



U.S. Environmental Protection Agency

Tracking Progress on U.S. EPA's Polybrominated Diphenyl Ethers (PBDEs) Project Plan: Status Report on Key Activities

EPA Polybrominated Diphenyl Ethers Workgroup
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In March 2006, EPA released its Polybrominated Diphenyl Ethers (PBDEs) Project Plan. The Project Plan outlines EPA's activities regarding PBDEs, a group of brominated flame retardant chemicals. The Project Plan identifies four major objectives:

1. Assess Substitutes for Pentabromodiphenyl Ether and Octabromodiphenyl Ether
2. Assess and Evaluate Decabromodiphenyl Ether
3. Assess Risks of Pentabromodiphenyl Ether and Octabromodiphenyl Ether
4. Track Developments Concerning Other Brominated Flame Retardants of Interest

The Project Plan presents EPA's key activities for each of these objectives. In this Status Report, EPA presents information on progress through December 2008 for each of the activities in the Project Plan. This is the third such report; previous status reports were released in March 2007 and March 2008. EPA will update this status report annually; the current status report can be found online, along with the PBDEs Project Plan, at <http://www.epa.gov/oppt/pbde>.

Status of Activities Under Objective 1: Assess Substitutes for Pentabromodiphenyl Ether and Octabromodiphenyl Ether

Activity 1.1

Text of March 2006 Project Plan

“EPA has formed a Furniture Flame Retardancy Partnership with several industry associations and other stakeholders. The Partnership has conducted a screening level hazard assessment of flame retardant chemicals that may be suitable substitutes for pentaBDE. For each alternative chemical, the available scientific studies have been reviewed and summarized, data gaps identified, and environmental and human health effect endpoints characterized. This screening assessment was completed in September 2005 and is available at <http://www.epa.gov/opptintr/dfe/pubs/projects/flameret/index.htm>. The information in this report will help furniture manufacturers incorporate health and environmental considerations into their selection of replacements for pentaBDE.”

Current Status

This activity has been completed. The final product is publicly available (see URL above).

Next Steps

None – activity completed.

Activity 1.2

Text of March 2006 Project Plan

“EPA will work with the Furniture Flame Retardancy Partnership to review additional data on flame retardant chemicals used in furniture as appropriate.”

Current Status

In 2007, the Partnership considered options for identifying any new hazard data on chemicals used as pentaBDE replacements and determined that necessary drivers for updating the table, including industry and NGO demand for further data, were not present.

Among the chemicals being used as a replacement for pentaBDE in furniture is Firemaster 550, produced by Chemtura Corporation. In 1997, Great Lakes Chemical Company (now Chemtura) entered into a Consent Order with EPA allowing the introduction into commerce of the brominated aromatic ester component of Firemaster 550.

In January 2005, the manufacturer entered into a modified Consent Order with EPA regarding the brominated ester component of Firemaster 550 (and related products). The Order specifies the additional testing and data needs required to allow continued manufacture and/or import of the chemical by Chemtura beyond January 2009. Those data needs include, among others:

- a migration study from foam containing the PMN substance;
- a two generation reproduction study in rats; and
- a developmental toxicity study in rats.

In October 2008, Chemtura submitted the two generation reproduction study and developmental toxicity study required by the modified Consent Order. EPA's review of these studies will be completed in 2009. The migration study will be submitted and reviewed in 2009.

Next Steps

Update table of hazard data for pentaBDE alternatives (Table 4-1 of screening assessment report, see Activity 1.1) if demand increases.

Activity 1.3

Text of March 2006 Project Plan

“EPA will monitor developments in the market for replacing octaBDE and will assess octaBDE substitutes if warranted.”

Current Status

Currently there is no formal assessment of alternatives to octaBDE ongoing at EPA. However, the Agency continues to monitor information on alternatives to octaBDE during participation as an Observer (i.e., not a Party) in the review and development of risk management evaluations and listing options for octaBDE under both the LRTAP POPs Protocol and the Stockholm Convention.

Next Steps

EPA will continue to monitor information collection and risk management policy development for octaBDE in international forums.

Status of Activities Under Objective 2: Assess and Evaluate Decabromodiphenyl Ether

Activity 2.1

Text of March 2006 Project Plan

“EPA is conducting a review of the available toxicology data for decaBDE, and will update the decaBDE assessment in EPA’s IRIS database. Completion of this assessment is projected for 2006.”

Current Status

The final Integrated Risk Information System (IRIS) assessment of decaBDE was completed in June 2008, and is available at <http://www.epa.gov/ncea/iris/subst/0035.htm>.

Next Steps

None – activity completed.

Activity 2.2

Text of March 2006 Project Plan

“EPA will monitor ongoing and planned research on the toxicity of decaBDE and its metabolites. Of particular interest are a developmental neurotoxicity study of decaBDE that is being sponsored by the European Union, and studies conducted by the FIRE project (Flame retardants Integrated Risk assessment for Endocrine effects; see www.rivm.nl/fire) in Europe. FIRE is conducting 28-day toxicity study in rats,

and may follow this with other animal studies. EPA will coordinate with the EU and the FIRE project to ensure that all relevant information regarding decaBDE toxicology is shared in a timely manner.”

Current Status

The European Union developmental neurotoxicity study, conducted in rats, was commenced in December 2007 and the industry sponsors project that they will provide a report on the study to EPA in February 2009. In addition, a separate study of decaBDE developmental neurotoxicity in mice has been published (Rice et al., Neurotoxicology and Teratology 2007).

The FIRE project has been completed and a summary report has been prepared. Several journal articles from the FIRE project have been published, including the 28-day study of decaBDE in rats (Van der Ven et al., Toxicology Letters 2008).

Next Steps

EPA will continue to track the availability of new toxicology data on decaBDE, and will review reports and articles when they are published.

Activity 2.3

Text of March 2006 Project Plan

“EPA will further investigate the environmental fate and metabolism of decaBDE, including the potential for formation of lower-brominated congeners by debromination of decaBDE in the environment. Through its VCCEP program, EPA has determined that additional data are needed to address the potential of decaBDE to degrade to other substances in the environment. EPA will work with the industry sponsors of the decaBDE VCCEP assessment to address this data need.”

Note - Data needs were identified as: anaerobic debromination in aquatic sediments and sludge digesters; photolysis in the indoor environment; rate of release from sources in the indoor environment; and migration from land-disposed goods, and subsequent anaerobic biodegradation under landfill conditions.

Current Status

The industry sponsor committed to conducting a Tier 2 VCCEP assessment for decaBDE in December 2005. The industry sponsor submitted an updated VCCEP document in February 2008. In May 2008, EPA announced the termination of the VCCEP process for decaBDE and its intent to prepare a TSCA section 4 test rule to satisfy the identified and still unmet data needs. In September 2008, the Brominated Flame Retardants Industry Panel (BFRIP) agreed to work with EPA to develop a TSCA section 4 enforceable consent agreement as the means to ensure development of the identified data needs. All documents are available at

<http://www.epa.gov/oppt/vccep/pubs/chem21.htm>.

Next Steps

If BFRIP satisfies EPA's conditions for proceeding with development of an enforceable consent agreement, EPA will announce development of the ECA and a public meeting in the Federal Register in early 2009. If BFRIP does not satisfy EPA's conditions, EPA will proceed with proposing a TSCA section 4 test rule.

Activity 2.4

Text of March 2006 Project Plan

"EPA will prepare a white paper that reviews the available information on the environmental fate of decaBDE. The purpose of this paper is to assess the potential for debromination of decaBDE through various natural mechanisms (e.g. exposure to light, breakdown via metabolism in living organisms), the rate, extent and conditions under which debromination may occur, and whether debromination of decaBDE is likely to be a significant source of lower-brominated PBDEs in humans and wildlife. The white paper will also identify additional studies that would be helpful to developing a better understanding of the environmental fate of decaBDE. Emerging information currently under development and anticipated over the coming year will be an important part of this evaluation, including data needs identified through VCCEP. This effort will be initiated in 2006, and the white paper will be peer reviewed in accordance with EPA's *Peer Review Handbook* and the Office of Management and Budget's *Final Information Quality Bulletin for Peer Review*."

Current Status

These topics will be addressed as part of a report on assessing exposure to PBDEs, being prepared by EPA's National Center for Environmental Assessment (NCEA). Chapter 3 of the draft report addresses environmental fate, with extensive text on decaBDE debromination and other fate pathways. The draft report has been released for public comment, and is available at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=198444>.

Next Steps

The draft report will be externally peer reviewed in early 2009. The goal is to finalize the report, considering public comments and peer review comments, during 2009.

Activity 2.5

Text of March 2006 Project Plan

"EPA will conduct an interim review of all available scientific information concerning decaBDE in 2006/2007. The information to be considered in this review will include CDC NHANES data on decaBDE body burdens in the U.S. population, other studies reporting decaBDE body burdens in the U.S., data from EPA's National Lake Fish Tissue Study, the EPA White Paper on environmental fate of decaBDE, information developed under VCCEP, and other studies that may become available

concerning decaBDE toxicology and environmental fate (including studies conducted or funded by EPA and other agencies listed in Appendices C and D). Based on this interim review, EPA will consider whether the information warrants pursuing additional research, risk assessment or regulation using existing legal authorities.”

Current Status

EPA has continued gathering and reviewing information on decaBDE (see Activities 2.1 – 2.4 above).

Next Steps

EPA will continue reviewing information on decaBDE as it becomes available. EPA will conduct the “interim review” of decaBDE when sufficient information is available. Forthcoming information that will be important to consider includes the developmental neurotoxicity study being conducted for the European Union (results expected February 2009) and the assessments of decaBDE environmental fate.

Activity 2.6

Text of March 2006 Project Plan

“EPA is preparing to propose a SNUR under the Toxic Substances Control Act (TSCA) for flame retardants identified as candidates for use to meet the residential upholstered furniture flammability standards under consideration by the State of California and the U.S. Consumer Product Safety Commission (CPSC). Sixteen chemical substances/categories, including decaBDE, are being considered for inclusion in the SNUR. The SNUR would require persons who intend to manufacture, import, or process any of these chemical substances, or articles containing them, for use as a flame retardant in residential upholstered furniture to notify EPA at least 90 days before commencing such activity. The required notice would provide EPA with the opportunity to evaluate the intended use, and if necessary, to prohibit or limit such activity before it occurs.”

Current Status

On March 4, 2008, the CPSC issued a notice of proposed rulemaking (16 FR 11702) on a new mandatory standard to address residential upholstered furniture fires. In a pre-publication press release, CPSC stated that under the proposal, manufacturers could meet the performance standard by using smolder-resistant cover fabrics or interior fire resistant barriers to protect the furniture’s internal filling material, which is the primary fuel in an upholstered furniture fire. CPSC’s objective is to reduce the fire risk in upholstered furniture without requiring the use of fire retardant chemical additives. Manufacturers will not be required to use chemicals to meet the proposed standard. In its environmental assessment, CPSC staff projects most manufacturers and importers would likely choose options that do not involve fire-retardants in fabrics or filling materials.

CPSC is evaluating comments received on the proposed standard, and is also preparing to conduct a full scale testing program to assess likely safety improvements associated with compliance with the proposed standard. The testing is scheduled to take place at CPSC and NIST facilities beginning in December 2008. The results of the testing and analysis will be incorporated into a briefing that CPSC staff hope to present to the CPSC commissioners during fiscal year 2009.

Work on the draft proposed Significant New Use Rule (SNUR) is on hold, pending the outcome of the CPSC rulemaking.

Next Steps

EPA will monitor development of the CPSC standard. If EPA determines that a SNUR is needed, it will make appropriate modifications to the draft SNUR and offer the Office of Management and Budget an opportunity to review in advance of proposal.

Activity 2.7

Text of March 2006 Project Plan

“EPA’s Furniture Flame Retardancy Partnership is coordinating with the CPSC and will discuss whether to undertake a project to evaluate environmentally preferable fabric flame retardant chemicals, barrier technologies, inherently flame retardant materials and other fire safety approaches.”

Current Status

No current activity. The need for decaBDE (or other chemical flame retardant additives) to meet such a standard will depend on the particular option selected by CPSC – see discussion above under Activity 2.6.

Next Steps

EPA will decide whether this project is needed when CPSC issues its final standard.

Status of Activities Under Objective 3: Assess Risks of Pentabromodiphenyl Ether and Octabromodiphenyl Ether

Activity 3.1

Text of March 2006 Project Plan

“In December 2004, EPA proposed a TSCA SNUR that would require prior notice to EPA from any entity planning to begin manufacture or import of pentaBDE or octaBDE, or any of the PBDE congeners that comprise these mixtures, for any use, after January 1, 2005. EPA plans to promulgate the SNUR in 2006. The SNUR will enable EPA to review any intended future manufacture or import of pentaBDE and

octaBDE. Based on health or environmental concerns that may be identified during such a review, EPA could take actions to prohibit or limit the production, processing, distribution in commerce, use, and disposal of these chemicals.”

Current Status

This activity has been completed. EPA promulgated the SNUR on June 13, 2006 (71 FR 34015). Available at: <http://www.epa.gov/oppt/pbde>.

Next Steps

None anticipated. Further activity would be necessary only if the Agency receives a notice from an entity intending to manufacture or import pentaBDE or octaBDE.

Activity 3.2

Text of March 2006 Project Plan

“EPA will prepare a white paper that reviews and synthesizes the available information on exposure pathways for PBDEs. The purpose of this paper is to address: first, the relative importance of different pathways of exposure (i.e. food vs. house dust vs. indoor air); and second, information on how PBDEs get into various exposure media (e.g., particular foods including fish, house dust, indoor air, sediments), including migration of PBDEs from products in use and releases from disposal or incineration of products. Information on current disposal and recycling practices for end-of-life products containing PBDEs will be collected. The white paper will also identify additional studies that would be helpful to developing a better understanding of exposure pathways for PBDEs. This effort will be initiated in 2006, and the white paper will be peer reviewed in accordance with EPA’s *Peer Review Handbook* and the Office of Management and Budget’s *Final Information Quality Bulletin for Peer Review*.”

Current Status

EPA’s National Center for Environmental Assessment (NCEA) is preparing a report on assessing exposure to PBDEs.

Chapters on Environmental and Exposure Media Concentrations (Chapter 4) and Human Exposure (Chapter 5) most directly address the subject of this White Paper as proposed in the Project Plan. A survey of the literature on exposure media concentrations for key PBDE congeners is presented in draft Chapter 4. These are combined with exposure factors for several pathways (inhalation, dust ingestion, food ingestion, etc.) in draft Chapter 5 to estimate an intake of PBDEs for adults and different age ranges of children, including infants. Then, a simple pharmacokinetic model converts intake doses to lipid concentrations, which are compared to measured concentrations in the literature. Key observations about exposure pathways, specific congeners, and uncertainties/data gaps are made. The draft report has been released for public comment, and is available at <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=198444>.

In addition, an article based on draft Chapters 4/5 is available:

Lorber, M (2008). Exposure of Americans to polybrominated diphenyl ethers. *Journal of Exposure Science and Environmental Epidemiology* 18(1):2-19.
<http://www.nature.com/jes/journal/v18/n1/abs/7500572a.html>

Research has suggested that house dust may be a substantial contributor to PBDE exposure. To further examine exposure pathway issues, EPA and the USDA have collaborated on a study of the bioavailability of PBDEs in house dust (Huwe et al., *Environmental Science and Technology* 2008).

Next Steps

The draft report will be externally peer reviewed in early 2009. The goal is to finalize the report, considering public comments and peer review comments, during 2009.

Activity 3.3

Text of March 2006 Project Plan

“EPA is conducting a review of the available toxicology data for tetra-, penta- and hexaBDE congeners under its IRIS program. Completion of these assessments is projected for 2006.”

Current Status

The IRIS assessments of the tetraBDE-47, pentaBDE-99 and hexaBDE-153 congeners were completed in June 2008, and are available at:
<http://www.epa.gov/ncea/iris/subst/1010.htm> (BDE-47),
<http://www.epa.gov/ncea/iris/subst/1008.htm> (BDE-99), and
<http://www.epa.gov/ncea/iris/subst/1009.htm> (BDE-153).

Next Steps

None - activity completed.

Activity 3.4

Text of March 2006 Project Plan

“Through its VCCEP program, EPA has identified additional toxicity information as a data need for both pentaBDE and octaBDE. Specifically, EPA has determined that the primary data needs are two generation reproductive toxicity studies for both pentaBDE and octaBDE. EPA will work with the industry sponsor of the pentaBDE and octaBDE VCCEP assessments to address these data needs. EPA will also seek further research on the toxicity of pentaBDE and octaBDE. Through these efforts, EPA will identify and prioritize proposed additional toxicology studies of individual PBDE congeners and/or PBDE mixtures common in human samples. EPA will consider developing a proposal for NTP to conduct a set of tests to better characterize the toxicology of several individual PBDE congeners.”

Current Status

No current activity identified. The industry sponsors declined to conduct the recommended testing for the VCCEP Tier 2 assessment.

Next Steps

EPA will continue to monitor the developing toxicological literature on pentaBDE, octaBDE and their constituent congeners, as well as trends in environmental levels and human body burdens, to inform any decisions about whether to seek testing by the National Toxicology Program (NTP) or by other means.

Activity 3.5

Text of March 2006 Project Plan

“EPA will conduct an interim review of all available scientific information concerning pentaBDE and octaBDE in 2006/2007. The information in this review will include CDC data on PBDE body burdens in the U.S. population, data from EPA’s National Lake Fish Tissue Study, NTP studies of pentaBDE toxicology, and other studies that may become available concerning toxicology and environmental fate of PBDEs (including studies conducted or funded by EPA and other agencies listed in Appendices C and D). Based on this interim review, EPA will consider whether the information warrants pursuing additional activities, which could include:

- initiating further studies of exposure levels, exposure pathways, and/or toxicology of PBDEs.
- conducting a risk assessment of pentaBDE, octaBDE, or selected congeners. A risk assessment of these chemicals would include a review of the hazards, a dose-response evaluation, an exposure assessment, and a risk characterization.
- activities to reduce potential exposures to lower-brominated PBDE congeners.”

Current Status

EPA has continued gathering and reviewing information on pentaBDE and octaBDE, including the IRIS assessments, analysis of exposure pathways, and work being conducted internationally.

EPA is working with representatives of Canada and Mexico on a PBDEs Team to identify opportunities for collaboration in managing this group of substances in North America, with the objective to reduce environmental and health risks. This effort was established by the Sound Management of Chemicals (SMOC) Working Group of the Commission for Environmental Cooperation (CEC). The primary goal of the Team is to assist Mexico in a Mexican PBDE inventory project, covering the sources of

exposure and including import and export information and disposal/end-of-life aspects of consumer products.

Next Steps

EPA will continue reviewing information on pentaBDE and octaBDE as it becomes available, including the body burden data now available from NHANES, several recently-published toxicology and epidemiology studies, and other relevant data. EPA will conduct the “interim review” of pentaBDE and octaBDE when sufficient information is available. Forthcoming information that will be important to consider includes trend data from NHANES on human body burdens; and trends in environmental measurements.

Status of Activities Under Objective 4: Track Developments Concerning Other Brominated Flame Retardants of Interest

Activity 4.1

Text of March 2006 Project Plan

“Any new flame retardants not already in commerce in the U.S. must be submitted to EPA for a premanufacture review under TSCA. During the review period, EPA may take action to prohibit or limit the production, processing, distribution in commerce, use, and disposal of new chemical substances that raise health or environmental concerns. EPA will continue to scrutinize new flame retardants proposed for manufacture and import into the U.S. market and, where appropriate, will seek control measures and/or development of additional data on such chemicals by their manufacturers under TSCA Section 5 authorities.”

Current Status

Premanufacture reviews are conducted on an as-needed basis whenever EPA receives a Premanufacture Notice for a new flame retardant.

Next Steps

Conduct review as-needed.

Activity 4.2

Text of March 2006 Project Plan

“EPA will monitor the developing science on brominated flame retardants, including TBBPA and HBCD. Among the important activities underway are studies of TBBPA and HBCD as part of the European Commission FIRE project. EPA will also monitor information on disposal and recycling practices for end-of-life consumer products containing flame retardant chemicals. EPA will review the available information on other brominated flame retardants in 2006/2007. Based on this review, EPA will

consider whether the information warrants pursuing additional activities, which could include initiating additional studies of environmental fate, exposure pathways, and/or toxicology of certain flame retardant chemicals, and conducting IRIS assessments of hazard and dose-response, and/or full risk assessments of certain flame retardant chemicals.”

Current Status

EPA has formed a multi-stakeholder partnership to evaluate flame retardants in printed circuit boards. Tetrabromobisphenol A (TBBPA) is currently the primary flame retardant used for this application. The partnership has identified seven specific flame retardants and fillers used in the leading alternative laminate materials. This flame retardants assessment is similar to the pentaBDE alternatives assessment conducted under Activity 1.1, but also focuses on end-of life issues (e.g. electronics waste disposal, such as incineration or burning).

Draft toxicological assessments of flame retardant chemicals in printed circuit boards are complete, and a draft report was released for public comment in November 2008. A study is underway to provide data on the combustion by-products that may be produced during end of life disposal of printed circuit boards containing flame retardants. The first phase of this study is addressing experimental design and provides data on three different types of flame retardants; the second phase will provide data on a larger group of laminates with different flame retardants and possibly different combustion scenarios. The first phase is in process and will inform the design of the second phase. Further information is available at <http://www.epa.gov/dfe/pubs/projects/pcb/index.htm>.

EPA has completed a Risk-Based Prioritization document for HBCD as part of the Chemical Assessment and Management Program (ChAMP), and assigned it a high priority (<http://www.epa.gov/hpvis/rbp/HBCD.3194556.Web.RBP.31308.pdf>). EPA identified worker, consumer and children's exposures; releases, presence and bioaccumulation in the environment; and other information pertinent to potential exposures to HBCD as information that would be useful for further evaluation of risks from exposure to HBCD. EPA has encouraged companies to provide any such information on a voluntary and non-confidential basis. EPA noted that forthcoming data and information from the NHANES and IRIS programs will assist EPA in making further decisions on HBCD.

EPA is conducting a review of the available toxicology data for HBCD under its IRIS program. Information on the status of this assessment is available at http://cfpub.epa.gov/ncea/iristrac/index.cfm?fuseaction=viewChemical.showChemical&sw_id=1102.

Next Steps

The toxicological assessments report on flame retardant chemicals in printed circuit boards will be finalized, considering any comments received, during 2009. Phase I of

the printed circuit board combustion testing should be completed in December 2008. Phase II testing should start in Winter 2009 and should take about six to nine months depending upon complexity of experiments, number of laminates to be evaluated and types of analyses to be conducted.