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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
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Item 5 (c) of the provisional agenda*

Matters related to the implementation of the Convention: consideration of chemicals for inclusion in Annex III to the Convention

Draft decision guidance document on octabromodiphenyl ether commercial mixtures

Note by the Secretariat

1. At its eighth meeting, the Chemical Review Committee finalized the text of the draft decision guidance document on octabromodiphenyl ether commercial mixtures.[1] The draft decision document, as contained in the annex to the present note, is forwarded to the Conference of the Parties for its consideration.

* UNEP/FAO/RC/COP.6/1.

[1] UNEP/FAO/RC/COP.6/9

Annex

Rotterdam Convention

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

Draft
Decision Guidance Document

Octabromodiphenyl ether commercial mixtures

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 […] meeting, held in […] on […], the Conference of the Parties agreed to list [chemical name] in Annex III of the Convention and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on […], 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.

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

[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.

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.

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STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
µg	Microgram
µm	Micrometer
ArfD	acute reference dose
a.i.	active ingredient
ADI	acceptable daily intake
ADP	adenosine diphosphate
ATP	adenosine triphosphate
BDE	bromodiphenyl ether
b.p.	boiling point
BFR	Brominated Flame Retardant
Bw	body weight
°C	degree Celsius (centigrade)
c-OctaBDE	octabromodiphenyl ether commercial mixture
CA	Chemicals Association
Cc	cubic centimetre
CEPA 1999	Canadian Environmental Protection Act, 1999
CHO	Chinese hamster ovary
Cm	Centimetre
D	Day
decaBDE	decabromodiphenyl ether
DNA	Deoxyribose Nucleic Acid
EC	European Community
EC_{50}	Effect concentration, 50%
ED_{50}	Effect dose, 50%
EEC	European Economic Community
EHC	Environmental Health Criteria
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
G	Gram
H	Hour
Ha	Hectare
i.m.	Intramuscular
i.p.	Intraperitoneal
IARC	international Agency for Research on Cancer
IC_{50}	inhibition concentration, 50%;
ILO	international Labour Organisation
IPCS	international Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)
hexaBDE	hexabromodiphenyl ether

STANDARD CORE SET OF ABBREVIATIONS

heptaBDE	heptabromodiphenyl ether
K	kilo- (x 1000)
Kg	Kilogram
Koc	organic carbon-water partition coefficient
L	Litre
LC_{50}	lethal concentration, 50%
LD_{50}	lethal dose, 50%
LOAEC	Lowest observed adverse effect concentration
LOAEL	lowest observed adverse effect level
LD_{LO}	lowest lethal dose
LOEL	lowest observed effect level
M	Metre
m.p.	melting point
Mg	Milligram
Ml	Millilitre
mPa	milliPascal
MTD	maximum tolerated dose
NA	not available
Ng	Nanogram
NOAEC	no-observed-adverse-effect-concentration
NOAEL	no-observed-adverse-effect level
NOEC	
NOEL	no-observed-effect level
nonaBDE	nonabromodiphenyl ether
NTP	National Toxicology Program
octaBDE	octabromodiphenyl ether
OECD	Organisation for Economic Co-operation and Development
PCB	
PCM	Phase contrast microscopy
PDBE	polybrominated diphenyl ether
PBDF	polybrominated dibenzofuran
PEC	predicted environmental concentration
PNEC	predicted-no-effect-concentration
POP	persistent organic pollutant
Pow	octanol-water partition coefficient
Ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used).
RAR	risk assessment report
RfD	reference dose for chronic oral exposure (comparable to ADI)
SMR	standardized mortality ratio
STEL	short term exposure limit
TLV	threshold limit value
TWA	time weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	Ultraviolet
VOC	volatile organic compound
WHO	World Health Organization

STANDARD CORE SET OF ABBREVIATIONS	
Wt	Weight

Decision guidance document for a banned or severely restricted chemical

Octabromodiphenyl ether commercial mixtures **Published:**

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

Common name

Octabromodiphenyl ether commercial mixtures,

typically containing hexabromodiphenylether, heptabromodiphenyl ether, octabromodiphenyl ether, nonabromodiphenyl ether and decabromodiphenyl ether

The commercially supplied octaBDE is a complex mixture of different congeners of polybrominated diphenyl ethers (PBDEs) e.g. penta-, hexa-, hepta-, octa-, and nonabromodiphenyl ethers and decabromodiphenyl ether (BDE) (POPRC, 2007).

Each of the congeners in the c-OctaBDE will exhibit a number of isomeric forms. Table 1 shows typical composition of c-OctaBDE flame retardants (UK, 2007, POPRC, 2008a);

Table 1: Typical composition of c-OctaBDE flame retardants (% by weight)

Main components	Up to 1994[a]	1997[c]	2000[d]	2001[e]	2006[f]	2006[g]
PentaBDE	10.5-12.0[b]		1.4-12.0[b]	≤0.5		
HexaBDE		5.5		≤12	10.5	0.3
HeptaBDE	43.7-44.5	42.3	43.0-58.0	≤45	45.5	12.8
OctaBDE	31.3-35.3	36.1	26.0-35.0	≤33	37.9	21.8
NonaBDE	9.5-11.3	13.9	8.0-14.0	≤10	13.1	18.9
DecaBDE	0-0.7	2.1	0-3.0	≤0.7	1.3	49.6

Note:
a) 1994 data are taken from WHO (1994).
b) This value is for the total amount of PentaBDE + HexaBDE.
c) 1997 data are from a composite sample from three suppliers to the EU (Stenzel and Nixon, 1997).
d) 2000 data are taken from RPA (2001) and represent the composition reported to the OECD under a Voluntary Industry Commitment.
e) 2001 data from the Great Lakes Chemical Corporation represent the upper bound composition based on random sampling of selected production lots from August 2000 to August 2001.
f) Data for DE-79 manufactured by Great Lakes Chemical Corporation, USA (LaGuardia et al., 2006).
g) Data for Bromkal 79-8DE manufactured by Chemische Fabrik Kalk, Germany (LaGuardia et al., 2006).

The c-OctaBDE is sold as a technical grade product under the Chemical Abstracts Service (CAS) Registry number for the OctaBDE isomer.
As seen above, the specification of the commercial mixtures may vary. 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.

This decision guidance document will focus on octabromodiphenyl ether commercial mixtures. PentaBDE is covered by its respective commercial mixtures as described in the decision guidance document on pentabromodiphenyl ether and pentabromodiphenyl ether commercial mixtures.

Chemical name and other names or synonyms

Octabromodiphenyl ether commercial mixtures typically containing:

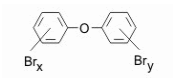
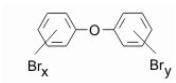
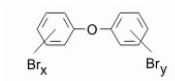
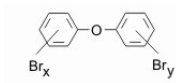
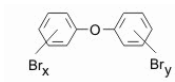
hexaBDE: hexabromodiphenyl ether (benzene, 1,1,1'-oxybis-, hexabromo derivative)

heptaBDE: heptabromodiphenyl ether (benzene, 1,1'-oxybis-, heptabromo derivative)

octaBDE: octabromodiphenyl ether (benzene, 11,1'-oxybis-, octabromo derivative)

nonaBDE: nonabromodiphenyl ether (benzene, 1,1,1'-oxybis-, nonabromo derivative)

decaBDE: decabromodiphenyl ether (bis(pentabromophenyl) ether (benzene, 1,1,1'-oxybis[2,3,4,5,6-pentabromo-])

Molecular formula	Octabromodiphenyl ether commercial mixtures typically containing:				
	$C_{12}H_4Br_6O$	$C_{12}H_3Br_7O$	$C_{12}H_2Br_8O$	$C_{12}HBr_9O$	$C_{12}Br_{10}O$
Chemical structure					
	where x + y = 6	where x + y = 7	where x + y = 8	where x + y = 9	where x + y = 10
	hexaBDE	heptaBDE	octaBDE	nonaBDE	decaBDE
CAS-No.(s)	36483-60-0	68928-80-3	32536-52-0	63936-56-1	1163-19-5
	Depending on the isomeric form, CAS numbers for different congeners, e.g. 2,2',4,4',5,5'-hexabromodiphenyl ether (CAS No: 68631-49-2) or 2,2',4,4',5,6'-hexabromodiphenyl ether (CAS No: 207122-15-4) and 2,2',3,3',4,5',6-heptabromodiphenyl ether (CAS No: 446255- 22-7), or 2,2',3,4,4',5',6-heptabromodiphenyl ether (CAS No: 207122-16-5) can apply. There may be other isomeric forms of hexa- , hepta- octa- and nonabromodiphenyl ethers or decabromodiphenyl ether present in commercial octabromodiphenyl ether mixtures.				
Harmonized System Customs Code Other numbers	2909 30				
Category	Industrial chemical				
Regulated category	Industrial chemical				
Use(s) in regulated category	**Canada** The notified regulatory action relates to the manufacture, use, sale, offer for sale or importation of octabromodiphenyl ether (octaBDE) commercial mixture and the industrial use of the chemical as flame retardants. In general, plastics are the primary end use for flame retardants. As such, PBDEs can be found in many items such as building and automobile materials, carpet underlay, furniture foam and electronic equipment. **European Union**[3] The notified regulatory action relates to diphenyl ether, octabromo derivatives (octaBDE) and their industrial use. Octabromodiphenyl ether is primarily used in the European Union in acrylonitrile-butadiene-styrene (ABS) polymers. Other minor uses include high impact polystyrene (HIPS), polybutylene terephthalate (PBT) and polyamide polymers. **Norway** The final regulatory action relates to diphenyl ether, octabromo derivatives (octaBDE) and their industrial use. Octabromodiphenyl ether has been used in Norway as a flame retardant in polymers (ABS), high impact polystyrene (HIPS) and in electrical and electronic equipment.				
Trade names	Bromkal 80; Bromkal79-8 DE, DE-79TM, ER 143; Tardex 80; FR 1208; Adine 404; Saytex 111 *This is an indicative list. It is not intended to be exhaustive.*				
Formulation types	None reported				
Uses in other categories	None reported				
Basic manufacturers	Production was phased out in the EU, Norway, Switzerland, Canada and the USA in the early to mid 2000's. In Japan, OctaBDE has never been produced; its import and sales				

3 At the time of 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.

were voluntarily phased out by 2005. There is no information available that indicates whether it is still being produced in developing countries. (UNEP 2008)

Previous known manufacturers were (POPRC, 2007):

Great Lakes Chemical Corporation, USA (LaGuardia et al., 2006).

Chemische Fabrik Kalk, Germany (LaGuardia et al., 2006).

2. Reasons for inclusion in the PIC procedure

OctaBDE 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 effectively ban octaBDE commercial mixtures as an industrial chemical, and;
- the final regulatory actions taken by the European Union and Norway, both to severely restrict the use of octaBDE including its commercial mixtures.

In the European Union and Norway concentrations of octaBDE congeners of up to 0.1% by weight are allowed[4].

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

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

Canada

Description of control action.

The Polybrominated Diphenyl Ethers Regulations: a) prohibit the manufacture of PBDEs in Canada (tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, nonaBDE and decaBDE congeners); and b) prohibit the use, sale, offer for sale and import of those PBDEs that meet the criteria for virtual elimination under CEPA 1999 (tetraBDE, pentaBDE and hexaBDE congeners), as well as mixtures, polymers and resins containing these substances.

The regulations do not apply to:

a) PBDEs that are contained in a pest control product within the meaning of subsection 2(1) of the Pest Control Products Act.

b) PBDEs, or to any resin, polymer or other mixture containing a PBDE, that is for use (a) in a laboratory for analysis; (b) in scientific research; or (c) as a laboratory analytical standard.

c) A product that is formed into a specific physical shape or design during its manufacture and that has, for its final use, a function or functions dependent in whole or in part on its shape or design, if that product contains a PBDE.

d) Any PBDE that is present as a contaminant in a chemical feedstock used in a process from which there are no releases of the PBDE, provided that the PBDE is destroyed or completely converted in that process to a substance that is not a PBDE.

The final regulatory action entered into force in June 2008.

Reason: Environment (immediate or long-term harmful effect on the environment or its biological diversity)

European Union

Description of control action.

The placing on the market and use of the octaBDE is prohibited as follows:

1. as a substance or as a constituent of substances or of preparations in concentrations higher than 0.1% by mass;
2. in articles if they, or flame retardant parts thereof, contain the substance in concentrations higher than 0.1% by mass[5].

The EC Members States shall apply the laws, regulations and administrative provisions necessary to comply with Directive 2003/11/EC as of 15 August 2004.

Reason: Human Health and Environment

4 However, in 2009 the COP4 of the Stockholm Convention decided to list congeners present in the commercial forms of pentabromodiphenyl ethers and octabromodiphenyl ethers having POPs characteristics. This decision was implemented in EU Regulation 757/2010 and will result in further restriction of the use of the octaBDE commercial mixture.

Norway

Description of control action.

It is prohibited to produce, import, export, sell and use octaBDE commercial mixtures in pure form, in preparations, in products, and in parts of products containing greater than or equal to 0.l % by weight of octaBDE commercial mixtures. Products containing more than 0.25 % octaBDE are classified as hazardous waste when they are discarded. Recycling and reuse of octaBDE and materials with octaBDE are not allowed.

Reason: Human Health and Environment

2.2 Risk evaluation (see Annex 1 for further details)[5]

Canada

Description of risk evaluation

An ecological screening assessment was made which involves an analysis of polybrominated diphenyl ethers (PBDEs). Conservative assumptions were used to determine whether the substances meet the criteria as defined in section 64 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999). This screening assessment examined various supporting information and developed conclusions based on a weight of evidence approach as required under Section 76.l of CEPA 1999. The assessment did not represent an exhaustive review of all available data; rather, it presented the most critical studies and lines of evidence supporting the conclusions. One line of evidence included consideration of risk quotients to identify potential for ecological effects. However, other concerns that affect current or potential risk, such as persistence, bioaccumulation, chemical transformation and trends in ambient concentrations, were also mentioned in the report of the assessment.

Seven PBDEs were identified in a pilot project list of 123 substances for screening assessment under CEPA 1999, on the basis of their potential persistence and/or bioaccumulation in the environment and inherent toxicity to organisms. Environment Canada's Ecological Screening Assessment Report indicated that the greatest potential risks from PBDEs in the Canadian environment were the secondary poisoning of wildlife, and effects on benthic organisms. The 2006 screening assessment report also concluded that PBDEs were entering the environment in a quantity or concentration, or under conditions that had or may have had an immediate or long-term harmful effect on the environment or its biological diversity. More specifically, it concluded that tetraBDE, pentaBDE and hexaBDE congeners met the criteria for persistence and bioaccumulation, as defined by the Persistence and Bioaccumulation Regulations of CEPA 1999. The screening assessment also concluded that their presence in the environment resulted primarily from human activity (*i.e.*, releases from product manufacturing and processing, and throughout the product life cycle). As a result, tetraBDE, pentaBDE and hexaBDE congeners met the conditions for virtual elimination, as set out in CEPA 1999.

European Union

Description of risk evaluation

A risk assessment was conducted 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 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.

Concerns identified with regard to human health include the extent of excretion into breast milk and cow’s milk, as well as on competition on T4 of transthyretin with octaBDE and the effects of prolonged exposure.

Concerns identified with regard to the environment include the possibility of secondary poisoning, especially via the earthworm route, for the hexaBDE component in the octaBDE commercial product from the use in polymer applications. There was also uncertainty about the possibility of degradation to more toxic and bioaccumulative compounds under some conditions, and about the possibility of long-term environmental effects that cannot be predicted easily. (UNEP/FAO/RC/CRC7/10, Add.2a and Add.2d)

Norway

Description of risk evaluation

Human health:

[5] References cited in this section can be found in the supporting documentation of the respective notifying countries.

The commercial octaBDE product (c-OctaBDE) classified as a reproductive toxicant, due to its effects on human health, with the risk phrases "may cause harm to unborn child", and "possible risk of impaired fertility". Studies and assessments provided evidence that c-OctaBDE may cause adverse effects, such as effects on reproductive organs and effects on development of the foetus. Effects of repeated exposure to c-OctaBDE consistently indicated that the liver was the key target organ, and liver effects had been observed in animal studies. It was assumed that in humans, components of c-OctaBDE might bioaccumulate in adipose tissue. The EU Risk Assessment Report presents information on the levels of components of c-OctaBDE measured in human samples including human milk, blood, and adipose tissue. Large variations among individuals were generally observed, but significant differences between the control population and occupationally exposed groups were also reported.
In a Norwegian study (Thomsen et al., 2006) the investigation of 66 hobby fishermen and women showed clear associations between the concentrations of PBDEs (including BDE-153, BDE-154, BDE-138 and BDE-183) in serum and the subject's age and intake of freshwater fish.

Environment:
According to available data, congeners of c-OctaBDE seem to resist degradation and thus have the potential to persist in the environment for a long time. They have potential for bioaccumulation and in addition there was monitoring evidence of biomagnification. Lower and higher brominated congeners (some of them present in c-OctaBDE) showed potential for long-range environmental transport. Analysis of the chemical properties of c-OctaBDEs seems to support this conclusion, as Henry's law constant is very similar to those of acknowledged POPs. Therefore, it can be expected that c-OctaBDE is subject to long range environmental transport.
Congeners of c-OctaBDE have been found in a variety of samples. They were detected inhuman samples, as well as in polar cod, ringed seals and mussels. In a study from Svalbard, Norway, congeners of c-OctaBDE were found to bioaccumulate in zooplankton, polar cod, and ringed seals. Evidence was also found in this study that hexaBDE (BDE-153) biomagnify in the Arctic food chain (ringed seal to polar bear) (Sørmo et al, 2006).Uptake is also demonstrated for birds. Knudsen et a1 (2005) reviewed temporal trends of PBDEs in eggs from three bird species, three locations and three sampling times (from 1983 to 2003) from Northern Norway. Spatial differences were only observed for hexaBDE (BDE-153), and increases in the measured concentration from 1983 to 2003 were observed for the hexaBDE (153 and 154) and the heptaBDE (BDE-183). In conclusion monitoring data document that some of the main components of the c-OctaBDE are taken up by organisms via the environment and bioaccumulate and biomagnify via the food chain.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

Canada *Description of regulatory measure*

The Polybrominated Diphenyl Ethers Regulations: a) prohibit the manufacture of PBDEs in Canada (tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, nonaBDE and decaBDE congeners); and b) prohibit the use, sale, offer for sale and import of those PBDEs that meet the criteria for virtual elimination under CEPA 1999 (tetraBDE, pentaBDE and hexaBDE congeners), as well as mixtures, polymers and resins containing these substances.

The regulations do not apply to:

a) PBDEs that are contained in a pest control product within the meaning of subsection 2(1) of the Pest Control Products Act.

b) PBDEs, or to any resin, polymer or other mixture containing a PBDE, that is for use (a) in a laboratory for analysis; (b) in scientific research; or (c) as a laboratory analytical standard.

c) A product that is formed into a specific physical shape or design during its manufacture and that has, for its final use, a function or functions dependent in whole or in part on its shape or design, if that product contains a PBDE.

d) Any PBDE that is present as a contaminant in a chemical feedstock used in a process from which there are no releases of the PBDE, provided that the PBDE is destroyed or completely converted in that process to a substance that is not a PBDE.

The final regulatory action entered into force in June 2008.

European Union *Description of regulatory measure*

The placing on the market and use of octaBDE is prohibited as follows:

1. as a substance or as a constituent of substances or of preparations in concentrations higher than 0.1% by mass.
2. in articles if they, or flame-retardant parts thereof, contain the substance in concentrations higher than 0.1% by mass.

The European Union banned the use of PBDE in new electronics and electronic products as of July 1, 2006 pursuant to the Directive on restrictions on hazardous substances (RoHS).

To control and minimise environmental impacts from products containing PBDEs that are already in use, Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) sets specific requirements with respect to collection, recovery, permitting of treatment installations, treatment standards and separation (European Union, 2002b). The Directive obliges Member States to adopt appropriate measures to minimise disposal of products containing PBDEs as unsorted waste and to achieve a high level of separate collection of WEEE. Since August 13, 2005 collection systems from households and take-back obligations were required. By December 31, 2006, separate collection of at least four kilograms of WEEE per inhabitant per year from private households was to be achieved. Treatment is only allowed in authorised installations complying with minimum technical requirements. In addition minimum treatment requirements were specified and specific targets are set as recovery rates per appliance (by weight) (POPRC, 2007).

Norway *Description of regulatory measure*

All formulations, products and parts of products containing greater than or equal to 0.l % by weight of octaBDE are banned from the market. Products containing more than 0.25 % octaBDE are classified as hazardous waste when they are discarded. Recycling and reuse of octaBDE and materials with octaBDE are not allowed.

3.2 Other measures to reduce exposure

Canada

In addition to the above described ban towards PBDEs, Canada is working on several other risk management actions, including: (i) a regulation to control PBDEs in domestic and imported manufactured products; (ii) a Performance Agreement with industry to minimize releases to the environment from the use of the DecaBDE commercial mixture in Canadian manufacturing operations; (iii) a detailed review of newly published science on the bioaccumulation and environmental transformation of decaBDE in order to determine whether further controls on this form of PBDE are warranted; (iv) development of a management strategy for PBDE-containing products at end-of-life, and; (v) monitoring Canadians' exposure to PBDEs (POPRC, 2007).

European Union

Brominated diphenylethers are mentioned as hazardous substances in the list of priority substances for water policy purposes, with the aim of progressively reducing pollution from these substances (European Union, 2000).

Norway

None identified

General

Stockholm Convention

HexaBDE and heptaBDE, which are the main components of octaBDE commercial mixture, are listed in Annex A of the Stockholm Convention, which means that they are targeted for elimination with a specific exemption for use as articles containing these substances for recycling.

The POPRC risk management evaluation from 2008 (UNEP/POPS/POPRC.4/15/Add.1) mentioned that in addition to the Polybrominated Diphenyl Ethers Regulations, Canada was working on several other risk management actions, including:

(i) a regulation to control PBDEs in domestic and imported manufactured products;

(ii) a Performance Agreement with industry to minimize releases to the environment from the use of the decaBDE commercial mixture in Canadian manufacturing operations;

(iii) a detailed review of newly published science on the bioaccumulation and environmental transformation of decaBDE in order to determine whether further controls on this form of PBDE are warranted;

(iv) development of a management strategy for PBDE-containing products at end-of –life;

(v) monitoring Canadians' exposure to PBDEs.

In addition, chapters 2.1 and 2.2 of the 2008 POPRC document(UNEP/POPS/POPRC.4/15/Add.1) list possible control measures, as well as information on their efficacy and efficiency. These include a ban/restriction on production and use and standards and other controls on production and waste handling.

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

Alternative chemicals (UNEP/FAO/RC/CRC.7/10)

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 (UNEP/FAO/RC/CRC.7/10)

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);
- use of barrier fabrics, wrappings or coatings for foams to replace chemical flame retardants; or
- 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 re-assemble products with components containing PBDEs

European Union

No information available

Norway

No information available

General

Stockholm Convention

The availability of practicable and economically viable substitutes (products/ chemicals and processes) from all uses of c-octaBDE has already been demonstrated in practice (POPRC, 2008a and b; POPRC, 2009) and has been identified by the persistent organic pollutant review committee (POPRC). Detailed information on such alternatives can be found in chapter 2.3 of the POPRC risk management evaluation from 2008 (UNEP/POPS/POPRC.4/15/Add.1).) and in the document “Additional information related to the commercial octabromodiphenyl ether risk management evaluation” (UNEP/POPS/POPRC.4/INF/10). POPRC has also developed a guidance document on considerations related to alternatives and substitutes for listed persistent organic pollutants and candidate chemicals 2009 (UNEP/POPS/POPRC.5/10/Add.1).

3.4 Socio-economic effects

Canada

OctaBDE is no longer manufactured, imported or used in Canada. Recent information collected from the industry indicated that historical uses of octaBDE have been completely phased-out. There were some minor remaining uses in 2005, but complete phase-out was achieved by 2006. The phase-out of octaBDE use by Canadian industry was confirmed by the industry association. No technical or economic impact on the industry was expected from the proposed Regulations as octaBDE use was phased out prior to the regulations coming-into-force in June 2008. In addition, users and suppliers of octaBDE confirmed that given the regulatory climate, customer demand for PBDE-free products, the availability of cost-effective alternatives, and the fact that octaBDE was not available in the market after 2005; it was not technically or economically viable to continue using octaBDE.

In May 2009, the hexaBDE and heptaBDE congeners were listed to Annex A to the Stockholm Convention on Persistent Organic Pollutants (POPs) requiring Parties to eliminate production and use. As a result of past releases to the environment due especially to human activities, POPs are now widely distributed over large regions (including those where POPs have never been used) and, in some cases, they are found around the globe. POPs can be found in people and animals living in regions such as the Arctic, thousands of kilometres from any major POPs source.

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

European Union

No detailed assessment was carried out. OctaBDE is used primarily to impart ignition resistance to polymers, primarily ABS type polymers that are used in electrical and electronic equipment. Because of the nature of flammability standard for electrical and electronic equipment, the removal of this material from the EC market is expected to have a relatively minor economic impact due to its limited use.

Norway

No information provided.

General

Stockholm Convention

Chapter 2.4 of the POPRC risk management evaluation from 2008 (UNEP/POPS/POPRC.4/15/Add.1) gives a summary of information on impacts on society of implementing possible control measures. It concludes that: "Given the conclusions of the Risk Profile (UNEP 2007) for c-OctaBDE, its widespread global occurrence in biota and in humans, action taken or underway to phase it out in developed and developing countries and the increased demand for alternatives to c-OctaBDE, the overall consequence of a full global phase-out is most likely to be positive. Overall, the cost for developed countries of a phase out of c-OctaBDE should be small, as discussed above. However, specialized waste management and disposal related to c-OctaBDE (stockpiles and articles) could be costly for some countries and financial and technical assistance to developing countries should be considered to address this aspect as required."

Countries should consider the results of this information in the context of their own national conditions.

4. Hazards and Risks to human health and the environment	
4.1 Hazard Classification	
WHO / IPCS	No information
IARC	No information

European Union	octaDBE (CAS-No. 32536-52-0): Classification pursuant to Directive 67/548/EEC: Repr. Cat. 2 - R61; May cause harm to the unborn child Repr. Cat. 3 - R62; Possible risk of impaired fertility Safety phrases: S53: Avoid exposure - obtain special instructions before use. S45: In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Classification pursuant to Regulation (EC) No 1272/2008 implementing the UN GHS: Repr. 1B – H360Df - May damage the unborn child. Suspected of damaging fertility. (Source: http://esis.jrc.ec.europa.eu/)
US EPA	Not available

4.2 Exposure limits

No information is available

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.

No information is 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 (SBC, 1994), 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 octaBDE along with the other new POPs that were listed in the Stockholm Convention in 2009. The work is proposed to be undertaken in collaboration with the Stockholm Convention (POPRC-6/3).

Stockholm Convention

C-octaBDE fulfils the POPs criteria of the Stockholm Convention and is 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 review committee (POPRC) on the basis of a technical paper (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 it is stated 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 pointed 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”.

Annexes

Annex 1 Further information on the substance

Introduction

The information presented in this Annex reflects the conclusions of the notifying parties: Canada, European Union and Norway. The notifications were circulated for consideration at the Committee's seventh meeting and have been published in document UNEP/FAO/RC/CRC.7/10.

Where possible, information on hazards provided by the notifying Parties has been presented together, while the evaluation of the risks, specific to the conditions prevailing in the notifying Parties are presented separately. This information has been taken from the documents referenced in the notification in support of their final regulatory actions to ban or severely restrict octabromodiphenyl ether or its commercial mixtures.

Annex 1 – Further information on octaBDE commercial mixtures

1. Physico-Chemical properties

Octabromodiphenyl ether commercial mixtures typically containing: hexabromodiphenyl ether, heptabromodiphenyl ether, octabromodiphenyl ether, nonabromodiphenyl ether and decabromodiphenyl ether.

Basic physico-chemical properties of individual congeners (EU, 2003)

Property	HexaBDE	HeptaBDE	OctaBDE	NonaBDE	DecaBDE
Water solubility [µg/L]	4.7	1.3	0.5	0.11	0.03
Log Kow	7.4	8	8.7	9.3	9.9
Vapour pressure [Pa]	$5.5 \cdot 10^{-6}$	$5.7 \cdot 10^{-7}$	$5.9 \cdot 10^{-8}$	$6. \cdot 10^{-9}$	$6.1 \cdot 10^{-10}$
Koc [L/kg]	1,060,250	1,221,640	1,363,040	1,514,430	1,665,830
BCF [L/kg]	< 4	< 4	< 4	< 4	< 4
Other modelling input data (estimated using EPI program)					
Melting point [°C]	197	211	226	240	255
Boiling point [°C]	467	498	528	559	590
Rate constant for reaction with atmospheric hydroxyl radicals [$cm^{2} \cdot s^{-1} \cdot molecule^{-1}$]	$9.77 \cdot 10^{-13}$	$5.49 \cdot 10^{-13}$	$2.10 \cdot 10^{-13}$	$1.92 \cdot 10^{-13}$	$1.74 \cdot 10^{-13}$

1.1	**Identity**	**Octabromodiphenyl ether commercial mixtures** typically containing: **HexaBDE:** hexabromodiphenyl ether (benzene,1,1'-oxybis-, hexabromo derivative) **HeptaBDE:** heptabromodiphenyl ether (benzene,1,1'-oxybis-, heptabromo derivative) **OctaBDE:** octabromodiphenyl ether (benzene,1,1'-oxybis-, octabromo derivative) **NonaBDE:** nonabromodiphenyl ether (benzene,1,1'-oxybis-, nonabromo derivative) **DecaBDE:** decabromodiphenyl ether (benzene,1,1'-oxybis-, decabromo derivative)
1.2	**Formula**	$C_{12}H_4Br_6O$ $C_{12}H_3Br_7O$ $C_{12}H_2Br_8O$ $C_{12}HBr_9O$ $C_{12}Br_{10}O$
1.3	**Colour and Texture**	Powder or flaked material
1.4	**Decomposition temperature**	Bromine is lost as the temperature increases (i.e. the substance decomposes), with an approximate 2% loss at 330°C and 40% loss at 395°C (European Communities, 2003a)
1.6	**Density (g/cm^3)**	A specific gravity of 2.9 has been quoted (European Communities, 2003a)
1.7	**Resistance to acids**	NA
1.8	**Resistance to alkalis**	NA

1.9	**Tensile strength (10^3 kg/cm^2)**	NA
2	**Toxicological properties**[6]	
2.1	**General**	
2.1.1	**Mode of Action**	NA
2.1.2	**Symptoms of poisoning**	NA
2.1.3	**Absorption, distribution, excretion and metabolism in mammals**	Only limited data are available. Animal data show absorption of octaBDE by oral or inhalation route with an accumulation of the parent compound or its metabolites in the liver and also in the adipose tissue and the lung following an inhalation administration. The extent of absorption and elimination can not be assessed from the data available. No information on the metabolism of octaBDE is available. Following oral administration, octaBDE is an inducer of xenobiotic metabolism with dose and time dependent relationship. Based on octaBDE physicochemical properties and analogy with PCBs, a dermal absorption of 4.5% may be estimated associated with a likely trend towards accumulation in the stratum corneum. Very limited data on human toxicokinetics are available. These data indicate that octaBDE, hexaBDE, heptaBDE and nonaBDE, which are components of c-OctaBDE, can be absorbed into the body and are distributed to the blood. Distribution to the adipose tissue was evidenced at least for octaBDE and hexaBDE. There are no data available on the rate of elimination or of bioaccumulation of octaBDE from human adipose tissue, but given the high lipophilicity of the compound and the adipose tissues accumulation observed in rats following oral or inhalation routes, it can be assumed that in humans octaBDE might bioaccumulate in these tissues as well. Following pregnancy hexaBDE and other PBDEs such as tetraBDE and pentaBDE are excreted in the breast milk. Unfortunately, such measurements were not carried out on octaBDE. However, based on the high lipophilicity of octaBDE, its potential to bioaccumulate in adipose tissues and the breast milk measured data with hexaBDE (component of c-OctaBDE), excretion of octaBDE in the breast milk may be expected to occur (Norwegian notification).
2.2	**Toxicology studies**	
2.2.1	**Acute toxicity**	The acute oral, inhalation and dermal toxicity of octaBDE have been studied in rats and rabbits. The available data showed that the acute oral toxicity of octaBDE is low with LD_{50}-values > 5 000 mg/kg. The acute inhalation of octaBDE (respirable particles) resulted in LC_{50}-values > 50 mg/L (0.05 mg/m^3) (European Communities, 2003a).
2.2.2	**Short term toxicity**	OctaBDE was administered orally to rats for 28 and 90 days. The liver was found to be the most sensitive target organ for the toxicity of octaBDE but NOAELs could not be established because of improper dosage selection. The LOAEL is 7.2 mg/kg/d based on liver histopathology and the occasionally increased liver weights. The toxicity of octaBDE was also studied after inhalation exposure for 14 days using particles of respirable sizes. Again, the liver was identified as the most sensitive target organ and a NOAEC of 1 mg/m^3 was derived for effects on the liver. Regarding local toxicity to the respiratory tract, a LOAEC of 1 mg/m^3 was defined (European Communities, 2003a).
2.2.3	**Genotoxicity (including mutagenicity)**	The data on the genotoxicity of octaBDE are limited. OctaBDE was studied for mutagenicity in bacteria either as the pure compound or as component in a mixture with other polybrominated diphenyl ethers. Usually, mutagenicity was not observed using metabolic activation and in different strains of *Salmonella typhimurium*. OctaBDE also did not induce unscheduled DNA-synthesis and sister chromatid exchanges in cultured cells or cytogenetic changes in human lymphocytes (European

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

Communities, 2003a).

2.2.4 Long term toxicity and carcinogenicity

Long term toxicity

No experimental data were available on the long-term toxicity of octaBDE (EU, 2003).

Carcinogenicity

No experimental data were available on the carcinogenicity of octaBDE. However, based on the low toxicity, structural similarity to other weak carcinogens such as PCBs and the effect on thyroid hormones and enzyme induction, it could indicate a potential for non-genotoxic carcinogenicity (European Communities, 2003a).

2.2.5 Effects on reproduction

Toxic effects of octaBDE to reproductive organs were studied in an inhalation study (Great Lakes, 2001). No treatment related effects on male reproductive organs were seen after exposure of rats up to 250 mg octaBDE/m^3. In females, absence of corpora lutea was observed in a recent well-conducted inhalation study, and a NOAEC of 16 mg/m^3 is identified for reproductive effects in female rats.

The developmental toxicity of commercial octaBDE was studied in two rats and in one rabbit studies. In rats, dose-dependent effects on the conceptus were seen after administration of doses > 10 mg/kg/d. In rabbits, slight toxicity to the foetus represented by decreased body weight gains was observed after 5 mg/kg/day. For the risk characterization, a NOAEL of 2 mg/kg/d was used (European Communities, 2003a).

2.2.6 Neurotoxicity/ delayed neurotoxicity, Special studies where available

Although the quality of the data have been questioned (European Communities, 2003a) behavioural disturbances have been reported when mice (10 days old) were exposed to a single dose of hexaBDE ether (0.45, 0.9 and 9 mg/kg bw/d) those effects being observed at 2, 4 but also 6 months of age. Nicotinic receptors were also affected in adult mouse in the previous conditions of exposure (Viberg, 2001). Delayed neurotoxic effects of c-OctaBDE are also reported; Neonatal mice exposed to a single dose of 0.45 mg BDE153/kg bw on postnatal day 10 showed when tested at 2, 4 and 6 months of age altered motor behaviour. Spatial learning ability and memory function in the adult mice were also affected (Viberg et al., 2001).

Eriksson et al. (2002) confirmed neurotoxic effects (aberrant behavioural responses) on developing male mice exposed to 0.45 to 9.0 mg/kg bw of BDE153 on day 10 of development. The effects were comparable to those observed for PCB153 leading the authors to speculate that interactive neurotoxic action may be possible between the two compounds.

The toxicological significance of these findings is not obvious since a clear interpretation of the significance for human health of the behavioural difference seen in mice has not been established. Moreover only an abstract of this study is available and some major information is lacking such as housing condition, randomization and number of animals. It is also noticeable that descriptions of the severity of the effects depending on the dose as well as quantitative data are not indicated. Moreover, no statistical treatment of the results and no standard deviation data are presented, so it is difficult to judge the degree of variability that might be expected within this study. Finally, no details regarding the historical negative control are reported. No firm conclusion can be drawn from the previous data (European Communities, 2003).

Neurotoxic effects have also been observed after a single oral dose of nonaBDE 206 or octaBDE 203 administered on postnatal day 3 or 10 to, or PBDE 183; with disturbances in spontaneous behaviour, leading to disrupted habituation and a hyperactive condition in adults at the age of 2 months. (Viberg et al., 2006).

c-OctaBDE may also affect neuronal signalling effects. E.g. *in vitro* studies indicates that BDE (including the HexaBDE 153) affected protein kinase C (PKC) and calcium homeostasis in cerebellar granule neuronal cultures in a similar way to those of a structurally-related polychlorinated biphenyl (PCB) (Kodavanti et al., 2005).

2.2.7 Immunotoxicity

According to the EU risk assessment (European Communities, 2003a), reported

studies did not show c-OctaBDE to have immunotoxic properties. Yet, in their risk assessment published 5 years later, POPRC reports a study which suggests that c-OctaBDE may impact the immune response in birds. The study in question was conducted with captive nestling American kestrels (*Falco sparverius*) (Fernie et al. 2005). Eggs within each clutch, divided by laying sequence, were injected with safflower oil or BDE congeners-47, -99, -100, and -153 dissolved in safflower oil (18.7 µg PBDEs/egg). For 29 days, nestlings consumed the same PBDE mixture (15.6+/-0.3 ng/g body weight per day), reaching PBDE body burden concentrations that were 120x higher in the treatment birds (86.1+/-29.1 ng/g ww) than controls (0.73+/-0.5 ng/g ww). PBDE-exposed birds had a greater PHA response (T-cell-mediated immunity), which was negatively associated with increasing BDE-47 concentrations, but a reduced antibody-mediated response that was positively associated with increasing BDE-183 concentrations. There were also structural changes in the spleen (fewer germinal centers), bursa (reduced apoptosis) and thymus (increased macrophages), and negative associations between the spleen somatic index and PBDEs, and the bursa somatic index and BDE-47. Immunomodulation from PBDE exposure may be exacerbated in wild birds experiencing greater environmental stresses.

2.2.8 Endocrine disruption

Alterations in thyroid homeostasis were reported with organochlorine compounds for many species, including humans. A thyroid hormone like affinity for the serum transport protein transthyretin was shown for hydroxylated PCBs.
Concerning PBDPOs, certain PBDPO congeners namely BDE-15 (DiBDPO) and BDE-77 (TeBDPO) after in vitro microsomal transformation into metabolites compete with thyroxin for a transport protein (TTR) suggesting a potential endocrine disturbing effect of these PBDPO metabolites. However, no studies on transthyretin-T_4 competition were available on OBDPO neither on DBDPO (EU, 2003).

2.2.9 Summary of mammalian toxicity and overall evaluation

Stockholm Convention

Assessing the toxicity of c-OctaBDE is complicated by the fact that c-OctaBDE is composed of a complex mixture of PBDE congeners and isomers. Data on the toxicity and ecotoxicity of several of the congeners is moreover scare and an in-depth assessment of the studies conducted have indicated that the experimental design (test design, exposure conditions and endpoint measured) is not appropriate for making a sound assessment of this type of chemicals. Nonetheless, the immunotoxicological and delayed neurotoxic effects observed after a single dose exposure require specific attention and give reason for concern given that certain c-pentaBDE congeners, hexa- and heptaBDE in particular are persistent and bioaccumulating substances that undergo long-range environmental transport.

3 Human exposure/Risk evaluation[7]

3.1 Food

In the European Union Risk Assessment Report (EU-RAR), exposures to humans via environmental routes have been estimated using EUSES and showed no increase for octaBDE from 1994 to 1999.
However, PBDEs have been steadily increasing over the last decades in biota including humans. Consequently, the question arises as to what extent these brominated flame retardants (BFRs) pose a risk to species higher in the food chain, in particular top predators and humans. Human exposure probably occurred mainly via food in analogy to PCBs and related compounds, but occupational exposure, *e.g.* through handling electronic equipment, might also play a significant role.
An important observation mentioned in the EU-RAR was that in contrast to *e.g.* PCBs and DDT, the levels of PBDEs were increasing in human milk: a study in Sweden showed a doubling in concentration every five years over the period 1972 to 1997 with BDE-47, being the predominant congener. From 1998 to 2000, a decrease in PBDE levels was noticed, which could be a consequence of the phase out of the commercial pentaBDE in Sweden (Guvenius Meironyté, 2002). The temporal trends

[7] References cited in this section can be found in the supporting documentation of the respective notifying countries.

and influence of age and gender on six BDE congeners was investigated on archived serum samples from Norway (Thomsen et al., 2002). The sum of the BDEs increased from 0.44 ng/g lipids in 1977 to 3.3 ng/g in 1999, with BDE-47 being the most abundant congener. BFR levels in the different age groups were relatively similar, except for the age group of 0-4 years, which had 1.6-3.5 times higher serum concentrations; breast milk being considered the main source. Recent data from the USA indicate that PBDE levels in mothers' milk are much higher than the values reported from Sweden and Norway as levels of approx. 200 ng/g lipid were reported in a pooled sample of mothers' milk from the USA (levels of 132, 27 and 15 ng/g lipid of BDE-47, BDE-99 and BDE-153, respectively) (Päpke et al., 2001). The latter data are not included in the EU-RAR.

PBDEs levels in biota, including human food items, have been steadily increasing over the last decades. A detailed risk assessment of PBDE in food was conducted by the Norwegian Scientific Committee, (VKM, 2005). This risk assessment identified fish as the main dietary source of PBDEs to the Norwegian population. In their assessment, the committee concluded that it was not possible to establish a tolerable daily intake for PBDEs based on the available literature at the time and that fish accounted for ¾ of the total dietary intake of these substances in the Norwegian population. A recommendation was made that the PBDE congeners with highest prevalence in Norwegian diet be included in the national monitoring program for food. In another Norwegian study (Thomsen et al., 2006) the investigation of 66 hobby fishermen and -women showed clear associations between the concentrations of PBDEs (including BDE-153, BDE-154, BDE-138 and BDE-183) in serum and the subjects' age and intake of freshwater fish

Based on the measured PBDE levels detected in various meat, fish and dairy food products, an average daily dietary intake estimate of PBDEs was calculated in a study carried out in Belgium. PBDE intake calculations were estimated between 23 and 48 ng/day of total PBDEs. Fish is the major contributor to the total daily PBDE-intake (around 40%) due to the high PBDE levels in this type of food, although it is only a minor constituent of the Belgian diet. Meat products account for around 30% of the total dietary intake of PBDEs. Dairy products and eggs contribute to a lesser degree (less than 30%, Voorspoels et al., 2007).

Schuhmacher et al. (2007) have carried out an study to compare levels of PBDEs due to dietary intake and population living near a hazardous waste incinerator (HWI), in Spain. This study suggests that dietary intake is more relevant for human exposure to PBDEs than living near the HWI. Dietary intakes of PBDEs for standard adult women were 72 and 63 ng/day for PBDEs, for residents in urban and industrials areas, respectively. Mean PBDE concentrations were 2.2 and 2.5 ng/g fat for women living in urban and industrial zones, respectively (POPRC, 2007).

Using modelling (EUSES), the contributions to human exposure via the environment from various food sources, air and drinking water have been estimated (Table 1, EU, 2002). The data indicates an estimated daily dose in the range of 11 to 0.42 µg/kg bw/day.

3.2 Air

OctaBDE is a solid with a very low vapour pressure (6.6.10-6 Pa at 21°C) and a calculated saturated vapour concentration (SVC) of 30 µg/m^3 at 21°C (European Communities, 2003a).

In spite of its low volatility octaBDE may undergo long-range environmental transport via air and is found (POPRC, 2007). E.g. Bergander et al. (1995) analyzed air samples from two areas of Sweden remote from industry, hexaBDE and heptaBDE were found in the particulate phase samples. Wang et al. (2005) on the other hand reported atmospheric concentrations for c-OctaBDE components for a large number of remote locations, and additional information about the presence of Penta to HeptaBDE congeners in air at several locations can be found in the review paper by de Wit et al. (2006). In another monitoring study carried out in coastal areas of Korea over one-year period, twenty individual PBDE congeners were found in atmospheric samples collected from urban, suburban and rural sites. DecaBDE (BDE 209) was the predominant congener (<93%) The depositional fluxes ranged from 10.1 to 89.0 µg/m2/year (Moon et al., 2007a). In northwest China, the measurements of total PBDEs (8.3 ± 4.0 pg/m3) in the samples collected at the

Waliguan Baseline Observatory (April to May, 2005) were at comparable concentration levels with other remote areas (Cheng et al., 2007). PBDEs have also been detected over the Indian Ocean (mean concentration of 2.5 pg/m3) and along the coastal line of Java, Indonesia (values of 15 pg/m3). Air back trajectory analysis is suggested in relation to the potential of PBDEs for long-range atmospheric transport from remote regions of areas more industrialized (Wurl et al., 2006) (POPRC, 2007).
In an occupational setting inhalation of dust and skin contact are likely the predominant routes of human exposure via air (European Communities, 2003a). When octaBDE is heated the vapour pressure will rise with a concomitant increase in the SVC. Hence, higher temperatures or heating e.g. during processing and manufacture may increase human exposure by inhalation, and may also result in exposure to breakdown products such as polybrominated dibenzodioxins and dibenzofurans) may also be emitted (POPRC, 2007).

The predicted atmospheric concentrations of octabromodiphenyl ether are all very low (<0.1 μg/m^3) (European Communities, 2003a). Monitoring data however show that air concentrations may be higher than predicted e.g. Strandberg et al. (2001) analyzed air samples from urban, rural and remote sites in the United States near the Great Lakes, and found that the average total c-OctaBDE-related congeners (i.e., sum of BDEs 153, 154 and 190) present in the samples ranged from approximately 0.2 to 0.9 pg/m3 (POPRC, 2007).

3.3 Water

Components c-OctaBDE are poorly soluble in water and estimated log Kows are in the range from 6.1-9.9 (European Communities, 2003a). In accord with this and with experimental detection limits of 0.1 and 0.07 μg/L c-OctaBDE congeners were not detected in two monitoring studies conducted by Japanese authorities (Environment Agency Japan 1991, POPRC, 2007). It is not known whether any of the sampling sites in the Japanese study were in the vicinity of a PBDE production site or a polymer processing site, the EU in their risk assessment considers that the Japanese monitoring studies are representative of industrial, urban and rural areas of Japan (European Communities, 2003a). Nonetheless, congeners of c-OctaBDE have been measured in water samples; Luckey et al. (2002) measured total PBDE (mono- to heptaBDE congeners) concentrations of approximately 6 pg/L in Lake Ontario surface waters in 1999, with HexaBDE congeners BDE153 and BDE154 each contributing approximately 5 to 8% of the total. There is also additional information on concentrations of c-OctaBDE components (HexaBDEs 153 and 154) in the dissolved phase in water in a study by Law et al. (2006).

3.4 Occupational exposure

Occupational exposure to c-OctaBDE may occur during manufacture, industrial processing in the plastic industry, equipment manufacture and end uses of flame-retarded products, The primary routes of exposure are via inhalation or dermal uptake of dust (European Communities, 2003a). Oral exposure on the other hand is considered to be of minor importance.
During manufacture, the highest inhalation and dermal exposures are likely to occur during bagging, check weighing and activities such as material sampling and maintenance (see Table below). Bag emptying during compounding and masterbatching is presumably equally important.

Estimated occupational exposure in different work-scenarios (European Communities, 2003a)

Scenario	**External inhalation exposure [mg/m^3]**	**External dermal exposure [mg/cm^2/day]**
Manufacture	5	1
Compounding and master batching - bag emptying - extrusion	 5 extremely low	 1 Negligible
Moulding	extremely low	Negligible
Equipment manufacture	extremely low	Negligible
End uses of flame	negligible	Negligible

retarded products		

These estimations are backed by monitoring data, which also reveal that the congener pattern may vary among workers depending on the type of work they conduct. In a Norwegian study (Thomsen et al. 2001) heptaBDE was only identified in plasma from electronics dismantling plant personnel whereas hexaBDE was detected in each occupational group with higher plasma levels at the electronics dismantling plant compared to the other groups.

3.5 Medical data contributing to regulatory decision

Human toxicokinetics data indicated that several components of commercial octaBDEs could be absorbed into the body and were distributed to the blood. Given the high lipophilicity of these compounds and the adipose tissues accumulation observed in rats following oral or inhalation routes, it could be assumed that in humans octaBDEs might bioaccumulate in these tissues. Similarly, following pregnancy, excretion of octaBDEs in breast milk may be anticipated.

3.6 Public exposure

Congeners of octaBDE been measured in human samples including mother's milk, blood and adipose tissue (European Communities, 2003a and PORC, 2007 for overview). The measured concentration levels are subject to individual variation and are generally lower among the general public than in occupationally exposed individuals. However, among the general public young children are exposed to higher levels than their parents. More specifically, Thomsen et al. 2002 found that levels in the different age groups were relatively similar, except for the age group of 0-4 years, which had 1.6-3.5 times higher serum concentrations: Breast milk was considered the main source to this exposure.

octa-BDE may be found in humans worldwide. Human exposure levels vary depending on region. E.g. in a study by Toms et al. (2007) the concentrations of PBDEs (18 congeners from BDE17 to BDE-183) found in mother's milk in Australia were lower than those reported from North America but higher than those reported from Europe and Asia. PBDEs were measured in samples of human blood serum taken from 23 donors in Wellington, New Zealand. Concentrations expressed as the sum of congeners 47, 99, 100, 153, 154, and 183 (∑PBDE) were – at an average of 7.17 ng ∑PBDE g (lipid)$^{-1}$ – within the range reported for human tissues in Europe, but lower than in Australia and North America (Harrad et al., 2007). Fernandez et al. (2007), have reported a study of the detection of PBDEs in the adipose tissue of women from Spain. Mean ∑PBDE (BDE 28, 75, 71, 47, 66, 77, 100, 119, 99, 85, 154, 153, 138, and 183) levels were 3.85 and 0.36 ng/g of lipid, respectively. Among PBDEs, congeners 153, 47, 183, 99, and 100 were the most frequent and abundant and together constituted 96% of the total amount of PBDEs in adipose tissue. Concentrations of PBDEs in this population were similar to those reported in other parts of Spain and in Swedish and Belgium populations but lower than those found in other Western countries (European Communities, 2003a and POPRC, 207).

By analyzing 21 pooled serum samples from Norwegian men (age 40–50 years) covering the years 1977-2003 Thomsen et al. (2007) found that the sum of seven PBDE congeners (IUPAC No. 28, 47, 99, 100, 153, 154 and 183) increased from 1977 (0.5 ng/g lipids) to 1998 (4.8 ng/g lipids). From 1999 to 2003 the concentration of PBDEs seems to have stabilized (European Communities, 2003a and POPRC, 2007).

3.7 Summary-overall risk evaluation

Canada

Notification not for human health reasons.

Norway

Human health

C-OctaBDE is classified as a reproductive toxicant, due to its effects on human health, with the risk phrases "may cause harm to unborn child", and "possible risk of impaired fertility". Studies and assessments provided evidence that c-OctaBDE may cause adverse effects such as effects on reproductive organs and developmental effects. Effects of repeated exposure to c-OctaBDE consistently indicate that the liver is the key target organ, and liver effects had been observed in animal studies. It is assumed that in humans, components of octaBDE might bioaccumulate in adipose

tissue.
The EU Risk Assessment Report presented information on the levels of components of c-OctaBDE measured in human samples including human milk, blood, and adipose tissue. Large variations among individuals were generally observed, but significant differences between the control population and occupationally exposed groups were also reported (European Communities, 2003a). Plasma concentrations of polybrominated diphenyl ether (PBDE) were determined in three Norwegian occupational groups (Thomsen et al., 2001). Samples were obtained from three groups of five individuals each working
a) at an electronics dismantling facility,
b) in production of printed circuit boards, and
c) in an analytical laboratory.
HeptaBDE was only identified in plasma from electronics dismantling plant personnel whereas hexaBDE was detected in each occupational group with higher plasma levels at the electronics dismantling plant compared to the other groups. No data on octaBDE was reported.
Thomsen et al. (2007) investigated the levels of PBDEs in 21 pooled serum samples archived from the general Norwegian population (from 1977 to 2003). In serum from men (age 40-50 years) the sum of seven PBDE congeners (28, 47, 99, 100, 153, 154 and 183) increased from 1977 (0.5 ng/g lipids) to 1998 (4.8 ng/g lipids). From 1999 to 2003 the concentration of PBDEs seems to have stabilized.
In another Norwegian study (Thomsen et al., 2006) the investigation of 66 hobby fishermen and -women showed clear associations between the concentrations of PBDEs (including BDE-153, BDE-154, BDE-138 and BDE-183) in serum and the subjects' age and intake of freshwater fish. In the EU risk assessment, hexaBDE, one component of commercial octaBDE, was identified as a potential developmental neurotoxicant in mice. Moreover slight fetotoxic effects in rabbits were reported following oral exposure to octaBDE, and effects on female fertility were seen in rats after inhalation exposure.

European Union

Workers

The conclusions of the evaluation concerning risks to workers were:
1. Concerns were identified about possible transthyrethin-T4 competition with octaBDE as well about the extent of excretion of commercial octaBDE into breast milk and the potential effects of prolonged exposure.
2. as regards exposure through manufacture (bagging and cleaning activities) and compounding and master batching (bag emptying), the following concerns were identified:
- systemic effects after inhalation and dermal repeated exposure,
- local effects in the respiratory tract after inhalation repeated exposure, and
- effects on female fertility after inhalation and dermal repeated exposure.

Humans exposed via the environment

The estimated indirect exposure via environment is very low compared to occupational exposure.

The conclusions concerning the risks for humans exposed via the environment were that: the safe use of commercial octabromodipheny1 ether was not established using the available information, since further information was needed on emissions into the environment from use or on soil-plant transfer and for exposure from local and regional sources on the concentration of octaBDE in cows. Concerns were identified on the extent of excretion of commercial octaBDE into breast milk and cow's milk, as well as on transthyretin-T4 competition with octaBDE and on the effects of prolonged exposure.

Stockholm Convention on POPs

The evaluation of the human and environmental risk of commercial octaBDE associated to its potential for long range transport must consider that the commercial product is a mixture of components with different properties and profiles, which may also be released to the environment due to its presence as components of other

PBDE commercial products and also produced in the environment by debromination of commercial decaBDE.
Although the production of c-OctaBDE has ceased in developed countries and there is no information suggesting that the chemical is produced elsewhere; it must be noticed that the product is still present and released from articles in use and during their disposal. Model estimations and measured levels in sewage sludge suggest that current emissions are still significant.
The persistence of the hexa to nonaBDE is well documented. The main route of degradation is debromination forming other BDEs, also of concern. The potential for certain components in c-OctaBDE to bioaccumulate and also for biomagnification in some trophic chains is also sufficiently documented and confirmed by the good agreement between field observations in monitoring programmes and toxicokinetic studies. Monitoring data in remote areas confirm the potential for long-range transport and at least for some congeners the relevance of atmospheric distribution in this process.
The highest difficulty appears for the estimation of the potential hazard of the commercial mixture and its components. There are traditional ecotoxicological and toxicological studies where no effects have been observed even at unrealistically high concentrations. However, an in-depth assessment of these studies considering in particular the properties and toxicokinetic of PBDE indicates that the test design, exposure conditions and measured endpoints are not appropriate for a sound assessment of these types of chemicals. Thus, the lack of effects reported in those tests should be considered with care. In addition, specific studies have reported particular hazards such as delayed neurotoxicity and immunotoxicity which may be particularly relevant in the assessment of both human health and ecosystem risks.
The increasing evidence related to debromination of octa and nona BDE into BDEs with POPs properties and considering that under Article 8, paragraph 7(a) of the Convention states that the lack of full scientific certainty shall not prevent a proposal from proceeding, it is concluded that the octa and nonaBDE components of the commercial octabromodiphenyl ether are likely, as a result of LRET, to lead to significant adverse human health and/or environmental effects, such that global action is warranted.

4 Environmental fate and effects[8]

4.1 Fate

4.1.1 Soil

OctaBDE is predicted to adsorb strongly onto sediment and soil and only a fraction of this, which was exposed to sunlight, will have the potential to photodegrade. Thus, although photodegradation of octaBDE is a possibility, the rate of reaction would be assumed to be effectively zero for environmental modelling purposes.
The rate of degradation of octaBDE under aerobic conditions and anaerobic conditions (by analogy with other BDEs) would be expected to be very low, although there were some indications that degradation may occur for some components of the commercial product under anaerobic conditions, albeit at a very slow rate. The rate of biodegradation is assumed to be effectively zero for environmental modelling purposes.
Koc = ca. 1,363,040 L/kg. octaBDE can be considered to be immobile in soil and it is unlikely to leach into groundwater.

4.1.2 Water

The persistence of c-OctaBDE components in the environment is well documented. The only relevant degradation pathways identified until now are photolysis, anaerobic degradation and metabolism in biota, acting through debromination and producing other BDEs which may have higher toxicity and bioaccumulation potential (POPRC, 2007).

While c-OctaBDE is stable to hydrolysis (European Communities, 2003a), , photolysis or photodegradation is likely to occur in water and mainly take place as a series of reductive debromination reactions whereby the various congeners of

[8] References cited in this section can be found in the supporting documentation of the respective notifying countries.

octaBDE are reduced into lower brominated diphenyl ethers.
Components c-OctaBDE are poorly soluble in water and estimated log Kows are in the range from 6.1-9.9 (European Communities, 2003a).

Concentrations of c-OctaBDE in UK sediments ranged from <0.44 to 3030 µg/kg dw (Allchin et al., 1999; Law et al., 1996; Environment Agency UK, 1997). The highest levels were in sediments downstream from a warehouse where c-DecaBDE was stored. C-OctaBDE was detected in 3 of 51 sediment samples from Japan in 1987 at concentrations from 8 to 21 µg/kg (detection limit 7 µg/kg; ww or dw not specified), and in 3 of 135 samples collected in 1988 at concentrations of 15 to 22 µg/kg (detection limit 5 µg/kg; ww or dw not specified) (Environment Agency Japan 1991).
Kolic et al. (2004) presented levels of PBDEs in sediments from tributaries flowing to Lake Ontario, and area biosolids in southern Ontario. Total hexa- and heptaBDEs (i.e., BDE 138, 153, 154 and 183) measured in sediment samples taken from fourteen tributary sites (only 6 sites were reported) ranged from approximately 0.5 to 4.0 µg/kg dw.

Historical trends of PBDEs in sediments have been determined in the Lake of Ellasjøen, Norwegian Arctic, where contamination is due to both atmospheric and biological transport. Maximum level of PBDEs was detected in 2001 (0.73 ng/g dw) (Evens et al., 2007). Marvin et al. 2007, have reported temporal trends in PBDEs in Niagara river suspended sediments from 1988 to 2004. Prior to 1988, PBDEs (sum of 16 congeners including decaBDE) were generally detected at low-ppb concentrations, but showed a trend toward increasing concentrations over the period 1980–1988. After 1988, PBDE concentrations in the Niagara River showed a more rapidly increasing trend (maximum of approximately 35 ng/g in 1995). DecaBDE was the predominant congener detected, and a similar situation has been observed in Europe (Eljarrat et al., 2005) and Asia (Moon et al., 2007b).

The study by Law et al. (2006) provides additional information on concentrations of c-OctaBDE components (HexaBDEs 153 and 154) for sediments at a background location (POPRC, 2007).

4.1.3 Air

A rate constant of 2.1E-13 cm^3 $molecule^{-1}$ s^{-1} had been estimated for the atmospheric reaction of octaBDE with hydroxyl radicals. The value was obtained using the Syracuse Research Corporation AOP program. Using this value, an atmospheric half-life of around 76 days could be estimated for octaBDE based on an atmospheric hydroxyl radical concentration of $5.0x10^5$ molecule/cm^3 (European Communities, 2003a).

Modelling with AOPWIN predicts half-lives for reaction with atmospheric hydroxyl radicals ranging from 30.4 to 161.0 d for hexa- to nonaBDEs, respectively (POPRC, 2007) which are consistent with a high persistency of c-OctaBDE in air. However, in the atmosphere, hexa to nonaBDEs are expected to strongly adsorb to suspended particles and to be removed via wet and/or dry deposition.

4.1.4 Bioconcentration, Bioaccumulation and biomagnification

The bioaccumulation potential of different PBDE congeners depends on the level of bromination. HexaBDE shows a significant potential for bioconcentration and biomagnification; heptaBDE biomagnifies through the food web but at a lower extent than that expected from the Kow. Octa and nonaBDE have been found in biota but no food-web biomagnification has been observed. Metabolisms and/or reduced bioavailability explain the divergences between observations and Kow predictions. The contribution of metabolism through debromination into other BDEs is supported by and increasingly amount of scientific evidence (POPRC, 2007).
Bioconcentration factors were reported (European Communities, 2003a) for carp. Assuming that the actual concentrations of the c-OctaBDE components were at or around the reported water solubility for the substance of 0.5 µg/L, then the BCF for octaBDE would be <9.5; for heptaBDE about <1.1-3.8 and for c-OctaBDE about <10-36. These BCF values are lower than would be expected from the substance's octanol-water partition coefficients. This can be explained by a reduced bioavailability, metabolisms or both.

The EU RAR (European Communities, 2003a) concluded that: "The results indicated that no significant bioconcentration of octaBDE was expected, unless the commercial product contained significant amounts of lower (≤6 bromines) brominated diphenyl ether components."

Of the different congeners of c-OctaBDE, bioconcentration from water is considered relevant only for hexaBDE.
The UK has re-analyzed the CITI (1982) bioconcentration data and suggests BCFs of up to and ~ 2,580 L to ~5,640 L/kg for isomers of hexaBDE.

However, the POPRC (2007) Risk profile concluded that: "A high potential for bioaccumulation (including a moderate potential for bioconcentration) and food-web biomagnification has been demonstrated for hexaBDE; and it is fully in line with the reported elimination rates.
The food-web biomagnification has been also demonstrated for heptaBDE, although at a lower extend than expected from the Kow; this fact can be explained by metabolism resulting in a relatively short half-life (experimentally demonstrated and explained by the authors by debromination).
The presence of octa and nonaBDE in biota is well-documented but its potential for bioaccumulation from water and food is much lower than expected from their Kow. Reduced availability, metabolisms or both can justify this fact.
The number of scientific papers demonstrating debromination of deca-, nona-, and octa- BDE to other PBDEs is continuously increasing; this is critical for the assessment as would indicate that the supposed low bioaccumulation potential could be in reality the consequence of metabolism to bioaccumulative PBDEs. A quantitative estimation
cannot be presented yet, but the debromination process has been already reported for aquatic organisms, mammals and birds."

4.1.5 Persistence

TetraBDE, pentaBDE and hexaBDE congeners met the criteria for persistence and bioaccumulation, as defined by the Persistence and Bioaccumulation Regulations of CEPA 1999.
Further, some PBDE congeners (tetra-, penta-, hexa-, hepta-) have been identified as Persistent Organic Pollutants (POPs) under the Stockholm Convention and the UNECE POP-protocol and as such are recognized as environmentally and biologically persistent substances that may undergo long-range environmental transport (POPRC, 2007). With regards to the biological persistence of , c-OctaBDE, HexaBDE is demonstrated to show a significant potential for bioconcentration and biomagnification; heptaBDE on the other hand biomagnifies through the food web but at a lower extent than that expected from the Kow. Octa and nonaBDE have been found in biota but no food-web biomagnification has been observed. Metabolisms and/or reduced bioavailability explain the divergences between observations and Kow predictions. The contribution of metabolism through debromination into other BDEs is supported by an increasing amount of scientific evidence.

4.2 Effects on non-target organisms

No information is available.

4.2.1 Terrestrial vertebrates

Available monitoring data indicated that, some heptaBDEs are present in organisms in the environment. This showed that the uptake of some of the main components of the c-OctaBDE takes place in the environment under natural conditions.
Unfortunately, wild populations are co-exposed to a mixture of PBDEs as well as to other related brominated and chlorinated persistent pollutants, and with the current level of knowledge epidemiological investigations can just present associations but no cause-effect relationships between the exposure/accumulation of the components of the commercial OctaBDE mixtures and potential adverse effects observed in wildlife (POPRC, 2007).

Mammals and birds
Knudsen *et a1*. (2005), reviewed temporal trends of PBDEs in eggs from three bird species, three locations and three sampling times (from 1983 to 2003) from Northern

		Norway. Spatial differences were only observed for hexaBDE (BDE-153), and increases in the measured concentration from 1983 to 2003 were observed for the hexaBDE (153 and 154) and the heptaBDE (BDE-183). Though controlled lab studies indicate a potential risk for adverse effects on the immune system and negative implications on bone structure and energy expenditure in birds no such effects have been reported in wild birds (POPRC, 2007). The lowest reported NOAEL for traditional endpoints is a NOAEL of 2 mg/kg/d based on slight fetotoxicity at 5 mg/kg/d (considered relevant in the EU report) or 5 mg/kg bw/d based on increased liver weights and decreased body weight gain among the maternal treatment group and delayed fetal skeletal ossification at 15 mg/kg bw/d (for those reviewers that do not consider relevant the slight fetotoxicity effects) described by Breslin et al. (1989) in a developmental toxicity study with Saytex 111 on New Zealand White rabbits exposed orally via gavage over days 7 to 19 of gestation (POPRC, 2007).
4.2.2	**Aquatic species**	Available data suggests that aquatic species bioconcentrate and bioaccumulate c-OctaBDE from their environment (POPRC, 2007). The EU RAR (European Communities, 2003a), presents a set of studies on the commercial mixture and concludes that for water it seems sensible to assume that no adverse effects on aquatic organisms are likely to occur at concentrations up to the substance's water solubility. However it must be noted, first, that aquatic organisms are also exposed from food and/or sediment; and second, that setting this strong conclusion on chemicals such as PBDEs requires multigenerational or at least full life-cycle assays on the three taxonomic groups covering a large list of sublethal effects, information which is unavailable at this time. Fish: *Oryzias latipes* (48 hours) LC_{50} > 500 mg/L. Invertebrates: *Daphnia magna* (21 days) NOEC (survival, reproduction, growth) > 2.0 µg/L Algae: No data. By analogy, the toxicity is expected to be low. Sediment organisms: *Lumbricus variegates* NOEC ≥ 1500 mg/kg_{dw}. Microorganisms: Activated sludge respiration inhibition (OECD 209) test. NOEC > 15 mg/L. (European Communities, 2003a)
4.2.3	**Honeybees and other arthropods**	No information is available.
4.2.4	**Earthworms**	*Eisenia foetida* (56 days): NOEC (survival, reproduction) ≥ 1470 mg/kg_{dw}. (European Communities, 2003a)).
4.2.5	**Soil microorganisms**	No information available.
4.2.6	**Terrestrial plants**	NOEC > 1500 mg/kg_{dw} soil. Six species; *Zea mays, Allium cepa, Lolium perenne, Cucumis sativa, Glycine max* and *Lycopersicon esculentum*. (European Communities, 2003a)

5	**Environmental Exposure/Risk Evaluation[9]**	
5.1	**Terrestrial vertebrates**	The EU risk assessment of octaBDE indicated no risk to the terrestrial compartment (European Communities, 2003a). The conclusion was based on worst-case PEC/PNEC comparison.
5.2	**Aquatic species**	For the aquatic compartment, the risk from exposure via surface water is thought to be low (European Communities, 2003a). Exposure to organisms via sediment is thought to be much more relevant for this substance and the risk to sediment-dwelling organisms was also found to be low. The risk to wastewater treatment processes was low.
5.3	**Honey bees**	No information is available.

[9] References cited in this section can be found in the supporting documentation of the respective notifying countries.

5.4 Earthworms

5.5 Soil microorganisms

No information is available.

5.6 Summary – overall risk evaluation

Canada

Seven polybrominated diphenyl ethers (PBDEs) were identified in a pilot project list of 123 substances for screening assessment under CEPA 1999, on the basis of their potential persistence and/or bioaccumulation in the environment and inherent toxicity to organisms.

Data relevant to the ecological screening assessment of PBDEs were identified in original literature, review documents, commercial and government databases and indices. In addition to retrieving the references from a literature database search, direct contacts were made with researchers, academics, industry and other government agencies to obtain relevant scans were conducted of the open literature, conference proceedings and the Internet for relevant PBDE information. Information obtained as of October 2004 was considered for inclusion into this document, while that received between November 2004 and October 2005 was reviewed, but not generally added. The information obtained between November 2004 and October 2005 was found to support the conclusions of this report determined with information received up to October 2004. In addition, an industry survey on PBDEs was conducted for the year 2000 through a Canada Gazette Notice issued pursuant to Section 71 of CEPA 1999. This survey collected data on the Canadian manufacture, import, uses and releases of PBDEs (Environment Canada, 2003). Toxicological studies were also submitted by industry under Section 70 of CEPA 1999.

Environment Canada's Ecological Screening Assessment Report indicated that the greatest potential risks from PBDEs in the Canadian environment were 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.

The 2006 screening assessment report also concluded that PBDEs were entering the environment in a quantity or concentration, or under conditions that had or might have an immediate or long-term harmful effect on the environment or its biological diversity. More specifically, it concluded that tetraBDE, pentaBDE and hexaBDE congeners met the criteria for persistence and bioaccumulation, as defined by the Persistence and Bioaccumulation Regulations of CEPA 1999. The screening assessment also concluded that their presence in the environment resulted primarily from human activity (that is, releases from product manufacturing and processing, and throughout the product life cycle). As a result, tetraBDE, pentaBDE and hexaBDE congeners meet the conditions for virtual elimination, as set out in subsection 77(3) of CEPA 1999.

Norway

According to available data, congeners of c-OctaBDE seem to resist degradation and thus have the potential to persist in the environment for a long time. They have potential for bioaccumulation and in addition there was monitoring evidence of biomagnification. Lower and higher brominated congeners (some of them present in c-OctaBDE) showed potential for long-range environmental transport.

Analysis of c-OctaBDEs chemical properties seems to support this conclusion, as Henry's law constant was very similar to those of acknowledged POPs. Therefore, it could be expected that c-OctaBDE was subject to long range environmental transport.

In Norway, congeners of c-OctaBDE have been found in a variety of samples. They have been detected *e.g.* in human samples, as well as in polar cod, ringed seals and mussels. In a study from Svalbard, Norway, congeners of c-OctaBDE were moreover found to bioaccumulate in zooplankton, polar cod, and ringed seals. Evidence was also found in this study that hexaBDE (BDE-153) biomagnifies in the Arctic food chain (ringed seal to polar bear) (Sørmo et.al, 2006). Uptake has also been demonstrated in wild birds. Knudsen *et a1*. (2005) reviewed temporal trends of PBDEs in eggs from three bird species, three locations and three sampling times (from 1983 to 2003) from Northern Norway. Spatial differences were only observed

for hexaBDE (BDE-153), and increases in the measured concentration from 1983 to 2003 were observed for the hexaBDE (153 and 154) and the heptaBDE (BDE-183). Available monitoring data thus collectively indicate that hexaBDEs as well as some heptaBDEs are present in wild organisms, which demonstrates that uptake of some of the main components of the c-OctaBDE to biota via environment occur in real-life exposure scenarios in the wild.

European Union

The available information indicates that the risk of secondary poisoning resulting from the use of octabromodiphenyl ether itself is low using the conventional PEC/PNEC approach. However, when the hexabromodiphenyl ether component present in c-OctaBDE products are considered, a possible risk of secondary poisoning via the earthworm route is indicated (European Communities, 2003a). The overall conclusion from the EU was that there was a need for further information and/or testing to provide more information on the risk of secondary poisoning from all sources of octaBDE. The additional information needed was highlighted as:

a. A more widespread monitoring project to determine whether the finding in top predators (including birds' eggs) is a widespread or localized phenomenon, and trends (if possible).
b. Further toxicity testing. The existence of a mammalian toxicity data set means that testing could be considered on birds (e.g. an avian reproduction test (OECD 206), with appropriate tissue analysis). Overall, the benefit of further vertebrate testing is open to question due to expected difficulties in achieving sufficiently high exposures. This leaves the toxicity issue with some unresolved uncertainty.
c. An investigation of the rate of formation of degradation products under environmentally relevant conditions over a suitably prolonged time period (e.g. years) - for example, an extended monitoring programme to determine trends in degradation product levels in various environmental compartments. This could be coupled with analysis of the parent compound to detect whether it is building up in the environment or has achieved equilibrium. A controlled field study (or studies) might be the way forward, with controlled continuous input of the substance and regular monitoring of other components.
d. Further toxicological work on the non-diphenyl ether degradation products, to determine if they pose a hazard or risk.

It was furthermore and lastly concluded that although available data were insufficient in certain respects, there were unacceptable risks to human health and the environment that necessitated regulatory action.

Stockholm Convention on POPs

The evaluation of the human and environmental risk of commercial octaBDE associated to its potential for long range transport must consider that the commercial product is a mixture of components with different properties and profiles, which may also be released to the environment due to its presence as components of other PBDE commercial products and also produced in the environment by debromination of commercial decaBDE.

Although the production of c-OctaBDE has ceased in developed countries and there is no information suggesting that the chemical is produced elsewhere; it must be noticed that the product is still present and released from articles in use and during their disposal. Model estimations and measured levels in sewage sludge suggest that current emissions are still significant.

The persistence of the hexa- to nonaBDE is well-documented. The main route of degradation is debromination forming other BDEs, also of concern. The potential for certain components in c-OctaBDE to bioaccumulate and also for biomagnification in some trophic chains is also sufficiently documented and confirmed by the good agreement between field observations in monitoring programmes and toxicokinetic

studies. Monitoring data in remote areas confirm the potential for long-range transport and at least for some congeners the relevance of atmospheric distribution in this process.

The greatest difficulty appears for the estimation of the potential hazard of the commercial mixture and its components. There are traditional ecotoxicological and toxicological studies where no effects have been observed even at unrealistically high concentrations. However, an in-depth assessment of these studies considering in particular the properties and toxicokinetic of PBDE indicates that the test design, exposure conditions and measured endpoints are not appropriate for a sound assessment of these types of chemicals. Thus, the lack of effects reported in those tests should be considered with care. In addition, specific studies have reported particular hazards such as delayed neurotoxicity and immunotoxicity which may be particularly relevant in the assessment of both human health and ecosystem risks.

The increasing evidence related to debromination of octa- and nonaBDE into BDEs with POPs properties and considering that under Article 8, paragraph 7(a) of the Convention states that the lack of full scientific certainty shall not prevent a proposal from proceeding, it is concluded that the octa- and nonaBDE components of the commercial octabromodiphenyl ether are likely, as a result of LRET, to lead to significant adverse human health and/or environmental effects, such that global action is warranted.

Annex 2 – Details on final regulatory actions reported[10]

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 Polybrominated Diphenyl Ethers Regulations:

a) prohibit the manufacture of PBDEs in Canada (tetraBDE, pentaBDE, hexaBDE, heptaBDE, octaBDE, nonaBDE and decaBDE congeners); and

b) prohibit the use, sale, offer for sale and import of those PBDEs that meet the criteria for virtual elimination under CEPA 1999 (tetraBDE, pentaBDE and hexaBDE congeners), as well as mixtures, polymers and resins containing these substances.

Commercial mixture	**PBDE congener Groups**						
OctaBDE	**tetraBDE**	**pentaBDE**	**hexaBDE**	**heptaBDE**	**octaBDE**	**nonaBDE**	**decaBDE**
	-	**0.5%**	**12%**	45%	33%	10%	0.7%

PBDE congeners targeted for virtual elimination in bold

The octaBDE commercial mixture is prohibited for manufacture, use, sale, offer for sale, and import due to the presence of pentaBDE and hexaBDE congeners.

3 Reasons for action

As a result of the 2006 risk evaluation, it was concluded that there were unacceptable risks to the environment that necessitated regulatory action.

4 Basis for inclusion into Annex III

The final regulatory action to prohibit the manufacture of PBDEs and to prohibit use, sale, offer for sale and import of tetraBDE, pentaBDE and hexaBDE congeners, as well as mixtures, polymers and resins containing these substances was based on a risk evaluation taking into consideration local conditions in Canada.

4.1 Risk evaluation

<u>Environment</u>

Seven polybrominated diphenyl ethers (PBDEs) were identified in a pilot project list of 123 substances for screening assessment under CEPA 1999, on the basis of their potential persistence and/or bioaccumulation in the environment and inherent toxicity to organisms.

Data relevant to the ecological screening assessment of PBDEs were identified in original literature, review documents, and commercial and government databases and indices. In addition to retrieving the references from a literature database search, direct contacts were made with researchers, academics, industry and other government agencies to obtain relevant scans were conducted of the open literature. Conference proceedings and the internet were consulted for relevant PBDE information. Information obtained as of October 2004 was considered for inclusion into this document, while that received between November 2004 and October 2005 was reviewed, but not generally added. The information obtained between November 2004 and October 2005 was found to support the conclusions of this report determined with information received up to October 2004. In addition, an industry survey on PBDEs was conducted for the year 2000 through a Canada Gazette Notice issued pursuant to Section 71 of CEPA 1999. This survey collected data on the Canadian manufacture, import, uses and releases of PBDEs (Environment Canada 2003). Toxicological studies were also submitted by industry under Section 70 of CEPA 1999.

[10] References cited in this section can be found in the supporting documentation of the respective notifying countries.

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.
The 2006 screening assessment report also concluded that PBDEs 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. More specifically, it concluded that tetraBDE, pentaBDE and hexaBDE congeners meet the criteria for persistence and bioaccumulation, as defined by the Persistence and Bioaccumulation Regulations of CEPA 1999. The screening assessment also concluded that their presence in the environment results primarily from human activity (that is, releases from product manufacturing and processing, and throughout the product life cycle). As a result, tetraBDE, pentaBDE and hexaBDE congeners meet the conditions for virtual elimination, as set out in subsection 77(3) of CEPA 1999.

4.2	**Criteria used**	Risks to the environment
	Relevance to other States and Region	Similar concerns to those identified are likely to be encountered in other countries where the substance is used, particularly in developing countries.
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: - 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); - use of barrier fabrics, wrappings or coatings for foams to replace chemical flame retardants; or - 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**	None reported.
7	**Other**	

Country Name: Norway

1	**Effective date(s) of entry into force of actions**	July 1, 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.
2	**Succinct details of the final regulatory action(s)**	It is prohibited to produce, import, export, sell and use octaBDE in pure form, in preparations, in products, and in parts of products containing greater than or equal to 0.1 % by weight of octaBDE.
3	**Reasons for action**	Potential risk to human health and the environment under prevailing conditions in Norway. More specifically all data evaluated and considered in Norway's risk evaluation of octaBDE indicated that octaBDE was an important contaminant of the Norwegian environment and of sufficient concern for human health and wildlife to warrant a national ban (SFT2009b).
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 octaBDE and commercial mixtures thereof based on a risk evaluation under the prevailing conditions in Norway.
4.1	**Risk evaluation**	Human health C-OctaBDE is classified as a reproductive toxicant, due to its effects on human health, with the risk phrases "may cause harm to unborn child", and "possible risk of impaired fertility". Studies and assessments provided evidence that c-OctaBDE may caused adverse effect such as effects on reproductive organs and developmental effects. Effects of repeated exposure to c-OctaBDE consistently indicate that the liver is the key target organ, and liver effects have been observed in animal studies. It is assumed that in humans components of octaBDE might bioaccumulate in adipose tissue. The EU Risk Assessment Report presented information on the levels of components of c-OctaBDE measured in human samples including human milk, blood, and adipose tissue. Large variations among individuals were generally observed, but significant differences between the control population and occupationally exposed groups were also reported. Plasma concentrations of polybrominated diphenyl ether (PBDE) were determined in three Norwegian occupational groups (Thomsen et al., 2001). Samples were obtained from three groups of five individuals each working: a) at an electronics dismantling facility, b) in production of printed circuit boards, and c) in an analytical laboratory. HeptaBDE was only identified in plasma from electronics dismantling plant personnel whereas hexaBDE was detected in each occupational group with higher plasma levels at the electronics dismantling plant compared to the other groups. No data on octaBDE was reported. Thomsen et al. (2007), investigated the levels of PBDEs in 21 pooled serum samples archived from the general Norwegian population (from 1977 to 2003). In serum from men (age 40-50 years) the sum of seven PBDE congeners (28, 47, 99, 100, 153, 154 and 183) increased from 1977 (0.5 ng/g lipids) to 1998 (4.8 ng/g lipids). From 1999 to 2003 the concentration of PBDEs seems to have stabilized. In another Norwegian study (Thomsen et al., 2006) the investigation of 66 hobby fishermen and -women showed clear associations between the concentrations of PBDEs (including BDE-153, BDE-154, BDE-138 and BDE-183) in serum and the subjects' age and intake of freshwater fish. In the EU risk assessment, hexaBDE, one component of commercial octaBDE, was identified as a potential developmental neurotoxicant in mice. Moreover slight fetotoxic effects in rabbits were reported following oral exposure to octaBDE, and effects on female fertility were seen in rats after inhalation exposure. Environment According to available data, congeners of c-OctaBDE seem to resist degradation and thus had the potential to persist in the environment for a long time. They had potential

		for bioaccumulation and in addition there is monitoring evidence of biomagnification. Lower and higher brominated congeners (some of them present in c-OctaBDE) showed potential for long-range environmental transport. Analysis of c-OctaBDE's chemical properties seems to support this conclusion, as Henry's law constant was very similar to those of acknowledged POPs. Therefore, it could be expected that c-OctaBDE was subject to long range environmental transport. Available monitoring data indicated that, as well as hexaBDEs, some heptaBDEs had recently been found to be present in organisms in the environment. This showed that uptake of some of the main components of the c-OctaBDE ether was occurring in the environment. Knudsen *et a1*. (2005), reviewed temporal trends of PBDEs in eggs from three bird species, three locations and three sampling times (from 1983 to 2003) from Northern Norway. Spatial differences were only observed for hexaBDE (BDE-153), and increases in the measured concentration from 1983 to 2003 were observed for the hexaBDE (153 and 154) and the heptaBDE (BDE-183). In Norway, congeners of c-OctaBDE have been found in a variety samples. It has been detected in, *e.g.* human samples, as well as in polar cod, ringed seals and mussels. In a study from Svalbard, Norway, congeners of c-OctaBDE were found to bioaccumulate in zooplankton, polar cod, and ringed seals. Evidence was also found in this study that hexaBDE (BDE-153) biomagnify in the Arctic food chain (ringed seal to polar bear) (Sarmo et al., 2006). The EU risk assessment suggested a potential risk of secondary poisoning from hexaBDE in other species via ingestion of earthworms (European Communities, 2003a)
4.2	**Criteria used**	Risks to human health and the environment.
	Relevance to other States and Region	Similar concerns to those identified are likely to be encountered in other countries where the substance is used.
5	**Alternatives**	None reported.
6	**Waste management**	Products containing more than 0.25 % octaBDE are classified as hazardous waste when they are discarded. Recycling and reuse of octaBDE and materials with octaBDE are not allowed. 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**	

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, octabromodiphenyl ether) (Official Journal of the European Union L42 of 15.2.2003, pp. 45-46) .
2	**Succinct details of the final regulatory action(s)**	The placing on the market and use of diphenylether, octabromo derivative $C_{12}H_2Br_8O$ is prohibited as follows: 1. as a substance or as a constituent of substances or of preparations in concentrations higher than 0.1% by mass. 2. in articles if they, or flame-retardant parts thereof, contain the substance in concentrations higher than 0.1% by mass.
3	**Reasons for action**	In the risk evaluation 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.
4	**Basis for inclusion into Annex III**	
4.1	**Risk evaluation**	<u>Workers</u> The conclusions of the evaluation concerning risks to workers were: 1. concerns were identified about possible transthyrethin-T4 competition with octaBDE as well about the extent of excretion of commercial octaBDE into the breast milk and the potential effects of prolonged exposure. 2. as regards exposure through manufacture (bagging and cleaning activities) and compounding and master batching (bag emptying), the following concerns were identified: - systemic effects after inhalation and dermal repeated exposure, - local effects in the respiratory tract after inhalation repeated exposure, and - effects on female fertility after inhalation and dermal repeated exposure. <u>Humans exposed via the environment</u> The conclusions concerning the risks for humans exposed via the environment were that: the safe use of commercial octabromodipheny1 ether was not established using the available information, since further information was needed on emissions into the environment from use or on soil-plant transfer and for exposure from local and regional sources on the concentration of octaBDE in cows. Concerns were identified on the extent of excretion of commercial octaBDE into breast milk and cow's milk, as well on transthyretin-T4 competition with octaBDE and on the effects of prolonged exposure. <u>Environment</u> The conclusions of evaluation concerning the risks to the environment were as follows: 1. There was a need for further information and/or testing as regards the risk of secondary poisoning from all sources of octaBDE. The PEC/PNEC approach used for secondary poisoning may not be appropriate, and may have underestimated the risks. A second aspect of the concern for secondary poisoning was that although the substance was persistent, there was evidence that it could degrade under some conditions to more toxic and bioaccumulative compounds. There was a high level of uncertainty associated with the suitability of the current risk assessment approach for secondary poisoning and the debromination issue. The combination of uncertainties raises a concern about the possibility of long-term environmental effects that cannot easily be predicted. Thus uncertainty was sufficient to warrant regulatory action;

		2. Of particular concern was the risk of secondary poisoning via the earthworm route for the hexaBDE component in the commercial octaBDE product from the use in polymer applications. 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.
4.2	**Criteria used**	Risks to human health and the environment.
	Relevance to other States and Region	The hexa and heptaBDE congeners of c-OctaBDE are recognized as persistent organic pollutants (POP) with the ability to undergo long-range environmental transport to remote regions (POPRC, 2006, see Norwegian supporting information, 2010), thus similar conditions of human and environmental exposure to that reported by Norway are likely to be encountered in other countries where the substance is used, particularly in developing countries.
5	**Alternatives**	None reported.
6	**Waste management**	None reported.
7	**Other**	

Previous notifications

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

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 37 38
Telefax	22 67 67 06
E-mail	christina.charlotte.tolfsen@klif.no

European Union

Institution	DG Environment European Commission
Address	Rue de la Loi, 200 B-I049 Brussels Belgium
Name of person in Charge	Juergen Helbig
Position of person in charge	Policy Officer
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Telefax	+322 296 7617
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Annex 4 – References

Regulatory actions

Commission 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-ex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:042:0045:0046:EN:PDF

Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy. (Water Framework Directive). Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:327:0001:0072:EN:PDF

Polybrominated Diphenyl Ethers Regulations (SOR/2008-218) under the *Canadian Environmental Protection Act, 1999*;

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 Norwegian Ministry of the Environment. Act no 922 of 1 June 2004.

Other Documents

Supporting documentation provided by Canada:

1. Canadian Environmental Protection Act, 1999 (CEPA 1999): Ecological Screening Assessment Report on Polybrominated Diphenyl Ethers (PBDEs). Environment Canada. June 2006.
2. *Polybrominated Diphenyl Ethers Regulations (SOR/2008-218);* http://canadagazette.gc.ca/rp-pr/p2/2008/2008-07-09/pdf/g2-14214.pdf#page=41

Supporting documentation provided by 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 Commission (2002): Scientific committee on toxicity, ecotoxicity and the environment (CSTEE) - Opinion on the results of the Risk Assessment of: Diphenyl ether, octabromo derivative. Environmental and Human Health Part. 2002. Brussels,C2/AST/csteeop/Octabromo Hum & Env 31102002/D(02)
3. European Communities (2003a): European Union Risk Assessment Report, diphenyl ether, octabromo derivative. Final report, 2003.
4. European Communities (2003b): Diphenyl Ether, Octabromo Derivative – Summary Risk Assessment Report. European Commission, Joint Research Center.

Supporting documentation provided by Norway

1. European Union Risk Assessment Report, diphenyl ether, octabromo derivative, Final report, 2002.
2. Knudsen LB, Gabrielsen GW, Verreault J, Barrett R, Skare JU, Polder A and Lie E. (2005) Temporal trends of brominated flame retardants, cyclododeca-1,5,9-triene and mercury in eggs of four seabird species from Northern Norway and Svalbard. SPFO-Report 942/2005. ISBN: 82-7655-497-0
3. Päpke O, Bathe L, Bergman Å, Fürts P, Guvenius DM, Herrmann T, Norén K. (2001) Organohalogen Compounds, 52, 197-200.
4. POPRC, 2007. Risk profile on commercial octabromodiphenyl ether. UNEP/POPS/POPRC.3/20/Add.6
5. POPRC, 2008a. Commercial octabromodiphenyl ether risk management evaluation. UNEP/POPS/POPRC.4/6
6. POPRC, 2008b. Additional information related to the commercial octabromodiphenyl ether risk management evaluation. UNEP/POPS/POPRC.4/INF/10
7. 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.

8. Sormo EG, Salmer MP, Jenssen BM, Hop H, Baek K, Kovacs KM, Lydersen C, Falk-Petersen S, Gabrielsen, GW, Lie E and Skaare JE. (2006) Biomagnification of polybrominated diphenyl ether and hexabromocyclododecane flame retardants in the polar bear food chain in Svalbard, Norway. Environmental Toxicology and Chemistry, Vol. 25, No. 9:. 2502–2511
9. Thomsen C, Knutsen H, Liane VH, Froshaug M, Kvalem HE, Haugen M, Meltzer HM, Alexander J and Becher G. (2008) Consumption of fish from a contaminated lake strongly affects the concentrations of polybrominated diphenyl ethers and hexabromocyclododecane in serum. Mol. Nutr. Food Res. 2008, 52: 228 – 237
10. Thomsen C, Liane VH, Becher, G. (2007) Automated solid-phase extraction for the determination of polybrominated diphenyl ethers and polychlorinated biphenyls in serum—application on archived Norwegian samples from 1977 to 2003. Journal of Chromatography B, 846: 252–263
11. Thomsen C, Liane VH, Frøshaug M, Becher G. (2006) The concentration of PBDEs in serum from a group of high consumers of fish from a PBDE contaminated lake in Norway. Organohalogen Compounds Vol 68: 786 - 789
12. Thomsen C, Lundanes E and Bechen G. (2001) Brominated flame retardants in plasma samples from three different occupational groups in Norway. J. Environ. Monit., 2001, 3, 366–370

Relevant guidelines and reference documents

1. POPRC, 2009. Guidance on considerations related to alternatives and substitutes for listed persistent organic pollutants and candidate chemicals 2009 (UNEP/POPS/POPRC.5/10/Add.1)
2. POPRC, 2010. "Technical Review of the Implications of Recycling Commercial Pentabromodiphenyl Ether and Commercial Octabromodiphenyl Ether".
3. UNEP, 2008. Risk management evaluation for commercial octabromodiphenyl ether (Document UNEP/POPS/POPRC.4/15/Add.1)