for some large compounds above the MW cutoff of 1,000 and an exact or specific cutoff cannot be demonstrated because bioaccumulation and chemical absorption are complex functions of diverse physiological processes.

The brominated poly(phenylether) hazard profile notes that impurities have been found in analogous substances and could potentially be present in this substance. A summary of the hazard designations for the impurities are provided in the hazard summary table as footnotes for this hazard profile. As indicated in Chapter 4 of the Alternatives Assessment, DfE assessment methodology evaluates all components that are anticipated to be present in the commercial product. As appropriate, this may include impurities, byproducts, or other chemicals present at <1%, unlike the EPA polymer exemption method of assessment. Typically this occurs when the hazard designation of these materials is anticipated to be of higher hazard then the other substances present. Test data for this substance is required to prove lack of impurities. The EPA polymer exemption criteria do not apply to this assessment.

H. Decabromodiphenyl Ethane, DBDPE (CASRN 84852-53-9)

Comment: Metabolites, degradants and transformation products have not been detected.

Response: The metabolites, degradants and transformation products section are compiled from studies listed in the decaBDE hazard profile. The entry was updated to address the likelihood of the formation of metabolites, degradants and transformation products: "Photodegradation – potential to form lower brominated congeners (Wang et al., 2010)."

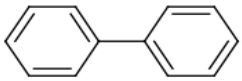
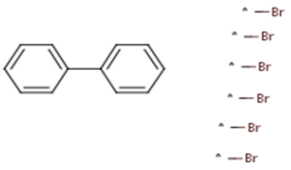
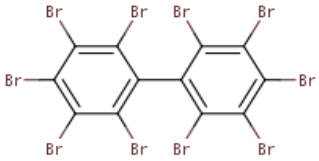
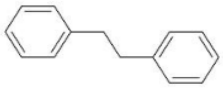
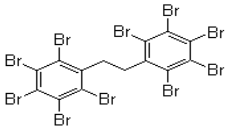
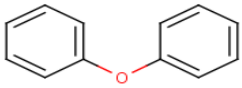
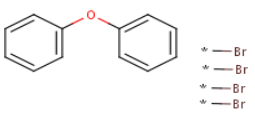
Comment: DBDPE's log K_{ow} is 3.55, comments about the measured log K_{ow} value should be deleted in the report.

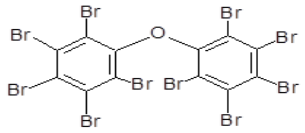
Response: The reference field of the log K_{ow} entry was updated to note that other secondary sources, Pakalin, 2007 and Dungey et al., 2007, were reviewed. Although the value 3.55 was obtained using experimental methods, log K_{ow} measurements for DBDPE are difficult due to limited solubility of the compound in water and octanol. There was enough concern about this

experimental study that one secondary source considered this study to be estimated, due to analytical uncertainties.

Also, a log K_{ow} of 3.55 for DBDPE is an aberration in relation to other experimental octanol-water partitioning coefficient values for analogous highly brominated compounds (CASRN 1163-19-5 and 13654-09-6). It is also a deviation from the trend, shown in Table 3 below, where a higher number of bromine substituents results in a higher log K_{ow} value. The non-brominated diphenylethane has an experimental log K_{ow} of 4.79

Table 3. Experimental Log K_{ow} for Select Biphenyls, Diphenylethanes, and Diphenyl Ethers

CAS Name	Structure	Experimental Log K_{ow}	Reference
Biphenyls			
92-52-4 Biphenyl		4.01	Hansch, 1995 as cited by HSDB
36355-01-8 Hexabromobiphenyl		6.39	Veith, 1979 as cited by HSDB
13654-09-6 Decabromobiphenyl		8.58	Anliker, 1988 as cited by HSDB
Diphenylethanes			
103-29-7 Diphenylethane		4.79	Sangster Log K_{ow} database
84852-53-9 DBDPE		3.55	Dungey, 2007
Diphenyl Ethers			
Diphenyl Ether 101-84-8		4.21	Hansch, 1987 as cited by HSDB
TetraBDE 40088-47-9		6.05	Sjodin, 2003 as cited by HSDB

CAS Name	Structure	Experimental Log K_{ow}	Reference
DecaBDE 1163-19-5		6.27	European Chemicals Bureau, 2002

Comment: The toxicokinetics comment based on Wang et al., 2010 in the human health effects section should be deleted for the following reasons: two other studies with labeled DBDPE have not detected DBDPE above background levels in blood, plasma, or tissues. Wang et al., 2010 did not analyze serum. Commenting that DBDPE is distributed to the liver, adipose tissue, and kidney based on negligible amounts is misleading. The method used by Wang et al., 2010 was non-specific. The identity of the purported metabolite methyl sulfone is questionable. Metabolite formation identification would require labeled test material and subsequent analysis of peaks containing label. An *in vitro* study reported that DBDPE did not metabolize. The comment in the summary that if absorbed DBDPE is distributed and undergoes biotransformation should be deleted. Remove mention of radioactivity in the Wang et al., 2010 study summary, as it was not used. Add a recently completed absorption, distribution, metabolism, and excretion (ADME) study using labeled DBDPE (Black, 2012).

Response: The "negligible" uptake in the 90-day animal study may not be indicative of the total uptake following decades of exposure. Even if uptake is poor or slow, if the total uptake from all sources is greater than elimination, this can lead to bioaccumulation. The Wang et al., 2010 study will remain included in the hazard profile. The "Data Quality" entry for the Wang et al., 2010 study was revised. The Black, 2012 study was added to the hazard profile.

Comment: DfE did not consider another two-year study in rats that found no evidence of carcinogenicity in rats at doses lower than those used by NTP. The effects observed in the NTP study are threshold related. The NTP study doses are expected to be zero order absorption kinetics where the other study was within a range for first order absorption kinetics would be expected. DfE Alternatives Assessment Criteria assign a Low hazard designation for substances with negative studies or robust mechanism based structure activity relationship (SAR). It is questionable that DfE does not explain how limited or marginal evidence of carcinogenicity translates into a Moderate human hazard. This is indirect contradiction to EPA's Guidelines for Carcinogen Risk Assessment that clearly state these and other key data are to be considered during hazard assessment. DfE states that its criteria mirror International Agency for Research on Cancer (IARC) classification approach, however IARC does not rate hazard. IARC classifies substances according to the strength of evidence.

Response: DecaBDE (CASRN 1163-19-5), another highly brominated flame retardant, was selected by experts in EPA's Office of Pollution Prevention and Toxics (OPPT) as a structural analog to DBDPE for the assessment of some human health endpoints that were lacking experimental data. Please see comments for the decaBDE carcinogenicity endpoint for further information in regards to DBDPE comments.

When there was an absence of data for this endpoint, carcinogenic effects could not be ruled out; therefore, a Moderate hazard was assigned. As explained in Section 4.4.1 of Chapter 4, the hazard designation for carcinogenicity was contingent on the level of evidence for increased incidence of cancer, and not potency. The definitions applied in DfE Alternatives Assessment Criteria are based on IARC levels of evidence (IARC, 2006). For example, a designation of Very High hazard requires that the substance be characterized as a "known or presumed human carcinogen," whereas a designation of Low hazard requires either negative studies or robust SAR conclusions. A designation of Moderate was applied as a default value when there was an absence of data suggesting High carcinogenicity, and an absence of data supporting Low carcinogenicity (i.e., a lack of negative studies or weak SAR conclusions).

Comment: Further details on DBDPE neurotoxicity were provided in the comment on decaBDE neurotoxicity.

Response: Prior to responding to this particular comment, EPA reviewed its approach for inclusion of data in developmental and neurotoxicity endpoints. To best align with the DfE hazard criteria, developmental neurotoxicity studies have been moved to – and are now only included in – the developmental toxicity section of the hazard assessment. While developmental neurotoxicity studies indicated potential hazard, positive indications for developmental neurotoxicity effects cannot be used to rationalize hazard for adult neurotoxicity. There was no evidence to support hazard potential for adult neurotoxicity. The hazard summary statement has been revised. The hazard designation for the neurotoxicity endpoint was changed from High to Low.

Comment: The highest dose tested in the 90-day study, 1,000 mg/kg/day, is incorrectly said to be LOAEL. The repeated dose effects reported were not adverse and should be corrected. The difference between observed and adverse effects should be made. DfE compares DBDPE to decaBDE and assumes potential for bioaccumulation. This interpretation is erroneous.

DfE expresses concern for DBDPE based on minimal histopathological changes observed in NTP's two-year studies in rats and mice fed decaBDE at uncommonly high doses. The rats in the NTP study were affected with mononuclear cell leukemia at a high incidence in the controls. The hepatic spleen changes are likely related to leukemia rather than decaBDE. Lymph node hyperplasia is a normal response to antigens and is not an adverse effect. Histological changes occurred at doses 3.2 and 6.6 times the limit dose of 1,000 mg/kg/day and are not relevant to human hazard evaluation. Also, incidence of hepatic granulomas was not dose related. A concern for adverse effects due to chronic exposure on NTP's two-year study is not relevant to the human health assessment of decaBDE.

Response: There will be no changes made to the 90-day study summary based on this comment. The LOAEL of 1,000 mg/kg-day was based on changes in liver weights with slight hepatocellular vacuolization and slight centrilobular hepatocytomegaly. The effect occurs at doses in the Low hazard criteria range. The hazard designation for repeated dose effects remains Low. The hazard summary statement for repeated dose effects was revised to remove the hazard for potential adverse effects based on analogy to decaBDE (NTP, 1986). When there was

information available to assess the adversity of an effect, it was reflected in the "Data Quality" section of the study entry.

Comment: Please correct the reference to Hardy et al., 2012, Hardy et al., 2011 and the "Data Quality" entry in the ecotoxicity section.

Response: The Hardy, 2004 references have been revised to Hardy et al., 2012 and Hardy et al., 2011.

Comment: The bioaccumulation designation was based on the monitoring data in terrestrial and aquatic species while stating that experimental data in fish are below a level of concern. No information was provided on the monitoring data considered by DfE. Chapter 4, page 4-23 of the report states: "If experimental BCFs <100 were available, the estimated upper trophic BAF from EPISuite™ was used preferentially if its use resulted in a more conservative hazard designation and the potential for metabolism was accurately accounted for within the model estimates." This statement is contrary to the DfE Alternatives Assessment Criteria since the upper trophic BAF is 62. Molecular size and shape of DBDPE are indicative of a low bioaccumulation potential. The environmental monitoring and biomonitoring levels detected are very low and some reports used non-specific methods of analysis. The Betts, 2009 citation is an op-ed piece and not a review article. The papers referred to by Betts utilized gas chromatography-mass spectrometry (GC-MS). The chemical is not suited to analysis by gas chromatography (GC), it is better suited to high performance liquid chromatography (HPLC). Alleged detection of DBDPE in seagulls and herring gull eggs was actually on gull eggs only. Five of the seven colonies sampled had no detectable DBDPE, which does not indicate bioaccumulation (Gauthier et al., 2009). A non-specific method was used by Law et al., 2006. Banasik et al., 2011 detection in giant panda was questionable. If DBDPE were actually detected in wildlife as reported in the literature, such detection does not indicate bioaccumulation as defined in the regulatory sense.

Response: The high bioaccumulation hazard designation for DBDPE is in black italic (i.e., *H*) – representing that this designation is estimated for this endpoint. There appears to be potential for accumulation of this compound and potential for accumulation of degradation products of this compound.

Molecular size and molecular dimension analysis were provided in the public comments for this compound. These structure-based estimations and comparisons provide an interesting perspective however available data do not support or eliminate hazard designations based on this analysis.

The DfE Alternative Assessment Criteria consider environmental monitoring data with regard to bioaccumulation when available (EPA, 2011a). The two experimental BCF values provide an indication of Low bioaccumulation in fish. However, the demonstrated presence of this compound in biological matrices, even without quantification, is an indication that there is potential for bioaccumulation hazard that may be dose, duration and possibly species dependent.

From Page 24 of the DfE Alternatives Assessment Criteria:

4.2.3 Bioaccumulation

Data on the capacity for a compound to bioaccumulate will be evaluated. Environmental monitoring data will be considered when available. The criteria used to make bioaccumulation designations are shown in Table 13. These criteria were derived from OPPT's New Chemicals Program [34], and Arnot & Gobas 2006 [7].

The bioaccumulation hazard summary has been updated to clarify the assessment of this endpoint:

> *HIGH: The bioaccumulation hazard designation is estimated based on decabromodiphenyl ethane monitoring data reporting detections in many different species including those higher on the food chain. Although the estimated bioaccumulation factor is low, the persistence of decabromodiphenyl ethane and its detection in many species from different habitats and trophic levels indicates high potential for bioaccumulation hazard in aquatic or terrestrial species.*

Regarding the monitoring sections of the hazard profiles, these entries are meant to be concise and contain data to aid stakeholders in their evaluation of potential alternatives. However, the bioaccumulation hazard designation for DBDPE is based on the monitoring data and as a result additional details have been provided in the ecological monitoring section. Presence of a substance in eggs is significant because the parent had to absorb and then deposit the substance into the egg which demonstrates bioavailability. Lack of detection in gull eggs may be due to food sources for the colonies studied. Both terrestrial and aquatic food chains are relevant to flame retardant exposure and bioaccumulation. The original monitoring studies are listed with references in the environmental monitoring and biomonitoring section whenever possible.

The estimated High bioaccumulation hazard designation based on monitoring data is consistent with the DfE Alternatives Assessment Criteria. The results of the DfE alternatives assessment are not a regulatory action.

I. Decabromodiphenyl Ether, DecaBDE (CASRN 1163-19-5)

Comment: Several comments requested the identification and review of measured data:

- A recent high-quality review of decaBDE's toxicology that included a human health risk assessment and published in a highly regarded journal, Critical Reviews in Toxicology, was not cited;
- Other recent high-quality data was only included in DfE's draft assessment after an initial review of the hazard summary by manufacturers in spring of 2012;
- Developmental effects and neurotoxicity should be based on new studies published after the EPA Integrated Risk Information System (IRIS), 2008 and EPA, 2008 reports; and
- The carcinogenicity endpoint did not consider a study from Kociba et al., 1975.

Response: DecaBDE is a chemical that has experimental data available for most endpoints evaluated in the DfE hazard profile. The literature review process for chemicals well characterized by experimental studies resulted in the collection of recent high-quality reviews or

peer-reviewed risk assessments supplemented with primary literature searches published after secondary sources were released.

The exclusion of the 2009 Critical Review in Toxicology study does not represent a failing of the assessment to have a thorough understanding of behavior and effects of the chemical. The hazard and risk assessments section was designed primarily to list assessments completed by governments or authoritative expert groups.

This report is a culmination of stakeholder involvement. Additional studies supplied by stakeholders were evaluated and added when sufficient cause was found to do so. The developmental effects and neurotoxicity studies mentioned, as well as the cancer study (Kociba et al., 1975) mentioned in this comment are addressed in more detail in the responses below.

Comment: Unknown/unverifiable synonyms for the chemical names should be removed from the assessment.

Response: The list of synonyms includes both common and less well known chemical and trade names that may be used to describe the material. These were collected and are available in public searches of the CASRN 1163-19-5. The synonyms with unverified primary sources were labeled as such in the hazard profile.

Comment: The chemical considerations section states that experimental values were used in the EPISuite™ estimations. It is suggested that EPISuite™ is run without experimental values since substances like decaBDE have limited solubility in water and organic solvents and are difficult to analyze.

Response: The EPISuite™ estimations were run with experimental values as indicated in the DfE methodology described in Chapter 4. The EPISuite™ program allows the user to input measured values, thereby improving the accuracy of the values estimated for other properties. Experimental values are entered whenever measured values for the pure component are available. The most predictive results are expected to be those that incorporate experimental data.

Comment: Request for clarification of the sources and values/rates of transformation entered into metabolites, degradants and transformation products section of the hazard profile.

Response: The data entered into the metabolites, degradants and transformation products section is based on entries found in the decaBDE hazard profile. For improved clarity, the metabolites, degradants and transformation products section was edited to separate the entries, as follows:

> *Photodegradation – potential to form lower brominated diphenyl ether congeners and possibly polybrominated dibenzofurans (European Chemicals Bureau, 2002); Fish metabolism - lower brominated diphenyl ether (BDE) congeners a range of penta- to nonaBDEs (with 2,2',4,4',5,6'-hexabromodiphenyl ether being most prevalent) (Noyes et. al., 2011); Anaerobic Biodegradation - lower brominated diphenyl ether congeners (Illinois EPA, 2007); Pyrolysis - polybrominated dibenzofurans and polybrominated dibenzo-p-dioxins (European Chemicals Bureau, 2002).*

The pyrolysis information discussed in this comment was also entered into the pyrolysis section of the hazard profile (Table 4):

Table 4. Revised Pyrolysis Section in DecaBDE Hazard Profile

PROPERTY/ ENDPOINT	DATA	REFERENCE	DATA QUALITY
Pyrolysis	Polybrominated dibenzo-p-dioxins (PBDDs) and polybrominated dibenzofurans (PBDFs) are formed by thermal reaction involving a free radical mechanism (Measured)	European Chemicals Bureau, 2000	Supporting information reported in a secondary source.

There are no criteria set for the minimum amount of detected substance or required transformation rate to report an entry into the metabolites, degradants and transformation section. Therefore, the fish metabolism study will remain, even though the amount detected was low. This fish metabolism study is noteworthy since few other mammalian-based studies reported the identity of the metabolite compounds detected.

Comment: Toxicokinetics data indicate decaBDE is poorly absorbed following oral and dermal exposure. DfE's statement that "even low levels of decaBDE are physiologically relevant due to its chemical properties" is not valid. DecaBDE is not reactive and is essentially inert. It is very poorly soluble in water and most organic solvents. DecaBDE has NOAELs of ≥1,000 mg/kg-day in repeated dose studies (NTP 14-day and 90-day studies, Hardy et al., 2002; Biesemeier et al., 2010; Biesemieier et al., 2011) and is not bioaccumulative (EPA, 2008). These properties indicate low levels are not physiologically relevant. This comment should be deleted.

Response: The statement as written in this section alluded to the chemical properties that include MW and the lipophilic nature of the compound, which indicates a potential for bioavailability and accumulation in adipose tissues. Although decaBDE is poorly absorbed, monitoring data indicate that the compound has been detected in higher trophic level organisms. These biomonitoring data suggest that decaBDE is absorbed by animals exposed to low levels of this compound in the environment. Because of this, and because adverse effects have been reported at low dose levels (6 mg/kg-day) in developmental studies, exposure to low levels of decaBDE is physiologically relevant, and concern for such exposure should be brought forward in the hazard assessment.

Comment: In the toxicokinetics section, the statement that monitoring studies in human volunteers should be clarified. To the best of our knowledge, no studies have been conducted whereby human volunteers ingested a known dose of decaBDE with subsequent monitoring of blood and breast milk. The studies refer to publications where samples collected from volunteers without known exposures were analyzed for decaBDE. This is an important distinction because rigorous attempt at analysis of decaBDE in human serum and breast milk have been unsuccessful. The analytical methods cited in the report should be evaluated. The Centers for Disease Control and Prevention (CDC) estimation of background serum levels of 2 ng/g lipid weight (lw) for the U.S. general population should be included in the hazard assessment. DfE

should take into consideration that concentrations in milk would be derived from serum and that at serum concentrations of 2 ng/g lw, movement into breast milk is expected to be negligible given decaBDE's diffusion-limited passage through cell membranes.

Response: Regarding the quality of the analytical data, the original studies were reviewed and assessed by EPA's IRIS program, and considered acceptable to include in the EPA IRIS toxicological profile. The EPA IRIS profile noted that the data do not provide information on the quantitative aspects of absorption or the kinetics of tissue retention but indicate a tendency for BDE-209 to distribute to these tissues. The study reporting a mean concentration of 0.9 ng/g lw/BDE-209, obtained using high resolution gas chromatography-mass spectrometry (HRGC-MS) with a labeled internal standard (Schecter et al., 2003).

The detection of decaBDE in breast milk, even at very low concentrations, is relevant to understanding its absorption and distribution in the body. If elimination of decaBDE in breast milk is not expected based on its properties, then its detection in multiple monitoring studies involving breast milk is all the more relevant and important for elucidating its distribution in the body. Breast milk is a known route of excretion for fat-soluble substances. Breast feeding is associated with reduced body burden of contaminants. The assumption that concentrations of decaBDE in milk would be derived from serum does not account for what is known about secretory processes associated with production of breast milk.

It is noted in the "Data Quality" field of these studies that the data is from biomonitoring studies and that no measured dosing studies in humans have been conducted. In response to this comment, the hazard summary statement has been revised to clarify further that the data is based on biomonitoring studies and not a dosing study:

> "*Monitoring studies in humans, with unknown levels of exposure, demonstrate that decabromodiphenyl ether can be absorbed, distributed to mammary tissue and secreted in human breast milk during lactation*."

Concerns raised about rigorous attempts at detecting decaBDE in human milk are not consistent with the reported detection of decaBDE in milk from other mammals (rats) as published by the submitter of this comment (Biesemeier, 2010).

Comment: In the toxicokinetics section, indicate that the skin of hairless mice was used in the *in vitro* dermal absorption study (Hughes et al., 2001 – as cited in EPA, 2008)

Response: The suggested revisions have been made to the hazard assessment.

Comment: In the toxicokinetics section, the addition of "Oral ADME *in vivo*" in the Property/Endpoint column is suggested.

Response: The suggested correction has been made to the hazard assessment.

Comment: In the toxicokinetics section, revision and addition of study details for several studies is suggested.

Response: Additional study details and some revisions have been made to the hazard assessment for several study descriptions including studies reported in NTP, 1986 and the Kociba, 1975 study described in European Chemicals Bureau, 2002.

Comment: In the toxicokinetics section, adding "Disposition after IV dosing" and "Disposition after oral dosing" categories in the Property/Endpoint column is suggested.

Response: No further property/endpoint categories are necessary, as the hazard profile has been updated by moving the IV dosing studies to the "Other" route category.

Comment: In the toxicokinetics section, new information on the disposition of decaBDE is presented in Biesemeier et al., 2010 and should be added to the oral ADME *in vivo* section of the Toxicokinetics section.

Response: This study was added to the hazard profile.

Comment: In the carcinogenicity section, DfE's concern for the potential carcinogenicity of decaBDE is misplaced. The results of the 1986 U.S. National Toxicology Program's (NTP) two-year carcinogenicity studies in rats and mice are indicative of low hazard given the excessive doses, the limited evidence of carcinogenicity, lack of mutagenicity, and an earlier two-year carcinogenicity study reporting no evidence of carcinogenicity at lower doses (Kociba et al., 1975). DfE did not consider the negative carcinogenicity study (Kociba et al., 1975) on decaBDE. DecaBDE is not listed by the NTP as a known or reasonably anticipated carcinogen and is classified by IARC as group 3 "not classifiable as to carcinogenicity to humans" based on "limited evidence in animals".

Response: The designation for decaBDE is Moderate based upon DfE's Alternatives Assessment Criteria that require definitive absence of an effect for a Low designation. NTP found positive evidence of carcinogenicity in male and female rats and equivocal evidence of carcinogenicity in male mice for decaBDE. In addition, EPA's IRIS assessment classified decaBDE as having "suggestive evidence of carcinogenic potential".

Comment: Regarding the NTP two-year study in mice, "equivocal evidence" of carcinogenicity in male mice for the NTP 1986 study should be qualified in the combined chronic toxicity/carcinogenicity section. The early loss of control male mice due to fighting impacted the numbers of tumors observed in controls at the end of the study. Please add that mortality in mice was unaffected by administration of dietary doses 3,200 to 7,780 mg/kg-day for two years. Also, indicate that the LOAEL in male mice for nonneoplastic lesions was 3,200 mg/kg-day for two years for the reader's accurate interpretation of the LOAEL.

Response: The "Data Quality" entry for this study has been revised to reflect that results were adjusted for intercurrent mortality (NTP, 1986; European Chemicals Bureau, 2002). It was already noted in the mouse study that there were no treatment-related adverse effects on survival. The systemic LOAEL is included in the study summary.

Comment: Regarding the NTP two-year study in rats in the combined chronic toxicity/carcinogenicity section, add that no adverse effects on food consumption or body weight were observed in rats. Also, note the systemic NOAEL and LOAEL were equivalent to 1,120 and 2,240 mg/kg-day, respectively, for two years, and the local effects LOAEL was equivalent to 1,120 mg/kg-day.

Response: Revisions have been made to the data summary to reflect the systemic LOAEL and NOAEL in units of mg/kg-day.

Comment: Requesting the addition of the Kociba et al., 1975 two-year carcinogenicity study in rats to the Combined chronic toxicity/carcinogenicity section because this study provides important hazard information. The study has typically been omitted from EPA reviews (including EPA, 2008) of decaBDE due to the comparatively low doses administered. This study provides significant new information with respect to hazard and risk identification and should be included. The highest dose in Kociba et al., 1975 was 1 mg/kg-day. No evidence of toxicity or carcinogenicity was observed. This is important to hazard evaluation since it clearly demonstrates a lifetime no effect level, even when the former 77% BDE-209 commercial product was used as a test article. The lack of effects observed in this study has relevance to any concern for toxicity due to metabolism of BDE-209 to lower brominated congeners. The test article administered by Kociba et al., 1975 was known to contain significant levels of nona- and octaBDEs and the length of study provided ample opportunity for the generation of lower brominated congeners and expression of toxicity. No adverse effects were observed and no appreciable accumulation was detected. The absence of effects indicates concern for toxicity due to metabolites can be disregarded. The results of this study are relevant to low environmental exposures because of the low doses administered in the diet.

Response: The study summary for Kociba et al., 1975 was added to the carcinogenicity section. The hazard designation was not changed based on this comment and remains Moderate.

Comment: Request to add the composition of test substance to the "Data Quality" section of the Norris et al., 1975 study in the reproductive and fertility effects endpoints section.

Response: The "Data Quality" entry for the Norris et al., 1975 study (as cited in European Chemicals Bureau, 2002) was revised to note the test substance composition.

Comment: DfE relies on outdated information in the developmental effects summary section that has been superseded by new data generated from GLP/guideline-compliant developmental neurotoxicity and prenatal developmental studies. EPA's IRIS evaluation was based on reported effects in neonatal mice after a single low oral dose that was not conducted according to GLP's established guidelines, etc. The experimental design used in this study is prone to producing false positives and has been discredited.

- Goodman (2009) performed a critical review of the available studies and did not find the Viberg study suitable for establishing an RfD.
- ILSI Research Foundation/Risk Science Institute expert working group published a report (Holson et al., 2008) stating that ignoring litter effects in the statistical analysis of DNT studies is simply not an acceptable practice.

- William and DeSesso (2010) published a review of studies concerning decaBDE stating that a lack of consistency across studies precludes establishment of a causal relationship between perinatal exposure to these substances and alterations in motor activity.

Response: The High developmental hazard designation for decaBDE results from a hazard-based approach using the most conservative NOAEL and LOAEL values from the available studies. A number of developmental neurotoxicity studies in rodents were included in the assessment. The hazard designation is based on several studies where developmental/neurodevelopmental effects were shown to occur at doses <50 mg/kg-day. Though there are inconsistencies, the majority of studies suggest that perinatal exposure affects motor activity. Using a hazard based approach; there is hazard potential for the developmental endpoint. The work by Biesemier et al. is included in the developmental toxicity section and was considered when assigning a hazard designation for this endpoint. However, this study does not rule out other neurodevelopmental effects. The EPA's IRIS assessment of decaBDE indicated developmental neurotoxicity as an endpoint of concern based on multiple studies showing similar effects.

Comment: For the prenatal exposure entry in the developmental effects section, the LOAEL should be corrected to 100 mg/kg/day. The Biesemeier et al., 2011 should be classified as pre- and postnatal exposure. Please add that this is a GLP/guideline compliant study.

Response: The Norris et al., 1973 study summary was revised to reflect that resorptions were not statistically significant in the high dose group. The developmental LOAEL remains as 10 mg/kg-day.

There is no category for pre- and postnatal exposure in the DfE alternatives assessment, so the Biesemeier et al., 2011 study will remain in the prenatal exposure section. The "Data Quality" entry for this study has been revised to reflect that it was conducted according to guidelines.

Comment: Developmental effects – for the Postnatal exposure entry, the Rice et al., 2007 study has been reviewed by Hardy et al., 2009 and Goodman, 2009. The reported changes in locomotor activity and T4 levels are not suitable for use in deriving a LOAEL.

Response: The Rice et al., 2007 data is summarized in the EPA Integrated Risk Information System (IRIS) assessment of DecaBDE. The EPA IRIS report indicated developmental neurotoxicity as an endpoint of concern based on multiple studies showing similar effects. The hazard designation for this endpoint was assigned based upon the most conservative NOAEL and LOAEL values in the available studies. This aligns with the assessment for DecaBDE published by EPA's Integrated Risk Information System (IRIS). Study limitations of summarized data are noted in the 'Data Quality' field for each study.

Comment: The hazard rating for neurotoxicity should be based on the Biesemeier et al., 2011 study for the neurotoxicity/developmental neurotoxicity section as recommended for the developments effects section

Response: Prior to responding to this particular comment, EPA reviewed its approach for inclusion of data in developmental and neurotoxicity endpoints. To best align with the DfE

hazard criteria, developmental neurotoxicity studies have been moved to – and are now only included in – the developmental toxicity section of the hazard assessment. While developmental neurotoxicity studies indicated hazard, positive indications for developmental neurotoxicity effects cannot be used to rationalize hazard for adult neurotoxicity. There was no evidence to support hazard potential for adult neurotoxicity. The hazard summary statement has been revised. The hazard designation for the neurotoxicity endpoint was changed from High to Low.

The 2008 EPA IRIS assessment of decaBDE indicated developmental neurotoxicity as an endpoint of concern based on multiple developmental neurotoxicity studies showing similar effects (EPA, 2008). Using a hazard-based approach, the hazard designation for Developmental Neurotoxicity was assigned based upon the most conservative NOAEL and LOAEL values in the available studies. Study limitations of available studies are noted in the "Data Quality" field of the study summary. The work by Biesemeier et al. (2011) is included in the developmental toxicity section and was considered when assigning a hazard designation for this endpoint. There is no category in the DfE alternatives assessment for Pre and Postnatal exposure, so the Biesemeier et al., 2011 study will remain in the prenatal exposure section.

Comment: In the repeated dose effects section, the EPA's 2008 IRIS report observed that short-term and subchronic studies demonstrated low toxicity with NOAELs of 3,000 mg/kg/d or higher and that decaBDE is not bioaccumulated. The 30-day study test material was the former 77% decaBDE product. DfE comments that the 30-day study appears consistent with the observed changes in the 2-yr study at higher doses. DfE does not take into consideration the difference in test article composition, the lack of liver and thyroid effects in NTP's 13-week study at doses higher than those administered by Norris, 1973, and the enormous doses administered over a lifetime of a two-year study. This comment should be deleted. The liver and thyroid changes observed in the Norris, 1973 study were not adverse. The EU Risk assessment recognized the NTP work as the most appropriate for assessing repeated dose effects. The EPA's 2008 IRIS report did not include the 30-day study and reference to is should be corrected. Recommend deleting the 28 day dietary study since it is not mentioned in the 2008 IRIS report but the EU Risk assessment and is unpublished.

Please add to the study with a 4-day administration to female Long Evans rats that in addition to no effects on body weight, liver weight or triiodothyronine (T3) or T4 levels that the commercial decaBDE product has no effects on Thyroid-stimulating hormone (TSH) levels also please note the study authors.

Response: The hazard designation for this endpoint was assigned based upon the most conservative NOAEL and LOAEL values in the available studies. The liver and thyroid effects in the 30-day rat dietary study were observed at dose levels which correspond to a Moderate hazard designation according to the DfE Alternatives Assessment Criteria as described in Chapter 4 of the report. The reference section for the 30-day study was revised to reflect that the study was not cited in the 2008 IRIS report. While liver and thyroid effects may have resulted from an adaptive response to treatment, toxic effects cannot be completely ruled out. The hazard designation was not changed based on this comment.

The 4-day study was revised to reflect that there were no changes in TSH levels; this change was also made in the endocrine activity section.

Comment: The endocrine effects section should be revised to reflect the very low conversion of decaBDE to metabolites. The Zhou et al., 2001 and Kociba et al., 1997 studies should be included in this section. Including the Maine study in this section is questionable, as the results are unpublished and not definitive.

Response: For endocrine activity, DfE provides a summary of available experimental or analog information and a summary statement, but does not provide a hazard designation. Any ongoing studies lacking study detail were identified as such. The Zhou et al., 2001 and Kociba et al., 1975 studies were added to the endocrine activity section.

Comment: In the terrestrial ecotoxicity section, the inclusion of the chicken embryo median lethal dose (LD_{50}) is questionable.

Response: The inclusion of the chicken embryo study did not affect the hazard designation as this endpoint has no published DfE criteria. The study summary has been revised to reflect that it was an egg injection study.

Comment: In the transport summary of the environmental fate section, the comment that decaBDE is expected to have Moderate potential for volatilization from surface water, based on modeling, is unlikely to represent decaBDE's environmental behavior.

Response: The Moderate potential for volatilization from surface water is based on the Henry's Law constant (using the VP/WSol estimations with the available experimental values entered; 4.4×10^{-4} atm-m3/mole at 25ºC) from EPISuite™ version 4.0. The Sustainable Futures Interpretive Assistance Document for Assessment of Discrete Organic Chemicals indicates that if experimental vapor pressure and water solubility data are available and entered as input data into EPISuite™, then the VP/WSol estimate (instead of the bond or group estimation method) should be used.

For decaBDE (CASRN 1163-19-5), the following experimental values were available in the hazard profile: log K_{ow}; boiling point; melting point; vapor pressure; and water solubility.

The phase a compound is expected to be found in the ambient atmosphere is based on the vapor pressure value. For decaBDE, the experimental vapor pressure used for environmental fate and transport analysis is 3.5×10^{-8} mm Hg. This experimental value is at the margin between being in both the vapor and particulate phase and being found mostly in the solid phase ($<10^{-8}$). The environmental fate summary was updated to reflect that decaBDE would likely only be found in the particulate phase.

Each hazard profile contains the EPISuite™ version used to run the estimates found in the DfE alternatives assessment in the chemical considerations section of the report.

Comment: The measured values used in the Henry's Law constant estimation should be included.

Response: The "Data Quality" field indicates which estimates were used for the Henry's Law constant. These values (measured vapor pressure and water solubility) are available in the hazard profile.

Comment: Persistence summary edits suggested with edits to note:

- Limited anaerobic biodegradation;
- Decabromodiphenyl ether may undergo photolysis to debrominated transformation products; however the majority of reaction products are unidentified, and DecaBDE's potential for photolysis is matrix-dependent;
- Remove discussion of metabolism;
- Clarification of the laboratory photodegradation studies.

Response: Suggested changes were incorporated into the alternatives assessment as follows:

> *VERY HIGH: The persistence potential for decaBDE is Very High; it is not expected to degrade rapidly under aerobic conditions. Slow degradation through debromination may occur under anaerobic conditions. The anaerobic experimental results are indicative of limited removal but at very low rates that are possibly background level degradation under the test conditions. Experimental studies indicate no degradation after 2 weeks in a ready biodegradation test, but no data were located for soil or water. Results from biodegradation estimation models also suggest decaBDE is recalcitrant under aerobic conditions. Nonguideline experimental studies indicate decaBDE may be capable of undergoing limited anaerobic biodegradation; however the removal rate also suggests Very High persistence. The initially formed degradation products are also expected to be persistent. DecaBDE is not expected to hydrolyze in the environment based on experimental data. Experimental data indicate that decaBDE may undergo photolysis to debrominated transformation products. Data concerning the kinetics of these photolysis reactions were not located.*

Comment: Additional studies were submitted for inclusion into the DfE alternatives assessment aerobic soil section.

Response: The Nyholm et al., 2010 and Liu et al., 2011 aerobic biodegradation studies have been added. However, the Sellstrom et al., 2005 study will remain in the Photodegradation section only since microbial degradation was not specifically studied. The addition of these studies result in no change to the persistence hazard designation.

Comment: For the anaerobic soil section, additional study details were submitted for inclusion into the DfE alternatives assessment. It is suggested that the Gerecke et al., 2005 and Skoczynska et al., 2005 study details be updated and the study attributed to Nies et al., 2005 could not be located. It is likely that this refers to Tokarz et al. 2008.

Response: The Gerecke et al., 2005 study reported in a peer-reviewed journal and summarized in a secondary source is displayed in the DfE hazard profile with the "Data Quality" statement: "Reported in a secondary source with limited study details."

The Nies et al., 2005 study details from the Illinois EPA, 2007 report are available at: http://cfpub.epa.gov/ncer_abstracts/index.cfm/fuseaction/display.abstractDetail/abstract/5534/report/2003. The Tokarz et al., 2008 paper is one of six papers published from this work. The data entry was updated to also report the mole fraction distribution of presumed metabolites.

The Skoczynska et al., 2005 study was not able to be verified. The "Data Quality" entry was updated to address this concern: "Primary source not available to be verified." This study was not used to make hazard designations and does not impact other sections of the alternatives assessment as the results are not relevant under environmental conditions.

Comment: In the photolysis section, the potential for photodegradation as well as the degradants produced is highly dependent on the matrix. This should be clearly stated in the document.

Response: Whenever possible, information from the photolysis studies were included in the data entries and for most compounds, the potential for photodegradation is dependent on the matrix. The Lagalante et al., 2011 and Stapleton et al., 2008 studies were added to the photolysis section. Additional data notes were added to the Sellstrom et al., 2005 study indicating that this was a field study and the soil had been plowed under. For most compounds, the potential for photodegradation is dependent on the matrix.

Comment: There were numerous comments on the bioaccumulation of decaBDE:

- The BAF was obtained using faulty methodology. Laboratory studies administering known amounts of BDEs have demonstrated decaBDE has a low potential for bioaccumulation.
- Correcting the Japanese Ministry of International Trade and Industry (MITI) study for water solubility is not appropriate.
- A BAF of 49,000 is inconsistent with the EPA's 2008 IRIS document.
- The extremely high BAF estimated by the model appear improbably for a substance that is poorly absorbed, have low systemic availability, is rapidly eliminated, and is not bioaccumulative in laboratory studies.
- The Noyes et al., 2011 fish metabolism study detects low amount of the lower brominated diphenyl ethers, whether this is due to metabolic debromination or some other process should be considered.

Response: The bioaccumulation concern for decaBDE is a result of multiple factors:

- Two BCF studies;
- Monitoring data;
- An estimated BAF value; and
- The bioaccumulation potential of the degradation, transformation, and metabolism products.

The publically submitted comments suggested fundamental problems with using the estimated BAFs or BCFs for decaBDE. The bioaccumulation hazard designation for decaBDE is an estimated high, represented with the black italic *H*. In contrast to the Low experimental bioaccumulation data, there appears to be potential for accumulation of this compound in higher trophic levels based on monitoring studies and some of the degradation, transformation and metabolism products. These derivatives are also expected to have potential to bioaccumulate. There is also the possibility from dietary studies that bioaccumulation of decaBDE is dose, duration and possibly species dependent in fish, as suggested in the public comments (page 110).

The MITI, 1998 study was reviewed from a primary source and the BCF study information has been revised (Table 5):

Table 5. Revised Fish BCF Section in DecaBDE Hazard Profile

PROPERTY/ ENDPOINT	DATA	REFERENCE	DATA QUALITY
Fish BCF	≤5 to ≤50 (Measured) 6 week exposure in *Cyprinus carpio* with sample concentrations of 60 ppb and 6 ppb, respectively using a method identified as flow-through bioaccumulation test of a chemical substance in fish or shellfish	MITI, 1998 as cited in European Chemicals Bureau, 2002; J-Check, 2013	Nonguideline study of a commercial product mixture containing ≥75% DecaBDE, approximately 17% nonaBDE and 8% octaBDE.

Regarding some of the specific bioaccumulation comments; the version of EPISuite™ used to estimate the BAF value is available in the chemical considerations section of the hazard profile. Version 4.0 was used at the time this hazard profile was prepared. The experimental values entered into the program are those available in the decaBDE hazard profile: log K_{ow}; boiling point; melting point; vapor pressure; and water solubility. The chemical structure and log K_{ow} are used by the EPISuite™ BAF estimation program.

The EPA's 2008 IRIS report states on page 64: "Studies of toxicokinetics of decaBDE reveal that the chemical can be absorbed by the oral route to a limited extent, does not accumulate in tissues, and undergoes clearance, largely as a result of metabolism in the liver and excretion in the bile."

The EPA's IRIS program and the EPA's DfE Alternative Assessment program do not evaluate chemicals using the same methods and criteria. Direct comparisons between the two programs are not clear-cut since the DfE alternative assessment is a hazard assessment which consider the intrinsic ability of the chemical to cause adverse effects.

The EPA IRIS entry, noted in the public comments (page 78), indicates toxicokinetic studies have provided evidence of absorbance and metabolism but not accumulation in tissues. The uptake of decaBDE into an organism may be slow or poor but it has been shown to occur.

Two other studies, Stapleton et al., 2004 and Kierkegaard et al., 1999, have been added based on stakeholder comment. The addition of these studies did not result in a change to the bioaccumulation hazard designation.

No change was made to the Noyes et al., 2011 study entry, as the entry correlates with the peer-reviewed journal article, which identifies the compounds as metabolites.

Comment: In the environmental monitoring and biomonitoring section. It is not apparent that all or even many, of the reported detections of decaBDE are reliable. Kolic et al., 2009 stated that as late as 2007, analysis of BDE-209 in environmental samples was not under control. Despite heavy use of mass spectrometry (MS) for the analysis of these compounds, it is ironic that new systematic studies of the full mass spectra of the compounds have appeared. The CDC was unable to measure decaBDE in human serum. As of 2010, CDC has been unable to analyze decaBDE in human milk. In general, the best results are obtained using ^{13}C-internal standard, high resolution mass spectrometry (HRMS) with monitoring for molecular ions, coupled with retention time and frequent blank determinations.

The Ecological Biomonitoring section should recognize the difficulty of decaBDE analysis at trace levels in environmental matrixes, the low systematic bioavailability of decaBDE observed in laboratory studies, and indicate the at DfE has not assessed the suitability or accuracy of the analytical methods used in reports of environmental detection.

The reference to decaBDE detection in breast milk in the human biomonitoring section should be deleted and substituted with the information from Daniels et al., 2010 that the CDC was unable to analyze breast milk for decaBDE. The report should include that the CDC was unable to analyze human serum for decaBDE despite use of a clean room and the document should include the estimate by Sjodin et al., 2008 that serum levels of 2 ng/g lipid weight.

Response: Although there are no criteria for monitoring studies, the referenced studies are from recent peer-reviewed journals and secondary sources. In more recent monitoring studies, MS analysis is commonly used with labeled internal standards providing confidence that decaBDE is being detected by these studies.

Regarding the quality of the analytical data, many of the original studies were reviewed and assessed by the IRIS program and considered acceptable to include in the IRIS toxicological profile. References to serum and blood studies were added to the hazard profile's Human Biomonitoring section from the EPA's 2008 IRIS report. Concerns about detecting decaBDE in human milk are not consistent with the reported detection of decaBDE in milk from other mammals (rats) as published by the submitter of this comment (Biesemeier, 2010).

Sjodin et al., 2008 states that "Children less than 12 years of age and some PBDE congeners, such as BDE-209, were not included in NHANES 2003–2004 report. Based on a NHANES 2001–2002 serum pool study the mean concentration of BDE-209 is about 2 ng/g lipids in those 12 years of age and older."

Daniels, 2010, also reports: "We were unable to measure BDE-209, the primary congener of the DecaBDE formulation, which is the only brominated flame retardant still produced in the United States. BDE-209 is stable but less likely to bioaccumulate and be detected at remarkable levels in human tissue compared with the lower brominated congeners because of its short half-life (i.e., 2 weeks in humans)."

Interpretation of this information should also consider additional analysis by some of the same authors, including the CDC (Thuresson et al., 2006): "BDE-209 has a short half-life in human blood. Because BDE-209 is commonly present in humans in general, the results of this study imply that humans must be more or less continuously exposed to BDE-209 to sustain the serum concentrations observed. BDE-209 is more readily transformed and/or eliminated than are lower brominated diphenyl ether congeners, and human health risk must be assessed accordingly."

J. Ethylene Bis-Tetrabromophthalimide, EBTBP (CASRN 32588-76-4)

Comment: DecaBDE is not a structural analog of EBTBP. DfE has mentioned that the MW and bromine content are similar but provides no explanation as to why EPA considers decaBDE is a suitable analog to EBTBP. One structure is based on diphenyl ether and the other is based on phthalimide. DecaBDE exists as one conformer with the aromatic rings orthogonal to one another with an approximate 120° angle. EBTBP has multiple conformers. Molecular size differences also exist. Analogy to decaBDE should not be used for the cancer and neurotoxicity hazard designations.

Response: In the absence of experimental data, data from an analog, professional judgment or from a computerized model are used by DfE to inform hazard designations. Without sufficient experimental results, estimates, chemical categories, structural alerts and analogs were evaluated for the EBTBP neurotoxicity endpoint.

In the draft report, data from decaBDE was used to support the neurotoxicity designation. During the public comment period, the neurotoxicity designation for decaBDE was revised from an experimental designation to an estimated designation. Since the neurotoxicity designation for decaBDE is no longer considered to be experimental, it is not be used to support other designations within the DfE methodology discussed in Chapter 4. There was no other suitable analog for EBTBP for this endpoint. In addition, EBTBP was not considered to possess a known structural-type mode of action and therefore, is not a neurotoxicity concern (EPA, 2011b). The hazard designation was changed to an estimated Low. The EBTBP neurotoxicity hazard summary, analog section and summary hazard table were edited based on this change. The hazard designation for carcinogenicity was changed from Moderate based on analogy to decaBDE to the default estimated Moderate based on a lack of sufficient experimental data for this substance.

Comment: EBTBP was rated as high based on DfE's statement that its assessment criteria indicate that an estimated BAF will be used when a single measured BCF value is available. DfE also said that EBTBP's estimated BAF is consistent with that anticipated for high MW chemicals with a high degree of bromination. The DfE draft document is incorrect in both instances.

1. Two measured values are available
2. Modelled data should not be used when experimental data is available
3. DfE's Alternative Assessment Criteria make no provision for a more conservative hazard designation
4. EPISuite's estimated BAF values are usable only if the potential for metabolism was accurately accounted for within the model estimate and no data was located on fish metabolism for EBTBP
5. DfE did not provide citations to support the contention that high MW chemicals with a high degree of bromination are highly bioaccumulative

Response: The DfE Alternatives Assessment Criteria states that when experimental log BAF or BCF is available and is <2, the application of the criteria is to be considered on a case-by-case basis.

Both the BAF and BCF are considered when performing comprehensive evaluation of the bioaccumulation potential of EBTBP. Measured BCF values for EBTBP are available from a guideline study; reported in a secondary source. However, this guideline study is most appropriately applied to organic chemicals with a log K_{ow} value of 1.5-6.0. The log K_{ow} of EBTBP is estimated to be 9.8 and the compound is expected to have limited solubility in water. Therefore there is concern with the suitability of the experimental results. Additionally, absorption in rats has been demonstrated in studies reported in the toxicokinetics section of this hazard profile.

Page 24 of the DfE Alternatives Assessment Criteria version 2.0, August 2011a.

When experimental BAF or BCF data are available:

1) If a measured log BAF or BCF is available and the value >2, apply the bioaccumulation criteria in Table 13.
2) If there are measured log BCF <2, consider application of the criteria on a case-by-case basis. For example, if there is a single measured log BCF <2, use the upper trophic BAF with metabolism from the BCFBAF model in EPI Suite. If there are several measured values which all support a designation of low bioaccumulation potential, then the chemical will be designated as such.
3) If there are measured log BAF < 2, then the chemical is designated as a Low for bioaccumulation.

Experimental fish metabolism data is not required to run the EPISuite's BAF model, as indicated in this comment. The Arnot-Gobas BAF model includes mechanistic processes for bioconcentration and bioaccumulation such as chemical uptake from the water at the gill surface and the diet, and chemical elimination at the gill surface, fecal egestion, growth dilution, and metabolic biotransformation (Arnot and Gobas, 2003). More details are available in the EPISuite™ supporting information files (http://www.epa.gov/opptintr/exposure/pubs/episuitedl.htm).

The hazard summary was revised so that the bioaccumulation hazard designation is based on the estimated BAF value. The assertion that high MW chemicals with a high degree of bromination are highly bioaccumulative was removed.

The high persistence of a compound allows for longer presence in the environment and greater opportunity to interact with biological systems. There is potential for limited degradation of EBTBP into less brominated compounds. Less brominated congeners of EBTBP, with lower MW values, may be more bioavailable then the parent compound.

K. Red Phosphorus (CASRN 7723-14-0)

Comment: Several stakeholders commented on the acute toxicity of red phosphorus, providing additional studies. The following comment is representative of the group of comments:

The acute toxicity of red phosphorous is characterized as Very High based on oral LD_{50} values of 11.5 mg/kg (rat, mouse), 105 mg/kg (rabbit), and 5 mg/kg (dog) taken from an alternatives assessment written for the Maine Department of Environmental Protection (DEP), cited from Registry of Toxic Effects of Chemical Substances (RTECS). These values are incorrect and unverifiable. Provided are acute toxicity studies for female rats: LD_{50} >15000 mg/kg bw. An acute inhalation study was not possible due to physical-chemical properties of red phosphorus and was waived because the oral LD_{50} >15 g/kg bw. Red Phosphorus is not sensitizing to skin therefore the acute dermal toxicity was waived as well. Here, no effects are to be expected. This correction results in a classification of Low for acute toxicity rather than Very High.

Response: Stakeholders provided several unpublished studies on acute mammalian toxicity of red phosphorus. These unpublished studies that have also been cited by ECHA, 2012; NRC, 1997; and Maine DEP, 2007 have been conducted according to Organisation of Economic Cooperation and Development (OECD) guidelines. These study details, including the test substance identity, could be assessed and verified. These values fall within the Low hazard designation criteria range. The hazard designation was changed from Very High to Low based on oral LD_{50} values >10,000 mg/kg and the hazard summary statement was revised. The values cited by stakeholders from RTECS could not be verified and study details could not be assessed; also, allotropic forms were not identified. White, yellow or black phosphorus do not necessarily have the same properties, fate, or toxicity as red phosphorus. White/yellow phosphorus is readily oxidized resulting in hazardous properties for toxicity due to its reactivity. Red phosphorus is less reactive and less toxic (EPA, 2010b; EFRA, 2013). However, potential formation of the highly toxic gas, phosphine, is a workplace safety issue.

Comment: Further clarification is necessary for the NRC, 1997 study notes in the dermal irritation section and it should be stressed that the composition of red phosphorus with butyl/rubber used for smoke screen purposes differs significantly from red phosphorus used for flame retardant purposes. Inclusion of this study means that no fair alternatives assessment can be performed for red phosphorus. The skin irritation after prolonged or repeated contact originates from a Material safety data sheet (MSDS) without experimental data.

Response: The “Data Quality” entry for the study cited in NRC, 1997 was revised to reflect that the test substance was red phosphorus butyl/rubber smoke. In addition, the “Data Quality” entry for the study description cited in Maine DEP, 2007 was revised to indicate the data presented was originally from a MSDS. No study details were provided in the Maine DEP, 2007 report or

in the MSDS, therefore, the results cannot be evaluated. The hazard designation was changed from High to Moderate based on this comment. The data indicate potential hazard for skin irritation and, as a result, a Moderate designation is appropriate for this endpoint.

L. Resorcinol Bis-Diphenylphophate, RDP (CASRN 125997-21-9 and 57583-54-7)

Comment: According to the hazard profile for resorcinol bis-diphenylphosphate (CASRN 125997-21-9 and 57583-54-7), this chemical has two CASRNs that are used interchangeably. However, only CASRN 125997-21-9 is listed on the non-confidential TSCA Inventory. A downstream user cannot safely assume that this chemical is considered by EPA to be on the Inventory.

Response: The two CASRNs (125997-21-9 and 57583-54-7) used in the hazard profile for resorcinol bis-diphenylphosphate are listed on the non-confidential TSCA Inventory.

M. Substituted Amine Phosphate Mixture

Comment: Suggestion to create and maintain separate, complete hazard summaries for the individual components, especially for mixtures and salts to avoid misinformed alternative selection by eliminating otherwise acceptable alternatives.

Response: The data used to populate the hazard table for the substituted amine phosphate mixture are separated out in the hazard assessment study tables within the hazard profile, whenever possible. Data were available for the mixture, the two substances, and the components of the substances, but not consistently for all endpoints. Therefore, the confidential nature of this mixture supported combining the components in the hazard table. Ideally, assessments of individual substances would be performed. Nonetheless, mixture data are also valuable.

N. Tetrabromobisphenol A Bis(2,3-dibromopropyl) Ether (CASRN 21850-44-2)

Comment: EPA should list regulatory citations in the hazard profiles. The TSCA regulatory status listed for tetrabromobisphenol A bis(2,3-dibromopropyl) ether (CASRN 21850-44-2) indicates that these chemicals are subject to a Section 4 test rule. The regulatory citation for this test rule should be referenced in the text. The report should also indicate if testing requirements have sunset, who is subject to the test rule, and list the tests required to be performed. For DBDPE (CASRN 84852-53-9), the regulatory citations for the Significant New Use Rule (SNUR) should be listed as well. The SNUR (40 CFR 721.536) also has a requirement under *Industrial, commercial, and consumer activities* as specified in 40 CFR 721.80q that EPA does not address in the report. 40 CFR 721.80q states that a significant new use of the substance is "Aggregate manufacture and importation volume for any use greater than that allowed by the section 5(e) consent order…". A chemical with a production volume cap that is unknown/confidential raises questions for the formulator/processor/user as to the chemical's long term availability as a decaBDE substitute. EPA needs to disclose all information about a chemical to facilitate informed decisions by downstream users.

Response: This report does not contain detailed regulatory status of each substance. The user can stay up to date with regulatory status by consulting the EPA Existing Chemicals webpage http://www.epa.gov/oppt/existingchemicals/ and the Federal Register.

O. Triphenyl Phosphate (CASRN 115-86-6)

Comment: EPA should list regulatory citations in the hazard profiles. The TSCA regulatory status listed for triphenyl phosphate (CASRN 115-86-6) indicates that these chemicals are subject to a Section 4 test rule. The regulatory citation for this test rule should be referenced in the text. The report should also indicate if testing requirements have sunset, who is subject to the test rule, and list the tests required to be performed. For DBDPE (CASRN 84852-53-9), the regulatory citations for the SNUR should be listed as well. The SNUR (40 CFR 721.536) also has a requirement under *Industrial, commercial, and consumer activities* as specified in 40 CFR 721.80q that EPA does not address in the report. 40 CFR 721.80q states that a significant new use of the substance is "Aggregate manufacture and importation volume for any use greater than that allowed by the section 5(e) consent order…". A chemical with a production volume cap that is unknown/confidential raises questions for the formulator/processor/user as to the chemical's long term availability as a decaBDE substitute. EPA needs to disclose all information about a chemical to facilitate informed decisions by downstream users.

Response: This report does not contain detailed regulatory status of each substance. The user can stay up to date with regulatory status by consulting the EPA Existing Chemicals webpage http://www.epa.gov/oppt/existingchemicals/ and the Federal Register.

P. Additional Minor Changes Based Upon Stakeholder Input

Table 6. Additional Minor Changes to DecaBDE Alternatives Assessment Report

Location of Edit	Edit Details
Ammonium Polyphosphate boiling point, water solubility and pH reference, reference section	Reference edited to Clariant Additives Exolit AP 422. **2011.** http://www.additives.clariant.com/bu/additives/PDS_Additives.nsf/www/DS-OSTS-7SHDAQ?open
Red phosphorus flammability reference and reference section	The potential formation of toxic phosphine gas is a serious workplace safety issue which requires special precautions or specially treated product forms. Clariant information sheet on handling of red phosphorus powder grades has been added as a reference in the hazard profile for red phosphorus.
BAPP oligomer entry and risk phrase entry	Text has been added to indicate that the BAPP n=1 structure comprises 80-85% of the mixture and the UK has supported the removal of the R53 classification and a request to remove this classification is currently being evaluated.

Location of Edit	Edit Details
Brominated polystyrene synonym section	The synonym section now contains: Benzene, ethenyl-, homopolymer, brominated (TSCA Inventory); Brominated ethenylbenzene homopolymer; Firemaster BP-411; Firemaster CP-44HF; FR-803P; Polystyrene, brominated; Pyro-Chek 68PB/BC; Saytex HP-775; Saytex HP-3010; Saytex HP-7010P; Saytex HP-7010G; Saytex HP-3010. Related trade name: PDBS 80 (CASRN 148993-99-1).
Confidential brominated polymer	Confidential Brominated Polymer has been changed to the TSCA generic name of brominated poly(phenylether) throughout the report.
Brominated poly(phenylether) TSCA Inventory entry	The TSCA Inventory status of each substance is no longer presented in this report.
Table 4-5	Phosphonate Oligomer and Polyphosphonate have the same CASRN but different hazard assessments. To clarify why these two chemicals have different hazard assessments, a footnote has been added to the hazard summary table for Phosphonate Oligomer. This footnote describes that Phosphonate Oligomer has a MW range of 1,000 to 5,000 and may contain significant amounts of an impurity, which causes the substance to have hazard designations that differ from its polymeric counterpart.
EBTBP Vapor Pressure	The vapor pressure information provided for EBTBP was added to the hazard profile.
DecaBDE Vapor Pressure, Water Solubility and Log K_{ow}	Primary sources reviewed and cited in the hazard profile.

II. General Comments on the Hazard Assessments and Conclusions

Comment: When professional judgment is exercised, the report should provide the information that this judgment relies upon.

Response: When quantitative structure activity relationship (QSAR) models were not available, professional judgment was used to identify hazards for similar chemicals using the guidance from EPA's New Chemicals Categories (EPA, 2010c). The categories identify substances that share chemical and toxicological properties and possess potential health or environmental concerns (EPA, 2010d). In the absence of an identified category, analogs for which experimental data are available were identified using EPA's Analog Identification Methodology (AIM) or by substructure searches of confidential EPA databases (EPA, 2012). If a hazard designation was still not available, the expert judgment of scientists from EPA's New Chemical Program would provide an assessment of the physical-chemical properties, environmental fate, aquatic toxicity, and human health endpoints to fill remaining data gaps. In some cases, judgment was based upon confidential analogs that cannot be revealed.

Comment: In the case of the automotive sector, none of the 32 identified alternatives has a hazard profile that is significantly preferable to decaBDE itself. While many of the potential alternatives for automotive applications have lower bioaccumulation potential, all have High or Very High hazard designations for persistence. There is no clear preferable alternative based on EPA's hazard assessment for use by the automotive industry. In the absence of an environmentally preferable alternative, what guidance can EPA provide for sectors that require the continued availability of an effective flame retardant?

Response: While finding environmentally preferable alternatives for the various sectors usually involves the consideration of trade-offs among hazard endpoints, in the case of alternatives for automotive applications there are in fact alternatives assessed in this report that are anticipated to be safer than decaBDE in terms of both health and aquatic impacts.

Persistence is not a distinguishing characteristic for flame retardants because flame retardants are designed to be persistent so that they retain their flame retardant function over the life of the product to which they are added. Persistence should not be ignored because it is not distinguishing, instead persistence must frame the significance of any toxicity or bioaccumulation potential.

From Table 3-2 in the draft report, 22 alternatives have potential for end-uses in the automotive sector (see Table 7 through Table 9). Companies looking for environmentally preferable alternatives can compare the hazard summary tables and the associated hazard profiles and choose those with low potential for bioaccumulation and lower chronic health and aquatic hazards. Several alternatives have generally low hazard designations across the hazard profile including but not limited to magnesium hydroxide, ammonium polyphosphate, and brominated polystyrene.

Decisions on trade-offs among the endpoints must be made by stakeholders as they also consider cost, application, and life cycle impacts which were beyond the scope of the EPA report.

Table 7. Screening-Level Hazard Summary for DecaBDE and Halogenated Flame Retardant Alternatives Used in the Automotive Sector

This table only contains information regarding the inherent hazards of flame retardant chemicals. Evaluation of risk considers both the hazard and exposure associated with the substance including combustion and degradation by-products. The caveats listed in the legend and footnote sections must be taken into account when interpreting the hazard information in the table.

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H,* and *VH*) were assigned using values from predictive models and/or professional judgment.

§ Based on analogy to experimental data for a structurally similar compound.

¤ This alternative may contain impurities. These impurities have hazard designations that differ from the flame retardant alternative, Brominated poly(phenylether), as follows, based on experimental data: HIGH for human health, HIGH for aquatic toxicity, VERY HIGH for bioaccumulation, and VERY HIGH for persistence.

T This chemical is subject to testing in an EPA consent order for this endpoint.

Chemical (for relevant trade names see the synonym section of the individual profiles in Section 4.8)	CASRN	Human Health Effects											Aquatic Toxicity**		Environmental Fate	
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
DecaBDE and Halogenated Flame Retardant Alternatives																
DecaBDE and Discrete Halogenated Alternatives																
Brominated Poly(phenylether)	Confidential	L	*L*¤	L	VL¤	*M*¤	*L*¤	L¤	L		L	VL	L	*L*¤	VH*T*	*H*T¤
Decabromodiphenyl Ethane	84852-53-9	L	*M*§	L	L	*H*§	*L*	L	L		VL	VL	L	*L*	VH	*H*
Decabromodiphenyl Ether	1163-19-5	L	M	L	L	H	*L*	M	L		L	L	*L*	*L*	VH	*H*
Ethylene Bis-Tetrabromophthalimide	32588-76-4	L	*M*	L	*L*	*M*§	*L*	L	*L*		VL	VL	*L*	*L*	VH	*H*
Tetrabromobisphenol A Bis (2,3-dibromopropyl) Ether	21850-44-2	L	*M*	M	*M*	*M*	*L*	*M*	L		L	L	L	*L*	VH	*H*
Tris(tribromoneopentyl) Phosphate	19186-97-1	*M*	*M*	L	*M*	*M*	*H*	L	L		*L*	*L*	*L*	*L*	*H*	*M*

**Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H,* and *VH*) were assigned using values from predictive models and/or professional judgment.

[d] This hazard designation would be assigned MODERATE if >5% of the particles are in the respirable range as a result of dust forming operations.

♦ Different formulations of the commercial product are available. One of these many formulations has an average MW of ~1,600 and contains significant amounts of lower MW components. These lower MW components have hazard potentials different than the polymeric flame retardant, as follows: HIGH estimated potential for bioaccumulation; HIGH experimental potential for acute aquatic toxicity; HIGH estimated potential for chronic aquatic toxicity; MODERATE experimental potential for developmental; and MODERATE estimated potential for carcinogenicity, genotoxicity, repeated dose, reproductive, and skin and respiratory sensitization toxicity.

Chemical (for relevant trade names see the synonym section of the individual profiles in Section 4.8)	CASRN	Human Health Effects											Aquatic Toxicity**		Environmental Fate	
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
Halogenated Flame Retardant Alternatives Continued																
Polymeric Halogenated FR Alternatives[P]																
Brominated Epoxy Polymers	68928-70-1	*L*	*L*♦	L	*L*♦	*L*♦	*L*	*L*♦[d]	L	♦	*L*	*L*	*L*♦	*L*♦	*VH*	*L*♦
Brominated Epoxy Resin End-Capped with Tribromophenol	135229-48-0	*L*	*L*	*L*	*L*	*L*	*L*	*L*[d]	L		L	VL	*L*	*L*	*VH*	*L*
Brominated Polyacrylate	59447-57-3	*L*	*L*	*L*	*L*	*L*	*L*	*L*[d]	*L*		*L*	*L*	*L*	*L*	*VH*	*L*
Brominated Polystyrene	88497-56-7	L	*L*	*L*	*L*	*L*	*L*	*L*[d]	*L*		L	*L*	*L*	*L*	*VH*	*L*

**Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

[P] The range of polymer molecular weight can be broad. The polymers listed here have low toxicity for human health and aquatic endpoints. Not all polymers will have this low toxicity; hazards will vary with physical-chemical properties.

Table 8. Screening-Level Hazard Summary for Organic Phosphorus or Nitrogen Flame Retardant Alternatives Used in the Automotive Sector

This table only contains information regarding the inherent hazards of flame retardant chemicals. Evaluation of risk considers both the hazard and exposure associated with the substance including combustion and degradation by-products. The caveats listed in the legend and footnote sections must be taken into account when interpreting the hazard information in the table.

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H,* and *VH*) were assigned using values from predictive models and/or professional judgment.

[d] This hazard designation would be assigned MODERATE if >5% of the particles are in the respirable range as a result of dust forming operations.

[§] Based on analogy to experimental data for a structurally similar compound.

[‡] The highest hazard designation of any of the oligomers with MW <1,000.

Chemical (for relevant trade names see the synonym section of the individual profiles in Section 4.8)	CASRN	Human Health Effects											Aquatic Toxicity**		Environmental Fate	
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
Organic Phosphorus or Nitrogen Flame Retardant (PFR or NFR) Alternatives																
Discrete PFR, NFR and P/NFR Alternatives																
Substituted Amine Phosphate Mixture [1]	Confidential	*H*	*M*	*M*	*M*	*M*	*L*	*M*	L	*M*[§]	M	VL	*M*	*L*	*H*	*L*
Polymeric PFR and NFR Alternatives																
Melamine Cyanurate[1]	37640-57-6	*L*	*M*	*M*	*M*[§]	*M*[§]	*L*	H	*L*		*L*	*L*	*L*	*L*	VH	*L*
Melamine Polyphosphate[1]	15541-60-3	L	*M*	*M*	*L*[§]	*L*	*L*[§]	*M*	*L*		L	VL	L	L	*H*	*L*
Polyphosphonate	68664-06-2	L	*L*	*L*	*L*	*L*	*L*	*L*[d]	*L*		*L*	*L*	*L*	*L*	*VH*	*L*
Phosphoric acid, mixed esters with [1,1'-bisphenyl-4,4'-diol] and phenol; BPBP	1003300-73-9	L	*M*	L	*L*[§]	*L*[§]	L	L	L		VL	VL	*H*[§]	*H*[§]	H	*M*[‡]
Poly[phosphonate-co-carbonate]	77226-90-5	L	*L*	*L*	*L*	*L*	*L*	*L*[d]	*L*		*L*	*L*	*L*	*L*	*VH*	*L*

**Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

[1] Hazard designations are based upon the component of the salt with the highest hazard designation, including the corresponding free acid or base.

Table 9. Screening-Level Hazard Summary for Inorganic Flame Retardant Alternatives Used in the Automotive Sector

This table only contains information regarding the inherent hazards of flame retardant chemicals. Evaluation of risk considers both the hazard and exposure associated with the substance including combustion and degradation by-products. The caveats listed in the legend and footnote sections must be taken into account when interpreting the hazard information in the table.

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H,* and *VH*) were assigned using values from predictive models and/or professional judgment.

[d] This hazard designation would be assigned MODERATE if >5% of the particles are in the respirable range as a result of dust forming operations.

[R] Recalcitrant: Substance is comprised of metallic species that will not degrade, but may change oxidation state or undergo complexation processes under environmental conditions.

[*] Ongoing studies may result in a change in this endpoint.

Chemical (for relevant trade names see the synonym section of the individual profiles in Section 4.8)	CASRN	Human Health Effects											Aquatic Toxicity**		Environmental Fate	
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
Inorganic Flame Retardant Alternatives																
Aluminum Diethylphosphinate	225789-38-8	L	*L*	L	VL	*M*	*M*	*M*	L		L	VL	M	M	*H*[R]	*L*
Aluminum Hydroxide	21645-51-2	L	*L*	L	*L*	L	M	*M*	L		VL	VL	*M*	*M*	*H*[R]	*L*
Ammonium Polyphosphate	68333-79-9	L	*L*	*L*	*L*	*L*	*L*	*L*[d]	L		VL	L	*L*	*L*	*VH*	*L*
Antimony Trioxide[1]	1309-64-4	L	M[*]	M	*M*	*L*	*L*	H	L		L	M	H	M	*H*[R]	*L*
Magnesium Hydroxide	1309-42-8	L	L	L	L	*L*	*L*	L	*L*		M	L	*L*	*L*	*H*[R]	*L*
Red Phosphorus	7723-14-0	L	*L*	*M*	*L*	*L*	*L*	*L*	L		M	M	L	L	H	*L*
Zinc Borate	1332-07-6	L	*L*	*H*	*M*	*M*	*H*	*L*	L		L	L	*H*	*H*	H[R]	*L*

**Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

[1] This compound is included in the ongoing EPA Work Plan evaluation for Antimony Trioxide.

III. Comments on Report Content (excluding Hazard Assessments)

Comment: Figure 2-7, which depicts the segmentation of decaBDE uses, by weight, in the U.S., is likely inaccurate because decaBDE is used in low volumes in aerospace parts and components. There has been a concerted effort in the aerospace industry over the past several years to identify and implement alternatives to decaBDE, likely making this information untimely and unreliable.

Response: At the time of publication of the report, the data in Figure 2-7 was the most comprehensive information DfE was able to locate regarding the segmentation of decaBDE uses. We understand that these depictions are shifting in response to voluntary industry efforts to implement decaBDE alternatives. Figure 2-7 has been removed from the report and its segmentation information has been integrated into the text of the report. The reader is also now advised that this data may not reflect current decaBDE usage among industries.

Comment: The supply chain for many complex durable goods may be more complicated than depicted by the schematic of flame retardant production and incorporation into an end product (Figure 5-3) if materials or parts containing decaBDE are used to build subcomponents or subassemblies that are ultimately aggregated into final products.

Response: Figure 5-3 depicts a simple supply chain and DfE recognizes that the production process may be more complex for goods that are built of various subcomponents. In light of this comment, an acknowledgement of more intricate supply chains and the role this plays in choosing alternatives is provided in the report prior to Figure 5-3.

Comment: While certain trade-offs may be contemplated when choosing alternatives, the minimum standards for safety cannot be compromised. This may make the selection of alternatives for decaBDE in the aerospace sector even more challenging. These difficulties should be reflected in the discussion in Section 6.6.

Response: EPA recognizes that safety must be a priority when considering alternatives for decaBDE. DfE has addressed this point by inserting text in Chapter 6 which states that stakeholders must not compromise product safety with their substitution decisions, in addition to considering other criteria such as hazard, economic, and social considerations. The section clarifies that the goal of alternatives formulation is to develop alternatives that meet product performance and drive safer chemistry on a path of continuous improvement; and, if information on a chemical does not exist, further testing may be done.

Comment: The use of the terms “viable” and “functional” is misleading and should be clarified or deleted. In defining an alternative’s “viability”, commercial availability should be a key factor. The report should also not assert that the alternative flame retardants are all “functional” replacements for decaBDE in certain plastics because EPA has not examined whether this is the case.

Response: Both the scope of the alternatives assessment and Chapter 1 of the report define viability as “the functional performance of a chemical as a flame retardant in certain plastics, not the environmental preferability of the chemical or other product performance criteria.” Industry

commercial availability is a key factor when making substitution decisions for it affects product availability and price. In the alternatives assessment EPA included both chemicals that are commercially available and under commercial development. That is, EPA included chemicals that show promise as alternatives if they are in commercial development and may be prominent alternatives in the future. Recognizing these points, EPA does not believe commercial availability is a major factor in viability due to the fact that commercial availability is dynamic; for example, a chemical that may not be produced at high volumes today may be a high production volume chemical in 10 years due to a change in market conditions. Given this is a factor that can vary, EPA will not consider commercial availability as a pre-requisite for viability.

As for functional performance for the alternative chemicals, EPA searched the current literature and worked with chemical and product manufacturers to determine which chemicals were functional in certain polymers. This information is summarized in Table 3-2. Chapter 3 clarifies that in addition to searching current literature, DfE worked with manufacturers to determine the functionality of each chemical; chemicals that were not deemed viable by industry experts on the partnership were excluded from the assessment.

Comment: Include a specific section in Chapter 1 entitled "Limitations of the Assessment" to bring the more significant deficiencies of the alternatives assessment approach to the forefront of the document and to more readily call this to readers' attentions.

Response: Edits have been made to Section 1.4 of the report to clearly inform readers that DfE's comparative hazard assessment does not consider performance or efficacy of the alternatives and that these considerations must be made separately in the decision-making process.

Comment: The alternatives assessment approach undertaken by EPA does not examine differential potential for the various flame retardants to migrate from a product.

Response: All of the alternatives assessed in this report are additive and have the potential to migrate or be released from a product because they are not chemically bound to a host polymer. The migration of a flame retardant from a product can occur during various phases of the product's life-cycle. Chapter 5 of this alternatives assessment discusses these life-cycle phases including extraction, chemical manufacturing, product manufacturing, use, and end-of-life and contains a table (Table 5-1) outlining the physical-chemical properties of each alternative that impact migration of the chemical from a product. In addition to Table 5-1, further details on physical-chemical properties are included in each chemical's hazard profile.

Comment: While EPA faced challenges in performing the alternatives assessment given the limited data available, the draft only states that "several chemicals included in this analysis appear to have more preferable hazard profiles with low human health and ecotoxicity endpoints, although they are highly persistent, a frequent property for flame retardants... However, because most of the hazard designations were based on estimated effect levels, there is less confidence in the results." It is essential that a reader be alerted early in the document that many of the core methodologies used in the analyses do not rely on empirical data. The addition of caveats cautioning readers about the availability and reliability of the data used to develop the hazard

profiles should address users concerns about the ultimate reliability that this alternatives assessment will provide in making informed substitution choices.

Response: DfE evaluated the chemicals in the report in accordance with its alternatives assessment methodology. This method aligns with the evaluation process for chemicals in the New Chemicals Program. As with many industrial chemicals, data are often limited. This report contains the best empirical and modeled information available on the toxicity and fate of these chemicals and provides an EPA analysis of available information as a basis for decisions. Although further data would be valuable in confirming or improving the assessment for some chemicals, all available data were reviewed and included in the report at the time of report publication. Limitations in the data are noted in the hazard profiles. The phrase "less confidence in the results" has been clarified in the report to mean that there is less confidence in hazard profiles for chemicals in which designations are based on estimated effect levels compared to chemicals with full experimental data sets.

Comment: Discussions of data limitations should be added prominently to Chapters 1 and 4 of the document rather than solely in Chapter 6.

Response: Data limitations are discussed repeatedly and appropriately in the hazard profiles and the supporting chapters. Many of the chemicals evaluated in this alternatives assessment do not have empirical hazard data. Although this is a limitation of the assessment, the absence of data should not prevent action being taken to promote the use of safer alternatives. Currently, TSCA does not require the generation of measured data for chemicals already in commercial use and has no minimum measured data requirements for new chemicals. EPA has developed a number of predictive modeling tools to produce estimated data that addresses these data gaps for TSCA. This software is also used by DfE in its alternatives assessments to fill data gaps for alternatives; the modeled data allows for a more comprehensive hazard evaluation of the chemicals when used prudently.

Comment: EPA inappropriately excluded certain alternatives from the assessment including tetrabromobisphenol A (TBBPA), a brominated epoxy resin without a tribromophenol end cap (known as F-2016), and a styrene/butadiene co-polymer produced by Dow.

Response: Although TBBPA is used globally as a flame retardant in a variety of applications, the technical experts in this partnership did not identify the substance as a prevalent alternative to decaBDE; furthermore, TBBPA had already been assessed through DfE's Partnership to Evaluate Flame Retardants in Printed Circuit Boards, a report that can be found in its draft form here: http://www.epa.gov/dfe/pubs/projects/pcb/index.htm. The hazard profile for TBBPA may be updated before the draft report is finalized.

The brominated epoxy resin without a tribromophenol end cap said to have been excluded from the report is in fact included in the report but with a different name. The commenter refers to this alternative as a brominated epoxy resin without a tribromophenol end cap (one commercial product is known by the trade name "F-2016"), while DfE's decaBDE alternatives assessment report refers to this same substance as TBBPA Glycidyl Ether, TBBPA Polymer in the draft

report and as Brominated Epoxy Polymers in the final report (CASRN 68928-70-1). The chemical has undergone a name change between the two drafts.

Based on DfE's communication with the manufacturer of the styrene/butadiene co-polymer, this alternative has not been marketed for use as a decaBDE alternative. A hazard profile for this chemical will be included in DfE's HBCD alternatives assessment report. Additional information about DfE's Partnership on Flame Retardant Alternatives for Hexabromocyclododecane (HBCD) can be found here: http://www.epa.gov/dfe/pubs/projects/hbcd/index.htm.

Comment: EPA should conduct an alternative analysis process prior to issuing any additional SNURs for existing chemicals to ensure that sectors requiring the continued availability of effective flame retardants will have information on environmentally preferable alternatives. The DfE program's work will be most useful to chemical users if reports are available well in advance of market-based or regulatory restrictions.

DfE and EPA's Chemical Control Division should work as closely together as possible to ensure that the DfE Alternatives Assessments are timely and useful. Specifically, we urge that there be close coordination between the DfE program and the pending TSCA SNUR regarding decaBDE. EPA should incorporate the findings of this assessment into its regulatory scheme for decaBDE and defer any further regulatory actions until safer alternatives are available.

The urgency created by the US manufacturers' unilateral phase-out schedule for decaBDE has forced users to make decisions about alternatives without the benefit of the DfE's final report. While we recognize that EPA has limited, if any, authority regarding the decisions by manufacturers to make (or not make) a certain chemical, the Agency certainly can control the timing of regulatory restrictions, and so we urge the Agency to recognize that a chemical user's ability to use the work of the DfE program is diminished if regulatory deadlines force chemical users to select alternatives before DfE reports are available. The commenter requested guidance from EPA about what effective flame retardants exist for industry sectors that may still require the use of flame retardant chemicals.

Response: Comments during rule-making processes are essential for EPA to provide an effective rule that considers the needs of sectors requiring continued availability of a substance. The final rule will include EPA's significant new use determination, for the purposes of the PBDE SNUR, and list the current ongoing uses that are not subject to notification requirements.

As a general clarification, SNUR requirements apply only to significant new uses; current uses are excluded from Significant New Use Notice (SNUN) submissions. With respect to the exemption for ongoing uses, EPA believes it is unlikely that the need for alternatives, reformulations, and major manufacturing process changes would occur based on the issuance of a SNUR. Since there is no obligation to cease current uses under a SNUR, and there is no way for EPA to anticipate all new uses of a chemical or chemical substance, conducting an alternatives assessment in conjunction with every SNUR is not an effective use of resources.

EPA's regulatory staff and the DfE program shared information during the development of the action plan, the rule and the alternatives assessment. Although the SNUR for PBDEs that

includes decaBDE was proposed in a unique situation because the phase-out of the chemical was imminent, this is not the first time that SNURs have been used to supplement voluntary phase out agreements (40 CFR 721.9582; 40 CFR 721.10000). Phase-out of decaBDE was announced by the manufacturers in late 2009, suggesting that preferable alternatives were available. EPA saw the importance of providing information on substitutes through the DfE alternatives assessment because of the reduction in availability of decaBDE after US manufacturer phase-out and the proposed subsequent test rule.

Comment: Add primary source (as cited in secondary source) to individual study summaries

Response: Many primary sources were cited when study clarification was necessary; however, not all were included.

Comment: Instead of describing data quality and reliability of data, for many of the studies EPA only listed "Reported in a secondary source". More details about the data quality should be provided.

Response: It is noted when a secondary source was utilized to summarize the study summary when it was reviewed and summarized in a suitable review. Other information about the data quality was provided in the hazard assessment study entry as discussed in Chapter 4 of the report. For chemicals that have been well characterized, the literature review focused primarily on the use of secondary sources, such as Agency for Toxic Substances and Disease Registry Toxicological Profiles (ATSDR) or IRIS assessments to maximize available resources and eliminate potential duplication of effort.

Various editorial changes were made to the report based on comments received during the public comment period. Table 10 summarizes the editorial changes made as a result of these comments, some of which are included in this document, and other changes resulting from informal discussions with stakeholders and EPA staff.

Table 10. List of Editorial Changes in Final Report

Page #	Change
UNIVERSAL CHANGES	
ii-xvi	Added an Executive Summary and list of Acknowledgements.
3-10, 4-30, 4-230 through 4-248, 5-7 through 5-12	Changed the name "Confidential Brominated Polymer" to "Brominated poly(phenylether)" as directed by the product manufacturer.
Throughout the report	Added Phosphoric acid, mixed esters with [1,1'-bisphenyl-4,4'-diol] and phenol; BPBP to the assessment.
3-9, 4-30, 4-195 through 4-205, 5-7 through 5-12	Merged and changed name of confidential brominated epoxy polymer/mixture to brominated epoxy polymer(s) and Mixture of brominated epoxy polymer(s) and bromobenzyl acrylate.
1-2, 3-4, 3-5, 6-1	Clarified that the alternatives included in the report are *potentially* viable and functional but not necessarily preferable in response to a formal comment that the terms "viable" and "functional" are misleading.
3-4, 6-2	Updated the total number of alternatives to reflect the number of alternatives evaluated in the final report.

Page #	Change
End of each chapter	Incorporated references at the end of each chapter rather than at the end of the report.
CHAPTER 1	
1-2	Explained that report does not evaluate the efficacy of decaBDE alternatives in regards to specific materials, product applications, or related standards but instead offers professional judgment about whether chemicals are likely to meet flammability tests in various uses. This edit was made in response to two informal comments requesting that the report states it did not evaluate efficacy.
1-2	Explained that selection of a chemical for evaluation in this report does not denote preferability in terms of environmental hazard, health hazard, or any other metric but does provides information that will enable informed selection of alternative flame retardants to decaBDE. This edit was made in response to a formal comment requesting that the limitations of the report be discussed in Chapter 1.
1-6	Added paragraph on the use of estimated data when empirical data cannot be located. The paragraph discusses how DfE Alternatives Assessments employs many of the same predictive modeling techniques in the absence of empirical data that TSCA uses. This edit is in response to a formal comment suggesting that the report addresses the limitations of the report in Chapter 1.
1-7	Restated that the report does not compare performance or efficacy of the alternatives in conjunction with the edit on Page 1-2.
CHAPTER 2	
2-1	Clarified that the materials outlined in Chapter 2 are those in which decaBDE is currently or was used in the past *across the globe*.
2-7	Removed Figure 2-7 and integrated information on the segmentation of decaBDE uses in the U.S. into the report. Also added a sentence stating that this information was the most conclusive data located on decaBDE uses at the time of report publication in light of the shifting landscape of decaBDE uses in certain industries and products. This edit was made in response to a formal comment suggesting that the figure was likely inaccurate and untimely because decaBDE is used in low volumes in aerospace parts and components, as there has been a concerted effort in the aerospace industry over the past several years to identify and implement alternatives.
2-7	Clarified that decaBDE uses outlined in Chapter 2 are referring to global uses and that references to regulatory statutes in Chapter 2 are referring to U.S. regulation.
2-7	Removed reference to Figure 2-7 because the figure was removed from the report.
2-11	Clarified that decaBDE is used as a flame retardant in certain products *in the U.S.*
2-13	Clarified language on standard FM 4996 in Table 2-2.
CHAPTER 3	
3-1	Explained the role of carbon monoxide as a combustion by-product in fire deaths.
3-5	Added textbox describing the relationship between DfE chemical alternatives assessments and the Toxic Substances Control Act.
3-6 through 3-14	Added footnote in Table 3-2: "For full chemical name and relevant trade names see the synonym section of the individual profiles in Section 4.8."
3-12	Updated CASRN for melamine polyphosphate to 15541-60-3.
3-12	Added footnote in Table 3-2 for melamine polyphosphate: "This CASRN is specifically for Melamine Pyrophosphate. Please consult the Chemical Considerations section of this chemical's hazard profile for additional identity information on the closely related melamine phosphate salts that are anticipated to have similar hazard profiles." This edit was made in conjunction with the updated CASRN for Melamine Polyphosphate.
3-16	Updated justification for exclusion for Green Armor to accurately reflect the most recent PMN status.
3-17	Updated the justification for exclusion and Inserted new text in table for "Short and Medium Chain Chloroparaffins:" Short-Chain Chlorinated Paraffins (SCCPs) Medium-Chain Chlorinated Paraffins (MCCPs) Long-Chain Chlorinated Paraffins (LCCPs) very Long-Chain Chlorinated Paraffins (vLCCPs)

Page #	Change
	Chlorinated paraffins are categories of chemicals and defined as: $C_x H_{(2x-y+2)} Cl_y$ SCCPs: $10 \leq x \leq 13$, $3 \leq y \leq 12$ MCCPs: $14 \leq x \leq 17$, $3 \leq y \leq 15$ LCCPs: $18 \leq x \leq 20$, $5 \leq y \leq 17$ vLCCPs: $x \geq 21$, $y \geq 5$ EPA has entered into Consent Decrees with the major manufacturers of SCCPs that end manufacture and distribution of these substances in U.S. commerce. EPA has also proposed a Significant New Use Rule for any use of "alkanes, C12-13, chloro" (CASRN 71011-12-6). EPA is requiring all manufacturers of all CPs (which are not correctly listed on the TSCA Inventory) to submit TSCA section 5 premanufacture notices for these substances, where they will be evaluated for potential regulatory action. In addition, EPA is evaluating whether the manufacturing, processing, distribution in commerce, use and/or disposal of MCCPs and LCCPs should also be addressed under TSCA section 6(a).
3-19	Included discussion of inherently flame retardant barriers in the section on inherently flame retardant materials. Added description of Layer by Layer technology.
3-22	In the "Mesoporous silicate particles" section, added the sentence "The network created by the MSP, combined with their surface chemistry, improves the char barrier formed during combustion that reduces flame intensity while simultaneously improving the mechanical performance of the polymer into which they are compounded."
3-23	Changed the flame retardant loading with for mesoporous silicate particles to 0.5 to 3 percent by weight MSPs from 2 to 8.
3-25	Specified that brominated flame retardants are the preferred choice of halogenated flame retardants from a manufacturer standpoint (excluding hazard, risk, or performance).
CHAPTER 4	
4-18	Changed "percent removal" to "percent of theoretical ultimate degradation" in biodegradation discussion.
4-21 through 4-23	Edited presentation of ECOSAR methods to be clear and concise.
4-24	Redefined definition of ultimate biodegradation to include reference to mineral oxides.
4-24	Added information about anaerobic degradation and the use any of electron acceptors.
4-24, 4-25	Specified parameters for biodegradation ready test to differentiate between oxygen demand and CO_2 production and dissolved organic carbon disappearance.
4-25	Provided reference to specific OECD biodegradation tests.
4-25	Minor wording edits to paragraph on Biowin models.
4-29	Added textbox describing the relationship between DfE chemical alternatives assessments and the Toxic Substances Control Act.
CHAPTER 5	
5-10	Updated K_{ow} numbers in Table 5-1 to reflect changes in the hazard profile.
5-12	Changed persistence designation and value for aluminum diethylphosphinate from "Very High" to "High" and from "180 days" to "60-180 days".
5-18	Explained that some supply chains may be more intricate than displayed in Figure 5-3.
5-22	Indicated that product recycling may by unregulated and/or regulated.
CHAPTER 6	
6-1 through 6-8	Updated text to reflect changes to hazard calls in the hazard profiles.
6-9	Discussed confidence in results for chemicals with seemingly preferable hazard profiles in which the

Page #	Change
	majority of designations are based on estimated effect levels.
6-11	For the Environmental Justice Considerations section, deleted the word minority from the first sentence of the first paragraph and added the text "people based on race, color, national origin, or income." Added the word "may" to the second sentence. Also deleted the word minority from the last sentence of the first paragraph and added the text "people of a certain race, national origin or income bracket."
6-11	Deleted the word "minority" in second paragraph of environmental justice discussion.
6-14	Added the text to substitution decision section: "As stakeholders proceed with their substitution decisions for decaBDE, the functionality and technical performance of each product must be maintained, which may include product performance in extreme environments over a lifecycle of many years. Critical requirements, such as product safety during operation cannot be compromised. When alternative formulations are developed, the stakeholders should also consider the hazard profiles of the chemicals used to meet product performance, with a goal to drive towards safer chemistry on a path of continuous improvement. When chemical substitution is the necessary approach, the information in this report can help with selection of safer, functional alternatives. The hazard characterization, performance, economic, and social considerations are all factors that will impact the substitution decision. When choosing safer chemicals, alternatives should ideally have a lower human health hazard, lower ecotoxicity, better degradability, lower potential for bioaccumulation, and lower exposure potential. Where limited data are available characterizing the hazards of potential alternatives, further testing may be necessary before a substitution decision can be made."
6-16 through 6-17	Updated text on the ENFIRO project to reflect publication of the final ENFIRO report.

IV. Changes to Hazard Summary Table

Revisions were made to the hazard designations of some of the alternatives based on comments received during the public comment period, new data, additional analogs, and the DfE criteria. The revisions are shown in Table 11 through Table 13.

Table 11. Screening Level Hazard Summary for DecaBDE and Halogenated Flame Retardant Alternatives Showing Changes from the Draft to Final Reports.

This table only contains information regarding the inherent hazards of flame retardant chemicals. Evaluation of risk considers both the hazard and exposure associated with the substance including combustion and degradation by-products. The caveats listed in the legend and footnote sections must be taken into account when interpreting the hazard information in the table.

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H,* and *VH)* were assigned using values from predictive models and/or professional judgment.

§ Based on analogy to experimental data for a structurally similar compound.

¤ This alternative may contain impurities. These impurities have hazard designations that differ from the flame retardant alternative, Brominated poly(phenylether), as follows, based on experimental data: HIGH for human health, HIGH for aquatic toxicity, VERY HIGH for bioaccumulation, and VERY HIGH for persistence.

T This chemical is subject to testing in an EPA consent order for this endpoint.

Chemical (for full chemical name and relevant trade names see the individual profiles in Section 4.8)	CASRN	Human Health Effects											Aquatic Toxicity**		Environmental Fate	
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
DecaBDE and Halogenated Flame Retardant Alternatives																
DecaBDE and Discrete Halogenated Alternatives																
Bis(hexachlorocyclopentadieno) Cyclooctane	13560-89-9	L	*M*§	*M*§	VL	VL	L	M	L		VL	*L*	*L*	*L*	VH	*H*
~~Confidential Brominated Polymer~~ Brominated Poly(phenylether)	Confidential	~~*L*~~ L	*L*¤	L	~~*L*¤~~ VL¤	~~*L*¤~~ *M*¤	*L*¤	~~*L*¤~~ L¤	~~*L*~~ L	~~*L*~~	L	VL	~~*L*~~ L	~~*M*^{T}¤~~ *L*¤	VH^T	~~*M*^{T}¤~~ *H*^{T}¤
Decabromodiphenyl Ethane	84852-53-9	L	*M*§	L	L	~~VL~~ *H*§	~~*H*§~~ *L*	L	L		VL	VL	L	*L*	VH	*H*
Decabromodiphenyl Ether	1163-19-5	L	M	L	L	H	~~H~~ *L*	M	L		L	L	*L*	*L*	VH	*H*
Ethylene Bis-Tetrabromophthalimide	32588-76-4	L	~~*M*§~~ *M*	L	*L*	~~L~~ *M*§	~~*M*§~~ *L*	L	*L*		VL	VL	*L*	*L*	VH	*H*
Tetrabromobisphenol A Bis (2,3-dibromopropyl) Ether	21850-44-2	L	*M*	M	*M*	*M*	*L*	*M*	~~*M*~~ L		~~*L*~~ L	~~*L*~~ L	~~*L*~~ L	*L*	VH	*H*
Tris(tribromoneopentyl) Phosphate	19186-97-1	~~*L*~~ *M*	*M*	~~*M*~~ L	~~*L*~~ *M*	~~*H*~~ *M*	*H*	~~*M*~~ L	~~*H*~~ L		*L*	*L*	*L*	*L*	*H*	*M*

**Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

Table 11 Continued

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H,* and *VH*) were assigned using values from predictive models and/or professional judgment.

[d] This hazard designation would be assigned MODERATE if >5% of the particles are in the respirable range as a result of dust forming operations.

♦ Different formulations of the commercial product are available. One of these many formulations has an average MW of ~1,600 and contains significant amounts of lower MW components. These lower MW components have hazard designations different than the polymeric flame retardant, as follows: HIGH (estimated) for bioaccumulation; HIGH (experimental) for acute aquatic toxicity; HIGH estimated for chronic aquatic toxicity; MODERATE (experimental) for developmental; and MODERATE (estimated) for carcinogenicity, genotoxicity, repeated dose, reproductive, and skin and respiratory sensitization toxicity.

Chemical (for full chemical name and relevant trade names see the individual profiles in Section 4.8)	CASRN	Human Health Effects											Aquatic Toxicity**		Environmental Fate	
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
Halogenated Flame Retardants Continued																
Discrete Halogenated Alternatives Continued																
Tris(tribromophenoxy) Triazine	25713-60-4	L	*L*	L	*L*	*L*	*L*	L	L		L	VL	*L*	*L*	VH	*H*
Polymeric Halogenated FR Alternatives[P]																
~~"TBBPA Clycidyl Ether, TBBPA Polymer"~~ Brominated Epoxy Polymers	68928-70-1	*L*	*L*♦	~~*L*~~ L	*L*♦	*L*♦	*L*	~~*M*~~ *L*♦[d]	~~*L*~~ L	♦	*L*	*L*	*L*♦	*L*♦	*VH*	*L*♦
Brominated Epoxy Polymer(s)	Confidential	*L*	*L*♦	*L*♦	*L*♦	*L*♦	*L*	~~*M*~~ *L*♦[d]	*L*♦	♦	*L*	*L*	*L*♦	*L*♦	*VH*	*L*♦
~~Confidential Brominated Epoxy Polymer #1~~	~~Confidential~~	~~*L*~~	~~*L*~~	~~*L*~~	~~*L*~~	~~*L*~~	~~*L*~~	~~*M*[d]~~	~~*L*~~		~~*L*~~	~~*L*~~	~~*L*~~	~~*L*~~	~~*VH*~~	~~*L*~~
~~Confidential Brominated Epoxy Polymer #2~~	~~Confidential~~	~~*L*~~	~~*L*♦~~	~~*L*♦~~	~~*L*♦~~	~~*L*♦~~	~~*L*~~	~~*M*♦[d]~~	~~*L*♦~~	~~♦~~	~~*L*~~	~~*L*~~	~~*L*♦~~	~~*L*♦~~	~~*VH*~~	~~*L*♦~~
~~Confidential Brominated Epoxy Polymer Mixture #1~~	~~Confidential~~	~~*L*~~	~~*L*♦~~	~~*L*♦~~	~~*L*♦~~	~~*L*♦~~	~~*L*~~	~~*M*♦[d]~~	~~*L*♦~~	~~♦~~	~~*L*~~	~~*L*~~	~~*L*♦~~	~~*L*♦~~	~~*VH*~~	~~*L*♦~~
~~Confidential Brominated Epoxy Polymer Mixture #2~~	~~Confidential~~	~~*L*~~	~~*L*♦~~	~~*L*♦~~	~~*L*♦~~	~~*L*♦~~	~~*L*~~	~~*M*♦[d]~~	~~*L*♦~~	~~♦~~	~~*L*~~	~~*L*~~	~~*L*♦~~	~~*L*♦~~	~~*VH*~~	~~*L*♦~~
Mixture of brominated epoxy polymer(s) and bromobenzyl acrylate	Confidential	*L*	*L*♦	*L*♦	*L*♦	*L*♦	*L*	~~*M*~~ *L*♦[d]	*L*♦	♦	*L*	*L*	*L*♦	*L*♦	*VH*	*L*♦

[P] The range of polymer molecular weight can be broad. The polymers listed here have low toxicity for human health and aquatic endpoints. Not all polymers will have this low toxicity; hazards will vary with physical-chemical properties.

[**] Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

Table 11 Continued

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H,* and *VH*) were assigned using values from predictive models and/or professional judgment.

[d] This hazard designation would be assigned MODERATE if >5% of the particles are in the respirable range as a result of dust forming operations.

Chemical (for full chemical name and relevant trade names see the individual profiles in Section 4.8)	CASRN	Human Health Effects											Aquatic Toxicity**		Environmental Fate	
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
Halogenated Flame Retardants Continued																
Polymeric Halogenated FR Alternatives[P] Continued																
Brominated Epoxy Resin End-Capped with Tribromophenol	135229-48-0	*L*	*L*	~~L~~ *L*	*L*	*L*	*L*	~~*M*[d]~~ *L*[d]	L		L	VL	*L*	*L*	*VH*	*L*
Brominated Polyacrylate	59447-57-3	*L*	*L*	*L*	*L*	*L*	*L*	~~*M*[d]~~ *L*[d]	*L*		*L*	*L*	*L*	*L*	*VH*	*L*
Brominated Polystyrene	88497-56-7	L	*L*	*L*	*L*	*L*	*L*	~~*M*[d]~~ *L*[d]	*L*		L	*L*	*L*	*L*	*VH*	*L*

[P] The range of polymer molecular weight can be broad. The polymers listed here have low toxicity for human health and aquatic endpoints. Not all polymers will have this low toxicity; hazards will vary with physical-chemical properties.

[**] Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

Table 12. Screening Level Hazard Summary for Organic Phosphorus or Nitrogen Flame Retardant Alternatives Showing Changes from Draft to Final Report

This table only contains information regarding the inherent hazards of flame retardant chemicals. Evaluation of risk considers both the hazard and exposure associated with the substance including combustion and degradation by-products. The caveats listed in the legend and footnote sections must be taken into account when interpreting the hazard information in the table.

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H,* and *VH*) were assigned using values from predictive models and/or professional judgment.

§ Based on analogy to experimental data for a structurally similar compound.

‡ The highest hazard designation of any of the oligomers with MW <1,000.

◊ The highest hazard designation of a representative component of the oligomeric mixture with MWs <1,000.

Chemical (for full chemical name and relevant trade names see the individual profiles in Section 4.8)	CASRN	Human Health Effects											Aquatic Toxicity**		Environmental Fate	
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
Organic Phosphorus or Nitrogen Flame Retardants (PFRs or NFRs) Alternatives																
Discrete PFR, NFR and P/NFR Alternatives																
Substituted Amine Phosphate Mixture [1]	Confidential	*H*	*M*	*M*	*M*	*M*	*L*	*M*	~~*M*~~ L	*M*§	~~*M*§~~ M	~~*VH*~~ VL	*M*	*L*	*H*	*L*
Triphenyl Phosphate	115-86-6	L	*M*	L	L	L	L	~~M~~ H	L		L	VL	VH	VH	L	M
Polymeric PFR and NFR Alternatives																
Bisphenol A bis-(diphenyl phosphate), BAPP	181028-79-5	L	~~*L*~~ *M*	L	*L*	*L*§	~~*L*~~ *L*§	L	L		L	L	L	L	H	*H*◊
Melamine Cyanurate[1]	37640-57-6	*L*	*M*	*M*	*M*§	*M*§	*L*	H	*L*		*L*	*L*	*L*	*L*	VH	*L*
Melamine Polyphosphate[1]	15541-60-3	L	*M*	*M*	*L*§	*L*	*L*§	*M*	~~L~~ *L*		L	VL	L	L	*H*	*L*
N-alkoxy Hindered Amine Reaction Products	191680-81-6	L	*M*	L	*H*	*H*	*L*	*H*	L		L	VL	*H*	*H*	H	*H*‡

** Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

[1] Hazard designations are based upon the component of the salt with the highest hazard designation, including the corresponding free acid or base.

Table 12 Continued

This table only contains information regarding the inherent hazards of flame retardant chemicals. Evaluation of risk considers both the hazard and exposure associated with the substance including combustion and degradation by-products. The caveats listed in the legend and footnote sections must be taken into account when interpreting the hazard information in the table.

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H,* and *VH*) were assigned using values from predictive models and/or professional judgment.

[d] This hazard designation would be assigned MODERATE if >5% of the particles are in the respirable range as a result of dust forming operations

[§] Based on analogy to experimental data for a structurally similar compound.

[‡] The highest hazard designation of any of the oligomers with MW <1,000.

[¥] Phosphonate Oligomer, with a MW range of 1,000 to 5,000, may contain significant amounts of an impurity, depending on the final product preparation. This impurity has hazard designations that differ from the polymeric flame retardant, as follows: MODERATE (experimental) for carcinogenicity, reproductive and repeated dose toxicity, skin sensitization, eye and dermal irritation; and HIGH (experimental) for developmental toxicity and acute & chronic aquatic toxicity.

Chemical (for full chemical name and relevant trade names see the individual profiles in Section 4.8)	CASRN	Human Health Effects											Aquatic Toxicity**		Environmental Fate	
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
Organic Phosphorus or Nitrogen Flame Retardants (PFRs or NFRs) Alternatives Continued																
Polymeric PFR and NFR Alternatives																
Phosphonate Oligomer[¥]	68664-06-2	L	*M*	*L*[§]	*L*[¥]	*L*[¥]	*M*[‡]	*L*[§¥]	*L*[§¥]		*M*[¥‡]	*M*[‡]	L[¥]	*H*[‡]	*VH*	*H*[‡]
Polyphosphonate	68664-06-2	L	*L*	*L*	*L*	*L*	*L*	~~*M*~~ *L*[*d*]	*L*		*L*	*L*	*L*	*L*	*VH*	*L*
Phosphoric acid, mixed esters with [1,1'-bisphenyl-4,4'-diol] and phenol; BPBP	1003300-73-9	L	*M*	L	*L*[§]	*L*[§]	L	L	L		VL	VL	*H*[§]	*H*[§]	H	*M*[‡]
Poly[phosphonate-co-carbonate]	77226-90-5	L	*L*	*L*	*L*	*L*	*L*	~~*M*[*d*]~~ *L*[d]	*L*		*L*	*L*	*L*	*L*	*VH*	*L*
Resorcinol Bis-Diphenylphosphate; RDP	125997-21-9	L	*M*[§]	L	L	~~VL~~ M	~~*M*~~ M	M	*L*		L	VL	VH	~~*H*[‡]~~ VH	M	*H*[‡]

[**] Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

Table 13. Screening Level Hazard Summary for Inorganic Flame Retardant Alternatives Showing Changes from Draft to Final Report

This table only contains information regarding the inherent hazards of flame retardant chemicals. Evaluation of risk considers both the hazard and exposure associated with the substance including combustion and degradation by-products. The caveats listed in the legend and footnote sections must be taken into account when interpreting the hazard information in the table.

VL = Very Low hazard L = Low hazard M = Moderate hazard H = High hazard VH = Very High hazard — Endpoints in colored text (VL, L, M, H, and VH) were assigned based on empirical data. Endpoints in black italics *(VL, L, M, H,* and *VH*) were assigned using values from predictive models and/or professional judgment.

[d] This hazard designation would be assigned MODERATE if >5% of the particles are in the respirable range as a result of dust forming operations.

[R] Recalcitrant: Substance is comprised of metallic species that will not degrade, but may change oxidation state or undergo complexation processes under environmental conditions.

[*] Ongoing studies may result in a change in this endpoint.

Chemical (for full chemical name and relevant trade names see the individual profiles in Section 4.8)	CASRN	Human Health Effects											Aquatic Toxicity[**]		Environmental Fate	
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
Inorganic Flame Retardant Alternatives																
Aluminum Diethylphosphinate	225789-38-8	L	*L*	L	~~L~~ VL	*M*	*M*	~~L~~ *M*	L		L	VL	M	M	*H*[R]	*L*
Aluminum Hydroxide	21645-51-2	L	*L*	L	*L*	L	M	~~L~~ *M*	L		VL	VL	*M*	*M*	*H*[R]	*L*
Ammonium Polyphosphate	68333-79-9	L	*L*	*L*	*L*	*L*	*L*	~~*M*~~ *L*[d]	L		VL	L	*L*	*L*	*VH*	*L*
Antimony Trioxide[1]	1309-64-4	L	~~L~~ M*	~~L~~ M	~~*L*~~ *M*	*L*	*L*	~~M*~~ H	L		L	M	~~M~~ H	M	*H*[R]	*L*
Magnesium Hydroxide	1309-42-8	L	L	L	~~*L*~~ L	*L*	*L*	L	*L*		M	~~*M*~~ L	*L*	*L*	*H*[R]	*L*
Red Phosphorus	7723-14-0	~~VH~~ L	*L*	*M*	*L*	*L*	*L*	*L*	L		M	~~H~~ M	L	L	H	*L*
Zinc Borate	1332-07-6	L	*L*	*H*	*M*	*M*	*H*	*L*	L		L	L	*H*	*H*	H[R]	*L*

[**] Aquatic toxicity: EPA/DfE criteria are based in large part upon water column exposures which may not be adequate for poorly soluble substances such as many flame retardants that may partition to sediment and particulates.

[1] This compound is included in the ongoing EPA Work Plan evaluation for Antimony Trioxide.

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