Public Comments Submitted on the Draft Final Report, "Flame Retardants Used in Flexible Polyurethane Foam: An Alternatives Assessment Update" – August 2015

DfE is releasing the final alternatives assessment update report on flame retardants used in flexible polyurethane foam. The report updates and supplements the previous 2005 alternatives assessment report developed by the DfE Furniture Flame Retardancy Partnership (FFRP), and was posted for a 60-day public comment period in June 2014. The report identifies flame retardant chemicals that are used to meet fire safety requirements for upholstered consumer products containing flexible polyurethane foam (FPUF), and updates flame retardant health and environmental profiles from the previous (2005) FFRP report with new information, using DfE's current criteria for identifying chemical hazards. The alternatives assessment update, in combination with CPSC's work, which may result in federal fire safety standards for upholstered furniture, should help to provide safer approaches to fire safe furniture, and offers a basis for informed decision-making by providing a detailed comparison of the potential human health and environmental effects of chemical alternatives. The final report will be posted on the DfE website, at http://www2.epa.gov/saferchoice/2014-update-report-flame-retardants-used-flexible-polyurethane-foam-publications. Additional information is available in the 2005 FFRP report (http://www2.epa.gov/saferchoice/environmental-profiles-chemical-flame-retardant-alternatives-low-density-polyurethane).

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 flame retardants in flexible polyurethane foam is one project in the broader scope of EPA's work on flame retardant chemicals. DfE has applied its alternatives assessment methodology to other flame retardant chemicals including decabromodiphenyl ether, hexabromocyclododecane in expanded polystyrene and extruded polystyrene foam, and flame retardants in printed circuit boards. As part of its chemical safety program, EPA has identified a Work Plan of chemicals for further assessment under the Toxic Substances Control Act. Information regarding workplan chemicals can be found here: http://www.epa.gov/oppt/existingchemicals/pubs/workplans.html.

DfE received comments from five entities on the updated draft report "Flame Retardants Used in Flexible Polyurethane Foam: An Alternatives Assessment Update." DfE greatly appreciates the effort of those who submitted comments.

Below, DfE presents and discusses the comments received on the draft assessment and indicates changes made to the text of the final report. Please note that the comments have at times been paraphrased, summarized and combined, as appropriate, for efficiency and readability; full versions are available in docket number EPA-HQ-OPPT-2014-0389 at www.regulations.gov.

Commenter: Clariant

Oligomeric phosphonate polyol

Comment: As the only producer of the oligomeric phosphonate polyol, Clariant suggests adding the product name Exolit OP 560 to the chemical substance name in the hazard tables, similar to what was done for V6 and proprietary products like Fyrol HF-5. This will make it easier for readers to recognize the substance.

Response: The preferred chemical identity information is the chemical name and CASRN when they are publicly available because this provides consistent and unambiguous chemical identity information for each substance. Consistency benefits a comparative hazard assessment. It also helps to keep the report as objective as possible so that there is not an appearance of EPA endorsing (or not) a particular company's product. The majority of substances are listed by their chemical name and CASRN.

The product name Exolit OP 560 is currently listed as a Trade Name in the 'Synonyms section' of the DfE AA profile for CASRN 363626-50-0 and readers are directed to this section in the Chemical column, as shown below. Product names and manufacturers may change more quickly than the report is updated, and therefore the chemical name for CASRN 363626-50-0 will remain as it is presented in the draft report.

Due to the proprietary natures of the new to market mixtures, their associated chemical names and CASRNs are not publicly available and the commercial names for these mixtures will remain in the summary hazard tables; however, the mixture components have been separated out similar to the Firemaster 550 entry. As noted in the comment, the new to market mixtures and V6 contain product names in the draft report. Because the identity of V6 is in the public domain, the trade name "V6" was removed from the hazard summary table for CASRN 38051-10-4, for consistency.

Chemical (for full chemical name and relevant trade names see the individual profiles in Section 4.8)	**CASRN**
Non-Halogenated Flame Retardant Alternatives continue	
Triphenyl phosphate (TPP)[†]	115-86-6
Tricresyl phosphate (TCP)[1]	1330-78-5
Isopropylated triphenyl phosphate (IPTPP)[†]	68937-41-7
Tris (p-t-butylphenyl) phosphate (TBPP)	78-33-1
Diethyl bis(2-hydroxyethyl)aminomethylphosphonate	2781-11-5
Oligomeric ethyl ethylene phosphate	184538-58-7
Oligomeric phosphonate polyol	363626-50-0

Commenter: Greg Howard

General

Comment: Pages 1-3 of the report states that the information included might be used to identify vPvB chemicals of concern under REACH. In addition to vPvB chemicals, the REACH regulations also refer to PBT chemicals as well as those with an "equivalent level of concern." The data in the FFR report may be useful in identifying substances in any of these categories.

Response: Text on page 1-3 was revised to include the identifications listed in this comment, as shown below:

"In addition, information in this report can be used to identify the Very Persistent Very Bioaccumulative chemicals, PBT chemicals, and those with an "equivalent level of concern" targeted under European Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) policy."

Comment: There is a reference on pages 1-2 to "section 0" that does not exist.

Response: The document was edited based on this comment.

NH-1 and HF-5

Comment: Include components of NH-1 and HF-5 on the hazard comparison table similar to what was done with Firemaster 550.

Response: The components of Emerald Innovation™ NH-1 and Fyrol™ HF-5 were added to the summary hazard comparison table, and the related hazard summary table footnote was revised.

Expandable graphite

Comment: Currently, hazard data is supplied for two washes that may be used in a commercial formulation (chromic acid and a confidential wash). The hazard for these washes is currently listed in a note and not in the table, making the hazard calls less comparable. A solution would be to include the washes as separate rows under Expandable graphite in the hazard comparison table to facilitate comparison.

Response: The DfE alternatives assessment (AA) evaluation methodology considers hazards for the residuals, impurities, byproducts, transformation products, degradation products and metabolites expected to be present in the chemicals, mixtures and blends being compared as alternatives. The hazards for the washes were considered and noted so that stakeholders are aware of the potential hazards to support informed decision making. At this time, the chemical alternative assessment profile for expandable graphite is focused on the chemical represented by CASRN 12777-87-6; the variations in manufacturing processes/washes will continue to be presented as a revised footnote. Adding new lines in the hazard summary table for the variations in manufacturing processes/washes will be considered for any future reports; however, DfE AA's current hazard summary tables typically list only the alternative chemical(s), mixture(s) and mixture component(s), and do not include process specific residuals.

Commenter: Chemtura

General

Comment: Request for deadline extension

Response: DfE agreed to receive additional comments via email after the comment period closing date of August 11, 2014 for docket EPA-HQ-OPPT-2014-0389. Three additional comments submitted by Robert Campbell of Great Lakes Solutions, a Chemtura business, were received on September 17, 2014, for the report, and are included in this document as Attachment 1.

TBB

Comment: The summary table found on page 2-2 does not appear to reflect the extent of toxicological and physical chemical information that Chemtura provided to DfE for the component identified as Benzoic Acid, 2, 3,4,5-tetrabromo-, 2-ethylhexyl ester (TBB CASRN 183658-27-7). A summary of the data we previously provided is provided. The tables should be amended with the relevant tables accordingly.

Response: The toxicology data submitted with the comment were captured in the draft assessment, with the exception of an eye irritation study and a 15-day chronic aquatic toxicity study in *Daphnia carinata*. The eye irritation study is now included, and changed the hazard designation from Low to Moderate. The daphnia study is also now included, and did not change the hazard designation of an estimated Low.

Most of the physical-chemical property data submitted by Chemtura will not be added, because the pure substance represented by CASRN 183658-27-7 was not measured in these studies.

The Environmental Fate and Transport section was updated to include the OECD 303A study, and the Bioaccumulation section was updated to include the OECD 305C study.

PROPERTY/ENDPOINT	DATA	REFERENCE	DATA QUALITY	PROPERTY/ENDPOINT
Water	**Aerobic Biodegradation**	>93% removal Test method: 303A: Activated Sludge Units - Simulation Test (Measured)	Submitted confidential study	Guideline study, submitted for a commercial mixture containing TBB. The substances did not biodegrade but showed removal (>93%) due to sorption to sludge.

PROPERTY/ENDPOINT	DATA	REFERENCE	DATA QUALITY	PROPERTY/ENDPOINT
	Fish BCF	BCFK edible tissue: 2.26 BCFK non-edible tissue: 2.70 BCFK whole fish: 2.47 According to OECD 305C in Trout (Measured)	Submitted confidential study	Guideline study, submitted for a commercial mixture containing TBB.

The other applicable experimental studies summarized in Attachment 1of the comment were included in the draft report. These studies do not change the Persistence or Bioaccumulation hazard designations. The summary hazard table was revised to improve clarity for Firemaster® 550 and the components' hazard designations.

IPTPP

Comment: Review the ECHA website and data set for IPTPP to check for discrepancies and to make sure all relevant data have been included regarding the mammalian toxicology, ecotoxicology and environmental fate. Also, review the PBT assessment for which ECHA has a different conclusion regarding persistence and bioaccumulation, when compared to the DfE profile.

Response: The ECHA website was consulted to confirm inclusion of relevant studies to the IPTPP profile. All reliable toxicology studies were captured in the draft assessment with the exception of an additional dermal sensitization study in mice that is negative for sensitization. The hazard designation is already Low based on a study in rabbits. The additional study in mice was added.

The physical/chemical properties entry for log K_{OW} and water solubility have multiple (4-5) entries with similar results as those reported in ECHA. Two entries were added for the ECHA results, as shown below. The ECHA environmental fate entries for IPTPP were reviewed and no new experimental values were identified.

PROPERTY/ENDPOINT	DATA	REFERENCE	DATA QUALITY
Water Solubility (mg/L)	0.367 mg/L (Measured) OECD 105; performed at 20°C	ECHA, 2013b	Data for commercial products, REOFOS 35 using a guideline study. Reported in a secondary source.
Log K_{ow}	4.92 to 5.17 (Measured)	ECHA, 2013b	Data for commercial products, Kronitex 50, Kronitex 100 and Kronitex 200. Reported in a secondary source.

Differences were noted between the ECHA PBT evaluations and the DfE AA hazard designations for IPTPP because the two sets of designations use different criteria and evaluation methods:

The ECHA website shows three PBT assessments for IPTPP. Two of the assessments state that the substance is not PBT / vPvB, because IPTPP does not meet the criteria for all three PBT benchmarks - Persistence, Bioaccumulation and Toxicity. One ECHA entry considers IPTPP to have Toxicity concern (T) but not Persistence (P/vP) or Bioaccumulation (B/vB) concern using Criteria based on Annex XIII of REACH.

The DfE alternatives assessment (AA) hazard designations, presented below, are based on DfE AA criteria. These DfE AA hazard designations are consistent with ECHA's PBT entry noting toxicity concern for both aquatic toxicity and reproductive toxicity. Additionally, the DfE Moderate persistence designation is in-line with ECHA evaluation of not P/vP.

Chemical	CASRN	Human Health Effects										Aquatic Toxicity		Environmental Fate	
		Acute Toxicity	Carcinogenicity	Genotoxicity	Reproductive	Developmental	Neurological	Repeated Dose	Skin Sensitization	Respiratory Sensitization	Eye Irritation	Dermal Irritation	Acute	Chronic	Persistence	Bioaccumulation
Isopropylated triphenyl phosphate (IPTPP)	68937-41-7	L	*M*	L	H	*H*	*H*	H	L		L	L	VH	VH	M	*H*

The estimated High Bioaccumulation hazard designation in the DfE report is based on estimated BAF values >1,000. DfE's criteria consider both BCF and BAF using the criteria presented below.

Bioaccumulation	Very High	High	Moderate	Low
BAF/BCF	> 5,000	5,000 – 1,000	<1,000 – 100	< 100
Log BAF/BCF	>3.7	3.7 – 3	<3 – 2	< 2

The ECHA bioaccumulation evidence consisted of BCF model data and read across to structural analog tricresyl phosphate. Tricresyl phosphate received a High Bioaccumulation hazard designation based on experimental BCF and BAF data in the DfE FFR report. The ECHA bioaccumulation conclusion used a geometric mean BCF value of 198.8773852 L/kg ww and a criteria cutoff value of BCF <2,000 (with no mention of BAF values).

Commenter: Lanxess

CAS# 13674-84-5 (Tris(2-chlor-1-methylethyl)phosphate) (TCPP):

Comment: An overview on the outcome of the EU Risk Assessment and all available data given in the transitional Annex XV report for REACH are available on the ECHA website. According to the EPA DfE, the most critical endpoints are Reproductive Toxicity/Fertility and Developmental Toxicity, which were designated as "High hazard." This designation is based on the result of a two-generation reproduction toxicity study in rats that resulted in a LOAEL of 99 mg/mg. This LOAEL is in line with the

EU Risk Assessment Report for TCPP and the Transitional Annex XV dossier for TCPP, which both concluded that TCPP should not be classified as a reproductive toxicant due to there being no evidence of adverse effects that were severe enough to trigger classification. Based on the EU judgment the High hazard designation seems to be overly conservative and not consistent with the actual hazard.

The classification as it is stated in the Transitional Annex XV report:
"Proposed classification for human health- An Annex XV proposing a harmonized classification and labelling for TCPP has been prepared by the rapporteur and submitted to ECHA, to be discussed by the Risk Assessment Committee (RAC) and the Socio-Economic Assessment Committee in due course. In this Annex XV Classification & Labeling (C&L) dossier the rapporteur proposes no classification for the harmonized classification endpoints (i.e., CMRs or respiratory sensitizer)."

In the EU Risk Assessment Report it is stated: *"In the two generation reproductive toxicity study with TCPP, an increase in oestrus cycle length and a decrease in uterus weight were observed in all dosed females in F0 generation and in high dose females in F1. The mean number of oestrus cycles was also increased in high dose animals of both generations. Effects were also noted on ovarian weights in all high dose females and pituitary weights in high dose females in F0 and all dosed females in F1. It is noted that all organ weight changes occurred in the absence of any histopathological changes, and it is accepted that uterine weight can fluctuate during the oestrus cycle. Therefore, the effects observed may be due to normal variation in cycling females. Based on the above, this is considered to be a borderline case between classification as Repro Cat 3, R62 and no classification for effects on fertility. In the same study, an increased number of runts was observed in all dose groups and a decrease in the mean number of pups delivered was observed in the mid dose group of F1 and the high dose groups of both generations. A decrease in pup weight was also noted during the lactation period. Pup mortality (PN1-4) was also increased in the low and high dose groups of F0 and in the high dose group of F1 (although the latter was mainly due to the loss of one litter of a single dam on PN4). Based on the above, it is possible that TCPP has an effect on the developing pups. Therefore, this is considered to be a borderline case between classification as Repro Cat 3, R63 and no classification for developmental toxicity..."*

Response: The data quality section for this study summary was edited to include that the uterine weight changes occurred in the absence of histopathological changes. EU 2008 notes that the estrus cycle state was not recorded at necropsy. EU 2008 also notes that uterine weight can fluctuate during the estrus cycle, and there is a possibility that the effects observed may be due to normal variation in uterus weight in cycling females. However, the LOAEL was determined to be 99 mg/kg-day based on uterine weight changes as a precautionary approach, because it cannot be ruled out that the effects on uterus weight were treatment related. The table in the EU 2008 document indicates that there are uterine weight effects at every dose, but does not report the severity of the change at any of the doses. In addition to female reproductive effects, the LOAEL for male reproductive toxicity is 293 mg/kg-day, with a NOAEL of 85 mg/kg-day for decreased seminal vesicle weight. The study summary will be edited to include this male reproductive effect. These LOAEL and NOAEL values cross the hazard criteria range of High to Moderate. Taken together, the reproductive effects in male and female F0 rats provide rationale for a High hazard designation.

Comment: The same observation can be made regarding the endpoint repeated dose toxicity. Again, the LOAEL/NOAEL could lead to a respective hazard category, but the effects observed are not severe enough to trigger classification, and therefore it is questionable that the "Moderate hazard" category would reflect the actual hazard.

Response: The hazard designation for Repeated Dose Effects is based on a NOAEL of 100 mg/kg-day (LOAEL = 1,000 mg/kg-day for increased mortality) identified in a 28-day oral exposure study in rats (Bayer, 1991c, as cited in EC, 2000; EU, 2008). DfE criteria values are tripled for chemicals evaluated in 28-day studies; there is uncertainty about where effects may occur given that the identified NOAEL (100 mg/kg-day) and LOAEL (1,000 mg/kg-day) bridges the Moderate (30 - 300 mg/kg-day) and Low (>300 mg/kg-day) hazard designation range; effects occurring within the Moderate range cannot be ruled out.

Comment: Neurotoxicity: A "Moderate hazard" category is designated by EPA DfE primarily based on structural alerts for organophosphate, whereas the *in vivo* studies which did not confirm the neurotoxicity hazard are mentioned, but no weight is given to these negative studies in the overall assessment. In addition, we would like to bring to your attention that for one of the *in vivo* studies (Sprague et al. 1981) a LOAEL is given for the study on delayed neurotoxicity that gives the impression in the document that neurotoxicity occurred in that study, whereas the LOAEL is actually related to systemic toxicity. In that study no neurotoxicity occurred, and therefore there is a NOAEL available (instead of a LOAEL) related to neurotoxicity.

Response: The Neurotoxicity hazard designation is based on a structural alert and an *in vitro* study. The *in vivo* studies were not designed to be comprehensive repeated dose neurotoxicity evaluations. There were no effects reported in the endpoints that the *in vivo* studies examined; however, other effects not evaluated for and those that might occur following longer exposure durations cannot be ruled out. There were no Functional Observational Battery assessments located for this substance. Due to this uncertainty, a Moderate hazard is warranted. The study description for Sprague et al., 1981 was revised to show a NOAEL = 13,200 mg/kg (highest dose tested) for the neurotoxicity endpoint.

Comment: Ecotoxicological studies: We disagree with the "High hazard" designation for chronic aquatic toxicity that EPA DfE based on estimated ChV values in fish (estimated for the phosphate esters ECOSAR class). An experimental NOEC for Daphnia magna indicated a Low hazard designation for mortality and reproduction, while the estimated ChV values fall within a low to moderate hazard range. Estimated ChV values for algae indicated a Moderate hazard designation. While experimental data for Daphnia suggests a Low hazard, there are no experimental chronic aquatic data available for fish and algae; therefore, it appears that an estimated "High hazard" designation was assigned to this endpoint. We feel the classification of "High hazard" is unjustified because:

1. Estimated results are considered non-reliable, as the substance is not well represented in ECOSAR v1.11.
2. Estimated values for fish and daphnia are in the same order of magnitude (NOEC 4.6 mg/L vs 2 mg/L). The experimental NOEC for daphnia is however one order of magnitude higher (32 mg/L).
3. A chronic value for algae is available (Desjardins 2004) 72h-NOEC 13 mg/L, EC10 42 mg/L.

Response: The ECHA website was consulted to confirm inclusion of relevant studies to the TCPP profile.

The hazard designation was changed from High to Moderate. The hazard statement summary was revised:

> **MODERATE: Based on experimental aquatic toxicity values for algae and estimated ChV values in fish, daphnia, and algae. An estimated chronic aquatic toxicity value derived using an acute-to-chronic ratio (ACR) for the phosphate esters class and was applied to the available experimental acute data for this chemical and indicated a Moderate hazard. An experimental NOEC for *Daphnia magna* indicated a Low hazard designation for mortality and reproduction, while estimated ChV values (Esters class) range from Low to High hazard range. There were no experimental chronic aquatic toxicity data located for fish. There is potential concern based on estimates and the uncertainty due to the lack of experimental data; therefore a Moderate hazard designation was assigned.**

CAS# 115-86-6 (Triphenyl phosphate) (TPP):

Comment: The "High hazard'" designation assigned by EPA DfE for Repeated Dose is triggered by the LOAEL/NOAEL, but the effects observed would not be severe enough to trigger classification in Europe, therefore it is debatable whether the "High hazard" designation reflects the actual hazard. As mentioned in the rationale, only one (23.5 mg/kg) of the two NOAELs would trigger "High hazard"; the other NOAEL (70 mg/kg) would trigger the next lower category. The reason for the different NOAELs is probably due to the variance in dose levels in the respective studies, instead of differences of toxicological relevance. In the study with the NOAEL of 23.5 mg/kg, the LOAEL was 161.4 mg/kg, and in the second study with a NOAEL of 70 mg/kg, the LOAEL was 350 mg/kg; with the large variance of doses in the first study, the real threshold could be much higher than 23.5 mg/kg, and would then be in line with the NOAEL of the second study.

Response: A LOAEL and NOAEL of 161.4 mg/kg-day and 23.5 mg/kg-day, respectively, for decreased body weight were identified for this study in ECHA, 2012. DfE criteria are for 90-day repeated dose studies. Criteria values are tripled for chemicals evaluated in 28-day studies. The NOAEL and LOAEL bridges the High (< 30 mg/kg-day) and Moderate (30 - 300 mg/kg-day) hazard designation range; effects occurring within the High range cannot be ruled out. Though the effects observed may not trigger classification in Europe, the toxicity values identified in ECHA, when applied to DfE criteria and using a conservative approach, warrant a High hazard designation for this endpoint.

Commenter: Natural Resources Defense Council (NRDC)

Expandable Graphite

Comment: It is unclear whether residuals from the chemical washes might be present as an additive along with the graphite flame retardant in the foam. This point should be clarified (*Comment 3, p. 3*).

Response: The footnote was updated to include this information as shown, below (added words are underlined):

♦ Expandable graphite commercial formulations are prepared using chemical washes which may be present in the final product as residues. The associated hazards vary depending on the specific wash chemicals used, and as a result, the hazards may change by manufacturer. One confidential wash has additional hazard concern as follows, based on experimental data: HIGH-Acute Toxicity, Eye Irritation, Dermal irritation. Other manufacturers may use a wash that contains chromic acid (CASRN 7738-94-5) with additional hazard concerns as follows, based on experimental data: HIGH-Acute Toxicity, Carcinogenicity, Genotoxicity, Reproductive, Repeated dose, Skin sensitization, Respiratory sensitization, Eye Irritation, Dermal irritation.

General

Comment: The report should clearly indicate which flame retardants do NOT have preferable profiles, based on the hazard assessment.

Response: The objective of DfE's Alternatives Assessment Program is to provide comparative hazard information that allows users to make informed choices and identify safer chemicals, rather than to identify chemicals of concern. EPA's workplan process under the Toxic Substances Control Act (TSCA) prioritizes chemicals that may be of concern for risk assessment and risk management, if needed.

Comment: Rather than concluding that the chemicals with significant data gaps indicate lower levels of concern than the other profiles in the report, the conclusion should more appropriately be that adequate data are needed to address these gaps. Only once these data are available can a hazard determination be established with any confidence…All of the chemicals indicated as "potentially preferable" are missing empirical data for at least half of the human health hazard endpoints, and none have any data available on potential endocrine disruption activity. We are very concerned that there are no data available for endocrine disruption for the entire category of flame retardants assigned lower levels of hazard in the other human health endpoints. This experience indicates that when there are significant data gaps associated with a chemical, caution is warranted and more study is needed before indicating that the chemical may be preferable.

Response: The goal of a DfE alternatives assessment (AA) is to provide access to the best information available—including both empirical and modeled data—that allows users to make informed choices and identify safer chemicals. To achieve this goal, EPA pragmatically fills data gaps, because of the potential consequences when an "inadequate data" designation is presented in a comparative chemical hazard assessment. The absence of test data may be assumed by some readers to be an indication of no concern (i.e., they may incorrectly believe that no data is equivalent to the lack of potential hazard or risk). This could result in unintended consequences as a result of uninformed alternative selection. Also, readers may avoid or disqualify inadequately characterized alternatives to stay with those of known hazards. Most chemical alternatives in this report have inadequate experimental data for some endpoints. If alternatives with complete data sets are the only alternatives considered for substitution, there would be few replacement options--with limited opportunities to provide incremental improvements in terms of reduced hazards, and could steer users to better characterized but less safe alternatives.

In the absence of primary or secondary data, hazard designations for DfE AAs are based on (1) Quantitative Structure Activity Relationships (QSAR)-based estimations from the EPA New Chemical

Program's predictive methods; (2) analog data; (3) class-based assignments from the EPA Chemical Categories document (structural alerts) and (4) expert judgment by EPA subject matter experts. The estimated designations are presented as black italics to explicitly indicate the lower level of confidence in hazard designations based on estimates versus those based on high-quality experimental studies. DfE follows a conservative approach when assigning hazard designations for endpoints based on estimated values, and especially when there are no data. For example, when evaluating an alternative with no experimental data, structural activity alert, nor satisfactory analog for a particular endpoint, a designation of Moderate is applied as a default value, when there is an absence of data suggesting High and an absence of data supporting Low (i.e., a lack of negative studies or weak SAR conclusions). This conservative approach to providing comparative hazard designations can facilitate opportunities for manufacturers to provide additional data.

Comment: The report should highlight previous DfE findings that flame retardants can contribute to the formation of toxic combustion by-products.

DfE's report, "Flame Retardant Alternatives for Hexabromocyclododecane," gives some general information about flame retardants and notes that some flame retardants "…contribute to hazardous by-products from a smoldering or fully engaged fire (e.g., carbon monoxide and smoke (Nelson 1998; Peck 2011)) when inhibiting combustion. Some halogenated flame retardants will yield additional hazardous by-products (e.g., halogenated dioxins and furans) during incomplete combustion (Sidhu, Morgan et al. 2013)." New studies add to the body of evidence that halogenated flame retardants, including polymerics, can increase fire toxicity. In its current evaluation of flame retardants in flexible polyurethane foam, DfE should acknowledge that the toxic, combustion-related by-products associated with flame retardants are also a health concern for upholstered consumer product uses, even if the hazards of combustion by-products are not evaluated.

Response: Edits were made to the report to further acknowledge the possible formation of transformation products from flame retardant combustion. The disclaimer in the hazard summary table and individual hazard profiles has been edited to explain that variations in end-of-life processes or degradation and combustion by-products are not addressed directly in the hazard profiles. Additionally, text was added to the report's Introduction and Section 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.

Comment: The inadequacy of the aquatic toxicity models for evaluating the poorly soluble flame retardants (TBB, TBPH, APP, and expandable graphite) is noted, yet Low hazard designations are still assigned for these endpoints. The model deficiencies are serious enough to make the predictions unreliable, requiring that hazard ratings not be assigned for the acute or chronic aquatic toxicity endpoints for these particular chemicals. As DfE has done for the respiratory sensitization endpoints, these endpoints should be left blank when data are not available and an appropriate model is not available. A "Low" rating should only be assigned when adequate data indicate a lack of aquatic toxicity, either empirical data or output from a validated model. Designation of a "Low" aquatic toxicity in the absence of such data and with chemicals known to fall outside of the model's predictive range is misleading. DfE should further develop its models to be able to account for and predict aquatic toxicity associated with poorly soluble substances. (*Comment 7, p. 5*)

Response: Difficulty in evaluating the aquatic toxicity hazards of poorly soluble substances is a weakness that is acknowledged in the report. EPA's Office of Pollution Prevention and Toxics (OPPT) is considering options to address this issue, and to that end recently hosted a technical workshop on this issue (see this URL for agenda and presentations from the workshop held on September 10-11, 2014: http://www.cvent.com/events/meeting-support-for-risk-assessment-division-rad-workshop-on-ecotoxicity-testing-of-difficult-to-tes/event-summary-383b42341aef47b9b6725dc36a2b1dd1.aspx). There were many items discussed at the workshop, including:

- Test guideline water solubility values (measured in distilled/de-ionized water) versus "functional" water solubility (i.e., measured either in the aquatic toxicity test vessels or closer to natural water). For difficult-to-test substances, these two water solubility values are often different.
- Analytical difficulties (both in terms of low concentrations as well as adsorption of the test substance onto particulates, inanimate surfaces, etc.) that result in high recovery losses, which confound both monitoring and toxicity test results.
- The possibility that if difficult-to-test substances are released to water, they may partition to sediments (so sediment monitoring and/or toxicity testing may be the appropriate environmental medium to evaluate).
- Whether the test substance is in the water column, in sediment – what is the bioavailability to biota?

Comment: Low bioavailability in and of itself is not sufficient to establish low hazard. DfE should consult with other EPA scientists on the appropriateness of this metric, given that other polymeric flame retardants with MW>1,000 have been found to contaminate biological specimens such as gull's eggs. Suggest creating more extensive guidance about how to consider bioavailability in combination with various hazards, as good guidance is not available from EPA or other sources, and this is a resource that assessors need (*Comment 9, p. 6*).

Response: DfE recognizes that bioaccumulation potential exists for some large compounds and polymers above the MW cutoff of 1,000 daltons, and an exact or specific cutoff cannot always be demonstrated, because bioaccumulation and chemical absorption are complex functions of diverse physiological processes. DfE also recognizes that Low expected bioavailability is no guarantee of 'no effects.' The molecular weight cutoff is used as a guideline value for large polymers in the absence of experimental data, based on the polymer assessment literature, the polymer exemption criteria for the New Chemicals Program, and Sustainable Futures Polymer Assessment guidance (Boethling and Nabholz, 1997; U.S. EPA, 2014; U.S. EPA 2012). Starting materials and lower MW oligomers (MW <1,000 monomers, dimers, trimers, etc.) are assessed as part of the AA evaluation of large polymers. Lower molecular weight components that have potential to be present in the product are also evaluated for bioavailability and toxic effects. Additionally, DfE AAs undergo review by EPA subject matter experts and stakeholders before the draft reports are published, and the public is encouraged to review the draft documents during the comment periods. These are the methods DfE's AA program uses as part of the conservative approach to provide comparative hazard designations for large polymers that lack experimental data.

Changes made by EPA based on internal review and informal comments:

EPA made clarifying changes to the aquatic toxicity profiles for several chemicals. For phosphate esters and phosphonate esters in this report, alternative predictive methodologies such as data derived acute-to-chronic ratios (ACRs) and read across to analogous substances were reported to address data gaps using a weight of evidence approach instead of ECOSAR predictions. Many of the chemicals and chemical mixture components in this assessment are phosphate or phosphonate esters, including Diethyl bis(2-hydroxyethyl)aminomethyl-phosphonate, Emerald Innovation™ NH-1, Fyrol™ HF-5, Isopropylated triphenyl phosphate, Oligomeric ethyl ethylene phosphate, Oligomeric phosphonate polyol, Phosphoric acid, P,P'-[2,2-bis(chloromethyl)-1,3-propanediyl] P,P,P',P'-tetrakis(2-chloroethyl) ester, Tricresyl phosphate, Triphenyl phosphate, Tris (1,3-dichloro-2-propyl) phosphate, Tris (2-chloro-1-methylethyl) phosphate, Tris (2-chloroethyl) phosphate, and Tris (p-t-butylphenyl) phosphate. ECOSAR v1.11 provides estimates for these compounds based on the esters, esters (phosphate), and neutral organic classes. These compounds are not well represented by ECOSAR v1.11 esters (phosphate) QSAR, which is based on underlying Log Kow methodology that does not adequately distinguish weak-to-strong esterase inhibition, resulting in low correlation of the class members. Additionally, certain modes of action have been previously associated with phosphate ester chemicals (i.e., potential for esterase inhibition and alkylation); therefore, the ECOSAR v1.11 esters and neutral organics QSARs are also not well representative of these chemicals. The ECOSAR v1.11 esters estimated values are reported in the assessment for comparative purposes. This approach is described in section 5.5.1 of the report. In addition, algal chronic toxicity data were correctly interpreted by transcribing NOEC values into the chronic aquatic toxicity sections. These improvements resulted in hazard designation changes for the following substances:
Diethyl bis(2-hydroxyethyl)aminomethylphosphonate – acute aquatic toxicity from low to moderate
Melamine – chronic aquatic toxicity from moderate to low.
Oligomeric phosphonate polyol – chronic aquatic toxicity from low to moderate
Phosphoric acid, P,P'-[2,2-bis(chloromethyl)-1,3-propanediyl] P,P,P',P'-tetrakis(2-chloroethyl) ester – chronic aquatic toxicity from high to moderate

In addition, the chronic aquatic toxicity value for tricresyl phosphate was changed from very high to high, because DfE does not assign very high or very low designations based on estimated values.

EPA also added a profile for the mixture Firemaster 600.

References

Boethling RS, Nabholz JV (1997) Environmental assessment of polymers under the U.S. Toxic Substances Control Act. Washington, DC: U.S. Environmental Protection Agency.

U.S. EPA (2012) Interpretive assistance document for assessment of polymers; sustainable futures summary assessment. Washington, DC: U.S. Environmental Protection Agency. http://www.epa.gov/oppt/sf/pubs/iadp_polymers_june2012.pdf September 17, 2012.

U.S. EPA (2014) New Chemicals. Polymer Exemption Overview. Washington, DC: U.S. Environmental Protection Agency. http://www.epa.gov/oppt/newchems/pubs/polyexem.htm September 16, 2014.

Attachment 1. Additional comments submitted for the report, "Flame Retardants Used in Flexible Polyurethane Foam: An Alternatives Assessment Update"

Great Lakes Solutions
1801 U.S. Highway 52 West
West Lafayette, Indiana 47906
T 765.497.6100
F 765.497.6060
www.greatlakes.com

Great Lakes SOLUTIONS
For a Better Tomorrow
A Chemtura Business

September 17, 2014

Attention: Kathy Hart via e-mail Hart.Kathy@epa.gov
Re: FRs in Flexible PU Foam AA update

Having now closely examined the June 2014 draft it is clear considerable effort was expended to examine a wide variety of sources to obtain data on the substances in this update. The following comments are made in addition to the ones made in our August 11 2014 submission. We offer the following suggestions and recommendations to help improve the presentation of information and data for these products.

1) In section 2.2 page 2-5 the statement is made at the end of the first paragraph that "As a whole, the components TBB and TBPH lack full data characterization necessary to adequately describe hazard and risk." As evidenced by the amount of predictive/professional judgment used on other substances in the assessment, this same statement could equally apply to these as well. It is not readily apparent why it was omitted from the others. Of course as mentioned in our original comments, it appears that he contractor had some difficulty interpreting the data that was relevant and available on TBB. We anticipate that once the contractor gets this sorted out, you may find this statement unnecessary.
2) In this same section in paragraph 2 the term "pseudo-persistence" is used in reference to chlorinated phosphorus alternatives. This terminology is rather strange and unfamiliar. Perhaps it needs to be either clarified with a footnote or further explained in the sentence.
3) In regard to the data summary and data tables associated with Emerald Innovation NH-1, I have compared the data cited against the data summaries found on our Safety Data Sheets for confidential components C and E. It appears that we may have some additional studies data which would supplement the data the EPA has already found in their own files and other available sources (e.g. ECHA, UK's PFR assessment and other published literature). However it does not appear likely that we have any new information that would substantially impact the hazard characterizations (i.e. Low, Medium, High) shown on pages 2-4 or 7-120. None the less, I have requested our toxicologist to prepare a list of all the available studies we currently hold on components of Emerald NH-1 and we will provide copies of those that are relevant.

Thank you for your consideration of our additional comments. If you have any questions or need clarification, please feel free to contact me.

Robert Campbell
Great Lakes Solutions a Chemtura business
West Lafayette Indiana
cc: Emma Lavoie via e-mail Lavoie.Emma@epamail.epa.gov