Response to Comments on the Draft Alternatives Assessment for Hexabromocyclododecane (HBCD) – June 2014

On September 24, 2013, the U.S. Environmental Protection Agency (EPA)'s Design for the Environment (DfE) program issued a draft alternatives assessment report titled *Flame Retardant Alternatives for Hexabromocyclododecane (HBCD)*. Under its enhanced chemicals management program, the EPA issued an action plan for HBCD that identified the flame retardant as persistent in the environment, bioaccumulative in living organisms, and highly toxic to aquatic organisms. The action plan called for the development of a multi-stakeholder alternatives assessment for HBCD conducted by DfE. The scope of this alternatives assessment focuses on HBCD's primary uses in expanded polystyrene foam (EPS) and extruded polystyrene foam (XPS). The draft report of this alternatives assessment was posted on the DfE website for public review and a 60-day comment period that was later reopened for an additional 12 days.

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 HBCD is one project in the broader scope of DfE's work on flame retardant chemicals. DfE has applied its alternatives assessment methodology to other flame retardant chemicals including decabromodiphenyl ether, pentabromodiphenyl ether in polyurethane foam in furniture, and tetrabromobisphenol A in printed circuit boards.

DfE received comments from seven entities on the draft report *Flame Retardant Alternatives for Hexabromocyclododecane (HBCD)* during the comment period, which ran from September 22 to November 22, 2013. The comment period was reopened for an additional 12 days from November 25 to December 6, 2013. The comments submitted illustrated the viewpoints of a variety of interests including chemical manufacturers, building and construction industry, non-governmental organizations, and state and local governments. Of the seven sets of comments DfE received, most addressed general report content. 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 text of the *Flame Retardant Alternatives for Hexabromocyclododecane (HBCD)*. 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/hbcd/about.htm.

Comments and DfE Responses

I. Comments on the Assessments of Specific Chemicals

A. HBCD

Comment: **Carcinogenicity –** The correct classification is Low for the carcinogenicity endpoint because the weight of evidence indicates a low probability for HBCD producing cancer.

- No treatment-related tumors were observed in mice exposed to very high doses of HBCD in a carcinogenicity study conducted by the National Public Health Research Institute, Biological Test and Safety Research Center, Japan
- HBCD is not considered to have genotoxic potential. The European Union concluded that HBCD lacks significant genotoxic potential both *in vitro* and *in vivo*, and suggested that "there is no reason to explore this endpoint further" (EU RAR, 2008)
- The systemic toxicity observed in repeated dose studies is not significant and restricted to liver and thyroid effects, which can be explained by HBCD-induced hypertrophy and liver enzymes at high doses resulting in thyroid hormone clearance.
- The DfE assessment reached its conclusion of moderate hazard based on: carcinogenic potential cannot be ruled out". This would mean that any chemical without a cancer bioassay would be determined as possessing moderate potential for producing cancer. However, it is clear that the weight of evidence from multiple repeated dose animal assays, including a cancer bioassay and guideline genotoxicity assays indicates a low potential for carcinogenicity.

Response: The hazard designation for the carcinogenicity endpoint is based on uncertainty due to a lack of adequate data for this substance. In the absence of sufficient carcinogenicity data, DfE's methodology assigns a Moderate hazard designation due to uncertainty. The single carcinogenicity study in mice was inconclusive rather than negative, due to high tumor incidence in control mice, and was therefore insufficient to assess the carcinogenicity of HBCD. DfE agrees that HBCD is not likely to be genotoxic based on the available data; this is reflected in the Low hazard designation assigned for genotoxicity in the AA report. While genotoxicity is an important mode of action that can result in the development of cancer, other mechanisms of action can result in carcinogenicity. A demonstrated lack of genotoxic potential does not necessarily indicate a low potential for carcinogenicity. The available systemic toxicity data were not considered in assessing the carcinogenicity endpoint. The study durations (28 or 90 days) for the repeated dose toxicity studies are not long enough to assess carcinogenic potential over a lifetime, and the types of examinations made during necropsy differ between the repeated dose and carcinogenicity studies. In addition, the available repeated dose studies were done in rats, while the carcinogenicity study was done in mice. The absence of reported tumors in the repeated dose studies is not sufficient evidence of a lack of carcinogenicity in rats, and cannot be used to bolster the results of the inadequate carcinogenicity study in mice.

Comment: **Reproductive effects –** The correct classification is LOW. The overall weight of evidence suggests that HBCD has a Low potential for reproductive toxicity. The weight of evidence includes:

- The reproductive effects cited by EPA in the quoted passage were largely non-specific and restricted to the high dose level, which were orders of magnitude higher than human exposure. The Benchmark Dose (BMD) calculations indicate that systemic toxicity occurs at lower doses than reproductive or developmental effects.
- There was no significant decrease in male or female fertility index in any of the dose groups and therefore no substance related effect on the fertility index.
- The primordial follicle counts are within historical control range and a highly unreliable parameter, so that the statistical findings should be regarded as of no biological relevance.
- No effects were observed on sperm parameters, estrous cyclicity, reproductive organ weights or histopathology in F_0 or F_1 adults.

Response: For human health endpoints, the hazard designation is based on potency, not expected human exposure levels. For endpoints evaluated using repeated exposure studies, DfE's methodology considers both the lowest observed adverse effect levels (LOAELs) and the no observed adverse effect levels (NOAELs) when they can be identified for each of the assessed studies. The lowest NOAEL and LOAEL reported for the reproductive toxicity endpoint fall within the Low and Moderate hazard criteria ranges. While DfE recognizes that no other reproductive effects were reported, the significance of the reduced number of primordial follicles reported in the Ema et al., 2009 study could not be dismissed altogether, and this effect could indicate a potential for reproductive effects not evaluated in this study. The decrease in number primordial follicle cells were found to be 30% less than the control (316.3 ± 119.5) at the LOAEL, 138 mg/kg-day (197.9 ± 76.9), but not at the lowest dose of 14.3 mg/kg-day (294.2 ± 66.3). DfE recognizes that the absolute numbers of cells reported in this study fall within the historical range (189.5 – 353.4, (mean = 295.6), and that some variability in these numbers is normal. However, the 30% treatment-related decrease at the 138 mg/kg-day dose level compared to controls in this study is a significant change. Using a conservative approach, reproductive effects related to this decrease cannot be ruled out; therefore a Moderate hazard designation is appropriate for this endpoint. The hazard summary statement was revised to include that there were no treatment-related effects on the fertility index and no effects on sperm parameters, estrous cyclicity, reproductive organ weights or histopathology in F_0 or F_1 adults.

Comment: **Developmental toxicity –** The correct classification is Low to Moderate. The overall weight of evidence suggests that HBCD has a Low to Moderate potential for reproductive [developmental] toxicity.

- In a developmental study (Ema et al., 2008) the spontaneous locomotor activity for 10 minute intervals and for a total of 60 minutes was not significantly different between control and HBCD treated groups in male and female F1 rats. On the first day of the T-Maze test no significant difference was observed between male and female treated animals and controls in each group. On day 3 of T-maze there was a better performance of treated males than controls (significantly shorter elapsed time at 1500 and 15,000 ppm and fewer numbers of errors at 15,000 ppm). In females there was no significant difference between control and HBCD treated groups. The authors also state in the discussion that in this study findings of Eriksson et al. (2006) in mice as decreased locomotion and worse performance in the Morris water maze could not be confirmed.

- HBCD effects on brain CNPase-positive oligodendrocytes were observed in rats at a dose >1,000 mg/kg-day, the highest dose, which exceeds the limit dose of 1000 mg/kg-day (Saegusa et al., 2009). There was no evaluation of whether the observation was predictive for functional effects. The observation occurred at excessive doses not being relevant for risk assessment.
- It is unclear why there was a decrease in T3 on PND 20 and no significant change in T4 (Saegusa et al., 2009). If only one circulating hormone is measured, T4 is typically measured rather than T3, because T4 levels are more dynamic (T4 levels are used to maintain T3 in a homeostatic range). Small sample sizes (10/group) may have contributed to some imprecision in their thyroid hormone measurements. It would have been helpful if the authors had collected thyroid weights on PND 20. Also, there were no corresponding thyroid histopathology changes at PND 20. Overall, their data support a point change in thyroid hormone levels better than a sustained change in thyroid function at this age. There is only a poor-dose response for changes in T3 and TSH at week 11 (greater effect at 1000 than 10,000). It is important to consider that there is typically very high variance in TSH levels (e.g., greater than 50% coefficient of variation in TSH is permitted in the new pubertal assay test guideline at 15 animals/dose). Also, thyroid hormone measurements can change rapidly and are subject to alterations by stress (e.g., Döhler, 1979); therefore point measurements of thyroid hormone are best supported by altered thyroid weights and histopathology to support perturbed thyroid function. No data were presented indicating altered thyroid histopathology in the offspring at PNW 11. Thus, the picture of altered thyroid function is not as strong as it first appears. While thyroid weights were increased in males on PNW 11, thyroid weights were decreased in female offspring (PNW 11) exposed to HBCD. The authors do not discuss this point.
- Effects on the offspring in a two-generation reproductive toxicity (Ema et al., 2008) study were relatively non-specific, and were limited to decreases in pup survival (F2 only) and pup weights (F1 and F2) at the high dose level, and changes in two maturational end points (i.e., eye opening, midair righting reflex) that the authors considered secondary to pup body weight effects.

Response: The developmental toxicity endpoint is assigned a High hazard designation based upon neurodevelopmental effects reported in the Eriksson et al., 2006 study (reduced habituation, decreased locomotion, and decreased rearing in neonatal male mice on PND 10) that occurred at dose levels that fall within the High range in DfE’s criteria (NOAEL = 0.9 mg/kg-day, LOAEL = 13.5 mg/kg-day). Though the Eriksson et al., 2006 study was a non-guideline study, it was adequate for assessing neurodevelopmental effects; exposure occurred during the peak period of rapid brain growth and the methodology was validated with known neurotoxic agents in previous studies.

Additional study details describing the locomotor activity and maze performance results from the Ema et al., 2008 study were added to the report to reflect the additional developmental effects noted in the comment. The study authors' conclusion regarding the correlation between delayed maturational milestones and low pup body weight was also added to the study summary. The changes in thyroid endpoints reported by Saegusa et al., 2009 were not used to assign the hazard designation for developmental toxicity.

The hazard statement summary for this study already notes that the effects reported for brain CNPase-positive oligodendrocytes occurred at the higher dose levels. Additional discussion regarding study limitations has been added to the data quality entry for this study summary based on the points raised in the comments.

Comment: **Neurotoxicity –** The correct classification is Low. The overall weight of evidence suggests that HBCD has a low potential for neurotoxicity

- The potential of selected brominated flame retardants, including HBCD, to affect neurological development was reviewed by Williams and DeSesso (2010). The overall evidence indicated a lack of consistency across studies therefore precluding establishment of a causal relationship between perinatal exposure to HBCD and alterations in motor activity.
- In a developmental study (Ema et al., 2008) the spontaneous locomotor activity for 10 minute intervals and for a total of 60 minutes was not significantly different between control and HBCD treated groups in male and female F1 rats. On the first day of the T-Maze test no significant difference was observed between male and female treated animals and controls in each group. On day 3 of T-maze there was a better performance of treated males than controls (significantly shorter elapsed time at 1500 and 15,000 ppm and fewer numbers of errors at 15,000 ppm). In females there was no significant difference between control and HBCD treated groups. The authors also state in the discussion that in this study findings of Eriksson et al. (2006) in mice as decreased locomotion and worse performance in the Morris water maze could not be confirmed.
- HBCD effects on brain CNPase-positive oligodendrocytes were observed in rats at a dose >1,000 mg/kg-day, the highest dose, which exceeds the limit dose of 1000 mg/kg-day (Saegusa et al., 2009). There was no evaluation of whether the observation was predictive for functional effects. The observation occurred at excessive doses not being relevant for risk assessment.
- The study by Lilienthal, et al. (2009) reporting that hearing appeared to be impaired suffers from several deficiencies that indicate the study is not sufficiently reliable to serve as the basis for definitive conclusions.
  - Nine groups were fed diets mixed with different HBCD concentrations, but it is not clear whether the average daily intakes were calculated on the basis of measured concurrent feed intake or whether they were estimated from historical control feed intake data.
  - The sample sizes are small for the endpoints measured (n = 4-6/sex/group) and this study was nested within a larger study (Van der Ven et al., 2009) that reported sample sizes of 6/sex/group. Some animals must not have contributed data in the present study but this was not made clear and reasons for leaving some

animals out of the measurements were not stated. In addition, Van der Ven et al., (2008) used a high fat diet, but didn't control for that properly.
  - The discussion addresses the differential effects in males and females for catalepsy in terms of enzyme induction (females being more sensitive than males). On the other hand, evoked potentials are affected in males, but not in females. The authors only stated that sex-related effects are not uncommon. No comments were made about the fact that in one case, females were more affected, and in the other males were.

Response: The hazard for the neurotoxicity endpoint is designated as Moderate based on the structural alert for cyclic halogenated aliphatic hydrocarbons. The Ema et al., 2008, Eriksson et al., 2006, and Saegusa et al., 2009 studies were not included in the Neurotoxicity section and were not evaluated for this endpoint hazard assessment because this section is relevant to adult neurotoxicity and not to developmental neurotoxicity. Comments for these studies are addressed in the developmental toxicity section. Deficiencies in the Lilienthal et al., 2009 study and the uncertainties of determining a causal relationship between perinatal exposure to HBCD and neurotoxic effects in rats were addressed in the data quality entry for this study. Due to the study limitations and uncertainty in interpreting the findings, the results of this study were not considered when assigning the hazard designation for this endpoint as is explained in the hazard statement summary. It is worth noting that the results of the Lilienthal et al., 2009 study suggest that there is a potential concern for the neurotoxic effects reported. The data quality statement for this study has been revised to include additional information about the study limitations.

Comment: **Repeated dose effects** – The correct classification is Low to Moderate: The overall weight of evidence suggests that HBCD has a low to moderate potential for repeated-dose effects.

- The systemic toxicity observed in repeated dose studies occurred only at high doses relative to human exposures and is restricted to liver and thyroid effects, which can be explained by HBCD induced hypertrophy and liver enzymes at high doses resulting in thyroid hormone clearance.

Response: The repeated dose endpoint is assigned a Moderate hazard designation based on observed effects in the thyroid and liver that fall within the Moderate range in DfE's criteria. Alterations in TSH levels were reported in F_0 rats in the Ema et al., 2008 study at a dose level of 14 mg/kg-day that is within the Moderate criteria range (10 – 100 mg/kg-day). Thyroid and liver effects in rat dams at doses within the Moderate hazard criteria range (LOAEL: 146 mg/kg-day, NOAEL: 14.8 mg/kg-day) were reported in the Saegusa et al., 2009 study, and increased liver weight in conjunction with histopathological findings were reported in rats following a 90-day exposure at 100 mg/kg-day (lowest dose tested, NOAEL: <100 mg/kg-day) in the Chengelis, 2001 study. In addition, there is potential for nephrotoxicity based on a structural alert for halogenated aliphatic hydrocarbons. The weight of evidence indicates a Moderate hazard designation for repeated dose effects.

<u>Comment</u>: **Respiratory sensitization –** Regarding the footnote in the Hazard Summary Table and text in 4.4.1 "At this time, there are no standard test methods for respiratory sensitization; as a result there was no designation for this endpoint": The correct classification is Very Low: HBCD is not a dermal sensitizer and not a reactive compound. Thus, there is a very low probability that HBCD would be a respiratory sensitizer.

<u>Response</u>: Currently, DfE's criteria do not include a Very Low hazard designation for the respiratory sensitization endpoint (only High, Moderate, and Low). DfE's criterion for a Low hazard designation is "Adequate data available indicating lack of respiratory sensitization". Respiratory sensitization was not characterized for HBCD, or for any of the alternatives, because no data were located, no suitable estimation methods were available, and no structural alerts were identified. Negative responses in dermal sensitization assays do not necessarily correlate with a lack of potential for respiratory sensitization. This endpoint remains a data gap (for HBCD and the alternatives) for this assessment, and therefore is not rated. The footnote in the Hazard Summary Table has been edited to indicate that no experimental test data were located for HBCD or its alternatives.

B. Butadiene styrene brominated copolymer

<u>Comment</u>: Dow agrees with the quoted conclusion "The butadiene styrene brominated copolymer has Low hazard designations (either measured or estimated) for all human health endpoints due to its high MW and limited potential for absorption" and with the evaluation as shown in the Summary table for butadiene styrene brominated copolymer.

<u>Response</u>: Thank you for your review and comment. Additional study details have been provided since the draft report causing a change in two hazard designations. Eye Irritation was changed to experimental Moderate because one study reported mild irritation, although this may have been due to the rabbits scratching their eyes (an indirect irritation response). The Acute Aquatic Toxicity hazard designation was changed to estimated Low because the reported experimental data for *daphnia* acute aquatic toxicity, EC_{50} >1,000 mg/L, was considered inadequate after further review as explained in a response later in this document.

<u>Comment</u>: Pages 4-104 and following cite Chemtura as the data source for several endpoints alongside of data citations from Dow. Under the technology agreement between Chemtura and Dow, all toxicological and property data used for Emerald Innovation™ 3000 is in fact based on Dow's own studies. Therefore, it would be most clear and accurate to remove the Chemtura citations and solely cite to Dow's data/studies.

<u>Response</u>: The citations in the final report have been appropriately attributed to Dow.

<u>Comment</u>: Numerous comments were received requesting that the monomers of the butadiene styrene brominated copolymer be considered as degradation products and that the evaluation of these monomers be included in the hazard assessment:

- On page 4-106, the statement is made here and in other locations in the document “This polymer is large, with a MW >1,000. It is expected to have few to no residual monomers.” What information does EPA have that supports this assumption? Other polymers have shown to contain substantial unreacted monomer and appreciable portions of limited polymerized fragments such as dimers, trimers, etc. Without data to the contrary, this document should include the assumption of the presence of monomers and other smaller molecules and should consider the toxicity of these fragments in the overall assessment of the alternative. Washington State in its assessment of alternatives to decabromodiphenyl ether (Deca-BDE) assessed potential Deca-BDE degradation products and the toxicity of those degradation products defined the overall toxicity of the parent compound. This practice is also common to most alternatives assessments and degradation products are considered in the GreenScreen™ chemical hazard assessment tool to define the toxicity of the parent compound. The reviewer believes that no alternative should be identified as potentially “safer” without information on degradation products and the potential impact those degradation products have upon human health and the environment. In lieu of scientific studies on degradation pathways, it is acceptable to consider monomers and other small chain molecules as a surrogate for degradation products. This issue is addressed more in subsequent comments.
- On the same page, the statement is made “… this polymer is large, with a MW >1,000. It is expected to have limited bioavailability; therefore, it has low potential for reproductive effects.” Professional judgment could indicate that because of its molecular size, the compound is not expected to cross the cell membrane. However, per an earlier comment, the assumption is made that there are no low molecular weight components. If this is not correct or cannot be substantiated, the comment about bioavailability is not valid. DfE should provide clear criteria on what is considered low or non-bioavailable and why. For example, should polymers above specific molecular weights be considered completely non-bioavailable? How is the assessment changed if they are biodegradable? What about a solubility threshold? Is there a solubility threshold below which substances should not be considered bioavailable? When is low bioavailability sufficient to make an assumption about lack of hazard and for which endpoints? Is it possible for something to be completely non-bioavailable? If so, how would that be determined?
- Although the reviewer understands EPA’s problems identifying degradation products for chemicals relatively new on the market for which little information is available, some attempt should be made to consider degradation products. In lieu of scientifically validated degradation studies, the reviewer recommends use of the polymeric monomers as a surrogate for degradation products. Scientific studies have shown that monomers, dimers, trimers, etc. are often degradation products of many polymers released into the environment. In addition, many polymers contain substantial amounts of unreacted monomer and limited reaction products such as dimer, trimers, etc. Therefore using polymeric monomers as surrogates for degradation products when other data is lacking provides valuable information on the overall potential toxicity of persistent polymers. The reviewer recommends EPA consider potential degradation products and their possible impact upon the environment throughout the various hazard endpoints evaluated. Consideration of monomers, dimers, trimers, etc. as reasonable degradation products should be included in the overall evaluation of alternatives until scientifically valid data on degradation products are provided.

- On page 5-2, the statement is made: "… the butadiene styrene brominated copolymer has Low hazard designations (either measured or estimated) for all health endpoints arising from its high MW and limited potential for absorption (U.S. EPA 2012b)." No consideration is made of the possible biological impact of both unreacted monomer and potential degradation products. Styrene, for example, is a known carcinogen and has been found as unreacted monomer in styrene resins. In addition until scientifically valid data are available, it is reasonable to include the polymer monomers as potential degradation products. Therefore the toxicity of monomers such as styrene should be included in the evaluation of this alternative. In addition, estimates should be provided of expected concentrations of identified monomers, oligomers and other additives or unreacted substances or impurities.
- On the following page, the statement is made: "Based on structure activity relationships (SARs), the potential for a molecule to be absorbed by an organism tends to be lower when the molecule is larger than 1,000 daltons. This is reflected in the estimated Low hazard designation for bioaccumulation for the butadiene styrene brominated copolymer." No consideration is included in the bioaccumulation potential for possible degradation products from this polymer, particularly the potential brominated degradation products. Until scientifically valid data are provided, it is appropriate to consider the monomers as potential degradation products and include their bioaccumulation potential in an assessment of the polymer.

<u>Response</u>: The findings in the draft Alternatives Assessment (AA) report Flame Retardant Alternatives for Hexabromocyclododecane (HBCD) are based on criteria from the DfE AA guidance. Following this guidance, metabolites, degradants and byproducts are considered in the overall hazard potential of HBCD and the three alternatives. The known degradation products are evaluated using the DfE AA criteria. In the event that a new or higher hazard designation (than the parent compound) is identified based on known or expected degradation products or byproducts, it is reflected in the assessment report.

Degradation products were identified and listed in the report when available from experimental studies. Theoretical degradation products, by known degradative and metabolic processes, were also considered. Experimentally identified metabolites, degradates or transformation products were not found for the three alternatives, but were found for HBCD. Degradation is expected to be limited for HBCD and the alternatives as indicated by the high persistence designations.

For the polymeric alternative, guidance from the polymer assessment literature and Sustainable Futures Polymer Assessment Guidance informed this assessment (Boethling and Nabholz, 1997; U.S. EPA 2012). In general, starting materials and lower MW oligomers (MW <1,000 monomers, dimers, trimers, etc.) are assessed when they have potential to be present in the product. Submitted data for this alternative indicates that butadiene styrene brominated copolymer does not have components with MW <1,000 present, this information is reported in the MW entry for the compound (<0.1% <1,000; <0.1% <500). Moreover, this polymer is regulated with a Significant New Use Rule (SNUR) that was finalized in June 2013. Manufacture (or import) of the polymer requires notification to EPA except in these cases: (1) the MW of the polymer is in the range of 1,000 to 10,000 daltons, or (2) the MW of the polymer is ≥10,000 daltons and less than 5 percent of the particles are in the respirable range of 10 microns or less (U.S. EPA 2013).

Using the lower MW oligomers or starting materials as analogs or surrogates for the degradation products of polymers is an approach that applies to polymers that may be cleaved by degradative processes. An example would be hydrolysis of a polyester to form smaller polymeric, oligomeric or monomeric fragments. However, the relevant degradation pathways for any substance are dependent on its chemical structure and functionality, and this approach may not apply to all polymeric structures. In the case of butadiene styrene brominated copolymer, the carbon-chain backbone of the polymer is chemically stable and lacks readily cleavable functionality. Therefore, degradation and/or depolymerization to yield low molecular weight fragments are not expected to occur, and such substances are not representative of this polymer, even as a worst case. For example, debromination by photolysis is a likely degradative process of this polymer, but this process does not produce products that are adequately represented by either its constituent monomers or low MW fragments. This degradation pathway and the resulting potential degradation products are discussed in the assessment. The monomers, dimers and trimers of butadiene styrene brominated copolymer are not expected to be present and are not presumed to be theoretical degradation products.

Comment: On page 4-110, the statement is made "This polymer is non-irritating to mildly irritating in rabbits eyes." This is not in agreement with subsequent data. A test is listed as meeting OECD guidelines and found to be "irritating". This test, however, is qualified because of an assumption that "… irritations may have been due to mechanical action (scratching) …" It is inappropriate to change the results of an OECD standard test based upon an assumption. In addition, a more recent poorly documented study also found the chemical to be "mildly irritating". Per DfE methodology, eye irritation should be assigned at least a medium level of concern because the polymer was found to be "mildly irritating to irritating" and not "non-irritating to mildly irritating" as indicated in the above quote.

Response: This hazard designation and summary was revised based on the submitted comment, as shown below.

MODERATE: This polymer is mildly irritating to rabbit eyes, with effects clearing within 72 hours post instillation.

Comment: On pages 4-111 and 4-112, the statement is made in reporting data for Chronic Toxicity: "As a result, the reported value exceeds this material's water solubility; immobility was reported in 10% (3/30) daphnids at the test dose (1,000 mg/L) following 24- and 48- hours of exposure, therefore the NOELR is determined to be at some concentration less than 1,000 mg/L." Having a NOELR is not very helpful in pinpointing a level of concern. Usually 100 ppm is considered low for aquatic toxicity. What is the difference between the GHS approach of assigning a toxicity value above the solubility limit and an assumption of NES? These results suggest that there may be something in the polymer which might be impacting daphnid mobility and may have impact for chronic effects. If as indicated in a previous comment, the polymer contains unreacted monomer or some degree of limited polymerization such as dimers, trimers, etc., these chemicals may be leaching from the polymer and having a long-term impact upon aquatic toxicity. Therefore this issue should be addressed in this section and it may be appropriate to assign a high level of concern based upon insufficient results.

Response: This acute aquatic toxicity hazard designation was revised to an estimated Low from an experimental Low based on the submitted comment.

Additional study details provided were evaluated and the assessment was updated. The experimental data was considered to be inadequate to determine a hazard designation because (1) the cutoff values are greater than the water solubility of the compound; (2) the study method used the water accommodated fraction (WAF) of the polymer and; (3) the WAF contained solvent impurities. A separate extraction study performed according to OECD 120, determined there were no detectable organic compounds dissolved in water from the polymer. The NOELR cutoff described in the study observations is also inadequate because it is not an endpoint used in the hazard designation criteria.

Therefore, both the chronic and acute aquatic toxicity hazard designations are estimated based on physical-chemical properties that result in an estimated NES. The reported experimental data for *daphnia* acute aquatic toxicity, EC_{50} >1,000 mg/L, corresponds to a Low designation but since it is considered to be an inadequate study the designation is based on the estimates.

Unreacted monomer, dimers, trimmers, etc. are not expected to be present based on the method of manufacture.

Please refer to the response to a related comment in section II of this document.

C. TBBPA-bis brominated ether derivative

Comment: On page 4-130, the identification of a Low level of concern for aquatic toxicity does not agree with the estimated values in the table and EPA’s toxicity endpoints identified in Table 4-2: Criteria Used to Assign hazard Designations. According to Table 4-2, a level of concern of Very High is assigned when “Acute aquatic toxicity – LC50 or half maximal effective concentration (EC50) (mg/L)” is “<1.0”. All of the values estimated for this compound for aquatic toxicity (page 4-130) are orders of magnitude lower than this value, ranging from 1.31 x 10-6 to 3.47 x 10-7 mg/L. Similar values are estimated for the Chronic Aquatic Toxicity that are orders of magnitude lower than the limit of 0.1 mg/L. The aquatic toxicity for this compound should be Very High and not the Low identified.

Response: The estimated values are all lower than 1.0 mg/L; however, the log K_{OW} for this chemical is >8.0. When the log K_{OW} of the chemical is greater than the endpoint specific cut-offs presented in the ECOSAR output, then no effects at saturation are expected for those endpoints. These estimated values were reported as NES; therefore the chemical is not soluble enough to reach effects concentrations (referred to as “No Effects at Saturation”). The DfE AA Criteria (v2.0) does not explicitly state that NES results in a Low designation however, Table 4-2.

Criteria Used to Assign Hazard Designations and the methodology described in Chapter 4 of this report further describes this assessment:

"For aquatic toxicity estimates obtained using SARs, when the estimated toxicity was higher than a chemical's water solubility (i.e., the estimated concentration in water at which adverse effects appear cannot be reached because it was above the material's water solubility), the chemical was described as having NES. An NES designation is equivalent to a Low ecotoxicity hazard designation for that endpoint".

Comment: On page 4-131, the statement is made: "TBBPA-bis brominated ether derivative is expected to have low mobility in soil based on estimations indicating strong absorption to soil. If released to the atmosphere, TBBPA-bis brominated ether derivative is likely to exist solely as particulate. Therefore, atmospheric removal will occur through wet or dry deposition as opposed to atmospheric oxidation. Based on the Henry's Law constant, volatilization from water or moist soil is not expected to occur at an appreciable rate. Fugacity models indicate that TBBPA-bis brominated ether derivative will partition predominantly to soil." Although the reviewer agrees with these statements, an important potential transport pathway is not addressed. Equally valid statements were made previously for large and heavily brominated flame retardants such as decabromodiphenyl ether. Subsequent studies showed, however, that many of these types of flame retardants absorbed strongly to particulate matter that was subsequently transported far from the point of release either through air or water transport. These factors need to be considered in transport of alternatives to HBCD.

Response: It is suggested that HBCD undergoes long-range atmospheric transport based on its detection in remote locations such as the Arctic, where no demonstrable local sources exist that can account for these exposures, transport (UNEP, 2009). The potential for long range transport is an environmental concern. Methodology for assessing this endpoint does not exist, and DfE AA criteria have not been established. Data indicating that a chemical has been transported far from the point of release may be included in the environmental monitoring sections for each hazard profile. Evaluation of the physical-chemical properties of HBCD and the three alternatives indicate that transport of these substances may be different and there are no data addressing, supporting or discrediting, the potential for long range transport of the TBBPA-bis brominated ether derivative, TBBPA bis(2,3-dibromopropyl) ether or the butadiene styrene brominated copolymer alternatives.

D. Minor Changes Based Upon Stakeholder Input

Page #	Change
EXECUTIVE SUMMARY	
vi	An aquatic toxicity (¥) footnote was added to the hazard designation table for CASRN 1195978-93-8, CASRN 97416-84-7, and CASRN 21850-44-2.
CHAPTER 4	
4-33, 4-107, 4-126, 4-146	An aquatic toxicity (¥) footnote was added to the hazard designation table for CASRN 1195978-93-8, CASRN 97416-84-7, and CASRN 21850-44-2.
4-125, 4-145,	Sustainable Futures references were revised for polymers and cutoff values.

Page #	Change
4-164	
4-138 through 4-140, 4-157 through 4-160	The description for the Narcosis classes (neutral organics) were entered into the ECOSAR entries for CASRN 3194-55-6 and CASRN 97416-84-7.
4-79 through 4-84, 4-138 through 4-140	NES data quality entries have revised wording for CASRN 3194-55-6 and CASRN 97416-84-7.
4-79 through 4-86, 4-138 through 4-140	Ecotoxicity estimations using ECOSAR reference ECOSAR (with version number) instead of EPI for CASRN 3194-55-6 and CASRN 97416-84-7.
4-7, 4-79, 4-118, 4-138, 4-157	Acute Toxicity was changed to Acute Aquatic Toxicity in the hazard summary endpoint title.
4-87, 4-104	A 6-week dietary study in Japanese quail (MOEJ, 2009) and an avian toxicity hazard summary was entered into the hazard profile for HBCD.
4-110 through 4-117, 4-119, 4-121, 4-122, 4-124, 4-125	References to Chemtura's 2011 MSDS were reassigned to their primary sources - Dow studies for log K_{ow}, oral acute mammalian toxicity, eye irritation and dermal irritation endpoints.
4-129, 4-130, 4-143, 4-144	New submitted data for Pyroguard SR-130; melting point, boiling point, water solubility and bioaccumulation data was entered from Dai-ichi Kogyo Seiyaku Co., 2012.

II. General Comments on the Hazard Assessments and Conclusions

Comment: Two comments were received on the bioavailability of HBCD and its alternatives:

- The HBCD alternatives assessment uses "not bioavailable" based upon professional judgment as the primary reason for identification of a Low level of concern for many of the hazard endpoints assessed. Although the reviewer supports the use of professional judgment, there is some concern about using the argument of bioavailability as the sole justification for assigning low levels of concern. During Ecology's assessment of alternatives to the flame retardant decabromodiphenyl ether, the argument was consistently made that the flame retardant was not bioavailable, it was too large to pass through a cell membrane and therefore it should be assigned a low level of concern. Subsequent research has shown these arguments related to bioavailability to be incorrect. Therefore bioavailability should not be used as the sole justification for a low level of concern for large halogenated chemicals without documented evidence supporting the claim for both the chemical and its degradation products. The review recommends that EPA take a more conservative approach and identify at least a medium level of concern if bioavailability is the only argument available. In addition, the reviewer believes this issue could be better handled if EPA issued specific guidance on bioavailability as it pertains to an alternatives assessment. More information is provided on this topic in subsequent comments.

- In the Ecotoxicity section on pages 5-2 & 5-3, the following statements are made: "Measured data were available for the butadiene styrene brominated copolymer...The butadiene styrene brominated copolymer is not expected to be bioavailable." This section does summarize the data for the butadiene styrene brominated copolymer as is done with both HBCD and the other alternative. Although data is indicated as being available, it does not identify whether any ecotoxicity concerns exist for the butadiene styrene copolymer and appears to minimize potential ecotoxicity concerns based upon assumptions related to bioavailability and the resultant exposure potential. A summary of the ecotoxicity data for the butadiene styrene brominated copolymer should be added along with reasoning how this data led to the identified level of concern. The effects above 1,000 ppm should be explained.

Response: In general, DfE AA methodology supports the use of a conservative approach as presented by this comment. Although a comprehensive set of specific guidelines for the analysis of bioavailability currently does not exist, justification for the hypothesis of limited bioavailability is supported by professional judgment, analog data and guidance from the available polymer assessment literature for high molecular weight polymers like the alternative, butadiene styrene brominated copolymer (Boethling and Nabholz, 1997; U.S. EPA 2012).

Butadiene styrene brominated copolymer (CAS RN 1195978-93-8), with a MW of 60,000-160,000 daltons, should not be manufactured with lower MW components and does not have reactive functional groups. As previously stated, this polymer is regulated with a SNUR that was finalized in June 2013. Manufacture (or import) of the polymer requires notification to EPA except in these cases: (1) the MW of the polymer is in the range of 1,000 to 10,000 daltons, or (2) the MW of the polymer is ≥10,000 daltons and less than 5 percent of the particles are in the respirable range of 10 microns or less (U.S. EPA 2013). It is not expected to pass through biological membranes by passive transport, not expected to be water soluble and is expected to have high persistence. This polymer is not comparable to decabromodiphenyl ether, which is a discrete organic compound with a molecular weight of 959.2 daltons. Decabromodiphenyl ether is assessed differently under the AA criteria than this high molecular weight polymer alternative that is at least 60 times larger.

DfE assessment methodology does not have a set criterion with a specific MW considered completely non-bioavailable. Nor is there a solubility threshold below which substances should not be considered bioavailable. Due to the complexity of biological systems, in the absence of experimental data, trends and analogs are used to support these estimated designations.

Comment: In the Executive Summary, the statement is made: "The hazard profile of the butadiene styrene brominated copolymer (CAS RN 1195978-93-8) shows that this chemical is anticipated to be safer than HBCD." This statement could be taken as an endorsement of this flame retardant as an alternative to HBCD without acknowledging the limitations of the review.

The statement needs to be qualified to indicate 1) data on the butadiene styrene brominated copolymer is not complete, 2) degradation products were not considered and 3) other products that do not use flame retardants should be considered. Comments are made later in the summary that support and add to these concerns such as “Long-term fate of the two alternatives…is not well understood.” [and] “Under conditions where fire or incineration occurs, a brominated substance may contribute to brominated dioxin and furan formation…” Before any comment is made which could be construed as support for the “safer” alternative, the limitations of the study should be identified.

Response: The statement that the butadiene styrene brominated copolymer is anticipated to be safer than HBCD is clearly supported by the results of the hazard assessment. The assessments of HBCD and the copolymer are based on scientific review and did consider degradation. In the Executive Summary, we state that the copolymer is anticipated to be safer but that long term fate in the environment is not well understood; this description of uncertainty is made up front in the report to caveat the conclusion of safety in comparison to HBCD. In addition, a disclaimer has been added to the hazard comparison table explaining that “Variations in end-of-life processes or degradation and combustion by-products are discussed in the report but not addressed directly in the hazard profiles” to be more transparent. Since it is standard for DfE assessments to acknowledge where data are lacking by listing hazard designations in black italics, and providing justification of the estimations in the full hazard profile, no further qualifications should be needed. The DfE review approach is described in Chapter 4 of the report. Assessment of long term degradation is beyond the scope of the report. Stakeholders might have further criteria they wish to apply to the DfE results.

Comment: The following comments were received requesting clarification about the assessment of polymers and the approach to describing data quality using the example of data on K_{ow} from the hazard evaluation of the butadiene styrene brominated copolymer:

- On page 4-12, the statement is made: “Although experimental data for the polymer were identified using the literature search techniques discussed above in Section 4.2.1, in the absence of experimental data, estimates were performed using professional judgment as presented in the SF Polymer Assessment guidance….” The reviewer is not clear what is being said here. The sentence starts out indicating experimental data were identified but then proceeds to state that professional judgment was used. Does this sentence indicate that professional judgment was used in lieu of experimental data? If so, this directly contradicts EPA policy which indicates experimental data always supersedes professional judgment. If it is saying that professional judgment is used when experimental data is lacking, this is in line with EPA policy. The meaning of the sentence needs to be clarified. The reviewer supports EPA policy of using experimental data before professional judgment and believes this should be the policy used in this document.
- On page 4-104, the Log K_{ow} provided by a possible manufacturer is identified as “Approximately 2 (measured)”. This data was determined “Inadequate… not consistent with the structure of the material.” As log K_{ow} is used as a surrogate for bioaccumulation in the DfE methodology and the value is the result of a measured test, the test results should be requested and evaluated for scientific accuracy and whether the test method

> met current OECD requirements. If the test method and value are deemed adequate, this result is suggestive of serious problems with this alternative, should be considered in the final hazard assessment and should not be dismissed as irrelevant. In addition, DfE's method states that observed data is preferable to modeled data or professional judgment and the actions here are contrary to the DfE method. This section needs to be edited to agree with EPA policy on alternatives assessment.

Response: This sentence was revised based on the submitted comment, as shown below.

'Using the literature search techniques discussed above in Section 4.2.1 experimental data for the polymer were identified for many, but not all, of the endpoints. Estimations, using professional judgment as presented in the polymer assessment literature, were used in instances where there was an absence of experimental data (Boethling and Nabholz, 1997; U.S. EPA 2012).'

To address the remaining concerns in this comment, it is important to note that professional judgment is used to determine the quality of experimental data. Each study entry in the report, whether it is experimental, estimated or calculated, is evaluated with considerations for the applicability of the data, the study design and confidence in the data source. Important factors concerning the quality of the study are outlined in the data quality statements (instead of non-explanatory standardized scoring methods, such as Klimisch codes). As a screening assessment, inadequate publicly available data are also reported to assist users in understanding the limitations of the studies and provide transparency as to why available data may not be used in the assessment. Weight of evidence and analysis of the endpoints and/or hazard designations are written to demonstrate the multiple lines of evidence that were considered. Unfortunately, it is impossible to simply accept all experimental data as the gold standard because there is the possibility that the data are not applicable or are of poor quality.

For example, in the draft report the log K_{OW} value provided by a manufacturer for Butadiene styrene brominated copolymer was reported in an MSDS with no additional details to assess the quality of the study. Subsequently, additional study details were provided. The entry was updated using the newly acquired study details, as shown below:

Approximately 2 (Measured) According to Guideline OECD 117; calculated for residual solvent from an acute invertebrate toxicity study water accommodated fraction (WAF) sample	Dow, 2007a; Dow, 2012	Inadequate, the log K_{OW} is not consistent with the structure of the material and does not represent the polymeric substance. The sample is from an acute invertebrate toxicity study WAF; polymeric components not found in the WAF were not evaluated. Additionally, this study did not definitively identify the peak detected from the WAF using OECD 117 “Partition Coefficient (N-octanol/water), High Performance Liquid Chromatography (HPLC) Method”. Separate analysis of WAF identified the impurities to be solvent present in the sample (i.e. 1,2-dichloroethane).

The test method for this entry was deemed inadequate because the source of the sample is a WAF sample with impurities, and is therefore not representative of the polymer. Professional judgment initially indicated concern with this log K_{OW} value because it was inconsistent with the structure of the material; this class of polymers is usually insoluble in both water and octanol, and a log K_{OW} cannot be measured.

High quality observed data is preferable to modeled data or professional judgment based on DfE assessment methodology and therefore evaluation of data using the DfE criteria involves analysis of the quality of the data. When insufficient study details are available, as demonstrated in the original MSDS entry, concerns about the data are included in the data quality entry as shown in the draft report.

III. Comments on Report Content (excluding Hazard Assessments)

Comment: Numerous comments were received on transformation products of HBCD and its alternatives, specifically halogenated dioxins and furans:

- DfE takes an interesting approach by considering transformation products as part of risk and not as part of the hazard assessment. However, hazardous and persistent transformation products can be a discriminating criterion between substances based on the inherent chemistry of the substances for certain known end of life pathways. Formation of dioxins, etc from combustion of halogenated flame retardants are a good example. Potential transformation products should be moved to a more transparent place in the DfE assessment; perhaps even to the hazard table based on known end of life pathways. You do a nice job discussing this in the report but it is easy to miss because it is not part of the hazard table.

- The alternatives assessment does not emphasize sufficient concerns associated with the continued use of halogenated chemicals and long-term impacts of those chemicals. Specifically, EPA should include concerns earlier in the Executive Summary about the formation of halogenated dioxins and furans during combustion of products containing halogenated furans and the potential impact upon sensitive populations such as fire fighters. This includes EPS/XPS used extensively in the housing market. This assessment should suggest potential users consider alternatives to halogenated flame retardants due to these concerns. In addition, EPA should not identify halogenated flame retardants as ‘safer’ alternatives before mentioning these concerns, particularly for chemicals lacking important data on long-term impacts upon human health and the environment.
- The report makes only the briefest mention of “accidental fires” that will inevitably destroy buildings containing polystyrene insulation (Incineration, Section 2.2.3). Brominated flame-retardants generate highly toxic brominated dioxins and furans under these conditions, and firefighters bear the brunt of exposure to these products. Firefighters in San Francisco and elsewhere are dying at alarming rates from rare cancers that are almost certainly linked to these exposures. The DfE report does not address the toxicity of combustion products from the proposed alternative flame retardants.
- During fires, halogenated flame retardants can add to the acute toxicity of the fire effluents and produce other toxic by-products. Dioxins may be contributing to the increased levels of cancers in fire service professionals. The provisions that lead to the use of HBCD and TCPP should be reconsidered, especially in light of the intent statement (of the International Code Council codes, which includes providing safety to fire fighters during emergency operations).” Babrauskas et al, 2012. p 750.

Response: Edits have been made to the report to bring the existing discussion of transformation products in the report to the forefront for readers. A disclaimer has been added to the hazard summary table to explain that starting materials other than residuals in the commercial product have not been considered in this hazard assessment, nor have variations in end of life processes or combustion. The disclaimer also directs readers to the pyrolysis sections of the hazard profiles to learn about the elements of combustion for the alternatives. Text has been added to the report’s Executive Summary and Chapter 3 to explain that the combustion of flame retardants is too complex and variable to adequately include all potential combustion by-products resulting from incomplete combustion in the report. Additionally, text has been added to the report regarding the limits to the ability to predict polymer decomposition in the environment and that this is a larger issue for end of life disposal of plastics.

Comment: There are challenges with considering long term transformation products as beyond the scope of this report. It would be unfortunate if after receiving a good hazard profile as reported by DfE, it is eventually learned that problematic transformation products ARE formed. There is a lot of uncertainty associated with transformation products from new flame retardants. How can DfE make this uncertainty more transparent? In the section on persistence and transformation products, can DfE do a deeper analysis of short term and long term transformation products and known transformation products from known end of life pathways?

Response: The hazard profiles included in the report are intended to be used for a screening level assessment of the health and environmental hazards of the primary chemical alternatives. We have stated that the long-term degradation products are outside of the scope of the project and disclaimed on the hazard comparison table that "Variations in end-of-life processes or degradation and combustion by-products are discussed in the report but not addressed directly in the hazard profiles."

Comment: There is concern over what unintended conclusions may be made by a reader of Sections 2.3 and 2.3.1 of the report. The descriptions of possible – emphasis on possible – HBCD exposure and human exposures are not adequately balanced by descriptions of the realities of HBCD and its use in EPS and XPS. Many of the exposure statements explicitly mention EPS and XPS, or implicitly imply EPS and XPS because of the frequent use of these terms in nearby statements. Sections 2.3 and 2.3.1 present an extensive list of possible HBCD exposure and possible human exposures from the use of HBCD in EPS and XPS, but there are only two qualifying statements; one at the end of the first paragraph in Section 2.3.1, which states " …one study did indicate that the HBCD releases from insulation are minor in comparison to textile applications (European Commission 2008)." and the first sentence on page 2-12, which states: "Room temperature solid state diffusion of HBCD out of polystyrene foams would be expected to be very slow and very low." These qualifying statements can be easily overlooked or discounted.

Response: Because a quantitative exposure assessment is outside the scope of this project, it is necessary for DfE to qualitatively discuss all potential HBCD exposure scenarios from its use in EPS and XPS. Edits have been made to Section 2.3 of the report to bring qualifying statements to the forefront for the reader. Specifically, DfE has added a sentence in Section 2.3 about HBCD's low volatility in EPS and XPS, stating that has been undetectable in indoor air by certain standard test methods.

Comment: The statement "Consumers have the potential to be exposed while the flame retarded product is in use (e.g., releases to the air from flame retarded textiles in furniture) or when it is disposed of or incinerated." in Section 2.3 could be qualified, as consumer exposure while EPS and XPS are in use is very unlikely. The polystyrene foam product safety assessment demonstrates HBCD is retained in a stable polymer matrix during its service life (Plastics Europe Exiba PS Foam Product Safety Assessment 2013). In addition, HBCD is expected to remain immobile in landfills (Env. Canada 2011a). Recent studies on polystyrene foam containing HBCD also show that the foam can be incinerated in state of the art municipal solid waste incinerators with a very high destruction efficiency for HBCD (awaiting publication, end 2013).

Response: Information about the disposal of HBCD-containing XPS and EPS is located in the sections of the report on landfilling and incineration. The tendency of HBCD to remain immobile in landfills is currently described Section 2.2.2. A discussion of the new incineration technologies that have a very high destruction efficiency for HBCD has been added to Section 2.2.3 of the report.

Comment: Thermal cutting of XPS generally occurs only in production plants where fan extraction is supplied and any worker exposure is mitigated due to restricted access to the area during cutting. The statement regarding thermal cutting in the second paragraph of Section 2.3.1 could be revised to say: "Occupational HBCD exposure may also occur as a result of thermal cutting of EPS and XPS at production plants and construction sites. XPS is not typically thermally cut at production plants or construction sites."

Response: Edits have been made to explain that occupational safety measures are taken when thermal cutting of XPS occurs at production plants. Specifically, the following sentence was added in Section 2.3.1: "When XPS is cut at production plants, fan extraction is supplied and worker exposure is mitigated due to restricted access to the area during cutting."

Comment: The report cites the recent study by Zhang et al. showing that workers who cut polystyrene risk exposure to high doses of respirable particles that, moreover, are enriched in volatile flame retardant components (HBCD). Clearly, occupational exposure risks extend far beyond the site of flame retardant manufacturing or formulation. Equivalent studies of the proposed alternative flame retardants for polystyrene are needed in order to assess the likely exposures and to identify the brominated species that will be present.

Response: DfE alternatives assessments help industries choose safer chemicals by comparing chemicals under similar exposure scenarios. While exposure can occur at many points in the life cycle of a flame retardant chemical, it is not unusual for exposure data to be minimal or lacking for certain chemical-product combinations. This is especially true for alternatives that are new to the market.

Comment: The qualifying first sentence on page 2-12 could further explain that HBCD in EPS and XPS insulation has such a low volatility as be undetectable in indoor air by standard test methods (e.g. Ausschuss zur gesundheitlichen Bewertung von Bauprodukten – AgBB,version May 2010).

Response: A review of Ausschuss zur gesundheitlichen Bewertung von Bauprodukten – AgBB,version May 2010 identifies the reference as an evaluation procedure for volatile organic compound emissions from building products and did not find support in the document that HBCD in EPS and XPS insulation has such a low volatility as be undetectable in indoor air by standard test methods. Without a reference for this statement, this information cannot be included in the report.

Comment: The key recommendation is to add CAS 21850-44-2 TBBPA bis (dibromopropyl ether) to the alternatives assessment which was highlighted by several companies as an alternative to HBCD at the Persistent Organic Pollutant Review Committee side event October 14, 2013. This substance appears in the current draft of the EPA's draft alternatives assessment of decabromodiphenyl ether and so we hope this effort would not substantially delay issuance of a final report.

Response: DfE agrees that TBBPA bis (dibromopropyl ether) should be assessed in this report based on industry suggestions conveyed at the POPRC side meeting. A hazard profile for this chemical has been added to the report and the report has been updated where needed to incorporate this alternative fully into the narrative.

Comment: With regard to HBCD and its hazard profile, we note a large number of studies have been evaluated for both the Human Health and the Aquatic Toxicity endpoints and the EPA appears to have closely followed its DfE Alternatives Assessment Criteria for Hazard Evaluation. Unfortunately, because the performance of a quantitative exposure or risk assessment is outside the scope of the DfE, the reader is left largely to guess about relevance of these hazards to actual human exposures and concentrations in the environment.

However, as noted several times in the DfE report, there have been risk assessments performed by non-U.S. authorities. Those assessments do include quantitative estimates of exposure and characterization of the risks. The major uses of HBCD have been in foamed polystyrene products in both the U.S. and other regions such as Canada, the EU and Australia. Therefore it would be informative and appropriate to provide an indication of characterization of risk by those countries while we await the outcome of the EPA’s HBCD Work Plan assessment.

For example, in the Australian assessment it is stated: “Public exposure to HBCD in the environment resulting from release of HBCD into household dust is not of concern due to the estimated low-level exposure. The assessment indicates that the greatest risk is to the environment and workers handling HBCD, and this needs to be managed.”

The DfE also cites a recent final screening assessment report published by Environment Canada and Health Canada in November 2011. In reference to this assessment, the proposed Canadian Risk Management Approach for HBCD (published that same month) states:

> “The final screening assessment report concluded that HBCD is entering or may be entering the environment in a quantity or a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity.
>
> The final screening assessment report also concluded that HBCD meets the criteria for persistence and meets the criteria for bioaccumulation, as defined in the Persistence and Bioaccumulation Regulations made under CEPA 1999. The presence of HBCD in the environment results primarily from human activity.
>
> The final screening assessment report also concludes that HBCD is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. The highest upper-bounding estimated intake of HBCD is expected to be in infants from ingestion of human milk and

> the mouthing of consumer products. A comparison of these exposure estimates with the critical effect levels results in margins of exposure that are considered adequate to address uncertainties in the health effects and exposure databases."

In the absence of U.S. based risk characterization information, inclusion of risk characterizations by other countries on a chemical substance used in the same manner as covered by the EPA's DfE report would provide additional rationale regarding the need for the DfE assessment. It also provides additional context for small users and suppliers within the U.S. who may not be aware of relevant findings in other regions of the world. Including the outcomes of risk assessments from other major regions of the world should be considered for all future DfE chemical assessments.

Response: The goal of DfE alternative assessments is to compare hazard between substances for a similar functional use. Risk assessments conducted by other governments are identified in the report so that decision makers can also consider those risk-based conclusions until the U.S. completes its own risk assessment for a given chemical. U.S. EPA is conducting a risk assessment for HBCD (http://www.epa.gov/oppt/existingchemicals/pubs/2013wpractivities.html).

Comment: On page iv, paragraph #2 states: "Under conditions where fire or incineration occurs, a brominated substance may contribute to brominated dioxin and furan formation, and impact fire parameters such as increased smoke and carbon monoxide." When it comes to smoke and CO, relative to non-flame-retarded EPS, flame-retarded EPS gives less CO and much slower smoke development as reported by Rossi, M., Camino, G., & Luda, M. (2001). Characterisation of smoke in expanded polystyrene combustion. Polymer degradation and stability, 74(3), 507-512.

Response: A comparison of the combustion by-products of non-flame-retarded foam and flame-retarded foam is not evaluated in this report. Information about combustion by-products is included so that readers can consider exposure scenarios from the use of brominated flame retardants when making substitution decisions. A review of the Rossi et al. (2001) paper found that the authors discounted the decreased CO emissions and smoke development as insignificant. Because the reference is not adequate to significantly change the text of the report, the word "increased" has been removed in this paragraph.

Comment: Numerous comments were received on the end of life of polystyrene and its additives:

- Since polystyrene is also a persistent material that undergoes transport over long distances in the ocean before breaking down, any brominated additives will be transported as well before breaking down to unknown products. Fish, birds, and other fauna will ingest these materials.
- Polystyrene foam insulation will either be removed with demolition debris, left in place (typically below grade), recycled, or destroyed by fire. Reuse and/or recycling of polystyrene insulation is feasible but is not typically done in the U.S. except in specific

large-scale projects. Additives such as HBCD and dibutyltin maleate will ultimately escape into the environment, while the proposed polymeric flame retardant will break down into unknown products that may be significantly more toxic than the breakdown products of polystyrene itself.
- Dibutyltin maleate will hydrolyze in the environment to highly toxic dibutyltin species, and these species are highly persistent. They are water-soluble and can enter the environment as leachate or through breakdown and dispersal of the polystyrene foam, as noted above.
- The summary table compares HBCD with the two proposed alternatives, showing their similarities and differences. The presence of toxic additives such as dibutyltin maleate is not considered in these comparisons.
- The Dow/Chemtura brominated polymeric flame retardant has a molecular weight range of 60,000 to 160,000, while containing less than 0.1% of species with molecular less than 1,000. The EPA notes that high molecular weight polymers have limited bioavailability, so they are not expected to exhibit any biological activity. The polymer is highly resistant to biodegradation, but exposure to UV light results in significant release of inorganic bromide. Degradation in the environment is expected to be very slow, but wide dispersal in the environment is likely both through land-filling and through improper disposal of construction materials or demolition debris. The specific effects of flame-retarded polystyrene foam particles in the environment (including the oceans) are unknown.
- On page 2-7, the statement is made: "The formulations of stabilizers in the literature ranged from 0.1 to 30 weight percent…." This statement identifies another potential problem with the use of EPS/XPS foams that is not addressed in the alternatives assessment, i.e. the toxicity of stabilizers that can comprise as much as 30 weight percent of the final foam. Several of the stabilizers identified, for example epoxy derivatives, metals, organotins, acrylic binders, etc. may have specific toxicity concerns associated with their use. The reviewer is not recommending that the scope of the alternatives assessment be expanded to include these chemicals but is recommending that this issue be added to the Executive Summary and other appropriate locations as a factor that should be considered before EPS/XPS resins are selected for use.

Response: While a material's end of life is an important factor to consider when selecting products, the purposes of this assessment are to: (1) identify viable alternatives for HBCD in EPS and XPS; (2) evaluate the human health and environmental profiles of HBCD and its alternatives; and (3) inform decision making as organizations choose safer alternatives to HBCD. Therefore, the end of life of polystyrene and its non-flame retardant additives (e.g., synergists and stabilizers) are outside of the scope of this report.

Comment: Numerous comments were received on the inclusion of alternative materials in Chapter 5 of the report:

- Perlite insulation does not require the addition of chemical flame retardants. Perlite insulation should have been considered as an alternative to HBCD. It is important in any alternatives assessment to consider the elimination of a toxic chemical without the necessity of replacing it with another, potentially hazardous material. This alternative appears viable as the statement is made: "It is most often used in roofs and walls, but can be used in all building applications, including floors …". As it is currently being used in similar applications, it should be considered as a preferable alternative to halogenated flame retardants and information considering the potential use of it and similar alternatives placed prominently in the Executive Summary.

- We applaud the inclusion of non-flame retarded EPS or XPS on page 5-9 in the list of alternatives as well as the inclusion of alternative materials altogether. A full assessment of alternatives for a particular flame retardant should assess the nonchemical approaches as well that may reduce multiple risks rather than offer a trade-off.
- Non-flame retarded EPS or XPS is discussed on page 5-9 of the report in the Alternative Materials section. This alternative which does not require the addition of chemical flame retardants should have been considered as a viable alternative to HBCD. It is important in any alternatives assessment to consider the elimination of a toxic chemical without the necessity of replacing it with another, potentially hazardous material. This alternative appears viable as the statement is made: "… in some countries, non-flame retarded EPS is used in ground or floor insulation below a concrete layer, or in wall cavities with thermal barriers …". As this alternative is already in use in other countries, it must be considered as a viable alternative to HBCD. It would be important to consider what flame retardants are used in the barrier and whether barriers could be established that do not require the addition of chemical flame retardants as has been found in other applications (mattresses, for example). The alternatives assessment should be expanded to include this as an alternative and EPA should consider this alternative as preferable to replacement of HBCD with another halogenated chemical.
- With the high aquatic toxicity of HBCD, the use of EPS and XPS below grade presents a potential for ground water pollution that has not been addressed. While the report estimates the alternatives to have low aquatic toxicity, the lack of data about breakdown products and their effects on the environment point to an area for improvement in this report. Given that below grade applications of foam insulation present no fire hazard, there is also reason to recommend that non-flame retarded foams be considered viable alternatives for such applications.

Response: Most DfE alternative assessments are focused on the identifying and evaluating the safety of Toxic Substances Control Act (TSCA) Work Plan chemicals and their chemical alternatives. DfE assessments are *not* materials comparison assessments, but instead characterize chemical hazards based on a full range of human health and environmental information. The evaluation of non-chemical approaches may require a life cycle assessment in addition to a hazard-based comparison. DfE's alternatives assessment approach is currently only designed for the latter. DfE will not conduct a full evaluation of XPS, EPS, or the alternative materials included in Chapter 5. Good product stewardship and monitoring of the substitute's behavior *in situ* may be needed to understand if unforeseen impacts of the material's use and to determine how materials are reclaimed at the end of product/building use. A number of other comments were related to break-down products of one alternative and were addressed earlier in this document.

Comment: On pages 5-4 through 5-6, the reviewer agrees with the importance of the [social considerations] issues included in this section; however, upon review of the section, the reviewer did not find any information related to HBCD and the alternatives relevant to these discussions. The issues of worker health and safety, environmental justice, etc. were explained but no information was provided on whether HBCD and the alternatives had any relevant impact to these considerations. There was no information relevant to HBCD and its alternatives from these perspectives. If EPA has no information on these topics relevant to the discussion, it should be clearly stated. Regardless some statement should be made concerning data EPA has collected on these issues relevant to HBCD and its alternatives.

Response: The section on social considerations in Section 5.1.2 of the report is included as a resource for decision makers considering substitutes for HBCD. The narrative presented is intended to facilitate a substitution decision within the context of a company's specific use scenario and was not intended to provide specific information HBCD. More detailed information on exposure to HBCD from occupational and consumer perspectives is included in Chapter 2 of the report.

Comment: Two comments were received suggesting the addition of a table summarizing alternative materials in the report:

- On page iv, the statement is made: "The report does not assess these materials, does not compare them to EPS or XPS, and does not assess flame retardancy needs for these materials." This statement is not completely true. Chapter 5 does include information on whether or not certain alternatives require flame retardants among other information. For example, on page 5-10, the statement is made: "Cementitious foam does not require a flame retardant (Healthy Building Network 2011)." In addition as indicated in a general comment, the reviewer recommends that EPA add a table to the Results section of the Executive Summary that identifies EPS/XPS and various alternatives while identifying important information such as "Currently Used", "Flame Retardants needed", etc. This information would be important to potential users of EPS/XPS foam to show that there may be alternatives that do not require the use of potentially toxic flame retardants while maintaining fire safety and which would potentially have a much lower long-term impact upon human health and the environment.

  Later on page 1-3 of the report, the statement is made that other studies included "… both flame retardant alternatives as well as alternative forms of insulation to the use of HBCD in building insulation." The reviewer strongly recommends that this also be an objective of the EPA alternatives assessment and, as indicated in other comments, information be included on alternatives to EPS/XPS that do not require the use of potentially toxic flame retardants.

- This alternatives assessment does not emphasize in the Executive Summary and elsewhere in the document that alternatives to polystyrene foam exist that either do not require the addition of flame retardants or use substantially smaller amounts of flame retardants. It is clear this assessment is not evaluating those alternatives but if alternatives provide the same or similar function as EPS/XPS, they should be indicated as an option

> worthy of consideration. Section 5.2 on Alternative Materials lists several viable alternatives that should be considered in lieu of polystyrene with substantial amounts of halogenated flame retardants. For example, perlite insulation appears to be a viable alternative to EPS and XPS. The reviewer recommends the addition of a table that lists EPS/XPS, alternatives and important considerations such as whether it is currently used in similar applications, does it contain flame retardants and particularly halogenated flame retardants, level of protection provided, etc. EPA should make it clear it is not making any recommendation but providing information for users' consideration. This information would be very useful to companies considering EPS/XPS containing halogenated flame retardants and present alternatives that may have a lower long-term impact upon human health and the environment.

Response: The inclusion of information on alternative materials in the report is intended to provide a general overview of materials that may be used as substitutes for EPS and XPS rigid foam containing HBCD. As a commenter points out, the report does include information on whether or not certain alternatives require flame retardants; however, this is not done for all of the alternative materials discussed in the report, so the narrative has been updated to acknowledge this. A life-cycle assessment would be needed in order to consistently and accurately compare the alternative materials referenced in the report. Such an assessment is beyond the scope of this report, and the published information identified does not consistently provide the comparable information necessary to develop the table suggested by the commenter.

Comment: On page 2-1, the statement is made: "… the volume of HBCD manufactured or imported in the U.S. was claimed confidential and cannot be described in this report." The reviewer recognizes that an argument could be made to keep the manufacturers, locations and individual contributions to HBCD manufacture confidential but does not agree that the gross amounts manufactured or imported into the U.S. should be kept confidential. The reviewer recommends that EPA review the confidentiality request and deny it as important information on potential exposure of humans and the environment to an acknowledge PBT, i.e., HBCD. Once the confidentiality request is denied, this information should be included in the report.

Response: The Chemical Data Reporting (CDR) rule, formerly known as Inventory Update Reporting (IUR) rule, requires manufacturers and importers to provide EPA with information on the production and use of chemicals in commerce in large quantities. CDR allows submitters to designate individual CDR data elements (e.g., production volume) as confidential business information (CBI). For the 2006 IUR, EPA only publically reported nationally aggregated production volumes, and did not report individual production volumes for any chemicals. However, for the 2012 CDR, EPA chose to make additional data publicly available by reporting both individual and aggregated production volumes, where possible, while still protecting CBI claims. In instances where no production volumes reported for a chemical were claimed as CBI, the public CDR database includes specific values for individual and aggregated production volumes for that chemical. However, if most or all production volumes reported for a given chemical were claimed as CBI, the individual CBI production volumes were not reported and, depending on the number of individual sites, aggregated production volumes were reported as ranges or were withheld. For many chemicals, the new reporting rules resulted in an increase in publicly available information. However, the small number of submitters that reported information for HBCD all claimed individual production volumes CBI, resulting in a withheld national production volume in the public database.

Comment: On page 2-6, the statement is made: "To manufacture XPS, polystyrene resin granules and additives, including blowing agents (typically hydrofluorocarbons (HFCs)) and flame retardants (i.e., HBCD), are mixed in an extruder." Given potential toxicity concerns that are surfacing with HFCs, this statement identifies a further toxicity concern with the use of XPS. It should be noted in any information identifying unreviewed toxicity concerns associated with XPS.

Response: The reference to HFCs in Chapter 2 of the report is provided to help readers understand the manufacturing process behind XPS production. Because the scope of this alternatives assessment focuses on identifying, evaluating, and informing decision-making about HBCD and its alternatives, an analysis of XPS toxicity is outside of the scope of this report.

Comment: Section 3.1.2 identifies regulations and methodology for requiring and testing flame retardants. California regulations have been a driver for the use of flame retardants. Recently California changed its flame retardancy requirements through updating TB 117-2013 (http://gov.ca.gov/news.php?id=18301). This change should be reflected in this alternatives assessment and it would be appropriate to indicate the impact the change might have upon the continued use of flame retardants.

Response: The changes to the California's TB 117-2013 are not relevant to building insulation. TB 117-2013 is a standard that defines the requirements, test procedure, and apparatus for testing the smolder resistance of materials used in upholstered furniture. For information about DfE's work with flame retardants in furniture, please visit http://www.epa.gov/dfe/pubs/projects/flameret/about.htm. ASTM E84 is the overarching flammability test for building materials in the U.S.

Comment: On page 5-1, the statement is made: "There are five general attributes evaluated in this assessment that can inform decision-making about the potential hazards associated with chemical alternatives: (1) human health hazard, (2) ecotoxicity, (3) persistence, (4) bioaccumulation potential, and (5) exposure potential." This statement is incorrect. There are only four attributes to be considered as part of a hazard evaluation, i.e. (1) human health hazard, (2) ecotoxicity, (3) persistence and (4) bioaccumulation potential. The fifth attribute identified above (exposure potential) is not part of a hazard evaluation but part of a risk assessment. Risk is a function of hazard and exposure. Therefore any reference to exposure in this hazard assessment section is inappropriate and must be removed. If EPA wishes to consider the risk associated with an alternative, it must do so in a Risk Evaluation section and must not attempt to confuse and mitigate any hazard concerns with exposure considerations. In addition, any risk evaluation must consider the full life cycle of exposure potential include manufacture, transport, storage, accidental release, use, end-of-life, etc.

As stated previously, the section on exposure potential on pages 5-3 and 5-4 is inappropriate for a section on hazard assessment but is more appropriate for a section on risk assessment. Risk is a function of hazard and exposure. This section considers solely the hazard concerns associated with HBCD and the two evaluated alternatives. If exposure potential is to be considered, it must be included in a section dealing with risk assessment. Remove Exposure Potential from the Hazard Assessment Section. If EPA wishes to consider exposure, it must do so in a section labeled Risk Assessment. In addition, the statement is made: "The DfE alternatives assessment assumes exposure scenarios to chemicals and their alternatives within a functional use class are roughly equivalent." The reviewer agrees with this assumption. The assumption, however, emphases the importance of excluding exposure from further consideration and indicates that previous statements about exposure impacts affecting toxicity are inappropriate and should be eliminated from the document.

Response: Exposure potential is considered a part of a hazard evaluation because it captures the intrinsic properties of chemical substitutes, including physicochemical properties, persistence and bioaccumulation. Under this approach, potential hazards associated with the health and environmental profiles in this report become the key variables and sources of distinguishing characteristics. For this reason, it is appropriate to include exposure potential, which encompasses environmental fate and transport based on persistence, bioaccumulation, and physical properties, in Chapter 5 of the report. Factors that can significantly change the exposure parameters of a substance (e.g., use of additive versus reactive flame retardants) are also important elements of a chemical's exposure potential.

Comment: On page 5-2, the statement is made: "There is also a lack of data to determine if TBBPA might be a degradation product of TBBPA- bis brominated ether derivative." Although technically true, it is not unreasonable to conclude that TBBPA could be a degradation product of the polymer. As a conservative estimate, TBBPA should assumed to be a degradation product until scientifically valid data on alternative degradation products are provided. This assumption should be included in the overall evaluation of the TBBPA containing polymer.

On the following page, the statement is made: "TBBPA-bis brominated ether derivative could theoretically release TBBPA, however, no experimental studies describing this degradation pathway were found." This statement does not make it clear what degradation products were identified and the potential impact those degradation products have upon persistence. If no studies are available, it is appropriate to consider TBBPA as a potential degradation product until scientifically valid data on alternative degradation products are provided.

Response: In assessing chemicals, DfE considers known or likely degradation products. Also assessing theoretical degradation products is likely to yield overly conservative assessments in this case. Possible release of TBBPA from substances such as TBBPA-bis brominated ether derivative is described in the report and can be considered by the user in their decision analysis. The following statement has been added to the entry on degradation products:

> "**Metabolites, Degradates and Transformation Products:** None identified; although this compound contains a TBBPA backbone, degradation of this compound to TBBPA has not been demonstrated in a published study. The hazards of the theoretical degradation products were not considered in this hazard assessment."

Users wishing to make conservative assessments could overlay the DfE hazard profile for TBBPA with the profile for TBBPA-bis brominated ether derivative or TBBPA bis(2,3-dibromopropyl) ether. Doing so identifies High hazard for aquatic toxicity and developmental toxicity of TBBPA. In turn potential degradation of TBBPA to BPA is possible under certain scenarios. Overlaying the DfE hazard profile for BPA would then need to be considered; this changes reproductive toxicity, skin sensitization and dermal irritation to measured Moderate. BPA is neither persistent nor likely to bioaccumulate. This demonstrates the shifting in hazard profile by considering different degradants. The assessment maintains likely persistence of the TBBPA based flame retardants in this assessment because they are not expected to degrade. Long term degradation products are beyond the scope of the DfE hazard assessment.

Comment: On page 5-4, the statement is made: "Since both of the alternatives in this report are new to the market, environmental monitoring or biomonitoring information are not available to inform this assessment. The polymer was commenced in 2011; the TBBPA derivative was probably only available in small quantities in Japan in 2013 based on communication with a Japanese manufacturer." It is not clear to the reviewer what is meant by the statement "The polymer was commenced in 2011." Which polymer does this refer to? The previous sentence states "Since both of the alternatives…", it is not clear which polymer the sentence refers to.

Response: Polymer refers to the butadiene styrene brominated copolymer; this has been clarified in the text of page 5-4. The term "commenced" refers to the production of a substance for commercial purposes after notification to EPA under the PMN program. 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. Because DfE alternatives assessments consider substances regardless of TSCA Inventory status, TSCA status has been removed from the report.

Comment: The discussion on page 5-9 about polyisocyanurate foams should include reference to emerging concerns about the use of chlorinated phosphate flame retardants as it is relevant to the viability of this alternative. TCPP, for example, is harmful to aquatic organisms and identified by California EPA as a carcinogen and placed upon their Prop 65 list of toxic chemicals.

Response: EPA is continuing implementation of its TSCA Work Plan and Action Plan efforts by beginning assessments on 23 chemicals in 2013, including 20 flame retardant chemicals. EPA will conduct full risk assessments on four flame retardant chemicals, as part of structurally similar groups. The three chemicals included in the Chlorinated Phosphate Esters Group are TCEP, TDCPP, and TCPP. These three substances are also being assessed in DfE's Furniture Flame Retardancy Report update (http://www.epa.gov/dfe/pubs/projects/flameret/about.htm). TDCPP (CASRN 13674-87-8) is identified on the Prop 65 list because it is known to the state of

California to cause cancer; TCPP (CASRN 13674-84-5) is a separate substance that is not identified on the Prop 65 list.

Comment: We are concerned that the chemicals identified in this alternatives assessment, as assessed by the Partnership, do not meet the criteria stated in the assessment itself. On page 2-4, the report states, “Alternatives to HBCD in EPS and XPS foam must be able to meet fire safety and other regulatory requirements while avoiding negative impacts on human health and the environment, maintaining the thermal and physical properties of the material, being compatible with manufacturing process, and being economically viable.” There are multiple instances in the report that note unknown hazards of the alternatives such as “The polymer is not expected to be bioavailable due to its very large size; long-term breakdown products are unknown” (page 5-4). When outcomes and impacts are unknown, there is no assurance that they will avoid negative impacts.

Response: Selection of the chemicals included in this report was not based upon the desired characteristics of an ideal flame retardant but rather on the likelihood that the chemical will be used in EPS or XPS foam insulation. The chemicals were chosen in this way so that product formulators can use the information provided in this report to select the safest flame retarding solution. Many of the chemicals evaluated in this alternatives assessment do not have empirical hazard data. 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. However, the absence of data should not prevent action being taken to promote the use of safer alternatives. The identification of data gaps, as done in this report, can encourage the development of future studies that can be used to inform decision making or product stewardship.

Comment: We suggest that long-term degradation products be included in the scope of the assessment, as they are an important element in assessing the avoidance of negative impacts as has been demonstrated by the history of other products. “Long-term degradation products, though beyond the scope of this assessment, are also important to consider as they might be more toxic, bioaccumulative or persistent (PBT) than the parent compound” (page 5-3).

Response: The challenge with assessing long-term degradation products is that the persistent degradation substances are difficult to predict and are not well understood through short-term experimental testing. The parent substances may behave differently than expected in environmental conditions, thus making the behavior of their degradation product unpredictable. Stakeholders still must make decisions today to enable moving to safer substances and cannot wait for years or research to understand long term fate in the environment. Product stewardship and product reclamation at end of life can help manage unforeseen environmental fate.

Comment: On page 3-4, the report includes the statement that “ASTM E84 assesses the flame spread and smoke development of building materials by employing the Steiner Tunnel Test to compare the flame spread and smoke development against standard materials (Weil and Levchik 2009; Harscher 2011).” For foam plastics, however, ASTM E84 is not reported to be accurate and this should be noted in this report as it leads to a false conclusion about the fire safety benefit of flame retardants. In an advisory notice by Factory Mutual, now FM Global, it was stated "Flame spread ratings by ASTM E 84 tunnel tests should be disregarded for foam plastics" (Factory Mutual, 1974, 1978). In Section 1.4 of ASTM E 84 itself, it states, "testing of materials that melt, drip, or delaminate to such a degree that the continuity of the flame front is destroyed, results in low flame spread indices that do not relate directly to indices obtained by testing materials that remain in place." (ASTM, 2012)

A recent peer-reviewed paper states "Foams complying with the building code requirement (FSI ≥ 75) can produce hazardous fire conditions if used in violation of codes without a thermal barrier." Babrauskas et al, 2012. p 742. The paper concludes with this comment. "An overall benefit of adding flame retardant-chemicals to the foam has not been established. As discussed above, in the presence of a code-mandated thermal barrier, these chemicals do not provide additional benefit in reducing fire hazard.

Response: The goal of this report is to assess the potential human health and environmental hazards of HBCD and its alternatives for use in EPS and XPS foam; it is not to critically review fire tests or insulation materials, even if potential solutions may be in building material or technology innovation. These fire and building safety standards have limitations, and many flame retardants are designed to meet the test by reducing or slowing flame spread, not to ultimately prevent fire.

Editorial Changes

Various editorial changes were made to the report based on comments received during the public comment period. Table 1 summarizes the editorial changes made in response to the submitted comments, some of which are included in this document and others that were received informally and internally at EPA.

Table 1. List of Editorial Changes in Final Report in Response to Public Comments

Page #	Change
UNIVERSAL CHANGES	
ii, iii, iv, vi, 3-3, 3-6, 3-7, 3-11, 4-1, 4-9, 4-24, 4-33, 5-1, 5-2, 5-3, 5-4	Integration of TBBPA bis(2,3-dibromopropyl) ether into report narrative
EXECUTIVE SUMMARY	
ii	The following sentences were added to the second paragraph in the Executive Summary: "*The hazard designations for this alternative are based upon high MW formulations of the polymer, where all components have a MW >1,000.* *The polymer is regulated with a Significant New Use Rule that was finalized in June 2013. Manufacture (or import) of the polymer requires notification to EPA except in these cases: (1) the MW of the polymer is in the range of 1,000 to 10,000*

Page #	Change
	daltons, or (2) the MW of the polymer is ≥10,000 daltons and less than 5 percent of the particles are in the respirable range of 10 microns or less (U.S. EPA 2013).” This edit was made in response to a comment suggesting that this is important information for any manufacturer interested in using this alternative to HBCD.
iv	The following edits and additions were added to the Results section: *“Under conditions where fire or incineration occurs, a halogenated substance may contribute to halogenated dibenzodioxin and dibenzofuran formation, increase the generation of PAHs, and impact fire parameters such as smoke and carbon monoxide (Sidhu, Morgan et al. 2013). However, combustion reactions are complex and variable and make inclusion of combustion by-products in hazard assessment challenging. Both halogenated and non-halogenated flame retardants may yield other toxic by-products that would need to be compared, not only halogenated dioxins and furans. For these reasons, the pyrolysis transformation products are not assessed in this report.”* These edits were made in response to a comment requesting that potential transformation products be moved to a more transparent place in the document, as well as a comment flame-retarded EPS gives less CO and much slower smoke development relative to non-flame-retarded EPS.
iv	The following edit was made to the Results section: *“The report does not assess these materials, does not compare them to EPS or XPS, and does not assess flame retardancy needs for each of these materials.”* This edit was made in response to a comment indicating the Chapter 5 does include information on whether or not certain alternatives require flame retardants.
v	The following sentence was added: *“Although outside of the report scope, decision makers should also consider the human health and environmental impacts of insulation’s non-flame retardant additives (e.g., synergists and stabilizers) discussed in Chapter 2 of the report.”* This edit was made in response to a comment recommending that the toxicity of additives in polystyrene foam be added to the Executive Summary.
vi	The following caveat was added to the hazard summary table: *“Variations in end-of-life processes or degradation and combustion by-products are discussed in the report but not addressed directly in the hazard profiles.”* This edit was made in response to a comment requesting that potential transformation products be moved to a more transparent place in the document.
CHAPTER 2	
2-3	Clarified that performance requirements for EPS and XPS foam are for their use as *thermal* insulation.
2-3	Redefined water absorption as the percentage, by volume, of water remaining within the specimen after immersion in water for a specified time.
2-3	Clarified the definition of dimensional stability to state that it is measured by a material’s ability to maintain its original size, shape, and dimensions *in response to thermal and humid aging*.
2-11	Indicated that the Zhang study on thermal cutting was a small-scale simulation study.
CHAPTER 3	

Page #	Change
3-1	The following edits and additions were added to the Results section: "Some halogenated flame retardants will yield additional hazardous by-products (e.g., halogenated dioxins and furans) during incomplete combustion *(Sidhu, Morgan et al. 2013). This incomplete combustion is too complex and variable for all of its potential combustion by-products to be adequately included in this report. Both halogenated and non-halogenated flame retardants may yield other toxic by-products that have not been identified in this report.*" These edits were made in response to a comment requesting that potential transformation products be moved to a more transparent place in the document.
3-1, 3-2	The following sentence was added to paragraph three in Section 3.1: *"Although an analysis of fire safe assemblies that do not require additive flame retardants is outside of the scope of this report, Chapter 5 provides a general overview of alternative insulation materials and the applications in which they may be used."* This edit was made in response to a comment suggesting that the use of non-flame-retarded fire safe assemblies be mentioned after the risk-risk trade-off discussion.
3-2	Clarified that gas phase flame retardants and condensed phase flame retardants each use a different mechanism to achieve flame retardancy. This edit was made in response to a comment that the former text implied that all substances used as flame retardants act in both the gas phase and the condensed phase.
3-2	Provided more detail for the description of additive flame retardants: "Because they are not chemically bound to the polymer, additive flame retardants *have a potential to migrate* out of the polymer *under certain conditions* over time. *Therefore plastic formulators must take this into account to avoid* reducing polymer fire safety *or causing exposure* to humans and *releases to* the environment." These edits were made in response to a comment that the former text did not capture the complexity of flame retardant migration.
CHAPTER 4	
4-22	Discussion of EPA's ECOSAR^{TM} estimation program was revised to address the estimates and equations in more detail in the methodology section of Chapter 4.
4-33, 4-34, 4-107, 4-126, 4-146	The following caveat was added to the hazard summary table and the hazard profiles: *"Variations in end-of-life processes or degradation and combustion by-products are discussed in the report but not addressed directly in the hazard profiles."* This edit was made in response to a comment requesting that potential transformation products be moved to a more transparent place in the document.
4-35	Editorial changes made to Chemical Considerations section of HBCD hazard profile
4-33, 4-146 through 4-166	Addition of TBBPA bis(2,3-dibromopropyl) ether hazard profile
4-108, 4-125	Updated the Chemical Considerations section of the butadiene styrene brominated copolymer to reflect the current regulatory information: *"This substance is subject to a Significant New Use Rule (SNUR) that was finalized in June 2013 (78 Federal Register 38210). Manufacture (or import) of the polymer requires notification to EPA except in these cases: (1) the MW of the polymer is in the range of 1,000 to*

Page #	Change
	10,000 daltons, or (2) the MW of the polymer is ≥10,000 daltons and less than 5 percent of the particles are in the respirable range of 10 microns or less (EPA, 2013).”
CHAPTER 5	
5-2	The following revisions were made to the Human Health Hazard section: *“The substance is marketed as greater than 60,000 daltons with negligible low MW components. U.S. Environmental Protection Agency (EPA) has regulated this polymer with a Significant New Use Rule (SNUR) that was finalized in June 2013. Manufacture (or import) of the polymer requires notification to EPA except in these cases: (1) the MW of the polymer is in the range of 1,000 to 10,000 daltons, or (2) the MW of the polymer is ≥10,000 daltons and less than 5 percent of the particles are in the respirable range of 10 microns or less (U.S. EPA, 2013).”* This edit was made in response to a comment suggesting that this is important information for any manufacturer interested in using this alternative to HBCD.
5-4	Removed *“The polymer was commenced in 2011; the TBBPA derivative was probably only available in small quantities in Japan in 2013 based on communication with a Japanese manufacturer.”* These sentences were removed because DfE alternatives assessments consider substances regardless of TSCA Inventory status.
5-9	Removed *“XPS”* in the sentence about non-flame retarded foam available to the food and packaging industry based on XPS industry input.
5-9	Explained that U.S. manufacturers generally only supply building insulation containing flame retarded resins *to reduce fire hazards of EPS and XPS after manufacturing and during transportation and construction*, in addition to meeting fire safety and construction codes.

References

Boethling, Robert S. and Nabholz, J. Vincent “Environmental Assessment of Polymers under the U.S. Toxic Substances Control Act”, pp. 187-234, in Ecological Assessment of Polymers Strategies for Product Stewardship and Regulatory Programs, Hamilton, John D. and Sutcliffe, Roger (eds.), (1997) Van Nostrand Reinhold.

UNEP (2009). Summary of the proposal for the listing of hexabromocyclododecane (HBCDD) in Annex A to the Convention. Stockholm Convention on Persistent Organic Pollutants.

U.S. EPA (2012b). Interpretive Assistance Document for Assessment of Polymers. Sustainable Futures Summary Assessment. Washington, D.C.

U.S. EPA (2013). Significant New Use Rules on Certain Chemical Substances. 78 FR 38210-38223.