

## Brominated Flame Retardants (BFRs): Hazard/Risk Information Sheets

PENTABROMODIPHENYLETHER (pentaBDE)

October 2008

### (i) Status of OECD Hazard Assessment

The SIDS Initial Assessment Profile (SIAP), prepared by the United Kingdom (Sponsor Country) and the European Commission was adopted by SIAM 11 (23–26 January 2001, Paris) and endorsed by the Joint Meeting (14 August 2001).

### (ii) Agreed recommendation for further work included in the SIDS Profile

The SIDS requirements are met. This substance has been discussed in the European Union Risk Assessment programme under Regulation (EEC) 793/93, and the conclusion is that there is a need to limit risks arising from the production, processing and use of polyurethane foam, on the basis of risks identified for the environment and uncertainties about risks to human health (especially infants exposed via breast milk). Other OECD member countries are therefore recommended, as a post-SIDS activity, to review the exposure situation in their countries, and in particular from treated articles and waste disposal to determine the need for similar measures. Some additional studies could also be performed, as follows:

- Information on the extent of dermal exposure in workers using an appropriate dermal absorption study (e.g. an *in vitro* study using human or pig skin); depending upon the outcome of this study (i.e. an indication of significant skin absorption) then it may be necessary to undertake an oral toxicokinetic study in order to provide adequate comparative information for interpretation of the oral dosing toxicity studies available.
- Health surveillance data to investigate signs of chloracne in workers.
- Further information on the effects of prolonged (e.g. lifetime) exposure for a substance that has the potential to accumulate within the body. A methodology should be developed to address this situation. This may involve the conduct of a lifetime study in rodents.
- Information on the toxicokinetics with respect to breast milk including uptake from breast milk into the infant, the time course of the excretion via breast milk during lactation in humans, and the future trends in levels in human breast milk.
- Information on the relative toxicity to the liver in young (neonatal) and adult animals.
- Further studies on potential effects on behaviour following neonatal dosing, in order to determine the reproducibility of effects, the effects of repeated dosing and the significance of the effects to human development.
- A multi-generation reproduction study in order to investigate whether or not other effects might be observed through exposure to breast milk. Designed correctly, such a study could address the issue of whether or not the young animal is more sensitive to liver effects and whether or not differences in behaviour are produced.

### (iii) Follow-up of the recommendation by industry

Information on the extent of dermal exposure in workers exits from an *in vitro* human and rat dermal absorption study. <sup>14</sup>C labelled 2,2',4,4'-tetrabromodiphenyl ether (TBDPE) was used as a surrogate for pentaBDE (this isomer being the predominant isomer and having physical/chemical properties that most favoured absorption). The human mean dermal delivery of applied dose was 3.13% and the human mean absorbed dose was 1.94% compared to 17.94% and 14.81%, respectively for rats. This study has been submitted and is acceptable to the EU. It was agreed that dermal absorption of pentaBDE is low and as

such would not lead to a need for the risk assessment to be reconsidered. It was also agreed that a summary of the absorption study should be added to the published risk assessment report as an appendix. The dermal absorption study was never made available to the SIAM as it was not considered necessary to alter the risk assessment.

#### **(iv) Follow-up of the recommendation by OECD member countries**

##### **AUSTRALIA**

Australia conducted a preliminary assessment on BFRs focusing on hazard and exposure, including the pentaBDE. A report, published in June 2001 can be accessed at: <http://www.nicnas.gov.au/publications/CAR/PEC/PEC20.asp>. A full risk assessment of pentaBDE is currently underway in Australia. Based on an interim risk assessment of certain polybrominated diphenyl ether congeners an interim ban on the import and/or manufacture of pentaBDE and mixtures containing the chemical is in place in Australia, effective 6 March 2007, pending the outcome of the full risk assessment.

##### **CANADA**

Canada has conducted a human health and an ecological screening risk assessment on PBDEs under the *Canadian Environmental Protection Act, 1999* (CEPA, 1999). The reports, published in 2006 can be accessed at: [http://www.ec.gc.ca/TOXICS/EN/detail.cfm?par\\_substanceID=201&par\\_actn=s1](http://www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=201&par_actn=s1). As a result, PBDEs were added to Schedule 1 (List of Toxic Substances) to CEPA, 1999 on December 27, 2006.

Canada has proposed regulations to prohibit the manufacture of seven PBDEs (tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, nonaBDE and decaBDE). The proposed regulations also prohibit the use, sale, offer for sale and import of tetraBDE, pentaBDE, hexaBDE and mixtures, polymers and resins containing these substances and prohibit the manufacture of these mixtures, polymers and resins. These Regulations represent an important first step in the risk management of PBDEs in Canada, with a focus on the three PBDEs that meet the criteria for virtual elimination under CEPA 1999.

##### **EUROPEAN UNION**

In view of the environmental risks identified in the EU risk assessment, the EU has decided to ban marketing and use of pentaBDE from 15 August 2004. The ban includes the marketing of articles containing pentaBDE (Directive 2003/11/EC of 6 February 2003 amending for the 24<sup>th</sup> time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations, OJ 15.2.2003, L42/45)

##### **JAPAN**

Ministry of the Environment of Japan conducted measurement of pentaBDE in air in 2001 and in air, water and sediment in 2002 and 2003. PentaBDE is not registered in Japan. Thus, it has been neither manufactured in nor imported to Japan so far.

##### **NEW ZEALAND**

PentaBDE is captured by the brominated diphenyl ethers entry on ERMA New Zealand's draft Chemicals of Concern list. A proposed condition of the regulatory framework by which certain hazardous products will be controlled after July 2006 will be the requirement for new and existing products containing chemicals on this list to be declared. The information collected will be used for risk reduction initiatives.

##### **SWITZERLAND**

Switzerland has harmonized the regulations on marketing and use of pentaBDE with those laid down in directive 2003/11/EC (24<sup>th</sup> amendment of directive 76/769/EEC) in the Ordinance on Risk Reduction related to Chemical Products (ORRChem), which entered into force on 1 August 2005. The placing on the market and use of pentaBDE as substance as well as in preparations and in articles with a content of pentaBDE equal to or exceeding 0.1% by mass is prohibited. Excluded from the ban are only the placing on the market and use of pentaBDE (as substance, in preparations and in articles) for analysis and research purposes.

## UNITED STATES

PentaBDE is included in the US Voluntary Children's Chemical Evaluation Program (VCCEP). The US manufacturers prepared an assessment evaluating health risk to children. This risk assessment was reviewed by a Scientific Peer Consultation in 2003. USEPA has a response to the reports from this review which addresses data needs for risk assessment (see: <http://www.epa.gov/oppt/vccep/pubs/chem22.htm>).

Great Lakes Chemical Corp. (now Chemtura), the only US manufacturer of pentaBDE and octaBDE, voluntarily phased out the production of both chemicals at the end of 2004. USEPA followed with a regulation that requires potential US manufacturers or importers to get EPA approval prior to resumption of production, for any use, of these two commercial mixtures, and the PBDE congeners that comprise these products. See Toxic Substances Control Act (TSCA) Significant New Use Rule at 40 CFR 721.10000.

A number of individual States in the US have taken action on the PBDEs. California prohibits the manufacturing, processing, or distributing in commerce of a product, or a flame-retardant part of a product, containing more than 0.1% pentaBDE or octaBDE on and after January 1, 2008. Minnesota, Rhode Island, Montana, Hawaii, Illinois, New York, Maine, Maryland, Michigan and Oregon have adopted laws similar to California's, and several other states are considering similar actions. The Minnesota law also requires a study of decaBDE and safer alternatives and encourages the state to procure products that do not contain PBDEs. Washington and Maine laws also include bans on decaBDE for specific uses. USEPA is working with industry under the US new chemicals program and on a voluntary basis for an orderly transition from pentaBDE to appropriate substitutes.

The US Center for Disease Control (CDC) has measured blood serum levels of PBDEs in the general US population for the period 2003-2004 (ages 12 years and older). The data are expected early 2008.

The USEPA has conducted a peer review of the scientific basis supporting the human health hazard and dose-response assessments of four PBDE congeners: 2,2',4,4'-tetrabromodiphenyl ether (BDE-47), 2,2',4,4',5-pentaBDE (BDE-99), 2,2',4,4',5,5'-hexabromodiphenyl ether (BDE-153), and decabromodiphenyl ether (BDE-209). The final assessment documents were made available on the Agency's Integrated Risk Information System (IRIS) website (<http://www.epa.gov/iris>) on June 30, 2008.

that will appear on the Agency's Integrated Risk Information System (IRIS) database. The final assessment documents are projected to be available on the IRIS website ([www.epa.gov/iris](http://www.epa.gov/iris)) in early 2008.

In 2004, EPA 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 (see: <http://www.epa.gov/dfc/pubs/projects/flameret/index.htm>). The information in this report has helped furniture manufacturers incorporate health and environmental considerations into their selection of replacements for pentaBDE. EPA intends to update this report with new information on chemicals already in the report, as well as with additional chemicals that have come on the market since publication of the original report. US manufacturers continue to look for safer flame retardant technologies to enhance their product stewardship efforts, and USEPA is working with industry under the TSCA new chemicals program and on a voluntary basis for an orderly transition from pentaBDE to appropriate substitutes.

### **(v) Other relevant information useful for the risk management of the pentaBDE**

## EUROPEAN UNION

PentaBDE is on the list of priority hazardous substances under the EU Water Policy Directive (Decision No 2455/2001/EC. OJ 15.12.2001, L331/335). This designation requires the cessation or phasing out of discharges, emissions and losses within 20 years. PentaBDE is in the European Pollutant Release and Transfer Register.

## **OSPAR**

PentaBDE is included in OSPAR's list of chemicals for priority action to protect the marine environment. An OSPAR Commission background document on brominated flame retardants (addressing pentaBDE) of 2001 was reviewed by Sweden and an update has been published by OSPAR in 2004. A next full review of this document is not planned before 2008.

## **STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS (POPs)**

In January 2005 pentaBDE has been proposed by Norway to be listed in Annex A to the Stockholm Convention on Persistent Organic Pollutants (POPs). The Persistent Organic Pollutants Review Committee (POPRC) concluded at its first meeting (7-11 November 2005) that pentaBDE meets the screening criteria specified in Annex D to the Convention. At its second meeting (6-10 November 2006) the POPRC adopted the risk profile for pentaBDE and decided that pentaBDE is likely, as a result of its long range environmental transport, to lead to significant adverse human health and environmental effects such that global action is warranted. It decided further to establish an ad hoc working group to prepare a risk management evaluation that includes an analysis of possible control measures in accordance with Annex F to the Convention. At its third meeting (19-23 November 2007) the POPRC adopted the risk management evaluation on pentaBDE. The documents of the POPRC meetings and on the chemicals review process can be accessed at: <http://www.pops.int/documents/meetings/poprc/poprc.htm>.

## **UNECE CONVENTION ON LONG-RANGE TRANSBOUNDARY AIR POLLUTION (LRTAP)**

In December 2003 Norway nominated pentaBDE as a candidate for inclusion in annex I, II or III of the 1998 Aarhus Protocol on Persistent Organic Pollutants under the UNECE LRTAP Convention. The Task Force on POPs concluded that the technical content of the dossier contained sufficient information for screening and supported the dossier's conclusion that pentaBDE be considered a POP. It was observed further by the Task Force that the combination of the potential for atmospheric transport, measured environmental and biotic levels, the exponential increases in these levels in some environments and the relation to toxic endpoints, indicated that pentaBDE had the potential to adversely affect human health and/or the environment as a result of LRAT (see document EB.AIR/WG.5/2005/1, paragraphs 52-55: <http://www.unece.org/env/documents/2006/eb/wg5/eb.air.wg.5.2005.1.e.pdf>). The Parties to the Convention took note of the conclusions of the Task Force (including Track A Reviews) and agreed at the 23<sup>rd</sup> session of the Executive Body (12-15 December 2005) that pentaBDE should be considered as a POP as defined under the Protocol (see report on the 23<sup>rd</sup> session, paragraph 26: <http://www.unece.org/env/documents/2006/eb/EB/ece.eb.air.87.e.pdf>). The Executive Body – representing the Parties to the Convention – requested that the Task Force to continue with an evaluation of the extent of release of pentaBDE to the environment, of socio-economic factors as well as management options on pentaBDE (Track B review). In its report for the 38<sup>th</sup> session of the Working Group on Strategies and Review (WGSR) to the Protocol on POPs (19-22 September 2006), the Task Force presented a brief summary of the current status on production, use and emissions of pentaBDE, outlined phase-out activities and other management options aimed at reducing emissions, concluded on the financial impact for manufacturers, consumers, and governments, and identified further work to be done (see document ECE/EB.AIR/WG.5/2006/10, 26 July 2006, paragraphs 54-81: <http://www.unece.org/env/documents/2006/eb/wg5/ece.eb.air.wg.5.2006.10.e.pdf>). On its 24<sup>th</sup> session the Executive Body noted the progress on Track B reviews for pentaBDE, invited the Task Force to continue its work and complete the reviews by the 40<sup>th</sup> session of the WG on Strategies and Review, and requested a proposal for revision of the Protocol from the WGSR (see document ECE/EB.AIR/89, 1 March 2007, paragraph 26: <http://www.unece.org/env/documents/2006/eb/EB/ece.eb.air.89.E.pdf>). Within its mandate the Task Force continued with exploration of management options and reported on progress for the 40<sup>th</sup> session of the WGSR. The Task Force also identified options for possible inclusion of pentaBDE into the POPs Protocol to the Convention on LRTAP (see document ECE/EB.AIR/WG.5/2007/14, 6 July 2007, paragraphs 18-29: <http://www.unece.org/env/documents/2007/eb/wg5/WGSR40/ece.eb.air.wg.5.2007.14.e.pdf>). Negotiations in the WGSR for amendments to the 1998 Protocol on POPs for pentaBDE and six other candidate

substances will start in April 2008 and continue in September for report to the Parties to the Protocol in December 2008.

#### **SWITZERLAND**

Based on results of a national substance flow analysis for selected BFRs in Switzerland, actual concentration levels in waste electrical and electronic equipment (WEEE) and their behaviour in a modern recycling plant have been determined experimentally for pentaBDE in 2003.

Selected BFRs, including pentaBDE, have been investigated in the Swiss National Research Programme NRP50 “Endocrine Disrupters – relevance to humans, animals and ecosystems” (see: <http://www.nrp50.ch/projects.html>). Within this research program a consensus platform "Brominated Flame Retardants" has been established. The consensus platform lasted from May 2006 to June 2007 and involved a total of 19 representatives of the chemical industry and downstream users of flame retardants, authorities and scientists. The consensus platform aimed at concluding on the impact of selected BFRs and recommended action for risk reduction – based on current scientific data. The final document of the consensus platform “Brominated Flame Retardants” has been published by the Swiss National Science Foundation (<http://www.nrp50.ch/uploads/media/finaldocumentenglish.pdf>).

The Swiss Cantonal authorities carried out in 2008 a market survey study on the use of brominated flame retardants in articles such as electrical and electronic equipment, upholstery furniture, textiles and insulating foams. PentaBDE was one of the target substances of this study.

<p><b>(i) Status of OECD Hazard Assessment</b></p> <p>The SIDS Initial Assessment Profile (SIAP), prepared by France (Sponsor Country for Human Health), the United Kingdom (Sponsor Country for Environment) and the European Commission was adopted by SIAM 16 (27–30 May 2003, Paris) and endorsed by the Joint Meeting (12 September 2003).</p>
<p><b>(ii) Agreed recommendation for further work included in the SIDS Profile</b></p> <p>The SIDS requirements are met. This substance has been discussed in the European Union Risk Assessment programme under the Regulation (EEC) 793/93, and is subject to marketing and use restrictions due to the risks identified. Other OECD member countries are therefore recommended, as a post-SIDS activity, to review the exposure situation in their countries to determine the need for similar measures. Some additional studies could be performed but in view of the marketing and use restrictions in several OECD countries, the sponsor country is unlikely to pursue these data gaps.</p> <p>For the environment, the following work could be considered:</p> <p>Further work is needed to address the concerns over the possible accumulation in, and effects on, top predators and also the possible formation of more accumulative and toxic congeners from photolytic processes in the environment. These areas are difficult to address with standard tests. Possibilities include:</p> <ol style="list-style-type: none"> <li>Consideration of a more widespread monitoring project to determine whether the finding in top predators (including birds' eggs) is a widespread or localised phenomenon and to identify any possible trends;</li> <li>Consideration of further toxicity testing on birds; and</li> <li>Consideration of an investigation on the rate of formation of degradation products under environmentally relevant conditions over a suitably prolonged time period (e.g. years).</li> </ol>
<p><b>(iii) Follow-up of the recommendation by industry</b></p>
<p><b>(iv) Follow-up of the recommendation by member countries</b></p> <p><b>AUSTRALIA</b></p> <p>Australia has conducted a preliminary assessment on BFRs focusing on hazard and exposure, including octaBDE. A report, published in June 2001 can be accessed at: <a href="http://www.nicnas.gov.au/publications/CAR/PEC/PEC20.asp">http://www.nicnas.gov.au/publications/CAR/PEC/PEC20.asp</a>. OctaBDE was removed from the Australian Inventory of Chemical Substances (AICS) effective 6 February 2007. The chemical or mixtures containing the chemical cannot be imported into or manufactured in Australia without prior notification to the National Industrial Chemicals Notification and Assessment Scheme. Manufacture and importation of octaBDE is also not permitted under the NICNAS exemption categories except as laboratory standards for analytical determination. Persons importing octaBDE for analytical purposes must comply with annual reporting obligations as required under the <i>Industrial Chemicals Notification and Assessment Act</i>.</p> <p><b>CANADA</b></p> <p>Canada has conducted a human health and an ecological screening risk assessment on PBDEs under the <i>Canadian Environmental Protection Act, 1999</i> (CEPA, 1999). The reports, published in 2006 can be accessed at <a href="http://www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=201&amp;par_actn=s1">http://www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=201&amp;par_actn=s1</a>. As a result, PBDEs were added to Schedule 1 (List of Toxic Substances) to CEPA, 1999 on December 27, 2006.</p> <p>Canada has proposed regulations to prohibit the manufacture of seven PBDEs (tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, nonaBDE and decaBDE). The proposed regulations also prohibit the use,</p>

sale, offer for sale and import of tetraBDE, pentaBDE, hexaBDE and mixtures, polymers and resins containing these substances and prohibit the manufacture of these mixtures, polymers and resins. These Regulations represent an important first step in the risk management of PBDEs in Canada, with a focus on the three PBDEs that meet the criteria for virtual elimination under CEPA 1999.

#### **EUROPEAN UNION**

The uncertainties concerning possible effects on the environment of octaBDE are sufficient to warrant risk reduction measures in the EU. The marketing and use of octaBDE has been banned since 15 August 2004. The ban includes the marketing of articles containing octaBDE (Directive 2003/11/EC of 6 February 2003 amending for the 24<sup>th</sup> time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations. OJ 15.2.2003, L42/45).

#### **JAPAN**

Ministry of the Environment of Japan conducted measurement of octaBDE in water and aqueous biota in 2002, and in air, water and sediment in 2002 and 2003. It also conducted initial risk assessment in 2004 (see: <http://www.env.go.jp/chemi/report/h15-01/pdf/chap01/02-2/05.pdf>, Japanese only).

#### **NEW ZEALAND**

OctaBDE is captured by the brominated diphenyl ethers entry on ERMA New Zealand's draft Chemicals of Concern list. A proposed condition of the regulatory framework by which certain hazardous products will be controlled after July 2006 will be the requirement for new and existing products containing chemicals on this list to be declared. The information collected will be used for risk reduction initiatives.

#### **SWITZERLAND**

Switzerland has harmonised the regulations on marketing and use of octaBDE with those laid down in directive 2003/11/EC (24<sup>th</sup> amendment of directive 76/769/EEC) in the Ordinance on Risk Reduction related to Chemical Products (ORRChem), which entered into force on 1 August 2005. The placing on the market and use of octaBDE as substance as well as in preparations and in articles with a content of octaBDE equal to or exceeding 0.1 % by mass is prohibited. Excluded from the ban are only the placing on the market and use of octaBDE (as substance, in preparations and in articles) for analysis and research purposes.

#### **UNITED STATES**

OctaBDE is included in the US Voluntary Children's Chemical Evaluation Program (VCCEP). The US manufacturers prepared an assessment evaluating health risk to children. This risk assessment was reviewed by a Scientific Peer Consultation in 2003. USEPA has developed a response to the reports from this review which addresses data needs for risk assessment (see: <http://www.epa.gov/oppt/vccep/pubs/chem23.htm>). US industry has declined to commit to further testing or involvement with VCCEP on octaBDE.

Great Lakes Chemical Corp. (now Chemtura), the only US manufacturer of pentaBDE and octaBDE, voluntarily phased out production of both those chemicals at the end of 2004. USEPA followed up with a regulation which requires notification prior to resumption of US manufacture or import, for any use, of these two chemicals, and the other PBDE congeners that comprise these products. See Toxic Substances Control Act Significant New Use Rule at 40 CFR 721.10000.

A number of individual States in the US have taken action on the PBDEs. California bans the manufacture or distribution in commerce of any product containing pentaBDE or octaBDE, taking effect in 2006. Minnesota, Rhode Island, Montana, Hawaii, Illinois, New York, Maine, Maryland, Michigan and Oregon have adopted laws similar to California's, and several other states are considering similar actions. The Minnesota law also requires a study of decaBDE and safer alternatives and encourages the state to procure products that do not contain PBDEs. Washington and Maine laws also include bans on decaBDE for specific uses.

The US Center for Disease Control (CDC) has measured blood serum levels of PBDEs in the general US population for the period 2003-2004 (ages 12 years and older). The data are expected late 2007/early 2008.

The USEPA has conducted a peer review of the scientific basis supporting the human health hazard and dose-response assessments of four PBDE congeners: 2,2',4,4'-tetrabromodiphenyl ether (BDE-47), 2,2',4,4',5-pentabromodiphenyl ether (BDE-99), 2,2',4,4',5,5'-hexabromodiphenyl ether (BDE-153), and decabromodiphenyl ether (BDE-209). The final assessment documents were made available on the Agency's Integrated Risk Information System (IRIS) website (<http://www.epa.gov/iris>) on June 30, 2008. USEPA is working with industry under the US new chemicals program and on a voluntary basis for an orderly transition from octaBDE to appropriate substitutes.

**(v) Other relevant information useful for the risk management of the octaBDE**

**EUROPEAN UNION**

OctaBDE is in the European Pollutant Release and Transfer Register.

**OSPAR**

OctaBDE is included on OSPAR's list of chemicals for priority action to protect the marine environment. An OSPAR Commission background document on brominated flame retardants (addressing octaBDE) of 2001 was reviewed by Sweden and published by OSPAR in 2004. A next full review of this document is not planned before 2008.

**STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS (POPs)**

In June 2006 octaBDE has been proposed by the European Commission, on behalf of the European Community, together with Member States of the European Union which are Parties to the Convention, to be listed in Annexes A, B and/or C to the Stockholm Convention on Persistent Organic Pollutants (POPs). The Persistent Organic Pollutants Review Committee (POPRC) concluded at its second meeting (6-10 November 2006) that octaBDE meets the screening criteria specified in Annex D to the Convention. At its third meeting (19-23 November 2007) the POPRC adopted the risk profile for octaBDE and decided that octaBDE is likely, as a result of its long range environmental transport, to lead to significant adverse human health and environmental effects such that global action is warranted. It decided further to establish an ad hoc working group to prepare a risk management evaluation that includes an analysis of possible control measures in accordance with Annex F to the Convention. The documents of the POPRC meetings and on the chemicals review process can be accessed at: <http://www.pops.int/documents/meetings/poprc/poprc.htm>.

**UNECE CONVENTION ON LONG-RANGE TRANSBOUNDARY AIR POLLUTION (LRTAP)**

In 2005 the European Commission, on behalf of the European Community, together with Member States of the European Union which are Parties to the 1998 Aarhus Protocol on Persistent Organic Pollutants under the UNECE LRTAP Convention, has proposed octaBDE as a candidate for inclusion into the Protocol on POPs. The Task Force on POPs concluded that the technical content of the dossier contained sufficient information for screening and supported the dossier's conclusion that octaBDE be considered a POP. It was concluded generally by the Task Force that the hazard characteristics of penta and hexa congeners contained in octaBDE, together with the monitoring information on these components, were indicative for the potential of environmental and/or human health effects due to LRAT (see document ECE/EB.AIR/WG.5/2006/10, 26 July 2006, paragraphs 15-18: <http://www.unece.org/env/documents/2006/eb/wg5/ece.eb.air.wg.5.2006.10.e.pdf>). The Parties to the Convention took note of the conclusions of the Task Force (including Track A Reviews) and agreed at the 24<sup>th</sup> session of the Executive Body (11-14 December 2006) that octaBDE should be considered as a POP as defined under the Protocol. (see document ECE/EB.AIR/89, 1 March 2007, paragraph 25: <http://www.unece.org/env/documents/2006/eb/EB/ece.eb.air.89.E.pdf>). The Executive Body— representing the Parties to the Convention – noted the progress on Track B reviews (evaluation of release to the environment, of socio-economic factors as well as management options) for octaBDE, invited the Task

Force to continue its work and complete the reviews by the 40<sup>th</sup> session of the Working Group on Strategies and Review (WGSR), and requested a proposal for revision of the Protocol from the WGSR (see document ECE/EB.AIR/89, paragraph 26). In its report for the 40<sup>th</sup> session of the WGSR (17-20 September 2007), the Task Force presented a summary update of the current status on production, use and emissions of octaBDE, outlined phase-out activities and other management options aimed at reducing emissions, concluded on the financial impact for manufacturers, consumers, and governments, and identified further work to be done. The Task Force also identified options for possible inclusion of octaBDE into the POPs Protocol to the Convention on LRTAP (see document ECE/EB.AIR/WG.5/2007/14, 6 July 2007, paragraphs 30-44: <http://www.unece.org/env/documents/2007/eb/wg5/WGSR40/ece.eb.air.wg.5.2007.14.e.pdf>). Negotiations in the WGSR for amendments to the 1998 Protocol on POPs for octaBDE and six other candidate substances will start in April 2008 and continue in September for report to the Parties to the Protocol in December 2008.

#### **SWITZERLAND**

Based on results of a national substance flow analysis for octaBDE and other important BFRs in Switzerland, actual concentration levels in waste electrical and electronic equipment (WEEE) and their behaviour in a modern recycling plant have been determined experimentally in 2003.

Selected BFRs, including octaBDE, have been investigated in the Swiss National Research Programme NRP50 “Endocrine Disrupters – relevance to humans, animals and ecosystems” (see: <http://www.nrp50.ch/projects.html>). Within this research program a consensus platform "Brominated Flame Retardants" has been established. The consensus platform lasted from May 2006 to June 2007 and involved a total of 19 representatives of the chemical industry and downstream users of flame retardants, authorities and scientists. The consensus platform aimed at concluding on the impact of selected BFRs and recommended action for risk reduction – based on current scientific data. The final document of the consensus platform “Brominated Flame Retardants” has been published by the Swiss National Science Foundation (<http://www.nrp50.ch/uploads/media/finaldocumentenglish.pdf>).

The Swiss Cantonal authorities carried out in 2008 a market survey study on the use of brominated flame retardants in articles such as electrical and electronic equipment, upholstery furniture, textiles and insulating foams. OctaBDE was of the target substances of this study.

<p><b>(i) Status of OECD Hazard Assessment</b></p> <p>The SIDS Initial Assessment Profile (SIAP), prepared by France (Sponsor Country for Human Health), the United Kingdom (Sponsor Country for Environment) and the European Commission was adopted by SIAM 16 (27–30 May 2003, Paris) and endorsed by the Joint Meeting (12 September 2003).</p>
<p><b>(ii) Agreed recommendation for further work included in the SIDS Profile</b></p> <p>The SIDS requirements are met. Further work is needed to address the concerns over the possible accumulation in, and effects on, top predators and also the possible formation of more accumulative and toxic congeners from photolytic processes in the environment. These areas are difficult to address with standard tests. In this respect, industry has volunteered to carry out, as part of the EU risk assessment:</p> <ol style="list-style-type: none"> <li>a) A more widespread monitoring project to determine whether the finding in predatory birds (including birds' eggs) is a widespread or localised phenomenon and to identify any possible trends; and</li> <li>b) A more detailed investigation of the rate of formation of photodegradation products under environmentally relevant conditions.</li> </ol> <p>In addition, consideration is being given to carrying out a further developmental neurotoxicological test (OECD 426 or similar).</p> <p>No further work is required for the human health assessment, however, as stated above, a neurotoxicity study may voluntarily be carried out for the environmental part and the results from this study could be useful to better assess the neurotoxicity properties of this substance.</p>
<p><b>(iii) Follow-up of the recommendation by industry</b></p> <p>As agreed with the EU Competent Authorities at the time of 2004 EU Risk Assessment update, industry has developed, with the French authorities, an independent 10-year biomonitoring programme and, in addition, also a developmental neurotoxicity study since the previous study had been declared invalid for risk assessment purposes.</p> <p>Also, a 10-year environmental monitoring study covering sediments, sewage sludge and bird eggs from several European countries has been initiated in 2005 to monitor the levels and time trends of decaBDE.</p> <p>Both monitoring programmes have now completed their second year and did not identify additional concerns. Results are reported to the authorities on a regular basis. The developmental neurotoxicity study has been started and is currently ongoing.</p> <p>Under its voluntary emission reduction program, BSEF, the global scientific forum of the major decaBDE producers commissioned:</p> <ol style="list-style-type: none"> <li>(1) The <i>Dutch Institute for Fisheries Research</i> (RIVO) to execute environmental monitoring; and</li> <li>(2) The German scientific institute <i>Gesellschaft für Arbeitsplatz- und Umweltanalytik (GfA)</i> to measure emission levels from industrial plants in Europe, covering all known applications.</li> </ol> <p>These independent emission measurements have been finalised and they demonstrate that:</p> <ul style="list-style-type: none"> <li>• DecaBDE is typically found in the environment close to emission sources;</li> <li>• Levels in the environment are low but increasing; and</li> <li>• DecaBDE-using industries can, and will, control the emissions.</li> </ul> <p>Levels in the environment do not show a consistent trend.</p>

Guiding “Code of Good Practice”, including The Best Available Technique for Emptying Bags Containing Brominated Flame Retardants, documents for (in)direct users in the textiles and plastics sector and regulators have been made available under the industry “Voluntary Emissions reduction and Control Action Programme” (VECAP).

In June 2007 a second VECAP Annual Report was published. The annual report reveals that, in the six EU member states (United Kingdom, France, Germany, Italy, Belgium and the Netherlands), 97% of decaBDE used in the EU textiles industry and 82% of decaBDE used in the EU plastics industry are now covered by detailed emissions surveys using the VECAP protocol. The third VECAP annual report was published in April 2008 ([http://www.bsef.com/product\\_stew/vecap/APR\\_2008\\_VECAP.pdf](http://www.bsef.com/product_stew/vecap/APR_2008_VECAP.pdf)). A certification scheme has been developed based on ISO9001/14001 principles. The organisation of the auditing process and delivery of the VECAP Certificate will be done by specialised certification bodies such as Bureau Veritas to guarantee maximum independence. Pilot trials of the certification scheme are in progress.

Apart from the EU member states, also North America (the US and Canada) is covered by VECAP programme as of 2006. This was introduced in the US in 2006 and 79% of the decaBDE users have committed to VECAP.

#### **(iv) Follow-up of the recommendation by OECD member countries**

##### **AUSTRALIA**

Australia has conducted a preliminary assessment on BFRs focusing on hazard and exposure, including the decaBDE. A report, published in June 2001 can be accessed at:

<http://www.nicnas.gov.au/publications/CAR/PEC/PEC20.asp>

In June 2005, the Australian Ministry for Health and Ageing declared a certain number of chemicals “Priority Existing Chemicals (PECs), including decaBDE. As a PEC, decaBDE is currently being assessed for its potential effects on human health and the environment by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The Australian authorities are currently compiling from importers and producers information on quantities and use of this substance as well as general scientific information which is already available.

##### **CANADA**

Canada has conducted a human health and an ecological screening risk assessment on PBDEs under the *Canadian Environmental Protection Act* (1999) (CEPA, 1999). The reports, published in 2006 can be accessed at [http://www.ec.gc.ca/TOXICS/EN/detail.cfm?par\\_substanceID=201&par\\_actn=s1](http://www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=201&par_actn=s1) As a result of these assessments, PBDEs were added to Schedule 1 (List of Toxic Substances) to CEPA, 1999 on December 27, 2006.

Canada has proposed regulations to prohibit the manufacture of seven PBDEs (tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, nonaBDE and decaBDE). The proposed regulations also prohibit the use, sale, offer for sale and import of tetraBDE, pentaBDE, hexaBDE and mixtures, polymers and resins containing these substances and prohibit the manufacture of these mixtures, polymers and resins. These Regulations represent an important first step in the risk management of PBDEs in Canada, with a focus on the three PBDEs that meet the criteria for virtual elimination under CEPA 1999.

##### **EUROPEAN UNION**

The EU published a comprehensive risk assessment in 2002, and an update was agreed in May 2004. Both the environment (UK Rapporteur) and the human health (France Rapporteur) risk assessment reports concluded that there is no significant risk on these areas and that therefore no risk reduction measures are needed. However, further studies were formally requested to address concerns over possible breakdown products and presence in humans and biota, and these were officially published in Commission Regulation (EC) No 565/2006 of 6 April 2006. A voluntary emission reduction programme was also agreed with industry at the same time (see above).

The European Commission Scientific Committee on Health and Environmental Risks (SCHER) adopted an Opinion in March 2005 on the Environmental Risk Assessment of decaBDE. The Opinion stated that the risk assessment had been “well done” ([http://ec.europa.eu/health/ph\\_risk/committees/04\\_scher/docs/scher\\_o\\_012.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_012.pdf)). Both the European Commission and the UK government, which led the environmental risk assessment, have made clear that the SCHER opinion provided no new evidence demonstrating a risk from decaBDE, and that the calls made in the Opinion for risk reduction measures to address the low levels of decaBDE found in some environmental studies are already being addressed by the industry’s monitoring and emissions control programmes developed in conjunction with the EU authorities.

In view of the large amount of ongoing scientific research on this substance, the UK rapporteur had committed to regularly update the risk assessment report (RAR). A second update report, covering both health and environment, was finalised in October 2007. The relevant EU Technical Committee agreed by a majority that the previous conclusions remained valid, and this was endorsed by the EU Competent Authorities in December 2007.

On the basis of both the May 2004 EU risk assessment update conclusions and on the results of the European Commission stakeholder consultation on the exemptions to the RoHS Directive, completed in July 2004, the European Commission adopted on 15 October 2005 Decision 2005/717/EC, exempting all polymeric applications of decaBDE from the RoHS Directive. The legality of this exemption was officially challenged by Denmark. The European Court of Justice annulled the exemption of decaBDE in the RoHS Directive on April 1, 2008. After an adaption period its use had to be phased out by July 1, 2008. (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62006J0014:EN:HTML>).

An environmental risk evaluation for a potential substitute has been published by the UK in 2007 under its Co-ordinated Chemicals Risk Management Programme (<http://publications.environment-agency.gov.uk/>, Environmental Risk Evaluation Report: 1,1'-(Ethane-1,2-diyl)bis[pentabromobenzene] (CAS no. 84852-53-9), product code: SCHO0507BMOR-E-E).

## **JAPAN**

DecaBDE is classified as class 2 monitoring substance by the Chemical Substance Control Law, which is not biodegradable and low bio-accumulative and toxic, and under the requirement to report manufactured and imported amount annually. DecaBDE is also included in PRTR law in Japan. The hazard assessment report and the preliminary risk assessment report have been published by NEDO, NITE, CERI in February 2005 and July 2005. Ministry of the Environment of Japan conducted measurement of decaBDE in air, water, sediment and aqueous biota in 2002 and 2003. It also conducted initial risk assessment in 2004 (see: <http://www.env.go.jp/chemi/report/h15-01/pdf/chap01/02-2/11.pdf>, Japanese only).

## **NEW ZEALAND**

DecaBDE is captured by the brominated diphenyl ethers entry on ERMA New Zealand's draft Chemicals of Concern list. On the basis of the public consultations concluded in January 2007, ERMA decided not to modify the list of 27 substances of potential candidates for reassessment. 20 out of 27 substances were prioritised for reassessment in coming years (+/- 5 years). DecaBDE has not been included in this group.

## **SWITZERLAND**

Switzerland has harmonized the regulation on the use of decaBDE in electrical and electronic equipment with the European Commission Decision 2005/717/EC (amending the annex to directive 2002/95/EC). The Federal Office for the Environment (FOEN) has published in 2007 a guidance document related to the state of technical progress with regard to the use of the flame retardant decabromodiphenyl ether (decaBDE) in electrical and electronic equipment. In order to align the Swiss regulation with the practice in the European Community, polymers in electrical and electronic equipment may contain decaBDE. This guidance will be reviewed depending on the technical progress, knowledge of the risk profiles of available substitutes, and changes in the regulation of decaBDE in the European Union.

## UNITED STATES

DecaBDE was included in the US Voluntary Children's Chemical Evaluation Program (VCCEP). The US manufacturers prepared a "Tier I" assessment and submitted it for Scientific Peer Consultation in 2003. Since that time the USEPA issued their perspective on the submission (see: <http://www.epa.gov/chemrtk/vccep/chem21.htm> and <http://www.epa.gov/chemrtk/vccep/finaldeca.pdf>) and suggested decaBDE go through a "Tier 2" assessment. Dialogue with US industry on this assessment to continue in 2008. The USEPA issued its "Data Needs Decision Document for Decabromodiphenyl Ether" in August 2005 (see: <http://www.epa.gov/oppt/vccep/pubs/chem21.htm>). The EPA determined that no additional hazard (toxicological) type studies were needed at this time. However EPA believed additional information was needed to further refine the nature and extent of children's exposures to decaBDE or breakdown products. The EPA has identified environmental fate and exposure studies that they have asked the producers to conduct as part of the Tier II commitment under their VCCEP pilot program. Further discussions and clarification occurred during 2006 and early 2007. Industry has conducted an extensive literature review of relevant toxicological and exposure studies published from the time of the original December 2002 VCCEP submission through the present, and expects to adequately characterize the risk to children from exposure to decaBDE in a Tier II VCCEP submission, without conducting additional testing as requested in USEPA's Data Needs Decision Document of August 2005. USEPA anticipates this new submission by January 2008, to be followed by a second Peer Consultation process. The producers indicated, however, that sufficient information already exists and declined to conduct further studies.

Several potential substitutes for decaBDE have been evaluated under the USEPA new chemicals program.

A number of individual States in the US have taken action on the PBDEs. In July 2003, California adopted a ban on the manufacture or distribution in commerce of any product containing pentaBDE or octaBDE, taking effect in 2006. Minnesota, Rhode Island, Montana, Hawaii, Illinois, New York, Maine, Maryland, Michigan and Oregon have adopted laws similar to California's, and several other states are considering similar actions. The Minnesota law also requires a study of decaBDE and safer alternatives and encourages the state to procure products that do not contain PBDEs. Washington and Maine laws also include a ban on decaBDE. – Washington prohibits decaBDE in mattresses as of January 2008, and intends to prohibit decaBDE in upholstered furniture and in TV/computer plastic housings January 2011, if a safe and technically feasible alternative can be found. Maine prohibits decaBDE in mattresses and home furniture, as of January 2008, and in TV/computer plastic housings January 2010.

The US Center for Disease Control (CDC) has measured blood serum levels of PBDEs (not including decaBDE however) for the period 2003-2004 in the general U.S. population (ages 12 years and older). The results were published in Environmental Science & Technology (<http://dx.doi.org/10.1021/es702451p>).

The USEPA has conducted a peer review of the scientific basis supporting the human health hazard and dose-response assessments of four PBDE congeners: 2,2',4,4'-tetrabromodiphenyl ether (BDE-47), 2,2',4,4',5-pentabromodiphenyl ether (BDE-99), 2,2',4,4',5,5'-hexabromodiphenyl ether (BDE-153), and decabromodiphenyl ether (BDE-209). The final assessment documents were made available on the Agency's Integrated Risk Information System (IRIS) website (<http://www.epa.gov/iris>) on June 30, 2008.

The USEPA has begun work on a draft regulation to complement a national flammability standard for residential upholstered furniture being considered by the US Consumer Product Safety Commission (CPSC). USEPA's work on the draft regulation is on hold, pending a decision by CPSC to propose the standard. CPSC staff is continuing to conduct lab testing and other technical research to support a possible standard. In July of 2007, CPSC staff attended an industry-sponsored meeting to solicit input from stakeholders. Options that CPSC is now considering include one that could probably be met with little or no use of flame retardants additives in cover fabrics or filling materials.

**(v) Other relevant information useful for the risk management of the decaBDE**

**EUROPEAN UNION**

On request of the EC Directorate General Environment (DG ENV) the European Chemicals Bureau (ECB) has published a report on “Alternatives to decabromodiphenyl ether (decaBDE) used in polymeric applications in electrical and electronic equipment, and assessment of the availability of potential alternatives to decaBDE” (see: [http://ecb.jrc.ec.europa.eu/documents/Existing-Chemicals/Review\\_on\\_production\\_process\\_of\\_decaBDE.pdf](http://ecb.jrc.ec.europa.eu/documents/Existing-Chemicals/Review_on_production_process_of_decaBDE.pdf)) The Report concludes that substitutes do exist on the market for decaBDE for the proposed applications and that many large electronic manufacturers claim to have moved to bromine-free alternatives. In addition literature data suggest that potential adverse environmental and human health effects of at least some substitutes may be minimal. However key data and information gaps in comprehensive risk assessments and hazard classification still exist, as well as uncertainties related to the potential impacts of degradation products of both decaBDE and its substitutes.

**OSPAR**

DecaBDE is included on OSPAR's list of chemicals for priority action to protect the marine environment. An OSPAR Commission background document on brominated flame retardants (addressing decaBDE) was reviewed by Sweden in 2001 and published by OSPAR in 2004. A next full review of this document is not planned before 2008.

**SWITZERLAND**

Selected BFRs, including decaBDE, have been investigated in the Swiss National Research Programme NRP50 “Endocrine Disrupters – relevance to humans, animals and ecosystems” (see: <http://www.nrp50.ch/projects.html>). Within this research program a consensus platform “Brominated Flame Retardants” has been established. The consensus platform lasted from May 2006 to June 2007 and involved a total of 19 representatives of the chemical industry and downstream users of flame retardants, authorities and scientists. The consensus platform aimed at concluding on the impact of selected BFRs and recommended action for risk reduction – based on current scientific data. The final document of the consensus platform “Brominated Flame Retardants” has been published by the Swiss National Science Foundation (<http://www.nrp50.ch/uploads/media/finaldocumentenglish.pdf>).

The Swiss Cantonal authorities carried out in 2008 a market survey study on the use of brominated flame retardants in articles such as electrical and electronic equipment, upholstery furniture, textiles and insulating foams. DecaBDE was one of the target substances of this study.

**UNITED STATES**

DecaBDE was listed on the US EPA’s list of SARA 313 substances many years ago (as a substance subject to annual reporting of releases to the environment by manufacturers and users of the substance). The majority of the releases are to EPA approved sites.

<p><b>(i) Status of OECD Hazard Assessment</b></p> <p>The SIDS Initial Assessment Profile (SIAP), prepared by Sweden (Sponsor Country) and the European Community was adopted by SIAM 24 (17–20 April 2007, Paris) and endorsed by the Joint Meeting (20 August 2007).</p>
<p><b>(ii) Agreed recommendation for further work included in SIDS Profile</b></p> <p><b>Human Health:</b> The chemical is a candidate for further work. The chemical possesses properties indicating a hazard for human health with regard to repeated dose toxicity and possible developmental neurotoxicity. Therefore, OECD member countries are invited to perform an exposure assessment and if then indicated a risk assessment. Note: A risk assessment performed in the EU in the context of the EU Existing Chemicals Regulation is in progress.</p> <p><b>Environment:</b> The chemical is a candidate for further work. The chemical possesses properties indicating a hazard for the environment (acute aquatic toxicity to algae, chronic toxicity to Daphnia, high bioaccumulation potential). Therefore, OECD member countries are invited to perform an exposure assessment and if indicated a risk assessment. Note: A risk assessment performed in the EU in the context of the EU Existing Chemicals Regulation is in progress.</p>
<p><b>(iii) Follow-up of the recommendation by industry</b></p> <p>Under its voluntary emission reduction program, BSEF, the global scientific forum of the major HBCD producers commissioned, is conducting initiatives in the HBCD production stage and the polystyrene foams and textiles applications.</p> <p>The sole HBCD production site in Europe, in the Netherlands, has developed methods and use state of the art technology to control air, water and solid waste emissions. These measures have resulted in a reduction in 2006 of total HBCD emissions to less than 0.4 grams per tonne.</p> <p>Polystyrene foams represent the largest use of HBCD (about 80% of total use) Since 2006, The bromine industry and expanded polystyrene foams (EPS) and extruded polystyrene foams (XPS) producers have taken action to reduce emissions to the environment through a voluntary emissions reduction programme, SECURE (Self Enforced Control of Use to Reduce Emissions). A vast majority of EPS/XPS producers, representing more than 95% of HBCD consumption of the members of industry federations PlasticsEurope and Exiba, have committed to this programme.</p> <p>Through the Voluntary Emissions Action Programme (VECAP), textiles manufacturers have committed to reduce HBCD emissions since 2006. Today, manufacturers representing more than 87% of HBCD use in the textile sector in Europe have signed up to VECAP. In the US and Canada 39% of HBCD users have committed to VECAP and 31% have established a mass balance survey. In Japan, VECAP involves producers and users from the textiles and polystyrene foam industry. After the launch in January 2007, significant progress has been achieved, with 88% of HBCD users committed to VECAP in 2008 (<a href="http://www.bsef.com/product_stew/vecap/APR_2008_VECAP.pdf">http://www.bsef.com/product_stew/vecap/APR_2008_VECAP.pdf</a>). In addition to the above mentioned programmes, industry has started a 10-year environmental monitoring programme in Europe to monitor the effectiveness of the emission reductions.</p>
<p><b>(iv) Follow-up of the recommendation by OECD member countries</b></p> <p><b>AUSTRALIA</b></p> <p>Australia has conducted a preliminary assessment on BFRs focused on hazard and exposure, including the HBCD. A report, published in June 2001 can be accessed at:  <a href="http://www.nicnas.gov.au/publications/CAR/PEC/PEC20/PEC20index.asp">http://www.nicnas.gov.au/publications/CAR/PEC/PEC20/PEC20index.asp</a>.</p>

In June 2005, the Australian Ministry for Health and Ageing declared a certain number of chemicals “Priority Existing Chemicals (PECs)”, including HBCD. As a PEC, HBCD is currently being assessed for its potential effects on human health and the environment by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The Australian authorities are currently compiling from importers and producers information on quantities and use of this substance as well as general scientific information which is already available.

#### **CANADA**

Canada is currently undertaking screening assessments for TBBPA and its derivative substances, and for HBCD. When completed, the draft assessments will be published in the Canada Gazette and posted on the CEPA Registry web site ([www.ec.gc.ca/CEPARegistry/participation](http://www.ec.gc.ca/CEPARegistry/participation)) for a 60-day public comment period. After consideration of the public comments, the final report with conclusions will be published in the Canada Gazette.

#### **EUROPEAN UNION**

The EU risk assessment report (Sweden rapporteur) was agreed by TC NES in November 2007, and then sent to the European Commission Scientific Committee on Health and Environmental Risks (SCHER) for review. SCHER has adopted an opinion on the human health part, and an opinion on the environmental part that was published in May 2008:

[http://ec.europa.eu/health/ph\\_risk/committees/04\\_scher/docs/scher\\_o\\_093.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_093.pdf).

#### **JAPAN**

In Japan, HBCD is classified as class 1 monitoring substance by the Chemical Substance Control Law, which is not biodegradable and highly bio-accumulative, and under the requirement to report manufactured and imported amount annually. Ministry of the Environment of Japan conducted measurement of HBCD in air, water, sediment and aqueous biota in 2003.

#### **UNITED STATES**

The USEPA has begun work on a draft regulation to complement a national flammability standard for residential upholstered furniture being considered by the US Consumer Product Safety Commission (CPSC). USEPA’s work on the draft regulation is on hold, pending a decision by CPSC to propose the standard. CPSC staff is continuing to conduct lab testing and other technical research to support a possible standard. In July of 2007, CPSC staff attended an industry-sponsored meeting to solicit input from stakeholders. Options that CPSC is now considering include one that could probably be met with little or no use of flame retardants additives in cover fabrics or filling materials.

Potential substitutes for HBCD, if not already in commerce as existing chemicals, would be evaluated under the USEPA new chemicals program.

EPA has decided to conduct an Integrated Risk Information System (IRIS) assessment of HBCD during 2008 (see US Federal Register, December 21, 2007 (Volume 72, Number 245), pp. 72715-72719). A schedule for the assessment will be posted at: <http://cfpub.epa.gov/ncea/iristrac/index.cfm>.

#### **(v) Other relevant information useful for the risk management of the HBCD**

#### **EUROPEAN UNION**

The EU rapporteur has prepared a draft Risk Reduction Strategy. An initial discussion of the report was held at the Risk Reduction Strategy Meeting (RRSM) in October 2007. The strategy is expected to be finalised at the following RRS in April 2008.

#### **OSPAR**

HBCD is included on OSPAR’s list of chemicals for priority action to protect the marine environment. An OSPAR Commission background document on brominated flame retardants (addressing HBCD) of 2001 was reviewed by Sweden and published by OSPAR in 2004. A next full review is not planned before 2008.

## **SWITZERLAND**

Selected BFRs, including HBCD, have been investigated in the Swiss National Research Programme NRP50 “Endocrine Disrupters – relevance to humans, animals and ecosystems” (<http://www.nrp50.ch/projects.html>). Within this research program a consensus platform “Brominated Flame Retardants” has been established. The consensus platform lasted from May 2006 to June 2007 and involved a total of 19 representatives of the chemical industry and downstream users of flame retardants, authorities and scientists. The consensus platform aimed at concluding on the impact of selected BFRs and recommended action for risk reduction – based on current scientific data. The final document of the consensus platform “Brominated Flame Retardants” has been published by the Swiss National Science Foundation (see: <http://www.nrp50.ch/uploads/media/finaldocumentenglish.pdf>).

The Swiss Cantonal authorities carried out in 2008 a market survey study on the use of brominated flame retardants in articles such as electrical and electronic equipment, upholstery furniture, textiles and insulating foams. HBCD was one of the target substances of this study.

<p><b>(i) Status of OECD Hazard Assessment</b></p> <p>The SIDS Initial Assessment Profile (SIAP), prepared by the United Kingdom (Sponsor Country) and the European Community was adopted by SIAM 20 (19-21 April 2005, Paris) and endorsed by the Joint Meeting (25 July 2005). SIAP was revised in October 2007 and endorsed by the Joint Meeting (26 February 2008).</p>
<p><b>(ii) Agreed recommendation for further work included in the SIDS Profile</b></p> <p><b>Human Health:</b> The chemical is currently of low priority for further work due to its low hazard profile.</p> <p>Note: no human health hazard of concern has been identified in an assessment performed in the European Union in the context of the EU Existing Substances Regulation (EEC) 793/93.</p> <p><b>Environment:</b> The chemical is a candidate for further work. The chemical possesses properties indicating a hazard. Based on the available exposure information, OECD member countries are invited to perform an exposure assessment, and if necessary a risk assessment for the environment.</p> <p>Note: a risk assessment performed in the context of the EU Existing Substances Regulation indicates that a possible risk to surface water, sediment and soil may exist from the use of this substance. Further post-SIDS testing is recommended to define more reliable PNECs for these compartments. In addition, further post-SIDS testing is recommended to investigate further the products from anaerobic degradation, in particular the formation of bisphenol-A. It is recommended that the following testing is undertaken:</p> <ul style="list-style-type: none"> <li>• A re-determination of the long-term NOECs for growth seen in studies with <i>Chironomus tentans</i> and/or <i>Crassostrea virginica</i> exposed via water;</li> <li>• Determination of the long-term toxicity with <i>Chironomus</i> sp. (or other similar organism) exposed via sediment (testing is currently ongoing); and</li> <li>• Determination of the long-term toxicity with soil-dwelling organisms (testing is currently ongoing).</li> </ul> <p>An investigation into the possible degradation to bisphenol-A in freshwater anaerobic sediments and/or anaerobic sewage treatment processes (3 studies are currently ongoing).</p>
<p><b>(iii) Follow-up of the recommendation by industry</b></p> <p>The RAR has identified a potential risk to water, sediment and soil, but only from the additive use of TBBPA. No risk from reactive use was identified.</p> <p>The potential degradation to BPA has also been investigated and is discussed in the risk assessment reports of both TBBPA and bisphenol-A (BPA). Based on the most recent available no-effect-levels of BPA (there are additional studies going on to refine these), no risk from this process was identified.</p>
<p><b>(iv) Follow-up of the recommendation by OECD member countries</b></p> <p><b>AUSTRALIA</b></p> <p>Australia has conducted a preliminary assessment on BFRs focused on hazard and exposure, including the TBBPA. A report, published in June 2001, can be accessed at: <a href="http://www.nicnas.gov.au/publications/CAR/PEC/PEC20/PEC20index.asp">http://www.nicnas.gov.au/publications/CAR/PEC/PEC20/PEC20index.asp</a>.</p> <p>In June 2005, the Australian Ministry for Health and Ageing declared a certain number of chemicals "Priority Existing Chemicals (PECs)", including TBBPA. As a PEC, TBBPA is currently being assessed for its potential effects on human health and the environment by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). The Australian authorities are currently compiling from importers and producers information on quantities and use of this substance as well as general scientific</p>

information which is already available.

#### **CANADA**

Canada is currently undertaking screening assessments for TBBPA and its derivative substances, and for HBCD. When completed, the draft assessments will be published in the Canada Gazette and posted on the CEPA Registry web site (<http://www.ec.gc.ca/CEPARRegistry/participation>) for a 60-day public comment period. After consideration of the public comments, the final report with conclusions will be published in the Canada Gazette.

#### **EUROPEAN UNION**

The EU risk assessment report – human health part (UK rapporteur) has been finalised in March 2005 and was published by the European Chemicals Bureau (ECB) in 2006. It concluded that no risks for human health have been identified for all uses and indicated no need for risk reduction measures. The Scientific Committee on Health and Environmental Risks (SCHER) opinion on this report can be viewed at: [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scher/docs/scher\\_o\\_020.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_020.pdf).

The final draft of the environmental risk assessment was submitted to the European Chemicals Bureau for publication in February 2008, following review by the SCHER in January 2008 (the opinion can be seen at: [http://ec.europa.eu/health/ph\\_risk/committees/04\\_scher/docs/scher\\_o\\_071.pdf](http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_071.pdf)). The final report was published in the official journal of the European Union on 18 June 2008 (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:152:0011:0020:EN:PDF>). The report takes account of the data submitted in accordance with the SIDS recommendations, and an updated OECD SIDS initial assessment profile was agreed by written procedure in August 2007. Potential risks were identified to surface water and sediment for two scenarios where TBBPA is used as an additive flame retardant and to soil for three scenarios where TBBPA is used as an additive flame retardant. A final conclusion on the relevance of degradation to bisphenol-A will be taken once further toxicity data are available for the latter substance in 2008.

#### **JAPAN**

Ministry of the Environment of Japan conducted measurement of TBBPA in water, sediment and aqueous biota in 2000 and 2003, and in air, water and sediment in 2002 and 2003. It also conducted initial risk assessment in 2002 (<http://www.env.go.jp/chemi/report/h14-05/chap01/03/22.pdf>, Japanese only).

#### **UNITED STATES**

The US electronics industry is currently engaging in a multi-stakeholder partnership with USEPA to better understand the full range of options for achieving the UL 94 V0 fire safety standard for printed circuit boards. The goal of the Flame Retardants for Printed Circuit Boards Partnership is to identify and evaluate commercially available flame retardants and their environmental, human health and safety and environmental fate aspects in the majority of printed circuit boards. Currently, >95% of boards meet fire safety standards through the use of brominated epoxy resins in which TBBPA forms part of the polymeric backbone of the resin. Alternative flame retardant materials are used in only 3–5 percent of the current FR-4 boards, but additional alternative flame retardant materials are also under development. The partnership plans to conduct an alternatives assessment to focus on environmental and human health considerations, building on the methodology of the Furniture Partnership (see pentaBDE section, above). The results, along with cost and performance information, will be used by the electronics industry in selecting flame retardants for printed circuit boards. See <http://www.epa.gov/dfe/pubs/projects/pcb/index.htm> for more information on this partnership.

#### **(v) Other relevant information useful for the risk management of the TBBPA**

#### **EUROPEAN UNION**

The EU rapporteur (UK) has prepared a draft Risk Reduction Strategy for additive TBBPA. A discussion of the report was held at the Risk Reduction Strategy Meeting (RRSM) in October 2007 and the report was agreed. The final version was published in the official journal of the European Union on June 18, 2008

(<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:158:0062:0064:EN:PDF>). For the risks identified from additive use, it was agreed that the respective sites should operate under IPPC guidelines. Local emissions to the environment should, where necessary, be controlled by national rules to ensure that no risk for the environment is expected. No risks for reactive use had been identified.

#### **OSPAR**

TBBPA is included on OSPAR's list of chemicals for priority action to protect the marine environment. An OSPAR Commission background document on TBBPA has been updated in 2005.

#### **SWITZERLAND**

Selected BFRs, including TBBPA, have been investigated in the Swiss National Research Programme NRP50 "Endocrine Disrupters – relevance to humans, animals and ecosystems" (see: <http://www.nrp50.ch/projects.html>). Within this research program a consensus platform "Brominated Flame Retardants" has been established. The consensus platform lasted from May 2006 to June 2007 and involved a total of 19 representatives of the chemical industry and downstream users of flame retardants, authorities and scientists. The consensus platform aimed at concluding on the impact of selected BFRs and recommended action for risk reduction – based on current scientific data. The final document of the consensus platform "Brominated Flame Retardants" has been published by the Swiss National Science Foundation (<http://www.nrp50.ch/uploads/media/finaldocumentenglish.pdf>).

The Swiss Cantonal authorities carried out in 2008 a market survey study on the use of brominated flame retardants in articles such as electrical and electronic equipment, upholstery furniture, textiles and insulating foams. TBBPA was one of the target substances of this study.

#### **UNITED STATES**

TBBPA is listed on the US EPA's list of SARA 313 substances (substance subject to annual reporting of releases to the environment by manufacturers and users of the substance).