Rotterdam Convention

Operation of the prior informed consent procedure
for banned or severely restricted chemicals

Decision Guidance Document

Pentabromodiphenyl ether (CAS No. 32534-81-9) and pentabromodiphenyl ether commercial mixtures

UNEP

Secretariat of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals[1] for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[2] in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its sixth meeting, held in Geneva from 28 April to 10 May 1013 the Conference of the Parties agreed to, list commercial pentabromodiphenyl ether (including tetrabromodiphenyl ether and pentabromodiphenyl ether), in Annex III of the Convention and adopted the decision-guidance document with the effect that this mixture became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on 10 August 2013, in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III of the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention. Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

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1 According to the Convention, the term “chemical” means a substance, whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.

2 According to the Convention, the term “Party” means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

STANDARD CORE SET OF ABBREVIATIONS	
$<$	less than
$\leq$	less than or equal to
$>$	greater than
$\geq$	greater than or equal to
µg	microgram
bw	body weight
BDE	bromodiphenyl ether
BFR	bromo flame retardants
°C	degree Celsius (centigrade)
c-PentaBDE	commercial mixture of pentabromodiphenyl ether
CAS	Chemical Abstract Service
CEPA 1999	Canadian Environmental Protection Act, 1999
CLP	Classification, Labelling and Packaging
CSTEE	Scientific Committee on Toxicity, Ecotoxicity and the Environment
CTV	critical toxicity value
d	day
DBDE	dibromodiphenyl ether
dw	dry weight
p,p'-DDE	*para*, *para'*-dichlorodiphenyldichloroethene
e.g.	for example
EC	European Community
EC_{50}	median effective concentration
ED_{50}	median effective dose
EEA	European Economic Area
EEV	estimated exposure value
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Commercial Chemical Substances
ENEV	estimated no-effects value
EPA	Environmental Protection Agency
EU	European Union
EUSES	European Union System for the Evaluation of Substances
FAO	Food and Agriculture Organization of the United Nations
FR2 laminate	laminate with phenolic resins to which flame retardant material has been added
g	gram
h	hour
ha	hectare
IARC	International Agency for Research on Cancer
ILO	International Labour Organisation

STANDARD CORE SET OF ABBREVIATIONS	
IPCS	International Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
k	kilo- (x 1000)
kg	kilogram
Koc	organic carbon-water partition coefficient
K_{OW}	octanol-water partition coefficient
kPa	Kilopascal
L	litre
LC_{50}	median lethal concentration
LD_{50}	median lethal dose
lw	lipid weight
LOAEL	lowest-observed-adverse-effect-level
LOEL	lowest-observed-effect-level
LOEC	lowest-observed-effect-concentration
log Kaw	logarithm of the air-water partition coefficient
log Koa	logarithm of the octanol-air partition coefficient
log K_{OW}	logarithm of the octanol-water partition coefficient
m^3	cubic metre
mg	milligram
ml	millilitre
mPa	milliPascal
MTD	maximum tolerated dose
ng	nanogram
NOAEL	no-observed-adverse-effect level
NOEC	no-observed-effect-concentration
NOEL	no-observed-effect-level
OBDE	Octabromodiphenyl ether
OECD	Organisation for Economic Co-operation and Development
Pa	Pascal
PBDE	polybrominated diphenyl ethers
PCB	polychlorinated biphenyls
PentaBDE	Pentabromodiphenyl ether (congener)
pg	picogram
PNEC	predicted-no-effect-concentration
POP	persistent organic pollutant
POPRC	Persistent Organic Pollutant Review Committee
ppm	parts per million
PUR	polyurethane foam
QSAR	quantitative structure-activity relationship
TetraBDE	Tetrabromodiphenyl ether (congener)
UNEP	United Nations Environment Programme
US EPA	United States Environmental Protection Agency
vs	versus
wt	weight
ww	wet weight
WHO	World Health Organization

Decision guidance document for a banned or severely restricted chemical

Pentabromodiphenyl ether (CAS No. 32534-81-9) and pentabromodiphenyl ether commercial mixtures[3] **Published: 10 August 2013**

1. Identification and uses (see Annex 1 for further details)

Common name

Pentabromodiphenyl ether

Pentabromodiphenyl ether commercial mixtures

Pentabromodiphenyl ether commercial mixtures are technical mixtures of different polybrominateddiphenyl ethers with varying degrees of bromination. The most abundant congeners are tetrabromodiphenyl ethers and pentabromodiphenyl ethers (POPRC, 2006). In this Decision Guidance Document, typical pentabromodiphenyl ether commercial mixtures will be abbreviated as c-PentaBDE and the name of the substance pentabromodiphenyl ether will be abbreviated as PentaBDE.

The specification of the commercial mixtures may vary, but generally is composed of the following congeners (European Communities, 2001b):

tribromodiphenyl ether, 0-1 % w/w;

tetrabromodiphenyl ether, 24-38 % w/w;

pentabromodiphenyl ether, 50-62 % w/w;

hexabromodiphenyl ether, 4-12 % w/w; and

heptabromodiphenyl ether, trace.

Each congener might exhibit a number of isomeric forms, although it is not clear which, in what proportion, and whether this will change depending on the supplier or by the manufacturing process. However, for TetraBDE, the main isomeric form is 2,2',4,4'-tetrabromodiphenyl ether; while for PentaBDE, the main isomer is 2,2',4,4',5 pentabromo diphenyl ether (WHO, 2003).

Information in this Decision Guidance Document focuses on pentabromodiphenyl ether and the main components of commercial pentaBDE mixtures: tetra- and pentabromodiphenyl ether. Hexabromodiphenyl ether is covered by the Decision Guidance Document on octabromodiphenyl ether commercial mixtures.

Chemical name and other names or synonyms

IUPAC name (main components):	Synonyms	
2,4,-dibromo-1-(2,4-dibromophenoxy) benzene or; 2,2',4,4'-tetrabromodiphenyl ether	TetraBDE	BDE-47
2,4,5-tribromo-1-(2,4-dibromophenoxy) benzene or; 2,2',4,4',5-pentabromodiphenyl ether	PentaBDE	BDE-99

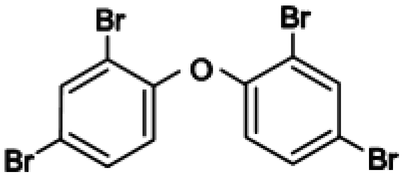
Molecular formula

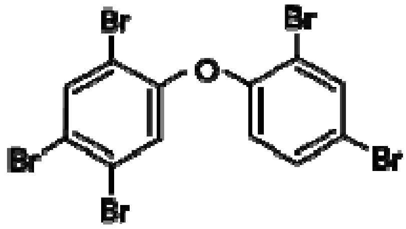
Name	Molecular formula
TriBDE	$C_{12}H_7Br_3O$
TetraBDE	$C_{12}H_6Br_4O$
PentaBDE	$C_{12}H_5Br_5O$
HexaBDE	$C_{12}H_4Br_6O$
HeptaBDE	$C_{12}H_3Br_7O$

3 The commercial product referred to as pentabromodiphenyl ether is a mixture of brominated diphenyl congeners with varying degrees of bromination which contains TetraBDE, and PentaBDE as main components.

Chemical structure

Main components (POPRC, 2006; WHO, 2003).





2,2',4,4'-tetrabromodiphenyl ether — 2,2’,4,4’,5-pentabromodiphenyl ether

TetraBDE — PentaBDE

CAS-No.(s)

Name	**CAS No[4].**
TriBDE	49690-94-0
TetraBDE	40088-47-9
PentaBDE	32534-81-9
HexaBDE	36483-60-0
HeptaBDE	68928-80-3

Harmonized System Customs Code

2909 30 (any PBDE)

Other numbers

Name	**EINECS No.**
TriBDE	---
TetraBDE	254-787-2
PentaBDE	251-084-2
HexaBDE	---
HeptaBDE	---

Category
Industrial

Regulated category
Industrial chemical

Use(s) in regulated category

Canada

The notified regulatory action relates to pentabromodiphenyl ether and its commercial mixtures (c-PentaBDE) and the industrial use of the chemical as flame retardants in polymers and resins. PentaBDE was used almost exclusively in flexible polyurethane foam in Canada.

European Union[5]

The notified regulatory action relates to diphenyl ether, pentabromo derivatives (PentaBDE) and their industrial use. At the time the notification was made, c-PentaBDE was used in the EU as a flame retardant additive for polyurethane (principally flexible foam for use in car seats, furniture and packaging) at typical loading of 10 % w/w. Several other uses have been reported in the literature (*e.g.* in textile and electronics) but it is not known if these currently occur in the EU.

Norway

The final regulatory action relates to diphenyl ether, pentabromo derivatives and their industrial use. c-PentaBDE has been used in Norway as a flame retardant in electrical and electronic equipment, polyurethane foam (PUR), textiles and in means of transportation.

4 Depending on the isomeric form, CAS numbers for different congeners, e.g. 60348-60-9 for 2,2',4,4',5-pentabromodiphenyl ether or 5436-43-1 for 2,2',4,4'-tetrabromodiphenyl ether can apply. There may be other isomeric forms of tetra- and pentabromodiphenyl ethers present in commercial pentabromodiphenyl ether mixture.

5 At the time the notification was made, the notifying regional economic integration organisation was called the European Community (EC). Following the entry into force of the Lisbon Treaty on 1 December 2009, the name changed to European Union (EU). The latter term is used throughout this Decision Guidance Document for consistency reasons. [FORMAT: Font looks strange?]

Stockholm Convention

According to the risk profile on c-PentaBDE that was developed by the Persistant Organic Pollutants Review Committee (POPRC) of the Stockholm Convention the c-PentaBDE is used or has been used in the following sectors (POPRC, 2006, p.9):

1. Electrical and electronic appliances – computers, home electronics, office equipment, household appliances and other items containing printed circuit laminates, plastic outer casings and internal plastic parts such as small run components with rigid polyurethane elastomer instrument casings.
2. Traffic and transport – cars, trains, aircraft and ships containing textile and plastic interiors and electrical components.
3. Building materials – foam fillers, insulation boards, foam insulation, piples, wall and floor panels, plastic sheeting, resins etc.
4. Furniture – upholstered furniture, furniture covers, mattresses, flexible foam components.
5. Textiles – curtains, carpets, foam sheeting under carpets, tents, tarpaulins, work clothes and protective clothing.
6. Packaging – polyurethane foam based packaging materials.

The most common use, accounting for 95-98 % of c-PentaBDE since 1999, has been in polyurethane foam (Hale *et al.*, 2002 in POPRC, 2006). This foam may contain between 10 and 18 % of the c-PentaBDE formulation. Polyurethane foam is mainly used for furniture and upholstery in domestic furnishing, automotive and aviation industry. Other uses are in rigid polyurethane elastomers in instrument casings, in epoxy resins and phenolic resins in electrical and electronic appliances, and construction materials. For some years now, the more highly brominated DecaBDE has been preferred in these applications. C-PentaBDE has also been incorporated in minor amounts in textiles, paints, lacquers, in rubber goods (conveyer belt, coating and floor panels) and in oil drilling fluids. Levels range from 5-30 % by weight. Up to the early 1990s, c-PentaBDE was used in printed circuit boards, usually FR2 laminates (phenolic resins) in Asia. Such FR2 laminates are used in household electronics (television, radio, and video), vehicle electronics, and white goods (washing machines, kitchen appliances, for example). In the early 1990s the amount c-PentaBDE used in textile treatment was 60 % of total use in the EU, but this application is now banned. C-PentaBDE has been identified as an additive flame retardant in textiles in national substance flow analyses in the ECE region (Danish EPA, 1999 in POPRC, 2006). Manufacturers of furniture textiles have stated that the textile contained 0.45 % PentaBDE in a Norwegian flow analysis reported in 2003. Stringent rules on flammability apply to textiles used in the public sector, the transport sector and business sector, but rules for domestic use are less consistent. According to information obtained from the bromine industry the use of c-PentaBDE as hydraulic fluid (as a component of a mixture) in petroleum borings and mining was discontinued 10-20 years ago. Australia (in POPRC, 2006) has reported uses in manufacture of polyurethane foams for refrigerators and packaging, and in epoxy resin formulations supplied into aerospace market and for use as potting agents, laminating systems and adhesive systems. The US (in POPRC, 2006) has reported use of c-PentaBDE in the aircraft industry. There is no use of c-PentaBDE in newer aircraft, and thus no exposure of the public, but c-PentaBDE is still used in military aircraft.

Trade names

Bromkal 70-5 DE; Bromkal 70; Bromkal 70 DE; Bromkal Gl; DE-60 F (a mixture of 85 % PentaBDE and 15 % of an aromatic phosphate); DE-71; FR 1205/1215; Pentabromprop; Saytex 115; Tardex 50.

This is an indicative list. It is not intended to be exhaustive.

Formulation types

Not applicable

Uses in other categories

Canada, European Union and Norway

No reported use as pesticide.

Basic manufacturers	C-PentaBDE has been produced in Israel, Japan, US and the EU. Today there is no production in Japan and c-PentaBDE was voluntarily withdrawn from the Japanese market in 1990 (UNECE, 2007, in SFT, 2009). There is no official information available from Israel of any present production or use of c-PentaBDE. The sole producer of c-PentaBDE in the US, the Great Lakes Chemical Corporation (now Chemtura), voluntary ended their production of c-PentaBDE by 1^{st} of January 2005 (Landry, S. Albermarle, in SFT, 2009). Investigations through direct contacts with industry and studies of relevant sources information on any historic or present production or use of c-PentaBDE in Eastern European countries outside the EU have been sought, but no information of such activities was found. *This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.*

2. Reasons for inclusion in the PIC procedure

PentaBDE and PentaBDE commercial mixtures are included in the PIC procedure as industrial chemicals. They are listed on the basis of:

- the final regulatory actions taken by Canada to ban PentaBDE and its commercial mixtures as industrial chemicals, and;
- the final regulatory actions taken by the European Union and Norway that both severely restrict the use of PentaBDE including its commercial mixtures.

In the European Union and Norway concentrations of PentaBDE of up to 0.1 % by weight are allowed. However, in 2009 the COP4 of the Stockholm Convention decided to list congeners present in the commercial forms of pentabromodiphenyl ether having POPs characteristics. This decision was implemented in the EU through Regulation (EU) 757/2010 and will result in further restriction of the use of the PentaBDE and its commercial mixtures.

No final regulatory action relating to pesticide uses have been notified.

2.1 Final regulatory action (see Annex 2 for further details)

Canada

The decision made was to ban the uses, manufacture, sale, offer for sale, and import of TetraBDE and PentaBDE congeners that meet the criteria for virtual elimination under Canadian Environmental Protection Act 1999 (CEPA, 1999). The decision does not apply to Tetra- and PentaBDE in pest control products, as well as polymers, resins and other mixtures containing these substances for use in a laboratory for analysis, in scientific research or as a laboratory analytical standard and those present as a contaminant (Polybrominated Diphenyl Ethers Regulations (SOR/2008-218)) under CEPA 1999. The decision was applied in June 2008.

Reason: Environment

European Union

The decision was to severely restrict the use and prohibit all applications of diphenylether, pentabromo derivative $C_{12}H_5Br_5O$ as substance or as constituent of substances or of preparations in concentration higher than 0.1 % by mass and in articles if they contain the substance in concentrations higher than 0.1 % by mass (Notification from EU, 2.2.1). The EU Members States shall apply the laws, regulations and administrative provisions necessary to comply with the Directive starting from 15 August 2004. Concentrations lower than 0.1 % will remain allowed thereafter (Directive 2003/11/EC). This might indicate that product containing concentrations less than 0.1 % may be allowed, and this is clearly stated in the notification form.

Reason: Human Health and the Environment

Norway

In 2004, Norway banned production, import, export, marketing and use of PentaBDE and mixtures containing more than 0.1 % per weight or more of PentaBDE. Products containing more than 0.25 % of PentaBDE are classified as hazardous waste when they are discarded. Recycling and reuse of PentaBDE and materials with PentaBDE are not allowed.

Reason: Human Health and the Environment

2.2 Risk evaluation of pentabromodiphenyl ether commercial mixture (see Annex 1 for further details)

Canada

Tetra- and PentaBDE can be found in many items such as building and automobile materials, carpet underlay, furniture, polyurethane foam and electronic equipment; and are released to the environment during the product's manufacture (UNEP/FAO/RC/CRC.7/8, and Add.1).

Environment Canada, under CEPA 1999, proceeded to implement a hazard and risk assessment on Tetra- and PentaBDE. It was based on a risk evaluation and took into account toxicology, environmental fate and behaviour, ecotoxicology, residues and availability of alternatives. The review concluded that Tetra- and PentaBDE were extremely toxic to most aquatic organisms tested. Even a 30-metre buffer zone to surface water was not sufficient to protect the aquatic environment. By repeated use of Tetra- and PentaBDE, some populations of invertebrates were adversely affected for a longer period. The result was published in June 2006, (Ecological Screening Assessment Report), in which it was concluded that Tetra- and PentaBDE are entering the environment in concentrations or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. Environment Canada's Ecological Screening Assessment Report indicated that the greatest potential risks from Tetra- and PentaBDE in the Canadian environment are the secondary poisoning of wildlife from the consumption of prey containing elevated concentrations of Tetra- and PentaBDE, and effects on benthic organisms, which may result from elevated concentrations of certain Tetra- and PentaBDE congeners in sediments, (UNEP/FAO/RC/CRC.7/8, and Add.1).

The notification describes the specific risks and outlines that the ban of Tetra- and PentaBDE uses significantly reduces the exposure of aquatic organisms and wildlife, therefore, the final regulatory action constitutes a preventative approach to ensure that these activities are not introduced in Canada.

European Union

The decision to ban c-PentaBDE was based on a risk assessment covering emissions and consequent environmental impact and human exposures at each stage of the life cycle of the chemical, from production, through processing, formulation and use, to recycling and disposal. Protection goals for the environment included the atmosphere, aquatic organisms, sediment-dwelling organisms, soil-dwelling organisms, microorganisms in waste water treatment plants, and mammals and birds exposed via accumulation through the food chain.

Exposure of humans from all relevant sources was considered, including exposures from consumer products, through air, food, and drinking water (man exposed via environment) and exposure at the workplace. It was concluded that although available data were insufficient in certain respects, there were unacceptable risks to human health and the environment that necessitated regulatory action. The risks to workers were that the estimated body burden of PentaBDE congeners arising from occupational exposure, mainly via dermal contact, is approximately 4-fold greater than the NOAEL derived from the rodent study (liver effects). Unacceptable risks to human health were identified including human exposed through environment and infants exposed through breast milk. Concerns to aquatic and terrestrial environment were also identified from production and/or use of polyurethane foams. This information is contained in UNEP/FAO/RC/CRC7/8/ and Add.2.

Norway

Norway's risk evaluation of c-PentaBDE was based on risk assessments undertaken by the EU and a report by the Nordic Council of Ministers (UNEP/FAO/RC/CRC7/8/ and Add.4), as well as scientific data that was considered particularly relevant to Norwegian conditions as given in the document UNEP/FAO/RC/CRC7/8/ and Add.4. The national evaluation took into account production, use, environmental fate and behaviour, exposure as well as toxicity to humans and wildlife. Socioeconomic factors were also considered. All data evaluated indicated that c-PentaBDE was an important contaminant of the Norwegian environment and of sufficient concern for human health and wildlife to warrant a national ban at concentrations greater than 0.1 % by weight.

The evaluation was also based on the review of scientific data generated for c-PentaBDE in the context of the conditions prevailing in Norway. The national evaluation took into account production, use, environmental fate and behaviour, exposure as well as toxicity to humans and wildlife. Data reviews were performed and documented according to generally recognized scientific principals and procedures.

In Norway, congeners of c-PentaBDE have been found in a variety of biotic samples. It has been detected in, *e.g.* human samples as well as in cod-liver and mussels. High levels of PentaBDE were found in fish from the Norwegian lake Mjøsa. Further studies detected significant amounts of PentaBDE in sediments and fish at different locations in Norway. Based on this evaluation there are concerns for serious damage to human health by prolonged exposure and concern for breastfed babies. PentaBDE was found in most compartments of the Norwegian environment and mainly fish, which is considered as important source of exposure to humans in Norway. It was considered alarming, especially for populations that are dependent on fish for their diet (*e.g.* indigenous people).

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Canada

The ban covers manufacture, use, sale, offer for sale, and import of TetraBDE and PentaBDE congeners that meet the criteria for virtual elimination under CEPA 1999. This is expected to result in a significant reduction of the quantity of chemical used and the number of its uses; and definitely, to cause an actual reduction of the risk to the environment especially wildlife and benthic organisms.

European Union

Directive 2003/11/EC prohibits all applications of PentaBDE as a substance and as constituent of substances or of preparations or in articles where the concentration exceeds 0.1 % by mass, starting from 15 August 2004. Concentrations lower than 0.1 % will remain allowed thereafter. Since the use of the chemical was severely restricted it can be assumed that this regulatory action will result in a significant reduction of quantities of the chemical used in the EU, the number of its uses and a significant reduction of risk to human health and the environment from exposure to c-PentaBDE at a local and regional level within the EU.

Norway

The 2004 ban covers all uses of PentaBDE and mixtures at concentrations equal to or greater than 0.1 % PentaBDE by weight. This will cause a significant decrease in the quantity of the chemical used or the number of its uses, certainly, this will result in a significant reduction of risk to human health and the environment

3.2 Other measures to reduce exposure

Description of any non-regulatory measures used by the notifying party to reduce exposure
The notifying Parties gave no indication.

General
If any internationally recognised measures to reduce exposure have been developed, they can be listed here.

3.3 Alternatives

It is essential that before a country considers substituting alternatives, it ensures that the use is relevant to its national needs, and the anticipated local conditions of use. The hazards of the substitute materials and the controls needed for safe use should also be evaluated.

Canada

Chemical alternatives to PBDEs are available for the vast majority of industrial and manufacturing applications, and these vary by application. However, several issues need to be addressed as some potential alternatives are:

- currently under scrutiny themselves;
- new proprietary chemicals for which data on environmental and health effects are very limited;
- more costly; and
- less effective, hence much higher levels are required and products may be less likely to meet flammability standards.

Alternative Techniques

The need for PBDEs can be reduced through the use of alternative techniques such as:

- use of materials that are less prone to fire hazard in electronics equipment (such as aluminium or "super-plastics" with very high oxygen requirements for combustion); and
- use of barrier fabrics, wrappings or coatings for foams to replace chemical flame design-for-environment (DFE) techniques for re-use of components containing PBDEs, as an alternative to land filling or recycling plastic materials containing PBDEs. Some of these alternative techniques present challenges, such as increased weight of final products and methods to collect, reuse and reassemble products with components containing PBDEs.

European Union
There is no information provided in the notification from the EU.

Norway
There is no information provided in the notification from Norway.

Stockholm Convention
A guidance report on alternatives to c-PentaBDE has been developed for the Persistent Organic Pollutants Review Committee of the Stockholm Convention. The report states that there are flame retardants commercially available (both chemical and non-chemical) which are less hazardous than c-PentaBDE, with reference to: Guidance on flame-retardant alternatives to pentabromodiphenyl ether (PentaBDE), 2008. The report can be found on the Stockholm Convention home page (see SFT, 2009).

3.4 Socio-economic effects

Canada

C-PentaBDE is no longer manufactured, imported or used in Canada. Recent information collected from the industry indicates that historical uses of c-PentaBDE have been completely phased-out. There were some minor remaining uses in 2005, and a complete phase-out was achieved by 2006. This phase-out of c-PentaBDE use was confirmed by the industry association. Neither technical nor economic impact on the industry was expected from the regulations as c-PentaBDE use has been phased-out. In addition, users and suppliers of PentaBDE confirmed that given the regulatory climate, customer demand for PBDE products, the availability of cost-effective alternatives, and the fact that c-PentaBDE was not available in the market after 2005; it was not technically or economically viable to continue using c-PentaBDE.

The estimated total cost to industry is zero, as they have already substituted c-PentaBDE with other flame retardants. It was not possible to quantify and monetize the preventative benefits of the regulations given that PBDE use by industry had been discontinued and future demand for the substance could not be estimated.

European Union

Data on production and use of c-PentaBDE are not available. The number of EU export notifications is zero since 2003 and, therefore, it can be expected that no exports have been carried out from companies located in the EU Member States.

Norway
Insert assessment of socio-economic effects undertaken in the notifying party if applicable.

There is no information provided by the notifying Party.

4. Hazards and Risks to human health and the environment	
4.1 Hazard Classification	
WHO/IPCS	
IARC	No data available.
European Union	**Classification of PentaBDE (CAS No 32534-81-9) pursuant to Regulation (EC) No. 1272/2008 Annex VI Table 3.2**: **Xn**; Harmful **N;** Dangerous for the environment **Risk phrases** **R48/21/22;** Harmful: danger of serious damage to health by prolonged exposure in contact with skin and if swallowed. **R64**; May cause harm to breast-fed babies. **R50/53**; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. **Classification of PentaBDE (CAS No 32534-81-9) pursuant to Regulation (EC) No 1272/2008 Annex VI Table 3.1:** STOT RE 2* - H373 - May cause damage to organs through prolonged or repeated exposure Lact. – H362 - May cause harm to breast-fed children Aquatic Acute 1 – H400 - Very toxic to aquatic life Aquatic Chronic 1 – H410 - Very toxic to aquatic life with long lasting effects * = This classification shall be considered as a minimum classification.
US EPA	USEPA has established oral reference doses for c-PentaBDEs of 2.0 µg/kg bw/d. To address the issue of contaminated fish, an interim reference dose for TetraBDE has been suggested at 1.0 µg/kg bw/d. EPA derived reference doses for PentaBDE of $2x10^{-3}$ mg/kg/day, (US EPA, 2002). The USEPA carcinogenicity classification for Tetra- and PentaBDE: Group D (not classifiable as to human carcinogenicity) (US EPA, 2005).

4.2 Exposure limits
Information is provided in point 2 Toxicological properties of Annex 1

4.3 Packaging and labelling	
The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:	
Hazard Class and Packing Group:	not available
International Maritime Dangerous Goods (IMDG) Code	not available
Transport Emergency Card	not available

4.4 First aid

NOTE: The following advice is based on information available from the World Health Organisation and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

Not available

4.5 Waste management

Basel Convention

Waste should be disposed in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996), any guidelines there under, and any other relevant regional agreements. The relevant measures identified are as follows:

(a) classification as hazardous waste; and
(b) specified disposal, methods and/or conditions, for example, incineration (temperature and time).

The emphasis of these measures is on the disposal of final products of manufacture after industrial and professional use.

In the near future, the Basel Convention technical guidelines on the environmentally sound management of persistent organic pollutants will be updated to encompass PentaBDE along with the other new POPs that were listed in the Stockholm Convention in 2009. The work is proposed undertaken in collaboration with the Stockholm Convention (POPRC-6/3).

Stockholm Convention

Tetra- and PentaBDE, the main components of c-PentaBDE, fulfill the POPs criteria of the Stockholm Convention and are listed in Annex A of the Convention with exemptions for recycling as specified in Part V of Annex A. Given that the objective for listing is elimination, the persistent organic pollutants review committee (POPRC, 2010) on the topic and information provided by parties and observers developed recommendations on the elimination of brominated diphenyl ethers from the waste stream. In their overall recommendation as captured in the Annex to decision POPRC-6/2 POPRC states that the objective is to eliminate brominated diphenyl ethers from the recycling streams "as swiftly as possible" and that the "principal recommendation is to separate articles containing brominated diphenyl ethers as soon as possible before recycling" as "failure to do so will inevitably result in wider human and environmental contamination and the dispersal of brominated diphenyl ethers into matrices from which recovery is not technically or economically feasible and in the loss of the long-term credibility of recycling". POPRC in their overall recommendation moreover point out that "time is short because articles containing brominated diphenyl ethers are already present in many existing waste streams as a result of the time frame of former production of these articles" and state that "brominated diphenyl ethers should therefore not be diluted since this would not reduce the overall quantity in the environment".

European Union

Following the inclusion of the nine new POPs, including PFOS, in the Stockholm Convention in 2009, the EU commissioned a comprehensive study on POPs and waste that provide information on sources, concentrations, past uses, waste and recycling issues (ESWI, 2011). The report will be used by the EU and its Member States to identify, manage and regulate POPs containing waste e.g. to set limit values for POPs in waste and to classify whether a waste is a POP waste or not.

Annexes

Annex 1 **Further information on the substance**
Annex 2 **Details on Final regulatory action**
Annex 3 **Address of designated national authorities**
Annex 4 **References**

Annex 1 Further information on the substance

Introduction

The information presented in the present annex reflects the conclusions of the three notifying Parties, namely Canada, European Union, and Norway. Where possible, information provided by these three Parties on hazards has been presented together, while the risk assessments, which are specific to the conditions prevailing in the Parties, are presented separately. This information is taken from the documents referenced in the notifications in support of the final regulatory actions severely restricting or banning pentabromodiphenyl ether and its commercial mixtures. The notification from Canada was first reported in PIC Circular XXXII of December 2010, the notification from the European Union was first reported in PIC Circular XIX of June 2004 and the notification from Norway in PIC Circular XXIX of June 2009.

The information in the following table reviews the properties of the congeners found in a typical commercial mixture of PentaBDE which is a brominated flame retardant and presents some model parameters for consideration of its possible inclusion in Annex III of the Rotterdam Convention and reasons for its nomination as a POP included in the Stockholm Convention.

Annex 1 – Further information on pentabromodipheny ether and on tetrabromodiphenyl ether, which are major components of pentabromodiphenyl ether commercial mixtures

1.	**Physical-Chemical Properties**	**TetraBDE**	**PentaBDE**
1.1	Identity	Tetrabromodiphenyl ether	Pentabromodiphenyl ether
1.2	Formula	$C_{12}H_6Br_4O$	$C_{12}H_5Br_5O$
1.3	Physical state (20ºC;101.325 kPa)	Viscous liquid or semi-solid	White crystalline solid (pure isomers of PentaBDE)
1.4	Molecular weight	485.8	564.7
1.5	Vapour pressure (25ºC; Pa)	Not available	4.69 x $l0^{-5}$ (commercial product)
1.6	Water solubility (25ºC; µg/L)	10.9	2.4 13.3 (commercial product)
1.7	Log K_{OW}	Not available	6.57
1.8	Henry's law constant (25ºC; Pa m^3/mol)	Not available	11
1.9	Log Koa	10.53	11.3l
1.10	Melting Point	Not available	-7 to -3 (commercial product)
1.11	Boiling Point	Not available	decomposes above 200ºC (commercial product)
1.12	Relative density		2.25-2.28 (commercial product)
2	**Toxicological properties**		
2.1	General		
2.1.1	Mode of Action	**Endocrine disruption** C-PentaBDE appears to induce changes in thyroid hormone homeostasis and to interfere with steroid hormone regulated processes (European Communities, 2001b; POPRC, 2006). **Neurotoxicity** Regarding the observed neurotoxicity in mice, no clear mechanism could be defined but effects of PentaBDE both via thyroid hormone disruption and directly on signal transmission in brain have been discussed. For example, a number of PBDEs were capable of inducing cell death of cerebellar granule cells in culture (Reistad *et al.*, 2002, Reistad and Mariussen, 2005, see POPRC, 2006).	
2.1.2	Symptoms of poisoning	Available data are limited but suggests that c-PentaBDE may induce a “chlor-acne” like response in both humans and animals (European Communities, 2001b). In animal studies with rats clinical symptoms of poisoning such as lacrimation, salivation, tachypnea (rapid breathing/ respiration), altered motor activity, eye squint, erythema / red staining around nose and eyes, nasal and respiratory “congestion”, abnormal gait, reduced activity and tremors have been observed (European Communities, 2001b).	

2.1.3	Absorption, distribution, excretion and metabolism in mammals	The available information regarding the absorption, metabolism and excretion of c-PentaBDE in humans and animals suggests that the substance is readily taken up and absorbed in all species tested (European Communities, 2001b; Peltola and Ylä-Mononen, 2001). Exposure route seems to have little influence on uptake and absorption, and once the substance is absorbed there appears to be little metabolism (European Communities, 2001b and references therein). Hence, in accord with its relatively high solubility in fat and biological persistency, PentaBDE and/or its metabolites are distributed to and stored in adipose tissue for prolonged periods of time. The liver is the main target organ. Excretion occurs via the biliary and faecal routes, and via breast milk (Norway, 2010). Following the total consumption of 672 ng of DE-71, a representative c-PentaBDE mixture, by male rats over a period of 21 days (approximately 120 ng/kg bw per day), an average of 36 % of the dose based on the total of major congeners was detected in the carcass and liver (Hakk *et al*., 2001 in Peltola & Ylä-Mononen, 2001). Mice and rats administered PBDE 47, one of the main congeners found in c-PentaBDE, retained 47 % (mice) and 86 % (rats) of the dose after 5 days (Örn & Klasson-Wehler, 1998 in Peltola & Ylä-Mononen, 2001). In a similar study, approximately 39 % of a single oral dose of 2.2 mg PBDE 99 (2,2',4,4',5-BDE) was found to be retained by rats 72 hours after the dose (Hakk *et al*., 1999 in Peltola & Ylä-Mononen, 2001; WHO, 2003). Two major congeners present in various c-PentaBDE formulations, PBDE 47 and 99, have been tested for potential developmental neurotoxicity in mice. Male NMRI mice were treated with a single gavage dose of PBDE 47 (0, 0.7 or 10.5 mg/kg bw) or PBDE 99 (0, 0.8 or 12.0 mg/kg bw) on postnatal day 10 and tested for aspects of spontaneous behaviour and spatial learning ability at 2-5 months of age (Eriksson *et al*., 2001 in Peltola & Ylä-Mononen, 2001). Both doses of PBDE 99 and the highest dose of PBDE 47 affected spontaneous behaviour, while only mice treated with the highest PBDE 99 dose exhibited reductions in learning and memory functions as assessed by a swim maze (WHO, 2003).
2.2	Toxicology studies	
2.2.1	Acute toxicity	**Rodents** Studies in rodents indicate that c-PentaBDE preparations are of low acute toxicity via oral and dermal routes of exposure, with LD_{50} values typically > 2000 mg/ kg; **LD50** (oral, rat) 2640-6200 mg/kg (European Communities, 2001b). Sign of toxicity observed included diarrhea, pilo erection, abnormal gait, reduced activity, tremors, and red staining around nose and eyes. **LD50** (dermal, rat) > 2500 mg/kg (European Communities, 2001b) **LD50** (dermal, rabbit) > 2000 mg/kg **LC50** (inhalation, 4 h, rat) > 200 mg/l **Skin**, eye and respiratory tract irritation: non irritant (several studies) Sensitisation; non sensitiser (several studies) **Humans** Unknown. No data available.
2.2.2	Short term toxicity	Unknown. No data available
2.2.3	Genotoxicity (including mutagenicity)	Data are limited, but c-PentaBDE is presumably not genotoxic and not mutagenic in mammals. Available in 17 *in vitro* data indicates that PentaBDE would not be mutagenic *in vivo* (European Communities, 2001b). While no *in vivo* studies have been conducted to address the potential mutagenicity/genotoxicity of PentaBDEs, commercial mixtures (Bromkal 70-5 DE, Saytex 115) have tested negative in standard bacterial reverse mutation assays (European Commission, 2000a). In addition, PentaBDE did not induce chromosomal aberrations in human peripheral blood lymphocytes following *in vitro* exposure (European Communities, 2001b).

2.2.4	Long term toxicity and carcinogenicity	*Long term toxicity* Based on the documentation available at the time POPRC in their risk assessment highlight that c-PentaBDE, like other polybrominated diphenyl ethers that enter the environment, have or may have an immediate or long-term harmful effect on the environment or its biodiversity (Environment Canada, 2006, POPRC, 2006). In humans, neurodevelopmental effects observed in animals at low tissue levels gives reason for concern for long term effects resulting from exposure to environmental concentrations. A similar conclusion was made by the EU who agreed to classify the substance with the following risk phrases: **R48/21/22**; Harmful: danger of serious damage to health by prolonged exposure in contact with skin or if swallowed. **R64**; May cause harm to breastfed babies. **R50/53**; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. Also in the EU risk assessment an unacceptable risk for vertebrates due to secondary poisoning was identified (European Communities, 2001b). The conclusion was later supported by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) of the European Commission (European Commission, 2000a). The lowest LOEL identified for c-PentaBDE to date for liver effects is 0.44 mg/kg bw/d for 90 days, which resulted in persistent enzyme induction (Carlson 1980). This finding is supported by the estimated lower confidence limit on a benchmark dose of DE-71 for CYP 2B induction of 0.54 mg/kg bw/d (4-day exposure) in a different rat strain (Zhou *et al.*, 2001 in Environment Canada, 2006). A chronic NOEL could be estimated at a dose 10-fold lower than the LOEL, or 44 µg/kg bw/d. Although hepatic enzyme induction would not be considered an adverse effect, justification for setting the NOEL at this level can be provided based on the persistent and bioaccumulative nature of PBDE congeners found in c-PentaBDE. In addition, dose-dependent increases in relative liver weight and hepatocytomegaly, potentially more adverse end-points, have been observed in rats following ingestion of DE-71 at ≥ 2 mg/kg bw/d for 90 days (European Commission, 2000b). In addition, a benchmark dose of DE-71 for neonatal thyroid hormone effects in rats has recently been estimated at 0.94 mg/kg bw/d (Zhou *et al.*, 2002 in Environment Canada, 2006). When the chronic NOEL is compared to environmental exposures for adults from "worse-case" scenario modeling exercises, margin of safety values would be only 0.8-22, or unacceptably low taking into account current deficiencies in the toxicological data base. **Carcinogenicity**: There are no carcinogenicity data available for c- PentaBDE, however, it is considered as a possible human carcinogen and pregnant women, embryos and infants maybe more vulnerable because of effects on thyroid hormone balance and central nervous system development (WHO, 2003; POPRC, 2006).
2.2.5	Repeated exposure	A **NOAEL** of 1 mg/kg bw/d was identified from repeated dose oral studies in rodents which indicated that the liver is the principal target organ affected by PentaBDE. A repeated dose dermal study in the rabbit ear model indicates that PentaBDE has the potential to induce a "chloracne-like" response.
2.2.6	Effects on reproduction	**Fertility**; There are no fertility studies available for PentaBDE, but in a 90-day study no histological changes were observed in the gonads or accessory sex organs of either sex at doses up to 100 mg/kg/d. **Development**: No evidence for specific developmental toxicity was seen with PentaBDE when tested up to maternally toxic doses.

2.2.7	Neurotoxicity/ delayed neurotoxicity, Special studies where available	A critical effect of c-PentaBDE seem to be developmental neurotoxicity. (Darnerud, 2003 in POPRC, 2006; VKM, 2005). The LOAEL value for PentaBDE could be set to 0.6-0.8 mg/kg body wt, based on the most sensitive effect observed, neurobehavioral effects during early development (Darnerud, 2003 in POPRC, 2006). The results of a study investigating possible neuro-behavioural effects in neonatal mice suggest differences in behavioural pattern between treated and control animals. However, there are uncertainties respect to significance of the differences observed and their relevance to human health. Although, recent studies on hydroxylated organo-halogens have indicated changes in thyroid hormone levels and neurobehavioural changes in both animals and humans (European Communities, 2001b).
2.2.8	Summary of mammalian toxicity and overall evaluation	In most cases the available toxicity studies have been conducted with a c-PentaBDE mixture, while only a limited number of studies have tested purified congeners (European Communities, 2001b). Thus, hazard characterization for PentaBDEs is not only limited in scope but confounded by a lack of accurate identification of congener composition and impurities (WHO, 2003, European Communities, 2001b). The main congeners of c-PentaBDE formulations, TetraBDE and PentaBDE are likely more toxic and bioaccumulative than the other congeners of c-PentaBDE mixtures (POPRC, 2006). In terms of the most sensitive experimental endpoints, PentaBDEs have consistently and in a dose-dependent manner induced a variety of effects in the liver (relative weight increases, vitamin A reduction, cytological alterations, and enzyme inductions) and thyroid (slight hyperplasia, T3/T4 decreases). The lowest LOEL identified to date for liver effects is 0.44 mg/kg bw/d for 90 days, which resulted in persistent enzyme induction. When the chronic NOEL is compared to environmental exposures for adults from "worse-case" scenario modeling exercises, margin of safety values would be only 0.8-22, or unacceptably low taking into account current deficiencies in the toxicological database (European Communities, 2001b; Darnerud, 2003 in POPRC, 2006; VKM, 2005). There are no data available that provide clear evidence, however, c-PentaBDE is considered as a possible human carcinogen and pregnant women, embryos and infants may be more vulnerable because of effects on thyroid hormone balance and central nervous system development. Sufficient data are available to establish that c-PentaBDE, due to the inherent properties of its components as regards of persistency, bioaccumulation, long-range environmental transport and toxicity, pose a sufficiently great risk to both humans and the environment to warrant a global ban (POPRC, 2006).
3	**Human exposure/Risk evaluation**	
3.1	Food	There are no direct emissions to food, but sewage sludge application and atmospheric deposition are predicted routes of release to soil and therefore expected to occur to open air crops. Fish and agricultural products are the main food sources of pentaBDE in humans (POPRC, 2006), fish from contaminated sources in particular (Sjödin *et al.*, 2003 in POPRC, 2006). Human dietary exposure via fish may also be especially important to populations with a high intake of seafood e.g. in their report the Norwegian Scientific Committee for Food Safety determined that fish accounted for ¾ of the total dietary intake of these substances in the Norwegian population (VKM, 2005). Additional analysis of other food commodities (vegetables, meats) found significantly lower levels (6.25-134 pg/g ww) compared to fish (EU-Supporting documentation; POPRC, 2006). The EU, in their risk assessment document, calculated PentaBDE levels in various food items using EUSES modelling (see Table 3.24 below). According to the results, levels of PentaBDE were high in root crops. Thus, besides PBDE-contaminated fish, root crops could be another major dietary

source for secondary poisoning for humans (see Table 1 below, European Communities, 2001b).

Table 3.24 Estimated concentrations of PentaBDE in food for human intake.

Food/media	Concentration in food/media	
	Polyurethane foam production	**Regional Sources**
Fish	4.38 mg/kg ww or 8.36 mg/kg ww	0.022 mg/kg ww or 0.041 mg/kg ww
Root crops	6.78 mg/kg ww	0.34 mg/kg ww
Leaf crops	0.031 mg/kg ww	2.9 x 10^{-4} mg/kg ww
Drinking water	2.7 x10^{-4}mg/L	1.4 x 10^{-5} mg/L
Meat	0.208 mg/kg ww	0.0065 mg/kg ww
Milk	0.066 mg/kg ww	0.0021 mg/kg ww
Air	28.3 ng/m^3	0.27 ng/m^3

In women reporting the highest frequency of fish consumption (5-6 meals per week), breast-milk concentrations of PBDEs were significantly higher (1.7 ng/g lipid) compared to those reporting consuming only 1-2 fish meals per week (0.77 ng/g lipid) (Sjödin *et al,*. 2003 in POPRC, 2006). PBDE 47 was also the major congener in the breast-milk samples (40 % of the total), while congeners 47, 99, 100 and 153 accounted for approximately 85 % of the PBDE fraction.

Analysis of breast-milk samples collected up to 1996 in Sweden indicated mean PBDE concentrations of 4 ppb (lipid), with the major congeners including PBDEs 47 (over 50 % of the total), 99, 153 and 100 (Lind *et al*., 2001 in Peltola & Ylä-Mononen, 2001). For the average breastfeeding infant, this would relate to an intake of approximately 11 ng/kg bw/d for PBDEs. Canadian human milk samples collected in 1992 contained on average 2.8 µg/kg (lipid) of total PBDEs, with the major congeners present similar to those found in foods, *i.e*. PBDEs 47, 99, 153 and 100. PBDE 47 accounted for an average of 50 % of the PBDE total, which was about 75-fold less than total PCBs. In a limited sample of adipose tissues collected at autopsy from Swedish subjects (n = 5) the average total PBDEs was 5.4 ppb (lipid), with the major congeners present similar to those in breast-milk (Meironyté Guvenius *et al*., 2001 in Peltola & Ylä-Mononen, 2001). In a survey conducting with 23 samples of breast adipose tissue collected from women in the San Francisco area during the late 1990s, average total PBDEs was 85.7 ng/g lipid, with a range of 17.2-462 ng/g (She *et al*., 2002 in Environment Canada, 2005). For the majority of samples, PBDE 47 was the predominant congener (average 42 %) with congeners 47 and 99 combined accounted for an average of 55 % of the total (range 25-83 %).

A similar association with PBDE congener 47 in blood was seen in Latvian men consuming fatty fish from the Baltic Sea (Sjödin *et al*. 1999, in Peltola und Ylä-Mononen, 2001). Men who reported consuming 12 or more meals of fatty fish per month had plasma PBDE 47 levels more than 9-fold higher than men who consumed 0-1 fish meals per month (2.4 *vs* 0.26 ng/g lipid) (European Communities 2001b, VKM, 2005).

Although food survey data are limited, initial reports from Sweden have indicated that an estimated dietary intake of total PBDEs would be in the range of approximately 51 ng/person/d for adults, or less than 1 ng/kg bw/d (Darnerud *et al*., 2001, in Peltola & Ylä-Mononen, 2001). Preliminary market basket surveys in Canada have estimated the daily intake of total PBDEs from food to be approximately 44 ng/person, compared to an intake of total PCBs of 285 ng/person (Ryan & Patry, 2001 in Peltola & Ylä-Mononen, 2001).

Major PBDE congeners found in various food commodities included PBDEs 47, 99, 100, 153, 154 and 183, with PBDE 47 (25 %) and 99 (43 %) comprising approximately 68 % of the total. Analysis of butter samples collected from various locations worldwide has also shown the major PBDE congeners present to be PBDEs 47, 99 and 153, with PBDEs 47 and 99 occurring at approximately equal concentrations (Jones *et al*., 2001 in Peltola & Ylä-Mononen, 2001).

		Levels of PBDEs in fish from Japanese markets ranged from 0.017 to 1.72 ng/g wet weight, with PBDE 47 (2,2',4,4') the predominant congener (approximately 60 % of the total). Some of the earliest PBDE residue data from fish collected in Sweden reported that PBDE 47 was the most abundant congener present, making up 70-80 % of the PBDE fraction (Andersson & Blomkist, 1981 in Fjeld *et al.*, 2004). In salmon collected from Lake Michigan in 1996, total PBDEs ranged from 0.77 to 8.12 ppm (lipid based), with PBDE congeners 47, 99 and 100 accounting for on average 88 % of the total and PBDE 47 approximately 65 % (Manchester-Neesvig *et al.*, 2001 in Fjeld *et al.*, 2004). In various species of fish collected in 1998–1999 from the mid-Atlantic region of the United States (Virginia), sum PBDEs ranged from less than 5 µg/kg (detection limit) to the highest recorded value for PBDEs in edible fish tissue of 47.9 mg/kg (lipid based) (Hale *et al.*, 2001 in Fjeld et al., 2004). PBDE 47 accounted for 40-70 % of the sum PBDEs and, in certain fish, exceeded the concentration of PCB 153 and *p,p'*-DDE. Farmed salmon available on Scottish and European markets had lower concentrations of total PBDEs (1.1-85.2 ng/g lipid) but, as with the wild fish, PBDE congeners 47, 99 and 100 represented on average 77 % of the total (Fjeld *et al.*, 2004). In comparison, the same three PBDE congeners comprise almost 80 % of the total PBDE fraction of Bromkal 70-5DE, a c-PentaBDE but with congener PBDE 47 comprising only 37 % of the total. Analysis of tissue samples from fish-eating birds has revealed similar PBDE congener patterns. Congeners 47, 99 and 100 were the major PBDEs detected in osprey from Sweden, with PBDE 47 contributing over 80 % of the total (Sellström *et al.*, 2001; in Environment Canada, 2005). Additional estimations of maximum total daily intake of c-PentaBDE have been attempted, based both on releases from a local point source (polyurethane foam production) and general background levels in air, water and foods (European Communities, 2001b). Subsequent modeling estimations from multimedia exposure have provided values of between 2.0 and 53 µg/kg bw/d. In a similar exercise, theoretical chronic daily intakes were calculated for various age segments of the population, using Monte Carlo analysis of frequency distributions both for concentrations of PBDEs found in a variety of food commodities and for the associated ingestion rates (Alaee & Wenning, 2002 in Environment Canada, 2005). Based on the most prevalent congeners found in c-PentaBDE mixtures, the average deterministic estimate was 0.85 µg/kg bw/d, while the probabilistic 50th and 95th percentiles were 1.47 and 2.73 µg/kg bw/d, respectively.
3.2	Air	PBDEs have been detected in a variety of environmental matrices, including air. Emissions to air are also significant over the lifetime of polyurethane articles containing PentaBDE through volatilization and from dust-borne PentaBDE (POPRC, 2006). Total emissions of PentaBDE to air are predicted to be higher than to water (wastewater), mainly as result of volatilization from the polymer product over its service life. The major components of c-PentaBDE have a sufficient half-life in air to be transported over long distances. C-PentaBDE has a high persistency in air, with a half-life of 11-19 days (Palm *et al.,* 2002, Vulykh *et al.*, 2004 in POPRC, 2006). Monitoring studies have detected a widespread occurrence in the European atmosphere (Shure *et al.*, 2004; Lee *et al.*, 2004; Jaward *et al.*, 2004; Harrad and Hunter 2004, Harrad *et al.* 2004; in POPRC, 2006) and Arctic (AMAP 2002 and AMAP 2005, Peltola & Ylä-Mononen, 2001; in POPRC, 2006). Modeling and environmental studies indicate that the transport occurs through a series of deposition/volatilization hops towards the poles, and particulate transport is also known to be important. Major releases to air are emissions from products during use, through volatilization of PentaBDE and dust-borne PentaBDE (POPRC, 2006).

3.3	Water	The predicted fate of PentaBDE in wastewater treatment plants (water) is that 90.7 % is adsorbed onto sewage sludge, 0.19 % is released to air and 9.11 % is released to surface water. Water is the second important environmental recipient of PentaBDE that is released into the environment (POPRC, 2006). Although, PentaBDE has low water solubility, it has been detected in lakes and seas, and can be transported with water in the soluble and particle phases (Peltola & Ylä-Mononen, 2001). The major emissions from industry are therefore expected to occur to water and land via sewage sludge. Although a variety of PBDEs are detectable in terrestrial samples (soil, sludge), it appears as though the aquatic environment represents the greatest potential for human exposure, especially waterways receiving direct input from industrial sources (Canada, EU and Norway supporting documents).
3.4	Occupational exposure	Occupational exposure may occur during the production of flame retardants-containing polyurethane foams and end-product manufacture (European Communities, 2001b). In Sweden, occupational exposure to PBDE has been identified among electronics recycling personnel (Sjødin *et al*., 1999; Thomsen *et al.* 2001; in Thomsen *et al.*, 2003) and in technicians responsible for repair and maintenance of computers (Jacobsson *et al*., 2002 in POPRC, 2006; Hagmar *et al.,* 2000 in Peltola & Ylä-Mononen, 2001) as well as in workers from a rubber factory and a municipal waste incinerator (Thuresson *et al*., 2002, Lee *et al*., 2002; in Thomsen *et al*., 2003). There are considerable uncertainties regarding the characterization of risks to workers. These uncertainties relate to the extent of inhalation and dermal exposure, the extent to which dermal absorption may contribute to the overall body burden, the mechanism of the 'chloracne-like' response observed in the rabbit ear study, the human health significance of the rodent liver effects and the approach to risk assessment for this substance, given its bioaccumulative potential (European Communities, 2001b).
3.5	Medical data contributing to regulatory decision	Not available.
3.6	Public exposure	Public exposure is likely to be produced since PBDE congeners, mainly specific to the commercial penta brominated diphenyl ether mixtures, have long-range atmospheric transport, are environmental persistent and bioaccumulate in various species (POPRC, 2006).
3.7	Summary-overall risk evaluation	**European Union** ***Workers*** There are considerable uncertainties regarding the characterization or risks to workers, therefore, at this stage, it is not possible to fully characterize the risk to human health for occupational settings. Further information to address the uncertainties is required. ***Consumers*** Exposure to PentaBDE is negligible; therefore, there are negligible risks to consumers. ***Indirect exposure through the environment*** As for the risk characterization for workers, there are considerable uncertainties associated with the toxicity data available and the approach to the risk characterization for a bioaccumulative substance. In addition, there are uncertainties with respect to the modeled exposure data for local sources of exposure. Consequently further information is required to address these uncertainties. ***Combined exposure*** The combined exposure is dominated by the occupational exposure. The estimates of both occupational exposure and exposure via the environment are derived from models and these estimates require refinement. In addition, as for workers, there are uncertainties surrounding the risk characterization. Hence, further information is required to address these uncertainties.

		Infants via milk The risk assessment for infants exposed via milk (human breast milk and cow's milk) is based on numerous assumptions regarding the PentaBDE content of milk, the feeding infant and regarding the significance of toxicological endpoints of concern to the neonate. Thus, the conclusion of the risk characterization is that further information is required to address these uncertainties. However, following the agreement of the risk assessment conclusions reached on a technical basis, Member States noted the uncertainties expressed regarding the risk characterization for infants exposed to PentaBDE from human breast milk. They also noted the conclusion that further information would be required to remove these uncertainties and refine the risk assessment. Member States were concerned that it would take a significant time to gather the information and that the resulting refined risk assessment could then indicate a risk to breast-feeding infants. Furthermore, the bioaccumulative properties of the substance could cause concentrations in breast milk to rise while data was being gathered. Consequently Member States agreed that risk reduction measures should be considered without delay for the sources of this exposure. **Norway** In 2000, the Nordic Council of Ministers on initiative from Norway developed and published a report on PentaBDE (Peltola & Ylä-Mononen, 2001). This report formed the basis of Norway's nomination of PentaBDE to the Stockholm Convention (VKM, 2005), and was equally important to the EU risk assessment on PentaBDE (EC, 2001) and peer-reviewed scientific literature reporting data from within Norway, when considering a national ban for PentaBDE in Norway (SFT, 2009). In the Nordic risk assessment report PentaBDE was assessed with regard to the screening criteria of the Stockholm Convention on POPs (Peltola and Ylä-Mononen, 2001). The monitoring data cited provided evidence of environmental contamination by PentaBDE also in remote regions. Data from air analyses were used to confirm this and showed that the major components of c-PentaBDE have a sufficient half-life in air to be transported over long distances. The studies also highlighted the potential of PentaBDE to bioaccumulate and induce adverse effects in both aquatic and terrestrial organisms. The major effects reported for laboratory mammals were liver disturbances and developmental neurotoxicity. Endocrine disrupting and dioxin like activity was reported from in vitro studies. In aquatic organisms, adverse effects on growth and reproduction were documented. A detailed risk assessment of PBDE in food was conducted by the Norwegian Scientific Committee (VKM, 2005). The report was not official till 2005 *i.e.* one year after the ban for PentaBDE in Norway and the EU entered into force. In their report the Norwegian Scientific Committee for Food Safety determined that fish accounted for ¾ of the total dietary intake of these substances in the Norwegian population. The dominating congeners and the main sources of dietary exposure to PBDEs were mainly attributed to TetraBDE and PentaBDE. The committee also concluded that it was not possible based on the available literature at the time to establish a tolerable daily intake for PBDEs. A recommendation was made that the PBDE congeners with highest prevalence be included in the national monitoring program for food. **Stockholm Convention** It is believed that long-time exposure to low doses of C-PentaBDE can result in adverse health effects to humans, since adverse effects have been demonstrated through animal studies and c-PentaBDE has been shown to accumulate in the human body (POPRC, 2006). However, since the half-life of c-PentaBDE in humans is not known it is not possible today to conclude on long-time exposure effects. This is true even for the US situation, where levels may be 10-20 times those observed in Europe, but pharmacokinetics, toxicology, exposure and other critical data are lacking. The available data nonetheless indicate the potential that endocrine- and neurodevelpmental

		effects can occur also in humans. It should also be noted that the neurotoxic effects of PBDEs, the c-PentaBDE congeners included, are similar to those observed for PCBs and children exposed to PBDEs are therefore likely to be prone to subtle but measurable developmental problems. Vulnerable groups could be pregnant women, embryos and infants, because of effects on the thyroid hormone balance, and the embryo's development of the central nervous system. During pregnancy, maintenance of the thyroid hormone balance is a physiological challenge. Embryos and infants are particularly vulnerable for reductions in thyroid hormone levels (VKM, 2005). Infants are exposed to PentaBDE through the diets of their mothers' milk, since PentaBDE is lipophilic and accumulates in the milk (VKM, 2005). **WHO (2003)** While uncertainties in the current exposure and toxicological database for PentaBDE hinder an accurate risk characterization, there are indications that margin of safety estimates may be unacceptably low, especially considering the environmental persistence and bioaccumulative nature of these compounds (WHO, 2003).
4	**Environmental fate and effects**	
4.1	Fate	C-pentaBDE is released into the environment from a variety of sources *e.g.* during manufacture of the commercial product, during manufacture of PentaBDE containing products and their use, dismantling and recycling activities and from waste and sewage sludge (POPRC, 2006, Rahman *et al.* 2001 in Sørmo *et al.*, 2001). C-PentaBDE and its main congeners are persistent, bioaccumulating and toxic substances that can undergo long range transport to remote regions (POPRC, 2006). They are recognized as ubiquitous environmental contaminants and have been detected in a variety of environmental matrices, including air, water, sediment and biota, hereunder also humans in all UN regions. Given their inherent properties, the main congeners of c-PentaBDE, tetra and PentaBDE are acknowledged as POPs of global concern and are subject to an international ban under the Stockholm Convention (POPRC, 2006, POPRC, 2007). When compared to other legacy POPs, brominated diphenyl ethers such as PentaBDE was found to have the highest bioaccumulation potential (BAF=1.8 in mussels for PentaBDE;POPRC, 2006). The main recipient is soil, followed by water and air (soil >>> water >> air).
4.1.1	Soil	Soil is the main recipient of all c-PentaBDE that is released to the environment (POPRC, 2006). From what is known there are no direct emissions to soil, but sewage sludge application and atmospheric deposition are predicted routes of release to soil (European Commission, 2000a; European Communities 2001b). The high logKow value indicates that PentaBDE adsorbs strongly to soils. Nonetheless, c-PentaBDE bound to soil can escape in different ways, The most important escape routes appears to be via suspended solids leaching to water and through wind erosion (POPRC, 2006). A small part of c-PentaBDE in the soil can also be volatilized, especially in conditions with warm weather. Though its persistence has been proved in other ways, using the Syracus Corporation's EPIWIN program the half-life of PentaBDE in different environmental compartments was estimated to 150 days (Palm 2001, Palm et al. 2002, in POPRC, 2006), which is below the numeric criteria for persistence in soil (> 180 d) set by Annex D of the Stockholm Convention. **Predicted environmental concentrations:** PUR production, local: 2.68 mg/kg ww. PUR production, regional: 0.13 mg/kg ww. The affinity of PentaBDE to sink onto soil, water and air is as follow: soil >>> water >> air.

		Measured concentrations in sediment and soil: In Norwegian Lake Mjøsa sediments: 0.6-27 ng/g dw (Fjeld et al. 2004). Inlet (north) and outlet (south) of the basin, concentrations were in range of 600-740 ng/g and 50–-350 ng/g based in the content of total organic carbon, respectively. C-PentaBDE constituted 60-70 % of the sum PBDEs (Fjeld *et al*., 2004). The concentrations of PBDEs in sediments from the Drammens River were in the range 4-80 ng/g d.w. Adjusted for the organic carbon content, the concentrations were in the range of 86-6 900 ng/g total organic carbon (Fjeld *et al.,* 2004). Wang et al. (2005, in POPRC 2006) detected levels of PentaBDE in soil and sediment collected in the vicinity of an open electronic waste disposal and recycling facility located in Guiyu, Guandong, China. Hassanin et al. (2004, in POPRC 2006), report concentrations of PentaBDE in United Kingdom soils of 78- 3200 pg/g dry weight. The congeners BDE-47 (TetraBDE), BDE-99 (PentaBDE), BDE-100, BDE-153 and BDE-154, covering the major constituents of the c-PentaBDE, dominated the average congener pattern in the soils. PentaBDE (BDE-99) levels in sediment have been reported from <0.2 until 51.4 ng/g dry weight (highest value from rivers at point source) by Palm *et al*., (2002, in POPRC 2006).
4.1.2	Water	Although PentaBDE has low water solubility, it has been detected in lakes and seas, and can be transported with water in the soluble and particle phases (Peltola & Ylä-Mononen*,* 2001, in POPRC 2006). The PUR industry released the substance to surface waters through waste water treatment plants. Predicted environmental concentrations: PUR production, local: 0.37 µg/L; PUR production, regional: 0.0015 µg/L. In Norwegian leachate water, process water, ground and surface water coming from landfills and industrial sites were in the range of 1-15 ng/L (sum of PBDEs; Fjeld *et al*., 2004).
4.1.3	Air	Predicted environmental concentrations: PUR production, local: 28.3 ng/m^3; PUR production, regional: 0.27 ng/m^3 BDE-47 and BDE-99 have been found in the Arctic air at the remote sites of Alert in Canada and Dunai in Russia. Total concentrations were <1-28 pg/m3 and BDE-47 and BDE-99 were the most abundant congeners in samples collected in 1994 (Alaee *et al*., 2000 in Environment Canada 2006). At another remote Arctic area in Pallas, Finland, BDE-47 and BDE-99 concentrations were measured between 0.3-2 pg/m^3 (Peltola, 2001 in Peltola & Ylä-Mononen, 2001). The same congeners were also observed at two Swedish sites, Ammarnäs and Hoburgen, remote from point sources (Bergander *et al*., 1995 in Peltola & Ylä-Mononen, 2001). The sum of PBDE concentration in the air varied in this study generally between ca. 1 and 10 pg/m^3 (Peltola & Ylä-Mononen, 2001). According to POPRC (2006), global emissions of PentaBDE to air during polyurethane foam production in 2000 ranged from 7500 to 13500 kg. Wong *et al*. (2001, in POPRC, 2006) examined the atmospheric partitioning characteristics of BDEs 47, 99 and 153, and predicted that tetra- and pentabromo-congeners will become gaseous at warmer air temperatures. Therefore, although the low measured vapour pressure values for the PBDEs indicate that volatilization is minimal at normal air temperatures, there is potential for release to air at the elevated temperatures reached during curing (European Communities 2001 in POPRC 2006). Studies of recipients to municipal solid waste incinerators have detected above-background levels of PentaBDE in both gaseous and particulate fractions in the air in the vicinity of the facility (Agrell et al., 2004, Law 2005, ter Schure *et al*., 2004b; in POPRC 2006). For more information see also section 3.2 of this document.

4.1.4 Bioconcentration and bioaccumulation

PentaBDE is an environmental contaminant that have long-range atmospheric transport, environmental persistent and bioaccumulate in various species.

The reported octanol/water partition coefficient (log K_{OW}) for PentaBDE is in the range of 6.5 -7.4 and indicates that c-PentaBDE has the potential to bioaccumulate in various species. PentaBDE-contaminated fish could be a major dietary source for secondary poisoning for humans (POPRC, 2006).

Fish bioconcentration factor: 14.350 L/kg (European Communities, 2001b).

The potential for PentaBDE to bioconcentrate and bioaccumulate is further corroborated by available monitoring data which show an increase of PentaBDE concentrations in biota with increasing trophic level in pelagic and Arctic food webs. Calculated values in the literature are summarized in Table 2.4 below (POPRC, 2006).

Table 2.4 Calculated bioaccumulation factors (BAFs) and biomagnification factors (BMFs) for one PentaBDE (BDE-99) in the literature from environmental studies in pelagic and Arctic food webs. The data are calculated using the mean lipid weight concentrations, except for the study performed by Sørmo et al. 2006, in which the values in brackets are BMFs calculated from mean whole body concentrations.

Variable	Organism	Area	Value	Reference
BAF	*Dreissena polymorpha*	Lake Mälaren, Sweden	1.8	Lithner et al. 2003
BMF	Guillemot egg/herring	Baltic sea	17	Sellström 1996
	Grey seal/herring	Baltic sea	4.3	Sellström 1996
	Salmon/sprat	Baltic sea	10	Burreau *et al.* 1999
	Salmon/sprat	Baltic sea	5.9	Burreau *et al.* 2000
	Atlantic Salmon/Small Herring	The Northern Atlantic Sea	3.8	Burreau *et al.* 2000
	Net plankton/Benthic organisms	Lake Ontario, Canada	7.1	Alaee *et al.* 2002
	Benthic organisms/Forage fish	Lake Ontario, Canada	0.8	Alaee *et al.* 2002
	T. libellula/Copepods	Svalbard, Arctic Norway	0.65 (1.3)	Sørmo *et al.* 2006
	G.wilkitzkii/Copepods	Svalbard, Arctic Norway	47.6 (19.0)	Sørmo *et al.* 2006
	Polar cod/Copepods	Svalbard, Arctic Norway	2.1 (1.6)	Sørmo *et al.* 2006
	Polar cod/*T. inermis*	Svalbard, Arctic Norway	1.9 (1.2)	Sørmo *et al.* 2006
	Polar cod/*T. libellula*	Svalbard, Arctic Norway	3.4 (1.3)	Sørmo *et al.* 2006
	Polar cod/*G.wilkitzkii*	Svalbard, Arctic Norway	0.04 (0.1)	Sørmo *et al.* 2006
	Ringed seal/*T. inermis*	Svalbard, Arctic Norway	26.8 (54.5)	Sørmo *et al.* 2006
	Ringed seal/*T. libellula*	Svalbard, Arctic Norway	43.1 (60.0)	Sørmo *et al.* 2006
	Ringed seal/*G.wilkitzkii*	Svalbard, Arctic Norway	0.6 (3.9)	Sørmo *et al.* 2006
	Ringed seal/Polar cod	Svalbard, Arctic Norway	13.7 (56.6)	Sørmo *et al.* 2006
	Polar bear/Ringed seal	Svalbard, Arctic Norway	0.3 (0.29)	Sørmo *et al.* 2006
	Polar bear/Ringed seal	Arctic Canada	3.4	Muir *et al.* 2006
	Polar bear/Ringed seal	Arctic Canada	11	Muir *et al.* 2006
	Polar bear/Ringed seal	Arctic Canada	8.0	Muir *et al.* 2006
	Polar bear/Ringed seal	Greenland	1.0	Muir *et al.* 2006
	Polar bear/Ringed seal	Svalbard, Arctic Norway	5.9	Muir *et al.* 2006

Study results on bioaccumulation and biomagnification in local food webs are summarised in POPRC (2006), section 2.2.2.1.

<table>
<tr><td>4.1.5</td><td>Persistence</td><td>C-PentaBDE is biologically and environmentally persistent and is recognized as a global POP under the Stockholm Convention (POPRC, 2006, POPRC, 2007).

The estimated atmospheric half- life is 12.6 days and it is not readily or inherently biodegradable.

Estimated half-lives of PentaBDE (BDE-99) in different environmental compartments is reported in POPRC (2006), see table below:

<table>
<tr><th>Environmental compartment</th><th>Half-life estimate (d)</th><th>References</th></tr>
<tr><td>Soil</td><td>150</td><td>Palm 2001, Palm et al., 2002</td></tr>
<tr><td>Aerobic sediment</td><td>600</td><td>Palm 2001, Palm et al., 2002</td></tr>
<tr><td>Water</td><td>150</td><td>Palm 2001, Palm et al., 2002</td></tr>
<tr><td>Air</td><td>19
11</td><td>Palm et al., 2002
Vulykh et al., 2004</td></tr>
</table>

The estimations were made with the use of Syracus Corporation’s EPIWIN program.

Although the persistency in soil is not fulfilled by these data, all the other criteria are.

In addition, the persistency of c-PentaBDE is further corroborated by the available monitoring data which documents the presence of PBDE congeners 47 and 99, main constituents of c-PentaBDE, in various environmental compartments, biota and humans.</td></tr>
<tr><td>4.2</td><td colspan="2">Effects on non-target organisms</td></tr>
<tr><td>4.2.1</td><td>Terrestrial vertebrates</td><td>No data available</td></tr>
<tr><td>4.2.2</td><td>Aquatic species</td><td>C-PentaBDE is present in the aquatic environment and is taken up by organisms on all trophic levels (see section 4.1.4 and POPRC, 2006).
Moreover, elevated levels are documented in top predators, mammals included e.g. observed levels in aquatic mammals vary from 0.8 ng/g lw in bird's beaked whale to 87 ng/g lw in bottlenose dolphins for BDE 99 and 3.0 ng/g lw in bird's beaked whales to 275 ng/g lw in killer whales, with the levels in striped dolphins and minke whales falling in between (Wolkers et al., 2004, in Sørmo et al., 2006). Reported adverse effects include effects on growth, reproductive output and behavioral learning. These effects have been observed in algae, zooplankton and fish, respectively (Källqvist et al., 2006, Timme-Laragy et al. 2006, in POPRC, 2006; see POPRC, 2006 for overview)

Predicted environmental concentrations and effect concentrations:

Rainbow trout:
NOEC: 8.9 µg/L
LOEC: 16 µg/L
(Wildlife International, 2000, in European Communities, 2001b).
Calanoid Arcatia tonsa:
$_{48h}$ LC_{50}, 2.37 mg/L
(Breitholz et al., 2001 in Peltola & Ylä-Mononen, 2001).
Cladoceran Daphnia magna:
$_{48h}$ EC_{50}, in Daphnia magna: 14 µg/L
NOEC: 4.9 µg/L
(CITI 1982, in European Communities, 2001b).
21-day reproduction NOEC: 5.3 µg/L
LOEC: 9.8 µg/L
(Drottar & Krueger, 1998, in European Communities, 2001b).</td></tr>
<tr><td>4.2.3</td><td>Honeybees and other arthropods</td><td>No data available</td></tr>
</table>

4.2.4	Earthworms	Predicted environmental concentrations: 34.3 mg/kg ww. *Lumbriculus variegates* with a lowest NOEC of 3.1 mg/kg dw
4.2.5	Soil microorganisms	No microorganisms in the sewage sludge have been tested.
4.2.6	Terrestrial plants	Terrestrial plants with a NOEC of 16 mg/kg dw and predicted NEC of 0.38 mg/kg dw with an assessment factor of 50. (EU notification)
5	Environmental Exposure/Risk Evaluation	
5.1	Terrestrial vertebrates	A possible local risk of exposure of the terrestrial compartment from local sources during manufacturing.
5.2	Aquatic species	Measurements of six BDE congeners that are common components of the PentaBDE commercial mixture within the entire Lake Michigan aquatic food web in the US indicate that BDEs were detected in all samples. The dominant BDE congener was PBDE 47. PBDE 47 levels were consistently greater than BDE 99, although these two compounds have the similar levels in the commercial mixture (Stapleton & Baker 2003, in Environment Canada, 2005). Studies show that different levels of TetraBDE and PentaBDE were found in marine mammals such as dolphins and whales at ng/g of lipid weight, with high levels found in killer whales and bottlenose dolphins. The levels vary from 0.8 in bird's beaked whale to 87 in bottlenose dolphins for PentaBDE and 3.0 in bird's beaked whales to 275 in killer whales, with the levels in striped dolphins and minke whales falling in between (Wolkers *et al*., 2004, in Sørmo *et al*., 2006).
5.3	Honey bees	A possible local risk to the honey bees (other insects) from the atmospheric local sources during manufacturing.
5.4	Earthworms	Predicted environmental concentrations: 34.3 mg/kg ww.
5.5	Soil microorganisms	Predicted environmental concentrations in agricultural soil: PUR production, local: 2.68 mg/kg ww. PUR production, regional: 0.13 mg/kg ww.
5.6	Summary – overall risk evaluation[6]	The available information indicates that PentaBDE has a high potential for bioconcentration and bioaccumulation. The available mammalian toxicity data allow a PNEC for secondary poisoning of 1 mg/kg food to be derived. Available data from risk quotient analysis performed by Canada, integrating known or potential exposures with known or potential adverse effects, suggest a risk for adverse environmental effects in both benthic organisms and wildlife consumers (POPRC, 2006). In addition, an unacceptable risk for top predators due to secondary poisoning have been identified (European Communities, 2001b, European Commission, 2000a).
		Canada The following information is contained in the supporting documentation presented by Canada. The lower brominated PBDEs (tetra- to pentaBDEs) are slightly more soluble in water and have a greater propensity for volatilization and atmospheric transport than more highly brominated PBDEs. Wania and Dugani (2003) examined the long-range transport potential of PBDEs using a number of models (i.e., TaPL3-2.10, ELPOS-1.1.1, Chemrange-2 and Globo-POP-1.1) and various physical and chemical properties (i.e., solubility in water, vapour pressure, log Kow, log Koa, log Kaw and estimated half-lives in different media). All models yielded comparable results, with TetraBDE showing the greatest potential for atmospheric transport and DecaBDE the lowest transport potential. The researchers estimated a characteristic travel distance (CTD) ranging from 1,113 to 2,483 km for TetraBDE, 608 to 1,349 km for PentaBDE, and 480 to 735 km for decaBDE. The CTD was defined as the distance a parcel of air has travelled until 1/e or approximately 63 % of the chemical has been removed by degradation or deposition processes (Gouin and Mackay, 2002).

6 References cited in this section can be found in the supporting documentation of the respective notifying countries

In an earlier study, Dugani and Wania (2002) also used models to predict that of the various PBDE congeners, those with four to five bromine atoms would have a higher long-range transport potential than lower or higher brominated congeners. They found that the transport of lower brominated congeners is limited by their degradation in the atmosphere, while the transport of the more highly brominated congeners is limited by their low volatility. Atmospheric degradation is reduced at low temperatures, so some of the models may underestimate the long-range transport potential of the lighter congeners (Dugani and Wania, 2002).

Measured concentrations of PBDEs in North American biota indicate that PBDE levels in Canadian biota are rising, with dramatic increases in tissue concentrations evident over the last two decades. The highest levels in biota are associated with industrialized regions; however, the increasing incidence of PBDEs in Arctic biota provides evidence for long-range atmospheric transport of these compounds (Stern and Ikonomou, 2000). PBDEs have been detected in all environmental media as well as sewage sludge, and there is evidence that their levels in the North American environment are increasing. PBDEs have been detected in sediment and soil samples collected in North America, and high concentrations have been measured in sewage sludge. Kolic *et al.,* (2004) determined levels of PBDEs in sediments from Lake Ontario tributaries flowing to Lake Ontario. The total PBDEs (tri-, tetra, penta-, hexa-, hepta- and decaBDEs) measured in sediment samples taken from fourteen tributary sites (6 reported) ranged from approximately 12 to 430 µg/kg dw. Of the reported sediment results, concentrations of Tetra- and PentaBDE ranged from approximately 5 to 49 µg/kg dw. BDE 47 and 99 were predominant congeners measured in sediments. Rayne *et al.* (2003a) measured PBDE concentrations (sum of 8 di- to pentaBDE congeners) ranging from 2.7 to 91 µg/kg OC in 11 superficial sediments collected in 2001 from several sites along the Columbia River system in south eastern British Columbia. Domestic wastewaters arising from septic field inputs were identified as potentially dominant sources of PBDEs in the region. Dodder *et al*., (2002) reported concentrations of total Tetra- and PentaBDE ranging from approximately 5 to 38 µg/kg dw in sediment from a lake in the U.S. located near suspected PBDE sources Hale *et al*., (2002, 2003) reported concentrations of total PBDEs (Tetra- and PentaBDE) of 76 µg/kg dw in soil near a polyurethane foam manufacturing facility in the United States, and 13.6 µg/kg dw in soil downwind from the facility.

Kolic *et al*. in 2004, determined levels of PBDEs in biosolids from southern Ontario municipal wastewater treatment plants (Reiner pers. comm. 2004). Of the reported biosolid results, total concentrations of Tetra- to PentaBDEs ranged from approximately 1,350 to 1,900 pg/kg dw. BDEs 47 and 99 were predominant in biosolid samples. La Guardia *et al.,* (2001) analyzed 11 sludge samples before land application from a sewage treatment facility in the Toronto area; Kolic *et al*., (2003) investigated PBDE levels in sewage sludge from 12 sites in southern Ontario; Hale *et al*., (2002) measured PBDEs (sum of BDEs 47 and 99) in sludge samples collected in 2000 from a regional sewage treatment plant discharging to the Dan River in Virginia, and the results showed concentrations of PBDEs 47 and 99 of 1.700 to 3500 µg/kg dw sludge.

Tetra- and PentaBDE are predicted by AOPWIN (v1.90) to have air degradation half-lives which exceed 2 days (*i.e*., ranging from 7.14 to 317.53 days). Further, Tetra- and PentaBDE have been measured in the Arctic environment in spite of their very low vapour pressures, providing evidence that they are subject to long-range atmospheric transport. Gouin *et al*., (2002) measured total PBDEs (sum of 21 congeners) ranging from 10 to 1300 pg/m3 in air samples collected at a rural southern Ontario site in early spring of 2000. Total PBDEs (congeners not specified) up to 28 pg/m^3 were detected in air samples from the Canadian Arctic collected over the period 1994-1995 (Alaee *et al*., 2000).

		Luckey *et al*., (2002) measured total (dissolved and particulate phases) PBDE (mono- to heptaBDE congeners) concentrations of approximately 6 pg/l in Lake Ontario surface waters in 1999. More than 60 % of the total was composed of PBDE 47 (TetraBDE) and PBDE 99 (PentaBDE). Stapleton and Baker (2001) analyzed water samples from Lake Michigan in 1997, 1998 and 1999 and found that total PBDE concentrations (PBDEs 47, 99 and 100) ranged from 31 to 158 pg/l. It has been shown that PBDE 47 is not subject to statistically significant anaerobic biodegradation over a period of 32 weeks. Neither PentaBDE is readily biodegradable based on short-term studies conducted under aerobic conditions. Due to these reasons, their common chemical structure, and due to issues relating to their chemical transformation, PentaBDE, and their brominated constituents are assessed as a group. Alaee *et al*., (1999) reported average concentrations in the blubber of marine mammals from the Canadian Arctic as 25.8 μg/kg lipid in female ringed seals (*Phoca hispida*),50.0 μg/kg in the blubber of male ringed seals, 81.2 μg/kg lipid in female beluga (*Delphinapterus leucus*) and 160 μg/kg lipid in male beluga. ln these samples, congeners of TetraBDE and PentaBDE were predominant. Ikonomou *et al*., (2000) reported PBDE concentrations in biota samples from the west coast and Northwest Territories of Canada. The highest concentration of total PBDE residues, 2269 μg/kg lipid, was found in the blubber of a harbour porpoise from the Vancouver area. With a concentration of about 1200 μg/kg lipid, a TetraBDE congener accounted for slightly more than half of the total PBDE in the sample. Ikonomou *et al*., (2002a, b) analyzed temporal trends in Arctic marine mammals by measuring PBDE levels in the blubber of Arctic male ringed seals over the period 1981-2000. Mean total PBDE concentrations increased exponentially from approximately 0.6 μg/kg lipid in 1981 to 6.0 μg/kg lipid in 2000, a greater than 8-fold increase. TetraBDE was again predominant, followed by PentaBDE. A marked increase in tissue PBDE levels was also evident in blubber samples collected from San Francisco Bay harbour seals over the period 1989-1998 (She *et al*., 2002). Concentrations of total PBDEs (mainly Tetra- and PentaBDE) rose from 88 μg/kg lipid in 1989 to a maximum of 8325 μg/kg lipid in 1998, a period of only 10 years. Stern and Ikonomou (2000) examined PBDE levels in the blubber of male southeast Baffin beluqa whales over the 1982-1997 and found that the levels of total PBDEs (tri- to pentaBDE) increased significantly. Mean total PBDE concentrations were about 2 μg/kg lipid in 1982 and reached a maximum value of about 15 μg/kg lipid in 1997. Total PBDE residues in the blubber of St. Lawrence estuary belugas sampled in 1997-1999 amounted to 466 (± 230) μg/kg wet weight (ww) blubber in adult males and 665 (± 457) μg/kg ww blubber in adult females. These values were approximately 20 times higher than concentrations in beluga samples collected in 1988-1990 (Lebeuf *et al*., 2001). Measured data indicate that Tetra- and PentaBDE are highly bioaccumulative, with bioconcentration factors (BCFs) exceeding 5000 for aquatic species; thus, they satisfy the criteria for bioaccumulation as described in CEPA 1999. Persistence and Bioaccumulation Regulations. The risk determined for each commercial product is a result of the combined activity of the various co-occurring PBDEs, adding complexity to the interpretation of the results. Empirical and predicted data indicate that all PBDEs subject to the ecological screening assessment are highly persistent, and each satisfies the requirements for persistence as defined by the Persistence and Bioaccumulation Regulations under CEPA 1999 (see Table 6 of the Canadian supporting documentation). Studies have shown the transformation of higher brominated PBDEs (*e.g.*, hepta- to decaBDEs) to lower brominated congeners (*e.g.*, Tetra- to PentaBDEs), which are associated with high levels of bioaccumulation. A dietary exposure study has shown that congeners of PentaBDE rapidly biotransform in the gut of carp (*Cyprinus carpio*), and at least 10–12 % is

debrominated to congeners of TetraBDE (Stapleton *et al*., 2004b, c; Stapleton and Baker, 2003).

There is a lack of data characterizing the toxicity of PBDEs to wildlife. Recent studies using rodents provide evidence that exposure to PBDEs may lead to behavioural disturbances, disruptions in normal thyroid hormone activity and liver effects (*e.g*., Eriksson *et al*., 2002; Zhou *et al*., 2001 and 2002, *Great Lakes Chemical Corporation* 1984). The relationship of these studies to potential effects from accumulation in the wild is not clear at this time.

There are a variety of data indicating that all PBDE congeners subject to this assessment are highly persistent and each satisfies the requirements for persistence as defined by CEPA 1999-Persistence and Bioaccumulation Regulations.

Canadian Risk Characterization

The approach taken in the Ecological Screening Assessment was to examine various supporting information and develop conclusions based on a weight of evidence approach as required under Section 76.1 of CEPA 1999. Particular consideration was given to risk quotient analyses and persistence, bioaccumulation, chemical transformation and trends in environmental concentrations.

This assessment has used data corresponding to commercial products, individual congeners and homologues/isomer groups. The presentation of data and the risk quotient analyses have been structured around the PBDE commercial products since a great deal of empirical data which are central to this assessment (*e.g.*, relevant to environmental toxicity) have been determined using the commercial products. Nonetheless, the risk analysis and scientific evidence presented in this report relate to all congeners found in the commercial product PentaBDE.

The risk determined for each commercial product is a result of the combined activity of the various co-occurring PBDEs, adding complexity to the interpretation of the results. Due to these reasons, their common chemical structure, and due to issues relating to their chemical transformation, PentaBDE, and their brominated constituents are assessed as a group.

Risk quotient analyses, integrating known or potential exposures with known or potential adverse environmental effects, were performed for each of the commercial PBDE products subject to this assessment. An analysis of exposure pathways and subsequent identification of sensitive receptors were used to select ecological assessment endpoints (e.g., adverse reproductive effects on sensitive fish species in a community). For each endpoint, a conservative Estimated Exposure Value (EEV) was selected based on empirical data from monitoring studies. Where monitoring data were not available, the EEVs were based on simple calculation procedures taking into account some degree of local environmental conditions, but largely relying on generic environmental parameters. Chemical concentrations from the Canadian and North American environment were used preferentially for EEVs; however, data from other regions in the world were used in the absence of sufficient Canadian data of satisfactory quality or to provide a weight of evidence. EEVs usually represented worse-case scenarios, as an indication of the potential for these substances to reach concentrations of concern and to identify areas where those concerns would be most likely.

An Estimated No-Effects Value (ENEV) was also determined by dividing a Critical Toxicity Value (CTV) by an application factor. CTVs typically represented the lowest ecotoxicity value from an available and acceptable data set. Preference was generally for chronic toxicity data, as long-term exposure was a concern. Where these data were not available, the following were used in order of preference: acute data, analogue data, quantitative structure–activity relationship (QSAR) data and data derived from equilibrium partitioning methods.

		Application factors were derived using a multiplicative approach, which uses 10-fold factors to account for various sources of uncertainty associated with making extrapolations and inferences related to the following: intra- and interspecies variations; differently sensitive biological endpoints; laboratory-to-field impact extrapolation required to extrapolate from single-species tests to ecosystems; and potential effects from concurrent presence of other substances. For substances that meet the persistence and bioaccumulation criteria as outlined in CEPA 1999 Regulations (see Table 6 in the Canadian supporting documentation), an additional application factor of 10 is applied to the CTV. Risk quotients derived for PBDEs are summarized in Table 8. Exposure data used as EEVs can be found in Tables 4 and 5 or are summarized in the notes to Table 8. Toxicity data used to determine CTVs and ENEVs are summarized in Table 7 in the Canadian supporting documentation. The risk quotient analysis indicates that the greatest potential for risk from PBDEs in the Canadian environment is due to the secondary poisoning of wildlife from the consumption of prey containing elevated PentaBDE and OctaBDE congener concentrations. Elevated concentrations of components of PentaBDE in sediments may present risk to benthic organisms. Therefore, risk associated with components of PentaBDE may be due to the use of OctaBDE or debromination of highly brominated PBDEs, in addition to the use of PentaBDE itself. The risk analysis for soil organisms indicates that risk quotients were below 1 for PentaBDE: however, the lack of data characterizing PBDE concentrations in soil and sewage sludge applied to soil indicates the need for further research. PentaBDE would present low potential for risk as a result of direct toxicity to pelagic organisms due to their very low water solubility. In the water column, risk associated with components of PentaBDE (Tetra- and PentaBDE congeners) may be due to bioaccumulation and toxicity to secondary consumers. There is a lack of data characterizing the toxicity of PBDEs to wildlife. Recent studies using rodents provide evidence that exposure to PBDEs may lead to behavioural disturbances, disruptions in normal thyroid hormone activity and liver effects (*e.g*., Eriksson *et al*., 2002; Zhou *et al*., 2001 and 2002, Great Lakes Chemical Corporation 1984). The relationship of these studies to potential effects from accumulation in the wild is not clear at this time. There are a variety of data indicating that all PBDE congeners subject to this assessment are highly persistent and each satisfies the requirements for persistence as defined by CEPA 1999 Persistence and Bioaccumulation Regulations. Although uncertainty regarding the possible transformation products of DecaBDE exists, there is sufficient evidence to conclude that some level of DecaBDE photo transformation likely occurs in the environment and that lower brominated PBDEs are being formed during this process. These products are likely to be more bioaccumulative than the parent compound and could be considered persistent and may be directly toxic to organisms. Measured data indicate that Tetra- and PentaBDE are highly bioaccumulative and satisfy the criteria for bioaccumulation in the CEPA 1999 regulations. Concentrations of PBDEs in herring gull eggs have increased exponentially between 1981 and 2000 at Lake Ontario, Huron and Michigan sampling sites. Concentrations of PBDEs (predominantly tetra- and pentaBDE congeners) have also increased exponentially between 1981 and 2000 in Arctic male ringed seals. Pyrolysis and extreme heating can cause all PBDEs to form brominated dibenzo-p-dioxins and dibenzofurans (European Communities 2001, 2002, 2003). These transformation products are considered brominated analogues of the TSMP Track 1 polychlorinated dibenzo-p-dioxins and dibenzofurans. The PBDEs subject to this assessment have low vapour pressures and low Henry's Law constants and are not expected to partition significantly into the atmosphere. As such, they are considered to present a negligible risk with

		respect to atmospheric processes such as global warming, stratospheric ozone depletion and ground-level ozone formation; however, they do reside in the atmosphere adsorbed to suspended particulates and can be transported over long distances. **Canadian conclusion for the Environment** It is therefore concluded that Tetra- and PentaBDE, which are found in commercial PentaBDE, are entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity and thus meets the criteria under Paragraph 64(a) of CEPA 1999. Based on considerations of potential contribution to atmospheric processes, it is concluded that PBDEs are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends, and thus do not meet the criteria under Paragraph 64(b) of CEPA 1999. The available data regarding persistence and bioaccumulation of Tetra- and PentaBDE indicate that they satisfy the criteria outlined in the Persistence and Bioaccumulation Regulations of CEPA 1999. Their presence in the environment results primarily from human activity, and they are not naturally-occurring radionuclides or naturally-occurring inorganic substances. **European Union** The risk characterisation is performed by comparing the PEC with the relevant PNEC for each environmental compartment/endpoint. A ratio above 1 indicates a concern. Consequently there is: 1. a possible local risk to the aquatic (sediment) compartment from local sources during the production of polyurethane foam; 2. a possible risk of the soil compartment from local sources during the production of polyurethane foam; 3. a possible risk of secondary poisoning of top predators due to the production of polyurethane foam and their subsequent use. It is not possible to carry out the PEC/PNEC comparison for sewage microorganisms since no toxicity data are available. Another area of concern with regard to both direct toxicity and secondary poisoning is the possible formation of brominated dibenzo-*p*-dioxins and dibenzofurans from articles containing the substance during combustion or other high temperature processes (*e.g.* incineration, landfill (where fires could occur) or accidental fires). Overall it can be concluded that PentaBDE, as a source of bromine, can contribute to (but is not the only source of) the formation of halogenated dibenzo-*p*-dioxins and furans generated during such processes. However, it is not possible to quantify the amounts or assess the environmental significance of these products. **Norway** The following information is contained in the supporting documentation from Norway (see focused summary in Norway, 2010). A comprehensive risk assessment of PentaBDE was carried out under the Existing Substances Regulation 793/93/EEC (EC, 2001). Norway as part of EEA was actively involved when the risk assessment of PentaBDE was developed. Within the EU and in those EEA countries which have implemented the CLP Regulation (EU, 2008), PentaBDE is considered and classified as a substance that may cause damage to organs through prolonged or repeated exposure that is harmful to breast-fed children and very toxic to aquatic life with long lasting effects (EC, 2001, EU, 2008, SFT, 2009). Adverse effects reportedly occur at low concentrations (EC, 2001). A 48 h acute toxicity test in *Daphnia magna* reported in the EU risk assessment gave an EC50 of 14 µg/L and a NOEC of 4.9 µg/L. A 21 day life-cycle Daphnia magna study on the other hand gave a NOEC of 5.3 µg/L and a LOEC of 9.8 µg/L. The first of these studies formed the basis of the proposal

		to classify this substance as "N; R50/53 Very toxic to aquatic organisms, may also cause long term adverse effects in the environment". In fish, a NOEC for growth of 8.9 µg/L was reported based on an early life stage toxicity test with rainbow trout (*Oncorhynchus mykiss*) (EC, 2001). The LOEC for the same endpoint was 16 µg/L. Adverse effects of PentaBDE in terrestrial plants were also reported. Studies on tomato and soybean showed a small, but significant effect to growth. Only for tomato could a NOEC of 125 mg/kg dwbe quantified. In vertebrates, the liver was identified the principal target organ affected by PentaBDE exposure, and based on a 30-day mouse study the NOEL for liver effects was determined to 0.45 mg/kg/day. Reported liver effects included increases in liver weight and hepatocytomegaly with histopathological changes, induction of a range of liver enzymes, and disturbances in cholesterol and porphyrin synthesis. Rodent studies also indicated neurotoxic and behavioral effects, disturbances of the thyroid hormone balance (decreased serum thyroxin) and development of chloracne-like symptoms by dermal exposure. A risk for secondary poisoning was identified both from environmental exposure not only to PentaBDE, but also via formation of brominated dibenzo-p-dioxins and dibenzofurans from articles containing the substance during combustion or other high temperature processes (e.g. incineration, landfill (where fires could occur) or accidental fires). Occupational exposure and ingestion of milk by infants were also recognized as risk factors that could pose a threat to human health.
		PentaBDE meets all the criteria to be classified as a persistent organic pollutant, it is persistent, toxic, bioaccumulates and undergoes long range transport (Peltola and Ylä-Mononen, 2001; see also POPRC, 2006 for new and additional information), and as of 2009, following the nomination by Norway in 2005, PentaBDE is officially considered a persistent organic pollutant (POP) under the Stockholm Convention and is encompassed by a global ban (Stockholm Convention, 2009b). Due to structural similarities additive effects with other BFRs, such as PentaBDE may be anticipated (Schlabach *et al*., 2002; Kortenkamp *et al*., 2009).
		Summary of actual (or potential) human exposure and risk resulting from environmental exposure
		The available information regarding the absorption, metabolism and excretion of PentaBDE in humans and animals suggests that the substance is readily taken up and absorbed in all species tested (European Communities, 2001b, Peltola and Ylä-Mononen, 2001). Exposure route seems to have little influence on uptake and absorption, and once the substance is absorbed there appears to be little metabolism (see European Communities, 2001b and references therein). Hence, in accord with its relatively high solubility in fat and biological persistency, PentaBDE and/or its metabolites are distributed to and stored in adipose tissue for prolonged periods of time. The liver is the main target organ. Excretion occurs via the biliary and faecal routes, and via breast milk.
		The literature cited in the notification of PentaBDE (SFT, 2009) documents the presence of PBDE congeners in human blood (Thomsen *et al*., 2002c) and in human breast milk (Thomsen *et al*., 2002b, Thomsen *et al*., 2002a), and is consistent with PentaBDE exposure and systemic uptake within the Norwegian population. Time-trend data revealed that the PentaBDE levels in human tissues had increased markedly in the period 1972-1997, and could still be increasing (Peltola and Ylä-Mononen, 2001). The presence and evidence for increasing levels of PentaBDE in breast milk was considered as particularly due to the special vulnerability of children, and especially infants (SFT, 2009).
		In the Norwegian population (VKM, 2005), as elsewhere (European Communities, 2001b), consumption of fish is an important route of exposure to congeners of c-PentaBDE. In a Norwegian context this was also found to be alarming because the intake of fish in the Norwegian population is relatively high (Fluge *et al*., 1998), and especially for populations that are

		dependent of fish in their diet (e.g. indigenous people). POPs like PentaBDE have sufficient half-life in air to undergo long-range transport (Peltola and Ylä-Mononen, 2001, see also POPRC, 2006 and EB AIR, 2005 for new additional evidence). They travel with sea-and air currents towards colder areas where they settle and accumulate in environment and biota. PentaBDE also resists abiotic and biotic degradation and persists in the environment for a long time and has a great potential for bioconcentration and bioaccumulation (European Communities, 2001b, Peltola & Ylä-Mononen, 2001). Available monitoring data also provides evidence for biomagnification. In carp the overall bioconcentration factor for c-PentaBDE was determined to 27,400 L/kg. Congeners of c-PentaBDE have in Norway been detected in environmental compartments both at the Norwegian mainland and the Norwegian arctic (Schlabach *et al*., 2002). Measurements include a variety of abiotic and biotic samples at multiple locations. Besides its presence in human samples, PentaBDE has been detected in marine organisms including cod and mussels (Schlabach *et al*., 2002). High levels of PBDEs, including congeners of c-PentaBDE were also previously found in fish from the Norwegian lake Mjøsa (Fjeld *et al*., 2001), and in sediments and fish at other locations in Norway (Schlabach *et al*., 2002, Fjeld *et al*., 2004). In a study from Svalbard, Norway, PentaBDE was found to bioaccumulate in zooplankton, polar cod, and ringed seals. Evidence was also found in this study that congeners of PentaBDE biomagnify in Arctic food chains (Sørmo *et al*., 2006). A number of specific PBDE congeners can be detected in all environmental trophic levels, including biota and humans. Based on results from limited market basket surveys and human residues, the commercial mixtures that most closely reflect actual exposures are the PentaBDEs *(e.g*. Bromkal 70-5 DE, DE-71, Saytex 115) (WHO, 2003). Commercial mixtures of pentaBDE are usually composed mainly of TetraBDE (24–38 %), PentaBDE (50–60 %) and HexaBDE (up to 10 %) isomers. For the majority of products, PBDE 47 (2,2',4,4'-) is the main TetraBDE, while PBDE 99 (2,2',4,4',5-) is the major PentaBDE congener (WHO, 2003).

Annex 2 – Details on final regulatory actions reported

Country Name: Canada

1	**Effective date(s) of entry into force of actions**	June 19, 2008
	Reference to the regulatory document	Polybrominated Diphenyl Ethers Regulations (SOR/2008-218) under the Canadian Environmental Protection Act, 1999**.**
2	**Succinct details of the final regulatory action(s)**	The notified regulatory action relates to pentabromodiphenyl ether (c-PentaBDE) commercial mixture and the industrial use of the chemical as flame retardants. The decision made was to ban the uses, manufacture, sale, offer for sale, and import of TetraBDE and PentaBDE, and of those PBDEs that meet the criteria for virtual elimination under CEPA 1999, polymers and resins containing these substances of PBDEs, with the exception of PBDEs that are contained in a pest control product or to any resin, polymer or other mixture containing a PBDE, that is for use (a) in a laboratory or analysis; (b) in scientific research; or (c) as a laboratory analytical standard, (d) or is present as a contaminant (Polybrominated Diphenyl Ethers Regulations (SOR/2008-218) under CEPA 1999.
3	**Reasons for action**	The regulatory action was taken to protect the environment. Environment Canada under the CEPA 1999, conducted a hazard and risk assessment on PBDEs. The result was the document published in June 2006, named Ecological Screening Assessment Report, in which it was concluded that PBDE are entering the environment in a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. Environment Canada's Ecological Screening Assessment Report indicated 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, which may result from elevated concentrations of certain PBDE congeners in sediments (Alaee, M. *et al.,* 1999 in Environment Canada, 2005). The final regulatory action constitutes a preventative approach to ensure that these activities are not introduced in Canada.
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect the environment. The regulatory action was based on a risk evaluation under the prevailing conditions in Canada.
4.1	**Risk evaluation**	PBDE are entering the environment in a concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity specially the secondary poisoning of wildlife from the consumption of prey containing elevated concentrations of PBDEs, and effects on benthic organisms.
4.2	**Criteria used**	Risk to environment
	Relevance to other States and Region	The regulatory action is expected to have no impact to other states and regions with the use of PentaBDE already completely phased-out in Canada.
5	**Alternatives**	Alternative chemicals Chemical alternatives to PBDEs are available for the vast majority of industrial and manufacturing applications, and these vary by application. However, several issues need to be addressed as some potential alternatives are: currently under scrutiny themselves; new proprietary chemicals for which data on environmental and health effects are very limited; more costly; and less effective, hence much higher levels are required and products may be less likely to meet flammability standards. Alternative Techniques; The need for PBDEs can be reduced through the use of alternative techniques such as:

1. use of materials that are less prone to fire hazard in electronics equipment such as aluminium or "super-plastics" with very high oxygen requirements for combustion;
2. use of barrier fabrics, wrappings or coatings for foams to replace chemical flame retardant; or
3. design-for-environment (DFE) techniques for re-use of components containing PBDEs, as an alternative to land filling or recycling plastic materials containing PBDEs. Some of these alternative techniques present challenges, such as increased weight of final products and methods to collect, reuse and reassemble products with components containing PBDEs.

6	**Waste management**	Techniques for re-use of components containing PBDEs, as an alternative to land filling or recycling plastic materials containing PBDEs. Some of these alternative techniques present challenges, such as increased weight of final products and methods to collect, reuse and reassemble products with components containing PBDEs.
7	**Other**	None

Previous notifications	None

Country Name: European Union

1	**Effective date(s) of entry into force of actions**	Directive 2003/11/EC entered into force on the day of its publication in the Official Journal of the European Union (*i.e.* 15 February 2003). The EC Member States shall apply the laws, regulations and administrative provisions necessary to comply with the Directive as from 15 August 2004.
	Reference to the regulatory document	Directive 2003/11/EC of the European Parliament and of the Council of 6 February 2003 amending for the 24th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether) (Official Journal of the European Union L42 of 15.2.2003, pp. 45-46) available at http://europa.eu.int/eur-lex/.
2	**Succinct details of the final regulatory action(s)**	The decision was to severely restrict the uses and prohibited all applications of diphenylether, pentabromo derivative C12 H5 Br5 O as substance and in preparations or articles if they contain the substance in concentration higher than 0.1 % by mass.
3	**Reasons for action**	The regulatory action was taken to protect both human health and the environment. PentaBDE has been used as flame retardant additive. The decision was based on a risk assessment covering emissions and consequential environmental impacts and human exposures at each stage of the life cycle of the chemical, from production, through processing, formulation and use, to recycling and disposal. Protection goals for the environment included the atmosphere, aquatic organisms, sediment-dwelling organisms, soil-dwelling organisms, microorganisms in waste water treatment plants, and mammals and birds exposed via accumulation through the food chain. Exposure of humans from all relevant sources was considered, including exposures from consumer products, through air, food, and drinking water (man exposed via environment) and exposure at the workplace. It was concluded that although available data were insufficient in certain respects, there were unacceptable risks to human health and the environment that necessitated regulatory action. The risks to workers were that the estimated body burden of PentaBDE arising from occupational exposure, chiefly via dermal contact, is approximately 4-fold greater than the NOAEL derived from the rodent study (liver effects). Unacceptable risks to human were identified including human exposed through environment and infants exposed through breast milk. Concerns to aquatic and terrestrial environment were also identified from production and/or use of polyurethane foams.
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect human health and environment. The regulatory action restricted uses of PBDE commercial mixtures based on a risk evaluation under the prevailing conditions in EC.
4.1	**Risk evaluation**	Unacceptable risks to human health and the environment necessitated regulatory action. The risks to workers were that the estimated body burden of PentaBDE arising from occupational exposure, chiefly via dermal contact, is approximately 4-fold greater than the NOAEL derived from the rodent study (liver effects). Unacceptable risks to human were identified including human exposed through environment and infants exposed through breast milk. Concerns to aquatic and terrestrial environment were also identified from production and/or use of polyurethane foams.
4.2	**Criteria used**	Risk to human and environment
	Relevance to other States and Region	Similar health and environmental concerns could arise in other countries where the substance is used, particularly in developing countries.
5	**Alternatives**	No information given
6	**Waste management**	No information given
7	**Other**	No detailed socio economic assessment was carried out. PentaBDE is used exclusively to import ignition resistance to polymers, primarily flexible polyurethane used in furniture. Because only the UK has a household furniture flammability standard, the removal of the material from the EC market is expected to have a relatively minor economic impact due to its limited use.

Previous notifications	None

Country Name: Norway		
1	**Effective date(s) of entry into force of actions**	01.07.2004
	Reference to the regulatory document	Regulations relating to restrictions on the manufacture, import, export, sale and use of chemicals and other products hazardous to health and the environment (Product Regulations), §2-20 Brominated flame retardants. Ministry of the Environment. Act No. 922 of 1 June 2004. http://www.lovdata.no/cgi-wift/ldles?doc=/sf/sf/sf-20040601-0922.html.
2	**Succinct details of the final regulatory action(s)**	It is prohibited to produce, import, export, sell and use pentabromodiphenyl ether in pure form, in preparations, in products, and in parts of products containing greater than or equal to 0.1 % by weight of pentabromodiphenyl ether.
3	**Reasons for action**	Potential risk to human health and the environment under prevailing conditions in Norway. The regulatory action was taken to protect both human health and the environment. Norway's risk evaluation of PentaBDE was based on risk assessments undertaken by the EU and a report by the Nordic Council of Ministers as well as scientific data that were considered particularly relevant to Norwegian conditions. The national evaluation took into account production, use, environmental fate and behaviour, exposure as well as toxicity to humans and wildlife. Socioeconomic factors were also considered. All data evaluated indicated that PentaBDE was an important contaminant of the Norwegian environment and of sufficient concern for human health and wildlife to warrant a national ban. Congeners of PentaBDE have been found in a variety of abiotic and biotic samples. It has been detected in, e.g. human samples as well as in cod-liver and mussels. High levels of PBDEs were found in fish from the Norwegian lake Mjøsa. Significant amounts of PBDEs were detected in sediments and fish at different locations in Norway. Based on the risk evaluation there are concerns for serious damage to human health by prolonged exposure and concern for breastfed babies. PentaBDE was found in most compartments of the Norwegian environment and mainly fish, which is considered as important source of exposure to humans in Norway. This was considered alarming, especially for populations that are dependent on fish for their diet (*e.g.* indigenous people).
4	**Basis for inclusion into Annex III**	The final regulatory action was taken to protect human health and environment. The regulatory action banned uses of PentaBDE commercial mixtures thereof based on a risk evaluation under the prevailing conditions in Norway.
4.1	**Risk evaluation**	Data evaluated indicated that PentaBDE was an important contaminant of the Norwegian environment and of sufficient concern for human health and wildlife to warrant a national ban. Based on the risk evaluation there are concerns for serious damage to human health by prolonged exposure and concern for breastfed babies. PentaBDE was found in most compartments of the Norwegian environment including fish, which is considered an important source of exposure to humans in Norway. This was considered alarming, especially for populations that are dependent on fish for their diet (*e.g.* indigenous people).
4.2	**Criteria used**	Risk to human health and environment
	Relevance to other States and Region	PentaBDE is widely recognized as a persistent organic pollutant with a high potential to bioconcentrate, bioaccumulate and a long-range transport to remote regions (POPRC, 2006, see Norwegian supporting information, 2010). Similar concerns to those identified and reported by Norway are likely to be encountered in other countries where the substance is used.

5	**Alternatives**	A guidance report on alternatives to PentaBDE has been developed for the Persistent Organic Pollutants Review Committee of the Stockholm Convention. The report states that there are flame retardants commercially available (both chemical and non-chemical) which are less hazardous than PentaBDE. (Guidance on flame-retardant alternatives to pentabromodiphenyl ether (PentaBDE), 2008). The report can be found on the Stockholm Convention home page.
6	**Waste management**	Products containing more than 0.25 % PentaBDE are classified as hazardous waste when discarded. Recycling and reuse of PentaBDE and materials with PentaBDE are not allowed (POPRC, 2006, Norwegian supporting information, 2010). Regulation on recycling and treatment of waste (Waste Regulation). Ministry of the Environment, Act no. 930 of 1 June 2004. http://www.lovdata.no/cgi-wift/ldles?doc=/sf/sf/sf-20040601-0930.html
7	**Other**	No information given

Previous notifications	None

Annex 3 – Addresses of designated national authorities

Canada

Institution	**Environment Canada** **Environmental Stewardship Branch** **Chemicals Sector Directorate** **Chemical Production Division**
Address	**200 Sacré-Coeur Blvd., 3rd Floor** **Gatineau, Quebec, K1A 0H3** **CANADA**
Name of person in Charge	**Bernard Madé**
Position of person in charge	**Director, Chemical Production Division**
Telephone	**(819) 994-4404**
Telefax	**(819) 994-5030**
E-mail	**SEC-ECS@ec.gc.ca**

European Union

Institution	**DG Environment** **European Union**
Address	**Rue de la Loi, 200** **B-I049 Brussels** **Belgium**
Name of person in Charge	**Jürgen Helbig**
Position of person in charge	**Administrator**
Telephone	**+322 299 48 60**
Telefax	**+32229676 17**
E-mail	**Juergen.Helbig@cec.eu.int**

Norway

Institution	**Climate and Pollution Agency**
Address	**P.O. box 8100 Dep,** **0032 Oslo, Norway**
Name of person in Charge	**Christina C. Tolfsen**
Position of person in charge	**Senior Adviser**
Telephone	**22 57 3738**
Telefax	**22 67 67 06**
E-mail	**christina.charlotte.tolfsen@klif.no**

Annex 4 – References

Regulatory actions

1. Polybrominated Diphenyl Ethers Regulations (SOR/2008-218) under the Canadian Environmental Protection Act, 1999. Consolidated version as of October, 6, 2010. http://laws-lois.justice.gc.ca
2. Directive 2003/11/EC of the European Parliament and of the Council of 6 February 2003 amending for the 24th time Council Directive 76/769/EEC relating to restrictions on the marketing and use of certain dangerous substances and preparations (pentabromodiphenyl ether, octabromodiphenyl ether) (Official Journal of the European Union L42 of 15.2.2003, pp. 45-46) available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:042:0045:0046:EN:PDF.
3. Regulation of brominated flame retardants §2-20 in "Regulations relating to restrictions on the manufacture, import, export, sale and use of chemicals and other products hazardous to health and the environment (Product Regulations)" by the Ministry of the Environment. Act No. 922 of 1 June 2004.

Other Documents

Supporting documentation provided by Canada

1. Canada (2011) Response to Request for Information on International Trade. Document UNEP/FAO/RC/CRC.7/8/Add.1, p. 42
2. Environment Canada (2006): Ecological Screening Assessment Report on Polybrominated Diphenyl Ethers (PBDEs) under the Canadian Environmental Protection Act, 1999 (CEPA 1999) (in English and French).
3. Goodman, J. (2011): Information on trade names of chemicals recently notified by Canada. Document UNEP/FAO/RC/CRC.7/8/Add.1, p. 101

Supporting documentation provided by the European Union

1. Commission Regulation (EU) No 757/2010 of 24 August 2010 amending Regulation (EC) No 850/2004 of the European Parliament and of the Council on persistent organic pollutants as regards Annexes I and III. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:223:0029:0036:EN:PDF
2. European Communities (2001a): Diphenyl Ether, Pentabromo Derivative - Summary Risk Assessment Report. European Commission. Joint Research Centre.
3. European Communities (2001b): European Union Risk Assessment Report diphenyl ether, pentabromo derivate. European Commission, Joint Research Centre.
4. European Commission (2000a): Opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) on the results of the Environmental Risk Assessment of Pentabromodiphenyl ether [CAS N° 32534-81-9], carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances. Opinion expressed at the 13th CSTEE plenary meeting, Brussels, 4 February 2000. http://ec.europa.eu/health/scientific_committees/environmental_risks/opinions/sctee/sct_out55_en.htm
5. European Commission (2000b): Opinion on the results of the Human Risk Assessment of: Pentabromodiphenyl ether [CAS N° 32534-81-9] carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances. Opinion expressed at the 16th CSTEE plenary meeting, Brussels, 19th of June 2000. http://ec.europa.eu/health/scientific_committees/environmental_risks/opinions/sctee/sct_out64_en.htm

Supporting documentation provided by Norway

1. Norway (2010): Focused Summary Pentabromodiphenyl Ether. Document UNEP/FAO/RC/CRC.7/8/Add.4
2. Fjeld, E., Knutzen, J., Brevik, E., Schlabach, M., Skotvold, T. Borgen, A. R. & Wiborg, M. (2001): Halogenated organic pollutants and mercury in Norwegian freshwater fish, 1995-1999. Report TA-1813/2001 (in Norwegian only). Oslo. NIVA, SFT, SNT.
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