Polybrominated Diphenyl Ethers (PBDEs) Action Plan

I. Overview

Polybrominated diphenyl ethers (PBDEs) have been widely used as flame retardants in a number of applications. Three commercial PBDE mixtures have been produced and used in the United States and elsewhere: commercial pentabromodiphenyl ether (c-pentaBDE), commercial octabromodiphenyl ether (c-octaBDE), and commercial decabromodiphenyl ether (c-decaBDE). Although manufacture and import of c-pentaBDE and c-octaBDE were phased out in 2004, PBDE congeners associated with those mixtures continue to be found in humans and the environment. Some reports indicate that levels are continuing to increase. Imported articles treated with c-pentaBDE and c-octaBDE could be a source of human and environmental exposure to these PBDE congeners. c-DecaBDE is still manufactured and used in the United States. Data suggest that debromination, physical or metabolic removal of bromine atoms, may convert decaBDE to more toxic PBDE congeners, contributing further to the potential risk from exposure to these congeners.

EPA is concerned that some of the component congeners are persistent, bioaccumulative and toxic and intends to initiate a number of actions to limit the exposure and release of PBDE congeners and/or articles to which they have been added. These actions are to: (1) Initiate rulemaking to propose a TSCA significant new use rule (SNUR) for the manufacture or import of articles to which c-pentaBDE or c-octaBDE has been added (a notice of proposed rulemaking is intended to publish in late 2010); (2) support and encourage the voluntary phase-out of the manufacture and import of c-decaBDE; (3) initiate rulemaking to simultaneously propose a SNUR and a test rule for c-decaBDE in late 2010 (the SNUR would designate manufacture (including import) of c-decaBDE or articles to which c-decaBDE has been added as a significant new use and the test rule under section 4 of TSCA would require development of information necessary to determine the effects that manufacturing, use or other activities involving c-decaBDE have on human health or the environment); (4) initiate rulemaking under Section 5(b)(4) of TSCA to add the commercial PBDE mixtures and/or the congeners they contain to the list of chemicals which present or may present an unreasonable risk to health or the environment (a notice of proposed rulemaking is intended to publish in autumn, 2010);and (5) develop an alternatives analysis for c-decaBDE (intended to begin in spring 2010).

As part of its efforts to address PBDEs, EPA intends to evaluate the potential for disproportionate impact on children and other vulnerable populations.

II. Introduction

As part of EPA's efforts to enhance the existing chemicals program under the Toxic Substances Control Act (TSCA)[1], the Agency identified an initial list of widely recognized chemicals, including polybrominated diphenyl ethers (PBDEs), for action plan development based on their presence in humans and the environment; their persistence, and toxicity; their use

[1] 15 U.S.C. §2601 *et seq.*

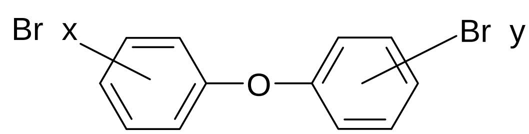
in consumer products; their production volume; or other similar factors. This Action Plan is based on EPA's initial review of readily available use, exposure, and hazard information on PBDEs. EPA considered which of the various authorities provided under TSCA and other statutes might be appropriate to address potential concerns with PBDEs in developing the Action Plan. The Action Plan is intended to describe the courses of action the Agency plans to pursue in the near term to address its concerns. The Action Plan does not constitute a final Agency determination or other final Agency action. Regulatory proceedings indicated by the Action Plan will include appropriate opportunities for public and stakeholder input, including through notice and comment rulemaking processes.

III. Scope of Review

This action plan addresses uses of the three commercial PBDE mixtures as flame retardants and concerns for human and environmental exposure resulting from their use.

The PBDEs are a family of chemicals with a common structure of a brominated diphenyl ether molecule which may have anywhere from one to ten bromine atoms attached. (Figure 1).

Figure 1. Brominated diphenyl molecule



$$x + y = 4 - 10$$

Each individual PBDE variant, distinguished from others by both the number of bromine atoms and the placement of those atoms, is referred to as a congener. For example, there are 42 tetrabromodiphenyl ether congeners, each with four bromine atoms in different configurations. Specific congeners, also known as isomers, in which both the number and location of bromine atoms is specified are given numbers, e.g., BDE-47. In theory, there could be as many as 209 PBDE congeners, but a much smaller number of congeners are commonly found in the commercial PBDE products and in measurements of PBDEs in humans and the environment (Table 1). Scientific studies, particularly those measuring presence of PBDEs in tissues and the environment, often repot their findings by BDE number.

PBDE congeners can be grouped according to the number of bromine atoms present in the molecule. TSCA inventory listings and regulations for PBDEs are based on these groups. (Table 2). The congeners used in flame retardants have between four and ten bromine atoms. EPA regulations of PBDEs generally apply to congeners grouped according to number of bromine atoms rather than specific congener/isomers designated by BDE number.

There are three types of commercial PBDE products, c-pentaBDE, c-octaBDE, and c-decaBDE, each contains a mixture of PBDE congeners (see Table 3).

Table 1. Selected PBDE Congeners		
Congener	Number of Bromine Atoms	Chemical Name
BDE-28	3	2,4,4'-tribromodiphenyl ether
BDE-47	4	2,2',4,4'-tetrabromodiphenyl ether
BDE-85	5	2,2',3,4,4'-pentabromodiphenyl ether
BDE-99	5	2,2',4,4',5-pentabromodiphenyl ether
BDE-100	5	2,2',4,4',6-pentabromodiphenyl ether
BDE-153	6	2,2',4,4',5,5'-hexabromodiphenyl ether
BDE-154	6	2,2',4,4',5,6'-hexabromodiphenyl ether
BDE-183	7	2,2',3,4,4',5',6-heptabromodiphenyl ether
BDE-197	8	2,2',3,3',4,4',6,6'-octabromodiphenyl ether
BDE-206	9	2,2',3,3',4,4',5,5',6-nonabromodiphenyl ether
BDE-209	10	2,2',3,3',4,4',5,5',6,6'-decabromodiphenyl ether

Table 2. PBDE Congener Groups			
Common Name	CAS Index Name	CASRN	Number Br atoms
TetraBDE	Benzene, 1,1'-oxybis-, tetrabromo derivative	40088-47-9	4
PentaBDE	Benzene, 1,1'-oxybis-, pentabromo derivative	32534-81-9	5
HexaBDE	Benzene, 1,1'-oxybis-, hexabromo derivative	36483-60-0	6
HeptaBDE	Benzene, 1,1'-oxybis-, heptabromo derivative	68928-80-3	7
OctaBDE	Benzene, 1,1'-oxybis-, octabromo derivative	32536-52-0	8
NonaBDE	Benzene, 1,1'-oxybis-, nonabromo derivative	63936-56-1	9
DecaBDE.	Benzene, 1,1'-oxybis-, 2,3,4,5,6-pentabromo-	1163-19-5	10

Table 3. Congeners In Commercial PBDE Mixtures		
Commercial Mixture	Major components	Minor components
c-pentaBDE	tetraBDE pentaBDE	hexaBDE
c-octaBDE	heptaBDE octaBDE	hexaBDE nonaBDE decaBDE
c-decaBDE	decaBDE	nonaBDE

A small number of the PBDE congeners are found most frequently, and in the greatest concentrations, in human and environmental samples. BDE-47 tends to be found more frequently than other congeners in measurements from humans, fish and other biota, followed by BDEs 99, 100, 153 and 154. In measurements of environmental media, like some samples of house dust, sediments, and indoor air, BDE-209 (decaBDE) seems to be dominant.

IV. Uses and Substitutes Summary

PBDEs are added to materials to reduce the risk of fires and to increase escape time when a fire occurs. They were widely used in textiles, plastics and polyurethane foam. PBDE treated articles were used in the home, in business settings, and in the transportation sector. Articles which were often treated with PBDEs include carpets, upholstery fabric, cushions, and plastics used as components in electrical appliances and equipment.

Domestic manufacture of c-pentaBDE and c-octaBDE stopped in 2004 when the Great Lakes Chemical Corporation (now Chemtura Corporation) voluntary phased out their production. The EPA subsequently promulgated a SNUR (74 FR 34015, June 13, 2006) which requires that anyone who intends to manufacture or import a chemical substance or mixture containing any of the congeners present in c-pentaBDE or c-octaBDE notify EPA at least 90 days in advance. The notice provides EPA with an opportunity to evaluate the intended new use and, if necessary, take action to limit or prohibit it. The SNUR did not address importation of articles to which c-pentaBDE or c-octaBDE has been added.

Most of c-pentaBDE's consumption took place in the United States. It was used primarily as an additive flame retardant in flexible polyurethane foams. A 2002 study estimated that 80 percent of c-pentaBDE was used in foam for furniture and mattresses, while the remaining amount was used in automotive applications (Hale et al., 2003). In 2005, EPA's Design for the Environment (DfE) program completed an alternatives analysis for pentaBDE in furniture foam which provided data to inform substitution to safer alternatives (http://www.epa.gov/dfe/pubs/projects/flameret/index.htm). This work complemented the voluntary phase-out and the SNUR.

c-OctaBDE was used in acrylonitrile-butadiene-styrene (ABS) plastic which was used as casing for certain electric and electronic devices used in both offices and homes. c-OctaBDE had a smaller market than c-pentaBDE and was more easily replaced.

c-DecaBDE, on the other hand, is still manufactured and widely used in the United States and abroad, although legislative action to restrict its use has been undertaken by some US states. Based on IUR data2 between 50 – 100 million pounds were manufactured or imported in the United States in 2005. That is of the same order of magnitude as the amount reported in 2002.

c-DecaBDE is an economical flame retardant because relatively small quantities are necessary to achieve a flame retardant effect. The three major product categories in which decaBDE are used as an additive flame retardant are: textiles, electronic equipment, and building and construction materials. Its primary use is in high impact polystyrene (HIPS) based products. Several potential substitutes exist for each major use of decaBDE. EPA has not evaluated the potential human health or environmental effects of all potential c-decaBDE substitutes.

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2 Information on Invertory update data is available at http://www.epa.gov/oppt/iur

V. Hazard Identification Summary

Human Health Effects

In its 2006 PBDE Project Plan, EPA summarized animal studies of various commercial mixtures and individual congeners which suggested potential concerns about liver toxicity, thyroid toxicity, developmental toxicity, and developmental neurotoxicity (EPA, 2006b). These findings and the presence of PBDEs in house dust and breast milk raise particular concerns about potential risks to children.

In 2008, EPA published peer reviewed Toxicological Reviews of four PBDE congeners: tetraBDE (BDE-47), pentaBDE (BDE-99), hexaBDE (BDE-153), and decaBDE (BDE-209), to support summary information on EPA's Integrated Risk Information System (IRIS)3 database (www.epa.gov/iris/).

Neurobehavioral effects was identified as the critical endpoint of concern for each of the four congeners (EPA, 2008a-d). The protocols for the studies were unique and did not conform to health effects test guidelines for neurotoxicity. For decaBDE, EPA also proposed that the data support a finding of "suggestive evidence of carcinogenic potential" (EPA, 2008d).

Through EPA's Voluntary Children's Chemical Evaluation Program (VCCEP)[4], industry-sponsored screening level risk assessments for pentaBDE, octaBDE and decaBDE were developed to evaluate the potential risks to children and prospective parents from potential PBDE exposures. In August, 2005, EPA released its Data Needs Decision documents on PBDEs. Noting the evidence suggesting developmental and reproductive effects, EPA requested that the sponsors provide 2-generation reproductive toxicity studies for both pentaBDE and octaBDE, to characterize risks to children (EPA, 2005a-b). These data were not made available through VCCEP, as the companies ceased their sponsorship of pentaBDE and octaBDE under VCCEP. For decaBDE, EPA indicated a need to further understand fate and transport of decaBDE in the environment, particularly with respect to the significance of its lower BDE breakdown products, as this could relate to its risk characterization (EPA, 2005c). The decaBDE data needs were not met by the VCCEP sponsors and decaBDE was subsequently terminated from the VCCEP program. EPA then announced its intention to proceed with a test rule under TSCA section 4. Before a test rule could be proposed, however, the main manufacturers or importers, Albemarle Corporation, Chemtura Corporation and ICL Industrial Products volunteered to phase out manufacture, import and sales of decaBDE. However, some relatively minor importation may be taking place with other companies.

Environmental Effects

At the time the EPA Project Plan was published in 2006, information on environmental effects of PBDEs was limited, with the most detailed reviews found in European Union risk

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3 Information on IRIS is available at http://www.epa.gov/iris/

[4] Information on VCCEP is available at http://www.epa.gov/oppt/vccep.

assessments of certain congeners. Since then, Environment Canada concluded that the greatest potential risks from PBDEs in the Canadian environment are the secondary poisoning of wildlife from the consumption of prey containing elevated concentrations of PBDEs and effects on benthic organisms that may result from elevated concentrations of certain PBDEs in sediments (Environment Canada, 2006). In a more recent report, Environment Canada has also concluded that decaBDE specifically is available for uptake in organisms and may accumulate to high and potentially problematic levels in certain species such as birds of prey or mammalian predators (Environment Canada, 2009a).

Laboratory studies have shown that congeners associated with c-pentaBDE and c-octaBDE are capable of producing adverse effects in a variety of organisms including birds, mammals, and fish. In some cases these effects were observed at exposures levels similar to levels found in the environment. American kestrels and chickens exhibited adverse effects in laboratory studies when exposed to levels of c-pentaBDE and c-octaBDE similar to those which have been observed in monitoring studies conducted in San Francisco Bay and the Great Lakes (McKernan et al., 2009). Adverse effects included histopathological changes in immune organs, altered reproductive behavior and decreased embryo survival and decreased hatching rates. Zhang et al. (2009) reported that c-pentaBDE produced adverse reproductive and developmental effects in ranch mink. Zhang et al. (2009) also conducted biomonitoring of wild mink from the Great Lakes region and concluded that margins of safety for mink are small and that mink from the Hamilton Harbor exceeded the no observed effect concentrations. Timme-Laragy et al. (2006) reported that c-pentaBDE produced developmental and behavioral effects of fish embryos including spine curvature and hatching delay.

Breakdown of PBDEs involves debromination, where highly brominated PBDEs can breakdown to form lesser brominated PBDEs. Although its overall significance is unclear, metabolic debromination of decaBDE to a variety of PBDE breakdown products has been observed in fish (carp, fathead minnows, rainbow trout; Kierkegaard et al., 1999; Stapleton et al., 2004; Stapleton et al., 2006); birds (Van den Steen et al., 2007), cows (Kierkegaard et al., 2006) and rats (Huwe and Smith, 2007). There is increasing concern that this process can be a significant source of exposure to lower brominated congeners.

VI. Physical-Chemical Properties and Fate Characterization Summary

PBDEs are expected to be minimally mobile in moving from soil to air or water, except as borne on particulate matter. Volatilization from moist soil surfaces is expected to be low to moderate depending on the number of bromine atoms. If PBDEs are released to water, the individual constituents of these complex mixtures would be expected to adsorb to sediment and suspended particulate matter, and it is thought that a substantial proportion is likely to be bound to particles in water. PBDEs are expected to exist in both the vapor and particulate phases in the ambient atmosphere based upon measured and estimated vapor pressures. The tetraBDE and pentaBDE congeners are distributed between vapor and particle phases but predominantly in the vapor phase; the hexa- and octaBDEs are mostly attached to atmospheric particles; and decaBDE is exclusively adsorbed to particles. Particulate phase compounds are removed from the atmosphere by wet and dry deposition (HSDB, 2009).

Based on available evidence, PBDEs can be debrominated under environmental conditions; however, the overall significance of this process is uncertain. DecaBDE undergoes photolytic and possibly microbial debromination under certain conditions (Environment Canada, 2009a; Stapleton, 2006). Photolysis is expected to be the dominant transformation process for decaBDE where the substance is significantly exposed to light. For example, it has been found that decaBDE undergoes photolytic debromination in house dust (Stapleton and Dodder, 2008). DecaBDE would also be exposed to light when waste sludge containing PBDEs is used as a soil amendment (Hale et al., 2001). However, the hydrophobicity of PBDEs implies that in the aquatic environment they will tend to partition to benthic sediments, where light exposure is insignificant.

That PBDE congeners with four to ten bromine atoms are highly persistent based on several lines of evidence, but especially by a large body of environmental monitoring data in both the United States and abroad (Environment Canada, 2009a; Shaw and Kannan, 2009; Vonderheide et al., 2008). Available data also indicate that tetra-, penta-, and hexa-BDE are highly bioaccumulative (Environment Canada, 2006). After reviewing the available information, EPA has concluded that decaBDE likely contributes to the formation of bioaccumulative and/or potentially bioaccumulative transformation products such as lower brominated PBDEs in organisms and in the environment. Studies have shown that that photodegradation of decaBDE may result in PBDEs from tri- to nona- and biodegradation of decaBDE may result in nona-, octa- and heptaBDEs (as reviewed in Environment Canada 2009 a).

The atmosphere and marine currents can transport PBDEs over relatively long distances (> 1,000 km). Evidence for this comes from the presence of PBDEs in the tissues of deep ocean-dwelling whales and other marine mammals far from anthropogenic sources (Shaw and Kannan, 2009), as well as from modeling (Wania and Dugani, 2003). The body burdens of PBDE congeners in a wide variety of biota indigenous to geographical areas ranging from the equator to the poles also substantiate their propensity for long-range transport (LRT), and constitute evidence of environmental persistence (Environment Canada, 2006).

VII. Exposure Characterization Summary

In recent years, scientists have measured PBDEs in human adipose tissue, serum and breast milk, fish, birds, marine mammals, sediments, sludge, house dust, indoor and outdoor air, and supermarket foods. The mechanisms or pathways by which the PBDEs move into and through the environment and humans are not known, but are likely to include releases from manufacturing of the chemicals, manufacturing of products like plastics or textiles, aging and wear of products like sofas and electronics, and releases at the end of product life (disposal, recycling). In general, levels of PBDEs in humans and the environment are higher in North America than in other regions of the world, a finding that is often attributed to the greater use of pentaBDE in North America (EPAb, 2006).

Environmental Exposure

The food chain is likely the largest contributor to environmental exposures with PBDE depositing in soil and water where fish and benthic organisms are initially exposed. Biomagnification occurs as predators up the food chain ingest the accumulated concentrations of

PBDEs from their prey (Chen et al., 2007; Voorspoels et al., 2007; Shaw and Kannan, 2009; Stapleton and Baker, 2003). In some studies evidence has been provided that the concentrations of PBDE in biota have doubled every 3 to 6 years, the doubling time depending on species, life stage, and location. PBDE concentrations in marine biota in North America are the highest in the world and are increasing (Shaw and Kannan, 2009). After reviewing the available information, EPA has concluded that the extent of accumulation of congeners is directly related to PBDE levels in diet. Observed differences in PBDE congener profiles in marine mammals from California, Alaska, and the Gulf of Mexico indicate that diet is a significant source of PBDE exposure in marine wildlife (Shaw and Kannan, 2009).

The concentration and distribution of congeners detected in the environment appears to depend on the proximity to a source of the congener in question and the media tested. Studies have been performed measuring waterways, sediments, and biota for PBDE concentrations in various known hot spots, such as the Great Lakes, the San Francisco Bay, and near a polyurethane foam manufacturing facility (ATSDR, 2004).

Human Exposure

The general population is exposed to PBDEs through the use of consumer products. Body burden data indicate that the general population appears to be exposed to primarily lower brominated BDEs (e.g., tetra and penta). PBDEs have been detected in human tissue, blood (usually serum), and milk. The primary source of human exposure to PBDEs, especially the lower brominated congeners, may be from dietary intake, particularly high fat content foods (ATSDR, 2004). The lower brominated tetra- and penta- congeners have also been detected in air samples and indicate that inhalation may also be a potential route of exposure for the general population (ATSDR, 2004). Inhalation exposures could also occur from off gassing of PBDEs from furniture and electrical appliances into indoor air, but little information is known about the potential exposure through this route (ATSDR, 2004). Dermal exposure may occur through contact with PBDE-containing products such as polymers and textiles. A large number of human samples have been analyzed, and the PBDE concentrations have increased by a factor of ~100 during the last 30 years (Hites as cited in 2007 BFR Conference abstracts). Exposures to PBDEs in some occupational settings, such as in computer recycling, can be higher than those of the general population (Cal/EPA PBDE Workgroup, 2008).

Recent human biomonitoring data are currently available from the Centers for Disease Control (CDS) *Fourth National Report on Human Exposure to Environmental Chemical* (http://www.cdc.gov/exposurereport/). This report was released on December 10, 2009, but the PBDE data have been published in the peer-reviewed literature (Sjodin et al., 2008). Although this is the fourth report from this federal agency, it is the first time that PBDEs were included as analytes. The data were obtained from samples from participants in the 2003-2004 National Health and Nutrition Examination Survey (NHANES). Ten different PBDE congeners were analyzed for (containing from three to seven bromines), including BDE-47, BDE-85, BDE-99, BDE-100, BDE-153, BDE-154 and BDE-183. Participants were aged 12 years and older and decaBDE was not included. BDE-47 was detected in serum from almost all of the participants and at the highest concentrations and it was highest in 12-19 year olds and those 60 years old and above. Furthermore, serum levels were highest in 12-19 year olds for other lower brominated congeners. In addition, these congeners were significantly correlated with each other, suggesting a similar pathway of exposure (Sjodin et al., 2008).

Lorber (2008), reviewed and synthesized the available information on exposure pathways for PBDEs, including the relative importance of different exposure pathways and how PBDEs get into various exposure media. The report explained the process used to gather exposure information, model body burden, and compare it to representative PBDE profiles in blood and milk. The analysis focused on indoor measurements of dust/soil and air, suggesting that the primary source for human exposures to PBDEs appears to be their use in commercial products that are part of the indoor environment (computer circuitry, foam cushions, fabrics in curtains, etc). Although the article recommended more research to verify the findings and better quantify identified uncertainties, it concluded that exposures to PBDEs through food and water ingestion and inhalation explained less than 20% of the human body burden, while 80 to 90% of total exposures in the indoor environment were through contact with house dust (Lorber, 2008).

To further examine exposure pathway issues, EPA and the USDA have collaborated on a study which examined the tissue distribution of PBDE congeners in male rats dosed to mimic PBDE exposure from food or household dust. This study found differences in PBDE congener distribution in the body. While the lower brominated congeners tended to distribute equally into lipids, plasma was the best matrix for detection of the higher brominated congeners (especially BDE-209), indicating that blood may be the most reliable matrix for overall PBDE biomonitoring (Huwe et al., 2008).

ATSDR (2004) states that a child's exposure may differ from that of adults because children drink more fluids, eat more food, breathe more air per kilogram of body weight and have a larger skin surface area in proportion to body volume. Their diets and behavior patterns are also different. Infants who consume breast milk may have higher exposure to lower brominated BDEs than children who drink formula (ATSDR, 2004). PBDEs have been found in breast milk in the U.S. and in Europe. The median concentration of total PBDEs was found to be 34.0 ng/g lipid, with the BDE 47 being the predominant congener present. Other populations identified with potentially high exposures are subsistence fishermen who consume PBDE-contaminated fish and Native Americans who reside in Arctic regions and consume whale and seal blubber (ATSDR, 2004). These populations are potentially exposed to lower brominated PBDEs (ATSDR, 2004).

VIII. Risk Management Considerations

U.S. EPA and State/Local Regulatory Reviews and Actions

PentaBDE and OctaBDE

c-PentaBDE and c-octaBDE are no longer produced or imported in the United States. The sole domestic producer, Great Lakes Chemical (now Chemtura), voluntarily terminated their production in 2004. In 2006, EPA issued a SNUR (74 FR 34015, June 13, 2006) that requires anyone who intends to manufacture or import any of the PBDE congeners found in c-pentaBDE and c-octaBDE to notify the Agency at least 90 days in advance. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit the activity before it occurs. However, the SNUR did not address the import of articles containing penta- or octa-BDEs.

Several states including California, Hawaii, Illinois, Maine, Maryland, Michigan, Minnesota, New York, Rhode Island, Oregon and Washington have banned c-pentaBDE and c-octaBDE.

DecaBDE

In the United States, decaBDE remains available for all uses and no federal action has been taken to restrict its use. DecaBDE was included in OPPT's Voluntary Children's Chemical Evaluation program (VCCEP) which identified a number of environmental fate testing needs. The c-decaBDE manufacturers did not adequately address these testing needs within VCCEP. Consequently, EPA announced its intention to proceed with a test rule under TSCA section 4.

The principal manufacturers and importer of c-decaBDE have committed to phase out the manufacture, import and sales of c-decaBDE starting in 2010. Ordinary production, import and sales of c-decaBDE would cease no later than December 31, 2012. Certain uses such as transportation uses or military applications may require an additional year to phase out. In any case the companies would cease sales for these uses no later than December 31, 2013. EPA intends to encourage other importers of c-decaBDE to join this effort. The commitment under discussion would not affect articles made with decaBDE. Recycling of materials containing decaBDE would also not be affected by the commitment.

Washington State banned the use of decaBDE in mattresses as of January 2008, and starting in January 2011, decaBDE will be prohibited from use in televisions, computers and upholstered furniture. Maine also banned decaBDE in mattresses and upholstered furniture as of January 2008 and will extend that ban to televisions and other plastic encased electronics by January 2010. Washington State and Maine conducted studies which concluded that adequate substitutes for decaBDE exist. Other states, such as Maryland and Oregon, have introduced similar legislation to ban the sale of products containing this flame retardant (Buckley, 2009).

International Regulatory Reviews and Actions

PentaBDE and OctaBDE

The European Union has banned both c-pentaBDE and c-octaBDE. The ban prohibits goods containing octaBDE and pentaBDE from being placed on the market in the EU. TetraBDE, pentaBDE, hexaBDE, and heptaBDE have been listed in Annex A of the Stockholm Convention (SC). Parties to the SC are required to prohibit or take measures to eliminate production and use of chemicals listed in Annex A. The listing for these PBDEs includes a specific exemption for articles containing these substances, and also permits recycling of such articles. TetraBDE, pentaBDE and hexaBDE are components of c-pentaBDE; hexaBDE and heptaBDE are components of c-octaBDE. Thus c-pentaBDE and c-octaBDE are effectively designated for elimination under the SC.

Canada's regulations effective in June 2008 prohibit manufacture of the tetra- through decaBDEs which resulted in prohibiting manufacture of the three commercial mixtures also. Canada is also working on regulatory controls to restrict PBDEs in manufactured and imported products (Environment Canada, 2009b).

Summaries of country actions to ban or severely restrict PBDEs can be found in the respective Risk Management Evaluations for each located on the Stockholm Convention website at http://chm.pops.int.

DecaBDE

As of July 1, 2008, the European Union banned decaBDE from use in electronics and electrical applications (Joined Cases C-14/06 and C-295/06). The ban applies to manufactured and imported electronics and electrical components in items placed on the market under its Restriction on Hazardous Substances Directive. However, decaBDE is allowed for use in other applications.

In addition to the regulations cited above, Environment Canada in March 2009 published for public comment a draft Performance Agreement for DecaBDE used at Canadian manufacturing facilities aimed at monitoring and minimizing release of c-decaBDE (Environment Canada, 2009b).

Ongoing Activities and Issues

c-PentaBDE and c-OctaBDE

PBDE congeners found in c-pentaBDE and c-octaBDE are widely distributed in soil, sediments and living organisms, including humans. PBDEs have been found in human tissue, blood and breast milk. The predominant congeners present tend to be the lower brominated forms (i.e., tetraBDE and pentaBDE). Infants and children as well as people who are occupationally exposed may be exposed at higher levels than the general public.

These chemicals persist in the environment and remain biologically available for a significant period of time. Some reports indicate their levels in both the environment and living organisms, including humans, are increasing. There are reports that these chemicals biomagnify as evidenced by high levels reported in some predators such as falcons, dolphins and seals. The presence of PBDEs in remote environments, such as the arctic, indicates that they may be subject to long range transport. The environmental fate and transport, as well as the routes of exposure for humans and other organisms, are not fully understood.

Exposure to PBDEs raises concerns for adverse effects to both humans and wildlife. EPA’s IRIS database identifies neurobehavioral effects as the critical endpoint of concern for the principal congeners present in c-pentaBDE and c-octaBDE. Laboratory studies have shown that congeners associated with c-pentaBDE and c-octaBDE are capable of producing adverse effects in a variety of organisms including birds, mammals, and fish. In some cases these effects were observed at exposures levels similar to levels found in the environment.

c-PentaBDE and c-octaBDE were withdrawn from the U.S. market in 2004. Each of the congeners contained in them is subject to a significant new use rule and may not be produced or imported in to the U.S. without advance notice to the EPA. The SNUR does not address articles to which these chemicals have been added. Although it does not appear that treated articles are currently being imported, that activity, if it were to resume, could be a potential source of exposure to PBDEs for humans and the environment.

<u>c-DecaBDE</u>

DecaBDE is expected to be persistent in the environment. It is widely found in sediments, sewage sludge, and dust particles in indoor air. Some reports indicate that environmental concentrations are increasing.

There is evidence that decaBDE is entering the food chain and biomagnifying. It has been found at high levels in predators such as peregrine falcons. There are very little data on the environmental toxicity of decaBDE; however there have been reports that it can be metabolized in organisms to lower brominated forms with known toxic effects.

EPA’s IRIS database identifies neurobehavioral effects as the critical endpoint of concern for decaBDE. EPA also proposed that the data support a finding of "suggestive evidence of carcinogenic potential".

Human exposure to decaBDE may occur in the home or work environment through the use of products to which it has been added. Exposure may also occur as a result of exposure to house dust containing decaBDE.

Although decaBDE is still being manufactured, imported and processed in the U.S., the Agency believes that there are suitable alternatives for all major uses of the chemical. Furthermore, the Agency believes that persons engaging in these activities are likely to voluntarily discontinue them.

<u>Children’s Health</u>

PBDEs are a concern for children’s health. The most sensitive outcome of PBDE exposure is adverse neurobehavioral effects following exposure during the postnatal period. PBDEs are used as flame retardants in many household products, and consequently PBDEs are present in house dust and environmental media (e.g., air, food). Children’s exposures to PBDEs are greater than those of adults due to higher intakes of food, water, and air per pound of body weight, as well as child-specific exposure pathways such as breast milk consumption and increased contact with the floor. International biomonitoring data report that children have the highest exposures to PBDEs; biomonitoring data have found PBDEs in cord blood and human milk. Some evidence suggests that there is an overlap in the range of PBDE toxicity and the range of current exposures. Thus, given the pervasive exposure to PBDEs, the persistence and bioaccumulation of PBDEs in the environment, and studies finding deleterious health effects, EPA believes risk management actions are warranted to insure adequate protection of children’s health.

X. Next Steps

In conducting this review of PBDEs, EPA considered a number of potential risk management actions, including regulatory actions under TSCA sections 4, 5 and 6; cooperative activities with other federal agencies; and voluntary actions through such programs as Design for the Environment (DfE).

Based on its screening-level review of hazard and exposure information EPA intends to initiate actions to protect the humans and the environment from exposure to PBDE congeners of concern due to manufacture (including import) of commercial PBDEs and/or articles to which they have been added.

On the basis of existing information, the Agency believes that the following actions would be warranted:

1. Initiate rulemaking to propose a TSCA significant new use rule (SNUR). The significant new use would be manufacture or import of articles to which c-pentaBDE or c-octaBDE has been added. This designation would require anyone who intends to manufacture or import articles to which these chemical substances have been added to notify EPA at least 90 days in advance. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit the activity before it occurs. A notice of proposed rulemaking is intended to publish in 2010.

2. Support and encourage the voluntary phase out of manufacture and import of c-decaBDE.
   a) As a result of negotiations with EPA, several companies have announced that they will undertake a three year phaseout of decaBDE. They have committed to initiate reductions of manufacture, import and sales of decaBDE starting in 2010. Ordinary production, import and sales of decaBDE would cease no later than December 31, 2012. Certain uses such as transportation uses or military applications may require an additional year to phase out. In any case the companies would cease sales for these uses no later than December 31, 2013. (http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/deccadbe.html)
   b) EPA intends to encourage other importers of decaBDE to join this effort.
   c) The voluntary phase out is not designed to address articles made with c-decaBDE.. Recycling of materials containing decaBDE would also not be affected by the commitment.

3. Initiate rulemaking to simultaneously propose a SNUR and a test rule for c-decaBDE in 2010.
   a) The SNUR would designate manufacture (including import) of c-decaBDE or articles to which c-decaBDE has been added as a significant new use. Essential uses and any other uses which have not been voluntarily phased out would not be included in the SNUR. The SNUR would be promulgated after the voluntary phase out is complete;
   b) The test rule under section 4 of TSCA would require development of information necessary to determine the effects that manufacturing, use or other activities involving c-decaBDE have on human health or the environment;

If the Agency determines that any manufacture (including import) of c-decaBDE or articles to which c-decaBDE has been added has not ceased, it intends to promulgate the test rule.

4. Initiate rulemaking under section 5(b)(4) of TSCA to add the commercial PBDE mixtures and/or the congeners they contain to the list of chemicals which present or may present an unreasonable risk to health or the environment. A notice of proposed rulemaking is intended to publish in autumn, 2010.

5. Develop an alternatives analysis for c-decaBDE. The alternatives analysis, which is intended to begin in spring 2010, will evaluate the efficacy, availability, cost and hazard levels of alternatives for a subset of critical uses of c-decaBDE. As part of its inquiry, EPA will explore the potential risks presented by PBDE substitutes. The alternatives analysis is intended to aid users of c-decaBDE in selecting suitable alternatives and avoiding unintended consequences.

As part of the Agency's efforts to address these chemicals, EPA intends to evaluate the potential for disproportionate impact on children and other sub-populations. The Agency will also continue to analyze the science as it pertains to making any necessary findings for the rulemakings indicated above

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