Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background document

to the Opinion on the Annex XV dossier proposing restrictions on
Bis(pentabromophenyl) ether

ECHA/RAC/RES-O-0000006155-77-01/D
ECHA/SEAC/[reference code to be added after the adoption of the SEAC opinion]

EC Number	CAS Number
214-604-9	1163-19-5

10 June 2015

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List of Acronyms

ABS	Acrylonitrile butadiene styrene
AGD	Anogenital distance
AMAP	Arctic monitoring assessment programme
ATH	Aluminium trihydroxide
ATO	Antimony trioxide
bw	Body weight
BC	Basel Convention
BEST	Subcommittee in Flame-Retardant Chemicals; Committee on Toxicology; Board on Environmental Studies and Toxicology
BFR	Brominated flame retardant
BMDL	Benchmark dose level
BSEF	Bromine Science and Environmental Forum
CAS No	Chemical Abstract Service registry number
CBI	Confidential business information
c-decaBDE	Commercial grade of decaBDE
CEPE	European Association of Coatings and Paints
CLP	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
CLS	Commission on Life Sciences
CMHR	Combustion modified high resistance (foam)
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
CONTAM	EFSA Panel on Contaminants in the Food Chain
CPR	Construction Products Regulation
dw	Dry weight
DecaBDE	Bis-(pentabromophenyl) ether
DecaMonitor	Industry funded programme for monitoring the concentration and trends of decaBDE in the environment: birds eggs, sewage sludge and sediments
DEFRA	Department for Environment, Food and Rural Affairs
DELS	Division on Earth and Life Studies
DNA	Deoxyribonucleic acid
DNEL	Derived No Effect level
DMEL	Derived Minimal Effect Level
EBFRIP	European Brominated Flame Retardant Industry Panel
EBP	Ethane, 1,2-Bis (pentabromophenyl)
EBTBP	Ethylene bis(tetrabromophthalimide)
EC No	European Inventory of Existing Commercial Chemical Substances (EINECS) number
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
ECJ	European Court of Justice
EEA	European Economic Area
EEE	Electrical and electronic equipment
EFRA	European Flame Retardant Association
EFSA	European Food Safety Authority
EoW	End of waste
EP	Epoxy resins
EPA	Environmental Protection Agency
EPDM	Ethylene propylene diene monomer

EPS	Expanded polystyrene
E-PRTR	European Pollutant Release and Transfer Register
ESR	Existing Substances Regulation
EU RAR	European Union Risk Assessment Report
EVA	Ethylene vinyl acetate
EVC	Ethylene vinyl chloride
FR	Flame retardant
GCMS	Gas chromatography mass spectrometry
HBCD	Hexabromocyclododecane
HeptaBDE	Heptabromodiphenyl ether
HexaBDE	Hexabromodiphenyl ether
HFR	Halogenated flame retardant
HFFR	Halogen-free flame retardant
HIPS	High impact polystyrene
HSE	Health and Safety Executive
IPPC	Integrated Pollution Prevention and Control
lw	Lipid weight
LOAEL	Lowest Observed Adverse Effect Level
LOD	Limit of detection
LOI	Limiting oxygen index
LOQ	Limit of quantification
LRT	Long-range transport potential
LRTAP	Long-range transport atmospheric pollution
MDH	Magnesium dihydroxide
MSC	Member States Committee
MSCA	Member State Competent Authority
MSW	Municipal solid waste
NACE	European Classification of Economic Activities
nd	Not detected
NonaBDE	Nonabromodiphenyl ether
OctaBDE	Octabromodiphenyl ether
OECD	Organisation for Economic Co-operation and Development
OECD ESD	OECD Emission Scenario Document
PA	Polyamides
PBDDs	Polybrominated dibenzo-*p*-dioxins
PBDE	Polybrominated diphenyl ether
PBDFs	Polybrominated dibenzofurans
PBT	Persistent, bioaccumulative and toxic
PBTE	Polybutylene terephthalate
PC	Polycarbonate
PE	Polyethylene
PEC	Predicted Environment Concentrations
PentaBDE	Pentabromodiphenyl ether
PES	Polyesters
PET	Polyethylene terephthalate
PI	Polyimides
PNEC	Predicted No Effect Concentration
PP	Polypropylene
PPE	Polypropylene ether
PPO	Polyphenylene oxide
PPS	Polyphenylene sulphide
PS	Polystyrene
PU / PUR	Polyurethane
PVC	Polyvinyl chloride
RCR	Risk Characterisation Ratio
RDP	Resorcinol bis(diphenylphosphate)
REACH	Regulation (EC) No 1907/2006 of the European Parliament and

	of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
RoHS	Restrictions of Hazardous Substances Directive
RPA	Risk & Policy Analysts Ltd
SBR	Styrene butadiene rubber
SC	Stockholm Convention
SD	Support Document
SLF	Shredder Light Fraction
SME	Small and Medium Enterprises
SVHC	Substance of Very High Concern
STC	Supplemental Type Certificate
TBBPA	Tetrabromo-bisphenol A
TBNPA	Tribromo-neopentyl alcohol
TCDD	Tetrachlorodibenzo-*p*-dioxin
TCPP	Tris(2-chloroisopropyl)phosphate
TDCP	Tris(1,3-dichloro-2-propyl) phosphate
TDCPP	Tris(1,3-dichloro-2-propyl) phosphate
TPO	Thermoplastic polyolefins
TPP	Triphenyl phosphate
TPU	Thermoplastic polyurethanes
UPE	Unsaturated polyesters
UPR	Unsaturated polyester resin
V-0	A classification under the UL 94 plastics flammability standard
VECAP	Voluntary Emissions Control Action Programme
w/w	Weight per weight
WEEE	Wastes from electrical and electronic equipment
WHO	World Health Organisation
XPS	Extruded polystyrene
XRF	X-ray fluorescence

PROPOSAL FOR A RESTRICTION

About this report

Bis(pentabromophenyl)ether (decaBDE) is widely used as an additive flame retardant with applications in many different sectors. It is mainly used in plastics and textiles but uses in adhesives, sealants, coatings and inks are also reported.

DecaBDE was identified as a PBT and vPvB according to the REACH Regulation and included in the Candidate List on 19 December 2012. Norway submitted a proposal to add decaBDE to the Stockholm Convention for Persistent Organic Pollutants on the 2 May 2013. To align risk management activities within the European Union and the Stockholm Convention, the European Commission requested ECHA on the 21 June 2013, to prepare an Annex XV restriction report on decaBDE in accordance with the REACH Regulation. ECHA has collaborated with the Norwegian Environment Agency throughout the drafting of the restriction proposal.

The risks of decaBDE to the environment and human health have been studied in the past under the Existing Substances Regulation (EEC No 793/93) and during the identification of decaBDE as a Substance of Very High Concern (SVHC). The RoHS Directive (2002/95/EC) has applied to decaBDE since 30 June 2008. Furthermore, since 2004 industry has had a Voluntary Emissions Control Action Programme (VECAP) to minimise releases of decaBDE to the environment in the EU.

This proposal is underpinned by the conclusions on the intrinsic hazard (i.e. PBT/vPvB properties) of decaBDE (SVHC support document (SD) 2012). Latest information from the literature published after the inclusion in the Candidate List has also been considered during the development of this report. This information supports the conclusions reached when decaBDE was identified as an SVHC.

Experience with PBT/vPvB substances has shown that they give rise to specific concerns based on their potential to accumulate in the environment and cause effects that are unpredictable in the long-term and are difficult to reverse (even when emissions cease). Therefore, the risk from PBT/vPvB substances cannot be adequately addressed in a quantitative way, e.g. by derivation of PNECs and a qualitative risk assessment should be carried out (see Annex I/6.5 of the REACH regulation). Emissions and subsequent exposure, in the case of a PBT/vPvB, can also be usefully considered as a proxy for unacceptable risk.

This restriction report is based on updated estimates of emissions of decaBDE in the EU combined with information on the cost of switching from the use of decaBDE to alternatives. The abatement cost of decaBDE emissions is then used to assess the cost-effectiveness and proportionality of the proposed restriction.

Apart from the close collaboration with Norway, this report is based on information collated on behalf of ECHA by a consultant. This information comprises stakeholder consultation, emission estimates and information on alternative substances and techniques. For readability, the report is concise. Additional details are given in Annexes.

In this report, "EU-wide" or "the EU" covers also the EEA, unless stated otherwise.

In addition, text in this report in *italics* is directly reproduced from the SVHC SD (2012).

A. Proposal

A.1 Proposed restriction

A.1.1 The identity of the substance

Table 1: Identity of decaBDE

EC number	214-604-9
EC name	Bis(pentabromophenyl) ether
CAS number	1163-19-5
Molecular formula	$C_{12}Br_{10}O$
Purity and impurities	The restriction will apply to decaBDE whatever its purity

A.1.2 Scope and conditions of restriction(s)

1. Original restriction proposal from the dossier submitter (ECHA)

Table 2: Scope and conditions of the restriction

Designation of the substance, of the group of substances or of the mixture	Conditions of the restriction
Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) CAS No 1163-19-5 EC No 214-604-9	1. Shall not be manufactured, used or placed on the market: - as a substance, - as a constituent of other substances, or in mixtures after [date of entry into force], if the concentration is equal or greater than 0.1 % by weight. 2. Articles or any parts thereof containing decaBDE in concentrations equal to or greater than 0.1 % by weight shall not be placed on the market. 3. By way of derogation, paragraph 2 shall not apply: - to articles that were in use in the Union before [date of entry into force] - to electrical and electronic equipment within the scope of Directive 2011/65/EU - to the production, maintenance, repair or modification of any aircraft or component eligible for installation: ○ produced in accordance with a type certificate or restricted type certificate, issued under Regulation (EU)216/2008, provided the application for such certificate was done before [date of entry into force], or ○ produced in accordance with a design approval issued under the national

Designation of the substance, of the group of substances or of the mixture	Conditions of the restriction
	regulations of an ICAO contracting State, provided the application for such approval was done before [date of entry into force], or ○ for which an ICAO contracting State has issued a Certificate of Airworthiness under the provisions of Annex 8 of the Chicago Convention, provided that such State issued the first Certificate of Airworthiness for an aircraft of the same aircraft type before [date of entry into force]

Note: a transitional period of 18 months after the date of entry into force is proposed for this restriction

2. Restriction proposal by RAC and SEAC

NOTE: this section will be updated after further evaluation by SEAC.

Designation of the substance, of the group of substances or of the mixture	Conditions of the restriction
Bis(pentabromophenyl)ether (decabromodiphenyl ether; decaBDE) CAS No 1163-19-5 EC No 214-604-9	1. Shall not be manufactured, used or placed on the market: - as a substance, - as a constituent of other substances, or in mixtures after [date of entry into force], if the concentration is equal or greater than 0.1 % by weight. 2. Articles or any parts thereof containing decaBDE in concentrations equal to or greater than 0.1 % by weight shall not be placed on the market after [date of entry into force]. 3. By way of derogation, paragraph 2 shall not apply: - to articles placed on the market for the first time before [date of entry into force] - to electrical and electronic equipment within the scope of Directive 2011/65/EU 4. By way of derogation, paragraphs 1 and 2 shall not apply to manufacture, use and placing on the market for the production, maintenance, repair or modification of any aircraft or component eligible for installation: ○ produced in accordance with a type certificate or restricted type certificate, issued under Regulation (EU)216/2008, provided the application for such certificate was done before [date of entry into force], or ○ produced in accordance with a design approval issued under the national

Designation of the substance, of the group of substances or of the mixture	Conditions of the restriction
	regulations of an ICAO contracting State, provided the application for such approval was done before [date of entry into force], or ○ for which an ICAO contracting State has issued a Certificate of Airworthiness under the provisions of Annex 8 of the Chicago Convention, provided that such State issued the first Certificate of Airworthiness for an aircraft of the same aircraft type before [date of entry into force]

A.2 Targeting

The proposal is based on the concern that led to the identification of decaBDE as an SVHC and its inclusion in the Candidate List as PBT/vPvB i.e. its widespread occurrence in the environment and wildlife. The PBT/vPvB properties of decaBDE have not been re-assessed as part of this report although relevant literature published after the inclusion of decaBDE on the Candidate List[1] has been identified and is considered. Additional information on the hazard of decaBDE to humans is included in the report to aid discussions on proportionality by describing the potential impacts of exposure to decaBDE more broadly.

The exposure assessment comprises a summary of relevant available biomonitoring and environmental monitoring data, which are considered as representative of aggregated EU exposure to decaBDE (including any contribution from long-range transport). No PNECs or DNELs have been calculated, as the risks of PBT/vPvB substances cannot, in general, be assessed quantitatively.

A.3 Summary of the justification

A.3.1 Identified hazard and risk

The hazard and risk of the use of decaBDE as a flame retardant in plastics and textiles are summarised as follows:

- DecaBDE meets the definition of a PBT/vPvB substance in accordance with Annex XIII of the REACH Regulation, and thereby fulfils the criteria in Articles 57(d) and (e) of REACH.
- Emissions of decaBDE in the EU are currently estimated at 4.74 tonnes per year and are predominantly associated with the service life, rather than the production or waste stage, of plastic and textile articles.
- In addition to PBT/vPvB concerns, exposure to decaBDE and lower brominated transformation products may result in neurotoxicity in mammals, including humans.
- Exposure of decaBDE in humans (including prenatal exposure) and the environment is widespread.

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[1] The latest publication included in the Annex XV SD dates from October 2012.

- The European environmental monitoring programme established under the Existing Substances Regulation shows no recent increasing or decreasing trend in concentrations in bird eggs, sediments and sewage sludge, despite the voluntary risk management measures by industry and implementation of legislative measures.
- The widespread distribution of decaBDE in the environment and in humans creates a high potential for long-term (lifetime) exposure to decaBDE and lower brominated PBDE (Polybrominated diphenyl ether) transformation products.

A.3.2 Justification that action is required on a Union-wide basis

The primary reason to act on a Union-wide basis is to effectively reduce the environmental exposure to decaBDE in the EU. DecaBDE is known to undergo long-range transport and emissions from one Member State could result in exposure in another, regardless of efforts of that Member State to reduce exposures within their own borders (i.e. through national legislation). Action on a Union-wide basis would limit the potential for trans-boundary exposure to decaBDE from EU sources, both within and outside the EU.

In addition, the fact that goods need to circulate freely within the EU stresses the importance of EU-wide action rather than action by individual Member States. Currently one EEA country (Norway) has a national restriction on decaBDE.

A.3.3 Justification that the proposed restriction is the most appropriate Union-wide measure

Effectiveness in reducing the identified risks

The proposed restriction will remove all emissions and related exposures of decaBDE to both humans and the environment in the EU (except any emissions resulting from derogated uses). Reduced emissions are used as a proxy for risk reduction. Three scenarios were used to estimate emissions (central, high and low) to account for uncertainties in the available data. Following the entry into force of the restriction, products (mainly plastic and textile articles) containing decaBDE will not be produced in the EU and will not be placed on the EU market. A transitional period of 18 months after entry into force is proposed to allow use of existing stocks.

Proportionality to the risks

Alternatives to decaBDE are available on the EU market for all uses. Many are technically and economically feasible and are considered less hazardous than decaBDE, although (for some alternatives) their properties are less well understood than decaBDE. Notably, the substance considered by industry to be the main alternative to decaBDE, Ethane-1,2-bis(pentabromophenyl) (EBP), is currently undergoing Substance Evaluation under REACH based on a concern that it may exhibit PBT/vPvB properties.

Due to low additional costs and technical characteristics, full transition to a drop-in alternative (i.e. EBP) was considered as the most probable outcome should the proposed restriction be adopted. The substitution costs are estimated to be €2.2m per year. The cost effectiveness (cost of reducing 1 kg of decaBDE emission) is estimated to be 464 €/kg. The cost-effectiveness of the proposed restriction for decaBDE is in the same order of magnitude (or lower) as previous restrictions under REACH on mercury and its compounds (i.e. phenylmercury), which has some similar environmental properties. However, the comparision of cost-effectivness between decaBDE and mercury compounds is not straightforward as their individual circumstances (i.e. hazard potential / exposure in the environment), are not directly comparable. This precludes the use of the cost-effectivness of previous restrictions as a benchmark of acceptable cost-effectiveness. However, this information remains relevant to a discussion on proportionality and is included as supporting information.

Given that decaBDE is widespread in the environment, including in top predators, and with no apparent decline in environmental exposures as a result of voluntary measures, the cost-effectiveness of the proposed restriction is considered to be proportionate to the risk reduction.

Practicality, including enforceability

A variety of alternative substances (and techniques) are available and in use for all applications. Furthermore, an important portion of the market has already phased out decaBDE. It is considered that all actors involved will be able to comply with the proposed restriction.

A concentration limit of 0.1 % w/w is proposed to enhance the enforceability of the restriction. Analytical methods to verify this concentration are well established.

Monitorability

The monitoring of the proposed restriction will be carried out through regular enforcement activities.

A.4 Uncertainties

Tonnages in imported articles: The information on imports of decaBDE in articles is limited, but are estimated to comprise a total equivalent to 10% of the imported decaBDE tonnage as a substance. There is considerable uncertainty in this estimate, which was based on a limited amount of information.

Emission estimates were based on extensive information gathering and used assumptions on emission factors, imported tonnage, tonnage used in textiles and plastics, indoor and outdoor applications, fractions of waste destined to incineration, landfill or recycling etc. The assumptions were based on information from industry, literature and consultation with stakeholders. In addition to a “central scenario”, two additional scenarios (high and low) describe the range of possible uncertainties. The long-term emission potential of decaBDE in landfills is poorly understood.

Cost estimates were based on the price difference between decaBDE and its alternatives, the ease in substituting decaBDE (drop-in alternatives will result in fewer costs than other alternatives) and the predicted future use of decaBDE. A sensitivity analysis on the main parameters influencing costs was carried out.

Hazard profile of alternatives: Less hazardous alternatives exist for all uses although data gaps and uncertainties exist.

Long-term trends in the environment: Despite the results of the first six years of the DecaMONITOR programme, trends are somewhat uncertain. No decreasing or increasing trend in environmental concentrations has been identified.

B. Information on hazard and risk

B.1 Identity of the substance(s) and physical and chemical properties

The information presented in this section is predominantly taken from the MSC Support Document (SD) for identification of decaBDE as PBT substance (SVHC SD, 2012). No new information relevant to this section has become available since the publication of the SD.

B.1.1 Name and other identifiers of the substance

Table 3: Name and other identifiers of decaBDE

EC number	214-604-9
EC name	Bis(pentabromophenyl) ether[a]
CAS number (in the EC inventory)	1163-19-5
Deleted CAS numbers	109945-70-2, 145538-74-5 and 1201677-32-8
CAS name	Benzene, 1,1’-oxybis[2,3,4,5,6-pentabromo-]
IUPAC name	1,1'-oxybis(pentabromobenzene)[b]
Index number in Annex VI of the CLP Regulation	Not applicable
Molecular formula	$C_{12}Br_{10}O$
Molecular weight	959.2 g/mole
Structural formula	
Synonyms	decaBDE; BDE-209; decabromodiphenyl ether; decabromodiphenyl oxide; bis(pentabromophenyl) oxide; decabromo biphenyl oxide; decabromo phenoxybenzene; benzene 1,1’oxybis-, decabromo derivative; DBDPE; DBBE; DBBO; DBDPO

a: The abbreviation decaBDE is used throughout this report to identify bis(pentabromophenyl) ether. The molecule is also known by its specific congener number (BDE-209). There is only a single decaBDE congener, whilst other PBDEs have multiple congeners (Appendix 2 of SVHC-SD provides a full list of these). Individual groups of PBDE congeners are also referred to in abbreviated form (e.g. hexaBDE for hexabromodiphenyl ethers)(SVHC-SD). The abbreviation c-decaBDE is used to refer to commercial bis(pentabromophenyl) ether.

b: The IUPAC name disseminated with registration information is different to the IUPAC names notified in the Classification and Labelling (C&L) inventory. The following IUPAC names have been notified to the C&L inventory: 2,3,4,5,6-pentabromo-1-(2,3,4,5,6-pentabromophenoxy) benzene, bis(pentabromophenyl) ether, decabromodiphenyl ether, decabromdiphenylether, decabromodiphenyl oxide (SVHC-SD).

B.1.2 Composition of the substance(s)

Commercial decaBDE (c-decaBDE) is supplied with a typical purity of 97-98%. Impurities in c-decaBDE include congeners of nonabromodiphenyl ether (with a typical concentration of 2.5%) and octabromodiphenyl ether (with a typical concentration of 0.04%). Trace amounts of other bromodiphenyl ether congeners may also be present (concentrations up to 0.005% w/w). No additives are incorporated into c-decaBDE (EU RAR, 2002).

B.1.3 Physicochemical properties

Table 4: Physicochemical properties

Property	Value
Physical state at 20°C and 101.3 kPa	Fine white to off-white crystalline powder
Melting point	300-310°C
Boiling point	Decomposes at >320°C
Vapour pressure	4.63×10-6 Pa at 21°C
Water solubility	<0.1 µg/l at 25°C (column elution method)
n-Octanol/water partition coefficient, Kow (log value)	6.27 (measured – generator column method) 9.97 (estimated using an HPLC method)[a]
Dissociation constant (pKa)	Not relevant

Source: EU RAR (2002)
a: not included in registration dossiers

Unless otherwise stated, the registration dossiers for decaBDE contain the same values for physicochemical properties as reported in the EU RAR (2002).

B.2 Manufacture and uses

Further details of the manufacture, import, export and use of decaBDE are provided in Annex B.

B.2.1 Manufacture, import and export of decaBDE

DecaBDE has not been manufactured in the EU since 1999 (ECB, 2002) and all uses in the EU are the result of imports of the substance (on its own or in mixtures) and in articles.

DecaBDE is jointly registered under REACH by five companies (importers or only representatives – see Table 5) that report (at the time of registration) a combined annual tonnage of between 10,000 to 100,000 tonnes[2].

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[2] ECHA Dissemination Database, http://echa.europa.eu/, accessed on 14/06/2014

Table 5: Registrants of decaBDE

Company	Location
Albemarle Europe SPRL	BE
Chemical Inspection & Regulation Service Limited	IE
Chemtura Europe Limited	UK
Everkem	IT
ICL-IP Europe B.V.	NL

Source: ECHA Dissemination Database, http://echa.europa.eu/, accessed on 14/06/2014

Import data for decaBDE as a substance (as opposed to contained within imported articles) are available for the years 2000 to 2012 from various sources. These data suggest that the imported tonnage of decaBDE into the EU is declining. The inclusion of decaBDE in the RoHS Directive and the identification of decaBDE as an SVHC may have contributed to this decline (Figure B1). The most recent available data suggests an imported tonnage less than that stated in registrations. For the emission and cost calculations in this report, imports of 4,000 tonnes/year will be used, derived from publicly available information. Information on imports of decaBDE in articles is limited, but they are estimated to comprise a total equivalent to 10% of the imported decaBDE tonnage as a substance (see Annex B.2.1.3). No re-export of decaBDE from the EU is considered likely to occur in either finished articles, mixtures or the substance.

For information on the global flame retardant market, see Annex B.2.1. To be noted that the use of decaBDE is in decline in North America[3].

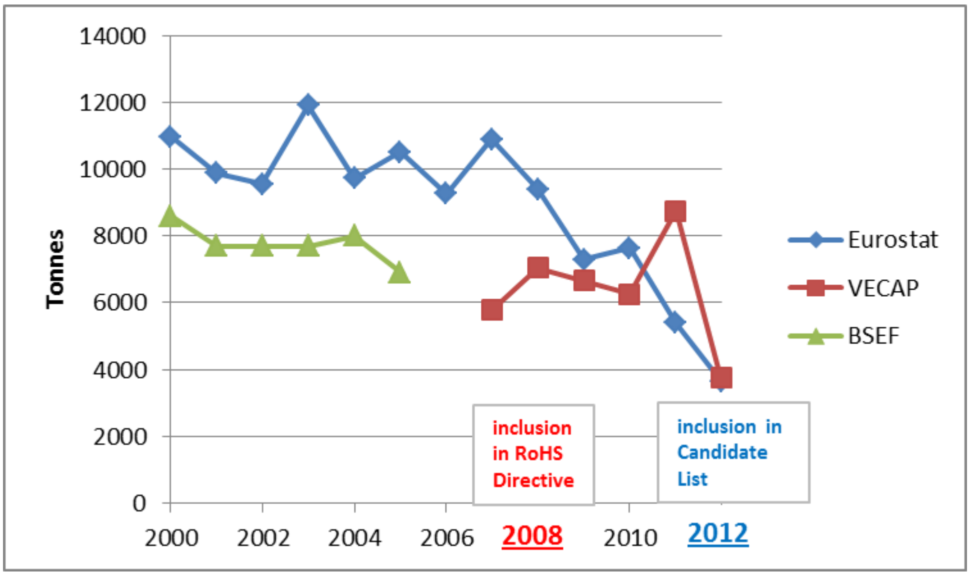

Figure 1: EU consumption of decaBDE (2000 – 2012)

Source: Eurostat (2013, as cited in RPA, 2014)[4], VECAP (2012)[5], BSEF (Bromine Science

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[3] US and Canadian manufacturers and importers have adopted a voluntary phase-out initiative for decaBDE. Accordingly, production and import of decaBDE is expected to have ceased in the US and Canada by the end of 2013, although this has not been confirmed formally. However, there is no evidence of any decline in the consumption of decaBDE in the Asia/Pacific region.

[4] Eurostat data for EU-Extra Imports by Tariff regime, product: brominated derivatives of aromatic ethers (excluding pentabromodiphenyl ether, 1,2,4,5-tetrabromo-3,6-bis"pentabromophenoxy"benzene and 1,2-bis"2,4,6-tribromophenoxy"ethane for the manufacture of acrylonitrile-butadiene-styrene [ABS]). Registrations are considered as the most reliable source, however Eurostat data cover a larger time-span and will be used to indicate **trends.**

and Environmental Forum) as cited in Earnshaw et al. (2013).

B.2.2 Uses

DecaBDE is used in the EU as an additive flame retardant in plastic and textile articles. These articles are used in the transport (automotive, aviation and marine), building/construction and mining sectors. Uses within these sectors include interiors and upholstery (carpets, seating and plastic components), roofing, insulation, piping/ducting/hoses and cables. Other uses of decaBDE include uses in adhesives/sealants, coatings and inks. No information on volumes for these uses is available.

DecaBDE is also used in the EU in domestic and commercial furnishings and fittings, e.g. in draperies and furniture (in foams, fillings and backcoats).

The proportion of decaBDE used in the EU in plastics (as opposed to textiles and other uses) has decreased from 81.7% (EU RAR, 2002) to 48% (VECAP, 2012). The use of decaBDE in textiles occurs predominantly in the UK, due to stringent fire safety standards (SVHC SD, 2012).

ECHA has received six notifications under article 7(2) (substance in article notifications), corresponding to less than 200 tonnes of decaBDE in articles[6] in the EU per year.

B.2.3 Uses advised against by the registrants

No uses are advised against by the registrants.

B.3 Classification and labelling

B.3.1 Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

DecaBDE is not listed in Annex VI of Regulation (EC) No. 1272/2008 (CLP Regulation).

B.3.2 Classification and labelling in classification and labelling inventory/Industry's self classification(s) and labelling

256 notifications of hazards have been made to the CLP inventory (see Annex B).

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[5] VECAP *data refer to "volume sold"*, so they cannot be assumed to equate to total imports.

[6] Data on Candidate List substances in articles, http://echa.europa.eu/web/guest/information-on-chemicals/candidate-list-substances-in-articles-table , accessed on 19/06/2014

B.4 Environmental fate properties

The environmental fate properties of decaBDE, in particular its potential to undergo biotic and abiotic debromination to form lower PBDEs, have been summarised previously (SVHC SD 2012) and were the key factor leading to the identification of decaBDE as an SVHC. The sub-sections on the environmental fate of decaBDE are therefore limited to a discussion of significant new information that has become available since the publication of the SVHC SD. An elaborated discussion of all new relevant information published since decaBDE was added to the Candidate List is documented in Annex B.

B.4.1 Degradation

B.4.1.1 Abiotic degradation

The SVHC SD (2012) concluded that photodegradation of decaBDE in the aquatic environment to form lower BDEs was likely to occur. However, based on the limited information available, no conclusion on the rate and extent of photodegradation in the aquatic environment was possible, at that time.

Two new studies that specifically investigate the photodegradation kinetics of decaBDE are now available (Leal et al., 2013; Wei et al., 2013). The photodegradation kinetics of decaBDE were found to be strongly dependent on the matrix (i.e. degradation was faster in solvents than in water). Equally, the half–life of decaBDE in water was found to vary considerably between 3.5 hours and 660 days, depending on environmental conditions (i.e. time of year, latitude). The presence of humic and fulvic acids in aquatic systems also reduced photodegradation rates.

The identification of photodegradation products or the underlying mechanism of degradation remains an area of uncertainty, although degradation products with both greater and lesser lipophilicity relative to decaBDE have been observed. This has prompted Wei et al. (2013) to suggest that the formation of polybrominated dibenzofurans (PBDFs) as well as lower brominated PBDEs may occur via the photodegradation of decaBDE.

Photo-degradation of decaBDE in curtains and car interiors was also identified as potentially important in the SVHC SD (2012), but the information available was not sufficient to reach a conclusion. New data reported by Kajiwara et al. (2013) is also inconclusive and therefore the significance of this degradation pathway remains uncertain.

B.4.1.2 Biotic degradation

The SVHC SD (2012) provides strong evidence that hexa- and hepta-BDE congeners can be formed from decaBDE under either actual or realistic worst-case environmental conditions in sediments and soils. No new significant information on the degradation of decaBDE in sediments, soils or sewage sludge has become available since decaBDE was added to the Candidate List.

A single study (CITI, 1992) on the biodegradation of decaBDE in surface waters was presented in the registration dossiers and the SVHC SD. This study reported no biodegradation over a two week period (as measured by biological oxygen demand) and it was concluded in registration dossiers and the SVHC SD (2012) that decaBDE was not readily biodegradable. Additional new non-standard data on microbial degradation (Lu et al., 2013; Shi et al., 2013) suggest that decaBDE can undergo microbiological mineralisation under aerobic conditions when used as a sole carbon source. However, these data are not sufficient to revise the existing conclusion that decaBDE is not readily biodegradable in the aquatic environment. Debromination was reported to occur via various lower PBDE congeners and other substances although no mass balance data are available.

B.4.2 Environmental distribution

No new relevant information is available.

B.4.3 Long range transport

"DecaBDE is associated mainly with particulates in the atmosphere and some modelling studies suggest that it will have a limited potential for long-range atmospheric transport because of rapid removal during wet deposition. However, it could be transported over longer distances during dry periods. The available monitoring data show that decaBDE is found in remote regions at low concentrations in air, sediment and wildlife. Local sources might be involved in some cases (for example decaBDE has been found in aqueous waste streams from Antarctic research stations). Migratory wildlife might also be exposed on their wintering grounds. Nevertheless, occurrence in lake sediment cores far from human habitation and detection in the air at remote locations suggests that long-range transport is occurring to some extent." (SVHC SD, 2012). This is one of the reasons that Norway has proposed that decaBDE should be included in the Stockholm Convention for POPs.

B.4.4 Bioaccumulation and transformation

B.4.4.1 Aquatic species

The SVHC SD (2012) concluded that fish can bioaccumulate decaBDE via their diet and transform it into lower PBDEs and methoxylated and hydroxlated PBDEs, although species differences in the extent of transformation are apparent. New data from laboratory studies with Fathead minnows (*Pimephales promelas*, Noyes et al., 2013), *Oryzias latipes* (Luo et al., 2013), *Cyprinus carpio* (Tian et al., 2012) and *Solea solea* (Munschy et al., 2011) describe additional evidence of the debromination of decaBDE in fish. Studies reported by Wan et al. (2013) and Feng et al. (2012) provide evidence that the observed debromination can occur directly within fish tissues, rather than by microbial fauna in fish guts prior to absorption.

The observation in field studies of different congener patterns in sediments and biota is often cited as potential evidence of biotic debromination of decaBDE, as is the presence of different congener ratios at different trophic levels. For example, Yu et al. (2012) reported that the relative contribution of decaBDE to the total of BDE load in fish from a Chinese lake was highly dependent on the trophic status of fish species, with herbivorous and omnivorous fish having a greater proportion of PBDE load (as decaBDE) than observed in predatory fish.

No clear congener trends could be observed in a lake food web study undertaken by Batrons et al. (2012). However, decaBDE was most readily detected in "basel resources" rather than at higher trophic levels and stable isotope analysis was also reported to indicate the biotransformation of decaBDE over trophic chains.

B.4.4.2 Terrestrial species

The SVHC SD (2012) concluded that decaBDE is metabolised in brown rats after oral and dietary exposure to lower PBDEs. Similarly, studies with European starling (Van den Steen et al., 2006 and 2007) suggest that metabolism to lower PBDE congeners can also occur in birds, although the available evidence was limited. Similar limited information on debromination of decaBDE was also presented for terrestrial and marine mammals (SVHC

SD, 2012).

A recent study by Letcher et al. (2014) supports the conclusion of the SVHC SD (2012). Letcher et al. (2014) report a half-life of decaBDE of approximately 14 days in the blood plasma of male kestrels (*Falco sparverius*) exposed in the laboratory to decaBDE. Lower brominated PBDE congeners were quantified in plasma and other tissues with the authors estimating that at least 80% of the lower PBDE congeners were present because of the metabolism of decaBDE, rather than from any other source. Yang et al (2014) studied effects of decaBDE on metabolic composition of urine and formation of lower brominated diphenylethers from decaBDE in rats after recieveing 100 mg/kg/day decaBDE during 20 days. Alterations in metabolite profile in urine of exposed rats were noted, but the toxicological implications are difficult to assess. Lower brominated diphenylethers were found, but as the administered decaBDE only had a purity of 97%, it is not clear if lower brominated analogues already were present in the administered substance.

Additional data on the biotransformation of decaBDE in plant species is now available. Lu et al. (2013) have outlined convincing evidence that decaBDE is biotransformed to lower brominated PBDEs in pumpkin (*Cucurbita pepo*). Similarly, Huang et al. (2013) have reported that decaBDE is biotransformed in root extracts of pumpkin (*Cucurbita pepo)*, ryegrass (*Lolium multiflorum*) and maize (*Zea mays)*.

B.4.5 Secondary poisoning

Not relevant for this dossier.

B.5 Human health hazard assessment

This section includes a summary of relevant human health hazard data for decaBDE. The PBT status of decaBDE was concluded based on the toxicity of its breakdown products. According to the SVHC SD (2012) tetra to heptaBDE fulfil the T criterion based on human health hazard properties (i.e. classification in CLP).

Notwithstanding the PBT/vPvB properties of its transformation/degradation products, decaBDE has also been associated with adverse effects that are not directly associated with its PBT/vPvB properties. These are described below as they may be usefully considered during discussions on the proportionality of any proposed restriction.

The human health hazard properties of lower PBDE congeners are summarised in section B.5.3 and further elaborated in Annex B.

No DNEL/DMEL values are presented as decaBDE is a PBT/vPvB substance and no quantitative risk characterisation has been undertaken in this report. The assessment is based on several reviews of decaBDE by regulatory authorities (e.g. EFSA, Health Canada, EU RAR), as well as recently published scientific literature. An elaborated discussion of the available information is presented in Annex B.

Based on available information, decaBDE has low acute toxicity, is not an irritant for skin or eyes and is not considered to be a sensitizer (Norris et al., 1975; ECB, 2002). In addition, the available studies suggest that decaBDE does not have a significant immunotoxic, genotoxic or carcinogenic potential (Health Canada 2006, EFSA 2011).

B.5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

Oral absorption in rats is reported to range from 7% to 26% (Health Canada, 2012). However, lower absorption (0.3% to 1.5%) has also been observed (NTP, 1986). Absorption via inhalation is estimated to be negligible (EFSA, 2011). Dermal absorption *in vitro* was found to be less than 20% (Hughes et al., 2001). In general, distribution of decaBDE is mainly to plasma and blood-rich tissues although some distribution to adipose tissue occurs (EFSA, 2011).

Based on organ fresh weights, the greatest concentrations of decaBDE were found in adrenals, kidney, heart, liver and ovary (EFSA, 2011; Sayer et al., 2010). Recent studies with rats (Biesemeier et al., 2010; Cai et al., 2011; Riu et al., 2008) reported that maternal administration of decaBDE during gestation results in accumulation in foetuses, pups and milk. However, levels observed in foetuses were lower (up to 10 fold lower) than in dams and levels in milk were lower than in maternal plasma (Biesemeier et al., 2010).

As concluded in section 3.3.2.2 (transformation in mammals) of the SVHC SD (2012), there is now good evidence from animal studies that decaBDE is biotransformed to lower brominated congeners in mammals (EFSA, 2011; Health Canada, 2012; Kortenkamp et al., 2014). However, uncertainties remain with respect to the extent that decaBDE is metabolised, where metabolism occurs and the complete range of metabolites that are formed (although many are known).

DecaBDE in humans is absorbed and distributed to blood, cord blood, placenta, foetus and to the infant via breast milk (Wu et al., 2010; Frederiksen et al., 2009). EFSA (2011) concluded that it seems likely that nonaBDEs and octaBDEs are formed in humans after exposure to decaBDE.

Thuresson et al. (2006) reported that the human half-life of PBDEs tends to increase with decreasing bromination of the PBDE congener. The apparent half-life for decaBDE was 15 days, while three nonaBDEs and four octaBDE congeners were found to have half-lives of 18-39 days and 37-91 days, respectively. Trudel et al. (2011) estimated a median half-life of decaBDE of 7 days based on concentrations in blood and a median half-life of 4 days based on concentrations in both blood and breast milk. These studies strongly indicate that decaBDE has a different pharmacokinetic behaviour compared to tetra- to hexabrominated PBDEs, whose half-life is measured in years rather than days (EFSA, 2011).

B.5.2 Toxicity for reproduction

B.5.2.1 Developmental toxicity

PBDEs, including decaBDE, are thought to result in developmental toxicity by exerting direct toxic effects on neuronal cells and stem cells (reviewed by Dingemans et al., 2011) or via effects on the thyroid hormone system. DecaBDE is regarded as a weak thyroid hormone disruptor sharing structural similarities (two ether linked phenyl rings) with thyroxine (T_4) and triiodothyronine (T_3) (Gilbert et al., 2012).

Developmental neurotoxicity associated with exposure to decaBDE has been reported in several studies (e.g. Viberg et al., 2003; Viberg et al., 2007; Johansson et al., 2008; Rice et al., 2009; Fujimoto et al., 2011). However, the effects observed in these studies have not been reproduced in other studies (e.g. Biesemeier et al., 2011; Wang et al., 2011) and limitations in the conduct of the studies have been noted (Hardy & Stedeford, 2008; Goodman, 2009; Hardy et al., 2009; Goodman et al., 2010).

Costa and Giordano (2011) reviewed the published literature on the neurodevelopmental toxicity of decaBDE. The weight-of-evidence indicated subtle developmental effects, particularly in pups subjected to tests for locomotor activity or cognitive behaviour. However, a review by Williams and DeSesso (2010) concluded that the lack of consistency across studies precluded the establishment of a causal relationship between perinatal exposure to brominated flame retardants and alterations in motor activity. Despite these concerns, the U.S. EPA used data from several of these studies when setting oral reference doses for decaBDE (US EPA, 2008). Equally, the Biesemeier et al. (2011) study has been critically evaluated by Shibutani et al. (2011), Health Canada (2012) and Fowles and Morgott (2013) who identified several methodological concerns that could have limited its potential to measure neurodevelopmental effects.

Additional studies on the neurobehavioral effects of decaBDE in rodents have recently been reported. Reverte et al. (2013) reported the effects of a single postnatal exposure to decaBDE in mice. Exposure to decaBDE induced long term effects in spatial learning (water maze test), which were dependent on age, sex and apoE genotype (a genetic factor that is associated with increased susceptibility for neurodegenerative diseases). Effects were more evident in apoE3 mice. Heredia et al. (2012) reported that oral subacute repeated gavage exposure to decaBDE in male young adult inbred wild type Tg2576 mice also resulted in delayed spatial learning (water maze test). Buratovic et al (2014) have repeated and somewhat extended the previous studies from the same laboratory (Viberg 2003, Viberg, 2007, Johansson 2008), using the litter as the statistical unit. DecaBDE was administered at dose levels of 0, 1.34, 5.76, and 13.4 mg/kg bw by gavage to mouse pups on PND3 (6 litters per group), where after effects on spontaneous behaviour were studied at 2 and 4 months of age, and effects on learning and memory at 5 and 7 months of age (only in males), brain neuroproteins at 7 months of age, and altered susceptibility of the cholinergic system at 2 months of age. Fairly consistent effects were found over time and in both sexes on all parameters, but with the brain protein markers more affected in males than in females. Mariani et al (2014) exposed pregnant mouse dams orally daily during GD 6-9 to 0.03, 0.3, 3, or 30 mg/kg/day decaBDE, and brains from GD13 embryos were later analysed for expression of three specific protein markers. DecaBDE seems to have been dissolved in DMSO whereas controls received peanut oil. None were affected at the lowest dose, two were statistically significantly affected at 0.3 mg/kg/day, and all three at 3 mg/kg/day. The dose-responses were not linear over the dose-range, but similar effects were caused in vivo by methyl-mercury and in vitro experiments perhaps supporting substance –related effects of decaBDE on brain cells.

Epidemiological studies have reported that exposure to decaBDE (and other PBDEs) during early life (prenatal or postnatal) may lead to delays in neurological development in children that affect cognition (Chao et al., 2011) or mental development (Gascon et al., 2012). However, these studies are limited by a small sample size. Several other epidemiological studies (Harley et al., 2010; Harley et al., 2011; Hoffman et al., 2012; Herbstman et al., 2008; Chevrier et al., 2010; Chevrier et al., 2011; Gascon et al., 2011; Roze et al., 2009; Eskenazi et al., 2013; Schreiber et al., 2010), not specific to decaBDE, support the notion that exposure to PBDEs generally, either alone or in combination, may result in human neurodevelopmental toxicity.

B.5.2.2 Other reproductive toxicity

DecaBDE, given during gestation and/or postnatally, did not generally cause reproductive effects at doses up to 500 mg/kg bw/day (EFSA 2011).

Van der Ven et al. (2008b), based on the results of a 28 day sub-acute toxicity study with rats (based on the OECD 407 guideline), reported that decaBDE may represent a hazard for reproductive health in adults, possibly by the modulation of sex steroids in the male genital system (at BMDL of 0.2 mg/kg bw/day). However, Health Canada (2012) argued that the effects observed in the Van der Ven et al. (2008b) study suggested an adaptive response rather than an adverse effect on reproductive function.

Tseng et al. (2013) reported a LOAEL for sperm DNA damage and excessive H_2O_2 production resulting from *in utero* exposure to decaBDE at doses as low as 10 mg/kg bw/day. Anogenital distance (AGD), sperm-head abnormalities and testicular histopathology (exhibited by severe vacuolization in the seminiferous tubules, associated with complete loss of spermatozoa and spermatids) were significantly affected in male offspring prenatally exposed to a decaBDE dose of 1500 mg/kg.

B.5.3 Human health hazard of other PBDE congeners

The human health classification according to Annex VI of Regulation (EC) No 1272/2008 for the commercial pentaBDE[7] product (main components tetra-, penta- but also significant hexacongeners) is Specific Target Organ Toxicity after repeated or prolonged exposure, STOT RE 2 (H373) and Lact (H362). The commercial octaBDE product (main components octa-, hepta- but also significant hexa- and nona congeners) is classified as toxic to reproduction Repr 1B (H360Df).

Single exposure to BDE-47, BDE-99, BDE-153, BDE-183, BDE-203 and BDE-206 in mice or rats induced behavioural changes including learning and memory disabilities (EFSA 2011; Kortenkamp et al., 2014). Repeated exposure of dams and/or neonatal rodents at different developmental stages to BDE-47, BDE-99, BDE-71 (25 % tetraBDE, 50-60 % pentaBDE and 4-8 % hexaBDE) induced long lasting behavioural alterations, particularly in the motor and cognitive domain (EFSA 2011). The developmental neurotoxicity of BDE-47, BDE-99 and BDE-153 is in particular well described (EFSA (2011; Costa and Giordano, 2011). BDE-99 is reported to be the most potent of these congeners, followed by BDE-153 and BDE-47 (EFSA 2011).

Nona-BDEs (-206, -207, -208), octa-BDEs (-196, -197, -198, -202, -203, -204) and hepta-BDEs (-183) are among the congeners identified as debromination products of decaBDE in studies with mammals (Kortenkamp et al., 2014). The nona-BDEs -206, -207 and -208 are by far the most abundant debromination products of decaBDE. Biochemical studies performed after *in vivo* exposure indicate that different PBDE congeners interfere with the expression of proteins involved in neuronal maturation, synaptogenesis and neuroplasticity (Kortenkamp et al., 2014). PBDEs are also reported to alter the expression of proteins that are involved in apoptotic pathways (Kortenkamp et al., 2014). Therefore, these mechanistic data support the conclusion that PBDEs, in addition to decaBDE, might interfere with essential processes of brain development resulting in alterations in neuronal plasticity and circuitry.

In general, epidemiological studies suggest an association between PBDEs and (sub)clinical hyperthyroidism and neuropsychological functioning (motor, cognitive and behavioural performance, and mental and physical development in children) (Harley et al., 2010; Harley et al., 2011; Hoffman et al., 2012; Herbstman et al., 2008; Chevrier et al., 2010; Chevrier et al., 2011; Gascon et al., 2011; Roze et al., 2009; Eskenazi et al., 2013; Schreiber et al., 2010).

B.6 Human health hazard assessment of physico-chemical properties

B.6.1 Explosivity

Due to its chemical structure, the substance is not expected to be explosive (EU RAR, 2002).

B.6.2 Flammability

The substance is used as a flame retardant based on its known stability (EU RAR, 2002).

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[7] The commercial pentaBDE product is also classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

B.6.3 Oxidising potential

No oxidizing properties are expected due to the chemical structure of the substance (EU RAR, 2002).

B.7 Environmental hazard assessment

The environmental hazard properties of decaBDE have been summarised previously (SVHC SD 2012). This section is limited to a discussion of significant new information that has become available since the publication of the SVHC SD. An elaborated discussion of all new information is available in Annex B.

No PNEC values have been derived as decaBDE is a PBT/vPvB substance and therefore no conventional risk characterisation has been undertaken as part of this report.

B.7.1 Aquatic compartment (including sediments)

DecaBDE is conventionally accepted as having limited aquatic toxicity. However, as cited in the SVHC SD (2012), a study with fathead minnows (*Pimephales promelas*) by Noyes et al. (2011) suggested that decaBDE may interfere with the thyroid hormone system in juvenile fish. Further data (Noyes et al., 2013), published after the SVHC SD report, provides further evidence (although from a non-standard test) that dietary exposure of decaBDE may interfere with the thyroid hormone system in juvenile fish and adversely affect reproduction. However, not all available data supports this conclusion (i.e. Garcia-Reyero et al., 2014).

B.7.2 Terrestrial compartment

One additional terrestrial toxicity study has become available since the preparation of the SVHC SD (2012). Plourde et al. (2013) investigated the association between markers of bone metabolism and structural integrity and concentrations of halogenated flame retardants in ring billed gulls (*Larus delawarensis*) breeding in the urbanised Montreal region. The authors observed that concentrations of hexa-, hepta-, nona- and decaBDE congeners in liver and decaBDE in plasma of male ring-billed gulls were negatively correlated with bone density (tarsus). The findings suggest that exposure to flame retardants can negatively affect bone tissue structure in birds.

B.8 PBT and vPvB assessment

B.8.1 Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

DecaBDE was identified as a PBT/vPvB as described in the Agreement of the Member State Committee: "*Bis(pentabromophenyl) ether [decabromodiphenyl ether] is identified as a substance meeting the criteria of Article 57 (d) as a substance which is persistent, bioaccumulative and toxic and of Article 57 (e) as a substance which is very persistent and very bioaccumulative, both in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC) 1907/2006 (REACH).*

DecaBDE is very persistent and widely detected in many environmental compartments (including wildlife species). On the basis of the available data it can be concluded that there is a high probability that decaBDE is transformed in the environment to form substances which themselves have PBT/vPvB properties, or act as precursors to such substances, in individual amounts greater than 0.1% w/w over timescales of a year" (ECHA MSC Agreement, 2012).

B.8.2 Emission Characterisation

B.8.2.1 Introduction

The aim of this section is to estimate the emissions of decaBDE from all relevant life cycle stages, namely the production of articles (including formulation and polymer processing), the article service life and the waste stage.

The emissions of decaBDE were estimated in previous EU RARs (2002, 2004 and 2007) and a summary of these estimates is given in Annex B.8.2.1. These estimates were supplemented by a further set of calculations performed during the development of this report using the methodology outlined in OECD Emissions Scenario Documents (ESD) (RPA, 2014)[8]. In the previous risk assessments the emissions estimations were presented at continental, regional and local scales. This is not relevant for this report as no quantitative risk characterisation (leading to RCRs) at local or regional scale was carried out. Instead, the emission estimates have been presented as total EU emissions.

Plastic and textile articles flame retarded with decaBDE are used across a range of different applications (see section B.2.2), each with different emission characteristics. Therefore, three emission scenarios (central, high and low) were developed to incorporate this variability. However, due to lack of data, it has not been possible to allocate emissions to specific types of plastic and textile articles. The high scenario uses emission factors taken predominantly from the OECD ESD. These factors generally lead to higher overall emissions. The low scenario combines the emission factors from the OECD ESD with measured data from the literature or provided by industry (for the production step, data from the 2013 VECAP report were used). For details on the high and low scenarios see Annex B.8.2. In the emissions calculations it was assumed, as no information on the volumes for other uses was available, that all of the imported tonnage is used for the production of plastic and textile articles.

The starting point for the calculations is the quantity of decaBDE entering the EU each year, either as imported substance (taken as 4,000 t/year, see B.2.1) or in imported articles. It is assumed that the quantity in imported articles is equal to 10% of the quantity imported as substance (RPA, 2014). However, this estimate is uncertain (see section F.7 Uncertainties).

The tonnage and emissions estimates are used in section F.2 for the calculation of substitution costs (€) and cost effectiveness (expressed in €/kg of avoided emissions of decaBDE). The total avoided emissions are used as a measure of the impact of the proposed restriction.

It should be noted that emissions from the manufacture of decaBDE (as it occurs outside of the EU) and emissions which occur outside of the EU but subsequently enter the EU via long-range transport (LRT) are not included in the calculations. However, concentrations measured in the environment or during biomonitoring may include contributions from emissions from outside the EU.

B.8.2.2 Results

The total emissions and emission factors under the central scenario are presented in Table 6. The majority of emissions are associated with the service-life of articles whilst production and waste life-cycle stages are associated with lower emissions. Estimates of emissions to water were supported by a complimentary analysis based on measured concentrations in

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[8] Use of OECD ESD is envisaged in ECHA Guidance

sewage sludge (Annex B.8.3).

Table 7 shows the estimated distribution of releases to the different environmental compartments. Although the initial modelling assumptions specify the releases to air, water and soil by the corresponding emission factors, the final fate of decaBDE is defined ultimately by its physicochemical properties. Thereby, even if initially released to air or water decaBDE is prone to finally partition to soil and sediment (see also section B.4). The relationship between emissions of decaBDE and subsequent exposure to decaBDE breakdown products is discussed in section B.9.4.

Table 6: Summary of estimated emissions of decaBDE from articles produced or placed on the market in the EU in 2014 – central scenario (t/year)

	Textiles	**Plastics**	**Total**	**share**
Production	0.16	0.15	0.31	7%
Article Service Life	3.03	1.12	4.15	87%
Waste	0.15	0.14	0.28	6%
Total	3.34	1.40	4.74	100%
Emission Factor	0.15%	0.07%	0.11%	

Source: Annex B8 (

Table **44***)*
Note 1: Emissions from the production of textiles and plastics were back-calculated from total emissions from production using the assumed ratio of plastics and textiles (52:48 %, see section B.2.2). As such, they might not accurately reflect the actual balance of emissions between textiles and plastics from this lifecycle step (emissions from plastics may be relatively lower compared to textiles). However, the total emissions from production would stay the same. For a detailed calculation according to the OECD ESD guidelines (high emissions scenario) see Table 50. Limitations on the way the VECAP emissions are reported did not allow detailed calculations to be made for the low emissions scenario. Consequently, it is not possible to reflect these detailed calcuations in the average emissions given in the table above.
Note 2: All figures are calculated as the average from the low and high scenarios

Table 7: Distribution of releases of decaBDE to the different environmental compartments in the EU in 2014 – central scenario

	(t/year)	**share**
Air	1.46	31%
Water	2.32	49%
Soil	0.96	20%
Total	4.74	100%

Source: Annex B8 (Table 45)

B.8.2.3 Timescale of emissions' occurence

The estimated emission figure of 4.74 t of decaBDE includes emissions from the production and subsequent service life and waste lifecycle steps of articles that are placed on the market in a given year (i.e. articles placed on the market in 2014 in the above calculations). Emissions from article production occur during the same year of the production. Emissions from article service life occur over 10 years (). Finally, emissions from waste in landfills occur for 30 years from the assumed end of the service life. Figure 2 gives a schematic representation of the occurrence of the decaBDE emissions in time. However, emissions from incineration and recycling operations occur shortly after the articles have reached their end of service life (this is not pictured in the figure). In addition, recycling might lead to the incorporation of decaBDE in new articles, which will continue to emit for a second service life (these emissions are not included in the calculations).

"Legacy emissions": emissions from the service life and the waste stage of the legacy articles (i.e. those placed on the market prior to any restriction) will continue after the entry into force of the proposed restriction. These emissions were not quantified in this restriction proposal, since they are not impacted by the proposed restriction. These emissions are considerable since imports of decaBDE were approximately two times higher than current imports (see Figure 1).

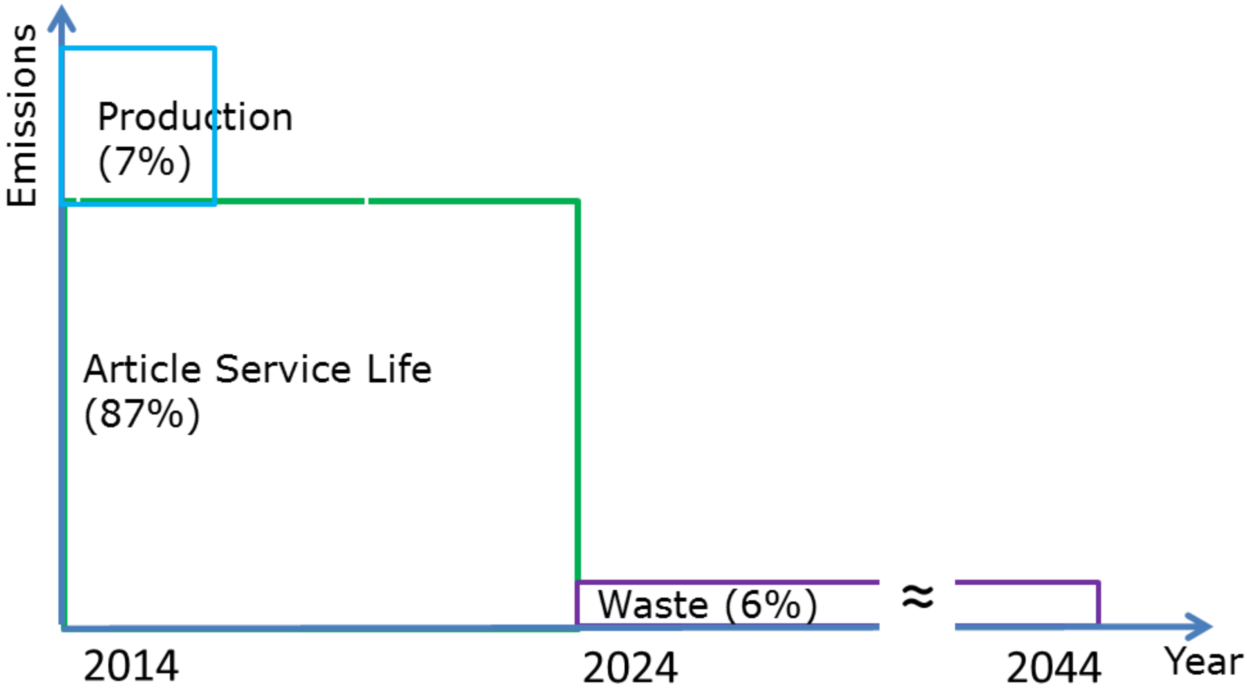

Figure 2: Timescale of emissions' occurrence – schematic view
Note 1: the figure represents emissions from the production, service life and waste lifecycle steps of the articles that are placed on the market in one year (i.e. 2014), that will be avoided when the restriction is implemented. Emissions from legacy articles and waste are not presented in this figure.
Note 2: the surface under the boxes represents the amount of emissions, however the figure is not to scale

B.9 Exposure assessment

B.9.1 General discussion on releases and exposure

A full exposure assessment for decaBDE has not been undertaken in this report, as would normally be expected, for several reasons.

REACH registration dossiers for decaBDE do not contain information on the environmental exposure of decaBDE, either on a per use, or on an aggregated basis. This is because the current registration is based on the information requirements prior the decision to identify decaBDE as a PBT/vPvB substance, i.e. as decaBDE was not classified by applicants as hazardous exposure assessment (including exposure scenario development) and risk characterisation were not required. As a consequence of the identification of decaBDE as a PBT/vPvB updates to the registration dossiers of decaBDE are now pending, but have not yet been received by the Agency.

Exposure estimates (i.e. Predicted Environmental Concentrations: PECs) were calculated during the ESR risk assessment for decaBDE (ECB 2002) and its subsequent updates (ECB 2004, ECB 2007) based on information on tonnages and risk management measures relevant at the time. However, both the tonnage of decaBDE used in the EU and the risk management measures in place during formulation and the production of articles (primarily as a consequence of the industry VECAP programme) have changed sufficiently that these PEC estimates are now considered to be out of date.

Updated emissions estimates were made during the preparation of this report (see section B.8.2). However, these estimates were undertaken to explore the potential effectiveness of different risk management options (see section E). As such, whilst estimating emissions to different environmental compartments, this modelling does not incorporate the subsequent likely fate of decaBDE in the environment (e.g. emissions to water are likely to selectively partition to sediments and emissions to air are likely to accumulate in soils). Equally, an estimate of bioaccumulation of decaBDE in aquatic or terrestrial biota has not been undertaken.

Therefore, updated PECs for decaBDE, based on contemporary information on tonnages and emissions are not included in this section of the report. Rather, the exposure assessment for decaBDE comprises a summary of relevant biomonitoring and environmental monitoring data. These monitoring and biomonitoring data may incorporate exposure to decaBDE emitted from additional, historic, uses. Therefore, these data should be considered as representative of both historic and contemporary EU exposure to decaBDE (including any contribution from long-range transport).

Exposure to humans and the environment is summarised in sections B.9.2 and B.9.3, respectively, and elaborated in Annex B. Data were collated from various regulatory and literature sources, including the EU RAR (2002) and updates. Where possible, information on human exposure is presented according to the relevant life-cycle stage[9] i.e. occupational exposure (including during the waste stage) or consumer exposure during article service-life (e.g. exposure via house dust). Disaggregation of the source contribution of different life-cycle stages to concentrations observed in the environment or wildlife has not been possible.

B.9.1.1 Summary of the existing legal requirements

Legislative controls, directly or indirectly, exist for decaBDE dating from the last 10 to 20 years. Table 8 summarises the relevant existing regulatory controls in the EU and Table 9 the relevant international initiatives (regulatory and voluntary). Further details of each of these existing legal requirements, including relevant international initiatives are given in Annex B.

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[9] Manufacture of decaBDE has not occurred in the EU since 1999. However, emissions associated with historic manufacture may influence the concentration of decaBDE reported in the environment or during biomonitoring.

Table 8: Summary of existing regulatory controls for decaBDE in the EU

Regulation	Summary
REACH[10]	DecaBDE was identified as an SVHC in December 2012 and added to the Candidate List.
Norwegian restrictions on decaBDE	Norway restricted the manufacture, import, export, placing on the market and use of decaBDE or preparations containing decaBDE from 1 January 2008. Articles or flame retarded parts of articles that contain 0.1 % by weight or more of decaBDE are covered by the restriction. However, it does not apply when the substance is used in vehicles (WEE-regulation, aircraft regulations, vessels or rolling stock for use on railways). In addition, Norway has a regulation on waste that sets a specific limit for hazardous waste containing decaBDE.
Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) directive[11]	All PBDEs, including decaBDE, are included in the restricted substances list and are not allowed in quantities higher than 0.1% w/w (weight of homogeneous material), although some categories of EEE are exempted (see Annex B).
Waste electrical and electronic equipment directive[12]	Annex VII of the recast WEEE Directive describes the selective treatment for materials and components of waste electrical and electronic equipment and include plastic containing brominated flame retardants. It specifies that separately collected plastics that contain BFRs (therefore, including decaBDE) should be removed and treated separately, in compliance with the Waste Framework Directive.
Waste Framework Directive[13]	The Waste Framework Directive provides a general framework of waste management requirements and sets basic waste management definitions. PBDEs or decaBDE are not explicitly mentioned.
Landfill Directive[14] & Council Decision 2003/33/EC	Directive 1999/31/EC aims to reduce the impact of landfilling of waste to the environment, through the introduction of strict technical requirements and procedures for waste and landfills. However, PBDEs or decaBDE are not explicitly mentioned.

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[10] Regulation 1907/2006 (REACH)

[11] Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE) - RoHS

[12] Directive 2002/96/EC on waste electrical and electronic equipment (WEEE)

[13] The Waste Framework Directive (WFD, 2008/98/EC)

[14] Directive 1999/31/EC

Regulation	Summary
Water Framework Directive[15] and amendments	The first list of priority substances includes “bromodiphenylether”, which is comprised of the sum of six tri- to hexaBDE PBDE congeners. The European Commission has subsequently proposed to identify octaBDE as a priority substance, because of its PBT properties (EC 2012). This refers to the commercial product, on the basis of its lower molecular weight PBDE content.
Industrial Emissions Directive[16]	The BREF on textile industry mentions backcoating and decaBDE in an Annex describing the various chemical agents that can be used. However, it does not discuss environmental risks.
European Pollutant Release and Transfer Register (E-PRTR)[17]	Brominated diphenyl ethers are included in the E-PRTR and information about releases per industrial activity and number of facilities are given by year and geographical area. PBDEs are included in the chemicals whose emissions need to be reported if the relevant emission values are exceeded. For these substances, there is only a water threshold value of 1 kg/year per installation falling under the provisions of the Industrial Emissions Directive.
Urban Waste Water Treatment Directive[18]	Neither the polymers nor the textiles finishing sectors are specifically covered by the Directive.

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[15] Directive 2000/60/EC
[16] Directive 2010/75/EC
[17] Regulation (EC) No 166/2006
[18] Directive 91/271/EEC

Table 9: Summary of existing international initiatives for decaBDE

Regulation	**Summary**
Voluntary actions in USA and Canada	The US EPA-Industry decaBDE Phase-Out Initiative includes the discontinuation of the use of decaBDE in electrical and electronic equipment (EEE) (except in transportation) and in all other uses except transportation and military uses by the end of 2012.
OSPAR Convention	Brominated flame retardants (including decaBDE) were identified as chemicals subject to priority action during the Ministerial Meeting of the OSPAR Commission of 1998 (Sintra) and were included in Annex 2 to the OSPAR Strategy with regard to Hazardous Substances Strategy (OSPAR, 2014). The overall aim of OSPAR Commission for substances chosen for priority action is to achieve by 2020 *a "cessation of discharges, emission and losses […] with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances"* (OSPAR, 2014).
The Stockholm Convention	The Stockholm Convention on Persistent Organic Pollutants was adopted on 22 May 2001 and entered into force on 17 May 2004 (Stockholm Convention, 2008). The main objective of the Convention is to protect human health and the environment from the threats presented by persistent organic pollutants (POPs). In May 2009, the Convention was amended to include tetraBDE and pentaBDE (congeners contained in commercial PentaBDE) and also hexaBDE and heptaBDE (congeners contained in commercial octaBDE) in Annex A (elimination) to the Convention. In May 2013, Norway submitted a proposal to list decaBDE as a POP under the Convention.
OECD Voluntary Industry Commitment	In 1994, an OECD monograph was published [OCDE/GD(94)96] which discussed the commercial and environmental life cycle of these substances as well as risk reduction measures implemented in Member countries and these countries' positions on the perceived risk from these substances (OECD, 1995).
BSEF Product Stewardship Programme (VECAP)	Established in 2004, the Voluntary Emissions Control Action Programme (VECAP) is a voluntary initiative run by BSEF under the Responsible Care Initiative to set high standards for chemicals management in the workplace, both at manufacturing sites and along the value chain. The aim of the programme is to reduce potential emissions of flame retardants to the environment through the promotion of manufacturing best practice among those involved along the value chain. This is achieved by increasing understanding of chemicals management in the value chain, promoting dialogue between industry, regulators and stakeholders and by implementing best practices.
EU Ecolabel	The EU Ecolabel criteria indicate that no use of flame retardants or flame retardant preparations is permitted where substances concerned are assigned one of a number of specified risk phrases and are present at more than 0.1% by weight.

B.9.1.2 Summary of the effectiveness of the implemented operational conditions and risk management measures

The RoHS Directive, which has applied to decaBDE since 2008, has removed the decaBDE that was previously used in EEE. However, the total amount of decaBDE placed on the market in the EU was not observed to decrease in the following years, plausibly because overall use in plastics and textiles (other than in EEE) increased. However, when decaBDE was included in the Candidate List a clear decrease in the amount used took place in the EU (see Figure 1). Although other legal requirements listed in section B.9.1.1 have the potential to contribute to reduction or control of emissions (and subsequent exposure), their impact could not be quantified. As mentioned in section B.9.1 there are currently no risk management measures/operational conditions in the registrations that could have been assessed here for their effectiveness.

In calculating the emissions from the **production** step, it was assumed in the low emissions scenario that industry would use best practice to minimise emissions to the environment i.e. according to VECAP guidelines. However, not all decaBDE users apply VECAP best practices. Even if all of the production industry that use decaBDE adopted VECAP best practice this would still give rise to significant emissions to the environment (see Annex B)

Article service life is the largest source of decaBDE emissions. For articles, various possible risk management options could be considered to reduce emissions. For example, the concentration of decaBDE in the article could be limited. However, lower concentrations of decaBDE would not provide sufficient flame retardancy in articles i.e. the technical function of the substance would be impaired. Alternatively, the article matrix could be designed to minimise the losses of decaBDE. However, the potential of this option is limited by the fact that decaBDE is an additive flame retardant, i.e. it is physically combined with the material being treated rather than chemically combined (as in reactive flame retardants). As a consequence there is the possibility that decaBDE may diffuse out of the article (EU RAR, 2002). It may also be possible to limit the outdoor uses of articles where there is greatest potential for emissions. However, the vast majority of the applications of decaBDE relate to indoor uses that would limit the effectiveness of this option (ECHA R.13, 2012). In conclusion, these risk management options are not considered to be effective, which is corroborated by the magnitude of releases from article service life.

Emissions from **waste** are close to emissions from production (see Table 6). Based on available data it appears that the ultimate fate of the vast majority of products containing decaBDE is landfill, which is the source of most of the emissions from waste (see Annex B), although the long-term fate of decaBDE in landfill is not well understood. Emissions from waste could potentially be reduced by making use of good practice in waste management. Emissions of decaBDE could be drastically reduced (but probably not to zero) by using incineration instead of recycling and landfill, although this is unlikely to be practical.

In summary, although some emission reductions could be envisaged through waste management, most of the emissions that originate from article service life cannot be abated with the application of risk management measures.

The results of the first six years of the 10 year environmental monitoring programme for decaBDE do not show any clear trend (decreasing or increasing) of decaBDE levels in environmental media (see Annex B). The absence of a decreasing trend in the environmental monitoring data indicates that the VECAP initiative, whilst effective in reducing emissions from the production stage, does not affect the most significant emissions in the decaBDE lifecycle i.e. article service life.

B.9.2 Human Exposure

PBT/vPvB assessment requires an identification of the likely routes by which humans and the environment are exposed to the substance (REACH Annex I/4.2). Various sources and pathways are relevant to an assessment of human exposure to decaBDE, such as exposure from food, drinking water, inhalation of air, ingestion of dust as well as dermal exposure. Further, the foetus is exposed to decaBDE through transport across the placental barrier and breast-fed children are exposed through consumption of breast milk.

Consumer exposure includes exposure from house dust, indoor air as well as dermal or oral contact with consumer products. DecaBDE is used in many consumer products including plastics, textiles and foam furniture and might leach from the products into house dust as well as both indoor and outdoor air. Thus the ingestion of house dust and inhalation of airborne particulates are potential exposure sources for decaBDE, as well as direct contact with consumer products. It is not well documented whether decaBDE migrates out of products onto existing dust particles or whether dusts are formed from the breakdown (abrasion) of the product matrix itself.

The indoor environment has recently been recognised as an important exposure pathway for consumers to PBDEs, as emphasised in the review by Harrad et al. (2010). This review reported decaBDE concentrations in indoor air ranging from <LOQ (limit of quantification) to 651 pg/m^3. In house dust (sampled from Germany, Sweden and the UK) the decaBDE concentrations ranged from 63 to 10,000 ng/g (Fromme et al., 2009).

There is growing evidence that occupancy in cars and, potentially, aeroplanes may be a significant source of PBDE exposure (Besis and Samara 2012). While the average time spent in cars is considerably less than time spent indoors, the median levels of decaBDE in dust from cars were about 20 times higher than in house dust, although the levels varied substantially between the studies. This is in line with a recent German study where the mean decaBDE concentration in car, house, and office dust samples were 940, 45 and 120 ng/g, respectively (Brommer et al., 2012).

Indirect exposure via the environment includes exposure from food and beverages, drinking water and inhalation of outdoor air. DecaBDE is widely present in food and is reported in concentrations ranging from ~2 to >50,000 pg/g wet weight as reviewed by Frederiksen et al. (2009a). The highest concentrations were generally measured in fish and shellfish. Measurements of decaBDE in Norwegian food in the period 2002-2006 have been reviewed by Knutsen et al. (2008) and the upper bound concentrations ranged from 45 to 1,964 pg/g wet weight. The highest concentrations were observed in the eggs of seagulls, followed by fish and dairy products, which included milk, cheese and butter. Domingo (2012) also reviewed the presence of PBDEs in food and estimated daily intakes concluding that despite differences in methodologies used, decaBDE contributes significantly to the total dietary intake of PBDEs.

Following the advice of the EFSA Panel on Contaminants in the Food Chain (CONTAM), a monitoring program was carried out in the EU starting in 2006. The results comprised up to 19 PBDE congeners analysed in 3,971 food samples from 11 European countries covering the period 2001-2009. DecaBDE was reported in 1,300 samples. The concentration of decaBDE was the highest among the measured PBDEs in almost all the food samples, except for "Fish and other seafood" and "Food for infants and small children". The mean lower bound (upper bound in parentheses) concentration across eight broad food categories ranged from 0.021 (0.11) pg/g wet weight in milk and dairy products to 2.22 (2.73) pg/g wet weight in products for special nutritional use.

Occupational exposure data, in general, are limited to high exposure occupation groups like electronics dismantlers in Europe (Sjödin et al., 1999; Jakobsson et al., 2002) and Asia (Bi et al., 2007). However, some data are also available from other occupational groups that may be exposed to decaBDE, such as firefighters (Shaw et al., 2013). In Sweden, the median decaBDE blood level in electronic dismantling workers and computer technicians was reported to be 4.8 and 1.53 ng/g lipids, respectively (Sjödin et al., 1999; Jakobsson et al., 2002), while a median of 35 ng/g lipids was reported among rubber workers (Thuresson et al., 2005). Exposure concentrations in Asia are significantly greater than in Europe.

The internal dose as measured through biomonitoring (e.g. blood concentrations) reflects an integrated exposure over time and takes individual differences into consideration (e.g. age and gender). A large number of scientific studies have shown decaBDE to be frequently detected in human blood and breast milk, proving that humans are subject to widespread exposure to decaBDE. Further, the presence of decaBDE in placenta and samples of cord blood confirms prenatal exposure. In many of the studies, decaBDE was the PBDE congener present in highest amounts, particularly in breast milk.

Median blood levels of decaBDE in European adults with no known occupational exposure are generally in the range of 0.5 to 5 ng/g lipids (reported values range from < 1 to 50 ng/g). The levels reported on a lipid basis seem to be quite similar in foetuses, children and adults throughout the world. However, significantly higher concentrations are seen in occupationally exposed persons.

In conclusion, the available evidence suggests widespread exposure of decaBDE to humans (of all ages). A large number of studies have shown decaBDE to be frequently detected in human blood and breast milk. In many of the studies, decaBDE was the PBDE congener present in highest amounts, particularly in breast milk.

B.9.3 Environmental Exposure

Monitoring data from a large number of reliable studies strongly suggests that decaBDE is present almost universally in the aquatic and terrestrial environment of the EU as well as within wildlife species, notably accumulated within the tissues and eggs of predatory and other bird species. Its presence in the tissues of so many species is a cause for concern.

Interim results (2005-2010) from a ten-year monitoring programme (known as the conclusion (i) monitoring programme, or DECAMONITOR)[19] commissioned to investigate the long-term trends of decaBDE concentrations in the EU confirm that decaBDE is widely distributed in the environment and biota and no trend (either increasing or decreasing) in concentrations is apparent (Leslie et al., 2012).

Terrestrial species (especially bird-eating species) appear to accumulate decaBDE to a greater extent than either aquatic organisms, or predatory birds that obtain their food from the aquatic environment.

The exact route of uptake into these organisms is not clear, but could be occurring via diet, water and air as well as through ingestion of contaminated sediment or soil.

DecaBDE can be found widely in sediments and sewage sludge, where it is frequently the dominant PBDE congener present. Sewage sludge is a potentially major source of decaBDE to agricultural land. The levels of decaBDE found in sludge in the EU in recent studies are generally around 0.1 mg/kg dry weight up to a few mg/kg dry weight. It is expected that

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[19] Requested by the EU Member States under Commission Regulation (EC) No 565/2006: O.J. No L 99, 07/04/2006 p. 003 - 005.

decaBDE will be persistent in agricultural soils once applied. Sellstrøm et al. (2005) detected levels of a few mg/kg dry weight in a farm soil in Sweden that had last received an input from sludge around 20 years previously.

B.9.4 Degradation and transformation

For completeness, human and environmental exposure to decaBDE should be considered alongside the potential for exposure to its breakdown products, principally the lower brominated PBDEs with PBT/vPvB properties that resulted in the identification of decaBDE as a PBT/vPvB substance. However, decaBDE is also known to degrade to other substances, such as hydroxylated and methoxy-PBDEs as well as PBDFs. Some of these substances have extensive and well studied adverse hazard profiles, whilst others have not yet been studied in detail but which have some cause for concern.

The degradation of decaBDE in environmental matrices and biota are reported in sections B.4.1 and B.4.4. and annexes B.4.1 and B.4.4. However, in most cases, there is only limited information available on the identity of possible breakdown products, their properties (i.e. would they meet the criteria for a PBT/vPVB substance) and the rates at which they are formed in different matrices. Appendix three of the SVHC SD for decaBDE (SD, 2012) presents PBT profiles for 15 hydroxylated and methoxy-PBDE breakdown products based on QSAR screening (EPIWIN v3.20). This exercise, whilst not a definite assessment, identified that all of the structures screen as potentially persistent and all are predicted to have log K_{ow} values greater than five. The assessment concluded that some of the substances have potential PBT/vPvB profiles that are of concern. The assessment does not cover all potential breakdown products of decaBDE. A more sophisticated assessment by Environment Canada (2010, cited in SVHC SD) concluded that a large proportion of metabolites could be bioaccumulative.

Based on potential transformation rates to lower PBDEs in sediments/soils reported in the SVHC BD, a transformation rate for decaBDE in the environment of between 0.1 and 10 % w/w per year could be expected, although the SVHC BD documents several uncertainties and limitations in the underlying laboratory and field studies that result in this estimate. Whilst the majority of decaBDE may be expected to accumulate in sediments and soils, transformation rates in other environmental matrices, including biota, are also important to consider. For example, Wei et al. 2013 have predicted half lives of decaBDE in surface water through photodegradation of between 3.5 hours to 660 days (dependent on environmental conditions). PBDFs were one of the breakdown products identifed. Data reported by Noyes et al. (2011), suggests that significant debromination of decaBDE to lower brominated congeners of concern occurs in juvenile fathead minnow (>60% of the accumulated dose of decaBDE over a 28 day exposure). Letcher et al. (2014) have reported that at least 80% of the PBDE load in male kestrels (Falco sparverius) exposed to decaBDE in the laboratory were present as a consequence of the debromination of decaBDE, rather than any other source (7.4 % of total BDE burden at the end of the exposure period was as lower brominated congeners of decaBDE). Similarly, Lu et al. (2013a) describe debromination of decaBDE in a 60-day exposure with pumpkin (*Cucurbita pepo*) that resulted in decaDBE accounting for 80, 67 and 50 % of the total BDE load in roots, stems and leaves, respectively (the remainder as a consequence of debromination). Eight lower brominated PBDEs, two hydroxylated PBDE breakdown products and a single methoxy-PBDE breakdown product were quantified. Whilst there remains uncertainties in some of these studies, the low transformation rate of decaBDE observed in sediments/soils may not adequately describe the exposure to decaBDE breakdown products in all matricies, particularly in biota once decaBDE is bioaccumulated.

The toxicokinetics of decaBDE are reported in section B.5.1 and annex B.5.1 and in section

3.3.2.2 (transformation in mammals) of the SVHC SD (2012). There is now good evidence from studies with mammals that decaBDE is biotransformed to lower brominated congeners (EFSA, 2011; Health Canada, 2012; Kortenkamp et al., 2014). However, it is still not clear at which rate decaBDE is metabolised, where the metabolism occurs and what is the whole range of metabolites formed (although many are known).

The proportion of decaBDE that degrades to different substances, and the rate at which this occurs, is relevant to any discussion on the proportionality of the proposed restriction. However, the information available is not sufficient to provide reliable estimates of the proportion of decaBDE breakdown products that will be produced and, with the exception of lower brominated PBDEs, the hazard and impact of these breakdown products. Equally, whilst degradation over the short-term (i.e. over a period of a year) gives important information, this should be balanced against the potential for decaBDE to act as a long-term source of PBT/vPvB substances to the environment and humans. Therefore, the rate at which breakdown products of decaBDE are formed in the environment cannot be reliably incorporated into the emissions / exposure assessment on a quantitative basis. Should transformation occur only slowly the cost-effectiveness of any restriction based on total emissions of decaBDE (per year) would be reduced. However, this would need to be balanced against the total sink of decaBDE and its potential to form PBT/vPvB substances over the long term and the potential hazardous properties of decaBDE itself.

In addition to the arguments above, it is also important to consider that the REACH regulation does not distinguish between different PBT or vPvB substances once they are identified. The obligations to minimise emissions and exposures throughout the lifecycle of the substances from manufacture or identified use are the same irrespective of the basis upon which a PBT or vPvB substance is identified.

B.9.5 Overview of monitoring data from tetra- to heptaBDEs

The basis for the identification of decaBDE as a PBT/vPvB was its potential to degrade into lower brominated PBDEs with PBT/vPvB properties. Therefore, the available exposure data for tetra- to heptabrominated PBDEs complements exposure data for decaBDE and is likely to be useful when considering the proportionality of the proposed restriction for decaBDE. These data are summarised in Annex B. It should be noted that because of historic and contemporary releases of lower PBDEs (from the commercial pentaBDE and octaBDE products) there is uncertainty with regards to the exact proportion of lower PBDEs detected in humans and the environment that are present because of the degradation of decaBDE i.e. they may have been released to the environment as lower PBDEs.

B.10 Risk characterisation

B.10.1 General introduction

In general, due to the high uncertainties regarding long-term exposure and effects, the risks of PBT/vPvB substances, such as decaBDE, to the environment or to humans via the environment cannot be adequately addressed in a quantitative way, e.g. by derivation of PNECs (or DNELs). Therefore, a qualitative risk assessment has been carried out.

This section summarises the sources, releases and likely routes of exposure of decaBDE to the environment and to humans and thereby indirectly to its PBDE transformation products. Exposure/emissions, in the case of a PBT/vPvB, are used as a proxy for risk when considering the cost-effectiveness and proportionality of the proposed restriction (Section E and F).

B.10.2 Summary of information on releases

DecaBDE is no longer manufactured in the EU but is imported as a substance (on its own or in mixtures) and in articles. It is released from the formulation and processing stage ("production"), the service life of articles and from the waste stage (recycling, landfilling and incineration). The total releases in the EU are estimated at 4.74 tonnes per year, which amounts to 0.11% of the total tonnage of decaBDE used every year.

The industrial use of decaBDE as a general purpose flame retardant is wide dispersive. DecaBDE is assumed to be used and released at many professional and industrial sites across the EU. More than a 100 sites of compounders/formulators, master batchers, injection moulders and finishers in the EU use decaBDE (SVHC SD 2012). Releases from production were estimated at 7% of the total emissions.

The service life of products and articles appear to be the major source of releases of decaBDE (87% of the total releases). DecaBDE is also found in imported articles. The amount of decaBDE imported in articles is not known with certainty but is estimated to be 10% of the amount imported as a substance.

Finally, 6% of the total emissions are released from waste. It appears that the ultimate fate of the vast majority of products containing decaBDE is landfill. It is estimated that 44% of plastics and 50% of textiles containing decaBDE are landfilled (see Annex B.8.2.4). The long-term emission potential of decaBDE in the landfills is poorly understood although there is a potential for a release to the environment of decaBDE, or its degradation products, at a later stage.

B.10.3 Humans

The main routes of human exposure to decaBDE include indirect exposure via the environment (via food consumption), inhalation of particulate bound decaBDE in indoor and outdoor air, and via skin uptake. The foetus is exposed to decaBDE through transport across the placental barrier and infants are exposed through the consumption of breast milk. The contribution of each pathway may vary substantially between individuals and within different populations. Direct contact with consumer products may be a source of exposure although detailed information on this route is not available. Median blood levels in the EU of decaBDE are generally in the range of 0.5 to 5 ng/g lipids for adults with no known occupational exposure (reported values range from < 1 to 50 ng/g). The levels reported on a lipid basis seem to be quite similar in foetuses, children and adults throughout the world. However, significantly higher concentrations are seen in occupationally exposed persons. Children of age 1 – 3 years appear to be the age group with the highest exposures. Breastfed infants are also quite highly exposed on a body weight basis.

B.10.4 Environment

B.10.4.1 Environmental exposure to decaBDE

DecaBDE is present almost universally in the European environment and in European wildlife, albeit in low concentrations in some species (i.e. marine mammals). DecaBDE can be found widely in sediments and sewage sludge, where it is frequently the dominant PBDE congener present. During wastewater treatment decaBDE partitions to sewage sludge, which can subsequently be incinerated, landfilled or applied to land. In recent studies the levels of decaBDE found in sludge in the EU are around 0.1 mg/kg dry weight up to a maximum of ~5 mg/kg dry weight. In air, decaBDE is principally associated with particulates and has the potential for long-range atmospheric transport during dry periods (as demonstrated by its occurrence in environmental media and wildlife in remote areas). Some studies indicate that the levels of decaBDE in the Arctic atmosphere are increasing.

DecaBDE is present in many aquatic and terrestrial species across trophic levels, including top predators and in the tissues of sensitive life stages such as bird eggs. Small amounts of decaBDE can cross the blood-brain barrier in rodents and birds. The exact exposure routes of decaBDE are not always clear, but could occur via diet, water and air as well as through ingestion of contaminated sediment or soil. Terrestrial species (especially bird-eating species) appear to have the highest levels in relative terms, i.e. Eurasian sparrowhawk and peregrine falcon.

Monitoring over the last decade has failed to demonstrate any clear decreasing trend in environmental levels (including in wildlife) indicating that the measures introduced have not affected the most significant emissions or the emissions have not been reduced sufficiently.

B.11 Summary of hazard and risk

The hazard and risk of the use of decaBDE as a flame retardant in plastics and textiles are summarised as follows:

- DecaBDE meets the definition of a PBT/vPvB substance in accordance with Annex XIII of the REACH Regulation, and thereby fulfils the criteria in Articles 57(d) and (e) of REACH.
- Emissions of decaBDE in the EU are currently estimated at 4.74 tonnes per year and are predominantly associated with the service life, rather than the production or waste stage, of plastic and textile articles.
- In addition to PBT/vPvB concerns, exposure to decaBDE and lower brominated transformation products may result in neurotoxicity in mammals, including humans.
- Exposure of decaBDE in humans (including prenatal exposure) and the environment is widespread.
- The European environmental monitoring programme established under the Existing Substances Regulation shows no recent increasing or decreasing trend in concentrations in bird eggs, sediments and sewage sludge, despite the voluntary risk management measures by industry and implementation of legislative measures.
- The widespread distribution of decaBDE in the environment and in humans creates a high potential for long-term (lifetime) exposure to decaBDE and lower brominated PBDE transformation products.

C. Available information on alternatives

C.1 Identification of potential alternative substances and techniques

The assessment of the technical and economic feasibility of alternatives to decaBDE is focused on the use of alternative **substances** (i.e. the use of chemicals that have flame retardant properties that can be substituted directly for decaBDE in articles) rather than alternative **techniques** (i.e. other means of achieving flame retardant properties in articles). The scope of the alternatives assessment was constrained on the basis that stakeholder consultation (section G) identified that the use of alternative substances was the most likely industry response should the use of decaBDE be restricted. The rationale used to limit the scope of the assessment, together with descriptions of some common alternative techniques, is elaborated in Annex C.1.1.

RPA (2014) identified almost 200 substances that could potentially be alternatives to decaBDE. A screening exercise was subsequently undertaken to shortlist the most relevant alternatives for a more detailed assessment (for details see Annex C.1.2.1). The aim of the screening exercise was to prioritise the most relevant alternatives on the basis of technical and economic feasibility, relative hazard (to decaBDE) and availability. Whilst the screening was intended to prioritise alternatives that would be most likely to be selected by industry, this does not exclude the possibility that other alternatives may also be relevant for some users. After screening, 13 alternatives were shortlisted for further assessment.

During the consultation on the Annex XV restriction report an additional alternative was identified for use mainly in for polypropylene (PP), polyethylene (PE) and Ethylene-vinyl acetate (EVA) (see also

C.2 http://paxymer.se/wp-content/uploads/2014/08/EnvironAssessPaxymer20130122.pdf). This alternative is not further assessed in the report.Assessment of shortlisted alternatives

The detailed assessment of each of the shortlisted alternatives of decaBDE is presented in Annexes C.2.1 to C.2.13 but the main elements assessed are presented here:

C.2.1 Availability of shortlisted alternatives

There is currently no information in the literature on the availability of the alternatives (RPA 2014). Therefore, market availability was assessed by checking if the substance was registered under REACH. Alternatives for which registration has been completed were considered as available, whilst those substances without a registration were not considered to be available. This assessment does not preclude that a substance without a registration may become available in the future.

C.2.2 Human Health and Environment Risks related to shortlisted alternatives

The assessment of net reduction of risk is limited to an assessment of hazard properties. This is because information on exposures associated with use of substances as an alternative to decaBDE are not available. Equally, decaBDE has PBT/vPvB properties that cannot be adequately assessed using conventional risk assessment. Conclusions on the human and environmental hazard of alternatives are summarised in Table 10. Several potential alternatives to decaBDE are currently undergoing Substance Evaluation under REACH and no definitive conclusion on their hazard profile can therefore be reached before this is completed. For some of the other alternative substances definitive hazard property information is also not available.

C.2.3 Technical and economic feasibility of shortlisted alternatives

The assessment of technical feasibility focuses on the identification of applications and materials where the substance has been reported to be used. Where an alternative is reported to have been used in a particular application it is considered to be technically feasible in these applications.

The assessment of economic feasibility comprises information on the required loading (i.e. concentration needed to achieve a certain flame retardancy requirement) and the price of alternatives. These are compared with typical concentrations and prices for decaBDE.

DecaBDE is incorporated in the plastic at a concentration of approximately 12% (RPA, 2014). This concentration rate is used for the comparison between decaBDE and alternatives, and subsequently in the substitution cost and cost-effectiveness calculations. The required concentrations of the alternative flame retardants were observed to vary significantly dependent on the application and desired level of flame retardancy performance.

DecaBDE is typically used in combination with 4% of antimony trioxide (ATO) which is used as a synergist[20]. However, this is also the case for some of the alternative substances. Therefore, this cost element is not considered in the assessment of the economic feasibility of shortlisted alternatives.

For the purposes of comparing the prices of decaBDE with alternative substances, the price of decaBDE is estimated at €4/kg, based on the information from the stakeholder consultation. The information on the prices of alternatives was either obtained from the consultation, literature or internet market places (mainly alibaba.com). It has not been possible to confirm the prices presented in the internet market places for all the substances. The substitution cost calculations and cost-effectiveness estimates (€ per kg of emission reduced) are presented in section F.2.

The conclusions on the technical and economic feasibility of alternatives to decaBDE are summarised in Table 10.

C.2.4 Conclusions on the shortlisted alternatives to decaBDE

Currently, only brominated flame retardants would appear to be able to act as drop-in replacements for decaBDE in a wide range of applications. Indeed EBP (alternative 12) is widely regarded as the substance most feasible for the industry to replace decaBDE from both a technical and an economic perspective. However, concerns related to the PBT/vPvB properties of EBP and the potential for associated risk management (i.e. identification as an SVHC) may affect the substitution strategy of companies. It is not possible to know at this stage precisely how companies will substitute decaBDE as many substances appear to be technically feasible and reasonably priced alternatives for specific uses of decaBDE. This is discussed in section F.7. Finally, it cannot be excluded that some users of decaBDE will switch to alternative techniques rather than alternative substances.

The relative risk to human health and the environment of alternatives compared to decaBDE has been assessed based on available information on hazard properties. For some alternatives, hazard property data are incomplete or uncertain. Other alternatives, notably

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[20] Many flame-retardant synergists do not have significant flame-retardant properties by themselves; however, their use increases the overall effectiveness of the flame-retardant system (US EPA, 2014).

EBP, are subject to ongoing regulatory scrutiny with regards to their hazardous properties. Therefore, for the purposes of this report, alternatives that appear to be less hazardous than decaBDE based on the available data, but with limited or incomplete hazard information or subject to ongoing regulatory scrutiny, are currently considered to offer a net reduction in risk relative to the use of decaBDE. This conclusion is subject to revision in the future should additional reliable information on the hazardous properties of alternative substances become available.

The shortlisted alternative flame retardants represent a small proportion of all potential alternatives for decaBDE. However, as they are all marketed and currently in use, it is believed that all of them (and many others that were not assessed in detail) may be used in greater volumes if decaBDE is not available. All of the short-listed alternatives can be considered affordable for the industry (as this was one of the criteria used to prioritise them). However, the available information does not allow them to be ranked, e.g. in terms of economic feasibility. In addition, there is uncertainty on required concentrations, prices and the potential R&D activities, or process changes needed, if decaBDE is replaced.

C.2.4.1 Plastics

The most prominent alternative to replace decaBDE in plastics is EBP. This is supported by several literature sources and consultation with industry and non-EU authorities (US EPA and Environment Canada, see Annex C.3.2 and RPA, 2014).

Many different polymer materials are currently flame-retarded with decaBDE. Therefore, there are opportunities for using different alternative substances, depending on the particular requirements of products (see Annex C.3.2). Some of these alternatives are potentially less hazardous than EBP and may offer a more sustainable long-term alternative to decaBDE.

C.2.4.2 Textiles

During the preparation of this report several industry stakeholders have confirmed that EBP would be the preferred alternative to decaBDE in textiles uses. This is based on its technically compatibility with existing processes and its price compared to decaBDE (RPA, 2014).

The substitution cost and cost-effectiveness calculations for textiles in Section F are based on the assumption of a full transition to EBP. Nevertheless, other alternatives may also be used, should decaBDE be restricted (see Annex C.3.2).

Table 10: Conclusion on the hazard profile of the shortlisted alternatives to decaBDE and of their technical and economic feasibility

No	Alternative substance	CAS No	Hazard profile	Technical feasibility	Economic feasibility
1	Triphenyl phosphate (TPP)	115-86-6	aq tox, neurotoxicity(?), ED(?)	Polymers only	Higher price, similar concentration
2	Magnesium hydroxide (MDH)	1309-42-8	P by default (metal)	Wide range, but inefficient	Lower price, higher concentration
3	Tris(1,3-dichloro-2-propyl) phosphate (TDCPP)	13674-87-8	Carc.cat.2, neurotoxicity(?), effects on female fertility(?), P,T	Textiles, limited range	Lower price, similar concentration
4	Aluminium trihydroxide (ATH)	21645-51-2; 8064-00-4	Insufficient information	Wide range, but inefficient	Lower price, higher concentration
5	Tetrabromobisphenol A bis (2,3-dibromopropyl ether)	21850-44-2	P, B, degradation products, CMR(?)	Mostly polymers	Lower price, similar or lower concentration
6	Ethylene bis(tetrabromophthalimide) (EBTBP)	32588-76-4	vP, B, debromination(?)	Drop-in	Higher price, same concentration
7	2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide	4090-51-1	Insufficient information	Viscose fibres only	Significantly higher price similar or lower concentration, requires more expensive raw materials
8	Resorcinol bis(diphenylphosphate) (RDP)	57583-54-7; 125997-21-9	P/vP, B(?)	Polymeric blends	Lower price, similar concentration, require changes in the production process
9	Bisphenol A bis(diphenyl phosphate) (BDP/BAPP)	5945-33-5; 181028-79-5	P(?), degradation products	Polymeric blends	Lower price, similar concentration, require notable changes in the production process
10	Substituted amine phosphate mixture (P/N intumescent systems)	66034-17-1	Acute tox., P	Polymers	Higher price, higher concentration, require changes in the production process

No	Alternative substance	CAS No	Hazard profile	Technical feasibility	Economic feasibility
11	Red phosphorous	7723-14-0	P by default (metal, hepatotoxicity(?), Aq tox 3 but test results would support Aq Chr 1	Certain polymers, cotton-rich textiles	Lower price, lower concentration
12	Ethane-1,2-bis(pentabromophenyl) (EBP)	84852-53-9	Subject to Substance Evaluation under REACH based on PBT/vPvB concern.	Drop-in	Higher price, same concentration
13	1,3,5-triazine-2,4,6-triamine (melamine)	108-78-1	No significant concerns	technically feasible*	economically feasible*

*Source: RPA (2014) and, where denoted by *, based on confidential information received from industry.*

NOTES:

i) The question mark (?) used above denotes that the hazardous property is “potential”, i.e. it cannot be considered as confirmed based on the available information.

ii) Under economic feasibility the available information on prices (€/kg) and concentrations (how much substance is needed to achieve the requested fire resistance) compared to decaBDE is summarised. In addition, potential costs, e.g. related to process changes are summarised. However, the fact that this information is not available, does not mean that these additional costs would not exist. The drop-in nature of the alternative reported under technical feasibility indicates that no significant additional costs related to adapting the process should exist. The price and concentration differences are categorised to lower, similar, and higher. The price is reported as lower or higher if the price difference is more than 10% compared to €4/kg for decaBDE. Similarly the concentration is reported lower if the required concentration is less than 7.5%, and higher, if the required concentration is higher than 20% (consultation and literature suggest concentrations of decaBDE between 7.5 – 20%)

iii) The alternative 12 (EBP) is highlighted with blue as it seems to be the most prominent alternative for industry to use.

D. Justification for action on a Union-wide basis

D.1 Considerations related to human health and environmental risks

DecaBDE is identified as an SVHC on the basis of its transformation in the environment to substances which themselves have PBT/vPvB properties. DecaBDE is widely dispersed in the environment and is found in remote regions. Humans are also exposed to decaBDE. It is used in a wide range of applications and there is a potential for release during the production of articles treated with decaBDE, and during the service life and disposal of such articles. Articles produced or imported in one Member State may be transported to and used in other Member States.

Since decaBDE has the potential for long-range transport, countries within the EU may be exposed to decaBDE emissions from other Member States, regardless of action to reduce decaBDE use within their borders. This, together with the measured levels showing widespread environmental occurrence, means that it is appropriate to consider Union-wide measures for risk reduction. This offers the most effective way to implement controls efficiently and uniformly within the EU.

D.2 Considerations related to internal market

Except for those restricted under the RoHS Directive, articles containing decaBDE are traded freely and may be used in all Member States. These products are both manufactured and imported into the EU. Norway, which has adopted the REACH Regulation as an EEA country, has adopted a national ban on decaBDE since April 2008 (see Table 8).

An EU-wide measure, such as a restriction, is preferred as it would prevent the potentially distorting effects that national risk management legislation may have on the free circulation of goods within the internal market. Similarly, regulating through an EU-wide action ensures the equitable treatment of producers and importers of decaBDE-containing articles in different Member States.

D.3 Other considerations

Having a Union-wide regulation could facilitate communication of legal requirements across all different actors. In particular, this could help with supply chains including producers of articles outside the EU and EEA.

D.4 Summary

The primary reason to act on a Union-wide basis is to effectively reduce the environmental exposure to decaBDE in the EU. DecaBDE is known to undergo long-range transport and emissions from one Member State could result in exposure in another, regardless of efforts of that Member State to reduce exposures within their own borders (i.e. through national legislation). Action on a Union-wide basis would limit the potential for trans-boundary exposure to decaBDE from EU sources, both within and outside the EU.

In addition, the fact that goods need to circulate freely within the EU stresses the importance of EU-wide action rather than action by individual Member States. Currently Norway (EEA) has a national restriction on decaBDE (see Table 8).

E. Justification why the proposed restriction is the most appropriate Union-wide measure

E.1 Identification and description of potential risk management options

E.1.1 Risk to be addressed – the baseline

DecaBDE is very persistent, is detected in many environmental compartments and will, with high probability, transform to form substances with PBT/vPvB properties. In addition to PBT/vPvB concerns, exposure to decaBDE or lower debrominated congeners may result in neurotoxicity in mammals, including humans. Exposure of decaBDE in humans, the environment and wildlife is widespread and shows no decreasing trend, despite the adoption of legislative (e.g. RoHS) and voluntary risk management measures by industry (i.e. the VECAP initiative). Finally, the widespread distribution of decaBDE in the environment, wildlife and in humans creates a high potential for long-term (lifetime) exposure to decaBDE and lower brominated PBDE transformation products.

Currently, decaBDE is only imported in the EU as a substance, in mixtures, and in articles (see section B.2). The imported quantities were recently reduced due to regulatory developments (inclusion in the Candidate List in December 2012, the proposal from Norway for inclusion in the Stockholm Convention for POPs and subsequent inclusion in the registry of intentions for preparing an Annex XV restriction proposal). Also earlier developments outside of the EU, notably the voluntary phase out agreed by industry in the US, have had an effect. However, our information suggests that manufacturing will continue elsewhere (China, Japan, see Annex B.2.1.5). This effectively means that decaBDE will still be available in the world market, despite the North American phase out.

Without an EU restriction some of the importers or users of decaBDE who have switched to an alternative in response to these regulatory developments (or who are currently considering a switch to an alternative) might consider switching back to (or staying with) decaBDE. This decision will depend on the cost of decaBDE relative to the cost of alternatives and on any related investment costs, e.g. infrastructure needed for switching between different flame retardants (if relevant). DecaBDE is currently less expensive than the alternatives assessed (see section C). However, this difference in cost might gradually change in response to the increasing demand for alternatives. Any return to the use of decaBDE would also depend on the regulatory status of the main alternatives (notably EBP).

Given the above, there is no compelling justification to assume a decreasing or increasing trend in the use of decaBDE in the absence of a restriction. In the baseline it is therefore assumed that imported quantities of decaBDE in the future will remain at the level reported for 2014, i.e. at 4000 tonnes per year (Figure 3). In addition, it is assumed that 400 tonnes of decaBDE is imported to the EU in articles.

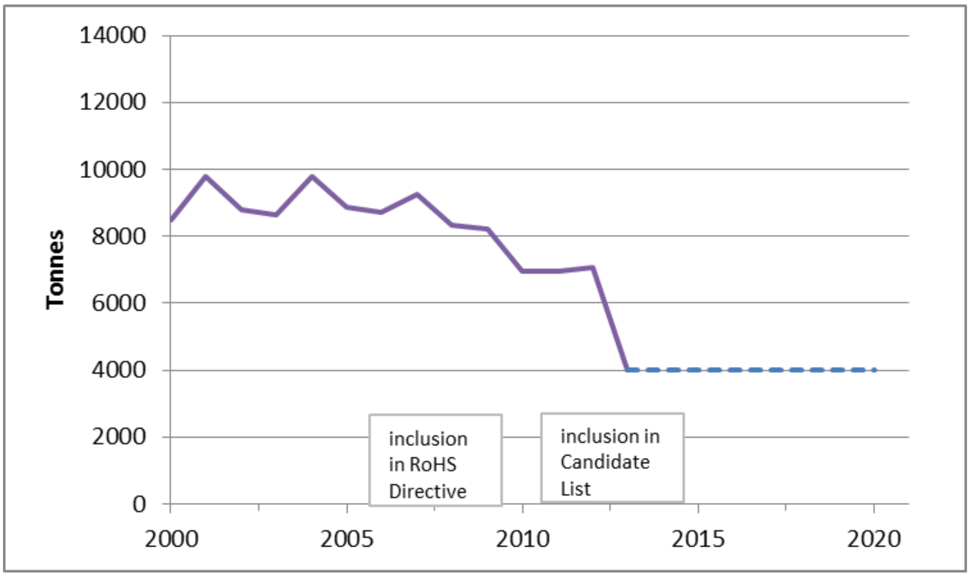

Figure 3: EU consumption of decaBDE – the baseline
Source: 2000 – 2012 values are calculated from average consumption data from Eurostat (2013, as cited in RPA, 2014), VECAP (2012) and BSEF (Bromine Science and Environmental Forum) as cited in Earnshaw et al. (2013) (see Figure 1).

E.1.2 Options for restrictions

A set of restriction options was developed based on the information on emissions and substitution costs presented in section F.2 (Table 12). Several of the candidate restriction options were structured according to the type of material that decaBDE is used in (plastics or textiles) and where manufactured articles are used (indoors or outdoors)[21]. A further set of candidate restriction options focussed simply on the life-cycle stage of decaBDE use, i.e. production, service-life or waste, with no consideration of article type (for a detailed analysis of all candidate restriction options see Annex E).

The restriction options were assessed in terms of their potential to reduce emissions (effectiveness) and their cost-effectiveness. It was concluded that a targeted restriction in either the indoor or outdoor compartments (focusing on plastics or textiles materials) would not completely remove emissions. In addition, a targeted restriction on e.g. outdoor uses alone would be very difficult to enforce. Therefore, a restriction combining both outdoor and indoor uses would appear to be an appropriate way to solve the problem.

A restriction on either the production life cycle stage or article use would be unlikely to result in sufficient emissions reduction, whilst also resulting in significant uncertainty in terms of likely consequences, both for emissions in the EU and for the global risk of decaBDE.

In conclusion, from an effectiveness perspective a restriction of the manufacture and use of both plastics and textile articles for both indoor and outdoor uses is considered as the most appropriate restriction option, and will be assessed further in section E.2.

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[21] This is a consequence of how the emission estimations and subsequent cost calculations were made (see sections B.8.2 and F.2).

E.1.3 Other Union-wide risk management options than restriction

E.1.3.1 Waste management

Given its effectiveness in abating decaBDE emissions (zero emissions assumed in the low emission scenario) a mandatory destruction (incineration) scheme could be considered as a risk management option for the waste life-stage. However, this option is not currently considered to be feasible because of the implementation challenges associated with harmonising waste management practices across the EU and the identification of the plastic and textile articles that contain decaBDE[22]. For more details see Annex E.

E.1.3.2 Authorisation

DecaBDE was identified by ECHA for prioritisation to Annex XIV of REACH (substances subject to Authorisation) in its 5th draft recommendation. However, in response to the proposal of Norway to add decaBDE to the Stockholm Convention on persistent organic pollutants the European Commission requested ECHA to prepare a complementary Annex XV restriction proposal for decaBDE. Based on this request, and to avoid potential regulatory uncertainty, ECHA did not include decaBDE in its 5th draft recommendation for inclusion in Annex XIV[23]. This risk management option is therefore out of the scope of the present assessment.

E.1.3.3 POP regulation

Regulation (EC) 850/2004 (the POP regulation) implements the Stockholm Convention on POPs in the EU. The proposal by Norway to include decaBDE in the Stockholm Convention is still under scrutiny and will be decided by the Conference of the parties in 2017. This means that the REACH restriction process will finalise earlier and the conclusions can be used to inform the Stockholm Convention process. If a substance is listed in the Stockholm Convention on POPs the practice is to implement this in the EU law by amending the POP regulation and by removing the corresponding restriction from Annex XVII of REACH.

E.1.4 Other Considerations

E.1.4.1 Manufacturing of decaBDE

DecaBDE is currently not manufactured in the EU. Consequently, the part of the restriction proposal restricting manufacturing of decaBDE in the EU yields no cost (or impact). Including this in the restriction is to prevent any future manufacturing of the substance in the EU.

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[22] An amendment to the POP Regulation (Regulation (EC) No 850/2004) requiring mandatory destruction of wastes where the sum of the concentrations of tetrabromodiphenyl ether, pentabromodiphenyl ether, hexabromodiphenyl ether and heptabromodiphenyl ether is greater or equal to 1 000 mg/kg (0.1 %) has recently been voted for, but is currently undergoing scrutiny prior to adoption. It is envisaged that the implications of this amendment, if adopted, on the risk management options appraisal for decaBDE will be reappraised after the submission of the report i.e. during opinion development

[23] http://echa.europa.eu/documents/10162/eaa1b117-d017-4446-bb3b-5497bd1c478a

E.1.4.2 Recycling

On average, approximately 20% of plastic waste is recycled in the EU every year. For textiles flame retarded with decaBDE, it was assumed that no (or very limited) recycling takes place (see Annex B.8.2.4). DecaBDE in plastics can be recycled many times with minimal loss of substance, i.e. articles currently on the market can be used to produce new flame retarded articles accompanied by emissions during their life-cycle (production, service life and waste). However, due to lack of information, the potential emissions from these recycled articles have not been estimated.

The proposed restriction should not negatively affect recycling activities[24] (reasons to promote recycling include the cost to replace recycled plastics with virgin material, including the additional environmental burden created by production of virgin materials). In section E.2.1.2.2, a concentration limit is proposed to enhance the enforceability of the restriction. This limit should be high enough to ensure that articles made from recycling can still be placed on the market (i.e. recycling activities will not be impaired). For more details see the document "Assessment of the need for a specific derogation for recycling" drafted by ECHA to aid the discussions in the Committees (Annex E.1.1.1).

E.1.4.3 Second hand market

The second hand market is relevant for several articles that are flame retarded with decaBDE. However, unlike articles placed on the market for the first time, the actors involved in the second hand market do not usually have the means to identify if an article contains decaBDE. In addition, a restriction on second hand market goods would be very difficult to enforce. It is thus considered disproportionate to include second hand market goods in the scope of the restriction. Therefore, the following derogation is proposed for articles placed on the second-hand market:

By way of derogation, the Restriction shall not apply to articles that were in use in the Community before [date of entry into force]

E.1.4.4 Derogation for the aviation sector

During consultation, comments were received from the aviation industry highlighting that the replacement would be difficult for products used in aircrafts that are currently in service, or will be manufactured in the future based on an existing type certificate. This is mainly because of the costs related to the certification process, and the complexity in the supply chain[25]. This does not mean that the available alternatives would not be technically feasible. Some aircrafts need certified parts, which might contain decaBDE, and before the new material or design change can be introduced on the aircraft, all test and compliance demonstrations have to be successfully completed and approved. This approval results in the issuance of a Supplemental Type Certificate (STC), change approval or repair approval. For these reasons, it is proposed to include in the restriction a derogation for aviation, when decaBDE is used based on a type certificate, that is issued before the restriction enters into force. The derogation will not apply to new type certificates (issued after the restriction

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[24] The Stockholm Convention contains provisions to allow recycling of articles that contain the listed PBDEs, provided this will not lead to recovery and re-use of the substance.
http://chm.pops.int/TheConvention/Overview/TextoftheConvention/tabid/2232/Default.aspx

[25] http://www.echa.europa.eu/documents/10162/13552/aviation_authorisation_final_en.pdf

enters into force). Consequently, substitution would need to take place when manufacturers are planning new aircrafts. According to information received in the call for evidence, this should be possible with the proposed transitional period of 18 months (see section E.1.4.6).

After consultation with the European Aviation Safety Agency (EASA), the following derogation is proposed for uses in the aviation industry:

"By way of derogation the Restriction shall not apply to the production, maintenance, repair or modification of any aircraft or component eligible for installation:

- *produced in accordance with a type certificate or restricted type certificate, issued under Regulation (EU)216/2008, provided the application for such certificate was done before [date of entry into force], or*
- *produced in accordance with a design approval issued under the national regulations of an ICAO contracting State, provided the application for such approval was done before [date of entry into force], or*
- *for which an ICAO contracting State has issued a Certificate of Airworthiness under the provisions of Annex 8 of the Chicago Convention, provided that such State issued the first Certificate of Airworthiness for an aircraft of the same aircraft type before [date of entry into force]"*

In this case, it could be challenging to define a time limitation for allowing existing type certificates to be applied. However, it is not considered necessary or helpful as the derogation is time limited by its very nature. Over time the old type certificates will not be used anymore. Finally, it needs to be ensured that derogated articles are available to their end users. This means that production (in the EU) or imports (from outside the EU) and placing on the market of derogated articles should be allowed under the restriction. This derogation should include the potential manufacturing and import of the substance itself, to be used for the production of the derogated articles.

According to information from the public consultation, the use of decaBDE in the aviation sector (derogated use), in the EU, is estimated at significantly less than 10 tonnes per year.

E.1.4.5 Interface with RoHS

As mentioned in Table 8 decaBDE is included in the restricted substances list and not allowed in quantities higher than 0.1% w/w (weight of homogeneous material). In order to avoid double regulation it is proposed that a derogation be included for the uses that are within the scope of the RoHS Directive.

"By way of derogation the Restriction shall not apply to electrical and electronic equipment within the scope of Directive 2011/65/EU"

However, some categories of Electrical and Electronic Equipment which are not in the scope of the RoHS regulation (RoHS article 2), fall into the scope of the proposed restriction (see Table 8). To note that there are currently no applications concerning decaBDE which are exempted in RoHS (exempted applications are listed in Annex III of the RoHS Directive).

E.1.4.6 Transitional period

- To allow enough time for producers and importers (including importers of articles) to sell their existing stocks and reducing the compliance costs, a transitional period of 18 months after entry into force is proposed.

E.2 Assessment of risk management options

E.2.1 Restriction option

An overall restriction on manufacturing, use and placing on the market of decaBDE and of mixtures and articles containing decaBDE is proposed. The proposed restriction incorporates the considerations on manufacturing, recycling, second-hand market, aviation sector and RoHS Directive, presented in the previous sections.

E.2.1.1 Effectiveness

E.2.1.1.1 Risk reduction capacity

The proposed restriction will eliminate nearly all the emissions and related exposures to decaBDE of both humans and the environment[26], although the restriction will not affect the stock of decaBDE-containing products in the EU. The abated emissions are used as a proxy of the risk reduction. For the reasons provided in section B and F, no quantified risk assessment and impact assessment has been carried out. Although it is expected that overall, substitution with available alternatives will reduce risks, it should be noted that the most probable alternative, EBP, is under substance evaluation.

E.2.1.1.1.1 Changes in human health risks

Human health risks are reduced but no quantified risk assessment is carried out.

E.2.1.1.1.2 Changes in the environmental risks

Environmental risks are reduced but no quantified risk assessment is carried out.

E.2.1.1.1.3 Other issues – timescale of emissions' occurence

E.2.1.1.2 The emissions of decaBDE include emissions from the production and subsequent service life and waste lifecycle steps of articles that are placed on the market in a given year (e.g. 2014). Emissions from article production occur during the same year of the production. Emissions from article service life occur over 10 years. Finally, emissions from waste in landfills occur for 30 years from the assumed end of the service life. Costs

The proposed restriction is technically and economically feasible. Technically feasible alternatives are available for existing uses of decaBDE at low additional cost. Table 11 shows the substitution costs and the cost-effectiveness of the proposed restriction.

Table 11: Substitution cost and cost effectiveness of restricting decaBDE in the EU

Substitution costs (M€/year)	2.2
Cost-effectiveness (€/kg)	464

Source: Section F.2

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[26] Although it has not been possible to estimate tonnage and related emissions linked to the use in aviation, it is expected that these emissions are small.

E.2.1.1.3 Proportionality

The cost-effectiveness of the proposed restriction option is estimated to be €464 per kg of decaBDE emission reduced.
The cost-effectiveness of the proposed restriction for decaBDE is in the same order of magnitude (or lower) as previous restrictions under REACH on mercury and its compounds (i.e. phenylmercury), which has some similar environmental properties (see section F.1). However, the comparision of cost-effectivness between decaBDE and mercury compounds is not straightforward as their individual circumstances (i.e. hazard potential / exposure in the environment), are not directly comparable. This precludes the use of the cost-effectiveness of previous restrictions as a benchmark of acceptable cost-effectiveness. However, this information remains relevant to a discussion on proportionality and is included as supporting information.

In addition, the results of a recent study looking at the valuation of precautionary control of DecaBDE (Yun, 2013) provide some indications regarding the proportionality of the proposed restriction (along with the other evidence provided in the section). Although the results of the study are not directly applicable to the proposed restriction, the study indicates a clear and potentially substantial willingness-to-pay amongst the general public for precautionary reductions in environmental accumulation and human health concerns for DecaBDE (see Annex F.1.2).

Therefore, taking into account:

- the availability of alternatives (C.2.4),
- the risks to be addressed (E.1.1), and
- the cost-effectiveness of the proposed restriction (Table 11)
- the indicative willingness to pay amongst the general public

the risk reduction achieved by the proposed restriction is considered proportionate to the costs. The cost-effectivness is in the same order of magnitude or lower than previous restrictions for PBT-like substances under REACH.

E.2.1.2 Practicality

E.2.1.2.1 Implementability and manageability

As discussed in section E.1.1 an important portion of the market has already phased out decaBDE. In addition, alternative substances are available for all uses. The implementation of the proposed restriction (by switching to alternative substances or techniques) is clear and understandable to all actors involved. In consequence, this restriction is implementable and manageable.

E.2.1.2.2 Enforceability

Enforcement activities should cover the import of decaBDE as such, in mixtures and in articles, and the production of articles in the EU. However, production of articles for the aviation sector, a use proposed for derogation, should continue. Therefore, import of decaBDE as such, in mixtures or in articles, or the production of articles in the EU (and subsequent placing on the market) should be permitted only if the final article is used according to the terms of the derogation proposed for the aviation sector.

For other articles placed on the market (i.e. except for derogated articles), enforcement authorities could check documentation from the supply chain confirming that the articles do not contain decaBDE. In addition, it can be envisaged to verify if the articles contain decaBDE by testing. Currently, 0.1% w/w is the limit that triggers the notification requirement under article 7(2)[27] of REACH and the information requirement under article 33 of REACH. This limit also applies to recycled articles. Finally, the same limit of 0.1% w/w is applied for PBDEs, including decaBDE, under the RoHS Directive (see Table 8). To enhance the enforceability of the restriction a concentration limit of 0.1% w/w is proposed.

Although no uses in mixtures were identified during consultation (except some very limited information on e.g. inks and coatings), the same limit of 0.1 % w/w is proposed also for mixtures. This is in line with previous restrictions on brominated flame retardants (see entry no 45. Diphenylether, octabromo derivative, of Annex XVII of REACH).

The proposed limit will ensure that decaBDE is not intentionally added to products since concentrations below this limit will not ensure flame retardancy. This is because decaBDE is used in much higher quantities to be effective. The range of reported concentrations is between 7.5 and 20% depending on the application (see section C.2). Finally, there is no information on any products that would contain decaBDE as impurity in concentrations higher than 0.1%, meaning that the restriction will not inadvertently affect any products into which decaBDE is not intentionally added.

Analytical methods, including sampling and preparation methods, to verify the concentrations exist and are well established (Danish EPA, 2014; IVM, 2013):

- X-ray fluorescence (XRF) screening (LOD 0.002% for Br)
- Gas chromatography mass spectrometry (GCMS) screening (LOD 0.00001%)
- GCMS Quantitative analysis

The limits of detection of the analytical techniques mentioned above are well below the concentration limit proposed in the restriction entry. In addition, the following measured concentrations have been reported:

- Danish EPA, 2014: the lowest measured concentration for Bromine by XRF is 0.0024 %

- IVM, 2013: very low measured concentrations are reported for decaBDE by Gas Chromatography, as low as 0.01 µg/g (0.000001%)

These concentrations are lower than the concentration limit proposed in the restriction entry, meaning that even if a LOQ is not formally reported it is shown that the analytical methods can measure concentrations lower than the restriction entry limit. In addition, techniques which have higher detection limits (0.025 % w/w), but which are considered more easy to use are available in the market. These methods can be applied also to recycled materials (IVM, 2013). In conclusion, the available techniques are sensitive enough to produce reliable analytical results for all relevant matrices to enable compliance monitoring and enforcement[28].

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[27] An additional requirement is that the substance is present in the articles in quantities totalling over 1 tonne per producer or importer per year.

[28] Some information on testing costs was collected by the RAC rapporteurs for a testing laboratory in DK: with a detection limit of 0.1% (the proposed limit) the price for a single test (replicate, 2 measurements of the same sample) is in the order of 650 €. If several articles are measured at the same time, the price drops to 400 €.

Regulation (EU) No 757/2010 that implements the Stockholm Convention on POPs in the EU for the listed PBDEs (tetra- to hepta- BDEs), sets a lower concentration limit (0.001 % w/w). However, for articles and mixtures made of recycled materials the concentration limit is 0.1 % w/w. A single, fit-for-purpose, concentration limit is considered as enhancing the enforceability of the proposed restriction. As mentioned above, the limit will ensure that decaBDE is not intentionally added to the products and consequently a lower limit would not increase the risk reduction capacity.

E.2.1.3 Monitorability

The monitoring of the restriction will be done through enforcement. No additional monitoring is envisaged.

E.2.1.4 Overall assessment of the restriction option

The assessed restriction fulfils all the criteria used in the assessment of the risk management options. The restriction would address the risk from the uses of concern. It is furthermore considered proportionate to the risks considering the costs to the society, as well as implementable and enforceable.

E.3 Comparison of the risk management options

Not relevant, based on the conclusions of the preliminary screening (section E.1.2) only one risk management option is put forward as the most appropriate.

E.4 Main assumptions used and decisions made during analysis

For the emission estimates see section B.8.2 and Annex B. For the substitution costs and cost-effectiveness estimates see sections F.2 and F.7.

E.5 The proposed restriction(s) and summary of the justifications

Several restriction options were assessed based on their contribution to total emissions reduction and their cost-effectiveness (see section E.1.2 and Annex E). Based on the analysis it was concluded that a general restriction, combining all the sub-options is the most appropriate restriction option. This option was further assessed as to its effectiveness, practicality and monitorability and was found to satisfy these criteria. Another risk management option based on waste management was also assessed but was not put forward for the detailed assessment. Finally, considerations related to the manufacture, recycling, second hand market, aviation sector and the RoHS regulation were presented. The conclusions reached are reflected in the proposed restriction.

In conclusion:

A restriction is considered the most appropriate risk management option to manage exposure and risks from the use of decaBDE in the EU.

A proposal for an Annex XVII entry is given in section A.1.2.

F. Socio-economic Assessment of Proposed Restriction

F.1 Human health and environmental impacts

The human health and environmental impact analysis in this report stems from the fact that decaBDE is a PBT/vPvB substance. In addition, the human health and environmental exposure information has been described in sections B.9.2 and B.9.3, leading to the conclusion that exposure to decaBDE is a cause for concern.

Instead of quantification and valuation of human health and environmental impacts, information on emissions is provided to aid the assessment of proportionality. The results are presented as cost of reducing a kg of decaBDE released to describe the cost-effectiveness of the proposed restriction (for more details see Annexes B and F).

To assess the proportionality of the estimated cost-effectiveness estimates, it would be desirable to have a comparator. This comparator can be a "benchmark" or a range of "benchmarks" on the level of costs and could be based e.g. on:

- studies on abatement or avoidance costs for PBTs and vPvBs, including information on the cost of past regulations,
- data on remediation or clean-up costs for PBTs and vPvBs, and
- economic valuation studies on benefits of reducing emissions from PBTs and vPvBs.

Annex F presents this type of information on another PBT substance (PCB) and PBT-like substance (mercury), and discusses the limitations in using it for the assessment of the proportionality of this case. However, even if it is not straight forward to establish benchmarks for acceptable level of costs with this information, they can be used to support the assessment of the proportionality. Especially the information on the cost-effectiveness of restrictions on mercury in measuring devices and phenylmercury compounds is considered relevant, as it indicates the level of costs for a PBT-like substance that has been considered acceptable in the context of REACH (see Box 1). This does not exclude the possibility that even higher cost-effectiveness estimates could be considered proportionate. The cost-effectiveness of the mercury in measuring devices restriction was estimated to be €4,100 per kg of mercury used (ECHA, 2011a, see Annex F.1). The estimates varied between the measuring devices from €0/kg to €19,200/kg. For phenylmercury compounds, the estimated cost-effectiveness was €649/kg mercury emitted (ECHA, 2011b, see Annex F.1). This is more cost-effective than the measuring devices restriction considering the fact that the figure is for a kg emitted, not used. In this restriction report, the cost-effectiveness estimates are also for a kg of decaBDE emitted. The estimated cost of € 464/kg of decaBDE emission reduced is in the same order of magnitude (see section F.2 and Annex F for details on the calculation).

Both **mercury** and **phenyl mercury** were restricted under REACH in 2012 under Commission Regulation (EU) No 847/2012 of 19 September 2012 (mercury) and Commission Regulation (EU) No 848/2012 of 19 September 2012 (phenylmercury compounds). These regulations make it clear in their recitals that both mercury and phenylmercury compounds have an equivalent level of concern to persistent, bioaccumulative and toxic substances (PBTs), in the case of phenylmercury because of its degradation products (in a similar way to decaBDE):

- (Regulation 847/2012 recital 4): …**Mercury** and its degradation products, mainly methylmercury, present an equivalent level of concern to persistent, bioaccumulative and toxic substances (PBTs) and have long range transport properties.

- (Regulation 848/2012 recital 8): ….the **phenylmercury compounds** are degraded in the environment and give degradation products, including methylmercury, with equivalent level of concern to persistent, bioaccumulative and toxic substances (PBTs). The interconversion of metabolites of phenylmercury compounds allows for long range transport properties. Therefore as transformation/degradation products with PBT-properties are being generated, the phenylmercury compounds themselves must be treated like PBT substances with regard to emission and exposure control. To this end, the exposures and emissions to humans and the environment should be minimised as much as possible.

Box 1: Mercury and phenylmercury compounds used as comparators for decaBDE

F.1.1 Damage potential in humans and in the environment

Annex 3 of the SEAC approach on the "Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC" describes some of the relevant factors that may contribute to the overall "damage potential" of PBTs in humans and the environment (ECHA, 2014). The relevant factors for decaBDE are described below.

Long range transport potential and findings in remote areas. DecaBDE is associated mainly with particulates in the atmosphere and some modelling studies suggest that it will have a limited potential for long-range atmospheric transport because of rapid removal during wet deposition. However, the available literature reports that it can be transported over longer distances, particularly during dry periods (see section B.4)).

DecaBDE is found in remote regions at low concentrations in air, sediment and wildlife (including in top predators, such as seals, birds and polar bear). Local sources might be involved in some cases, but, occurrence in lake sediment cores far from human habitation and detection in the air at remote locations suggests that long range transport is occurring. Levels of decaBDE in the Arctic atmosphere are increasing.

Affected compartments. DecaBDE is widely detected in the European environment, residing mainly in sediments and soils at concentrations up to several milligrams per kilogram (parts per million) on a dry weight basis. DecaBDE has shown in many studies to be the most abundant PBDE congener in sediments, sewage sludge, soil, dust and air (See section B.9).

Exposure of organisms. DecaBDE is present in many types of aquatic and terrestrial wildlife species (including the eggs of predatory birds) at numerous geographical locations. Although tissue concentrations are often low (close to the limits of analytical detection, or below), decaBDE can attain concentrations up to a few hundred micrograms per kilogram (parts per billion) on a wet weight basis in some top predators.

Human exposure. DecaBDE is less readily absorbed into human and animal tissues, in particular in fat tissues, than lower brominated BDEs. However, there is evidence of considerable binding of decaBDE to proteins and decaBDE may be more likely to accumulate in blood-rich tissues and body fluids. DecaBDE is frequently detected in human matrices, demonstrating that humans are extensively exposed to deca-BDE. Inhaled and ingested dust is probably a major route of human exposure, together with ingestion of food, while direct dermal contact may also play a role (Fredriksen et al. 2009). In particular, the predominance of decaBDE in house dust may be a major exposure route for small children. The developing foetus and infant will also be exposed through placenta and via mother's milk.

Environmental trends. Monitoring data fails to show any clear decreasing trend in levels over the last decade, despite the measures already introduced (industry voluntary emission reduction programme (since 2004) and the restrictions in RoHS on decaBDE in EEE (since

2008)). This indicates that the measures introduced either do not affect the most significant emissions from the decaBDE lifecycle or the measures have not reduced emissions. Some studies indicate that the levels of decaBDE in the Arctic atmosphere are increasing.

Stock in society. DecaBDE is present in a large variety of articles, with a potential to accumulate in society depending on the service life of the article. Use of decaBDE started as early as 1970 and the consumption in the EU in the period 1991-2010 is estimated at 150 Ktonnes (Earnshaw et al., 2013). Emissions from legacy articles constitute an additional, non quantified (in this report), but important source of release and exposure.

Timescale of emissions' occurrence: The emissions of decaBDE include emissions from the production and subsequent service life and waste lifecycle steps of articles that are placed on the market in a given year (e.g. 2014). Emissions from article production occur during the same year of the production. Emissions from article service life occur over 10 years. Finally, emissions from waste in landfills occur for 30 years from the assumed end of the service life (see section B.8.2.3).

Transformation to lower brominated PBDEs: As discussed in Part B, during dry periods decaBDE may reside in the *atmosphere* on fine particulates for days. Phototransformation to several per cent nonaBDEs can be expected under such conditions. These will ultimately be deposited to sediments and soils. Small amounts of other substances such as octa- and heptaBDEs might also be formed in some circumstances.

In *aquatic environments*, decaBDE has the potential to photodegrade relatively quickly, and nona-, octa-, hepta- and hexaBDE congeners have been observed to be formed in freshly spiked sediment following exposure to light over 96 hours under laboratory conditions.

However, only a very small fraction of the total decaBDE present in *aquatic environments* will be available for photodegradation (due to light attenuation, shielding, etc.). Photolysis in sediments might therefore not be an important mechanism in the environment. A similar conclusion can be drawn for *soil*. Reaction with reductants (e.g. iron-bearing minerals and sulphide ions, etc., some of which may be water-soluble) present in anaerobic conditions in both sediments and soils is a possible additional abiotic transformation route, but it is not possible to estimate the extent or rate of any transformation based on the available data.

Degradation under environmentally realistic conditions in sediments and in aerobic soil in the presence of plants have both been shown to lead to the formation of tetra- to heptaBDE congeners (as well as octa- and nonaBDEs). There is strong evidence that hexa- and heptaBDE congeners can be formed in the environment in sediments and soils. There is also evidence that decaBDE transforms (i.e. is metalbolised) to lower brominated PBDEs after it has been accumulated in biota e.g plants and animals. These findings are supported by a range of other laboratory studies, and also monitoring data, although the interpretation of data is not always straight forward (see B.4 for a detailed discussion).

In conclusion, it is well demonstrated that emissions of decaBDE will lead to exposure to the environment and humans to decaBDE as well as to lower brominated PBDEs. However, uncertainty remains regarding the rate of formation of such compounds, which will to a high degree depend on environmental conditions. Nevertheless, it is appropriate to consider the effects related to PBDEs as a group in the present restriction proposal (see section B.9.4).

Transformation to other degradation products: The PBT properties of lower brominated PBDE congeners underpinned the classification of decaBDE as a PBT substance. However, other decaBDE breakdown products, such as hydroxyl and methoxy PBDEs, may have PBT profiles that are of concern, or other adverse toxicity profiles e.g. PBDFs (furans), which have been identified in fish and other biota as a result of metabolism (see section B.9.4).

Neurotoxicity: In addition to PBT/vPvB concerns, exposure to decaBDE and lower brominated transformation products may result in neurotoxicity in mammals, including humans (see section B.5.2.1).

F.2 Economic impacts

The available information to estimate substitution costs is limited. Some information is available on the prices and concentrations of the flame retardants. However, quantified information on possible R&D activities and investments costs is often missing. This limits the possibilities for the substitution costs calculations for most of the alternative substances discussed in Section C.

The economic impact assessment for textiles focuses on EBP, which, as discussed in Section C, is assumed to be the primary replacement for decaBDE, especially in textiles. The available information supports the assumption that EBP is a drop-in substitute for decaBDE allowing cost calculation simply based on prices and concentration, excluding R&D and potential changes in the process.

Also in plastics, EBP seems to be the most prominent alternative for industry to use. However, there are reasons to assume more variety in the substitution strategy of the users of decaBDE. The large variety of polymer materials provides more opportunities for using different alternative substances, depending on the substrate and the particular needs of products. Because of this, and the fact that for plastics information on the prices of the polymers is available, a supplementary approach is adopted in Annex F.2 to estimate the substitution costs for plastics.

To calculate the substitution costs and cost-effectiveness, it is assumed that the entire consumption of decaBDE would be replaced by EBP both in textiles and plastics. This appears to be the most `convenient' alternative as it does not require alteration of formulations and it is not much more expensive than decaBDE. For the purposes of the calculation of substitution costs, the price of decaBDE is estimated at €4/kg and the price of EBP at €4.5/kg. In other words, EBP is estimated to be €0.5/kg (12%) more expensive than decaBDE.

As described in section E.1.1, it is not possible to confirm any trend in the future emissions of decaBDE without the restriction. Consequently, these results are representative for all the years after the entry into force of the proposed restriction. Table 12 and Table 13 summarise the annual compliance costs and cost-effectiveness estimates, and the related assumptions on the tonnages used and emitted. The substitution costs and cost-effectiveness estimates are presented also individually for different application areas, and the emissions for different lifecycle stages.

The annual compliance costs are estimated to be €2.2 million. The cost-effectiveness estimates vary between different applications from €30 per kg (outdoor textiles) to €770 per kg (indoor plastics). The reasons for this are the significantly higher emission factors for outdoor applications compared to indoors. On average, the cost of reducing one kg of decaBDE is estimated to be €464 per kg.

Table 12: Substitution costs estimates

	Textiles		**Plastics**		**Total**		
	Indoor	**Outdoor**	**Indoor**	**Outdoor**	**Textiles**	**Plastics**	**All**
Imported as substance (t/year)	1976	104	1918	2	2080	1920	**4000**
Imported in articles (t/year)	198	10	192	0	208	192	**400**
Total amount (t/year)	2174	114	2110	2	2288	2112	**4400**
Cost difference between decaBDE and EBP (€/kg)	**0.5**						
Substitution costs (€/year)	1 086 800	57 200	1 054 944	1 056	1 144 000	1 056 000	**2 200 000**

Source: Annex B,

	Plastics		**Textiles**	
	air	water	air	water
EF Handling	0	6.0E-05	0	6.0E-05
EF Compounding	1.0E-07	5.1E-06		
EF Conversion	5.0E-07	5.0E-07		
EF Finishing			4.1E-05	1.0E-04
Total EF	6.0E-07	6.6E-05	4.1E-05	1.6E-04
RMM efficiency	99%			
Imported tonnage (tonnes)	4000			
Fraction in plastics	48%	48%		
Fraction in textiles			52%	52%

Emissions (t)	0.00	0.13	0.09	0.33
Emissions (%)	0%	23%	16%	61%

Source: derived from RPA, 2014

Table 51*: Assumptions on emission calculations*
Note: Substitution costs = Cost difference between decaBDE and EBP x Total amount

Table 13: Costs-effectiveness estimates

	Textiles		**Plastics**		**Total**		
	Indoor	**Outdoor**	**Indoor**	**Outdoor**	**Textiles**	**Plastics**	**All**
Emitted from production (t/year)	0.15	0.01	0.15	0.00	0.16	0.15	**0.31**
Emitted article service life (t/year)	1.14	1.89	1.08	0.03	3.03	1.12	**4.15**
Emitted from waste (t/year)	0.14	0.01	0.14	0.00	0.15	0.14	**0.28**
Total emitted in lifecycle (t/year)	1.44	1.90	1.37	0.04	3.34	1.40	**4.74**
Total emission factor	0.07%	1.66%	0.06%	1.66%	0.15%	0.07%	0.11%
Cost effectiveness (€/kg)	756	30	773	30	342	754	**464**

Source: Table 12 and Annex B, Table 49: Detailed emission calculations
Note: Cost effectiveness = Substitution costs / Total emitted in lifecycle

F.3 Social impacts

Restricting the placing on the market of decaBDE may affect the employment in companies manufacturing decaBDE. This depends on whether they produce also the alternatives substituting decaBDE. However, as decaBDE is not currently manufactured in the EU, these impacts would occur outside the EU.

The restriction would impact also the importers of decaBDE. Currently five companies have registered to import decaBDE. However, these companies import also other substances, including alternatives to decaBDE. Importers of decaBDE-containing articles can also be assumed to continue importing articles with alternative flame retardants.

The capability to switch to alternatives may differ between users of decaBDE. However, there are no reasons to assume differences in the labour inputs required in the production of decaBDE or alternative-based articles and products, and the negative impact to employment in one company (if any) should mainly be offset by positive impacts in other companies. In other words, the impacts on employment are mainly distributional and not a cost to the society as such. However, the redeployment of staff always includes some adjustment costs, e.g. related to temporary unemployment of workers when finding new jobs, although it is difficult to place a figure on these adjustment costs in practice. In summary, no social impacts are estimated to take place as a result of the proposed restriction.

F.4 Wider economic impacts

As the estimated compliance costs are small, the proposed restriction should not lead to wider economic impacts.

F.5 Distributional impacts

The proposed restriction is expected to have limited impact on different actors in the supply chain including importers of decaBDE and decaBDE-containing articles. The distributional impacts are not societal costs as such, as the negative impacts (if any) faced e.g. by one producer of decaBDE based article would be compensated by impacts on the producers of the products based on alternative flame retardants.

There is not much information available on whether the affected companies are SMEs or not. According to RPA (2014) many backcoating finishers would be SMEs. Even if the companies would be SMEs, it seems reasonable to assume that they would be able to switch to the alternatives, if decaBDE is not available anymore.

According to RPA (2014), 50% of decaBDE in textiles is placed on the market in the UK due to most stringent fire safety requirements and 50% in the rest of the Europe. For plastics, there are no reasons to assume any differences in the consumption of decaBDE between the EU Member States. Consequently, both costs and benefits related to the restriction would be concentrated in the UK.

F.6 Main assumptions used and decisions made during analysis

As described in F.1, the emissions are used as a proxy for the benefits. The assumptions made on the estimation of the emissions are described in detail in Annex B.8.2.

The information on prices of decaBDE and EBP (as well as other alternatives reported in

Section C) are reported by RPA (2014), and derived from online market places for suppliers of chemicals (e.g. Alibaba.com). In these market places each substance may be supplied by a range of companies, and often, these suppliers give their prices as a range. Therefore, RPA used the median price for each supplier and averaged the medians across all suppliers of a specific substance. Prices that looked suspiciously/strangely high or low were excluded from the calculation.

Other assumptions made for the substitution cost and cost-effectiveness calculations are described in section F.2.

F.7 Uncertainties

The main results are presented in Table 14, which includes two uncertainty analyses varying the following parameters

- the amounts of decaBDE used,
- emission factors, and
- price difference between the decaBDE and alternative flame retardants.

These input parameters are highlighted with *red italic*. The changes in parameters give different results on the emitted amount of decaBDE (proxy of risk reduction capacity), annual substitution costs (economic impact) and cost-effectiveness (proportionality).

The changes made in the used amounts per year reflect, for example, potential changes in trend (amount of decaBDE used in the coming years) and the uncertainty especially in the amounts of decaBDE imported to the EU in articles.[29]

As described in section B, there is uncertainty in the emission estimation. To describe this uncertainty, low and high emission scenarios were introduced, and the corresponding emission factors were used in the scenarios below. The emission factors affect both emission reduction and cost-effectiveness, but do not affect the substitution costs.

The difference in prices between decaBDE and alternative flame retardants has significant impact on the substitution costs and cost-effectiveness. However, it does not affect the emission reduction. The changes made in this parameter reflect, for example, the uncertainty in the current and future price of decaBDE and EBP. It can be also considered to reflect the different substitution strategies of the industry, i.e. with what alternative flame retardant the industry will substitute decaBDE. However, companies will decide which alternative to use, and when possible, avoid alternatives with unreasonably high costs.

The results of these scenarios suggest that the annual substitution costs may vary between €0.5m – €12m (central estimate being €2.2 million) and the cost-effectiveness between €125 - €4000/kg (central estimate being €464/kg). Other scenarios with different combinations of input parameters could be carried out. However, the uncertainty range would not be much affected.

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[29] To be noted that substitution costs increase linearly with increasing amount in imported articles whereas cost-effectiveness increases very little with increasing amount in imported articles. This is because the emissions corresponding to the productions of articles are now occurring outside the EU (and excluded from the analysis), leading to proportionately less emissions inside the EU. If, for instance, we double the assumed amount in imported articles (20% instead of 10% of the amount of decaBDE imported as substance) we will obtain (the detailed calculation is not presented here):

- Emitted amounts: 5.14 tonnes (instead of 4.74 tonnes)
- Substitution costs: 2.4 M€ (instead of 2.2 M€)
- Cost effectiveness: 467 € (instead of 464 €).

Table 14: Sensitivity analysis of the main parameters

Central scenario	
Used amount (kg/year)*	*4 400 000*
Emission factor	*0.11%*
Emitted amount (kg/year)	4 740
Cost difference between decaBDE and alternative (€/kg used)	*0.5*
Substitution costs (€/year)	2 200 000
Cost-effectiveness (€/kg of emission reduced)	464
Low substitution costs and high cost-effectiveness scenario	
Used amount (kg/year)*	*2 000 000*
Emission factor	*0.20%*
Emitted amount (kg/year)	4 000
Cost difference between decaBDE and alternative (€/kg used)	*0.25*
Substitution costs (€/year)	500 000
Cost-effectiveness (€/kg of emission reduced)	125
High substitution costs and low cost-effectiveness scenario	
Used amount (kg/year)*	*6 000 000*
Emission factor	*0.05%*
Emitted amount (kg/year)	3 000
Cost difference between decaBDE and alternative (€/kg used)	*2*
Substitution costs (€/year)	12 000 000
Cost-effectiveness (€/kg of emission reduced)	4 000

* These include decaBDE imported in articles.

Note: Figures presented in this table have been rounded, which could lead to errors if they are used as the basis for recalculations

G. Stakeholder consultation

During the drafting of the restriction proposal several stakeholders were consulted including industry, Member States and non-EU authorities. The information provided covered uses, tonnages and emissions of decaBDE, and the availability and technical and economic feasibility of alternatives. Previous consultations from the identification of decaBDE as SVHC phase were also taken into consideration in the preparation of this Annex XV report. For more details see Annex G.

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ANNEXES

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Tables

Figures

Introduction to the Annexes

Annexes are provided to supplement the information summarised in the core report. To aid the reader section headings in the core report and annexes share identical titles and numbering. However, as certain sections of the core report do not require a corresponding section in the annexes, readers are advised that the section numbering in the annexes is not always consecutive.

Annex B

B. Information on hazard and risk

B.2 Manufacture and uses

B.2.1 Manufacture, import and export of decaBDE

B.2.1.1 Information collected under REACH

Registrations

Five companies (importers and/or only representatives) have jointly registered decaBDE reporting a combined tonnage of between 10,000 – 100,000 tonnes/year (Table 15).

Table 15: Companies that have registered decaBDE

Company	Location
Albemarle Europe SPRL	BE
Chemical Inspection & Regulation Service Limited	IE
Chemtura Europe Limited (US03)	UK
Everkem	IT
ICL-IP Europe B.V. (OR1)	NL

Source: ECHA Dissemination Database, http://echa.europa.eu/, accessed on 18/03/2014

Pre-registrations

Some additional registrations might be expected for the following registration deadline (1 June 2018, for substances in the tonnage band of 1-100 tonnes), but no accurate estimation of their number can be made based on the available pre-registration data. Approximately 800 pre-registrations have been received across all tonnage bands[30].

Notifications under Article 7(2)

Six notifications under Article 7(2) (substance in article notifications) were received[31]. Less than 200 tonnes of decaBDE present in articles have been notified. All the notifications come from producers of articles and from downstream users. Approximately 20% of these articles are imported. For more information from notifications, including tonnes of decaBDE used and the articles descriptions see Annex B.2.

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[30] REACH-IT, accessed on 16/08/2013

[31] ECHA Dissemination Database, http://echa.europa.eu/, accessed on 31/03/2014

B.2.1.2 Historical data on manufacturing, imports and exports

Manufacturing

DecaBDE has not been manufactured in the EU since 1999 (EU RAR, 2002), which is confirmed in registrations. In the past, manufacturing occurred in the Netherlands, France and the United Kingdom (WHO, 1994).

Imports

Information about imports of decaBDE in the period 1999-2012 in the EU is shown in Table 16. There are clearly discrepancies among sources but the consumption of decaBDE seems to have declined recently. This may link to regulatory pressures over a number of years with most prominent the provisions of the RoHS Directive which prohibits the use of decaBDE in a wide range of EEE, and later on the identification of decaBDE as an SVHC under REACH Regulation.

The current REACH registrations relate to imports above 100 tonnes, however some small-scale importers of decaBDE, were also identified (example of a China based supplier: imported quantities have fallen considerably, from between 100 – 1,000 t/y in 2007 to between 10 – 100 t/y since 2010) including imports of very low quantities and one-off or intermittent orders (e.g. 1 tonne just once or 10 kg/y only for laboratory use) (RPA consultation, 2014).

Table 16: Imports of decaBDE to the EU

Year	**Eurostat** (2013)*	**VECAP** (2012)**	**BSEF** (2010)***	**REACH Registrations**
1999			8,500	
2000	10,963		8,600	
2001	9,866		7,700	
2002	9,555		7,700 (8,300/EU RAR 2004)	
2003	11,905		7,700	
2004	9,731		8,000	
2005	10,515		6,900	
2006	9,255			
2007	10,897	5,767		The amount imported into the EU is according to registrations in the lower end of 10,000-100,000 t/y****
2008	9,398	7,030		
2009	7,293	6,648		
2010	7,640	5,000 – 7,500		
2011	5,393	7,500 – 10, 000		The amount imported into the EU is according to registrations and subsequent communications to ECHA
2012	3,650	2,500 – 5,000		
2013				
2014				

	1,000 – 10,000 t/y****

Source:
** Eurostat data for EU-Extra Imports by Tariff regime, product: brominated derivatives of aromatic ethers (excluding pentabromodiphenyl ether, 1,2,4,5-tetrabromo-3,6-bis"pentabromophenoxy"benzene and 1,2-bis"2,4,6-tribromophenoxy"ethane for the manufacture of acrylonitrile-butadiene-styrene [ABS]). Registrations are considered as the most reliable source, however Eurostat data cover a larger time-span and will be used to indicate* ***trends.***
***VECAP data refer to "volume sold", so they cannot be assimilated to total imports*
****As cited in Earnshaw et al. (2013)*

Since decaBDE is now only imported into the EU any export tonnage, if any, is likely to be small. It is possible that decaBDE is exported from the EU in finished articles or masterbatch (compounded plastic pellets containing the decaBDE as an additive) (EU RAR,2002). However, no reliable information to quantify these exports was available.

B.2.1.3 Imports and exports of decaBDE in articles

According to EU RAR (2004) the estimates of EBFRIP (European Brominated Flame Retardant Industry Panel) on the quantities of decaBDE that were imported into the EU in articles, in 2003, are shown in Table 17.

Table 17: Estimated imports of decaBDE in plastic articles

Origin	**Quantity of decaBDE (t/y)**	**Products involved**
Asia	400	Non-TV consumer electronics
Asia	400	TV sets
Unspecified	500	Flame retarded polystyrene
Total	**1,300**	

Source: EBFRIP (2003) as cited in EU RAR (2004)

As electrical and electronic equipment (EEE) containing decaBDE can no longer be imported to the EU (RoHS Directive), only imports of flame retarded polystyrene articles and articles which are exempted by RoHS can continue (see Table 17). However, no information on the import of articles that are exempted for RoHS were reported during consultation (RPA, 2014). In 2002, a total of 9,600 tonnes of decaBDE was imported (8,300 tonnes as a substance and 1,300 tonnes in articles) (EU RAR, 2004). This corresponded to approximately 15% of decaBDE imports as articles, of which9% in EEE applications, now banned, and 6% in flame retarded polystyrene. In order to take into account any additional unidentified imports the remaining relevant volume of 6% was increased to 10%. The same percentage was assumed for textiles as well.

KemI (1994) estimated the quantities of decaBDE imported into Sweden in 1993. It was thought that 17 tonnes of decaBDE were imported as substance, with a further 20 tonnes imported present in plastic compound for use in production of printer housings, plastic foils, cable and electrical components. It was also estimated that around a further 400 t/y of decaBDE could be imported into the country in pre-formed plastic goods such as televisions and computer casings. However, this is no longer relevant as electrical and electronic equipment containing decaBDE can no longer be imported into the EU.

B.2.1.4 Amounts to be used for emission estimation and cost-effectiveness calculations

The emission estimations and considerations on cost-effectiveness are based on the amount of decaBDE used in the EU (see section B.8). The following assumptions were made:

- Imports of 4,000 tonnes /year, derived from the publically available data reported in Table 16.
- There is considerable uncertainty associated with estimates of the amount of decaBDE imported to the EU in articles. Based on the data presented in Table 17 the tonnage of decaBDE associated with imported articles has been assumed to correspond to 10% of imported substance tonnage.
- There is no export of decaBDE from the EU (either as a substance or in articles).

B.2.1.5 The global flame retardant market and future trends

DecaBDE consumption in China, North America and Japan

Variations in the consumption of decaBDE outside the EU may not follow EU patterns. For example, decaBDE use in China increased significantly in the first half of the 2000s, as shown in Table 18.

Table 18: Historical data on decaBDE consumption in China (tonnes)

Source	**Year**			
	2000	**2001**	**2004**	**2005**
Xia *et al.* (2005), Zou *et al.* (2007)		13,500		30,000
Xiang et al. (2007)	10,000		25,000	
Chen *et al.* (2007)	10,000			30,000

The production/import volume of decaBDE in the US is reported to have been in the range of 25,000 – 50,000 tons in the period 2002-2006 (Stockholm Convention, 2013). A decaBDE phase-out initiative is in place, agreed between the US EPA and the decaBDE manufacturers and importers in North America. Accordingly, production or import of decaBDE is expected to have ceased in the US and Canada by the end of 2013.

Japan estimates production in 2013 of 600 tonnes and import of 1,000 tonnes, mainly for use in vehicle seats (60%), construction materials (19%) and textiles (15%)[32]. These imports are not necessarily to the EU.

The global flame retardant market

The global demand for flame retardant additives is expected to rise by over 6% per year to 2.2 million metric tonnes in 2014[33]. This is partly due to increasing and more stringent fire safety requirements and the use of more flammable materials. The Asia/Pacific region will continue to be the largest and fastest-growing market for flame retardants through 2014,

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[32] Information from Japan is available at: http://chm.pops.int/TheConvention/POPsReviewCommittee/Meetings/POPRC9/POPRC9Followup/decaBDESubmission/tabid/3570/Default.aspx

[33] Available online at: http://www.freedoniagroup.com/industry-study/2709/world-flame-retardants.htm

accounting for nearly half of the world demand.

The total market for flame retardants in the US, Europe and Asia in 2007 amounted to about 1.8 million tonnes and was valued at US$4.2/€3.5 billion. Table **19** and Table 20 show the breakdown of the flame retardant market by value.

Table 19: Global market of flame retardants - The Flame Retardants Market by value

Flame retardant	**2007**	**2011**
Brominated	34%	19.7%
Antimony trioxide	16%	8.4%
Chlorinated	7%	11.3%
Organophosphorous	20%	14.6%
Aluminium hydroxide	13%	40.4%
Other	10%	5.6%

Source: http://www.flameretardants-online.com/web/en/home/index.htm

In 2007, halogen and antimony oxide accounted for 57% of the market value (38% by volume) because of the extensive use of brominated flame retardants in Asia, see Table **19** and

Table 21.

Table 20: Global market of flame retardants - Sales of Flame Retardants by Region

Region	**Brominated**	**Antimony oxides**	**Chlorinated**	**Organo-phosphorous**	**Aluminium hydroxide**	**Other**
United States	260	102	100	306	248	110
Europe	250	110	103	328	232	228
Asia	918	485	88	204	79	86

Source: http://www.flameretardants-online.com/web/en/home/index.htm
Note : Figures are in US $ million, with a total of US $ 4.2 billion, data for 2007

Table 21 provides the consumption of flame retardants by region and volume in 2007. The value of the market is projected to grow at 6.9% per year to US$7.1 billion in 2017. Different flame retardants are prominent in different world regions. China and India are focusing on increased fire safety, particularly in the area of electronics. It should be noted though that a significant portion of electronic parts or products are manufactured in China and India and are exported to Europe and the US, and so demands and regulations there will affect flame retardant use worldwide. Asia/Pacific is expected to account for 50% of the world demand by 2014 as measured by value (Clariant International, undated) (Markets and Markets, undated).

Table 21: Global market of flame retardants by volume

Region	Brominated	Antimony oxides	Chlorinated	Organo-phosphorous	Aluminium hydroxide	Other
United States	64	33	33	72	345	75
Europe	45	20	40	83	280	61
Asia	302	88	58	54	110	58

Consumption of Flame Retardants by Region, based on volume. Figures are 1,000 tonnes, with a total of 1.8 million metric tonnes, data for 2007
Source: *http://www.flameretardants-online.com/web/en/home/index.htm*

B.2.2 Uses

DecaBDE is used as an additive flame retardant in plastics/polymers and textiles. Additive flame retardants are physically combined with the material being treated whereas reactive flame retardants are chemically combined. Flame retardants inhibit the ignition of materials and slow the rate at which flames spread. They therefore play a key role in product safety (SVHC Annex XV report, 2012).

DecaBDE is mainly used in conjunction with antimony trioxide which, although not a flame retardant in its own right, acts as a synergist to increase the effectiveness of decaBDE and other halogenated flame retardants. It does this by catalysing the release of radicals from halogenated flame retardants. Zinc oxide is another commonly used synergist. Depending on the application, the decaBDE/antimony trioxide system may be combined with other flame retardants to achieve the desired fire performance (SVHC Annex XV report, 2012).

Although an estimate of the total amount of decaBDE used in the EU was retrieved from registrations, it was not possible to apportion this with certainty to individual uses, even though some information on the relative tonnage used in textiles and plastics is available (see section B.8). Registrations also contained information on the identified uses. Some further categorisation based on final products (applications) was made using information from literature and obtained via consultation. More detailed information, including the various production steps and different materials which can be flame retarded with decaBDE, can be found in RPA (2014).

B.2.2.1 Split between textiles and plastics

The share of plastics in the use of decaBDE has decreased from 81.7% in 2002 (EU RAR, 2002) to roughly two thirds in 2010 (VECAP, 2010) and is currently estimated as less than 50% (VECAP, 2012).

The 2012 VECAP report mentions that, at least among the member companies, the volume of decaBDE used in textiles was slightly larger than that for plastics (VECAP, 2012). The reported breakdown was 52% for textiles and 48% for plastics (which were the values taken forward to the analysis). The transport and construction sectors are significant users of decaBDE in textiles, responding to increasingly stringent fire safety legislation (particularly in the UK). However, consultation with the textile industry has indicated that the use of decaBDE in textile applications has declined considerably since 2012, possibly as a result of the substance being identified as a SVHC. However, this trend has not been quantified (RPA, 2014).

B.2.2.2 Identified Uses

Table 22 contains a summary of the identified uses of decaBDE from REACH registrations.

Table 22: Identified uses of decaBDE from REACH registration

#	Use
1	Adhesive and sealant
2	Coatings and inks formulation
3	Coating used in textile backcoating
4	Coating and inks application (consumer, industrial and professional use)
5	Coating used in textile
6	Coatings – Industrial application of coatings
7	Converting*
8	Filled dispersion used in transportation
9	Filled dispersion used in construction
10	Foam production for construction
11	Formulation of flame retardant preparation
12	Formulation coating preparation
13	Formulation polyester and S102E – liquid filled dispersion
14	Industrial composites manufacturing
15	Manufacturing of formulated resins (gel coats, etc.)
16	Manufacturing of VE resins
17	Professional application of coatings
18	Professional composites manufacturing
19	Recycling
20	Thermoplastic production (masterbatch and compound)**
21	Thermoplastic used in automotive
22	Thermoplastic used in construction

#	Use
23	Transformation
24	Wire and cable used in automotive
25	Wood and plastic composite

Source: compiled from ECHA "Search for Chemicals", http://echa.europa.eu/, accessed on 18/03/2014 (RPA, 2014)
Note: the use descriptors linked to each identified use can be found in the ECHA website
* conversion: manufacturing of semi-finished or finished article
** compounding: formulation and inclusion in the polymer matrix

B.2.2.3 Applications and sectors

Around 2010, the consumption of decaBDE across different sectors in the US could be broken down as follows (excluding import in articles): automotive and transportation 26%, building and construction 26%, textiles 26%, electrical and electronic equipment (EEE) 13% and others 9% (Danish EPA, 2013). Excluding EEE, the relative consumption would be: automotive and transportation 30%, building and construction 30%, textiles 30% and others 10%. This is consistent with the latest information from Europe.

Table 23 presents information on various applications and broader sectors where decaBDE is used.

Table 23: Applications and sectors of decaBDE

Applications	Sector	Comment
Upholstery	Textiles & Furniture Transport	Potentially in mattresses (outside covers). Upholstery for seating in public buildings and transport vehicles (usually applied as backcoating).
Foams and fillings	Textiles & Furniture	Use in synthetic latex foam for mattresses
Military tents	Military equipment	Assuming that inherently flame retardant fibres are not used. Use in disaster relief tents.
Draperies	Building & Construction	In public buildings (e.g. hospitals, prisons, theatres) Backcoating is usually applied on synthetics because they cannot retain decaBDE used as an additive.
Carpets	Transport	Use in aircraft (Annex XV dossier, 2012). Not considered likely to be present in carpets for consumer use.
Roofing	Building & Construction	Opaque roofing materials (manufactured from unsaturated PES) are mentioned by EFRA. Polyolefin-based roofing materials. Cross-linked elastomeric compositions based on plasticised PVC / nitrile rubber or PE.
Insulation	Building & Construction	DecaBDE is used in PVC/nitrile blends (see roofing). Such blends can be used to insulate heating pipes or A/C systems. PU-Europe denies the use of decaBDE in PU-based thermal insulation.

Applications	Sector	Comment
Cables, wires and piping	Building & Construction Transport	Not in EEE, unless use is exempted from RoHS Directive. Piping might use decaBDE. France has reported use of decaBDE in cables.
Sealants & adhesives	Building & construction Transport	Adhesive tapes (identified by Norway). Adhesives imported to Finland until 2010 also contained decaBDE. An identified use in the registration dossier (although use is denied by industry).
Coatings	Building & construction Textiles & Furniture	In textiles as backcoating. In buildings possibly in protective coatings.
Automotive	Transport	Wire and cables, small components (e.g. switches, connectors), other thermoplastics, textiles and upholstery.
Aircraft	Transport	Adhesives & tapes, ducting, moulding parts, composites, fabrics, films, insulation, interiors and sealants.
Trains	Transport	In seat fabrics, intercar barriers and hoses, some electrical components
Pallets	Storage & Distribution	Mentioned in US EPA, 2012.
Inks and paints		No information from RPA consultation. Mentioned as identified use.

Source: RPA, 2014

B.2.3 Uses advised against by the registrants

No uses were advised against by the registrants.

B.3 Classification and labelling

DecaBDE is not listed in Annex VI of Regulation (EC) No. 1272/2008 (the CLP Regulation). As mentioned in section 5 of SVHC-SD, recent studies suggest effects on fish and amphibians after long-term exposure to decaBDE at or around the water solubility limit or via diet. Difficulties maintaining test concentrations and the use of non-standard methods imply that further studies are undertaken (potentially using standardised test guidelines) before they are used for classification purposes. However, they suggest that chronic aquatic classification for decaBDE may be justified.

The registrants of decaBDE state in their dossiers that the substance is not classified. The CLP Inventory published on the ECHA website (ECHA, 2013 (checked on 05/08/2013)) contains 169 joint notifications as "not classified" for decaBDE and various other additional classifications (Table 24).

Table 24: Self-classification and labelling in the CLP Inventory

No of various CL	Hazard Class & Category Codes	Hazard Statement codes	Pictograms & Signal Word Codes	Number of notifiers

No of various CL	Hazard Class & Category Codes	Hazard Statement codes		Pictograms & Signal Word Codes	Number of notifiers
1	Not classified	-	-	-	169
2	Acute Tox.4	H302	Harmful if swallowed	GHS07	25
	Acute Tox.4	H312	Harmful in contact with skin	Wng	
	Eye Irrit.2	H319	Causes serious eye irritation		
3	Acute Tox.4	H302	Harmful if swallowed	GHS07	23
	Acute Tox.4	H312	Harmful in contact with skin	Wng	
	Acute Tox.4	H332	Harmful if inhaled		
4	Muta.2	H341	Suspected of causing genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	GHS08 Wng	14
	STOT RE 2	H373	May cause damage to organs (or state all organs affected if known) through prolonged or repeated exposure (state route of exposure if it is conclusively proven that no other routes of exposure can cause the hazard)a		
5	Aquatic Chronic 4	H413	May cause long lasting harmful effects to aquatic life	-	19
6	-	H413	May cause long lasting harmful effects to aquatic life	GHS07 GHS05 GHS08 Dgr	2
		H351	Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)		
		H318	Causes serious eye damage		
		H302	Harmful if swallowed		
7	Eye Irrit.2	H319	Causes serious eye irritation	GHS08	1
	Muta.2	H341	Suspected of causing genetic defects (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	Dgr	
8	Acute Tox.4	H302	Harmful if swallowed	GHS07	1

No of various CL	Hazard Class & Category Codes	Hazard Statement codes		Pictograms & Signal Word Codes	Number of notifiers
	Eye Irrit.2	H319	Causes serious eye irritation	Wng	
	Aquatic Chronic 4	H413	May cause long lasting harmful effects to aquatic life		
9	-	H312	Harmful in contact with skin	-	1
	Aquatic Chronic 4	H413	May cause long lasting harmful effects to aquatic life		
10	Aquatic Chronic	H413	May cause long lasting harmful effects to aquatic life	-	1

The information contained in the CLP inventory is not necessarily comprehensive, accurate, complete or up to date and has not been reviewed or verified by the Agency or any other authority. The database is refreshed every two weeks with new or updated CLP notifications from manufacturers and importers. The notifications with similar classifications are aggregated for display purposes.

B.4 Environmental Fate Properties

Bis(pentabromophenyl) ether is identified as PBT according to Article 57 (d) and as vPvB according to Article 57 (e) of REACH, respectively. Agreement of the Member State Committee (MSC) on the identification of bis(pentabromophenyl) ether was adopted on 29 November 2012, as follows[34]:

"DecaBDE is very persistent and widely detected in many environmental compartments (including wildlife species). On the basis of the available data it can be concluded that there is a high probability that decaBDE is transformed in the environment to form substances which themselves have PBT/vPvB properties, or act as precursors to such substances, in individual amounts greater than 0.1% w/w over timescales of a year.

New information from the scientific literature, published after the inclusion of decaBDE on the Candidate List, was reviewed by ECHA in collaboration with the Norwegian Competent Authority. Similar to the SVHC-Support Document, the focus of this section is the transformation of decaBDE to lower brominated congeners which themselves have PBT/vPvB properties, or act as precursors to such substances. This new information supports the current knowledge related to the PBT/vPvB status of decaBDE, i.e. it reinforces the previous conclusions of the MSC.

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[34] SVHC support document available from: http://echa.europa.eu/candidate-list-table/-/substance/2403/search/1163-19-5/term

B.4.1 Degradation

B.4.1.1 Abiotic degradation

B.4.1.1.1 Hydrolysis

There is no new information found.

B.4.1.1.2 Phototransformation in air

There is no new information found.

B.4.1.1.3 **Phototransformation in articles**

Kajiwara and colleagues analysed whether decaBDE was degraded in curtains that were exposed to natural sunlight over a period of 371 days (Kajiwara et al., 2013).

The initial test material (polyester curtains) contained 130 000 mg total BDE/kg (table 1 of the publication), of which the bulk (120 000 mg/kg) was decaBDE. However, the amounts of the different BDE congeners provided by the authors in Table 1 of the main paper and Table 1 of the study-supporting information do not correspond. Adding the values for the different congeners from Table 1 of the supporting information results in a total of 122 477.973 mg total BDE/kg, not 130 000 mg/kg, as it is listed in Table 1 of the main paper. It is unclear whether this discrepancy is just a rounding error, as decaBDE concentrations seem to be presented with only two significant digits. However, such discrepancies make the analyses of mass balances problematic. For example, BDE206 and BDE207, the next most prominent congeners after decaBDE, are listed with concentrations of 1 400 and 940 mg/kg, respectively, at the beginning of the tests, i.e. within the range of the discrepancy noted above. The concentrations of BDE206 and BDE207 are only marginally changed after the 371 days exposure to sunlight (1100 and 1200 mg/kg, respectively).

After 329 days, a substantial PBDF (polybrominated dibenzofurans) formation was observed, reaching a total concentration of 27 mg PBDF/kg, which is more than ten times the initial concentration. In fact, PBDF concentrations show a clear time-dependent increasing trend, indicating a constant production and accumulation in the test material (i.e. the PBDF production rate was exceeding PBDF-photodegradation).

However, the decaBDE concentration did not change significantly during the exposure time. The initial concentration of 120 000 mg/kg decaBDE is subsequently observed to fluctuate between 160 000 mg/kg on day 105 and 110 000 mg/kg on days 189 and 301-357, without a clear time-dependent trend. In addition, the concentrations of the lower brominated BDE congeners, although some of their concentrations display substantial fluctuations, do not show a consistent pattern that can be related to the exposure time in a simple manner.

The study is technically well implemented and seems reliable. The authors use state-of-the-art analytical techniques, quantify the analytical results by isotope dilution with the corresponding ^{13}C-labelled congeners and provide the detection limits in the study-supporting information. Additional details are provided in an earlier study (Kajiwara et al., 2008, as cited in the SVHC SD). All numerical values are also provided.

In summary, no conclusion on from which BDE congeners the PBDFs are produced could be made. Whilst decaBDE made up the bulk of the total initial BDE load, 5.8%

(=75 000 mg/kg) consisted of other PBDE congeners, a mass that could easily produce the 27 mg/kg concentration of PBDFs observed. Susceptibility to photolysis seems, in general, to be positivity correlated with increasing bromination level. Therefore, it can be assumed that decaBDE was at least a major source for the observed PBDFs.

B.4.1.1.4 Phototransformation in water

Leal et al. (2013) published a study in which the photodegradation of decaBDE in water was investigated. The aim of the study was to determine the half-life of decaBDE in water and to analyse the influence of various humic substances on the process. A consistent, time-dependent, photodegradation of decaBDE was observed in a sunlight simulator, following pseudo-first order reaction kinetics. DecaBDE (98% purity) was initially dissolved in acetonitrile and the concentration at the start of the experiment in water was 5 µg/L (0.1% acetonitrile). Since water is more polar and not a good hydrogen donor lower quantum yields were obtained in water than in polar solvents. Hence, the use of an organic solvent to solubilize decaBDE may have confounded the results. The concentration of decaBDE used at the start of the experiment was above its water solubility.

The estimated half-life of decaBDE in water was 69 minutes, compared to 3.3 minutes in methanol. The authors estimated, based on these data, an outdoor half-life (not further specified) of decaBDE of 3.5 hours, a half-life in the Baltic Sea in summer at 60°N of 36 days, and a half-life in the North Atlantic Ocean of 660 days in winter also at 60°N.

Humic substances extended the half-life of decaBDE in water substantially. DecaBDE was degraded by roughly[35] 33% after one hour of light exposure without humic acids present, it was only degraded by approximately 5% in the presence of 8 ppm humic acids. Fulvic acids influenced degradation less effectively than humic acids e.g. decaBDE was degraded by approximately 10% in the presence of 16 ppm fulvic acid. Complex natural dissolved organic matter, collected on XAD-columns from a river in Portugal, did not significantly inhibit photodegradation at 8 ppm. The protective effect of humic substances was attributed to a combination of a screening effect, i.e. light absorption by the humic substances, and quenching, i.e. hydrophobic interactions between the humic substances and decaBDE led to an inactivation of the excited state of decaBDE, which is a prerequisite for photodegradation.

The study was not designed to identify photodegradation products and the degradation of the 2% impurities in the decaBDE standard were not investigated. The degradation mechanisms of decaBDE in water are not yet understood. However, the authors provide a brief summary of the complex chromatographic pattern that was detected after decaBDE photodegradation. Degradation products with a lower lipophilicity than decaBDE (i.e. a shorter retention time in the chromatographic system, consistent with a debromination and/or the production of PBDFs) were present, but so were degradation products with a higher lipophilicity (i.e. higher retention times in the chromatographic system) than decaBDE. The study does not provide further details on the specific chemical nature of these degradation products. In addition, the authors did not investigate the pattern of photodegradation products in the presence of humic substances.

B.4.1.1.5 Phototransformation in soil

Photodegradation might contribute to the degradation decaBDE in soil, as indicated in the studies by Gorgy et al. (2013) and Du et al. (2013). However, the studies do not

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[35] Unfortunately, the data are not presented as numbers, but only as a figure. This makes it difficult to extract quantitative values from the publication.

differentiate between biotic and abiotic processes. The studies are described in section 4.1.2.4 on biodegradation.

B.4.1.1.6 Photolysis in other media

Wei et al. (2013) analysed the debromination pattern of a broad range of BDE congeners, including decaBDE, in hexane. The paper is included in this analysis because the authors argue, based on existing literature, that the principal photolysis pathway is independent of the matrix in which it takes place. However, as discussed in detail by Leal et al. (2013), photolysis kinetics are strongly matrix-dependent. DecaBDE was rapidly degraded in hexane. After 2 hours radiation under natural sunlight an initial concentration of 60 mg/L was completely photolysed. A broad range of debromination products were formed in the process, including all possible nona-BDEs and a complex pattern of lower brominated BDEs (as presented in Table 25). Based on these data, Wei et al. (2013) argue that, in general, higher bromination of the parent compound leads to increased photolysis. This observation supports the notion that decaBDE was the major source for the PBDF production in curtains observed by Kajiwara & Takigami (2013).

Table 25: Debromination products during 0-8 hour sunlight exposure of decaBDE in hexane (from Wei et al., 2013). A slash indicates a congener pair that was not separated during the gas-chromatography

Group	Debromination products
nona	BDE206, BDE207, BDE208
octa	BDE195, BDE194, BDE196, BDE203/200, BDE197, BDE204, BDE201, BDE202
hepta	BDE190, BDE181, BDE180, BDE191, BDE183, BDE184, BDE188
hexa	BDE138/166, BDE131/141/158, BDE139, BDE153, BDE146, BDE133/136, BDE144, BDE154, BDE148, BDE155/126
penta	BDE85, BDE118, BDE89, BDE99, BDE90, BDE119, BDE101, BDE100, BDE103
tetra	BDE77, BDE66, BDE47, BDE49, BDE75, BDE52
tri	BDE37, BDE28/33

This led the authors to suggest the following general photolysis pathway for decaBDE:

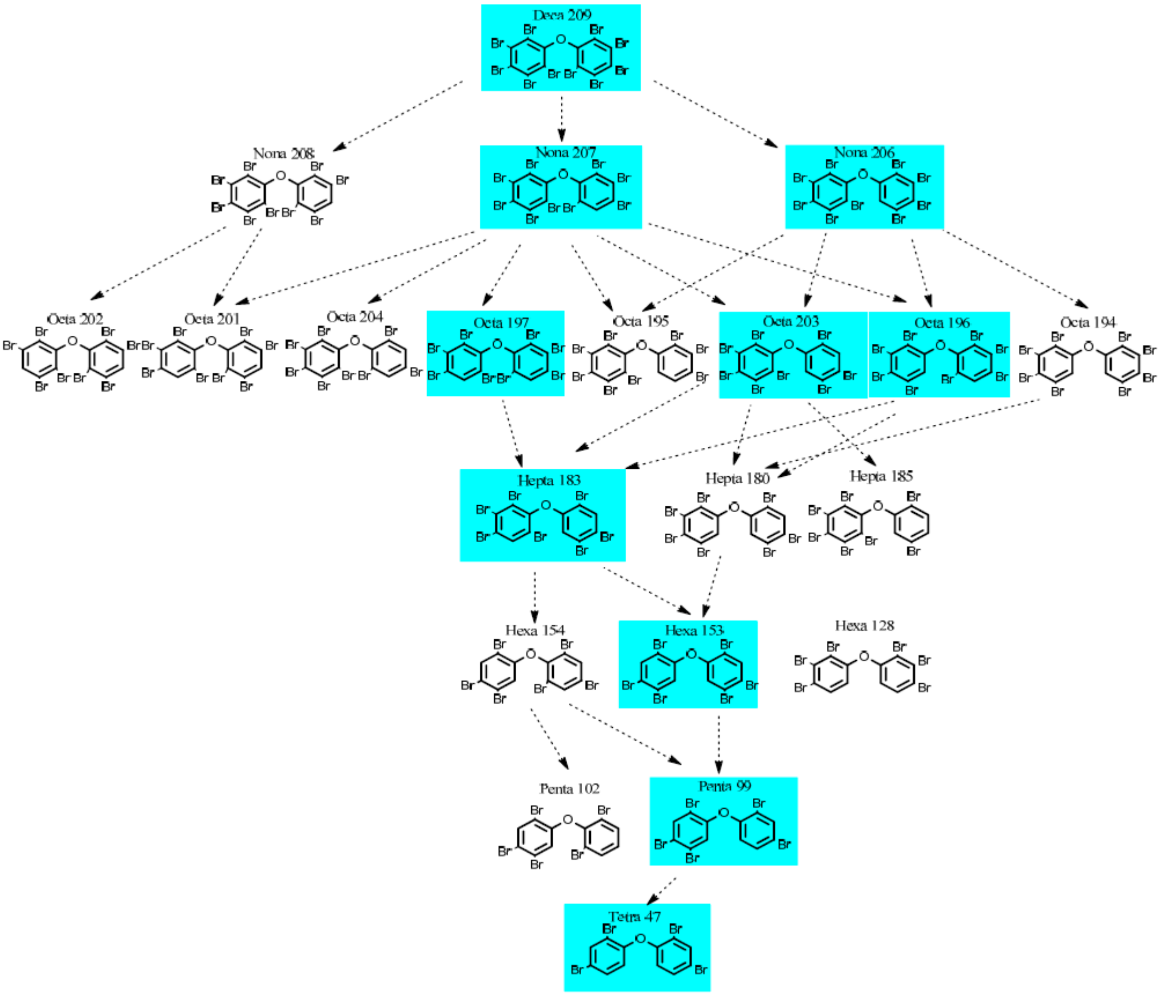

Figure 4 Debromination pathway for decaBDE (Wei et al., 2013). Congeners highlighted in blue are dominant in commercial mixtures.

Kim et al. (2014) present a QSAR for the reductive debromination of decaBDE and other BDE congeners. This QSAR is based on the calculation of the free energy change for the debromination reaction under "standard" conditions i.e. a concentration of 1 mol/L (960 g/L) and elevated levels of zerovalent iron. These conditions are far beyond anything relevant for environmental assessments. However, if the relationships between the debromination preferences of the individual BDEs also hold for realistic concentrations the QSAR could help model expected BDE congener patterns after initial environmental deposition of decaBDE. However, the authors do not comment on the relative behaviour of PBDE congeners and therefore the study does not provide any immediately relevant information on the abiotic degradation of decaBDE.

B.4.1.1.7 Summary and discussion of new information on abiotic degradation

The studies provide evidence for decaBDE photolysis under realistic light exposure scenarios. The photodegradation kinetics are strongly dependent on the matrix in which decaBDE is present. In the study by Leal et al. (2013) the half-life of decaBDE in water was estimated at 69 minutes. However, the result should be interpreted with caution since the use of organic solvents to solubilize decaBDE may have affected the results (increased the apparent degradation rate). The half-life under environmental conditions was estimated to be between 36 days (summer) and 660 days (winter) in the marine environment of the Northern hemisphere. The presence of humic substances extends the half-life of decaBDE in water substantially, depending on their actual composition.

In a study by Wei et al. (2013) a complete photolysis of decaBDE in hexane was seen after 2 hours. DecaBDE treated consumer products were shown to generate PBDFs (polybrominated dibenzofurans). However, a definitive degradation pathway from decaBDE to PBDFs was not identified.

The study by Leal et al. (2013) that investigated the photolysis of decaBDE in water did not provide mechanistic details, nor did it identify the resulting degradation products. However, as argued by Wei et al. (2013), the type of photodegradation products are generally independent of the matrix in which decaBDE is present. If this is indeed the case, then photolysis under environmental conditions can be expected to produce all possible nona-BDEs, and a complex pattern of lower brominated BDEs, in stoichiometric proportion to the mass of decaBDE initially present. However, it was also observed that photodegradation in water leads to the generation of products with a higher lipophilicity than decaBDE. Further investigation would appear to be necessary.

Table 26: Relevant new studies on abiotic degradation

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
Kajiwara et al., 2013	Photolysis in consumer product (curtains) over 371 days	decaBDE	Nona- and octaBDEs, PBDFs in the product	Final conc. after 371 days (mg/kg): BDE47: 0.045 BDE99: 0.073 BDE138: 0.013 BDE153: 0.16 BDE154: 0.041 BDE183: 0.69 BDE191: 0.13 BDE196: 23 BDE197: 38 BDE207: 1100 BDDE206: 1200 BDE209 (decaBDE): 1.2E4
Leal et al., 2013.	Photolysis in water	decaBDE, 98% purity (dissolved in ultrapure water to a concentration of 5 µg/l, initially dissolved in acetonitrile and introduced in water at 0.1% acetonitrile)	Not identified	Half-life under test conditions 69 minutes. Estimated outdoor half-life near water surface 3.5 hours. Estimated ocean half-lives: 36 (Summer)-660 (Winter) days

Refe-rence	**Species, type of study**	**DecaBDE form**	**Metabolites observed (tissues)**	**Measured amounts**
Wei et al., 2013	Photolysis in hexane	decaBDE > 98% purity	BDE206, BDE207, BDE208, BDE195, BDE194, BDE196, BDE203/200, BDE197, BDE204, BDE201, BDE202, BDE190, BDE181, BDE180, BDE191, BDE183, BDE184, BDE188, BDE138/166, BDE131/141/158, BDE139, BDE153, BDE146, BDE133/136, BDE144, BDE154, BDE148, BDE155/126, BDE85, BDE118, BDE89, BDE99, BDE90, BDE119, BDE101, BDE100, BDE103, BDE77, BDE66, BDE47, BDE49, BDE75, BDE52, BDE37, BDE28/33	decaBDE (60mg/L) was completely photolysed after 2 hours exposure to natural sunlight.
Kim et al., 2014	QSAR development for reductive debromination	Does not apply (modelling study)	Does not apply (modelling study)	Does not apply (modelling study)

B.4.1.2 Biotic degradation

B.4.1.2.1 Biodegradation in water

Lu et al. (2013b) grew *Bacillus cereus* for 12 days using decaBDE as the sole carbon source (1-20 mg/L). Debrominated BDE congeners as well as free bromine were monitored. The presence of free bromine indicates complete mineralization of the initial decaBDE. Lower rates for the complete mineralization, compared to the disappearance of the initial decaBDE, indicates that intermediates are formed. After 12 days, 88% of the decaBDE that was initially present was degraded. The following intermediates were identified: BDE15, BDE28, BDE154, 2′,3′-Dihydroxy-4,4′-dibromodiphenyl ether, 2-Hydroxy-4-bromo-adipic acid, 4-Bromophenol, 4-Bromocatechol. No concentrations for the degradation products were given in the publication. Based on these data the authors suggest the following pathway for the biotic degradation of decaBDE by *Bacillus cereus*:

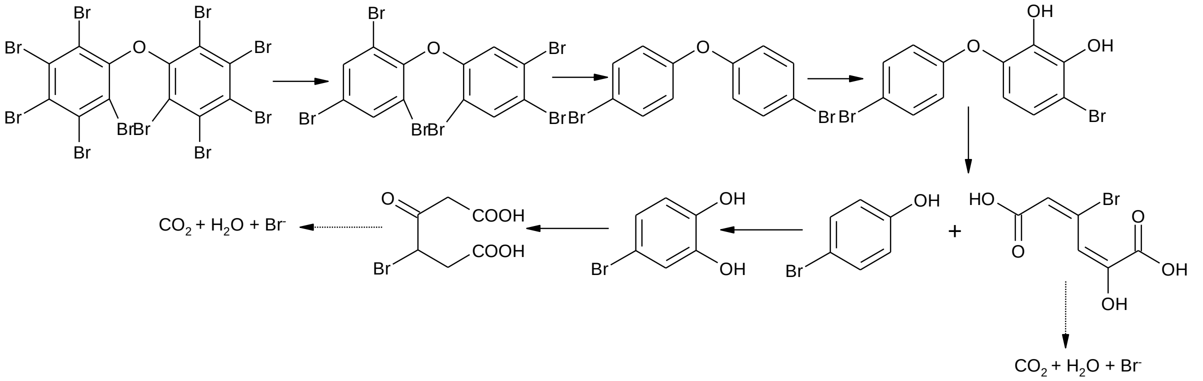

Figure 5 Pathway for the biotic degradation of decaBDE by *Bacillus cereus*, as suggested by (Lu et al., 2013b)

The study convincingly demonstrates the aerobic degradation of decaBDE. However, it should be noted that the conditions of the study were very artificial, in particular the very high concentrations of decaBDE used (up to 20 mg/L – above the water solubility). No mass balance was possible, as the concentrations of metabolites were not quantified in the publication. In fact, the decaBDE used was of unspecified impurity and it is therefore not possible to estimate the contribution of possible impurities to the observed congener pattern. BDE154, especially, is a known decaBDE component. However, BDE15 and BDE28 are not known to be impurities of decaBDE. The suggested biodegradation pathway might not be complete, but does provide major intermediates.

Support for the findings reported by Lu et al. (2013b) comes from a study in which *Pseudomonas aeruginosa* was exposed over 7 days to 1 mg/L decaBDE (Shi et al., 2013). 56% of the decaBDE present was degraded after 7 days when glucose was present, i.e. the decaBDE concentration decreased from 1 mg/L to 0.44 mg/L. Without glucose only 20% were degraded. Other carbon sources also increase the degradation speed, but not as efficiently as glucose. The presence of cadmium had only marginal impacts on decaBDE degradation, unless it was added at toxic concentrations. This led to a lower decaBDE degradation rate, a clear indication of biotransformation rather than abiotic degradation. Bromine production was lower than decaBDE degradation, indicating the presence of debrominated congeners. The decaBDE standard used contained ~0.8% BDE206, 0.8% BDE207 and 0.4% BDE208. Concentrations of BDE207 and BDE208 increased during the exposure, indicating decaBDE debromination by *Pseudomonas*. The authors identified BDE183, BDE196, BDE197, BDE202, BDE203, BDE207 and BDE208 as degradation products and it was demonstrated that their concentrations increased constantly during the exposure time. No mass balance was provided.

B.4.1.2.2 Biodegradation in sediments

Canadian data on degradation in lake sediments are referred to in the SVHC, but only as preliminary results. These data are currently under peer review for publication (Orihel et al., in press) and describe the formation of small amounts of nona- and octaBDEs from ^{13}C-labelled decaBDE over a period of 30 days in intact lake sediment cores held in situ to simulate natural conditions. Slow debromination of decaBDE was observed with the formation of all nona-BDEs (-206, -207, -208) and 4 to 5 octa-BDEs (-196, -204/197, -201,- 202, -203) and trace amounts of hepta-BDE (-180, -183, -190), hexa-BDE (-138/166,-139, -154), penta-BDE (-99, -105, -116, -126), and di-BDE (-10). The mechanisms associated with the observations (abiotic or microbial degradation) are not identified.

B.4.1.2.3 Biodegradation in sewage sludge

Rodríguez-Rodríguez et al. (2012) treated sterilised STP sludge for 26 days in the dark in a bioslurry reactor amended with the fungus *Trametes versicolor*. DecaBDE was present in raw sludge at a concentration of 232 ng/g dry weight, BDE183 at 0.61 ng/g, BDE 154 at 5.48 ng/g, BDE99 at 6.05 ng/g and BDE47 at 5.39 ng/g. After treatment, sludge contained lower concentrations of decaBDE (145 ng/g, removal of 37.5%), but also of all other lower brominated congeners (removal of BDE47=23.7%, BDE99=46.4%, BDE154=53.3%), with the exception of BDE183, which was not degraded. Bromination level and degradation do not seem to be correlated. Solid-phase treatment (pre-mixing the sludge with straw or pellets) with *Trametes versicolor* decreased the concentration of decaBDE in the final sludge to an even higher extent (by 86%, compared to 37.5% in the bioslurry treatment).

Unfortunately, no control was used in the study (i.e. a bioreactor with sterilised sludge, but no added fungus). Therefore, no definitive conclusion as to whether the degradation that was observed for most BDE congeners, including decaBDE, was driven by biological or abiotic processes is possible. It is specifically discussed in the SVHC SD that reductants such as iron-bearing minerals and sulphides might lead to increased biodegradation under anaerobic conditions. Although the relative oxygen level in the reactor was maintained above 40%, it cannot be ruled out that anaerobic pockets were present in the reactor which may have influenced the observed degradation. However, photodegradation can be excluded as the experiments were run in the dark. As the decaBDE degradation was very substantial, it is likely that a substantial proportion was driven by the fungus. However, as the concentration of the lower brominated BDEs was not observed to increase during the study no conclusion as to which congeners decaBDE was degraded to is possible. In fact, the relative proportions of the monitored BDE congeners (BDE28, BDE47, BDE99, BDE100, BDE153, BDE154, BDE183, decaBDE) remained constant.

Hale et al. (2012) analysed the BDE congener profiles in biosolids from the Chicago area. They compared expected profiles, based on an emission-based exposure modelling with measured profiles. For decaBDE, modelled and measured concentrations agreed well, while concentrations of BDE206, BDE207 and BDE208 were much higher than modelled, (4-fold for BDE206 and BDE207, 23-fold for BDE208), which the authors take as an indication of decaBDE degradation to these three congeners. Although these conclusions would explain the observed pattern, it is hard to estimate the overall uncertainty of the exposure model, which relies on high quality emission data. No differentiation between biotic and abiotic processes was possible. DecaBDE in the influent and effluent of 20 different STP-plants in Canada were assessed by Kim et al. (2013). The total BDE load varied between 21 and 1000 ng/L (median 190 ng/L), while BDE levels in effluents were between 3 to 270 ng/L (median 12 ng/L). DecaBDE accounted for 39% of the total influent concentration of BDEs and 26% of the total effluent concentration of BDEs, i.e. it is disproportionately removed during wastewater treatment. Whether this is due to stronger sorption to suspended solids, compared to the lower brominated congeners, or some other mechanism (i.e. photolysis or biodegradation) is not known.

B.4.1.2.4 **Biodegradation in soil and plants**

Degradation of decaBDE in the terrestrial compartment was investigated in a 4-year lysimeter study (Nov. 2007 – Nov. 2011) by Du et al. (2013). Only two individual lysimeters were used in the study: one control and one exposed to decaBDE. In addition, a significant loss of greater than 50 % of the initially added decaBDE was observed during the study. Due to these shortcomings, the results and conclusions from this study should be interpreted with caution.

DecaBDE was mixed at a final concentration of 23.3 mg/kg into the topsoil layer (0-15 cm depth), which was subsequently covered with another layer of uncontaminated soil in order to "*minimise evaporation and photolysis of decaBDE*". Two crops were grown on the lysimeters. Wheat was sown in November and harvested in May and rice was then sown in June and harvested in October. Soil core samples were collected in May 2008, Nov. 2008, Nov. 2009, Nov. 2010 and Nov 2011, and sampled at various depths down to 80cm below the surface and analysed for the presence of decaBDE and other lower brominated BDEs: BDE28, BDE47, BDE99, BDE100, BDE153, BDE154 and BDE183.

DecaBDE was detected in the 0-30 cm fraction on all occasions, with maximum concentrations observed at 10-20cm depth. Measurements up to and including Nov. 2009 indicate a gradual translocation of decaBDE into deeper soil layers, with substantial amounts present at depths > 30cm. However, at all sampling events after Nov. 2009, decaBDE was almost completely absent in depths below 30cm. Based on the known volume of the soil cores extracted from the lysimeter and the different volumetric weights of the soil at different depths, the authors could account for 94.3 and 108.1% of the decaBDE during the first two years of the study, respectively. However, in the last two years of the study recovery was only 33.8% and 35.5%, respectively. No corresponding increase of lower brominated congeners was observed. Greater than half of the decaBDE initially added to the lysimeter is unaccounted for during the last two years.

One possible explanation for this loss could be vertical transport (leaching) from the lysimeters. Unfortunately, leachates were not collected and analysed. Weather data did not indicate increased rainfall in years 3-4. Higher temperatures and consequently an elevated biodegradation and/or volatilization of decaBDE and/or its degradation products might be another possibility. However, again, weather data did not indicate increased temperatures during the second half of the experiment. Uptake in plants might explain the observed disappearance of decaBDE. However, it would be hard to develop a hypothesis, as to why plant uptake should be different in years 3-4 than in years 1-2. In addition, concentrations in plants only accounted for < 0.1% of the total added decaBDE.

DecaBDE always accounted for 99.8-99.9% of the total BDEs present in soil. Unfortunately, the authors do not present the chemical purity of the decaBDE used for the study. Assuming that the typical purity of a commercially available decaBDE standard is somewhere between 98% and 99%, it is impossible to conclude from the study whether decaBDE was actually debrominated – or whether either (a) the detected lower brominated congeners were already present in the decaBDE standard, and/or (b) the detected lower brominated congeners are a degradation product of any of the impurities present. According to La Guardia et al. (2006), technical decaBDE contains BDE194, BDE196, BDE197, BDE203, BDE206, BDE207 and BDE208 as impurities. Assuming that those congeners were also present as impurities in the decaBDE standard that was used in the Du et al. (2013) study the presence of lower BDE congeners e.g. BDE206, BDE207 or BDE208 cannot be definitely associated with degradation as they may have been present as a result of impurities in the test substance. Equally, the presence of BDE47, which contributed up to 65.2% to the total amount of lower brominated congeners, and which is not a typical impurity of decaBDE, could suggest that abiotic or biotic debromination may have been occurring in lysimeters. However, as BDE47 is a major component of the commercial pentaBDE product, and background contamination with BDE47 of between 0-0.4 µg/kg was found in the control lysimeter, the presence of this congener in soils cannot be considered to be definitive evidence that biotic degradation occurred. Unfortunately, no further details on the distribution of background BDE47 concentrations between different soil levels is available. Therefore, comparative assessment between BDE47 concentrations in control and decaBDE treated lysimeters was not possible.

The authors conclude that the observation that decaBDE accounts for 99.8-99.9% of the total BDEs present indicates "*the persistence and low degradation of decaBDE in actual field soils*". However, the 99.8-99.9% value is relative to the total amount of BDEs present, and it is not discussed if decaBDE might debrominate and the lower brominated congeners either evaporate, leach out or undergo further degradation in soil.

The authors suggest the following debromination pathway for decaBDE:

decaBDE (BDE209) → BDE183 → BDE153/154 → BDE99 → BDE47 → BDE28

However, the unexplained loss of decaBDE that occurred during the second half of the experiment limits the potential for this study to derive such a pathway with any certainty. In addition, the direct debromination from decaBDE to BDE183 would require the direct loss of two bromine atoms, which seems incompatible with the suggested photolytic debromination pathway (Wei et al., 2013), which begins with the formation of nonaBDEs.

Plants growing on the decaBDE-exposed lysimeter have measurable concentrations of this compound plus lower brominated congeners in all parts (grain, shell, stem, leaf) clearly showing that BDEs are taken up by plants and distributed within tissues. It is unclear if the lower brominated congeners are taken up directly from the soil or if they are degraded within plant tissues. Unfortunately, the results are presented in such a way that they cannot be analysed further.

Gorgy et al. (2013) investigated BDE concentrations in soil over a period of a year (Aug 2006 – July 2007) after an application of sewage sludge (80 tons/hectare). BDE concentrations in sludge were, as follows (in pg/g dry weight): BDE47: 347, BDE99: 425, BDE100: 85, BDE153: 40, BDE154:35, BDE183: 13, decaBDE: 509 000. That is, decaBDE contributed 99.8% of the total BDE load. Concentrations of all congeners in the topmost layer (0 – 5 cm depth) had consistently decreased one year after the initial application, following an exponential trend. DecaBDE concentrations decreased from 162 000 pg/g to 10 000 pg/g. BDE concentrations in the soil layer between 5 – 25 cm depth, in contrast, increased consistently during the same time interval (the decaBDE concentration increased from 50 – 875 pg/g). Concentrations of BDEs in the lowest investigated layer (25 – 45 cm) also increased, with the exception of decaBDE, whose concentrations increased over the first six months from zero to roughly 1 000 pg/g, but then decreased to approximately 800 pg/g[36]. Concentrations of all BDEs in depths > 45 cm were assessed by the authors as "negligible".

It is important to note that the depletion of the topmost layer is almost two orders of

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[36] Again, data are presented in a figure (figure 2 of the publication), making it hard to retrieve actual values, unless they are specifically listed in the text.

magnitude higher than the accumulation in the lower soil layers (after adjusting the concentration values for the different total volumes of the three investigated soil layers), indicating that it is not only simply vertical transport (leaching) that is responsible for the depletion of the initial BDE load. BDE depletion was faster during summer, leading the authors to hypothesize that volatilisation, photodegradation and microbial biodegradation, all might contribute to the BDE loss in the upper layer. Depletion kinetics were congener-specific.

The study does not provide information on the abiotic or biotic degradation of decaBDE as a complex mixture of different BDEs was present in the applied biosolids. Equally, as the applied biosolids were mixed with the soil it is also not possible to differentiate between biosolid-specific processes, and soil-driven processes (e.g. different biodegradation by different bacterial communities).

Lu et al. (2013a) conducted a 60-day experiment in which the fate of decaBDE in a growth chamber with pumpkin (*Cucurbita pepo*) was investigated. The sterilised soil contained 4743-4850 µg/kg decaBDE, which was translocated into the plants: all parts contained decaBDE after the exposure, with decreasing concentrations in the order root > stem > leaf (roughly[37] 2300, 350 and 8.5 µg/kg dry weight, respectively). Uptake was strongly correlated with root lipid content. However, co-exposure to Cu led to lower concentrations of decaBDE in all plant tissues, indicating an active role of the plant in the uptake process, which was inhibited by exposure to Cu. Less than 0.01% of the total decaBDE was accumulated by the plants.

Eight lower brominated BDEs were quantified in pumpkin (BDE138, BDE183, BDE191, BDE196, BDE197, BDE206, BDE207, BDE208). The amount in soils was only 6% of the amount detected in plants, suggesting that the congeners were the result of biodebromination by pumpkin. The data also indicate very low translocation rates from the plants back into the soil and negligible photodegradation and other abiotic decaBDE degradation in soil. Nona-BDEs (BDE206, BDE207 and BDE208) represented the highest percentage of the lower brominated BDEs (60-70%) found in the plants. Additionally, two OH-PBDEs (4-OH-BDE-154 and 6-OH-BDE-169) and one MeO-PBDEs (4-MeO-BDE-153) were identified in pumpkin tissues. At the end of the study, decaBDE represented 80% of the total BDE burden in roots, 67% in stems and 50% in leafs. Experiments with ^{14}C-labelled decaBDE did not detect ultimate biodegradation (mineralisation) of decaBDE by pumpkin.

As the experiments were run under sterile conditions, bacterial degradation can be excluded as a possible cause for the debromination. Photolysis in the soil was prevented by black foil. Only very small amounts of lower brominated BDEs were found in soil, which also indicates that they were not present in the decaBDE test material initially applied (for which no purity information is provided in the paper). Taken together, the data convincingly demonstrate the biological degradation of decaBDE by pumpkin. Unfortunately, the purity of the decaBDE test material is not stated, but assuming once more that the congener profile of the decaBDE test material is equivalent to that of technical decaBDE, the presence of BDE138, BDE183, BDE191 BDE196, BDE197 strongly indicates biotransformation.

The ability of plants to biologically degrade decaBDE was also demonstrated in a study by Huang et al. (2013), who investigated decaBDE degradation by crude root extracts of Italian ryegrass (*Lolium multiflorum*.), pumpkin (*Cucurbita pepo*) and maize (*Zea mays*). In addition, *in vitro* degradation by isolated nitroreductase and glutathione transferase is described in the study. Root extracts degraded an initial concentration of 5 µg/L decaBDE within 24hours at 0°C by roughly 50% (no numerical values given), while in the controls

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[37] Again, no numeric values are given in the publication.

only 6.1-9% of the initial decaBDE was degraded after 96 hours. The kinetic constant in the samples is hence roughly ten times bigger than in the control. decaBDE degraded faster than any of the other tested congeners (BDE28, BDE47, BDE99). A broad spectrum of lower-brominated congeners was found (BDE1, BDE3, BDE4, BDE7, BDE8, BDE11, BDE15, BDE17, BDE28, BDE47, BDE49, BDE66, BDE74, BDE99, BDE100, BDE154, BDE183, BDE206, BDE207, BDE208), the major congeners were BDE66, BDE183, BDE206 (no numerical values given). Slight differences in the pattern of lower brominated BDEs were visible between the three species. Small amounts of OH-metabolites were also found (not in maize), but no MeO-metabolites.

A linear correlation between the *in vivo* nitroreductase activity and the decaBDE debromination rate was seen, indicating the involvement of this enzyme in the debromination step. In fact, *in vitro* incubation of decaBDE for 96 hours with either isolated nitroreductase or glutathione transferase led to the production of BDE206, BDE207, BDE208 and BDE7.

Exposure to decaBDE significantly reduced the activity of glutathione transferase in ryegrass and maize, as well as nitroreductase in maize. It is unclear, whether this is an actual inhibition of the proteins, or whether the enzymes simply do not produce their typical product, which is then quantified spectrophotometrically, when exposed to decaBDE - but instead are involved in the debromination of decaBDE.

Taken together, the time dependence in decaBDE degradation and the occurrence of several lower brominated congeners that are not known to be decaBDE impurities (BDE66, BDE183, resp. BDE7) strongly support the author’s hypothesis that decaBDE is biologically degraded in the three plant species, and that nitroreductase and glutathione reductase play an important role in this process.

Wang et al. (2011) exposed Alfalfa to 5 µg/kg decaBDE over 60 days in order to analyse OH-BDE transformation products. Four OH-PBDEs were detected in roots (3'-OH-BDE7, 3'-OH-BDE28, 5-OH-BDE47 and 6-OH-BDE47) at concentrations of 0.97, 0.15, 0.02 and 0.15 ng/g dry weight, respectively. Only two OH-PBDEs (3'-OHBDE7 and 4'-OH-BDE17) were detected in shoots at 1.33 and 0.04 ng/g dry weight, respectively. No metabolites were detected in the controls, indicating metabolisation in the plants. The “classic” lower-brominated decaBDE-transformation products were not analysed. The study provides a clear indication that alfalfa biotransforms decaBDE, or one of the impurities present in the decaBDE test material (which was of unstated purity), into hydroxylated metabolites, but does not allow more quantitative statements.

Wang et al. (2014) monitored the complex BDE pattern at four selected sampling spots near an e-waste site in China and surveyed the concentrations of 41 BDE congeners in soil and plants. DecaBDE was the dominant congener in soil, contributing between 61.4 and 93.7% of the PBDE contents in the soils at three of the samplings spots, and between 37.7 and 53.2% of the total BDE congeners at sampling spot four. In general, the congeners known to be present in either deca-, penta- or octa-BDE accounted for 81.6-99.8% of the total BDEs present in soil. 27 BDE congeners not known to be present in the commercial products contributed the rest. Plant roots and leafs were found to contain 33, resp. 26 different BDE congeners.

A summary of the BDE patterns found are given in Table 27, below, which is reproduced from the Table 1 of the Wang et al. (2014) study.

Table 27: Congeners and the total concentration of PBDEs detected in the soils, plant root and leaf samples by Wang et al. (2014)

Homologues	**Soils**	**Roots**	**Leaves**
Mono-BDEs	BDEs-1,2,3 (0.04-3.2, mean, 1.3)	BDEs-1,2,3 (n.d.-18.2, mean, 3.2)	BDEs-1,2,3 (0.4-17.5,mean,8.2)
Di-BDEs	BDEs-10,7,8,12/13,15 (0.6-13.0, mean, 2.0)	BDEs-10,7,8,12/13,15 (0.7-22.5, mean,5.6)	BDEs-10,7,8,12/13,15 (1.2-23.3, mean, 9.2)
Tri-BDEs	BDEs-32,17,25,33/28,35,37 (0.1-18.1, mean, 2.4)	BDEs-17,25,33/28,37 (n.d.-2.0, mean, 0.4)	BDEs-32,17,25,33/28,35,37 (n.d.-7.8, mean, 0.8)
Tetra-BDEs	BDEs-49.71,47,66,77 (0.7-127.9, mean, 18.1)	BDEs—49,47,66 (n.d.-20.4, mean, 3.5)	BDEs-49.71,47,66,77 (0.4-7.3, mean, 3.6)
Penta-BDEs	BDEs-100,119,99,85,126 (n.d.[a]-92.9, mean, 13.2)	BDEs-100,99,85,77 (n.d.-13.5, mean, 2.0)	BDEs-100,119,99,85 (n.d.-5.2, mean, 0.9)
Hexa-BDEs	BDEs-154, 153 (n.d.-42.8, mean, 8.8)	BDEs-154,153 (n.d.-6.8, mean, 0.4)	BDEs-154 (n.d.-6.7, mean, 0.7)
Octa-BDEs	BDEs-202,201,204/197, 198/199/200/203,196,205,194,195 (n.d.-219.6,mean, 15.0)	BDEs-202,201,204/197, 198/199/200/203,196 (n.d.-13.4, mean, 0.8)	
Hepta-BDEs	BDE-183 (n.d.-751.5,mean, 49.6)	BDE-183 (n.d.-60.2, mean, 4.2)	
Nona-BDEs	BDEs-208,207,206 (n.d.-54.7, mean, 4.4)	BDEs-208,207,206 (n.d.-3.5, mean, 0.2)	
Deca-BDEs	BDE-209 (5.0-11940.2, mean, 783.5)	BDE-209 (n.d.-5.3, mean, 2.0)	

Data within parenthesis are the total concentrations (ng g $^{-1}$ dw) of PBDE homologues in soils, plant roots and leaves, respectively.
[a] n.d.=not detected.

The total amounts of BDEs in soil and plant roots were strongly positively correlated. However, the relative proportions of the different congeners were different, in particular with respect to decaBDE, which contributed only to a very minor extent to the BDEs in plant roots. Mono-to penta-brominated congeners dominated in roots, plus MeO-BDEs, which demonstrates either a preferred uptake of these congeners via roots, foliar uptake of lower brominated congeners with a higher vapour pressure, and/or BDE debromination. The data reported in the study do not allow to disentangle these processes. A comparison of the OH- and MeO-BDE accumulation pattern with previously published accumulation data of plants growing near a completely different emissions source (seafood processing plant) led the authors to hypothesize that BDEs are actively transformed to OH- and MeO-BDEs in the investigated soil-plant system.

Table 28: Relevant new studies on degradation in plants

Refe-rence	**Species, type of study**	**DecaBDE form**	**Metabolites observed (tissues)**	**Measured amounts**
Lu et al., 2013a	60 day exposure of pumpkin (*Cucurbita pepo*)	unstated purity	- BDE138, BDE183, BDE191, BDE196, BDE197, BDE206, BDE207, BDE208 (majority in soil but some in the plants) - 4′-OH-BDE154, 6-OH-BDE169 and 4-MeO-BDE153 (only in plants)	Only provided as summary figures
Huang et al., 2013	Exposure of decaBDE to root extracts from Italian ryegrass (*Lolium multiflorum*.), pumpkin (*Cucurbita pepo*), and maize (*Zea mays*). Exposure of decaBDE *in vitro* to nitroreductase and glutathione transferase.	unstated purity	- Degradation from root extracts: BDE1, BDE3, BDE4, BDE7, BDE8, BDE11, BDE15, BDE17, BDE28, BDE47, BDE49, BDE66, BDE74, BDE99, BDE100, BDE154, BDE183, BDE206, BDE207, BDE208. 3′-OH-BDE7(pumpkin), 2′-OH-BDE3 (ryegrass) - Degradation from isolated enzymes: BDE7, BDE66, BDE99, BDE206, BDE207, BDE208	- 5 μg/L decaBDE was degraded within 24hours at 0°C by roughly 50% (no numerical values given).
Wang et al., 2011	Exposure of alfalfa to 5 μg/kg decaBDE over 60 days	unstated purity	- 3′-OH-BDE7, 3′-OH-BDE28, 5-OH-BDE47, 6-OH-BDE47, OH-PBDEs (3′-OHBDE7, 4′-OH-BDE17	- 3′-OH-BDE7, 3′-OH-BDE28, 5-OH-BDE47 and 6-OH-BDE47 at concentrations of 0.97, 0.15, 0.02 and 0.15 ng/g dry weight, respectively. - Two OH-PBDEs (3′-OHBDE7 and 4′-OH-BDE17) were detected in shoots at 1.33 and 0.04 ng/g dry weight.

Refe-rence	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
Wang et al., 2014	Survey of the complex BDE pattern near an e-waste site in China	Complex mixture of BDEs	Soil (values in parentheses give average conc. in ng/g dry weight): - BDEs-1,2,3 (1.3) - BDEs-10,7,8,12/13,15 (2.0) - BDEs-32,17,25,33/28,35,37 (2.4) - BDEs-49,71,47,66,77 (18.1) - BDEs-100,119,99,85,126 (13.2) - BDEs-154, 153 (8.8) - BDEs-202,201,204/197,198/199/200/203,196,205,194,195 (15.0) - BDE-183 (49.6) - BDEs-208,207,206 (4.4) - BDE-209 [decaBDE] (783.5) Roots (values in parentheses give average conc. in ng/g dry weight): - BDEs-1,2,3 (3.2) - BDEs-10,7,8,12/13,15 (5.6) - BDEs-17,25,33/28,37 (0.4) - BDEs-49,47,66 (3.5) - BDEs-100,99,85,77 (2.0) - BDEs-154,153 (0.4) - BDEs-202,201,204/197, 198/199/200/203,196 (0.8) - BDE-183 (4.2) - BDEs-208,207,206 (0.2) - BDE-209 [decaBDE] (2.0) Leaves (values in parentheses give average conc. in ng/g dry weight): - BDEs-1,2,3 (8.2) - BDEs-10,7,8,12/13,15 (9.2) - BDEs-32,17,25,33/28,35,37 (0.8) - BDEs-49,71,47,66,77 (3.6) - BDEs-100,119,99,85 (0.9) - BDEs-154 (0.7)	

B.4.1.2.5 Summary and discussion of new information on biotic degradation

In the following discussion it is generally assumed that the impurities contained in the decaBDE test materials used in the studies described in this section of the report comprise the same congeners as the commercial decaBDE product, i.e. BDE194, BDE196, BDE197, BDE203, BDE206, BDE207 and BDE208 (La Guardia et al., 2006). Based on this notion, any other congener found in an experiment is either a (bio)degradation product of decaBDE or of any of the listed possible decaBDE impurities (i.e. a hepta-BDE such as BDE202, can originate from either the impurities BDE206-208, or from decaBDE itself, or is the result of the combined debromination of all of those congeners).

The observed pattern of BDE-congeners in the organisms or compartment from a micro- or mesocosm or a field study is a result of several interlinked processes, namely: (i) congener- and organism-specific biodegradation, (ii) congener-specific photolysis, (iii) congener-specific environmental fate processes (depending on the test system, e.g. via leaching from a soil-column, evaporation from a body of soil), (iv) congener- and organism-specific biological elimination (e.g. passive diffusion or active elimination from an exposed organism) and finally, (v) congener- and organism-specific uptake. This network of interlinked processes leads to an incredibly complex system, where the establishment of causal links or the calculation of mass balance is a major challenge, and often not possible. It also leads to highly congener-specific BDE-distributions between the different components of a system.

All analysed studies provide direct or indirect clues for a debromination of decaBDE or its impurities. However, none of them allows for the calculation of a mass balance, i.e. a statement of how much of the initial decaBDE was (bio)degraded to which lower brominated congener.

The available field studies show the high dynamic that results from an initial application of either pure decaBDE or BDE-contaminated sludge, but provide only indirect and not always sufficiently documented evidence for decaBDE degradation.

The experiments by Lu et al. (2013b) and Shi et al. (2013) provide evidence for the aerobic degradation of decaBDE to simple brominated organics, such as 4-bromophenol and to inorganic bromine. In addition, the study by Rodríguez-Rodríguez et al. (2012) provides strong evidence for a biodegradation of decaBDE and several lower-brominated congeners by the fungus *Trametes versicolor*. However, the informative value of this study would have been significantly higher, if it would have included an appropriate control.

The papers by Lu et al. (2013a) and Huang et al. (2013) provide compelling new evidence on BDE biotransformation in plants. Lu et al. (2013a) presents convincing evidence that decaBDE is biotransformed in pumpkin. The authors unfortunately do not provide a mass balance that would allow an estimate how much of the initial decaBDE was biotransformed. However, the work under sterile, dark conditions and the identification of BDE138, BDE183, BDE191 BDE196, BDE197, 4-OH-BDE-154, 6-OH-BDE-169 one 4-MeO-BDE-153 provide very strong evidence for a biological degradation of decaBDE by plants. Huang et al. (2013) provides similarly convincing evidence, especially by recording the kinetics of the decaBDE degradation and the use of *in vitro* experiments. However, again, the study results do not allow the calculation of a mass balance of the fate of the initially applied decaBDE.

Canadian mesocosm studies (Orihel, in press), provide conclusive evidence of slow debromination of decaBDE and the formation of all nona-BDEs (-206, -207, -208) and 4 to 5 octa-BDEs (-196, -204/197, -201,- 202, -203) and trace amounts of hepta-BDE (-180, -183, -190), hexa-BDE (-138/166,-139, -154), penta-BDE (-99, -105, -116, -126), and di-BDE (-10) in lake sediments. However, the (bio)degradation mechanisms associated with these observations (abiotic or microbial degradation) are not identified.

Table 29: Relevant new studies on biotic degradation

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
Du et al., 2013	Lysimeter study, determination of BDEs in the soil + plants that grew on the lysimeter. Termination of the study after 4 years.	purity not reported	BDE-28, 47, 99, 153, 154, 183	- Most values only give as summary figures. - Numbers mentioned in the text : decaBDE concentrations: 29.2-101.1 µg/kg in 2008 wheat, 30.3-47.7 µg/kg in 2009 wheat, 19.5-36.7 µg/kg in 2009 rice, 1.8-32.6 µg/kg in 2010 rice, and 2.8-7.3 µg/kg in 2011 rice - Loss of decaBDE from the system after 4 yrs 64.4% .
Gorgy et al., 2013	Field study with sludge-amended soil that contained decaBDE and other BDE congeners over 12 months	Field study with complex BDE pattern. Concentrations in the applied sludge were as follows (in pg / g dry weight): BDE47: 347, BDE99: 425, BDE100: 85, BDE153: 40, BDE154:35, BDE183: 13, decaBDE: 509 000.	BDE47, BDE99, BDE100, BDE153, BDE154, BDE183, decaBDE (all already present at the beginning of the experiment)	- Values after at the end of the experiment only given in summary figures. - Numbers mentioned in the text: the major congener concentrations decreased with time in the 0.00-0.05 m layer from 5E3-162E^3 pg/g dw to 3E3-130E^3 pg/g dw, and then further to 10-230E^3 pg/g dw, at 4, 8 and 12 months, respectively. - In the next (0.05-0.25 m) layer the concentrations of the same congeners were n.d.-50 pg/g dw, 6-150 pg/g dw and 22-875 pg/g dw, respectively, thus increasing with time. - In the lowest of these three layers (0.25-0.45 m) these concentrations were nd or very low, with some apparent increase over time.
Rodríguez-Rodríguez et al., 2012	Bioreactors that were run for 26 days with fungi-amended STP sludge (*Trametes versicolor*)	Study with STP sludge with complex BDE pattern. decaBDE was present in raw sludge at a concentration of 232 ng / g dry weight, BDE183 at 0.61 ng / g, BDE 154 at 5.48 ng / g, BDE99 at 6.05 ng / g, and BDE47 at 5.39 ng / g	BDE47, BDE99, BDE154,BDE183 (all already present at the beginning of the experiment)	- 37.5% removal of decaBDE - BDE47=23.7% removal - BDE99=46.4% removal, BDE154=53.3% removal - BDE183, was not degraded

Reference	**Species, type of study**	**DecaBDE form**	**Metabolites observed (tissues)**	**Measured amounts**
Hale et al., 2012	Comparative study on observed vs. predicted BDE concentrations in biosolids of the Chicago area (archived sludges/biosolids from 1975 to 2008)	Does not apply, no experiments were conducted	BDE congeners considered in the study: BDE47, BDE49, BDE66, BDE85, BDE99, BDE100, BDE153, BDE154, BDE183, BDE196, BDE197, BDE203, BDE207, BDE207, BDE208, decaBDE	Does not apply, no experiments were conducted
Lu et al., 2013b	Exposure of *Bacillus cereus* over 12 days to 1-20 mg/L decaBDE	unstated purity	BDE15, BDE28, BDE154, 20,30-Dihydroxy-4,40-dibromodiphenyl ether, 2-Hydroxy-4-bromo-adipic acid, 4-Bromophenol, 4-Bromocatechol	Not provided
Shi et al., 2013	Exposure of *Pseudomonas aeruginosa* to 1mg/L decaBDE over 7 days	>98% purity	BDE183, BDE196, BDE197, BDE202, BDE203, BDE207, and BDE208	Not provided

B.4.2 Environmental distribution

B.4.2.1 Adsorption/desorption

No new relevant information was found.

B.4.2.2 Volatilisation

No new relevant information was found.

B.4.2.3 Distribution modelling

No new information was found.

B.4.3 Long-range transport

A report from the Northern Contaminants Program was published in 2013 (NCP, 2013) with a collection of monitoring data that covers results on POPs in the Canadian Arctic over the period of 2003 up to early 2013. The data are also partly referred in the SVHC SD from individual papers previously published.

The NCP (2013) report extensively documents that decaBDE is deposited to the Arctic environment, it is bioavailable to the organisms living there and is widespread in Arctic food webs. Among other results the report refers analysis of snow cores from the Devon Island Ice Cap in Nunavut that show that decaBDE was the major PBDE congener present in the samples, followed by nona-BDEs, both accounting for 89% and 7% of total BDE, respectively. DecaBDE concentrations were remarkably high compared to other POPs with concentrations ranging from 9.5 ng L-1 to 100 ng L-1 in 2008 and in the same range in 2005 and 2006. Results from measurements in air at Alert (NU) in Canada in the period 2002–2009 showed that decaBDE was one of the dominant PBDE congeners (average 24%, range 0.66–79%). It was noted however that the levels at Alert may be influenced by the historical use of PBDEs at the military base and the Global Atmospheric Watch (GAW) laboratory facility where the air sampler is located. (NCP, 2013).

Results from 2013 (Norwegian Environment Agency; 2014) from the Zeppelin Mountain station at Svalbard (Arctic station under the Arctic Monitoring and Assessment Programme) showed monthly mean concentrations of decaBDE in air varying from 0.56 to 1.11 pg/m$^{3.}$. DecaBDE and BDE-47 were the most abundant BDE congeners representing 45-65% and 9-27% of the sum BDEs, respectively. No significant long term trend could be seen compared to results from previous years.

At Jan Mayen (Arctic Island in the North Atlantic Ocean) dissolved concentrations of PBDEs in sea water were measured (Climate and Pollution Agency, 2012a). DecaBDE was found at a concentration of 2.5 pg L-1, which was close to the limit of detection but nevertheless allowing tentative estimation of dissolved concentrations. Concentrations of PBDE-47 and PBDE-99 were 0.27 and 0.58 pg L-1, respectively. Data for PBDEs in air was not reported due to high uncertainty in the data.

Dickhut et al. (2012) detected decaBDE, BDE 100, BDE 99 and BDE 47 in air, snow and sea ice throughout western Antarctica between 2001-2007 providing further evidence of the long-range transport of this compounds over remarkable long distances. Concentrations were low compared to remote regions of the northern hemisphere, except of one sampling site nearby a possible local source due to a fire at a research station in September 2001. DecaBDE levels in Antarctic sea ice are reported as stable and unchanged in the period 2001-2007 , whereas a significantly decline was seen for BDE

47, 99, 100.

B.4.3.1 Summary and discussion of new information on long range transport

DecaBDE is one of the most abundant BDE congeners measured in air in the Arctic. It is deposited to the Arctic environment, e.g. as documented by the occurrence in snow cores in the Devon Ice Cap being the major BDE congener found there. Furthermore it is extensively documented that decaBDE is found in Arctic wildlife. Although local sources may be present to some extent the available data from remote regions overall show that decaBDE is detected in these areas as a result of long-range transport.

B.4.4 Bioaccumulation and transformation

Similar to the SVHC-Support Document bioaccumulation data for decaBDE itself are not the primary focus of this dossier because decaBDE was considered to meet the definition of a PBT/vPvB substance according to the Annex XIII criteria based on all available information, among others the evidence of transformation in soil and sediments to form lower brominated PBDE congeners, which either have PBT/vPvB properties, or act as precursors to substances with PBT/vPvB properties, as well as evidence of transformation to such substances within biota.

B.4.4.1 Aquatic species

B.4.4.1.1 Field studies

Numerous field studies have been published since the SVHC-Support Document was adopted, however, given the complex nature of environmental exposure conditions (i.e., contaminant mixtures, uncontrolled conditions), most of these studies are not suited to the determination of debromination pathways. Still, the following field studies provide valuable information on environmental levels and bioavailability of decaBDE (and other PBDEs) in a range of environmental aquatic species from different parts of the world. Some of these studies also provide indicative information on debromination patterns.

B.4.4.1.1.1 Invertebrates

Liu et al. (2013) provide an overview of the BDE congener patterns in mudsnails (*Cipangopaludina cahayensis*) and sediment samples from an electronic waste recycling site in China (Liu et al., 2013). They included decaBDE, BDE183, BDE154, BDE153, BDE100, BDE99, BDE47 and BDE28 in their analysis. BDEs in sediment comprise 97% decaBDE, while it only represents between 5.5% and 7% of the total BDEs in snails. BDE47 and BDE99 are the most common congeners in the snails (between 41%-42%, and 26%-29%, respectively). The study, however, does not allow to pinpoint the causes for the increased prevalence of those lower brominated congeners in the snails, which could be caused by a comparatively lower uptake of decaBDE, and/or decaBDE debromination in the snails. That is, decaBDE debromination obviously took place, but it is unclear whether this happened in soil (biotic and/or abiotic) or within the organisms. The complex interplay between congener specific uptake and elimination kinetics makes it impossible to estimate the relative contribution of the different processes. BDE pattern did not differ between snails of different age, indicating that the internal concentrations are in equilibrium with environmental concentrations, and neither growth dilution or accumulation takes place.

B.4.4.1.1.2 Fish

Although varying levels and detection frequencies are observed, monitoring data show that decaBDE is bioavailable and is taken up by fish (Ren et al., 2013; Santín et al., 2013). Ren et al. conducted a survey on BDEs in fish from an industrial region in Northeast China (Ren et al., 2013), where an average of 19 ng/g lipid weight of total BDEs were found, with BDE47 contributing 6 ng/g lipid. Unfortunately, no actual figures are provided on the concentrations of the different BDE congeners. Figure S2 in the supporting information provides an overview of the relative congener ratios. BDE28 and BDE47 are the most common lower brominated congeners. Also substantial relative fractions of decaBDE were detected in several fish samples, it accounted for 50% of the total body burden in one sample, the average fraction was 19%.

The congener distribution described in a study by Satin et al. (2013) on fish from Iberian rivers showed, once more, the typical BDE congener-pattern. In total, the following congeners were found: BDE28, BDE47, BDE100, BDE153,BDE154, BDE183 and decaBDE. The quantitatively most common congener was BDE47, which, additionally, was also found in each sample. DecaBDE was only detected in fish from 2 of the 4 sites, maximum amounts were found in fish from the Llobregat river, with a median concentration of 10.9 ng/g lipid. BDE47 was present at this site at 77.4 ng/g lipid. Sampled fish belonged to different species, as it was not possible to collect the same species at all sites. This, however, is not considered during the data presentation. The reported congener pattern is hence also influenced by species-specific differences in debromination kinetics and feeding behaviour.

Teil et al. determined bioaccumulation factors (BAFs) as c(biota)/c(water) and biota sediment accumulation factors (BSAFs) as c(biota)/c(sediment) for BDEs, Polychlorinated Biphenyls, and Phthalates in roach, chub and perch from the Orge river in France (Teil et al., 2012). BDE28, BDE47, BDE99, BDE100 and decaBDE were detected. However, BAFs for BDEs are not further presented in the result or discussion section. Teil et al. (2012) mentioned that "*no correlations were found between contents and bromination degree, whatever the species and organs considered, due to major debromination activities" as cited by (Stapleton et al. 2004)*".

BSAFs were dependent on species and BDE congener. The lowest BSAFs were observed for decaBDE (0.1-0.3). BDE28 had the generally highest BSAF (6.8 in perch, 23 in chub, 29.2 in roach). This pattern is consistent with the hypothesis of a debromination of decaBDE in the three fish species. It is, however, most likely also heavily impacted by the different feeding strategies of the species, as well as different uptake and elimination kinetics, and the data do not provide the basis to comparatively assess the interconnection of those processes.

A total of 1.42 ng/L decaBDE was detected in river water (dissolved + bound to particulate matter), which, according to the authors "*accounts for roughly 90%*" of the total BDE load in the river water. Using this figure, one would conclude that 0.16 ng/L lower brominated congeners were present (actual figures are unfortunately not presented in the study). In sediments decaBDE was detected in a concentration of 4-140 ng/g dry weight and 43.6-120.6 ng/g of the lower brominated congeners. Again, no precise figures are given for the different sampling sites. The authors conclude that "*decaBDE was the main compound (90 ± 6%) followed by BDE-99 (4 ± 2%), BDE-47 (3 ± 2%), and BDE-100 (0.8 ± 0.4%). A small contribution of the other compounds was observed (approximately 2%).*" Given the initially listed congeners that were detected somewhere during the study, "*the other*" compounds should be BDE28. In any way, the authors state that decaBDE comprised 90% of the total BDE load in both sediment and water. Interestingly, sediment concentrations of decaBDE as well as the lower brominated congeners increase consistently during the three sample campaigns (7/2009, 10/2009, 4/2010). BDE content in fish muscle was not correlated with lipid content, season and sex. 12-18 ng/g dry weight of total BDEs were found, with no difference between the species. Seasonal differences in total BDE burden in muscles are in the text of the publication assumed to be significantly different, with lower BDE amounts in July. The accompanying figures (5 & 6 of the publication), however, indicate on miniscule differences across seasons. BDE concentrations were unevenly distributed amongst tissues (gonad > liver > muscle).

BSAFs for decaBDE and 20 additional BDE congeners were determined in a study by Chen in demurral and pelagic fish from Taiwanese rivers (D. Chen et al., 2013). DecaBDE had the lowest BSAF of all congeners in demurral fish (1.6) and a BSAF of 0.6 in pelagic fish (BDE183 had a lower BSAF than decaBDE in pelagic fish (0.3), BDE71, BDE85 and BDE138 also had a BSAF of 0.6). DecaBDE was by far the most prominent BDE congener in sediment, with concentrations higher in the dry season, which is attributed by the authors to increased sediment run-off during the wet season. Absolute BDE amounts varied between 0.5 and 90 ng/g dry weight in sediment and 2.3 (*Oreochromis niloticus niloticus*) and 33.7 (*Varicorhinus barbatulus*) ng/dry weight in fish.

A hyperbolic trend between bromination and BSAF was observed, with a higher BSAF for lower brominated congeners, similar to the previously discussed study by (Teil et al., 2012). DecaBDE consistently had the lowest BSAF, with one exception (BDE183 in pelagic fish). Consequently, fish contained higher relative proportions of the lower brominated congeners (especially BDE47, BDE100, BDE119, BDE126, and BDE154) than sediments. Again, no conclusion can be derived on the relative importance of the different factors and processes impacting the final BDE congener composition in fish. As, based on a PCA analysis, the BDE composition of pelagic fish was more similar to each other than to demersal fish, the biology and feeding strategy of the exposed organisms had a visible impact on the final BDE pattern.

DecaBDE accounted for 94% of the BDEs in the analysed sediments in a study by (He et al., 2012), who analysed BDE occurrence in the environment of a river in South China. In water, decaBDE only accounted for 18%, in the particulate phase for 79%. In sediment, decaBDE accounted for more than 95% of the total BDE load. Concentrations in fish (mud carp, (*Cirrhina molitorella*), plecostomus (*Hypostomus plecostomus*) and nile tilapia (*Tilapia nilotica*)), were dominated by BDE47, additionally, plecostomus also had a major body burden of BDE99. The authors hypothesize, that this pattern is caused by two interlinked factors: (a) it is known from previous studies that BDE99 is de-brominated to BDE47 in carp, and hence it is argued that plecostomus does not express a similar debromination pathway, (b) plecostomus lives and feeds at the bottom of rivers, where, the species has a higher chance to ingest sediment, which contains a higher relative proportion of BDE99. Mud carp as well as nile tilapia mainly feed on phytoplankton. Both hypotheses go together with the fact that also decaBDE was detected at higher frequencies and concentrations in plecostomus. Whether the observed high load of BDE47 might actually come from the commercial penta-product is not discussed. BDE47 does not occur in substantial amounts in sediments, but might be leaching into the water from nearby waste sites.

The ratios of nona-BDEs (sum of BDE208, 207, and 206 as the first debrominated congeners) and decaBDE in plecostomus (0.47) were drastically higher than those in sediments (0.05), which indicates differential uptake and/or metabolism of decaBDE. But the ratio was also significantly lower than in mud carp (7.4) and nile tilapia (9.6), consistent with the hypothesis that also decaBDE debrominates to a much lower extent in plecostomus than in mud carp and nile tilapia.

Echols and colleagues report BDE concentrations in three fish species (common carp, largemouth bassand channel catfish) from three sites in Arizona (Echols et al., 2013) and proposed a debromination tree diagram for PBDEs, Figure 6. Massive differences in total BDE load were found, driven by the different emissions sources near the sampling sites

(STP-effluent vs. irrigation return water). DecaBDE was the least prominent BDE congener in all fish at all sites, with concentrations between 1.8 and 0.3 ng/g lipid, total BDE concentrations were between 108 000 and 57 ng/g lipid. It should, however, be mentioned that there seems to be a discrepancy between table 1 in the publication, which lists the concentrations of the individual BDE congeners and table 2 in the supporting information (table S2), which is supposed to provide the same data aggregated according to BDE group (Tetra-BDEs, Penta-BDEs, etc). However, the data are different at least for decaBDE, which is a group of its own. DecaBDE concentrations around 3 ng/g lipid are for example reported for the Hayden site in the main manuscript, while the corresponding entry in table S2 indicates that no decaBDE was detected in fish from this site.

Most prominent group of BDE congeners were the tetra-brominated BDEs, which constituted up to 86% of the total BDE load. BDE47, the main ingredient of the commercial penta-BDE product, was always the most predominant congener. Six BDEs (BDE17, BDE 28, BDE47, BDE49, BDE100 and BDE153, in decreasing order of concentration) were found in all species.

The BDE congener pattern was compared to a previously published debromination scheme from (Zeng et al., 2010; Zeng et al., 2008), and the authors concluded that "*nearly all congeners reported in Table 1 matched those modelled.*" The occurrence of lower brominated congeners that are not present in any of the commercial products is a strong indication for a debromination. However, it is not evident how the authors concluded that this debromination takes place in the fish. It is equally plausible to assume that at least partly the debromination step takes place in the environment (which includes prey species), with subsequent direct uptake of the lower brominate congener, either via food, the ingestion of sediment or even via passive diffusion from the water.

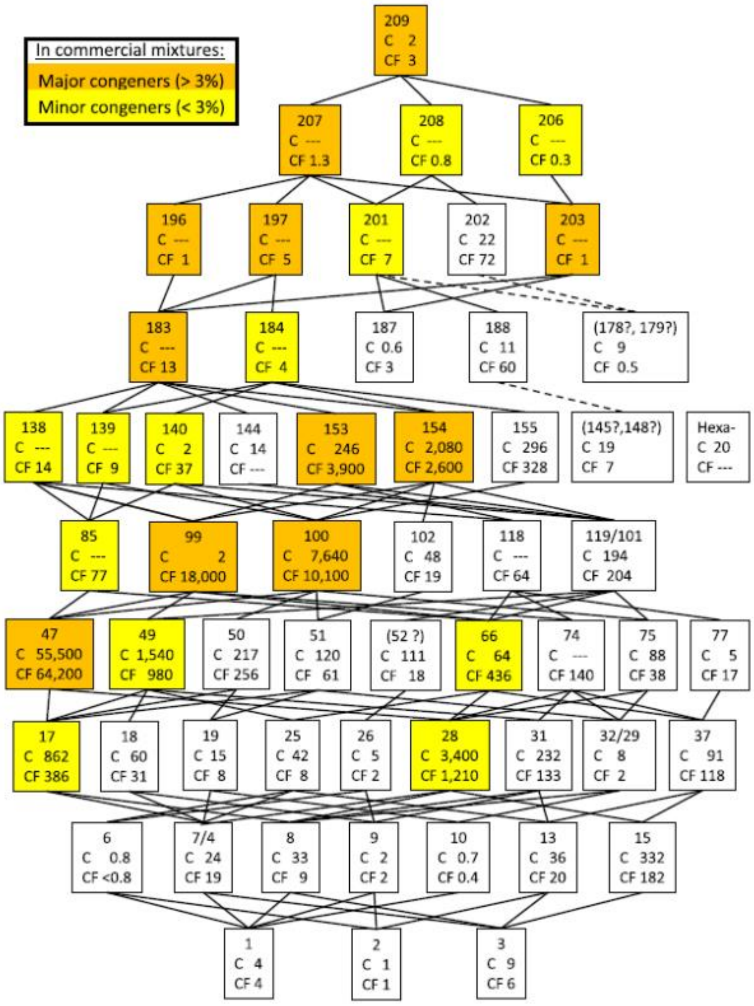

Figure 6: Debromination tree diagram for PBDEs found in fish (catfish – CF and carp – C) from Arizona (from Echols et al. 2013).

14 BDE congeners were surveyed in muscle tissue from the deep-sea fish *Alepocephalus rostratus, Coelorinchus mediterraneus and Lepidion lepidion* and the red-shrimp *Aristeus antennatus* from the North-Western Mediterranean Sea by (Koenig et al., 2013). More than 70% of the BDE burden in fish were from BDE28, BDE47, BDE99, BDE100 and BDE154. BDE153 and decaBDE were also important contributors to the BDE load in shrimps. Total BDE concentrations were as follows: *Alepocephalus:* 0.92, *Coelorinchus:* 0.61 *Lepidion:* 0.58, *Aristeus:* 0.47 ng/g wet weight. DecaBDE comprised 12%, 3%, 3% and 36%, based on wet weights (data on lipid-normalized amounts are not presented for decaBDE). The authors restrict further discussion of the importance of possible debromination steps for the observed BDE pattern on penta- and octa-BDE products.

Some studies had a special focus on trophic transfer and biomagnification in food chains. (Yu et al., 2012) analysed 200 samples of 24 fish species from the largest freshwater lake in China. Most commonly detected congeners were BDE47, BDE154 and decaBDE. decaBDE was detected in all fish (4-70%), but its concentration was highly dependent on the trophic status of the sampled fish species. In herbivorous and omnivorous fish, the contribution of decaBDE to the total PBDEs was high, ranging from 15.0 to 69.6% (average 38.3%), while in carnivorous fish, decaBDE only represented between 3.7 and 19.7% (average 10.3%) of the total PBDEs. This is in line with the hypothesis, that closer contact by herbivorous and omnivorous fish to sediments leads to an increased intake of higher brominated congeners.

BDE47 was the most common individual congener (10-50% contribution in each sample). BDE154 was common in predatory fish, but not in herbivorous fish. The authors hypothesize that this is caused by an increased capacity of predatory (carnivorous) fish to debrominate decaBDE. However, it could also be speculated that BDE154 is simply biomagnified to a higher extent than other BDE congeners. Unfortunately, no trophic magnification factor for BDE154 is provided. Trophic magnification factors were exceeding 1 for BDE-17, BDE-28 and BDE-100, indicating biomagnification. Interestingly, the trophic magnification factor for BDE-99 is not even 50% of the trophic magnification factor for BDE-100, despite the close chemical similarity between both compounds. However, in general the trophic magnification factor shows a hyperbolic relationship to logP, with a maximum at around 7.2.

Also Batrons and his colleagues (2012) provide a food-chain based analysis of BDE congener-distribution in a high mountain lake ecosystem. They grouped organisms of a remote ecosystem into "basal resources" (microbial communities, which had a dual role also as primary producer), "primary consumers" and "secondary consumers" and fish and analysed BDE concentrations in each of them. Only decaBDE was found to a substantial extent in the basal resources (0.04 ng/g dry weight), while BDE190, BDE183, BDE99 and BDE47 were only found in trace amounts (0.01 ng/g dry weight). The congener pattern becomes more complex with increasing trophic level, primary consumers contained 6 congeners (but no decaBDE), secondary consumers 10 congeners (including decaBDE), while fish in the end contained 7 congeners excluding decaBDE. However, the dominant congeners differ, and huge variations exist between different species on the same trophic level - indicating that traits such feeding patterns or life cycles have a profound impact.

Relative decaBDE concentrations in basal resources were 50%, however with distinct differences: autotrophic microorganisms had the highest relative decaBDE concentrations, microbial communities from the top sediment the lowest. The authors hypothesize that this is due to anaerobic dehalogenation within the top sediment communities. UV levels at the sediment layer was lower than for any of the other communities, i.e. photodegradation was excluded as a reason for the lower dominance of decaBDE in top sediment communities.

Stable isotope analysis further indicated decaBDE biotransformation over the trophic chains. The BDE pattern in fish resembles that of primary consumers (especially in relation to the lack of decaBDE), however the isotopic composition (Br79:Br81) of BDE47 closely resembles that found in basal resources. Under the assumption that BDEs are in fact funnelled through the foodweb, this would point to a strong biological fractionation somewhere during the feeding process (abiotic (photolytic) debromination does not differentiate between Br79 and Br81). The authors put forward the hypothesis that this biological fractionation takes place in the fish gut (i.e. during the uptake process), which would also offer an explanation why the total BDE load in fish was surprisingly low. An alternative hypothesis, which is only briefly mentioned by the authors, would be that the BDEs are accumulated differently in the various fish organs (the analysis in the paper is based solely on muscle samples). A third hypothesis, not mentioned in the paper, would be that the BDE uptake into fish is not only dependent on food uptake, but also on direct uptake through the water phase or after contact with sediment. The studies discussed earlier seem to clearly indicate that decaBDE is only marginally bioavailable at best, which in summary would explain why (i) no decaBDE was found in fish, and (ii) the isotopic composition of BDE47 resembles that in primary resources. Unfortunately, no data on the isotopic composition of the BDEs in the different abiotic compartments are given.

Zeng et al. (2013) surveyed sediments and two fish species (mud carp and northern snakehead) from a pond contaminated by e-waste in Southern China. 30 unspecified BDE congeners were detected in sediment, as the most prominent ones the authors list BDE47, BDE99, BDE183, decaBDE, accounting for 3.1%, 3.5%, 6.8% and 64.9% of the total BDE load, respectively. All congeners were also found in both fish species. No quantitative details are given, but the authors state that "*The congener profiles in the mud carp and the northern snakehead have major contributions from lower brominated PBDE congeners, such as BDE28, 49, 47, 100, 154, and 153, which were different from that in the sediment. These results can be attributed to the combined effects of lower bioavailability and debromination of highly brominated congeners.*"

Most common BDE congeners in mud carp were BDE47 (45.5%), BDE153 (15.3%), BDE49 (9.8%), BDE154 (7.8%), BDE100 (7.7%), and BDE28 (4.9%). The congeneric pattern was different in northern snakehead mainly contained BDE47 (60.4%), BDE153 (2.1%) and BDE49 (3.7%).

The biomagnification factor ranged between 0.3 and 4.5. BDE28, BDE47,BDE100, BDE154, and BDE155 had BMFs larger than 1, suggesting biomagnification. BMFs of several PBDE congeners, including BDE153 and BME183 had biomagnification factors below 1, suggesting biotransformation or elimination.

Stable isotope composition of BDE47, BDE100, and BDE99 in sediment closely resembled the composition of commercial products. BDE47 in carp is depleted in 13C, which is taken as an indication of biotransformation of BDE99 in this species. No significant difference in the isotopic composition of BDE100 in fish was found, indicating that this congener is not biotransformed.

The stable isotope data strongly indicate biotransformation of (most likely) to BDE99 to BDE47 in carp. The analysis does not provide data on decaBDE (bio)degradation, though.

B.4.4.1.2 Laboratory studies

B.4.4.1.2.1 Invertebrates

The BDE bioaccumulation kinetics was the centre of a study by Zhang et al. (2013), using the aquatic oligochaete *Lumbriculus variegatus* as the test organism. The worms were first exposed for 28 days to field-contaminated sediment, and transferred to clean sediment for 21 days afterwards. The following congeners were analysed: BDE28, BDE47, BDE99, BDE100, BDE153, BDE154, BDE183 and decaBDE. DecaBDE was the most common congener, both in sediments as well as in the worms. Concentrations were 1866 ± 160 ng/g dw in the sediment, and 10640 ± 2773 ng/g lipid at steady state in worms, with a BSAF of 0.103 ± 0.025. The elimination rates for the various PBDE congeners, with logP values spanning 6 orders of magnitude, differed only little, indicating that not only passive, lipophilicity-dependent diffusion is responsible for clearing the BDEs from the biota. The authors hypothesize that biotransformation and faecal elimination play an additional important role in PBDE elimination. In contrast, uptake was strongly inverse correlated with log P.

BSAF was highest for BDE47, followed by BDE28. DecaBDE had the lowest BSAF The study does not provide any insight into BDE (bio)transformation.

B.4.4.1.2.2 Fish

Luo et al. (2013) studied the bioaccumulation and debromination of decaBDE in medaka (*Oryzias latipes*) exposed to 1 to 1000 ng/l decaBDE. DecaBDE was detected in the muscle of fish from all treatment groups after 15 days exposure, or longer. Also several lower brominated BDEs were found, in particular BDE47, BDE155, and BDE99, all not belonging to the group of known decaBDE impurities. decaBDE comprised only between 7 and 17% of the total BDE body burden after 60 days exposure.

A particularly substantial body burden of BDE155 was found, which is an impurity of the commercial penta-BDE mixture. Unfortunately, no details are provided on impurities of the used decaBDE standard, or the congener composition in the test water. It is, however, unlikely that the standard was contaminated with BDE155 in amounts that could explain the congener pattern in the experiment, where BDE155 contributed 74% of the total BDE load (after 30 days exposure to 1 µg/L). Concentrations of decaBDE and BDE155 did not increase linearly over time, but instead seem to peek at day 30 and decline afterwards. The concentrations of BDE47, however, increased especially at the end of the exposure time (60 days).

The study provide clear proof that decaBDE is taken up via the water phase and subsequently biodegraded. However, it is unclear whether the debromination takes place in the fish tissue or is driven by gut microbiota. A mass balance that would allow to estimate how much of the initial decaBDE has been transformed in total is not provided, and it is not possible to recalculate a mass balance from the presented data. The half-life of decaBDE in the muscle of medaka was estimated between 16.5 to 19.4 days. However, it is not clear how the authors actually calculated this value.

Tian et al. (2012) studied the bioaccumulation and metabolism of sediment-associated PBDEs in benthic invertebrates and fish in water/sediment microcosms. Two types of microcosms were studied; group A containing both benthic invertebrates (tubificid worms) and carp (Cyprinus carpio), and group B with carp only. 11 BDE congeners were included in the analysis (BDE28, BDE47, BDE99, BDE100, BDE153, BDE154, BDE183, BDE206, BDE207, BDE208, and decaBDE). Exposure was achieved via sediment, using commercial products (DE-71, DE-79, and DE-83). The resulting initial congener pattern in the sediment was analytically determined prior to the experimental start, and was strongly dominated by decaBDE (70%, 1340 ng/ g dry weight). No decaBDE was detected in the fish after 20d exposure in the water/sediment system. Detected congeners were: BDE28, BDE47, BDE100, BDE153, BDE154, BDE206, BDE207, and BDE208, with BDE47 being the most abundant congener. However, high concentrations of decaBDE were detected in fish faeces, comparable the sediment concentrations. It was hence hypothesized that decaBDE was taken up by the fish, but not bioaccumulated. This might, although not mentioned by the authors, also indicate that decaBDE simply passed the fish gut, without entering the organism, and was debrominated by fish gut microbiota, with the resulting lower brominated congeners then taken up by the fish. Due to the low water solubility of decaBDE, it was also concluded by the authors that the main uptake route of decaBDE is via suspended solid matter, i.e. sediment particles.

If the fish could get in contact with the contaminated sediment, BDE uptake was significantly higher/faster. The authors conclude that benthic organisms might in general be higher exposed to BDEs, which seems to be also confirmed by the monitoring studies reviewed in this document. Presence or absence of worms did not have an impact on the BDE pattern in fish.

After 80 days exposure the worms contained a complex congener pattern, including decaBDE. The PBDE concentrations in the worms were significantly higher than those in the fish, and the congener profile of the seven major congeners (BDE28, BDE47, BDE99, BDE100, BDE153, BDE154, and BDE183) was also distinctly different from that of fish tissues. However, the system reached steady state with respect to the distribution worm<->sediment, but steady state for fish was not reached. The concentration of decaBDE in the worm at the end of the experiment was only 25 ng/g dw, i.e. the BSAF was only 0.01.

The study does provide strong evidence of decaBDE degradation and proves that it is at least partly biological, but does not allow to calculate a mass balance in order to determine decaBDE (bio)degradation rates. It is also not possible to elucidate the sequence of debromination steps.

Wan et al. (2013) studied the bioaccumulation mechanism of decaBDE in Chinese sturgeons (*Acipenser sinensis*) from the Yangtze River. Contrary to less brominated PBDEs, lipids did not play an important role in the biodistribution of decaBDE in fish. The average concentration of decaBDE was 54.5 ng/g ww in liver, 47.4 ng/g ww in gills, 41.9 ng/g ww in intestine, 21.9 ng/g ww in stomach, 19.1 ng/g ww in muscle, 7.5 ng/g ww in heart, 6.8 ng/g ww in gonad, 4.9 ng/g ww in adipose, and 2.8 ng/g ww in egg.

In vitro metabolism of decaBDE by microsomal fractions of sturgeon indicated that decaBDE was rapidly metabolized in the liver (rate constant K = 0.039 h^{-1}, half-life 18 h, 65.6% of 25 pmol of decaBDE depleted after 24 h). After a 24 h incubation, the liver microcosms biotransformed 96-97% of the decaBDE when exposure concentrations ranged from 25 to 500 µg/l. Debromination products included penta- (BDE-126, formation rate K = 0.026 h^{-1}), hexa- (BDE-154, K = 0.006 h^{-1}), hepta- (BDE-183, BDE-184 with K = 0.016 h^{-1}, BDE-188), and octa-BDEs (BDE-201, BDE-202, BDE-204/197).

Feng et al. (2012) exposed juvenile rainbow trout (*Oncorhynchus mykiss*) to decaBDE of 98% purity at five concentrations from 50 to 1000 ng/g wet weight (nominal) for 21 days via a single intraperitoneal injection. Major details of the study are also given in (Feng et al., 2010), which are hence listed in the table below.

Concentrations of debrominated BDE congeners demonstrated the metabolisation of decaBDE in a tissue-dependent manner. The central table of the publication is reproduced below. Analytical checks at the beginning of the experiment confirmed that the concentrations of all BDE metabolites were below the detection limit in the used fish food and the test compound itself.

The study shows with great reliability that decaBDE is degraded by rainbow trout. Due to the application of the decaBDE via injection an involvement of the gut microflora can be excluded. However, the data do not allow to calculate to what extent decaBDE was degraded, a mass balance can hence not be established.

Table 30: Tissue distributions of decaBDE, total PBDEs, hydroxylated BDEs (OH-BDEs), and methoxylated BDEs (MeO-BDEs) at different gradient dose after 21-day exposure to decaBDE

Dose	decaBDE (ng/g)			Total PBDEs (ng/g from graph)		
ng/g	Liver	Blood	Kidneys	Liver	Blood	Kidneys
50	38.5	ND	30.7	110	35	90
100	80.3	ND	41.3	275	80	125
200	57.2	ND	31.2	175	130	115
500	49.0	ND	17.6	160	60	65
1000	48.3	ND	18.1	170	65	70

Dose	Total OH-BDEs (ng/g from graph)			Total MeO-BDEs (ng/g from graph)		
ng/g	Liver	Blood	Kidneys	Liver	Blood	Kidneys
50	240	80	230	35	100	150
100	275	125	370	40	125	190
200	325	140	330	50	135	200
500	160	115	230	25	125	140
1000	110	80	200	20	110	130

Thyroid hormone TT3 and TT4 levels were little affected, but levels of FT3 and FT4 were reduced. The hormone levels were negatively correlated with concentrations of hydroxylated BDEs.

Juvenile common sole (*Solea solea*) were exposed to a mixture of six BDE congeners (BDE28, BDE47, BDE99, BDE100, BDE153 and decaBDE) via food for a period of 84 days by (Munschy et al., 2011). The congeners were detectable in fish already after an exposure of seven days. Steady state was not reached.

It was shown that decaBDE was metabolized with a half-life of 43 days. However, as the fish were exposed to a complex mixture of BDE's, it is unclear, from which higher brominated congeners the final metabolites originate. However, BDE183, BDE202 and an unknown hepta-BDE, which were both amongst the detected metabolites can only originate from decaBDE, i.e. clearly demonstrate the bio-debromination of decaBDE. BDE49 and an unknown penta-BDE were the main metabolites, and could also originate from the debromination of the administered BDE153. The study does not allow to calculate a mass balance. Again, it is unclear whether the debromination takes place in the fish tissue or is driven by gut microbiota.

Data reported for the accumulation and debromination of decaBDE by Noyes et al, (2011) were originally considered during the development of the SVHC SD for decaBDE. The Noyes study (2011) reported that based on a suite of decaBDE metabolites (consisting of 32 lower brominated PBDE congeners), approximately 5.8% of the BDE-209 exposure was estimated to be bioavailable to juvenile fathead minnow over a 28-day exposure. However, the analysis did not take into account BDE-209 that was accumulated by the juvenile fish, but not metabolised. Further analysis of the data presented in the manuscript, including the amount of BDE-209 that was accumulated but not metabolised suggests that, whilst there is some uncertainty with regards to the precise mass balance, the uptake of BDE-209 from food over the 28-day exposure was ~10 % of the cumulative exposure of ~ 0.45 nmol/fish and that there was significant conversion (>60 mol %) of the accumulated decaBDE to lower molecular weight PBDEs of concern over the same period (Table 31).

Table 31: Analysis of BDE-209 metabolism in juvenile fathead minnow (After Noyes et al. 2011)

PBDE congener	**Concentration (ng/g w/w)**	**Concentration (nmol/g w/w)**	**Concentration nmol/fish[a]**
BDE-209	488	0.509	0.0134
BDE-202	75	0.094	0.0025
BDE-201	5	0.006	0.0002
BDE-188	120	0.166	0.0044
BDE-179	85	0.118	0.0031
BDE-154	215	0.334	0.0088
Unknown hexa 1	80	0.124	0.0033
Unknown hexa 2	50	0.078	0.0020
Unknown hexa 3	10	0.016	0.0004
BDE-101	30	0.053	0.0014
Sum of PBDE[b]	**Excluding BDE-209[e]**	1.077	0.0260[f]
	Including BDE-209	1.586	0.0394[f]
% BDE-209 accumulated or	**Excluding BDE-209[e]**	**-**	**5.78**
	Including BDE-209	**-**	**8.75**

metabolised after 28 days$^{c/d}$

a: weight of fish at day 28 assumed to be 0.026 grams
b: Only a limited suite of PBDE congeners were analysed. If additional metabolites were formed, including hydroxylated metabolites then both the degree of accumulation from food and metabolism would increase.
c: cumulative exposure to BDE-209 reported by Noyes et al. 2011 as 0.45 nmol/fish, although this could not be verified based on the data reported in the paper or the supplementary information
d: metabolism is likely to be greater over longer time periods.
e: excluding BDE-209 from the calculation (as was done in Noyes et al., 2011) leads to a lower % of accumulated or metabolised substance
f: conversion of decaBDE to lower conceners of concern is > 60 % (0.0260/0.0394=0.66)

In another study (Noyes et al, 2013) higher concentrations of BDE-202 (3400 ng/g lw), BDE-188 (7400 ng/g lw), BDE-179 (5900 ng/g lw) and BDE-154 (14000 ng/g lw) than of BDE-209 (2700 ng/g lw) were measured in fish after 28 days exposure of adult Fathead Minnow to decaBDE (97% purity), 300 ng/g. The study showed increasing formation of BDE-209 debromination-products over time.

B.4.4.1.3 Summary and discussion of new information on transformation in aquatic species.

Several studies analysed BDE-congener pattern in complex systems, including field studies. All of them have in common that they provide evidence for decaBDE bioavailability and (biotransformation to lower congeners but the relative impact of the different fate processes on the final congener distribution is often unclear.

All new studies that analysed the degradation of decaBDE under controlled laboratory conditions in aquatic species used fish as test organisms. Luo et al. (2013) estimated a half-life between 16.5 to 19.4 days in a study in Japanese medaka, with the main metabolites being BDE47, BDE155, and BDE99, all not belonging to the group of (main) decaBDE impurities. Half-life in juvenile sole was estimated at 43 days by Munschy et al. (2011), with BDE183, BDE202 and an unidentified hepta-BDE as decaBDE metabolites. The study of Feng et al. (2012) shows with great reliability that decaBDE is biotransformed by rainbow trout. The study also observed OH-BDEs and MeO-BDEs metabolites. Due to the application of the decaBDE via injection an involvement of the gut microflora could be excluded.

Table 32: Relevant new studies on bioavailability and transformation of decaBDE in aquatic animals

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
(Liu et al., 2013)	BDE patterns in mudsnails (*Cipangopaludina cahayensis*) and sediment samples from an electronic waste recycling site in China were surveyed.	Environmental survey with complex BDE patterns.	decaBDE, BDE183, BDE154, BDE153, BDE100, BDE99, BDE47 and BDE28 were detected.	- No direct information on decaBDE (bio)degradation given - Total BDE body burden of the snails 3.11-3.66 ng/g wet weight, sediment 848 ng/g dry weight.
(Teil et al., 2012)	Survey of BDE patterns in roach, chub and perch from the Orge river in France	Environmental survey with complex BDE patterns.	BDE28, BDE47, BDE99, BDE100 and decaBDE were detected	- No direct information on decaBDE (bio)degradation given - Total BDE content excl. B decaBDE in sediment was 0.76 to 6.1 ng/g dry weight, decaBDE content was 4-140 ng/g dry weight. Fish contained 12–18 ng/g dry weight of non-decaBDE BDEs. decaBDE concentrations are not given.
(C.-Y. Chen et al., 2013)	Survey of BDE patterns in demersal and pelagic fish as well as sediments from Taiwanese rivers	Environmental survey with complex BDE patterns.	BDE17, BDE28, BDE47,-49, BDE66, BDE71, BDE77, BDE85, BDE99, BDE100, BDE119, BDE126, BDE138, BDE153, BDE154, BDE156, BDE183, BDE184, BDE191, BDE196, BDE197, decaBDE were detected	- No direct information on decaBDE (bio)degradation given - Total BDE content in sediments 0.5-90 ng/g dry weight. Fish contained between 1.3-33.7 ng/g dry weight.
(Echols et al., 2013)	Survey of BDE patterns in concentrations in three fish species (common carp, largemouth bass,	Environmental survey with complex BDE patterns.	BDE10, BDE9, BDE7/4, BDE6, BDE8, BDE13, BDE15, Tri:, BDE19, BDE18, BDE32/29, BDE26, BDE17, BDE25, BDE31, BDE28, BDE37,	- No direct information on decaBDE (bio)degradation given

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
	and channel catfish) from three sites in Arizona		BDE50, BDE69, BDE75, BDE51, BDE49, BDE47, BDE74, BDE66, BDE77, BDE102, BDE100, BDE119/101, BDE99, BDE118, BDE85, BDE155, BDE154, BDE153, BDE139, BDE140, BDE138, BDE188, BDE184, BDE183, BDE202, BDE201, BDE197, BDE203, BDE196 were detected	- BDE burden in fish was 56.9 - 1.8e^5 ng/g lipid
(Ilyas et al., 2013)	Survey of BDEs in sludge, sediment and fish from a municipal dumpsite in Indonesia	Environmental survey with complex BDE patterns.	BDE15, BDE28, BDE47, BDE99, BDE100, BDE153, BDE154, BDE183, BDE196, BDE197, BDE206, BDE207, decaBDE were found.	- No direct information on decaBDE (bio)degradation given - Total BDE in sludge 4.5 ng/g dry weight, 6.6-11 ng/g lipid in fish
(Ren et al., 2013	Survey of BDEs in fish from an industrial region in Northeast China	Environmental survey with complex BDE patterns.	BDE17, BDE28, BDE47, BDE66, BDE71, BDE85, BDE99, BDE100, BDE153, BDE154, BDE183, BDE190, decaBDE, BDE were included in the analysis. Not stated, whether all were actually found.	- No direct information on decaBDE (bio)degradation given - Mean total BDE body burden was 18.89 ng/g lipid.
(Santín et al., 2013)	Survey of BDEs in fish from Iberian rivers	Environmental survey with complex BDE patterns.	BDE28, BDE47, BDE100, BDE153,BDE154, BDE183 and decaBDE were found	- No direct information on decaBDE (bio)degradation given - Total BDE body burden was between below detection limit to 520 ng/g lipid.
(Koenig et al., 2013)	BDE congeners were surveyed in muscle tissue from the deep-sea fish *Alepocephalus rostratus, Coelorinchus mediterraneus and Lepidion lepidion* and the	Environmental survey with complex BDE patterns.	BDE17, BDE28, BDE47, BDE66, BDE71, BDE85, BDE99, BDE100,138, BDE153, BDE154, BDE183, BDE190, decaBDE were found.	- No direct information on decaBDE (bio)degradation given Total BDE concentrations were as follows:

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
	red-shrimp *Aristeus antennatus* from the North-Western Mediterranean Sea			- *Alepocephalus:* 0.92, *Coelorinchus:* 0.61 *Lepidion:* 0.58, *Aristeus:* 0.47 ng/g wet weight
(Yu et al., 2012)	Survey of BDEs in 24 fish species from the largest freshwater lake in China.	Environmental survey with complex BDE patterns.	BDE17, BDE28, BDE47, BDE66, BDE100, BDE99, BDE85, BDE154, BDE153, BDE138, BDE183, BDE190, decaBDE were found	- No direct information on decaBDE (bio)degradation given - Average total BDE body burden varied between 8.6 and 74.3 ng/g lipid, depending on the species
(Bartrons et al., 2012)	Survey of BDEs in organisms from different trophic levels in a remote mountain lake ecosystem	Environmental survey with complex BDE patterns.	BDE17, BDE28, BDE35, BDE71, BDE47, BDE66, BDE77, BDE100, BDE99, BDE85, BDE154, BDE153, BDE138, BDE156, BDE183, BDE190, decaBDE were found	- No direct information on decaBDE (bio)degradation given - Total BDE concentrations are as follows: basal resources, 0.2 ng / g dry weight; primary consumers, 18 ng / g dry weight; secondary consumers, 12 ng / g dry weight, fish 2.3 ng / g dry weight
(Zhang et al., 2013)	Exposure study using the aquatic oligochaete *Lumbriculus variegatus* which was exposed to field-contaminated sediment	Exposure to field sample with complex BDE pattern	BDE28, BDE47, BDE99, BDE100, BDE153, BDE154, BDE183 and decaBDE were detected.	- No direct information on decaBDE (bio)degradation given - Total BDE amount in sediment: 2003 ng/g dry weight, total BDE body burden in worms: 2749 ng/g lipid (steady state).

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
(Luo et al., 2013)	decaBDE bioaccumulation and debromination study in medaka (*Oryzias latipes*) over 60 days exposure to 1, 10, 100, 1 000 ng/L	decaBDE of unstated purity	BDE-28, BDE-47, BDE-100, BDE-99, BDE-155, BDE-154 were detected	- Concentrations of all BDE congeners are given in table 1 of the paper. After 60 days exposure to 1 µg/L (maximum exposure) the following concentrations were detected (in ng / g wet weight): BDE28 0.8 BDE47 26.6 BDE100 4.33 BDE99 15.7 BDE155 42.5 BDE154 3.19 decaBDE 11.4
(Tian et al., 2012)	Bioaccumulation and metabolism of sediment-associated PBDEs in benthic invertebrates (tubificids) and fish (carp, *Cyprinus carpio*) were studied in water/sediment microcosms.	Exposure to field sample with complex BDE pattern	- BDE28, BDE47, BDE100, BDE153, BDE154, BDE206, BDE207, and BDE208 were found in fish - BDE28, BDE47, BDE100, BDE99, BDE154, BDE153, BDE183, BDE208, BDE207, BDE206 were found in sediment and worms	- No direct information on decaBDE (bio)degradation given - Concentrations in fish were dependent on the sampling time and exposure (with/without sediment contact). Details are given in tables S1-S3. - Initial concentrations in the sediment were as follows (ng/g dry weight): BDE28 1.01 BDE47 68.1

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
				BDE99 103 BDE100 19.4 BDE153 43.1 BDE154 13.2 BDE183 210 BDE206 39.2 BDE207 89.4 BDE208 7.64 decaBDE 1340 - Sediment concentrations after the different sampling intervals are also given in tables S1-S3 - Concentrations in the worms after 80 days were as follows (in ng/g dry weight): BDE28 6.26 BDE47 317 BDE100 95.8 BDE99 332 BDE154 57.3 BDE153 50.2 BDE183 22.2 BDE208 0.34 BDE207 5.17 BDE206 0.86 decaBDE 25.0

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
(Wan et al., 2013)	Survey of the BDE body burden of Chinese sturgeon (*Acipenser sinensis*)	Environmental survey with complex BDE patterns.	- BDE196, BDE206, BDE207, BDE208, and decaBDE were detected	- No direct information on decaBDE (bio)degradation given
(Feng et al., 2012)	Controlled exposure of rainbow trout to decaBDE at five concentrations from 50 to 1000 ng/g wet weight for 21 days via a single intraperitoneal injection	98% purity	- 5-MeO-BDE 47, 6-MeO-BDE 47, 4′-MeO-BDE 49, 2′-MeO-BDE 68, 5′-MeO-BDE 100, 4′-MeO-BDE 103 - 3′-OHBDE 28 and 4-OH-BDE 42	- The peak concentrations of total MeO-BDEs in liver, blood and kidney are as follows - 49.41, 137.8, and 200.1 ng/g wet weight - The study refers to (Feng et al. 2010) for further details on the lower brominated BDEs. Some details are given below.
(Feng et al., 2010)	Controlled exposure of rainbow trout to two decaBDE concentrations (100 and 500 ng/g wet weight) for 21 days via intraperitoneal injection	98% purity	- BDE3, BDE7, BDE15, BDE28, BDE47, BDE49, BDE66, BDE71, BDE77, BDE85, BDE99, BDE100, BDE119, BDE126, BDE183, BDE184, BDE197, BDE206, BDE207, decaBDE were detected - OH-BDEs and MEO-BDEs were detected (5MBDE47, 6MBDE47, 4PMBDE49, 2PMBDE68, 5PMBDE99, 5PMBDE100, 4PMBDE101, 4PMBDE103)	- Concentration details provided in tables 1-4 of the paper. - Concentrations varied substantially between blood, liver and muscle, and dependent on the decaBDE exposure level.
(Munschy et al., 2011)	Exposure of common sole (*Solea solea*) to a mixture of six BDE congeners (BDE28, BDE47, BDE99, BDE100, BDE153 and decaBDE) via food for a		- The original BDEs (BDE28, BDE47, BDE99, BDE100, BDE153 and decaBDE)) were detected, which could be partly consist of debromination products at the end of the exposure.	- decaBDE half-life 43 days - Highest concentrations for tri- to hexa BDEs were 2.8-10.6 ng/g ww and 0.06 ng/ g wet weight for decaBDE.

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
	period of 84 days		- Additionally unidentified tetra, hepta-BDE and penta-BDE plus BDE49 and BDE202 were detected in fish	
(Zeng et al., 2013)	Sediments and two fish species (mud carp and northern snakehead) were analysed for BDEs. Samples originate from a pond contaminated by e-waste in Southern China.	Environmental survey with complex BDE patterns.	- 30 unspecified BDE congeners were detected in sediment, the authors list BDE47, BDE99, BDE183, decaBDE as the most prominent ones	- No direct information on decaBDE (bio)degradation given - Total BDE in sediment was 3000 -3700 ng/g weight. - Total BDE in fish was 3.2E4-9.2E4 ng/g lipid, with a species specific congener pattern.

B.4.4.2 Terrestrial species (and marine mammals)

Field studies

- **Invertebrates**

She et al. (2013) collected apple snails (*Pomacea canaliculata)* from a contaminated e-waste recycling site in China. DecaBDE was the predominant congener in snail tissues, ranging from 1.50 to 5.69 (average 2.24) ng/g dw, and accounting for 43% of the total PBDEs. Strong differences in congener composition between paddy soil, rice plants and snails demonstrate the impact of biota. But it is unclear, whether the differences are driven by differential uptake, differential depuration, and/or biotransformation processes. The study does hence not allow direct conclusions on decaBDE (bio)transformation.

The same organism was also used in a study by Koch et al. (2014), in which decaBDE accumulation after a 30 day exposure was investigated. The study does not provide any information on decaBDE degradation.

- **Birds**

In vitro biotransformation of decaBDE was investigated by (Chabot-Giguère et al., 2013) in microsomal preparations from field-collected ring-billed gull (*Larus delawarensis*) from the St. Lawrence River basin near Montreal, a hot-spot for flame retardants. High concentrations of decaBDE were found in gull livers, and they correlate strongly with the sum of hepta, octa- and nona-BDE congeners. No significant depletion of decaBDE occurred over a 90 min exposure with the liver microcosms, and no other PBDE congeners were detected, indicating that CYP-mediated reductive debromination is not likely to be a significant metabolic pathway in this species.

Several studies that were published during the recent years monitored BDE concentrations, including decaBDE, in different bird species, respectively their eggs. These studies did not specifically aim to provide information on decaBDE (biotransformation and are hence only briefly summarized in the following. (Chen et al., 2012a) analysed BDEs in four gull species and found that the congener pattern in their eggs is dominated by BDE47, BDE99, BDE100, BDE153, BDE154 and decaBDE. However, also BDE183 was frequently detected, indicating the debromination of decaBDE. Further details, however, are not given in the publication.

Guerra et al. (2012) analysed BDE burdens in peregrine falcon eggs (*Falco peregrinus*) in Canada and Spain. The authors identified BDE-153 as one of the dominating congeners. Based on previous studies, they hypothesize that this is caused by its longer half-life, accumulation as a debromination product, and/or biomagnification. Also the presence of BDE153 might indicate decaBDE breakdown.

BDE burdens in passerine bird (light-vented bulbul, long-tailed shrike, and oriental magpie-robin) were analysed by Sun et al. (2012). The authors observed strong species-specific differences, with the relative amount of BDE153 being a major difference. This congener was a major part of the mixture in shrikes and magpies, but only contributed slightly to the BDE burden of bulbuls. The authors speculate, based on previous studies, that this is driven by species-differences in diet and biotransformation. BDE body burdens are only given as sum values, and are not broken down into the concentrations of the individual congeners. However, the presence of hexa- and hepta-BDEs indicate decaBDE breakdown.

Starlings were monitored for BDE by D. Chen et al. (2013), and the authors found a BDE burden that closely matched the conger composition of the commercial penta-BDE formulation. DecaBDE was also commonly found, together with several hexa- and hepta-BDEs. Hong and colleagues monitored resident and migratory birds in south Korea (Hong et al., 2014) and found BDE-202 especially in seagulls, which is considered a marker for previous exposure to decaBDE. More details on the interplay of bioaccumulation, degradation and elimination rates of decaBDE and BDE-202 are not investigated in the paper.

BDE202 was also a common congener found in owls in a study by Yu et al. (2013). In fact, owls contained significantly higher relative BDE-202 amounts (in comparison to their decaBDE burden) as kestrels. As the prey species (rats, resp. sparrows) contain similar PBDE-patterns, the authors interpret the higher relative BDE-202 amount as an indication of a greater biotransformation capacity for decaBDE in owls. However, the authors do not discuss the possibility of different uptake (bioaccumulation) rates between owls and kestrels. DecaBDE was the most commonly found BDE congener in birds from the Pearl River in China Sun et al. (2014). Also BDE 47 and 99, the two major congeners of the commercial PentaBDE product were frequently detected. Hexa- and hepta-congeners indicate decaBDE breakdown, but no further details are given.

The BDE body burden of kingfishers (*Alcedo atthis*) and their prey fish were analysed near an e-waste recycling site in China (Mo et al. 2012). The authors found higher relative concentrations of both BDE202 and BDE207 in the birds, compared to their prey. This is interpreted by the authors as a decaBDE biotransformation. However, no further details on the interplay between bioaccumulation, elimination etc. are provided.

BDE202 was also frequently (83% of the samples) found in eggs of white stork (*Ciconia ciconia*) in a study by (Munoz-Arnanz et al., 2011). Again, this is interpreted as a result of the degradation of decaBDE, which accounted for roughly 40% of the total BDE burden. Congener profiles in the bird did not have any resemblance to the congener profile of any of the commercial BDE products, which was taken as another indication for the presence of degradation processes.

BDE202 was also found in a study by (Crosse et al., 2012) on sparrow hawks (*Accipiter nisus*) eggs from in the UK. Together with the detection of BDE196, BDE197, BDE201 and BDE203, this is taken as evidence for either decaBDE uptake (although the congener itself was not measured) and subsequent breakdown, or decaBDE degradation somewhere further down the foodchain and subsequent bioaccumulation/biomagnification of the octa- and nona-BDEs.

- **Mammals**

DecaBDE was only detected in 7% of seal liver samples in a study by Shaw et al. (2012), but, if present, contributed to a high fraction of the total PBDE load (up to 40 ng/g lipid). It was equally rarely detected in seal blubber, but, if detected, only contributed to a minor extent. BDE-183 and an unknown octa-BDE were most dominant in seal blubber. DecaBDE levels in seal liver were up to 10-fold higher than in their prey. The authors observed clear age-related differences in the BDE profiles in seals. BDE28 was more dominant in pubs, while BDE153 and BDE155 were more dominant in adults. The authors indicated that those differences are a consequence of different feeding behaviour (lactation in pubs, and hence lactational transfer from mother to pub) and age-related differences in the ability to metabolize and eliminate PBDEs. The study does not allow to tear apart the different drivers for the final PBDE patterns observed in seals.

Mizukawa et al. (2013) analysed residue levels and patterns of PBDEs, their hydroxylated and methoxylated PBDEs in the blood of various terrestrial mammals in Japan, including cats, raccoon dogs, dogs, masked palm civets, foxes, raccoons, badgers, and mongooses. Animals were collected in various regions of Japan between 2006 and 2011. High proportion of decaBDE was found in the blood of all species, suggesting exposure to municipal waste and soil containing higher levels of deca-BDE products. In all terrestrial mammals 6OH-/MeO-BDE47 and 2OH-/MeO-BDE68 accounted for up to 80 % of all quantified total OH-PBDE. The abundance of 6OH-/MeO-BDE47 and 2OH-/MeO-BDE68 might be originating from the marine environment through food such as fish or the ability to metabolise PBDEs. However further information of the prey and dietary source was not available.

Laboratory studies

- **Invertebrates**

Earthworms were exposed via soil over 21 days to decaBDE in a study by Zhang et al. (2014) at three concentration levels (1, 10, 100 mg/kg). The compound accumulated in the tissue, in strong correlation to the levels in the soil. Lower brominated BDEs were found in the worm tissue from day 7 onwards, congeners observed were BDE47, BDE99, BDE153, BDE206, BDE208. Complex interactions of the decaBDE transformation were found when earthworms were co-exposed with Pb. The presentation of the study does unfortunately not allow a more detailed analysis of the results . The study shows that decaBDE is bioavailable to earthworms and that a decaBDE degradation takes place somewhere in the system. It is, however, unclear whether the degradation takes place in the worms or in the soil.

- **Birds**

Male kestrels (*Falco sparverius*) were exposed to 116,000 ng of decaBDE (>98% purity) per day for 21 days, followed by a 25-day depuration period in a study by Letcher et al. (2014). decaBDE was found in the bird's plasma (end of uptake and depuration period) as well as liver and fat (end of depuration only) samples, in concentrations greatly exceeding background concentrations (total BDEs in exposure group was more than two orders of magnitude higher than in the control group). The mean decaBDE level in plasma was 1474 ng/g wet weight at the end of the uptake period, and dropped by 88% after the 25 day depuration period. This results in a decaBDE half-life in plasma of approximately 14 days. Lower brominated BDE-congeners were quantified in plasma, and the authors estimate that at least 80% of the non-decaBDE concentration in the kestrel tissues and plasma originates from decaBDE debromination by the kestrels. PBDE congeners found in plasma included nona-BDEs (208, 207 and 206), followed by octa-BDEs (197, 196, 201 and 203), and the hepta-BDEs 180 and 183 and BDE-153 in liver and/or fat. Total BDE burden in plasma at the end of the exposure period was 1 583 ng/g wet weight, of which 1 474 ng/g wet weight were decaBDE and 109 ng/g wet weight (= 7.4%) were lower brominated congeners (concentrations related to lipid are: 181 013 ng/g decaBDE and 13 465 ng/g (=7.4%) lower brominated congeners). Given that the different congeners have different depuration rates and distribution between the different tissues (and no samples from lipid or liver tissue were taken directly after the exposure), it is not possible to draw conclusions on the actual biotransformation kinetics of decaBDE. DecaBDE exposure caused elevated levels of cytochrome P450 1A1 activity, providing further evidence of biological metabolisation of decaBDE by the birds.

Concentration levels are provided in detail in table 1 of the supporting information, which are reproduced in Table 33 below. The study is based on a total of 22 individuals.

Table 33: Concentration levels of the most prominent PBDE congeners measured in tissue of American kestrels

	Not detected	Group	Detected in 1 or 2 (n) individual	Detected in < 50% individuals (n)	Detected in ≥ 50% individuals (n) or *all
Liver	99, 139, 154, 179, 188, 202	decaBDE	7, 138, 140, 171, 181, 182(2), 190, 191	153(5), 170(9), 180(7), 183(6), 201(5)	196*, 197(13), 203(16), 206*, 207*, 208*, decaBDE*
		Control	183	153(3)	decaBDE*
Fat	7, 119	decaBDE	140(2), 179(2), 205	99(8), 138(7), 139(5), 170(4), 171(4), 181(6), 182(8), 188(4), 190(5), 191(7), 194(10)	153*, 154*, 180*, 183*, 184(11),195*, 196*, 197*, 201*, 202(13), 203*, 206*, 207*, 208*, decaBDE*
		Control	99, 180(2), 201, 202, 203(2)	n/a	153*, 154*, 183(8), 196(8), 197*, 206*, decaBDE*
Plasma time 1	7, 99, 119, 138, 139, 140, 170, 171, 179, 180, 181, 182, 184, 188, 190, 191, 202,	decaBDE	153	183(4), 194(4), 195(5), 201(8)	196*, 197(19), 203(19), 206*, 207*, 208*, decaBDE*
Plasma time 2		decaBDE	153(2), 183	201(6), 203(3)	196(12), 197(14), 206*, 207*, 208*, decaBDE*

The congeners that were not detected in any samples were BDE-1,- 2, -3, -10, -15, -17, -28,- 54, -49, -71,- 47, -77,- 66, -100, -85, -155; only decaBDE was detected in all samples of both exposed and control birds. Congeners that were determined to be above detection limits in all individuals are denoted with a *. The n-value in brackets depicts the number of individuals in which that congener was detected out of the 22 exposed or 11 control individuals. Plasma time 1 indicates plasma taken at the end of the uptake period, while time 2 is after a 25 d elimination period.

- **Mammals**

Several studies on rats provides good evidence that decaBDE is biotransformed to lower brominated congeners in mammals (EFSA, 2011, Kortenkamp et al., 2014) (for more information see section B.5). These data are of relevance to wild mammals as well.

B.4.4.2.1 Summary and discussion on transformation in terrestrial species and marine mammals

The study by (Letcher et al., 2014) confirms decaBDE biotransformation in male kestrels. DecaBDE was shown to be taken up by the birds, distributed within different tissues and biotransformed. The following congeners, not known to be impurities of decaBDE were found in all exposed individuals, but not in the controls in the same tissue: BDE196, BDE180, BDE195, BDE201 and BDE203. Several additional congeners were found in some of the exposed individuals. The authors estimate a half-life of decaBDE in the blood plasma of kestrels of 2 weeks, and that least 80% of the non- decaBDE concentration in the kestrel tissues and plasma originates from decaBDE debromination. The authors show that cytochrome P450 levels in the exposed birds are elevated, which can be taken as further evidence of a biological transformation of decaBDE.

Several laboratory studies on rats provide good evidence that decaBDE is biotransformed to lower brominated congeners in mammals. These data are of relevance to wild mammals as well.

The other studies largely focused on surveying BDE congener pattern in a range of organisms and environmental matrices. Indications of (bio)degradation, such as the occurrence of decaBDE -related congeners that are not known to be impurities of commercial decaBDE provide indirect evidence of decaBDE degradation. However, in these studies it is usually unclear, which process led to the formation of the lower brominated congeners.

Table 34: Relevant new studies on bioavailability and transformation of decaBDE in terrestrial species and marine mammals

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
(She et al., 2013)	Apple snails (*Pomacea canaliculata)* , soil and rice plants from a contaminated e-waste recycling site in China were surveyed for BDEs.	Complex mixture of BDEs	Concentrations in paddy soil (average, ng/g dry weight) BDE 28: 0.22 BDE 47: 1.42 BDE 66: 0.31 BDE 99: 1.37 BDE 100: 0.3 BDE 153: 0.72 BDE 154: 0.44 BDE 183: 1.03 decaBDE: 22.5 Concentrations in rice plants (average, ng/g dry weight) BDE 28: 0.06 BDE 47: 0.37 BDE 66: 0.07 BDE 99: 0.17 BDE 100: 0.03 BDE 153: 0.02 BDE 154: 0.01 BDE 183: 0.06 decaBDE: 0.71	

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
			Concentrations in snails (average, ng/g dry weight)	
			BDE 28: 0.1	
			BDE 47: 0.53	
			BDE 66: 0.18	
			BDE 99: 0.6	
			BDE 100: 0.16	
			BDE 153: 0.17	
			BDE 154: 0.17	
			BDE 183: 0.5	
			decaBDE: 2.24	
(Zhang et al., 2014)	Exposure of earthworms via soil over 21 days to 1, 10, 100 mg/kg decaBDE	> 98% purity	BDE47, BDE99, BDE153, BDE206, BDE208	No numerical details provided in the paper
(Chabot-Giguère et al., 2013)	*In vitro* biotransformation in microsomal preparations from field-collected ring-billed gull (*Larus delawarensis*)	unstated purity	None	None
(Letcher et al., 2014)	Exposure of male kestrels (*Falco sparverius*) to 116,000 ng of decaBDE per day for 21 days	>98% purity	decaBDE, BDE-208, BDE-207, BDE-206, BDE-203, BDE-202, BDE-201, BDE-197, BDE-196, BDE-195, BDE-194, BDE-184, BDE-183, BDE-180, BDE-170 were detected in bird tissue	Details given in a separate table.
(Chen et al., 2012a)	Field survey of BDE congeners in eggs of four gull species (	Environmental survey with complex BDE patterns.	Most commonly detected congeners BDE47,BDE99, BDE100, BDE153, BDE154 and decaBDE	- No direct information on decaBDE (bio)degradation given - Total BDE burden varied between 0.5

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
				and 12 ng/g wet weight. No details on the congener concentrations given.
(Guerra et al., 2012)	Field survey of BDE congeners in eggs of peregrine falcons (*Falco peregrinus*)	Environmental survey with complex BDE patterns.	BDE47, BDE99, BDE100, BDE153, BDE154, BDE183,BDE197,BDE207, decaBDE were detected	- No direct information on decaBDE (bio)degradation given - BDE congener pattern per sampling site summarized in table 3 of the publication
(Sun et al., 2012)	Survey of BDE body burden in light-vented bulbul, long-tailed shrike and oriental magpie-robin	Environmental survey with complex BDE patterns.	BDE28, BDE47, BDE66, BDE85, BDE99, BDE100, BDE153, BDE154, BDE183, BDE169, BDE197, BDE202, BDE203, BDE206, BDE207, BDE208, decaBDE were detected	- No direct information on decaBDE (bio)degradation given - Total BDE amount 56-5200 ng/g lipid
(D. Chen et al., 2013)	Survey of BDE body burden in starlings	Environmental survey with complex BDE patterns.	BDE17, BDE28, BDE47, BDE49, BDE66, BDE85, BDE99, BDE100, BDE138, BDE153, BDE154, BDE183 and decaBDE were detected	- No direct information on decaBDE (bio)degradation given - Total BDE body burden between 6.7 and 280 ng/g wet weight
(Yu et al., 2013).	Survey of BDE body burden in on kestrel (*Falco tinnunculus*), eagle owl (*Bubo bubo*), and little owl (*Athene noctua*), as well as in their primary prey, the Eurasian tree sparrow (*Passer montanus*) and the brown rat (*Rattus norvegicus*).	Environmental survey with complex BDE patterns.	BDE28, BDE47, BDE99, BDE100, BDE153, BDE154, BDE183, BDE196, BDE197, BDE201, BDE202, BDE203, BDE206, BDE207, BDE208 and decaBDE were detected	- No direct information on decaBDE (bio)degradation given - Median BDE body burden is 400 ng/g lipid weight.

Reference	**Species, type of study**	**DecaBDE form**	**Metabolites observed (tissues)**	**Measured amounts**
				- Owls contained significantly higher relative BDE-202 amounts, which is interpreted as an indication of a greater biotransformation capacity for decaBDE in owls
(Sun et al., 2014)	Survey of BDE body burden in eggs of light-vented bulbul, yellow-bellied prinia, plain prinia, and dark green white-eye.	Environmental survey with complex BDE patterns.	BDE28, BDE47, BDE66, BDE100, BDE99, BDE85, BDE154, BDE153 and BDE183, BDE202, BDE197, BDE 203, BDE196, BDE207, BDE206 and decaBDE were detected	- No direct information on decaBDE (bio)degradation given
(Mo et al., 2012)	Survey of BDE body burden in common kingfishers (*Alcedo atthis*) and their prey fish	Environmental survey with complex BDE patterns.	BDE 28, BDE 47, BDE 66, BDE 85, BDE 99, BDE 100, BDE 153, BDE 154, BDE 183, BDE 196, BDE 197, BDE 202, BDE 203, BDE 206, BDE 207, BDE 208, decaBDE were detected	- No direct information on decaBDE (bio)degradation given - Total BDE body burden 8760 ng/g lipid weight in the birds and 2150-6940 ng/g lipid weight in prey fish
(Munoz-Arnanz et al., 2011)	Survey of BDE body burden in white stork (*Ciconia ciconia*)	Environmental survey with complex BDE patterns.	BDE17,BDE28, BDE47, BDE66, BDE85, BDE99, BDE100, BDE153, BDE154, BDE183, BDE184, BDE191, BDE194, BDE195, BDE196, BDE197+204, BDE198+199+200+203,	- No direct information on decaBDE (bio)degradation given - Total BDE body burden 1.64-9.08 ng/g wet weight

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
			BDE201, BDE202, BDE205, BDE206, BDE207, BDE208, and decaBDE were detected.	
(Crosse et al., 2012)	Survey of BDE body burden in sparrowhawk (*Accipiter nisus*)	Environmental survey with complex BDE patterns.	BDE35, BDE47, BDE99, BDE100, BDE138, BDE153, BDE154, BDE183, BDE196, BDE197, BDE201, BDE203 were detected	- No direct information on decaBDE (bio)degradation given - decaBDE itself not included in the survey - Total BDE body burden 33-2280 ng/g wet weight.
(Shaw et al., 2012)	Survey of BDE body burden of harbour seals	Environmental survey with complex BDE patterns.	BDE28, BDE47, BDE49, BDE85, BDE99, BDE100, BDE153, BDE154, BDE155, BDE181, BDE183, BDE184, BDE191, BDE197, decaBDE, BDE66, BDE196 were detected	- No direct information on decaBDE (bio)degradation given - Total BDE body burden in 4400, 1680, and 969 ng/g lipid in male pups, female pups, and adult males, resp.
Mizukawa et al., 2013	Survey of body burden of various terrestrial mammals cats, raccoon dogs, dogs, masked palm civets, foxes, raccoons, badgers, and mongooses	Environmental survey with complex BDE patterns.	BDEs, their hydroxylated metabolites (OH-PBDEs), and methoxylated PBDEs (MeO-PBDEs)	- No direct information on decaBDE (bio)degradation given - decaBDE analysed in blood < 4.2 -21,000 pg/g blood wet weight - Total BDE concentration < 4.2 - 26,000 pg/g blood wwt

Reference	Species, type of study	DecaBDE form	Metabolites observed (tissues)	Measured amounts
				- Total OH-BDE concentration 1.6 - 1,700 pg/g blood wwt - Total MeO-BDE concentration <1.0 - 230 pg/g blood wwt

B.5 Human health hazard assessment

This section includes relevant human health hazard data for decaBDE. The PBT status of decaBDE was concluded based on the toxicity of its breakdown products. According to the SVHC SD, tetra to heptaBDE fulfil the T criterion based on human health (i.e. classification in CLP).

Notwithstanding the properties of the transformation products, decaBDE has also been associated with adverse effects in its own right and these are described below as they may be usefully considered during discussions on the proportionality/cost-effectiveness of any proposed restriction in addition to considerations of potential PBT/vPvB impacts mediated through breakdown products.

The human health hazard properties of lower PBDE congeners are briefly described in section B.5.9.3.

No DNEL/DMEL values are derived as decaBDE is a PBT/vPvB substance and no quantitative risk characterisation has been undertaken.

In this section information from several reviews of the substance by Authorities (e.g. EFSA, Health Canada, EU RAR) is compiled, as well as recent scientific literature relevant to the toxicity of the commercial decabromodiphenyl ether (c-decaBDE) or decaBDE (the single fully brominated PBDE) in humans and in laboratory animals that was not considered in the reviews by Authorities.

DecaBDE has a low acute toxicity. Female Sprague Dawley rats intubated with single doses of up to 2,000 mg/kg b.w. of a decaBDE mixture survived with no signs of toxicity during the 14 days observation period. Male albino Spartan rats given a single dose of up to 5,000 mg/kg b.w. of decaBDE survived with normal weight gain during the 14 days observation period (Norris et al., 1975; ECB, 2002; EFSA, 2011).

According to available information, decaBDE is not an irritant for skin or eyes and is not considered to be a sensitizer (Norris et al., 1975; ECB, 2002).

Moreover, the available studies suggest that decaBDE does not have a significant immunotoxic, genotoxic or carcinogenic potential (Health Canada, 2006; EFSA, 2011).

DecaBDE is absorbed and distributed in humans and can be transferred from the mother to the foetus and the breast-fed child. Developmental neurotoxicity is the reported critical toxicity of decaBDE and several other PBDEs. This toxicity is thought to arise through disruption of the thyroid hormone (TH) system and direct toxicity to neuronal cells and stem cells. Epidemiological studies report that decaBDE (and other PBDEs) delay the neurological development and affect cognition. In laboratory animals, decaBDE affects early foetal/neonatal development, the thyroid, and potentially other parts of the endocrine system.

The neurotoxicity of c-decaBDE and decaBDE to terrestrial mammals has mainly been investigated in rodents. The majority of the available developmental studies used oral administration; however, only a few studies were carried out according to regulatory guidelines.

B.5.1 Toxicokinetics (absorption, metabolism, distribution and elimination)

Animal data: In animal studies, oral absorption in rats range from 7-26% (Health Canada,

2012) but was found to be much lower (0.3-1.5%) in a rat diet study by NTP (NTP, 1986). Absorption via inhalation is estimated to be negligible (EFSA, 2011). Dermal absorption was studied in an *in vitro* experiment and was found to be less than 20% (Hughes et al., 2001). In general, distribution of decaBDE is mainly to plasma and blood-rich tissues, and to a less extent to adipose tissue (EFSA, 2011). Based on organ fresh weights, the highest concentrations were found in adrenals, kidney, heart and liver (EFSA, 2011). In a distribution study by Seyer and co-workers, the highest concentration was found in the adrenal glands and the ovary (Seyer et al., 2010). A recent study reported that administration of decaBDE to rats from gestation day (GD) 7 to post natal day (PND) 4, at an oral dose of 5 µmol/kg bw/day, decaBDE was increased temporally in maternal blood, placenta, foetuses and neonates. The levels in foetuses and pups were 10-fold lower than in the dams. More decaBDE was found in neonate whole-body samples at PND 4 than in foetal whole-body samples during pregnancy (GD 15 and 21) (Cai et al., 2011). In another recent experimental study, decaBDE was given by gavage in corn oil to rats from GD 6 to PND 4 at the doses of 100, 300, and 1000 mg/kg bw/day (Biesemeier et al., 2010). Plasma levels in GD 20 foetuses were 2.5–5-fold lower than in the dams, and in both dams and foetuses there was a lack of dose–response. In a study by Riu et al., rats were orally administrated from GD 16-19. On GD 20, foetuses (whole litter) contained 0.43% of the administrated dose and 0.47% was found in the placenta. DecaBDE was also found in brains of dams (0.01%) (Riu et al., 2008). Levels of decaBDE in milk were lower than in the mother's plasma (Biesemeier et al., 2010).

There is now good evidence from studies with mammals that decaBDE is biotransformed to lower brominated congeners (EFSA, 2011; Health Canada, 2012; Kortenkamp et al., 2014). However, it is still not clear by which rate decaBDE is metabolised, where the metabolism occurs and what is the whole range of metabolites formed. An overview of the biotransformation of decaBDE is given by EFSA (2011) and Health Canada (2012). Available data indicate that debromination is the first step in the biotransformation of decaBDE *in vivo*, followed by hydroxylation to phenols and catechols. These metabolites may be conjugated via Phase II reactions and excreted via bile and faeces (Health Canada, 2012). Several rodent studies have demonstrated metabolism of decaBDE into other congeners (Huwe & Smith, 2007; F. Wang et al., 2010a). In the study by Huwe and Smith (2007) it was suggested that neutral debrominated metabolites constituted only a fraction (1%) of the total PBDE mass balance in exposed rats, indicating that decaBDE is mainly hydroxylated and methylated. Three nonaBDEs (206, 207 and 208) and four octaBDEs (196, 197, 201 and 203) and one heptaBDE (183) were identified in the body tissues. Cai et al. (2012) reported the impurities of the decaBDE used in their studies (Cai et al., 2011; Zhang et al., 2011) as BDE-206 (0.3%), -207 (0.7%) and -208 (0.4%), with a non-quantifiable trace of octaBDE. Although all these congeners occurred in rat tissues after exposure to decaBDE, the observation of additional debrominated congeners, including BDE-196, -197, -198, -203, -204 can only be explained by the debromination *in vivo*, and there is good evidence that debromination has indeed occurred.

Excretion of decaBDE by rats is almost exclusively through the faecal route, and negligible amounts are eliminated in urine (El Dareer et al., 1987; Mörck et al., 2003). Mörk and co-workers (2003) reported that 90% of the decaBDE administrated orally to rats was found in faecal excretion and the majority (65%) was as metabolites. Excretion via the bile accounted for 10% and was almost exclusively as metabolites. The authors of the study suggested that decaBDE was metabolised by the micro flora in the gastrointestinal tract or that active transport out to the gut lumen accounted for the high level of metabolized decaBDE in the faeces compared to the bile. In a study by Riu and co-workers, 6.5% of the administrated dose to rats was found in livers, while only 0.29% was measured in the kidneys. In this study about 0.1% of the decaBDE was excreted via urine (Riu et al., 2008). Half-lives of decaBDE in rodents have been reported to be 2.5 days (Sandholm et al., 2003).

Human data: Human data have demonstrated that decaBDE is absorbed and distributed to blood, cord blood, placenta, and foetus, and to the infant via breast milk (Wu et al., 2010; Frederiksen et al., 2009) (Table 35, see also section B.9.6). In a recent study from a hospital close to an e-waste recycling location in the Wenling area in China, several BDEs (BDE-28, BDE-47, BDE-99, BDE-100, BDE-153, BDE-154, BDE-183, BDE-197 and decaBDE) were found in aborted foetuses (10-13 weeks gestation, n=65), placenta (n=65) and maternal blood (n=31) from healthy pregnant women who chose a surgical abortion because of unwanted pregnancy. The mean total PBDE concentrations were 4.46, 7.90 and 15.7 ng/g lipid weight in the foetuses, placentas and maternal blood, respectively, dominated by decaBDE (1.55, 2.93 and 5.05 ng/g lipid, respectively). Based on maternal blood levels of BDEs compared to levels in foetus, the author indicated that low-brominated congeners (BDE-28, BDE-99 and BDE-47) cross the placenta more easily than higher-brominated congeners (BDE-197, decaBDE and BDE-153) (Zhao et al., 2013).

Notably high decaBDE concentrations in workers raise concern about debromination of decaBDE. In the study by Qu et al. (2007), BDE-183, 197, 207 and 208 were detected in high concentrations in the workers blood, and were significantly correlated to lower brominated congeners like BDE-153. The results indicate that c-decaBDE exposure increased the human burden with highly brominated PBDEs other than decaBDE, either by *in vivo* debromination of decaBDE and/or through direct emission from commercial decaBDE product.

EFSA (2011) concluded that it seems likely that nonaBDEs and octaBDEs are formed in humans after exposure to decaBDE, as supported by the data from a cross-sectional study of rubber workers, using a technical decaBDE product containing only trace levels of octa- and nonaBDEs and showing substantial concentrations of these congeners in the serum samples (Thuresson et al., 2006). The rate at which this conversion occurs is not known.

Thuresson et al. (2006) modeled apparent serum half-lives of PBDEs with 7-10 bromine substituents, using data from occupationally exposed workers sampled before, during and after a vacation period. The data suggested that the human half-life of PBDEs tends to increase at decreasing bromination of the PBDE congener. The calculated apparent half-life for decaBDE was 15 days, while three nonaBDEs and four octaBDE congeners were found to have half-lives of 18-39 days and 37-91 days, respectively. The relatively short half-life of decaBDE as compared with other PBDEs can be explained by a rapid clearance and a susceptibility of decaBDE to undergo dehalogenation and substitution reactions (Thuresson et al., 2006). The half-life of decaBDE was also assessed by Trudel et al. (2011), who estimated a median value of 7 days based on concentrations in blood, whereas a median of 4 days was found when calculations were based on levels in both blood and breast milk. These studies strongly indicate that decaBDE has a different pharmacokinetic behaviour compared to the tetra- to hexabrominated PBDEs, whose half-life is in years (EFSA, 2011). Although the conversion rate of decaBDE to lower brominated PBDEs is not known, this biotransformation probably influences the concentration of nona- and octabrominated congeners in the serum as well as their apparent half-lives.

Conclusion on toxicokinetics: In animal studies, oral absorption is between 7-26% and dermal absorption is below 20%. DecaBDE is distributed to several tissues, with highest concentrations in adrenal glands and ovary. In a rat study decaBDE was shown to be distributed to the foetuses (0.5% of the total dose), the foetal plasma concentrations were lower compared to the dams. DecaBDE is metabolised in rats to congeners ≥ BDE-183 (a heptacongener). Studies indicate that debromination is the first step followed by hydroxylation to phenols and catechols that may be conjugated via Phase II reactions and excreted via bile and faeces. Of the administrated decaBDE dose 90% was found in faecal excretion and the majority (65%) was as metabolites. However, excretion via bile accounted for only 10% which was almost exclusively metabolites. Why there is more metabolised decaBDE in the faecal excretion than in bile is still unknown. However, excretion of decaBDE by rats is almost exclusively via the faecal route and negligible amounts are eliminated via the urine. DecaBDE has been found in maternal blood, cord blood, placenta, foetuses and breast milk, reflecting that decaBDE is absorbed and distributed in humans and be transferred from the mother to the foetus and to breast-fed children.

B.5.2 Toxicity for reproduction

B.5.2.1 Developmental neurotoxicity

Animal data: Developmental neurotoxicity is the reported critical toxicity of several PBDEs (Eriksson et al., 2001; Branchi et al., 2002; Viberg et al., 2003; Viberg et al., 2004; Kuriyama et al., 2005; Rice et al., 2007; Viberg et al., 2007; Rice et al., 2009; Suvorov et al., 2009; Xing et al., 2009; Blanco et al., 2013; H. Zhang et al., 2013) (Table 35) and is thought to arise through disturbance of the thyroid hormone (TH) system and direct toxicity to neuronal cells and stem cells. Developmental neurotoxicity has previously been reported for decaBDE in several studies (e.g. Viberg et al., 2003; Viberg et al., 2007; Johansson et al., 2008; Rice et al., 2009; Fujimoto et al., 2011), but a lack of such effects were reported in other publications (e.g. Biesemeier et al., 2011).

In support of the toxicological findings in earlier studies, neurobehavioral effects of decaBDE in rodents during juvenile development or adulthood have been reported more recently. In Reverte et al. (2013), the authors investigated the effects of postnatal exposure to decaBDE in transgenic mice (with C57BL/6NTac background) with apolipoprotein E (apoE) genotype, a genetic factor that is associated with increased susceptibility for the development of neurodegenerative diseases. On postnatal day (PND) 10, transgenic mice of both sexes carrying apoE2, apoE3 and apoE4 were orally exposed to 0, 10 or 30 mg/kg of decaBDE. Single postnatal exposure (PND 10) to decaBDE induced long term effects in spatial learning (water maze test), which were dependent on age, sex and apoE genotype; these effects were more evident in apoE3 mice. Brain-derived neurotrophic factor (BDNF) levels were lower in the frontal cortex of apoE4 mice and higher in the hippocampus of exposed mice, independent of the genotype. The results provide evidence of long-lasting effects in spatial learning and memory after early exposure to decaBDE. Furthermore, Heredia et al. (2012) report that oral subacute repeated gavage exposure to decaBDE in male young adult inbred wild type Tg2576 mice showed a reduction in anxiety levels and delayed learning in a spatial memory task in a water maze test. The authors conclude that although the results indicate that behavioural effects were present in a young adult exposed population of wild type Tg2576 mice, further studies on chronic exposure to decaBDE are clearly necessary in order to corroborate these effects.

The studies by Viberg et al. (2003; 2007) and Johansson et al. (2008) have consistently reproduced results indicating alterations in behaviour, habituation and memory that persisted in adult mice and rats when they were administered a single dose of decaBDE during the “brain growth spurt” period. The lowest decaBDE dose causing effects on the nervous system in an acute dosing study was 2.22 mg/kg-bw (Johansson et al., 2008). DecaBDE was administered to 3-day-old mice as a single oral dose, and assessment at 2 and 4 months of age indicated neurobehavioral changes, including decreased spontaneous activity (locomotion, rearing and total activity; hypoactivity) during the first 20 minutes after the mice had been placed in a new environment. Additionally, a reduced ability to habituate was reported (i.e., the treated mice were hyperactive during the latter period, compared with controls). These findings generally showed a dose–response relationship at

2.22 mg/kg-bw and above. A comparison between the abilities of animals treated with a single dose to habituate at 2 and 4 months indicated a poorer performance at 4 months following a single dose (2.22 mg/kg bw and greater), suggesting a decreasing capacity to habituate with time (Johansson et al., 2008). Similarly, in mouse studies that followed a similar protocol, behavioural effects were reported at 2.22 mg/kg-bw and above. In these mice, a single oral dose on postnatal day (PND) 3 and assessment at 2–6 months of age showed treatment-related changes in spontaneous behaviour, decreased activity (hypoactivity) and poorer habituation (Viberg et al., 2003). Rice et al. (2007) reported that neurobehavioural changes (alterations in reflexes, struggling behaviour, grip strength and locomotor activity) were noted in young mice (aged 14–70 days) following previous gavage administration of 6 mg/kg bw/day on PNDs 2–15. Similar effects (changes in locomotion, rearing, activity and habituation) were observed at 2 months of age in young rats that had been dosed on PND 3 with a single gavage dose of 6.7 mg/kg bw (Viberg et al., 2007). Although the first study (Rice et al., 2007) did not replicate a consistent depression in motor activity over time, the follow-up study (Rice et al., 2009) showed neurobehavioral deficits (less efficient response to fixed-ratio schedule of food reinforcement, fixed-interval schedule and light–dark visual discrimination) in mice when they were tested at an older age (16 months). In this case, the results were similar to those of Viberg et al. (2003; 2007) and Johansson et al. (2008). These data suggest that ageing appears to unmask behavioural effects not evident at a younger age, i.e. early decaBDE exposure appeared to impair learning behaviour in older mice that was not detectable in younger mice. Although the exact dosing protocols utilized by Rice et al. differed from those utilized by the Viberg and Johansson studies, in both cases, a consistent finding was that developmental behavioural effects following decaBDE exposure appeared to worsen with age (consistent with a decreasing capacity to habituate with time).

Costa and Giordano (2011) reviewed the published literature on the neurodevelopmental toxicity of decaBDE. The weight-of-evidence, based on the analysis of the majority of the 14 studies conducted in rats or mice, with protocols ranging from exposures during pregnancy to exposures during PNDs 2–41 (on either single or repeated days), indicated subtle developmental effects, particularly in pups subjected to tests for locomotor activity or cognitive behaviour. Other researchers (Hardy & Stedeford, 2008; Goodman, 2009; Hardy et al., 2009; Goodman et al., 2010) have noted several limitations of the former studies ranging from purity of the test compound, the experimental design, the methodology used for analysis and presentation of data and lack of information on the motion-measuring device. Further, e.g. the review by Williams and DeSesso (2010) concluded that the lack of consistency across studies precludes establishment of a causal relationship between perinatal exposure to brominated flame retardants and alterations in motor activity. Despite this, the US EPA used the studies from Eriksson and Viberg when setting oral reference doses for decaBDE (US EPA, 2008).

In support of these studies, Fujimoto et al. (2011) showed that decaBDE (98% purity) resulted in reductions in the neural connections between the left and right brain hemispheres (the corpus callosum area) and caused irreversible white matter hypoplasia targeting oligodendrocytes in rats. This effect was accompanied by developmental hypothyroidism. In this study, the highest dose of each chemical was determined with a preliminary dose-finding study by estimating the dose range that causes changes in thyroid weights and histopathological findings of thyroid glands in dams but does not affect pregnancy, implantation or delivery. 8 dams per group were provided with a soy-free diet containing 0 (control), 10, 100 or 1000 ppm of DBDE from GD 10 to postnatal day (PND) 20 (PND 0: the day of delivery).

In the study on rats (modified OECD TG 426) with decaBDE (Biesemeier et al., 2011), no clinical signs, or any neurobehavioral changes, effects on startle response, or learning behaviour, were reported at any dose level. Motor activity behaviour was assessed at two, four, and six months of age. Results from the study by Wang et al. (2011) suggest that spontaneous behaviour assessed by the open field test in rats did not change significantly compared to the control group. Biesemeier et al. (2011) suggest that the probable reason is that the nervous systems in charge of spontaneous behaviour in the 50-day-old rats were already mature when decaBDE exposure began, suggesting that decaBDE may not affect spontaneous behaviour in adult male rats. The Biesemeier study has been critically evaluated by Shibutani et al. (2011) who noted the omission of measurement of thyroid-related effects, histopathological parameters on neuronal migration, oligodendroglial development, discussions of the significant decreases in the hemisphere height and decrease in the pons and cortex vertical thicknesses. The Biesemeier study has also been discussed in the Health Canada (2012) report and in Fowles and Morgott (2013). The limitations listed were that the numbers of pups found dead were higher in the 100 and 1000 mg/kg bw/day groups than in the control group, and several other treatment-related effects were observed at 1000 mg/kg bw/day (number of missing pups was increased, some of the motor activity parameters showed significant differences at 6 months in both sexes and a few of the brain morphometric analyses were significantly different at PND 21 in males and females and at PND 72 in males). Although Biesemeier et al. (2011) considered that these effects were within historical control values and an increased number of deaths at 100 and 1000 mg/kg bw/day were not related to treatment, several different parameters were affected, historical control data were not provided in the supplementary data and significant differences in a number of motor activity parameters all occurred at the same time point (PND 180). Additionally, Biesemeier et al. (2011) did not provide an explanation for the increased number of missing pups at 1000 mg/kg bw/day. Therefore, Lowest Observed Adverse Effect Level (LOAEL) (100 mg/kg bw) and No Observed Adverse Effect Level (NOAEL) (10 mg/kg bw) values were suggested in the Health Canada (2012) report, compared to the NOAEL value of 1000 mg/kg bw reported in Biesemeier et al. (2011).

Human data: A number of studies have assessed the risk of decaBDE and other PBDEs to humans. The primary focus has been on assessing the risk for developmental neurotoxicity, which is generally regarded as the most critical effect in mammals.

Risk characterisations of decaBDE conducted by Health Canada (2012) and USEPA (2008, 2010) have suggested that the daily intake of decaBDE in the USA and Canada was not likely to result in neurodevelopmental toxicity even for infants. EFSA also concluded that current dietary exposure or the intake of decaBDE by breast-fed infants does not constitute a health concern in the EU (EFSA, 2011). Furthermore, a recent PBDE risk assessment based on oral, dermal and inhalation exposure of the most sensitive and highly exposed group, infants and children up to 5 years of age, indicates no risk for adverse health effects in infants that are restrained in a car seat (Fowles and Morgott, 2013).

However, a mixture risk assessment for combined exposures to several PBDEs (BDE-28, -47, -99, -100, -153, -154, -183, -196, -197, -201, -202, -203, -206, -207, -208, decaBDE) in humans shows that acceptable levels are exceeded for all age groups, particularly for small children (Kortenkamp et al., 2014). On the basis of common modes of action and common adverse outcomes, the study finds that it can be expected that PBDEs may produce combined developmental neurotoxicity in humans (Kortenkamp et al., 2014). Kortenkamp and co-workers concluded that since decaBDE is a source of more toxic, lower brominated PBDEs which have the capacity to work together with decaBDE to produce combined toxicity, an evaluation of decaBDE in isolation, without taking account of such combination effects, would significantly underestimate the toxicity of decaBDE. Furthermore Kortenkamp and co-workers report that decaBDE undergoes transformation reactions which liberate the more toxic lower brominated congeners, both through biotic processes in humans and in other organisms, as well as abiotic transformations in the environment.

Publications reporting that decaBDE exposure takes place already during the early phases of human development, i.e. *in utero* via placental transfer or postnatally via mothers milk (Gómara et al., 2007; Kawashiro et al., 2008; K. Wu et al., 2010; Miller et al., 2012), support that the developmental neurotoxicity observed in mammalian models could have implications also for humans. According to Gascon et al. (2012), decaBDE lead to lower mental development scores in children 12-18 months of age. The observation of a linkage between decaBDE exposure levels and lower mental development scores found in the latter study is consistent with Chao et al. (2011), who reported that human prenatal or postnatal exposure to decaBDE potentially delays the neurological development and affects cognition. These epidemiological studies on decaBDE (Gascon et al., 2012; Chao et al., 2011) are limited by a rather small number of individuals. However, several epidemiological studies (Harley et al., 2010, 2011; Hoffman et al., 2012; Herbstman et al., 2008; Chevrier et al. 2010, 2011; Gascon et al., 2011; Roze et al., 2009; Eskenazi et al., 2013; Schreiber et al., 2010) support the notion that exposure to PBDEs may result in human neurodevelopmental toxicity. In these studies individual PBDEs may act alone or in combination with others to exert the reported effects.

B.5.2.1.1 Mechanisms underlying the developmental neurotoxicity of decaBDE and other PBDEs

Two mechanisms for developmental toxicity are discussed in the literature: PBDEs may act via exerting direct toxic effects on neuronal cells and stem cells, and by effects on the thyroid hormone system.

Effects on neuronal cells and stem cells
Numerous studies show that decaBDE can exert direct toxic effects on neuronal cells (reviewed by Dingemans et al., 2011, Table 36); it can interfere with neuronal signalling events such as calcium, and it induces oxidative stress and apoptosis (Chen et al., 2010c; Huang et al., 2010; Liang et al., 2010; Al-Mousa and Michelangeli, 2012). DecaBDE is further shown to cause changes in gene expression, intracellular protein levels, and disturbance of synaptogenesis and cell differentiation (Pacyniak et al., 2007; Viberg et al., 2008; Viberg, 2009; Zhang et al., 2010; Song et al., 2013). DecaBDE is also shown to lead to disturbance of cellular voltage-gated sodium channel currents (Xing et al., 2010) which may lead to neurotoxicity. The weight of evidence from these publications supports that decaBDE and other PBDEs may cause neurodevelopmental toxicity.

The central cholinergic pathway is the major pathway of learning and memory, and acetylcholine (Ach) is an important neurotransmitter involved in the learning and memory function. Ach exerts its biological effect through combining with the receptor. Ach esterase catalyses the hydrolysis of Ach at cholinergic synapses to keep the normal transmission of nerve impulses. Disturbance of the cholinergic system may lead to cognitive impairment. DecaBDE is shown to lead to decrease in Ach levels (Liang et al., 2010). Calcium-mediated processes are important for long-term potentiation (LTP) (Williams & Johnston, 1989) which is a major cellular mechanism that underlies learning and memory, and deletion of the calcium/calmodulin-dependent protein kinase II (CaMKII) gene in mice is shown to result in impairment in LTP (Silva, 1992). Effects that may lead to impairment of LTP after exposure to decaBDE have been reported (Viberg et al., 2008; Xing et al., 2009), supporting the hypothesis that decaBDE may affect learning and memory. Furthermore, several publications indicating that also other PBDEs than decaBDE affect the cholinergic system in both mice and rats brain (Fischer et al., 2008; Viberg et al., 2003, 2007; Liang et al., 2010) further support that decaBDE may have a potential to affect the cholinergic system which could be an important mechanism for cognitive deficits in mammals.

Effects on the thyroid hormone system by decaBDE and its metabolites
PBDEs are suspected of disturbing the thyroid hormone (TH) system (Gilbert et al., 2012)

being critical for proper development of several organs including the brain (Ahmed et al., 2008). DecaBDE is commonly regarded as a weak TH disruptor sharing structural similarities (two ether linked phenyl rings) with the THs thyroxine (T_4) and triiodothyronine (T_3) but differ in ring substituents. DecaBDE metabolites and particularly lower BDE congeners may more closely resemble the THs. DecaBDE and its metabolites could disturb TH receptors regulating genes in cells of the developing embryo and/or affect maternal and embryonic thyroid gland production of THs as well as anterior pituitary gland production of thyroid-stimulating hormone (TSH) (Gilbert et al., 2012). Severe TH deficiency during pregnancy can result in developmental effects including mental retardation, but for mild TH deficiencies neurodevelopmental effects are more uncertain. Several rodent studies have demonstrated metabolism of decaBDE into other high congeners (down to BDE-183) (Wang et al., 2010; Huwe & Smith, 2007).

When 20 BDEs were compared in two TH *in vitro* assays ('T3 like' and 'TTR-T4 displacement') (Hamers et al., 2006), BDE-38 and -127 were the most potent 'T3 like' BDEs. Among higher (≥183) congeners, BDE-183 and -185 acted as T3 agonists and -206 as an antagonist. BDE-190 and decaBDE gave no response. Regarding 'TTR-T4 displacement', 6-OH-BDE-47 was the most potent BDE whereas among higher (≥183) congeners, BDE-185 and -190 displayed some activity. BDE-183, -206, and decaBDE gave no response (Hamers et al., 2006). However, other studies have found that decaBDE (Ibhazehiebo et al., 2011) and 4-OH-BDE-188 (Ren et al., 2013) can act as relatively potent T3 antagonists. Moreover, BDE-183 was found not to have any T3 antagonistic activity (Ibhazehiebo et al., 2011). Moreover, using a primary culture system of rat cerebellar cells, decaBDE (10^{-10} M) inhibited T_4 induced (astrocytes deiodinate T_4 into T_3 taken up into neurons) dendrite arborization of Purkinje cells (Ibhazehiebo et al., 2011); the same experimental data were also published by Xiong et al. (2012).

Animal data on TH/TSH effects due to decaBDE administration are not consistent (see Table 37) and studies with administrated decaBDE that reported significant changes in TH/TSH levels are often orders of magnitude higher than measured human exposures. Also, few (Rice et al., 2007; Kim et al., 2009; Fujimoto et al., 2011) of the animal studies indicating neurodevelopmental effects upon decaBDE or decaBDE exposure have measured the TH/TSH levels. Whereas some animal studies report decreased T_3 levels upon high decaBDE (Chi et al., 2011; Fujimoto et al., 2011) and decaBDE exposures (Lee et al., 2010), also no change (Wang et al., 2010), and even an increase in T_3 has been reported (Van der Ven et al., 2008; Wang et al., 2011). For T_4, a similar number of animal studies report decreases in T_4 levels at high decaBDE (Rice et al., 2007; Chi et al., 2011; Fujimoto et al., 2011) and decaBDE (Kim et al., 2009) exposures as those reporting no change (Tseng et al., 2008 Van der Ven et al., 2008; Wang et al., 2010; Wang et al., 2011; Lee et al., 2010). For TSH, two animal studies (Kim et al., 2009; Lee et al., 2010) both report increased TSH levels at the highest decaBDE exposures. Regarding thyroid organ effects, high repeated (3200 and 6650 mg/kg bw/day for 103 weeks) dietary administration of decaBDE induced thyroid follicular cell hyperplasia in male B6C3F_1 mice but not in female mice, and not in either sex of F344/N rats (NTP 1986). However, three (non-guideline) studies indicate that decaBDE and decaBDE exposure at lower levels may adversely affect the developing thyroid organ in offspring: i) decaBDE administration by gavage (40 and 320 mg/kg bw/day) in pregnant Sprague-Dawley Crl:Cd rats during GD6-GD18 resulted in significantly increased thyroid weights in F1 males on PND42 (Kim et al., 2009); ii) decaBDE administration by gavage (300 and 600 mg/kg bw/day) in male neonatal Sprague-Dawley rat pups during PND10-42 resulted in thyroid gland histological changes on PND42 (Lee et al., 2010); and iii) repeated decaBDE administration in pregnant Sprague-Dawley rats from GD10 to PND20 significantly increased the incidence of thyroid diffuse follicular cell hypertrophy in male offspring on PND20 in the highest dose group, i.e. 1000 ppm (66.3-224.3 mg/kg bw/day) (Fujimoto et al., 2011).

Among human studies (Table 38), some have reported associations between TH/TSH levels and decaBDE (or other high congeners ≥ 183) exposure. However, levels of T_3 and T_4 would be expected to decrease (possibly with a compensatory TSH increase) with BDE exposure but the observed outcomes vary considerably showing both positive or negative associations as well as no association, or a mixed outcome depending on congener. Noticeably, corrections for confounders can have a large impact on associations observed.

Conclusion on developmental neurotoxicity: Most toxicological studies with decaBDE or technical mixtures have been carried out using different experimental designs with single or repeated dosing during gestation, postnatally or in adulthood. Most of the studies were carried out with a limited number of dose groups and not according to established guidelines. In laboratory animals, decaBDE affects early foetal and neonatal development, and epidemiological studies support that exposure to decaBDE and other PBDEs may result in human neurodevelopmental toxicity. Overall, the weight of evidence from the publications suggests that PBDEs cause neurodevelopmental toxicity.

B.5.2.2 Other developmental toxicity

Animal data: EFSA reported in 2011 that decaBDE given during gestation and/or postnatally, generally did not cause reproductive effects at doses up to 500 mg/kg bw/day (EFSA, 2011). In a rat study based on OECD 407 28 day sub-acute toxicity study (van der Ven et al., 2008b), the weight of the epididymis showed a significant dose-dependent decrease with maximal decrease of 22.5%, whereas the weight of the seminal vesicle significantly increased with dose (maximal increase of 38.3%), at a benchmark dose lower confidence limit (BMDL) of 0.2 mg/kg bw/day. No effects on epididymal sperm counts or morphology were observed. Notably, increased expression of hepatic CYP1A and CYP2B (BMDLs 0.5–0.7 mg/kg bw/day) were observed. In females, the most sensitive effect was decreased activity of P450c17 (CYP17), which is a key enzyme in the androgen synthesis pathway, in adrenals (BMDL 0.18 mg/kg bw/day). The authors conclude that decaBDE may represent a hazard for reproductive health in adults, possibly by modulation of sex steroids in the male genital system at BMDL of 0.2 mg/kg bw/day. In 2012, Health Canada reported that the decrease in the epididymis, coupled with the simultaneous increase in the weight of the seminal vesicle exhibited in male rats in the study conducted by van der Ven et al. suggests adaptive rather than adverse effects on reproductive function since the two organs are functionally related (Health Canada 2012). It should be noted, however, that van der Ven used a non-standard way of estimating BMDL (Hardy et al., 2008; van der Ven et al., 2008a).

In a study by Tseng et al. (2013), pregnant CD-1 mice were gavaged once daily with corn oil (control), 10, 500, and 1500 mg/kg bw of decaBDE from GD 0 to GD 17. The animals were killed at PND 71. The study documents LOAEL for sperm DNA damage and excessive H_2O_2 production resulting from *in utero* exposure to doses as low as 10 mg/kg bw/day. Anogenital distance (AGD), sperm-head abnormalities, and testicular histopathology (exhibited by severe vacuolization in the seminiferous tubules, associated with complete loss of spermatozoa and spermatids) were significantly affected in male offspring prenatally exposed to 1500 mg/kg. Significant increases in the tendency for sperm DNA denaturation (alpha-T) induction and the DNA fragmentation index (DFI) were observed in all treated groups ($P<0.05$). An increase of sperm H_2O_2 generation was observed in the 10 and 1500 mg/kg bw/day groups compared to the control group ($P<0.05$). In summary, developmental exposure to decaBDE induced sperm-head abnormality, oxidative stress, chromatin DNA damage, decreased AGD and testicular histopathological changes at doses between 10-1500 mg/kg bw/day. Notably, effects on sperm were observed at the lowest dose of 10 mg/kg bw/day. These pre-mutagenic lesions in germ cells - if not repaired - may become mutagenic, indicating that adverse reproductive effects can possibly occur upon decaBDE exposure, contrary to suggestions in previous reports.

Conclusion on reproductive toxicity: The weight of evidence suggests that in utero exposure to decaBDE at high parental doses may cause reproductive toxicity and lead to developmental abnormalities such as decreased AGD and testicular histopathological changes, sperm-head abnormality, and sperm chromatin DNA damage. The possible modulation of sex steroids in the male genital system cannot be entirely ruled out.

B.5.2.3 Developmental neurotoxicity of other PBDE congeners

The classification according to Annex VI of Regulation (EC) No 1272/2008 for the commercial pentaBDE[38] product (main components tetra-, penta- but also significant hexacongeners) is with respect to human health; Specific Target Organ Toxicity after repeated or prolonged exposure, STOT RE 2 (H373) and Lact (H362). The commercial octaBDE product (main components octa-, hepta- but also significant hexa- and nona congeners) is classified as toxic to reproduction Repr 1B (H360Df).

Most toxicological studies with individual PBDE congeners or technical mixtures thereof have been carried out using different experimental designs with single or repeated dosing during gestation, postnatally or in adulthood. Most of the studies were carried out with a limited number of dose groups, and not according to appropriate guidelines. Main targets for PBDE toxicity were the liver, thyroid hormone homeostasis, and the reproductive and nervous system, where effects on neurodevelopment is regarded as the most critical endpoint.

Most epidemiological studies suggest an association between PBDEs with (sub)clinical hyperthyroidism, and with neuropsychological functioning (motor, cognitive and behavioural performance, and mental and physical development in children) (Harley et al., 2010, 2011; Hoffman et al., 2012; Herbstman et al., 2008; Chevrier et al., 2010, 2011; Gascon et al., 2011; Roze et al., 2009; Eskenazi et al., 2013; Schreiber et al., 2010). Single exposure to BDE-47, BDE-99, BDE-153, BDE-183, BDE-203 and BDE-206 in mice or rats induced behavioural changes including learning and memory disabilities (EFSA, 2011; Kortenkamp, 2014). Repeated exposures to PBDE congeners have been performed by exposing dams and/or neonatal rodents at different developmental stages; GD6-18; GD6-PND21; PND2-15; PND6-12; from 4 weeks before mating until PND21 followed by behavioural analyses of the offspring at different ages (EFSA, 2011). Repeated exposures by exposing dams and/or neonatal rodents at different developmental stages to BDE-47, BDE-99, DE-71 (25 % tetraBDE, 50-60 % pentaBDE and 4-8 % hexaBDE) induced long lasting behavioural alterations, particularly in the motor and cognitive domain (EFSA, 2011). The developmental neurotoxicity of BDE-47, -99 and -153 is in particular well described (see the reviews by EFSA, 2011, and Costa and Giordano, 2011), where BDE-99 is reported to be the most potent of these congeners, followed by BDE-153 and BDE-47 (EFSA, 2011).

Nona-BDEs (-206, -207, -208), octa-BDEs (-196, -197, -198, -202, -203, -204) and hepta-BDEs (-183) are among the congeners identified as debromination products of decaBDE in studies with mammals (Kortenkamp, 2014). The nona-BDEs -206, -207 and -208 are by far the most abundant debromination products. Biochemical studies performed after *in vivo* exposure indicate that different PBDE congeners interfere with the expression of proteins involved in neuronal maturation, synaptogenesis and neuroplasticity. Other findings show that PBDEs alter the expression of proteins that are involved in apoptotic pathways.

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[38] The commercial pentaBDE product is also classified as Aquatic Acute 1 (H400) and Aquatic Chronic 1 (H410).

Therefore, these mechanistic data support that PBDEs, in addition to decaBDE and/or debromination products of decaBDE, might interfere with essential processes of brain development resulting in alterations in neuronal plasticity and circuitry.

Conclusion on human health: Developmental neurotoxicity is the reported critical toxicity of several PBDEs and is thought to arise through disruption of thyroid hormones and direct toxicity to neuronal cells and stem cells. Human data have demonstrated that decaBDE is absorbed and distributed to blood, cord blood, placenta, and foetus, and to the infant via breast milk. Exposure of decaBDE *in utero* in animals via placental transfer or postnatally via mothers milk also support that the developmental neurotoxicity observed in mammalian models could have implications also for human health. Furthermore, epidemiological studies suggest that exposure to decaBDE and other PBDEs may result in human neurodevelopmental toxicity. *In utero* exposure to decaBDE at high parental doses may cause reproductive toxicity and lead to developmental abnormalities.

Risk assessments of decaBDE have suggested that the daily intake of decaBDE in the USA and Canada was not likely to result in neurodevelopmental toxicity. EFSA also concluded that current dietary exposure or the intake of decaBDE by breast-fed infants does not constitute a health concern in the EU. However, these risk assessments do not take into account the potential effects that several PBDEs could exert in concert, inducing additive effects. The available toxicological data suggests that it can be expected that exposure to mixtures of PBDEs may produce combined developmental neurotoxicity in humans.

Since decaBDE is a source of more toxic lower brominated PBDEs, an evaluation of decaBDE in isolation, without taking account of the fact that decaBDE undergoes biotransformation which liberate lower brominated congeners in organisms, as well as debromination reactions in the environment, would significantly underestimate the toxicity of decaBDE.

The high persistence of decaBDE combined with wide distribution in the environment creates a high potential for lifetime exposure and uptake in organisms. Hence a pool of decaBDE in many localities will act as a long-term source of degradation products through both abiotic and biotic transformation, which would also lead to exposure of humans via the environment.

Table 35: Neurobehavioral and neurodevelopmental effects and transfer to foetus of decaBDE

Species	**Exposure**	**LOEL/ NOEL**	**Purity**	**Outcome**	**Reference**	**Comments**
Transgenic mice with C57BL/6NTac background	Oral 0, 10 or 30 mg/kg bw, PND 10		Not stated	Long term effects (in particular apoE mice) in spatial learning in (Morris Water Maze task) both at 4 and 12 months after exposure. BDNF levels lower in the frontal cortex of apoE4 mice and higher in the hippocampus of exposed mice, independent of the genotype.	Reverte et al., 2013	
Inbred adult wild type Tg2576 mice	Gavage 0, 20 mg/kg bw/day for 15 days		Not stated	Reduction in anxiety levels and a delayed learning in a spatial memory task	Heredia et al., 2012	
Children 12-18 months of age	Epidemiol. study	N.A.	N.A.	Lower mental development scores (regression analysis)	Gascon et al., 2012	Limited sample size; larger longitudinal studies should be performed to confirm the findings in the general population
Sprague–Dawley Crl:CD (SD) rats	Gavage: 0, 1, 10, 100, or 1,000 mg/kg bw/day; GD 6 to weaning	10 mg/kg bw ; NOAEL, 100 mg/kg bw ; LOAEL)	97.5% decaBDE; 2.5% nona-BDEs	None	Biesemeier et al., 2011	GLP, DNT OECD 426. As assessed by Health Canada. Study authors concluded 1000 mg/kg bw was a NOAEL.

Species	Exposure	LOEL/NOEL	Purity	Outcome	Reference	Comments
Sprague–Dawley Crl:CD (SD) rats	Gavage: 0, 1, 100, 300 or 1,000 mg/kg bw/day; GD 6 – GD 20 or GD 6 to LD 4	N.A.	97.5% decaBDE; 2.5% nona-BDEs	decaBDE is transferred to foetus. Levels in foetus plasma is 2.5-5-fold lower than plasma levels in dams, but higher levels in nursing pups.	Biesemeier et al., 2010	GLP, non-OECD study.
Sprague–Dawley rats.	Orally 5 µmol/kg bw; GD 7 to postpartum day 4.	N.A.	>98%	Placental and milk transfer of decaBDE and its metabolites to foetuses or neonates during pregnant and lactational period, and indications of bioaccumulation	Cai et al., 2011	Rats from local supplier not affiliated to the multinational suppliers.
Human infants 8-12 months	Epidemiol. study	N.A.	N.A.	Human prenatal or postnatal exposure decaBDE potentially delays neurological development; affects cognition	Chao et al., 2011	Limited sample size; larger longitudinal studies should be performed to confirm the findings in the general population
Sprague–Dawley rats CD(SD)IGS from Charles River, Japan.	Orally soy-free diet: 0, 10, 100, 1000 ppm (up to 240 mg/kg bw/day); GD 10 to PND 20.	NOAEL: 0.7-2.4 mg/kg bw /day	>98%	Neurodevelopmental effects: (thyroid follicular cell hypertrophy, irreversible white matter hypoplasia in brain (oligodendrocytes) from 24 mg/kg bw, accompanied with developmental hypothyroidism	Fujimoto et al., 2011	Tracing of animals to litters and cages is unbalanced.

Species	Exposure	LOEL/NOEL	Purity	Outcome	Reference	Comments
Adult CD-1 Swiss mice	Gavage 0, 0.1, 40, 80 and 160 mg/kg bw/day; 15, 30 or 60 days.	NOAEL 0.1 mg/kg/day	>98%	Malonyldialdehyde increased and SOD decreased in brain tissue at 40–160 mg/kg bw/day, acetylcholinesterase activity decreased at 80 and 160 mg/kg bw/day, but there were no significant changes at 0.1 mg/kg bw/day.	Liang et al., 2010	
C57BL6/J mice	6 and 20 mg/kg bw oral; PND 2-15.	6 mg/kg bw; NOAEL, 20 mg/kg bw; LOAEL	99.5%	Impaired learning in old (16 months old), but not in young (3 months old) mice. Impulsivity in the high dose (20 mg/kg bw).	Rice et al., 2009	Partly according to US EPA guideline study with litter as statistical unit. Behavioural effects appear to worsen with age.
Wistar rats	20 µmol via a metal gastric tube. Exposure 19 to 20 days: pregnancy, lactation via mother's milk, lactation via intragastric administration, after weaning, prenatal to life.	-	99%	Impairment synaptic plasticity; reduced long-term potentiation (LTP) of adult rats; more serious effects on the postsynaptic cell excitability in synaptic plasticity, and the lactation period was the most sensitive time of development.	Xing et al., 2009	

Species	Exposure	LOEL/NOEL	Purity	Outcome	Reference	Comments
Pregnant Wistar rats		100 mg/kg bw; NOAEL, 300 mg/kg bw; LOAEL	Not stated	Decreased BDNF and GAP-43 in offspring hippocampus, decreased habituation in mice	Jiang et al., 2008	In Chinese, as cited in Fowles et al., 2013
Wistar rats	Gavage: 2 mg/kg bw/day GD16-19.		>99%	The levels in the foetuses; 0.46μg/g, in placenta;2.48μg/g and in brain; 0.11 μg/g.	Riu et al., 2008	
Neonatal male NMRI mice	1.34, 2.22, 13.4, or 20.1 mg/kg bw single dose; PND 3 (10–16 per group).	1.34 mg/kg bw ; NOAEL, 2.22 mg/kg bw ; LOAEL	>98%	Decreased habituation (dose-response) in mice worse with age; altered response to nicotine at 4 months. Consistent with earlier studies on mice and indicating nicotinic cholinergic mode of action.	Johansson et al., 2008	No tables are presented that show the number of animals in each litter, cage and test group. Note narrow exposure period.
Sprague-Dawley rats	6.7 and 20.1 mg/kg bw single dose oral; PND3	6.7 mg/kg bw; LOAEL	98 %	Alterations in spontaneous behaviour indicating decreased Habituation at both doses (2 months old); alterations in nicotine response at high dose (2 months old)	Viberg et al., 2007	Not used litter as experimental unit. Note narrow exposure period.

Species	Exposure	LOEL/NOEL	Purity	Outcome	Reference	Comments
Inbred C57BL6/J mice	6 and 20 mg/kg bw/day oral; PND 2-15	6 mg/kg bw ; NOAEL, 20 mg/kg bw ; LOAEL	99.5 %	At 6 mg/kg bw/day and above; effects on palpebral reflex (age 14 days), struggling behaviour (age 20 days), grip strength (age 14 and 16 days) and locomotor activity (age 70 days). Learning behaviour was impaired at 20 mg/kg-bw (ages 70 days and 1 year). There were no effects on growth or postnatal developmental milestones, anogenital distance or crown–rump length.	Rice et al., 2007	Partly according to US EPA guideline study with litter as statistical unit. Results did not replicate a consistent depression in motor activity over time.
NMRI male mice	1.34, 2.22, 13.4 and 20.1 mg/kg bw single dose oral	2.22 mg/kg bw ; NOAEL, 20.1 mg/kg bw ; LOAEL	Not stated	PND3: Alterations in spontaneous behaviour and habituation (2, 4 and 6 month old) PND10 and PND 19: no alterations detectable	Viberg et al., 2003	Not used litter as experimental unit. Note narrow exposure period.
Sprague-Dawley rats	Gavage: 100; 300; 1,000; mg/kg bw/day GD0-GD19	NOEL; 1,000	97.34 % decaBDE, 2.66 % nona- and octa-BDE	No developmental effects	Hardy et al., 2002	OECD/GLP

Table 36: Mechanistic studies of decaBDE neurotoxicity

Test system	Exposure level	Effect: LOEL	Purity	Reference
Primary neural stem/progenitor cells (from PND 1 SDrats)	3.2 µg/mL BDE-47; 6.0 µg /mL decaBDE; 6.0 µg/mL decaBDE + 3.2 µg/mL BDE-47	Alteration of 19 differentially expressed proteins after exposure to decaBDE and/or BDE-47. Cofilin-1 and vimentin was decreased by decaBDE.	98.3%	Song et el., 2013
SH-SY5Y neuroblastoma cells	1-50 µM	Cytotoxic (LC(50) being 28 ± 7 µM), induced cell death by apoptosis through activation of caspases, increased intracellular [Ca(2+)] levels and oxidative stress, caused rapid depolarization of the mitochondria and cytochrome c release, µM levels caused β-amyloid peptide (Aβ-42) processing and release from these cells with a few hours of exposure. These results therefore shows that these pollutants are both neurotoxic and amyloidogenic in-vitro	97%	Al-Mousa and Michelangeli, 2012
Hippocampus; analyses were performed at PND10	20.1 mg/kg bw (LOAEL)	Alterations in the expression of CAMKII (increased in hippocampus), BDNF (decreased in hippocampus), GAP43 (increased in hippocampus; decreased in cortex)	98 %	Viberg et al., 2008
Mice hippocampus analyses were performed at PND10	20.1 bw (LOAEL)	Altered synaptophysin; supports that decaBDE can disturb components of normal brain maturation and act as a developmental neurotoxicological agent	98 %	Viberg et al., 2009

Test system	Exposure level	Effect: LOEL	Purity	Reference
Primary neonatal hippocampal neuron (GD19-21 SD rats)	10, 30 and 50 µg/ml for 24 h	Induction of apoptosis (AnnexinV/PI staining) with a LOEL of 10 µg/mL; induced p38 MAPK expression (protein level) with a LOEL of 10 µg/mL; increase in ROS and NO levels with a LOEL of 10 µg/mL; increased calcium ion content with a LOEL of 10 µg/mL; increased expression of malondialdehyd (MDA) with a LOEL of 30 µg/mL; decreased SOD activity with a LOEL of 10 µg/mL; decrease in global DNA methylation with a LOEL of 10 µg/mL; induction of cytotoxicity (MTT) with a LOEL of 10 µg/mL	98 %	J. Chen et al., 2010
Brain samples from 10 week old CD1 Swiss mice. Analyses performed 20, 40 or 60 days after exposure.	Chronic toxicity: 0.1, 40, 80, 160 mg/kg bw/day by gavage for 15, 30 or 60 days	Increased activity of acetylcholinesterase with a LOEL of 80 mg/kg b.w. per day after 15 days of exposure; decreased SOD activity with a LOEL of 40 mg/kg bw/day after 15, 30 and 60 days of exposure; induction of MDA activity with a LOEL of 40 mg/kg b.w. per day for 15, 30 and 60 days of exposure. Experimental results suggested that the nervous system was permanently damaged through the cholinergic system enzyme	98%	Liang et al., 2010
Hippocampal neural stem cells from neonatal SD rats	0.01, 0.03 and 0.05 mM. Exposure: 7 days	MTT assay: decreased viability of neural stem cells; suppression of neurite outgrowth; suppression of the differentiation of neural stem cells into neurons in a concentration dependent manner; enhanced differentiation of neural stem cells into glial cells.	Not stated	Zhang et al., 2010

Test system	Exposure level	Effect: LOEL	Purity	Reference
Primary cultured rat hippocampal neurons	0.05 μM to 2 μM	Irreversibly decrease of voltage-gated sodium channel (VGSC) currents (I(Na)) at very low dose and in a concentration-dependent manner. These results suggested that decaBDE could affect VGSCs, which may lead to changes in electrical activities and contribute to neurotoxicological damages.	99%	Xing et al., 2010
Primary cerebellar granule cells from 7-day-old mice	1 to 50 μM	BDE-47, BDE-99, BDE-100, BDE-153, and decaBDE decreased cell viability and induced apoptotic cell death, which was prevented by antioxidants. They also caused oxidative stress, as indicated by an increase in reactive oxygen species and in lipid peroxidation.	99.9%	Huang et al., 2010
C57BL6 mice, PXR-knockout backcrossed five generations to C57BL/6 background	100 μmol/kg/day, for 4 days	Induced PXRdependent gene expression in mice; no induction of AhR-dependent gene expression; reporter gene assays, using either murine PXR (mPXR) or human PXR (called steroid X receptor, SXR) transfected into HepG2 cells, revealed weak induction potencies of decaBDE	Not stated (from Sigma)	Pacyniak et al., 2007

Table 37: Animal studies on associations between higher BDE congeners (≥183) with TH/TSH levels

Species	Exposure	Purity	NOEL/LOEL/BMDL	TH/TSH effects	Reference	Comments
Adult Sprague-Dawley male rats	House hold 'dust mimic' mixture (BDE-71, decaBDE, HBCD, BDE-79); 0.02, 0.2, 2, 20 mg/kg/day for 70 days	44.2% decaBDE	Not stated	• Decrease in serum T_4 at the highest dose (20 mg/kg/day) • No effect on serum TSH at any dose	Ernest et al., 2012	Unclear which BFR that was responsible for observed effects
Pregnant C57 mice	decaBDE by gavage: 150, 750, 1500, 2500 mg/kg bw on GD7-9	Not stated	Not stated	Maternal serum • Decreased total T_4 and total T_3 at the highest dose (2500) • Decreased total T_4 at the next highest dose (1500)	Chi et al., 2011	
Pregnant Sprague-Dawley rats	decaBDE in food: 10, 100, 1000 ppm on GD10-PND20	>98%	LOAE: 10 ppm (0.7-2.4 mg/kg bw/day) was related to developmental effects (not thyroid effects)	Male offspring: • Decreased serum T_3 at 1000 ppm (66.3-224.3 mg/kg bw/day) on PND20 • Decreased serum T_4 at 1000 ppm on PNW11 • No effects on TSH	Fujimoto et al., 2011 (Saegusa et al. 2012 used the same TH data)	

Species	Exposure	Purity	NOEL/LOEL/BMDL	TH/TSH effects	Reference	Comments
Sprague-Dawley males	Repeated decaBDE (10 and 50 mg/kg bw/day) gavage for 90 days	≥99%	Not stated	• Increased serum total T_3 •No effects on serum total T_4	Wang et al., 2011	
Sprague-Dawley males	Repeated decaBDE (100 mg/kg bw/day) gavage for 90 days	≥99%	Not stated	• No effect on serum T_3 and T_4 levels	Wang et al., 2010	
Sprague-Dawley rat pups	decaBDE by gavage: 100, 300, 600 mg/kg bw/day during PND10-42	98%	Not stated	• Decrease in serum T_3 at all doses • No changes in serum T_4 • Increased TSH at 300 and 600 mg/kg BW	Lee et al., 2010	
Pregnant Sprague-Dawley Crl:CD rats	decaBDE by gavage; 5, 40, 320 mg/kg bw/day during GD6-18	98%	Not stated	F1 gen, 320 mg/kg, PND42: • Decreased serum free T_4 in F1 females • Increased serum TSH levels in F1 males and females	Kim et al., 2009	Stated doses in Mat./ Meth. are much higher than in Abstract

Species	Exposure	Purity	NOEL/LOEL/BMDL	TH/TSH effects	Reference	Comments
Pregnant CD1 mice	decaBDE by gavage: 10, 500, 1500 mg/kg/day on GD0-17	98%	Not stated	Male offspring on PND71: • Decreased serum total T_3 in 10 and 1500 (not 500) groups • No changes in serum total T_4 levels in any group	Tseng et al., 2008	Not a clear dose-response effect in total T_3
Wistar rats	Gavage 1.87, 3.75, 7.5, 15, 30, 60 (2x30; 4 h interval) mg/kg bw for 28days	Commercial decaBDE, >97%	BMDL (NOAEL point of departure alternative): 0.2 mg/kg bw/day based on increased weight of seminal vesicle/coagulation gland in males	• Limited increase in total T_3 at highest dose (BMDL 33 mg/kg BW/d) in females. No effect in males • No effect on total T_4 in either sex	Van der Ven et al., 2008	
C57BL6/J mice pups	Oral admin. of 6, 20 mg decaBDE/kg bw on PND2-15	99.5%	Not stated	• Dose dependent decrease in male serum T_4 on PND21	Rice et al., 2007	[a]Questionable statistical analyses

[a] In a review article by Goodman (2009), the T_4 data were reanalysed using ANOVA and Neumann-Keuls posttest giving no statistically significant differences between treated animals and controls.

Table 38: Human studies on associations between higher BDE congeners (≥183) in serum, cord blood, milk, house hold dust (indirect) and TH/TSH levels in people

Subjects	Chemicals analysed	TSH/TH measured	Outcome for higher (≥183) BDE congeners	Reference	Comments
Volunteers (n=124; 60 m/64 w) from Northern China	Serum BDE-17, 28, 47, 66, 99, 100, 153, 154, 183 and decaBDE	Serum total T_3, free T_4, and TSH	• Total T_3 correlated with decaBDE and inversely with BDE-183 • Free T_4 and PBDEs did not correlate • TSH correlated with BDE-183	Huang et al., 2014	
Males (n=62), 18-54 year old, from couples seeking infertility treatment in Massachusetts	House hold dust PBDE congeners (31) and alternate FRs (6)	Serum total T_3, free T_4, and TSH	• Dust octaBDE (∑BDE-183 and -201) was sign. positively associated with serum free T_4 and TSH, but not with total T_3 • No association between decaBDEs (∑BDE-206, -207, -208 and - decaBDE) and total T_3, free T_4 or TSH	Johnson et al., 2013	BFR levels were not measured *in vivo*.
Pregnant women, central (n=42) and southern (n=107) Taiwan	Breast milk BDE-28, -47, -49, -85, -99, -100, -153, -154, -183, -196, -197, -206, -207, decaBDE	Cord blood T_3, T_4, free T4, and TSH	• No associations found between BDE-183, -196, -197, -206, -207, or decaBDE with T_3, T_4, free T_4 or TSH	Shy et al., 2012	At delivery, cord blood hormones can stem from both mother and child
High school students (n=515), Belgium	Serum BDE-47, -99, -100, -153, - decaBDE, HBCD, TBBPA	Serum free T_3, free T_4, and TSH	• No associations found between decaBDE and free T_3, free T_4 or TSH	Kicinski et al., 2012	

Subjects	Chemicals analysed	TSH/TH measured	Outcome for higher (≥183) BDE congeners	Reference	Comments
Mothers and their children (n=46-239), Norway	Breast milk BDE-47, -99, 153, -154, -decaBDE (n=46), HBCD	Child blood TSH	• No associations found between decaBDE and TSH	Eggesbø et al., 2011	
Pregnant women (n=25), California	Serum PBDEs (37): lower (BDE-17 to -154), higher (BDE-183 to decaBDE), and hydroxylated (OH-BDE-17 to -137)	Serum total and free T_4, and TSH	• BDE-207 was inversely associated with TSH, but not with total and free T_4. • For other higher BDEs no associations were found	Zota et al., 2011	
Pregnant mothers (n=482) and their children at 4 yrs. of age. Menorca, Spain	Cord blood (n=88) and serum from 4 year old children (n=244) were analysed for BDEs 12-13, 17, 32, 28-33, 47, 66, 71, 85, 99, 100, 116, 119, 126, 138, 153, 154,155, 183 and 190	Serum total T_3, free T_4, and TSH in 4-yr old children	• Levels of THs were not associated with PBDE exposure (specific outcomes for BDE-183 and -190 are not stated)	Gascon et al., 2011	Only BDE-47 was quantified in a reasonable number of samples
Occup. & non-occup. (n=236 & 89) people at e-waste recycling in SE China. Contr. (n=117)	Serum BDE-77, -85, -126, -203, -205, decaBDE. PBB 077, 103, decaBDE	Serum total and free T_3, total and free T_4, and TSH	• BDE-205 was positively associated with total T_4 but not with free T_3, free T_4, or TSH • For BDE-203 and decaBDE no associations were found	Wang et al., 2010	
Pregnant women (n=270), California	Serum BDE-17, -28, -47, -66, -85, -99, -100, -153, -154, -183	Serum total and free T_4, and TSH	• No associations found between BDE-183 and total and free T_4, or TSH	Chevrier et al., 2010	

Subjects	Chemicals analysed	TSH/TH measured	Outcome for higher (≥183) BDE congeners	Reference	Comments
Workers (n=11) at an electronic recycling facility in Örebro, Sweden	Repeated plasma analyses over 1.5 yrs. for BDE-28, -47, -99, -100, -153, -154, -183	Repeated plasma analyses over 1.5 yrs. for total T_3, free T_4, and TSH	• In one worker, a positive correlation was found between T_3 and BDE-183	Julander et al., 2005	

B.6 Human health hazard assessment of physico-chemical properties

B.6.1 Oxidizing properties

No oxidizing properties are expected due to the chemical structure of the substance. (EU RAR, 2002)
DecaBDE gives no reason for concern in relation with its physico-chemical properties.

B.6.2 Explosivity

Due to its chemical structure, the substance is not expected to be explosive (EU RAR, 2002).

B.6.3 Flammability

The substance is used as a flame retardant based on its known stability (EU RAR, 2002).

B.7 Annex -B.7 Environmental hazard assessment

New information from the scientific literature, published after the adoption of the SVHC Support Document, was reviewed by ECHA in collaboration with the Norwegian Competent Authority.

DecaBDE is a PBT/vPvB substance. Since the risks of PBT/vPvB substances cannot be assessed quantitatively, e.g. by comparing PECs with PNECs, as undertaken in conventional risk assessment, no PNEC values are derived and no risk characterisation is undertaken.

B.7.1 Aquatic compartment (including sediments)

As described in the SVHC SD (SD, 2012), feeding studies with fathead minnows (*Pimephales promelas*) have previously indicated that decaBDE may interfere with the thyroid hormone system in juvenile fish (Noyes et al., 2011).
Noyes et al. (2013) report the results from a further study to evaluate the effects of exposure to environmentally relevant concentrations of decaBDE (obtained from Sigma-Aldrich; 97% purity) on thyroid functioning/signalling and to further elucidate mechanisms of thyroid dysfunction in fathead minnows. Two exposures of decaBDE were selected. These were intended to reflect environmentally realistic exposures from a contaminated environment (300 ng/g bw/day) and from background levels (3 ng/g bw/day). Adult males received dietary exposures for 28 days followed by a 14-day depuration phase. The effects on circulating thyroid hormone levels, relative iodothyronine deiodinase (Dio) activity and mRNA levels in the brain and liver were measured along with transcript abundances of genes encoding thyroid hormone receptors (trα, trβ) and several membrane bound transporters. In addition, the gonadosomatic index (GSI) was measured as an indicator of the potential effect of decaBDE on reproduction. Compared to controls, fish in the low exposure treatment experienced a 53% and 46% decline in circulating total thyroxine (TT4) and 3,5,3′-triiodothyronine (TT3) levels, respectively. In fish from the high exposure treatment group TT4 and TT3 levels declined by 59% and 62%, respectively. Brain deiodinase activity (T4-ORD) was reduced by 65% in both treatment groups. DecaBDE elevated the relative mRNA expression of genes encoding deiodinases, nuclear thyroid receptors, and membrane transporters in the brain and liver in patterns that varied with time and dose, likely in compensation to hypothyroidism. Statistically significant declines in

the gonadal-somatic index (GSI) were measured at all sampling time points. At day 28 a GSI decline of 23% at low doses and 31 % at high doses was measured which also extended through the depuration period. Further a statistically significant increase in percent cumulative mortality was measured at both doses.
Observed effects at the low dose were consistent with the higher dose, suggesting a nonlinear relationship between decaBDE exposure and thyroid dysfunction.

Garcia-Reyero et al. (2014) did not observe effects on thyroid hormone levels in fish after exposure to decaBDE. In this study zebra fish (*Danio rerio*) embryos were exposed from 4 h to 8 days post fertilization to decaBDE spiked sediment (12.5 mg/kg nominal concentration) under static conditions in the dark. DecaBDE affected the expression of neurological pathways and altered the behaviour of larvae, although it had no measurable effect on thyroid hormone function or motorneuron and neuromast development. The authors speculate that the absence of thyroid endocrine disruption in their study may be explained by shorter exposure and/ or lower doses than those employed by other authors.

DecaBDE has also been shown to induce oxidative stress in the liver of goldfish (*Carassius auratus*). Two studies of the effects of decaBDE exposure on hepatic biomarkers of oxidative stress in the goldfish are available (Feng et al., 2013a; Feng et al., 2013b). Feng et al. (2013 a,b) injected intraperitoneally 10, 50 and 100 mg/kg of decaBDE, dissolved in corn oil, for 7, 14 and 30 days. Results showed that oxidative stress was evoked evidently for the experimental groups with longer exposure duration, as indicated by significant inhibition in the antioxidant enzymes activities (superoxide dismutase, catalase, glutathione peroxidase) and decrease in the reduced glutathione level, as well as simultaneous elevation of lipid peroxidation level measured by malondialdehyde content. Some effects were observed in the lowest dose tested (10 mg/kg body weight).

Summary and discussion of new information

The SVHC Support Document concluded that the lowest aquatic NOEC appears to be around 0.001 mg/l (1 μg/l), which is in the region of the reported solubility limit of decaBDE in pure water. Despite methodological limitations due to the low solubility a concern for ecotoxicological effects of decaBDE on aquatic organisms was raised based on studies indicating effects on important biological endpoints including reproduction, development, endocrine system and growth in fish and amphibians.

A controlled feeding study by Noyes et al. (2013) with fathead minnows at environmentally relevant concentrations provides further evidence that decaBDE may interfere with the thyroid hormone system in juvenile fish and may affect reproduction due to declined (GSI) and increased mortality. Exposure via food is considered to be more relevant than exposure via water.

Garcia-Reyero et al. (2014) did not observe effects on thyroid hormone levels in zebra fish. However, the authors identified limitations of the test system that would limit the potential to detect adverse effects associated with decaBDE.

Papers published by Feng et al. (2013 a, b) demonstrate that decaBDE induce oxidative stress in the liver of goldfish (Carassius auratus) for the experimental groups with longer exposure duration. However these effects are biomarker responses and they are deemed not to be of equivalent concern as conventional adverse responses.

B.7.2 Terrestrial compartment

Plourde et al. (2013) investigated the association between markers of bone metabolism and structural integrity and concentrations of halogenated flame retardants in ring billed gulls

(Larus delawarensis). The authors observed that concentrations of the hexa-, hepta-, nona- and decaBDE congeners BDE-154, -183, -201 and decaBDE, respectively, in liver and decaBDE in plasma of male ring-billed gulls breeding in the urbanized Montreal region were negatively correlated with trabecular and cortical bone mineral density of the tarsus. Measured decaBDE concentrations in liver were in the range 2.74–283 ng g-1 ww, with a mean value of 51.6 ng g-1 ww. Plasma samples had concentrations in the range between 0.70 and 19.1 ng g-1 ww, and a mean concentration of 5.33 ng g-1 ww. No information on confounding factors like health of bird, habitate quality etc. are available. However these results may suggest that exposure to flame retardants can negatively affect bone tissue structure by light demineralisation and bone metabolism in birds.

Summary and discussion of new information

As described in the SVHC Support Document birds exhibit some of the highest concentrations of decaBDE reported in wildlife. The data presented by Plourde et al. (2013) suggests that exposure to decaBDE and lower brominated congeners may negatively affect bone tissue structure and bone metabolism in birds.

B.7.3 Microbiological activity in sewage treatment systems

No new information has become available since the publication of the SVHC SD.

B.8 PBT and vPvB assessment

According to REACH, Annex I, section 4 "The objective of the PBT and vPvB assessment shall be to determine if the substance fulfils the criteria given in Annex XIII and if so, to characterise the potential emissions of the substance. A hazard assessment in accordance with Sections 1 and 3 of this Annex addressing all the long-term effects and the estimation of the long-term exposure of humans and the environment as carried out in accordance with Section 5 (Exposure Assessment), step 2 (Exposure Estimation), cannot be carried out with sufficient reliability for substances satisfying the PBT and vPvB criteria in Annex XIII."

"Therefore, a separate PBT and vPvB assessment is required. The PBT and vPvB assessment shall comprise the following two steps which shall be clearly identified in part B, section 8; Step 1) Comparison with the criteria and step 2) Emission characterisation."

Further, according to REACH Annex I, Section 4.2 , the emission characterisation for PBT/vPvB substances must "contain an estimation of the amounts of the substance released to the different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses, and an identification of the likely routes by which humans and the environment are exposed to the substance."

B.8.1 Assessment of PBT/vPvB Properties – Comparison with the Criteria of Annex XIII

The text in this section is in its entirety based on the Agreement of the Member State Committee (MSC Agreement, 2012) on the identification of Bis(pentabromophenyl) ether [decabromodiphenyl ether] as a substance of very high concern, according to Articles 57 and 59 of Regulation (EC) 1907/2006, adopted on 29 November 2012[39].

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[39] http://echa.europa.eu/documents/10162/1f83d2de-8eaf-405a-90a1-a9e2d0651459

Agreement of the Member State Committee in accordance with Article 59(8):

Bis(pentabromophenyl) ether [decabromodiphenyl ether] is identified as a substance meeting the criteria of Article 57 (d) as a substance which is persistent, bioaccumulative and toxic and of Article 57 (e) as a substance which is very persistent and very bioaccumulative, both in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC) 1907/2006 (REACH).

UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Persistence, Bioaccumulation and Toxicity:

Decabromodiphenyl ether [decaBDE] is widely detected in the European environment, residing mainly in sediments and soils at concentrations up to several milligrams per kilogram (parts per million) on a dry weight basis. It is also present in many types of aquatic and terrestrial wildlife species (including tissues of sensitive life stages such as bird eggs) at numerous geographical locations; although tissue concentrations are often low (close to the limits of analytical detection, or below), it can attain concentrations up to a few hundred micrograms per kilogram (parts per billion) on a wet weight basis in some top predators.

Primary degradation half-lives in sediment and soil significantly exceed 180 days, indicating that decaBDE is 'very persistent' according to the Annex XIII criteria. On the basis of the available data, it can also be concluded that there is a high probability that decaBDE is transformed in soil and sediments to form substances which either have PBT/vPvB properties, or act as precursors to substances with PBT/vPvB properties, in individual amounts greater than 0.1% over timescales of a year. Transformation to such substances within biota provides an additional pathway for the exposure of organisms. High persistence combined with wide distribution in the environment creates a high potential for lifetime exposure and uptake in organisms, and a pool of the substance in many localities that will act as a long-term source of degradation products through both abiotic and biotic transformation.

The PBT/vPvB nature of the principal transformation products of deca BDE, i.e. tetra-, penta-, hexa- and heptaBDE congeners, has already been recognised by their inclusion as persistent organic pollutants (POPs) in Annex A of the Stockholm Convention, implemented in the EU as Commission Regulation (EU) No. 757/2010.

Experiments have shown that nonaBDEs can be degraded to octaBDEs by anaerobic bacteria (Gerecke et al., 2005 and 2006). He et al. (2006) and Lee and He (2010) have shown that octaBDE can be biodegraded by anaerobic bacteria collected from a range of locations to hexa-, penta- and tetraBDEs. Stapleton et al. (2004b) showed that Common Carp (Cyprinus carpio) exposed to BDE-99 and BDE-183 (a penta- and a heptaBDE congener, respectively) via the diet could metabolise these substances to BDE-47 (a tetraBDE congener) and BDE-154 (a hexaBDE congener) respectively. It therefore seems likely that nona- and octaBDE congeners are also precursors of the congeners with PBT/vPvB (respectively POP) properties. Indeed, UNEP (2007) concluded that the octa- and nonaBDE congeners are also likely to lead to significant adverse human health and/or environmental effects, such that global action is warranted, due to their transformation to other PBDEs.

The following conclusions are reached for each congener group.

Congener group	***Persistence***	***Bioaccumulation***	***Toxicity***
TetraBDE	*vP*	*vB*	*T*
PentaBDE	*vP*	*vB*	*T*
HexaBDE	*vP*	*B, some are vB*	*T*
HeptaBDE	*vP*	*B, based on weight of evidence*	*T*
OctaBDE	*vP*	*Probably not B*	*Possibly T*
NonaBDE	*vP*	*Probably not B*	*The lack of relevant data means that it is not possible to reach a conclusion.*

Summary of PBT profiles for specific congener groups

- *TetraBDE congeners meet the PBT and vPvB criteria.*
- *PentaBDE congeners meet the PBT and in some case the vPvB criteria.*
- *HexaBDE congeners meet the PBT and in some case the vPvB criteria.*
- *HeptaBDE congeners meet the vP and T criteria. They do not appear to meet the B or vB criteria based on an estimated fish BCF, but the weight of available evidence suggests that they can be considered to be B. HeptaBDEs are therefore considered to be a PBT substance.*
- *OctaBDE congeners meet the vP criteria, but probably do not meet the B criteria. They possibly meet the T criteria*[40]*.*
- *NonaBDE congeners meet the vP criteria, but probably do not meet the B criteria. There are insufficient data to conclude on T.*

Conclusion:

DecaBDE is very persistent and widely detected in many environmental compartments (including wildlife species). On the basis of the available data it can be concluded that there is a high probability that decaBDE is transformed in the environment to form substances which themselves have PBT/vPvB properties, or act as precursors to such substances, in individual amounts greater than 0.1% w/w over timescales of a year.

DecaBDE is therefore considered to meet the definition of a PBT/vPvB substance in accordance with Annex XIII of the REACH Regulation, and thereby fulfils the criteria in Articles 57(d) and (e).

Reference:
1. Support Document Bis(pentabromophenyl) ether [decabromodiphenyl ether] (Member State Committee, 29 November 2012)
http://echa.europa.eu/documents/10162/27064fdb-1cb4-4d37-86c3-42417ec14fb6

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[40] *The European Commission has proposed to identify octaBDE as a "Priority Hazardous Substance" in the context of the Water Framework Directive, because of its PBT properties (EC, 2012). However, it is understood that this refers to the commercial product, on the basis of its lower molecular weight PBDE content. The Environmental Quality Standard for "brominated diphenyl ether" only concerns the sum of six tetra- to heptaBDE congeners.*

B.8.2 Emission Characterisation

B.8.2.1 Previous EU risk assessments

The environmental releases of decaBDE have been estimated in a series of previous EU risk assessments – an initial EU RAR report was published in 2002, which was subsequently followed by two updates, in 2004 and in 2007. The initial RAR calculations estimated a total emission factor of ~7% (EU RAR, 2002, Entec, 2011). In the 2004 update new calculations using lower emission factors were undertaken, giving a significantly lower total emission factor of ~0.5%. New information from literature was presented in the 2007 update (EU RAR, 2007). The estimates from both the 2004 and 2007 updates were included in the Annex XV dossier for identification of decaBDE as an SVHC (Annex XV, UK 2012). However, the total emission factor remained the same as in the 2004 update (~0.5%). In this assessment, ~99% of the emissions were attributed to the disposal of textiles, although it was highlighted that there was considerable uncertainty in the emission factors used.

However, these previous assessments do not represent the current situation, and need to be updated, for the following reasons:

- For the production life-cycle stages, new emission estimates have been published by the Voluntary Emissions Control Action Programme (VECAP, 2013)
- When the previous EU RARs were drafted, use of decaBDE under RoHS was still allowed, and plastic EEE articles constituted the major use of the substance. The EU RAR (2002) was based on an assumed tonnage split of ~80% used for plastics/polymers and 20% for textiles. This split was revised slightly in EU RAR (2004) to 70% of total use in plastics/polymers and 30 % in textiles. The RoHS Regulation now prohibits the use of decaBDE in EEE and recent information (VECAP, 2012) indicates that the current distribution in tonnage between plastics/polymers and textiles uses should be approximately a 52:48 % split.
- New studies on the emissions of decaBDE have become available in the literature. However the studies and assumptions presented in the previous risk assessments will also be used here whenever relevant.
- OECD emission scenario documents are now available for textiles (OECD, 2004) and plastic additives (OECD, 2009) and together with the ECHA Guidance documents (ECHA R16, R17 and R18) these provide a refined basis for undertaking an emissions assessment.

B.8.2.2 Production of articles

B.8.2.2.1 Emission Factors

The exact number of sites of use of decaBDE in the EU is unknown. However, as a general purpose flame retardant decaBDE is assumed to be used (and released) at many industrial and professional sites. The Annex XV report (Annex XV SVHC, 2012, and references cited therein) indicate more than 100 sites of compounders/formulators, master batchers, injection moulders and finishers.

VECAP (2013) presents the latest emission estimations from the production stage in the EU (see section B.2.2.2 Identified Uses), with a total emission factor of 1.5E-05 (15 g/t).

However, the VECAP tonnage does not cover all the decaBDE which is put into the EU market. For the purposes of this report it will be considered that the VECAP emission estimates represent current industrial best practice. However, no verification of this data has been done by ECHA. For comparison, the emissions estimates made with the OECD ESD yield, overall, higher emissions to the environment (RPA, 2014). Table 39 shows the emission factors used in the low and the high emissions scenarios, for the total tonnage of decaBDE imported in the EU.

It is important to note that VECAP does not provide any information about emissions during the service life of articles or during disposal of articles at the end of their service life (Annex XV SVHC, 2012).

Table 39: Emission factors for Article Production

	Low emissions scenario	**High emissions scenario**
	VECAP	OECD ESD
Total EF	1.5E-05*	1.4E-04**

*emissions to air, water and soil
**emission to air and water
Source: derived from VECAP (2013) and RPA (2014)
NOTE: the OECD ESD methodology used in RPA (2014) estimates emissions from production to air and water. VECAP has in addition reported emissions to soil.

B.8.2.2.2 Obligation to minimise emissions

DecaBDE was identified as a PBT/vPvB and added to the Candidate List on 19 December 2012. Consequently, the chemical safety assessment in the registration dossier must be in line with this status[41]. PBT/vPvB status triggers a number of obligations under REACH, notably related to exposure assessment and to the adoption of risk management measures which **minimise** exposures and emissions to humans and the environment, throughout the life cycle of the substance that results from manufacture or identified uses (REACH Annex I).

Based on the above, it is considered that EU companies using decaBDE, even if they are not currently members of VECAP, will need to adopt the VECAP best practices, or better, in order to comply with their obligation to minimise the emissions. This is the rationale behind the low emissions scenario presented in the previous section.

B.8.2.3 Article service life

B.8.2.3.1 Emissions Factors

The emissions from article service life have been estimated using emissions factors from the OECD ESD for plastics (OECD, 2009) and textiles (OECD, 2004), the previous EU RARs and from other available literature (

Table **40**).

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[41] The registrants of decaBDE have not yet updated their registration, after the identification of decaBDE as PBT/vPvB and its inclusion in the Candidate List for Authorisation (REACH-IT accessed on 12/06/2014).

Table 40: Emission factors for Article Service Life

	Plastics			**Textiles**		
	Air	**Water**	**Soil**	**Air**	**Water**	**Soil**
Indoor use	5.00E-04 2.40E-05[1]	5.00E-04	-	5.00E-04 3.20E-05[2]	5.00E-04	-
Washing*	-			-	5.00E-04[3]	-
Outdoor use**	5.00E-04	1.60E-02***		5.00E-04	1.60E-02***	

Source:OECD 2004, OECD 2009, ECHA R16, RPA 2014 and references below
All Emission Factors taken from OECD ESD except 1, 2 and 3 below:
[1] Morf et al., 2007, based on data from Sakai et al., 2006 (measurements on EEE plastics)
[2] Thomas et al. (2006), as cited in EU RAR 2007, (measurements on upholstery, wear and ageing)
[3] EU RAR, 2004 from Use Category Document on plastics additives based on loss of DEHP from regular washing of PVC flooring.
*2% of textiles with decaBDE are subject to washing (EU RAR, 2004)
**0.1% of plastics with decaBDE are used outdoors (EU RAR, 2002 and 2004). 5% of textiles with decaBDE are used for tents (RPA, 2014)
***emissions to water *or* soil

NOTE: all emission factors estimate emissions during the whole service life of the article, assumed to be 10 years in average for all article types.

From

Table **40** it can be seen that the emission factors from the OECD ESD for, both plastics and textiles uses are identical. Outdoor use is associated with higher emission factors than indoor use for both the water and soil compartments (there is no emission to soil assumed from indoor use by the OECD ESD). The same emission factor is used for air, for both indoors and outdoor uses. For indoor uses, in addition to the emission factors from the OECD ESD, reliable measured data are also available. These data were used in the calculations in addition to the OECD ESD data. No measured emission factors for outdoor uses of decaBDE were found in the literature.

B.8.2.3.2 Indoor and Outdoor uses/washing of textiles

An important distinction for article use is whether the articles are used indoors or outdoors, as the outdoor emissions cannot be easily contained and may also result on the soil or water, without necessarily passing through an abatement system such as a municipal WWTP. Given the uses of decaBDE (see section B.2), both outdoor and indoor applications are possible, although the indoor applications seem to be more prevalent. For plastics a figure of 0.1% was used for outdoor applications in the previous EU risk assessments (EU RAR, 2002 and 2004).

For textiles, the majority of the applications that may be treated with decaBDE are for use indoors, e.g. upholstered furniture, contract furniture (e.g. seating for public buildings), curtains, etc. The identified outdoor applications include tents (estimated to be 5% of the use of decaBDE in textiles) and in the seats of cars. For cars, the confirmed quantities are small compared to the total consumption of decaBDE (<100 t/y). Nevertheless, some other objects (e.g. furniture) could be used outdoors, either continually or intermittently (RPA, 2014). In the absence of more detailed information it will be assumed that 5% of articles containing decaBDE are used outdoors.

For the washing of textiles the assumptions used in the EU RAR (2004) will be used. Although most of the textiles flame retarded with decaBDE are not thought to be subject to regular washing, some of them may be washed from time to time (e.g. curtains and loose covers).

B.8.2.3.3 Uncertainties in the final destination of releases from service life

Due to the low volatility of decaBDE at ambient temperature, releases to air through volatilisation will not be significant (RPA, 2014). The only expected emissions to air should be in particulate form after wear of the article. In that case, at least for indoor uses, they would be expected to mostly deposit on surfaces and then rinsed to wastewater or end up in solid waste after vacuum cleaning (Morf et al., 2007). DecaBDE contained in the wastewater which enters the waste water treatment plant (WWTP), will predominantly partition to sludge, which can subsequently be incinerated, landfilled or applied to agricultural soils. Similar considerations could be made also for outdoor uses. These differentiations in the final destination of releases to air, water or soil have not been taken into account in the emission estimations.

B.8.2.3.4 Scenarios for releases from article service life

Two emission scenarios are considered (see Table 41). The "high emissions" scenario uses emission factors from the OECD ESD, which are considered as worst case for both indoor and outdoor uses. The "low emissions" scenario uses data from the OECD ESD for outdoor uses (since no data have been found elsewhere) and measurements for indoor uses. Both scenarios use the emission factor from the EU RAR (2004) for textile washing. The total emission factor for the high emission scenario is 1.4E-03 (~0.14 %). The total emission factor for the low emissions scenario is 4.7E-04 (~0.05%).

Table 41: Emission Factors used in the Article Service Life scenarios

	Low emissions scenario	**High emissions scenario**
Outdoor uses	OECD ESD	OECD ESD
Indoor uses	Measurements	OECD ESD
Textile washing	EU RAR, 2004	EU RAR, 2004
Total EF	**4.7E-04**	**1.4E-03**

B.8.2.4 Waste Stage

B.8.2.4.1 Waste fractions used in the emissions calculation

Waste management practices vary across the EU and are changing over time as Member States (MS) implement new legislative measures. The shares of recycling, incineration and landfill vary greatly among MS (Lindner 2012, as cited in RPA, 2014).
e used for emission estimation.

Table **42** presents the shares to be used for emission estimation.

Table 42: Waste Fractions used in the emission estimations

	Plastics	Textiles
Landfill	44%	50%
Incineration	37%	50%
Recycling	19%	0%

Source for the amounts: derived from Lindner (2012), Eurostat (2014) and RPA (2014)
For plastics:
EU-wide averages were calculated by multiplying the shares per country (Lindner, 2012) with the population-derived weight of each country (Eurostat, 2014).
Corrections were made for DE, SE and NL for which the corresponding quantities were assumed to be incinerated (RPA, 2014):
- Germany and Sweden do not recycle WEEE containing decaBDE
- No plastic waste is landfilled in Netherlands

For textiles:
It is assumed that no (or insignificant) recycling takes place (derived from RPA, 2014)

B.8.2.4.2 Emission factors for waste

The emission factors for the waste stage were taken from available literature and from the assumptions used in the previous EU RARs (Table 43). Although emission factors are given in OECD ESD and ECHA Guidance, these were not used to describe the waste stage emissions of decaBDE (RPA, 2014). The above considerations are briefly explained in the sections below.

Table 43: Emission factors used for the waste stage

	Air	Water	Source	Scenario
Recycling	1.30E-08	-	Sakai et al. (2006), e-waste recycling facility	Low
Recycling	4.30E-05	-	Morf et al. (2007), automobile recycling plant	High
Incineration	0	-	EU RAR, 2004	Low
Incineration	1.80E-06	-	Sakai et al. (2006), from Tamade et al. (2002)	High
Landfill	0	-	EU RAR, 2004	Low
Landfill	1.0E-5		Morf et al. (2007), particle emissions from unloading	High
	7.1E-06		Morf et al. (2007) gas and particle during landfill operations	High
		6.80E-07	Morf et al. (2007), calculated from measurements of concentration of decaBDE in leachate	High and Low

B.8.2.4.3 Recycling

The management of waste from transportation, building and EEE is regulated by specific legislation around the EU which calls for their separate collection and treatment. The rate of collection and the methods of treatment vary from country to country. Most plastics from transportation applications are shredded then sent for recycling or energy recovery (RPA, 2014). The share of plastics used in transportation, building and any remaining EEE uses are not known, however, to calculate the emissions, emissions factors for decaBDE release are available for automotive recycling and for e-waste recycling facilities. These are considered to cover the two main types of plastic waste containing decaBDE (Table 43). EU RAR (2004) used an intermediate emission factor from a plant recycling EEE plastics (2.40E-05). ECHA Guidance, indicates a release factor from shredding to air of 0.1 for plastics, derived by expert judgement. The shredding process can be described by ERC 12a, namely "Industrial processing of articles with abrasive techniques (low release)". The default emission factor to air for this category of operations, which includes cutting or grinding of textiles and plastics, is 2.5% (or 0.025). This emission does not take the presence of RMMs into account. Assuming the use of dust filters, with an efficiency of 99% would lower the emission factors (RPA, 2014)[42]. However, since emission factors derived from measurements are available these will be used in this report for the recycling step, in preference to default emission factors, following the approach used in the EU RAR (2004). Emissions during recycling of plastics containing decaBDE may also occur to water, but again the efficiency of emission abatement measures should be taken into consideration. For emissions to water a factor of 0.25% is provided in the guidance (ECHA, 2012c). In addition, re-melting and reshaping of waste plastics into new products is essentially similar to the manufacturing process (compounding and conversion), so it should be expected that the emissions are similar as well (ECB, 2002). Potential emissions to water are not included in the calculations in the absence of any monitoring data. For textiles, it will be assumed that no textiles containing decaBDE are recycled (RPA, 2014) (Table 43).

Materials containing decaBDE can be recycled several times with only a small fraction of decaBDE being lost (Hamm et al., 2001, as cited in Earnshaw et al., 2013), meaning that there could be more articles in circulation (with the related emissions) every year due to recycling. However, the fraction of the recycled plastics used to produce new recyclate-based articles is unknown. A recent study on the presence of PBDES which are already identified as POPs (tetra-, penta-, hexa- and hepta-) has revealed the presence of those, together with decaBDE in End of Life Vehicles and Waste of Electrical and Electronic Equipment. DecaBDE was frequently found in plastic fractions from shredded automotive and WEEE materials and recycled plastic pellets (IVM, 2013). However, the emissions from the subsequent use of these materials is not taken into account in the emission estimates.

B.8.2.4.4 Incineration

For incineration, it can be assumed that organic substances will be destroyed and emissions to both air and water will be zero. This is the approach taken in the EU RAR (2002 and 2004), and will be used for the low emissions scenario. There may still be residues of inorganic materials left in the flyash, which will be disposed of as solid waste (see section B.8.2.5.5). ECHA guidance (ECHA, 2012c) suggests an emission factor of 0.01% to air and water from incineration facilities for organic waste. It is also mentioned in the guidance that emissions from pre-treatment operations, such as shredding, are very small, compared to overall incinerator emissions, so they need not be calculated separately.

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[42] The dust filters might then be incinerated or landfilled, giving rise to another source of potential emissions, but this effect is disregarded here due to lack of data.

However, emission factors for incineration are also available from the literature (Table 43). These suggest greater emissions associated with incineration and will therefore be used for emissions estimates derived under the high emissions scenario. An additional concern associated with incineration is the formation of other hazardous substances such as PBDDs or PBDFs during the incineration process as a result of incomplete combustion (RPA,2014). This additional concern is not considered within this assessment, but may be an additional benefit of the proposed restriction.

B.8.2.4.5 Landfill

Emissions of decaBDE to the environment associated with disposal via landfill will depend on many factors, such as to the design of the landfill as well as to the properties of the additive and the nature of the polymer in which it has been used. The maximum potential loss could be calculated from the amount of additive remaining in the plastic at disposal, but in reality it is unlikely that all this amount would actually be released from the landfill. However, the long-term fate of decaBDE in the landfills is poorly known, and a potential for release to the environment of decaBDE (or its degradation products) cannot be excluded at a later stage.

For emissions to **water**, ECHA's guidance document suggests an emission factor of 3.2%. However, this seems to be very high, based on the very low water solubility of decaBDE. The release factor cited in ECHA guidance is the highest of a range of values for plastic additives listed in the OECD ESD (RPA, 2014). The 2002 EU RAR on decaBDE had commented that leaching from plastics in landfills is not likely to take place, but erosion and wear of particles containing decaBDE could constitute another transportation pathway for decaBDE to the leachate.

Recent monitoring of landfill leachates has shown the presence of decaBDE in ng/L concentrations (SFT, 2009). Similarly, decaBDE has been found to be the dominant PBDE congener in landfill sediments. Recent publications also indicate that releases of decaBDE from landfills do occur (D. Chen et al., 2013). Morf et al. (2007) has estimated an emission factor based on data from Osako et al. (2005 as cited in Morf et al., 2007) and this will be used to estimate emissions from landfill via leachate[43] in both the low and high emission scenarios. The leachate could subsequently be directed to a WWTP but other practices are also possible (directed to sewer for example, or re-injected to the landfill). However the breakdown of these final destinations of the leachate and the variability of practices across the EU are not known and therefore this aspect has not been taken into account in the calculations.

For emissions to **air**, the OECD ESD for plastics as well as ECHA guidance for the estimation of emissions in the waste stage (OECD 2009, ECHA 2012c), consider that the emissions for non-volatile substances to air are practically zero. This will be used in the low emissions scenario.

However, the EU RAR (2002 and 2004) considered an emission factor of 2% for waste generated **at the final disposal** of products (both plastics and textiles), particularly where articles are dismantled or subject to other mechanical processes. This factor could include emissions also from final disposal in landfills. Morf et al. (2007) detail several mechanisms for atmospheric emissions which are expected to occur on landfills: emissions during unloading, emissions of dust caused by operations done on landfills and wind as well as

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[43] Morf used a concentration of decaBDE in leachate of 4.6 ng/L, but he reported also lower and higher values. Data from SFT (2009) show that considerably higher concentrations of decaBDE in leachate are possible (highest is ~4700 ng/L). However there is considerable variability from one landfill to another suggesting that use of the value above may lead to an underestimation of decaBDE emissions in some instances. The value of 4.6 ng/L was used for both the low and high emissions scenarios.

gaseous emissions. These types of emissions added together give an overall emission factor of 1.71E-05. In the absence of other data this factor will be used for the high emissions scenario.

It will also be considered that a landfill will continue to emit during 30 years (Earnshaw, 2013). It appears that the ultimate fate of the vast majority of products containing decaBDE is landfill (Earnshaw, 2013) (decaBDE in products which initially follow a different waste management route, may also end up in landfill, e.g. fly ash containing decaBDE from incineration).

B.8.2.5 Other literature sources/additional sources of emissions

The approach used to calculate emissions is the so-called steady state approach where it is considered that the chemical flow in society has reached an overall equilibrium, i.e. the annual quantity removed (by waste incineration, degradation etc.) is just as high as the quantity added annually (ECHA, R17). Another approach would consist of allowing the quantity of decaBDE entering the society to vary overtime (i.e. the steady state hypothesis is not fulfilled) and this can be done by using dynamic substance flow analysis models (Morf et al., 2007; Earnshaw et al., 2013). In addition, this type of model allows the prediction of emissions arising in the future from a use today. For example, an article containing decaBDE which is disposed of via landfill today, will emit decaBDE for many years after disposal. Finally, this type of model can also incorporate improvements in emission abatement techniques over a given period of time.

Apart from the emission pathways considered above, additional pathways also exist (e.g. emissions from deconstruction, uncontrolled incineration, accidental fires, fire mitigation water etc) (Morf et al., 2007; Earnshaw et al., 2013; Schenker et al., 2008). In addition, these authors have considered internal flows of decaBDE (for example from recycling to production, from landfill to WWTP and many more).

This additional model complexity contributes to give a more realistic picture of the life-cycle emissions of decaBDE. However, given the uncertainties in the underlying data available, the steady-state approach adopted for this analysis is considered to be sufficiently robust to estimate emissions of decaBDE and compare between low and high emissions scenarios. In addition to recycling, incineration and landfill, other pathways for emissions of decaBDE from waste have been identified. Plastic and foam containing decaBDE was shown to be present as impurity in ferrous scrap used in electric arc furnace (EAF) steel making. It was estimated that 41 – 46 kg/year of decaBDE are emitted at global level (Odabasi et al., 2009). Using the values generated in this study, this would lead to an emission of 7 – 8 kg decaBDE/year, corresponding to a total production using EAF of ~70 Mt in the EU-27 (Worldsteel, 2013), which is insignificant compared to the total emissions from the uses considered in this analysis.

B.8.2.6 Results of emissions estimations

Emissions under the high scenario are a factor of three greater than emissions under the low scenario. EU RAR (2004) used an overall emission factor of 0.5% (three times higher than the high emissions scenario) due to more conservative assumptions for the emissions from article service life.

Table 44: Summary of total emissions

	Low emissions scenario (t/year)	High emissions scenario (t/year)	**Central scenario (t/year)**
Production	0.06	0.56	**0.31**
Article Service Life	2.07	6.23	**4.15**
Waste	0.04	0.52	**0.28**
Total	2.17	7.32	**4.74**
Total Emission Factor	0.05%	0.17%	**0.11%**

Table 45: Summary of releases to different environmental compartments

	Low emissions scenario (t/year)	High emissions scenario (t/year)	**Central (t/year)**
Air	0.15	2.78	**1.46**
Water	1.04	3.61	**2.32**
Soil	0.98	0.93	**0.96**
Total	2.17	7.32	**4.74**

B.8.2.6.1 Detailed results on releases to different environmental compartments

Table 46: Releases to the different environmental compartments - Production

	Low Emissions Scenario (tonnes)	**High Emissions Scenario (tonnes)**
Air	0.03	0.09
Water	0.01	0.47
Soil	0.02	-
Total Emissions	0.06	0.56

Note: The following compartment specific emission factors were used:
Low Emissions Scenario : Air: 8 g/t, Water, 2 g/t, Soil 5 g/t (VECAP, 2013)
High Emissions Scenario : Air: 24 g/t, Water, 117 g/t, Soil 0 g/t (RPA, 2014)

Table 47: Releases to the different environmental compartments – Article Service Life

	Low Emissions Scenario (tonnes)	**High Emissions Scenario (tonnes)**
Air	0.12	2.20
Water	0.99	3.10
Soil	0.96	0.93
Total Emissions	2.07	6.23

Note: the following assumptions were made:
For indoor emissions obtained by measurements (low emissions scenario) the distribution to different environmental compartments is not provided by default. The following distribution was used: air 50%, water 25%, soil 25% (Morf et al., 2008)
For the remaining Outdoor uses, both scenarios: air

Table 48: Releases to the different environmental compartments - Waste

	Low Emissions Scenario (tonnes)	High Emissions Scenario (tonnes)
Air	5.21E-06	0.48
Water	0.04	0.04
Soil	-	-
Total Emissions	0.04	0.52

B.8.2.6.2 Summary of Emission Calculations

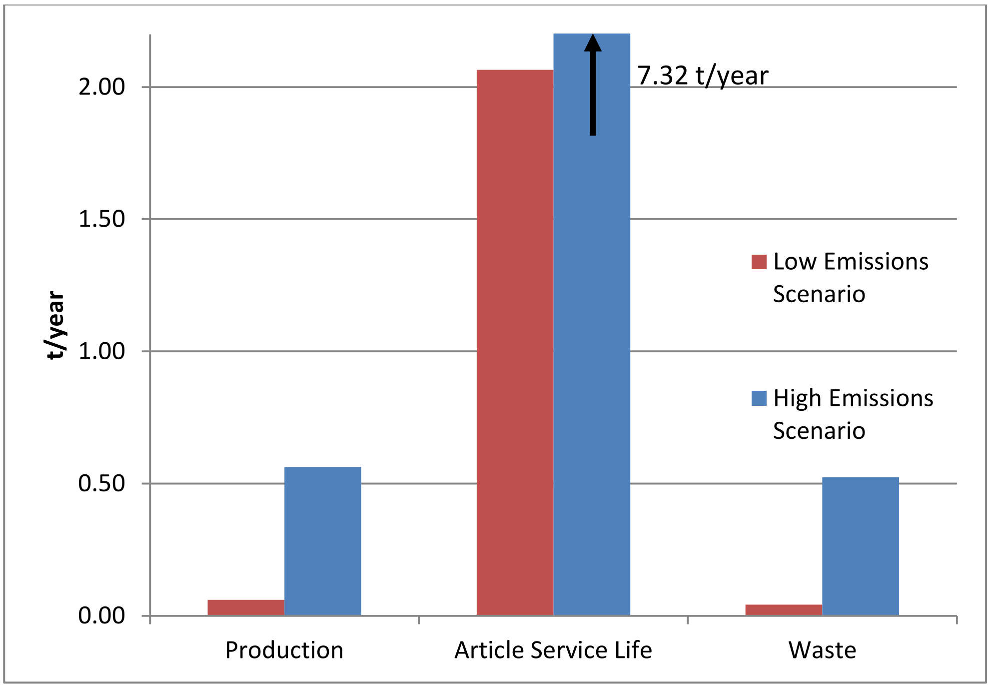


Figure 7: Summary of emission estimations

Table 49: Detailed Emissions Calculations

	Scenario Low Emissions	Source/Assumptions	Scenario High Emissions	Source/Assumptions
Imported tonnage (t)	4000	Registrations/communication to ECHA	4000	Registrations/communication to ECHA
PRODUCTION				
EF production - (Air, Water and Soil)	1.5E-05	based on emissions of 15 g/t (VECAP, 2013)	1.4E-04	based on emissions of 140.6 g/t (RPA, 2014)
Emissions from production (t)	0.06		0.56	
SERVICE LIFE				
Remaining tonnage (imported-emitted) (t)	4000		3999	
Tonnage imported in articles (t)	400		400	
Total tonnage in articles (t)	4400		4399	
Textiles				
EF textiles indoor use	3.2E-05	Thomas et al. (2006), as cited in EU RAR 2007, (measurements on upholstery, wear and ageing) - Air, Water and Soil	5.00E-04	EF textiles indoor use - Air (OECD ESD)
EF textiles indoor use - Water	-		5.00E-04	EF textiles indoor use - Water (OECD ESD)
Emissions from Textiles indoor use (t)	0.07		2.17	

	Scenario **Low Emissions**	**Source/Assumptions**	**Scenario** **High Emissions**	**Source/Assumptions**
EF textiles washing (Water)	5.0E-04	EU RAR, 2004 from Use Cat. Doc on plastics additives based on loss of DEHP from regular washing of PVC flooring	5.00E-04	EU RAR, 2004 from Use Cat. Doc on plastics additives based on loss of DEHP from regular washing of PVC flooring
Emissions from Textiles washing (t)	0.02		0.02	
EF textiles outdoor use - Air	5.0E-04	OECD ESD	5.00E-04	OECD ESD
EF textiles outdoor use - Water or Soil	1.6E-02	OECD ESD	1.60E-02	OECD ESD
Emissions from Textiles Outdoor use (t)	1.89		1.89	
Plastics				
EF plastics indoor use	2.4E-05	Morf et al., 2007, based on data from Sakai et al., 2006 (measurements on EEE plastics) – Air, Water and Soil	5.00E-04	EF plastics indoor use - Air (OECD ESD)
EF plastics indoor use - Water	-		5.00E-04	EF plastics indoor use - Water (OECD ESD)
Emissions from Plastics Indoor use (t)	0.05		2.11	
EF plastics outdoor use - Air	5.0E-04	OECD ESD	5.00E-04	OECD ESD
EF plastics outdoor use - Water or Soil	1.6E-02	OECD ESD	1.60E-02	OECD ESD
Emissions from Plastics Outdoor use (t)	0.03		0.03	
Total EF article service life	4.7E-04		1.4E-03	
Total Emissions from service life (t)	2.07		6.23	

	Scenario		Scenario	
	Low Emissions	**Source/Assumptions**	**High Emissions**	**Source/Assumptions**
WASTE				
Tonnage entering waste (total in articles-emitted)	4398		4393	
Recycling				
EF Recycling - Air	1.3E-08	Sakai et al., 2006, e-waste recycling facility	4.3E-05	Morf et al., 2007, automobile recycling plant
Emissions from Recycling (t)	5.2E-06		0.02	
Incineration				
EF Incineration - Air	0	EU RAR, 2004	1.8E-06	Sakai et al., 2006, from Tamade et al., 2002
Emissions from Incineration (t)	0		0.003	
Landfill				
EF Landfill - Water	6.8E-07	Morf et al., 2007, measurements in leachate	6.8E-07	
EF Landfill - Air	0	EU RAR, 2004	1.0E-05	Morf et al., 2007, particle emissions from unloading
EF Landfill - Air	-		7.1E-06	Morf et al., 2007, gas and particle during landfill operations
Emissions from Landfill (t)	0.04		0.50	
EF waste stage	9.6E-06		1.2E-04	
Emissions from waste stage (t)	0.04		0.52	

	Scenario **Low Emissions**	**Source/Assumptions**	**Scenario** **High Emissions**	**Source/Assumptions**
Remaining at disposal (entering waste - emitted)	4398		4393	
Total EF	0.05%		0.17%	
Total emissions (t)	2.17		7.32	

Table 50: Emissions from production calculated according to OECD ESD

	Plastics		Textiles	
	air	water	air	water
EF Handling	0	6.0E-05	0	6.0E-05
EF Compounding	1.0E-07	5.1E-06		
EF Conversion	5.0E-07	5.0E-07		
EF Finishing			4.1E-05	1.0E-04
Total EF	6.0E-07	6.6E-05	4.1E-05	1.6E-04
RMM efficiency	99%			
Imported tonnage (tonnes)	4000			
Fraction in plastics	48%	48%		
Fraction in textiles			52%	52%
Emissions (t)	0.00	0.13	0.09	0.33
Emissions (%)	0%	23%	16%	61%

Source: derived from RPA, 2014

Table 51: Assumptions used in the emissions calculations

Assumptions		Source
Fraction of tonnage in Imported in Articles	10%	RPA, 2014
Fraction of textiles with decaBDE	52%	VECAP, 2012
Fraction of plastics with decaBDE	48%	VECAP, 2012
Fraction of textiles with outdoor applications	5%	RPA, 2014
Fraction of plastics with outdoor applications	0.1%	EU RAR 2002, 2004
Fraction of textiles subject to washing	2%	EU RAR, 2004
Fraction of recycled plastics	19%	calculated from Lindner 2012 as cited in RPA, 2014
Fraction of incinerated plastics	37%	
Fraction of landfilled plastics	44%	
Fraction of recycled textiles	0%	derived from RPA, 2014
Fraction of incinerated textiles	50%	
Fraction of landfilled textiles	50%	
Years in landfill	30	Earnshaw et al., 2013

B.8.2.6.3 Production

Table 52: Emissions from Production

	Low Emissions Scenario	High Emissions Scenario	Average
Total Emissions from production (t)	0.06	0.56	0.31
Total EF Production	1.5E-05	1.4E-04	7.8E-05

B.8.2.6.4 Article Service Life

Table 53: Emissions from Article Service Life

	Low Emissions Scenario	High Emissions Scenario	Average
Textiles indoor use (t)	0.07	2.17	1.12
Textiles washing (t)	0.02	0.02	0.02
Textiles Outdoor use (t)	1.89	1.89	1.89
Plastics Indoor use (t)	0.05	2.11	1.08
Plastics Outdoor use (t)	0.03	0.03	0.03
Total emissions from Article Service Life (t)	2.07	6.23	4.15
Total EF Article Service Life	4.7E-04	1.4E-03	9.4E-04

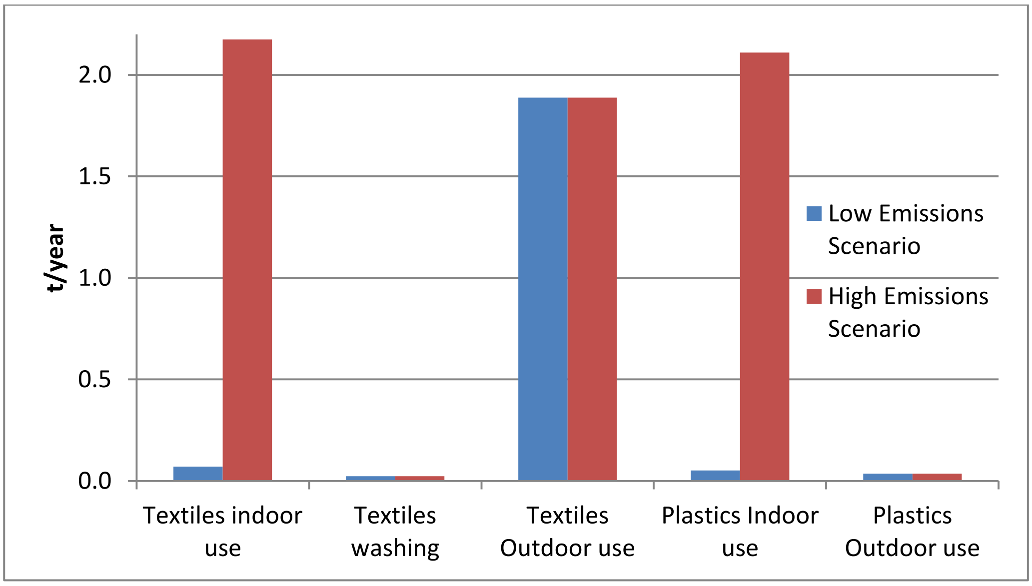


Figure 8: Emissions from Article Service Life

B.8.2.6.5 Waste Stage

Table 54: Emissions from Waste

	Low Emissions Scenario	**High Emissions Scenario**	**Average**
Recycling (t)	5.21E-06	0.02	0.01
Incineration (t)	0.00	3.46E-03	0.00
Landfill (t)	0.04	0.50	0.27
Total Emissions from Waste (t)	0.04	0.52	0.28
Total EF Waste	9.61E-06	1.19E-04	6.45E-05

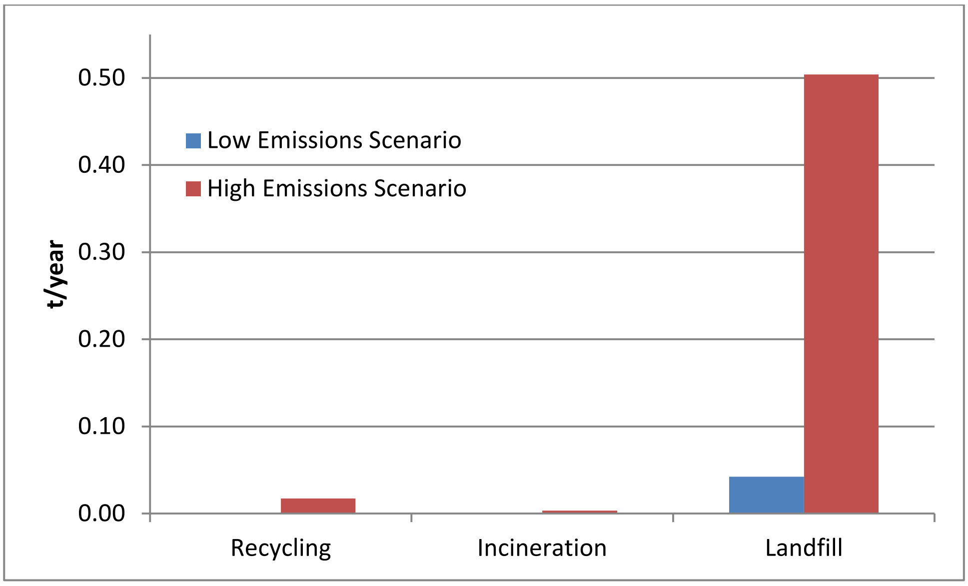


Figure 9: Emissions from Waste

B.8.3 Validation of decaBDE emissions estimates: back-calculation of emissions to water based on measured concentrations of decaBDE in sewage sludge+

B.8.3.1 Introduction

The emissions estimates for decaBDE were derived using generic emissions factors in combination with the estimated annual use tonnage of decaBDE as both a substance and in imported articles. As such, these estimates are based on a series of assumptions, which may or may not be reliable. To evaluate the validity of the emission estimates, a complementary assessment has been performed that is underpinned by observed concentrations of decaBDE in sewage sludge. Observed concentrations in sludge are then back-calculated to a total EU tonnage of decaBDE emitted to water based on the amount of sludge produced annually in the EU. The results of the two analyses are then compared. Since decaBDE nearly completely partitions to sludge during wastewaster treatment (see for example Rayne and Ikonomou, 2005, as cited in Morf et al 2007: decaBDE partitions to an extent of 97.3% into sludge), emissions of decaBDE to the environment via WWTP effluent are not considered in the model. Both deterministic and probabilistic assessments were performed.

B.8.3.2 Methodology

Model

The following model was used:

Emissions to water (t/year) = Concentration in sludge (μg/kg dry weight) * 1E-9[a] * Amount of sludge per person per year (t/year, person) * dry weight correction factor[b] * Population

a: 1 μg = 10^{-9} kg

b: a dry weight correction factor was incorporated into the model as there is a difference in water content between de-watered sludge produced during waste water treatment and "dried sludge" prepared as part of laboratory determinations of the concentration of decaBDE. This factor is uncertain.

Concentration of decaBDE in sludge

Data on the concentration of decaBDE in sewage sludge were obtained from the EU RAR conclusion (i) monitoring programme (also known as the decaMONITOR programme) supplemented with data from other European monitoring programmes i.e. from Germany, Norway and Spain (Environment Agency, 2009; ECHA, 2014, see Table 55).

Concentrations of decaBDE in sludge are observed to be approximately one order of magnitude greater in the UK and IE than those observed in the rest of the EU. Therefore total EU emissions were calculated as the sum of UK/IE emissions and the remainder of the EU-27 emissions.

Table 55: Concentrations of decaBDE in sewage sludge in the EU

STW description and data source	**Sludge concentration[a] (μg/kg dry weight)**
UK - rural domestic wastewater (decaMONITOR)	3,201 ± 216 (2006) / 3,810 ± 2,580 (2007)
UK - mainly textile input (decaMONITOR)	3,931 ± 335 (2006) / 5,110 ± 1,770 (2007)
UK - mixed domesic and industrial wastewater (decaMONITOR)	708 ± 843 (2006) / 3,000 ± 310 (2008)
UK - mixed domestic and industrial wastewater (decaMONITOR)	4,004 ± 259 (2006) / 4,050 ± 631 (2007)

STW description and data source	Sludge concentration[a] (µg/kg dry weight)
UK - urban domestic wastewater (decaMONITOR)	2,985 ± 843 (2006) / 5,490 ± 2,890 (2007)
IE – domestic wastewater (decaMONITOR)	7,963 ± 676 (2006) / 5,170 ± 989 (2007)
NL – mainly domestic wastewater (decaMONITOR)	270 ± 34 (2006) / 248 ± 145 (2007)
NL – mainly domestic wastewater (decaMONITOR)	407 ± 6 (2006) / 208 ± 29 (2007)
NL – domestic, industrial (25%) and rainwater run-off from roads (decaMONITOR)	304 ± 4 (2006) / 410 ±14 (2007)
NL – mainly domestic wastewater (decaMONITOR)	399 ± 15 (2006) / 353 ± 28 (2007)
NL – mainly domestic wastewater (decaMONITOR)	381 ± 68 (2006) / 463 ± 35 (2007)
NL – large capacity, including domestic wastewater (decaMONITOR)	309 ± 18 (2006) / 180 ± 0 (2007)
DE – samples from 11 municipal waste water treatment plants (2002-2003)	256 (median) 97 – 2,217 (range)
ES – Urban waste water treatment plant in Barcelona with a flow of 2,083 m^3/hour (2005)	1,082
ES – Urban waste water treatment plant in Burgos with a flow of 600 m^3/hour (2005)	393
ES – Urban waste water treatment plant in Lleida with a flow of 2,917 m^3/hour (2005)	508
ES – Urban waste water treatment plant in Pampolna with a flow of 4,313 m^3/hour (2005)	356
ES – Urban waste water treatment plant in Tarragona with a flow of 305 m^3/hour (2005)	80.6
NO – submitted as part of Annex XIV dossier development	269 (mean) 44 – 1,000 (range)

a: results from the decaMONITOR programme are reported as mean ± standard deviation

Sludge per person per year

The amount of sludge generated in the EU-27 in 2010 is estimated at 11 564 ktonnes in dry weight (Milieu, 2008). Divided by the EU-27 population this results in 0.023 tonnes (dry weight) per year per person (see Table 56).

Population

Population values for 2010 for the UK (62.5 million), IE (4.5 million) and the EU-27 (499 million) were taken from Eurostat (2014).

B.8.3.3 Deterministic assessment

A deterministic assessment was carried out to estimate the total emissions of decaBDE to water. In the absence of average EU concentrations, a representative (likeliest) value was chosen for the UK/IE sludge concentration and for the EU sludge concentration excluding UK/IE, using the available information (Table 55). The likeliest values for the concentration in sludge are shown in Table 56. The likeliest dry weight correction factor was taken from a Finnish WWTP, considered to be representative of the EU (Table 56). Although the deterministic assessment does not take into account the variability of the parameters, it can provide some insight on the likely magnitude of decaBDE emissions to water.

B.8.3.4 Probabilistic assessment

Monte Carlo simulation (using Oracle Crystal Ball software) was undertaken to explore the consequence of the variability observed in the underlying input data on total EU decaBDE emissions. Triangular distributions, defining the most likely, minimum and maximum input values were defined based on approximate ranges for three of the model input parameters: UK/IE sludge concentration, EU sludge concentration excluding UK/IE and the dry weight correction factor (Table 56). Each of these distributions were randomly resampled on 2000 occasions and the resulting values used as inputs to the model.

Table 56: Data distributions for the probabilistic assessment

Distributions of WWTP parameters				
	Likeliest	**Min**	**Max**	**Source / comment**
Concentration in sludge EU excluding UK,IE (μg/kg dry weight)	**300**	**50**	**2000**	Table 55
Concentration in sludge in UK/IE (μg/kg dry weight)	**4000**	**700**	**8000**	Table 55

Distributions of WWTP parameters				
	Likeliest	**Min**	**Max**	**Source / comment**
Amount of sludge per person and per year (t dry weight/year, person)	**0.023**	**-**	**-**	**Calculated from Milieu, 2008**
dry weight correction factor	**0.3**	**0.1**	**1**	**Likeliest value from Finnish WWTP (Helsinki region,** Viikinmäen jätevedenpuhdistamo, 2014**)**

B.8.3.5 Results and Discussion

Deterministic assessment

This deterministic assessment resulted to a water emission of 2.76 tonnes per year (for the detailed calculations see Table 57). This value is inside the range of the predicted value for the high and low emission scenarios (Table 58).

Table 57: Deterministic assessment – emissions to water

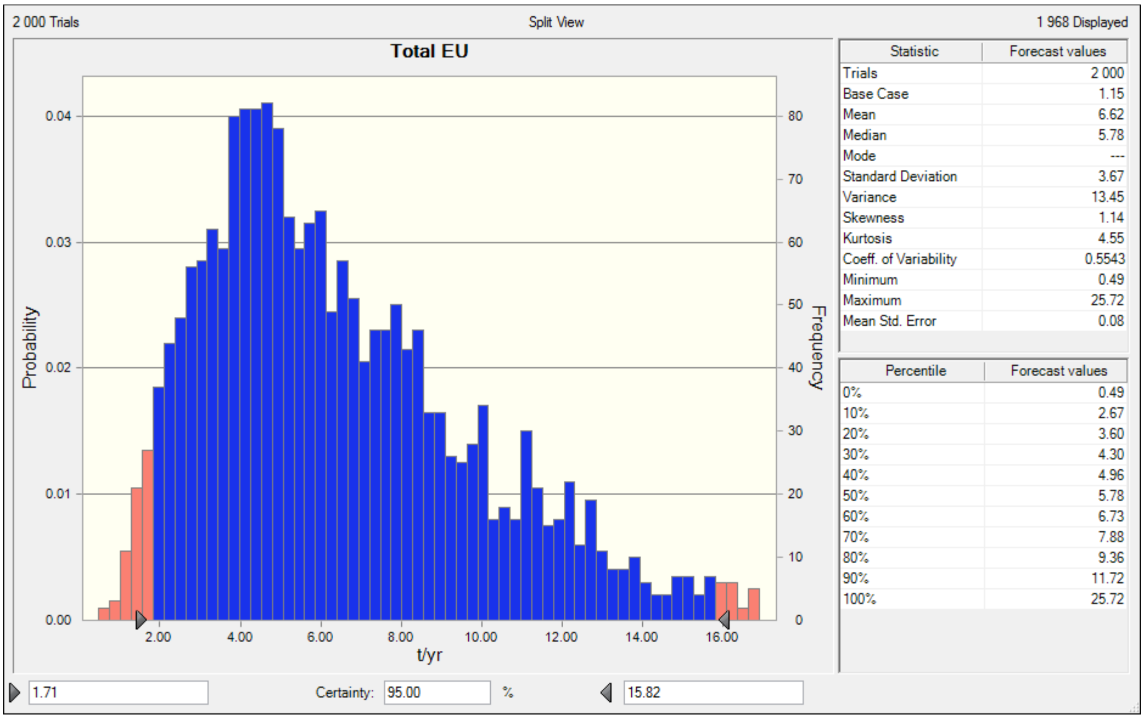
Geographical area	EU27-(UK+IE)	UK+IE	EU27
Concentration in sludge (µg/kg dry weight)	300	4000	
Conversion factor (µg to tonnes)	1.E-09	1.E-09	
Amount of sludge per person per year (t/year, person)	0.023	0.023	
Dry weight correction factor	0.3	0.3	
Population (millions)	432	67	
Emissions to water (t/year)	**0.90**	**1.86**	**2.76**

Source: calculated with the equation of section B.8.3.2

Probabilistic assessment

The probabilistic assessment derived mean and median total EU emissions to water of decaBDE of 6.62 and 5.78 t/year, respectively. Ninety-five percent of the predictions are between 1.71 to 15.82 tonnes/yr, whilst the 10th and the 90th percentile emission estimates are 2.67 and 11.72 t/yr, respectively (Figure 10).

The range in predictions, as determined by the 10th and 90th percentiles, span approximately a factor of 10 (an order of magnitude). The relative contribution/importance of the three input parameters that were subject to Monte Carlo simulation were explored with a sensitivity analysis (Figure 11). Greater than 50% of the variability observed in individual predictions of EU emissions to water was due to the uncertainty in the dry weight assessment factor whilst approximately 10% of the variability was associated with the UK/IE decaBDE concentration in sludge.



Statistic	Forecast values
Trials	2 000
Base Case	1.15
Mean	6.62
Median	5.78
Mode	---
Standard Deviation	3.67
Variance	13.45
Skewness	1.14
Kurtosis	4.55
Coeff. of Variability	0.5543
Minimum	0.49
Maximum	25.72
Mean Std. Error	0.08

Percentile	Forecast values
0%	0.49
10%	2.67
20%	3.60
30%	4.30
40%	4.96
50%	5.78
60%	6.73
70%	7.88
80%	9.36
90%	11.72
100%	25.72

1.71 Certainty: 95.00 % 15.82

Figure 10: Probability distribution of Total EU emissions of decaBDE

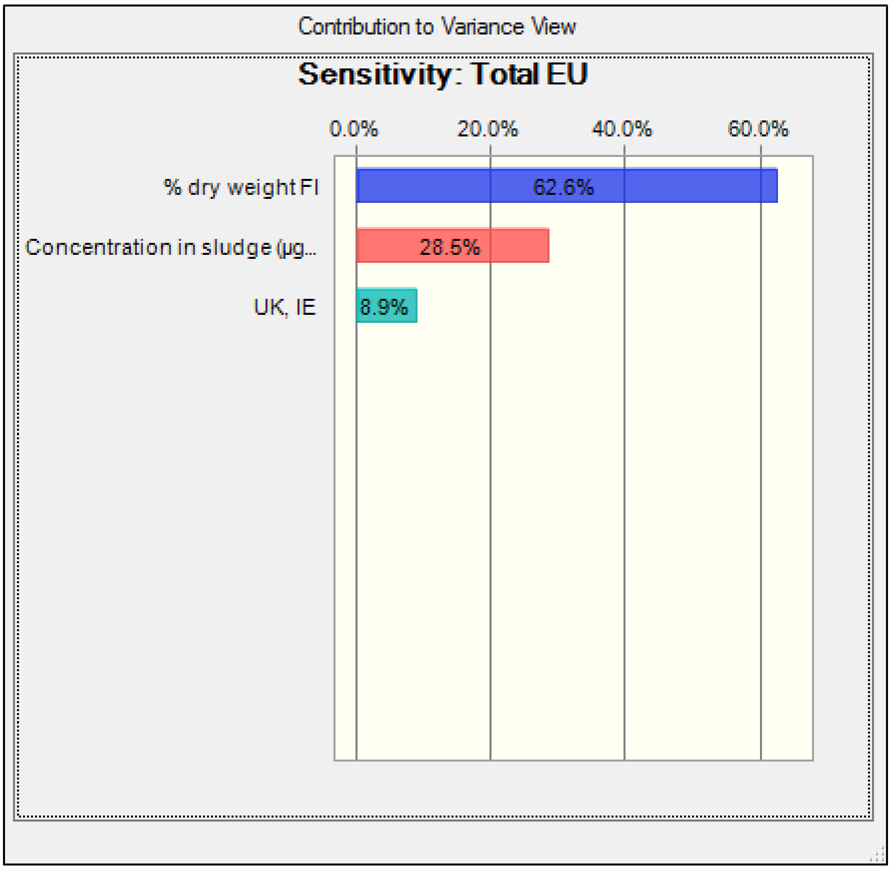


Figure 11: Sensitivity analysis of model input parameters

The emissions of decaBDE to water from various life-cycle stages are reported to range from 1.04 to 3.61 tonnes per year under the low and high emissions scenarios, respectively (Table 58). Although we do not know what proportion of emissions to water will enter a WWTP (and therefore partition to sludge), we will assume that an emission to water will most probably enter the WWTP (meaning that emissions from outdoor sources, which might enter directly the surface water, are also included).

This range of emissions are within the same order of magnitude as those predicted by the probabilistic analysis from measured sludge concentrations. In fact, the emissions to water predicted on the basis of sludge measurements are marginally greater than those presented in the report. This is most likely to be because the emissions in the report are based on predicted tonnages/emissions for 2014, which are 2-3 times lower than the tonnage used in the EU when the sludge measurements were made.

Table 58: Emissions to water in the Annex XV report (2014 tonnage)

Comparison with Annex XV calculations:	**Tonnes/yr**	**Tonnes/yr**
Emissions to water	**High**	**Low**
Production	0.47	0.01
Service Life	3.10	0.99
Waste	0.04	0.04
Total	**3.61**	**1.04**

Conclusions

The emissions estimates presented in the Annex XV report are supported by a complimentary analysis of emissions to water based on measured concentrations in sludge. Therefore, the emissions estimates presented in the Annex XV report should be considered as reliable.

B.9 Exposure assessment

B.9.1 General discussion on exposure

Exposure assessment in an Annex XV report for restrictions should ideally be conducted based on exposure scenario information submitted by registrants (ECHA 2007). This is in order that the specific uses and related life-cycle stage(s), that may pose an unacceptable risk to human health or the environment, can be identified. Other relevant risk assessment information i.e. risk assessment conducted under other Community Regulations or Directives can also be included in Annex XV restriction dossiers (Article 69(4) of REACH).

Further, according to section 4.2 of Annex I to REACH, the emission characterisation for PBT/vPvB substances shall in particular "contain an estimation of the amounts of the substance released to the different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses, and an identification of the likely routes by which humans and the environment are exposed to the substance."

As outlined previously, the REACH registration dossiers for decaBDE do not contain information on exposure either on a per use, or on an aggregated basis. This is because the current registration of decaBDE is based on the information requirements prior the decision to identify decaBDE as a PBT/vPvB substance, i.e. as decaBDE was not classified by applicants as dangerous, exposure assessment (including exposure scenario development) and risk characterisation were not required in registration dossiers. Updates to the registration dossiers of decaBDE are pending from the applicants based on the identification of decaBDE as a PBT/vPvB but have not yet been received by the Agency.

Exposure estimates (i.e. Predicted Environmental Concentrations: PECs) were calculated during the ESR risk assessment for decaBDE (ECB, 2002) and its subsequent updates (ECB, 2004; ECB, 2007) based on information on tonnages and risk management measures relevant at the time. However, the tonnage of decaBDE used in the EU and the risk management measures in place during both the formulation stages and during the production of articles (primarily because of the industry VECAP programme) have changed sufficiently that these PEC estimates are now considered to be out of date.

Updated emissions estimates have been made during the preparation of this annex XV report (see section B.8.2 and Annex B.8.2). However, these estimates were predominantly made to explore the potential effectiveness of different risk management options (see section E). As such, whilst estimates of emissions to different environmental compartments have be made, this modelling does not incorporate the subsequent likely fate of decaBDE in the environment (i.e. emissions to water are likely to selectively partition to sediments and emissions to air are likely to accumulate in soils). Equally, bioaccumulation of decaBDE in aquatic or terrestrial biota has not been undertaken.

Therefore, updated PECs for decaBDE, based on contemporary information on tonnages and emissions are not included in this section of the report. Rather, the exposure assessment for decaBDE presented here comprises a summary of relevant available biomonitoring and environmental monitoring data, which should be considered as representative of aggregated European exposure to decaBDE (including any contribution from long-range transport). Human and environmental exposure are presented in sections B.9.2 and B.9.3, respectively. Data have been collated from various regulatory and literature sources, including the EU RAR (ECB 2002) and updates (ECB 2004 and 2007). Where possible, information on human exposure is presented on the basis of relevant life-cycle stage[44], i.e. occupational exposure (including during the waste stage) or consumer exposure during article service-life. Disaggregation of the source contribution of different life-cycle stages to concentrations observed in the environment or wildlife has not been possible.

In addition to exposure data of direct relevance to Europe, exposure data obtained from other geographical areas is also described. Whilst these data are not of direct relevance to decisions on risk management in Europe they provide additional context on the levels of exposure to decaBDE observed worldwide. In addition, because of the long-range transport potential of decaBDE, emissions in other parts of the world may also affect Europe.

The section concerning human exposure (B.9.2) is based on reviews published in the scientific literature (Lorber 2008; Frederiksen et al., 2009a; Harrad et al., 2010; Besis and Samara, 2012; Ni et al., 2013), regulatory reports (EFSA 2011; Health Canada 2012; Kortenkamp et al., 2014) and newer information in recently published scientific papers, i.e. between 2010 and 2014. In addition, some earlier papers are mentioned specifically, either because they have not been included in the reviews or reports, or are of particular importance.

The section on environmental exposure (B.9.3) is a summary of data collated as part of the

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[44] Manufacture of decaBDE has not occurred in the EU since 1999. However, emissions associated with historic manufacture may influence, to an unknown extent, the concentration of decaBDE reported in the environment or during biomonitoring.

ESR risk assessment of decaBDE (EC 2002, ECB 2004, ECB 2007) and more recent data collated by, or on behalf of, European Member States (e.g. EA 2009; Kortenkamp et al., 2014). The levels of decaBDE in the environment are also reported in several other reviews (de Wit et al., 2006; de Wit et al., 2010; Environment Canada, 2010/2011; Letcher et al., 2010). Data collated as part of the Member State Competent Authority (MSCA) consultation on a potential restriction under REACH for decaBDE are also described (RPA 2014).

Prior to the sections on human and environmental exposure the existing legal requirements for decaBDE, and their influence on human and environment exposures, are discussed (section B.9.1.1).

B.9.1.1 Summary of existing legal requirements

Legislative controls, directly or indirectly, exist for decaBDE dating from the last 10 to 20 years. The subsequent sections of this report describe the relevant existing regulatory controls in the EU and Table 9 the relevant international initiatives (regulatory and voluntary).

B.9.1.1.1 Existing regulatory controls in the EU

Existing Substances Regulation

DecaBDE was included on the 1st priority list of the Existing Substances Regulation (ESR), Council Regulation (EEC) No 793/93. Based on the results of the risk evaluation of decaBDE (ECB 2002) and amendments (ECB, 2004; ECB, 2007), the EU Commission concluded, that there was a need for additional information to adequately characterise and assess aspects of the risks to human health and the environment from exposure to decaBDE. Specifically, the need for the following information requirements were identified (EEC/2008/C 131/04 and EC/565/2006):

- further developmental neurotoxicity study in mice or rats (workers/humans exposed via the environment),

- a suitable human bio-monitoring programme, including breast milk and blood, and the need for a trend analysis with annual reporting over a ten year time period (humans exposed via the environment), and

- an environmental monitoring programme including birds, sewage sludge, sediment, and air to establish the trends in levels of contamination for the substance and its more toxic and bioaccumulative degradation products, with annual reporting over a 10 year time period (environment/aquatic and terrestrial ecosystem).

REACH

DecaBDE was identified as an SVHC in November 2012. As such, it was added to the Candidate List in December 2012, which creates legal obligations to companies manufacturing, importing or using such substances, whether on their own, in preparations or in articles.

Norwegian restrictions on decaBDE

Norway restricted the manufacture, import, export, placing on the market and use of decaBDE or preparations containing decaBDE from 1st of January 2008. Also articles or flame retarded parts of articles that contain 0.1 % by weight or more of decaBDE are covered by the restriction. However, it does not apply when the substance is used in vehicles (WEE-regulation, aircraft regulations, vessels or rolling stock for use on railways).

In addition, Norway has a regulation on waste which sets a specific limit for hazardous waste containing decaBDE. If the waste contains decaBDE ≥ 0.25 % it is defined as hazardous waste, and has to be delivered to special treatment. Hazardous waste is regulated in the Norwegian Waste Regulations Chapter 11, appendix 3, Part B: Specific limit values for selected substances[45] .

Restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) Directive

Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (EEE), known as RoHS, which seeks to protect human health and the environment from certain hazardous substances, including the environmentally friendly recovery and disposal of waste EEE.

The original RoHS has been recast into Directive 2011/65/EU, taking the technical development of EEE without PBDEs into account. The recast directive expands the scope to include medical devices and control and monitoring equipment. All PBDEs, including decaBDE, are included in the restricted substances list and are not allowed in quantities higher than 0.1% w/w (weight of homogeneous material), although some categories of EEE are not in the scope of RoHS (see Table 59). The RoHS also states that an EEE compliant with the CE certification is considered compliant with the requirements of the Directive. The restriction under RoHS prevents decaBDE from being used in the majority of its previous uses in plastics.

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[45] http://www.miljodirektoratet.no/no/Regelverk/Forskrifter/Regulations-relating-to-the-recycling-of-waste-Waste-Regulations/Chapter-11-Hazardous-waste/

Table 59: Scope of the RoHS Directive

EEE under the scope of RoHS	EEE not in the scope of RoHS
Large and small household appliances	EEE used for military and defence purposes
IT and telecommunication equipment	Equipment that will be sent to space
Consumer equipment	Large-scale stationary industrial tools (i.e. large-scale machinery, equipment and components functioning together)
Lighting equipment	Large-scale fixed installations (combination of several types of apparatus in a fixed location)
Electrical and electronic tools	Transport vehicles (excluding two-wheeled electric vehicles)
Toys, leisure and sport equipment	Non-road mobile machinery exclusively for professional uses
Medical devices	Active implantable medical devices (e.g. pacemakers)
Monitoring and control instruments, including industrial monitoring and control instruments	Photovoltaic panels, that are to be installed by professionals
Automatic dispensers	B2B equipment designed and used solely for R&D
Other EEE not covered by the categories above	Specifically designed components of equipment excluded from the scope of the directive, without which, the equipment cannot function and which have to be replaced by the same component

Waste electrical and electronic equipment Directive

Directive 2002/96/EC on waste electrical and electronic equipment (WEEE) aimed to prevent and to promote reuse, recycling or other recovery methods for WEEE, while improving the environmental sound management of the processes along the EEE supply chain. Its scope is waste from EEE, with the exception of equipment for defence, safety and security. This directive, has been now recast, with Directive 2012/19/EU, taking into account the technical progress in EEE and the waste hierarchy. The directive also promotes separate collection of WEEE and sets collection and recovery targets, based on declared quantities of EEE by importers and manufacturers.
Annex VII of the recast WEEE Directive describes the selective treatment for materials and components of waste electrical and electronic equipment and include plastic containing **brominated flame retardants**. It specifies that separately collected plastics that contain BFRs (therefore, including decaBDE) should be removed and treated separately, in compliance with the Waste Framework Directive.

Waste Framework Directive

The Waste Framework Directive (WFD, Directive 2008/98/EC) provides a general framework of waste management requirements and sets basic waste management definitions. It prioritises the prevention of waste and preparation for reuse over recovery (i.e. recycling and energy recovery). Furthermore, material recovery is considered preferable to energy recovery, while disposal is the last choice.

Another important component of the WFD is the introduction of the concept of "End-of-Waste" (EoW), which refers to waste streams that can cease to be considered as waste, after a recovery process has taken place[46]. **Of relevance to decaBDE** is a draft technical proposal for plastic waste (JRC, 2013). The proposed criteria include the hazard classification of the waste plastic according to CLP, as well as the presence of SVHC or POP above the acceptable concentration limits.

Annexes to the WFD define the disposal operations, recovery operations and the properties of waste which render it hazardous and examples of waste prevention measures, e.g. the promotion of research and development into the area of achieving cleaner and less wasteful products and technologies and the dissemination and use of the results of such research and development.

Another important document, Decision 2000/532/EC[47], establishes a list of wastes, including a distinction between hazardous and non-hazardous wastes. It is closely linked to the list of hazard classification criteria which are contained in Annex III to the Waste Framework Directive. The classification of waste as hazardous should be based, inter alia, on the Community legislation on chemicals, in particular concerning the classification of preparations as hazardous, including concentration limit values used for that purpose.

Landfill Directive (Directive 1999/31/EC) & Council Decision 2003/33/EC

Directive 1999/31/EC on the landfill of waste aims to reduce the impact of landfilling of waste to the environment, through the introduction of strict technical requirements and procedures for waste and landfills.

The Council Decision 2003/33/EC "*establishing criteria for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive 1999/31/EC*" specifies criteria, which waste must fulfil in order to be accepted in a certain landfill class. These criteria include the identification of the composition, the source and origin of the waste and could also include testing to determine the degree of leaching of certain inorganic and organic parameters (e.g. heavy metals, chlorine, fluorine, organic content, PCBs).

Neither of these two documents mentions decaBDE or PBDEs explicitly. Nevertheless, they are briefly mentioned in order to indicate the approach regarding the characterisation of waste (which could include decaBDE) and the protection of soil and water.
It should be noted that depositing sludge on soil, which has been mentioned as a significant source of decaBDE contamination (COHIBA 2012), falls outside the scope of the landfill directive. The criteria described in the Council Decision include other halogen atoms as chlorine and fluorine concentrations in the leachate of the waste, but do not include bromine.

EU Water Framework Directive and amendments (Directive 2000/60/EC)

This Directive entered into force in 22 December 2000, and it has subsequently been amended by Decision No 2455/2001/EC and Directives 2008/32/EC, 2008/105/EC and 2009/31/EC.

Its ultimate aim is the elimination of priority hazardous substances and to contribute to

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[46] Available at: http://susproc.jrc.ec.europa.eu/activities/waste/index.html

[47] Commission Decision of 3 May 2000, replacing decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste.

achieving concentrations in the marine environment near background values for naturally occurring substances. This Directive establishes a framework for control of certain "priority substances" that present a significant risk to or via the aquatic environment. A list of 33 substances (or groups thereof) was adopted towards the end of 2001, through the Decision No 2455/2001/EC named as the Fist List of Priority Substances, to become the Annex 10 of the Water Frame Directive. Amongst the priority substances, there are certain priority hazardous substances for which the Commission will submit proposals for a cessation or phase-out of discharges, emissions and losses.

The first list was replaced by Annex II of the Directive 2008/105/EC on Environmental Quality Standards, also known as Priority Substances Directive, which set the Environmental Quality Standards (EQS) for the substances in surface waters (river, lake, transitional and coastal) and confirmed their designation as priority or priority hazardous substances, the latter being a subset of particular concern.

The first list already included PBDEs among which only pentaBDE has been identified as a priority hazardous substance in 2001, following the COMMPS1 (COmbined Monitoring-based and Modelling based Priority Setting scheme) procedure.

The European Commission has proposed to identify octaBDE as a "Priority Hazardous Substance" in the context of the Water Framework Directive, because of its PBT properties (EC, 2012). However, it is understood that this refers to the commercial product, on the basis of its lower molecular weight PBDE content. The Environmental Quality Standard for "brominated diphenyl ether" only concerns the sum of six tetra- to heptaBDE congeners.

The Integrated Pollution Prevention and Control (IPPC) Directive (Directive 96/61/EC) and Industrial Emissions Directive (Directive 2010/75/EC)

The purpose of Directive 96/61/EC "*concerning integrated pollution prevention and control*" (IPPC) was to achieve integrated prevention and control of pollution arising from industrial activities. It lays down measures designed to prevent or, where that is not practicable, to reduce emissions in the air, water and land from the above mentioned activities, including measures concerning waste, in order to achieve a high level of protection of the environment taken as a whole.

Emission limit values, parameters or equivalent measures prescribed by the Member States' Competent Authorities should be based on the best available techniques (BAT) without prescribing the use of one specific technique or technology and taking into consideration the technical characteristics of the installation concerned, its geographical location and local environmental conditions. BAT are described in the BAT reference documents (known as BREF) which apply to the different industry sectors that fall under the provisions of the IPPC Directive.

The BREF on textile industry mentions backcoating and decaBDE, in an Annex describing the various chemical agents that can be used. However, it does not discuss in length its relevance to environmental risks. Furthermore, the BREF has not been updated since 2003, so it has not taken into account any more recent information that has been produced.
The current draft for wastewater treatment plants mentioned that PBDEs were contained in the sludge and monitoring requirements, but this particular entry appears stricken out, therefore it should not be taken into account as it will probably not be included in the amended document.

The provisions of the IPPC Directive have now been included in the Industrial Emissions Directive 2010/75/EU (IED) which is effective as of January 2014. This Directive has integrated the IPPC directive with six other directives, including the old Directive 2000/76/EC on waste incineration.

The IED includes emission limit values for waste incineration plants (and therefore the requirement for monitoring), but PBDEs are not included in them. Instead of that, it sets limit values for dioxins and furans. These substances are also included in the list of "*polluting substances*", along with organohalogens, which also include PBDEs. The limit values for these substances should be respected before a permit is issued to a facility.

European Pollutant Release and Transfer Register (E-PRTR)

The *European Pollutant Release and Transfer Register (E-PRTR)* according to Regulation (EC) No 166/2006 is the Europe-wide register that provides easily accessible key environmental data from industrial facilities in European Union Member States and in Iceland, Liechtenstein, Norway, Serbia and Switzerland. It replaced and improved upon the previous European Pollutant Emission Register (EPER).

The register contributes to *transparency and public participation in environmental decision-making*. It implements for the European Community the UNECE (United Nations Economic Commission for Europe) PRTR Protocol to the Aarhus Convention on "Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters".

Brominated diphenyl ethers are included in the E-PRTR and information about releases per industrial activity and number of facilities notifying can be scrutinized by year and geographical area.

PBDEs are included in the chemicals whose emissions need to be reported if the relevant emission values are exceeded. For these substances, there is only a water threshold value of 1 kg/y per each installation falling under the provisions of the IPPC Directive.

Urban Waste Water Treatment Directive (Directive 91/271/EEC)

Directive 91/271/EEC concerns the collection, treatment and discharge of urban wastewater and the treatment and discharge of waste water coming from certain industrial sectors. Its aim is to protect the environment from any adverse effects due to discharge of such waters. It should be noted that neither the polymers nor the textiles finishing sectors are specifically covered by the Directive.

This Directive touches upon the potential risks from decaBDE to the aquatic environment only indirectly, as it targets the organic load of wastewater without specific reference to any substance or group of substances. It is evident that adherence to the provisions of the Directive must provide some protection to surface waters from releases of decaBDE, however, this measure has a rather weak and undefined effect on the potential risks from the substance in question.

Restrictions on other PBDEs: REACH Annex XVII restrictions on penta- and octaBDE

The placing on the market and use of penta- and octaBDE as a substance, in mixtures and in articles in concentrations greater than 0.1 % by weight was restricted in 2004. Later, these restrictions were listed in Annex XVII to REACH (entries 44 and 45, respectively). The entry 44 on pentaBDE was removed from the Annex XVII after the inclusion of the substance into Annex I to The Stockholm Convention (see below) and in the POP Regulation (EU 757/2010).

B.9.1.1.2 International initiatives

Voluntary actions in USA and Canada

In December 2009, three major manufacturers of decaBDE sent letters to the US EPA informing it that they would be phasing-out the production or import of decaBDE in the United States, as part of the EPA-Industry decaBDE Phase-Out Initiative, resulting from recent discussions between the authorities and the major manufacturers and importers. The commitment includes the discontinuation of the use of decaBDE in electrical and electronic equipment (EEE) (except as used in transportation equipment) and in all other uses except transportation and military uses by the end of 2012. Transportation (e.g. automobiles, airplanes, and certain warehousing and shipping equipment) and military uses was believed to require an additional year to complete the phase out. This was primarily because of the complexity of these uses (cars and planes have a very large number of parts that rely on flame retardant chemistry) and long lead times for qualifying and certifying new materials.

The complete liquidation of any residual stocks of decaBDE after six months of the phase-out was also in the commitment. The three companies who agreed to take part in this Phase-Out Initiative were Albemarle (producer), Chemtura (producer) and ICL Industrial Products (importer producing in Israel) (US EPA, 2012b). Consultation with the industry has not been able to confirm if the phase-out has been successfully implemented.

Chemtura Corporation (July 2010), Albemarle Corporation (October 2010) and ICL Industrial Products (December 2010) have also made a voluntary commitment referring to decaBDE in Canada, specifying that:

- Phase-out of decaBDE exports and sales for electrical and electronic equipment by the end of 2010
- Phase-out of decaBDE exports and sales for all other uses, except transportation and military, by the end of 2012
- Phase-out of decaBDE exports and sales for transportation and military uses by the end of 2013.

The Stockholm Convention

The Stockholm Convention on Persistent Organic Pollutants was adopted on 22nd May 2001 and entered into force on 17th May 2004 (Stockholm Convention, 2008).

The main objective of the Convention is to protect human health and the environment from the threats presented by persistent organic pollutants (POPs). So far, 179 Parties have ratified the Convention. The initial list of substances under the Convention was consisting on 12 POPs introduced in Annex A (elimination), Annex B (restriction) and /or Annex C (unintentional emissions). In May 2009, the Convention was amended to introduce nine new POPs. These included FRs such as tetraBDE and pentaBDE (congeners forming commercial PentaBDE) and also hexaBDE and heptaBDE (congeners forming commercial octaBDE) in Annex A (elimination) to the Convention. In May 2013, Norway submitted a proposal to list decaBDE as a POP under the Convention. Regulation EC 850/2004 aligns EU legislation with the provisions of the international agreements on POPs.

OSPAR Convention

Brominated flame retardants (including decaBDE) were identified as chemicals subject to priority action during the Ministerial Meeting of the OSPAR Commission of 1998 (Sintra) and were included in Annex 2 to the OSPAR Strategy with regard to Hazardous Substances Strategy (OSPAR, 2014).

The overall aim of OSPAR Commission for brominated flame retardants (and the other hazardous substances chosen for priority action) is to achieve by 2020 *a "cessation of discharges, emission and losses […] with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances"* (OSPAR, 2014).

OECD Voluntary Industry Commitment

In 1991, OECD's Risk Reduction Programme began an investigation of BFRs to explore the possibility of taking further action to reduce risk. In 1994, an OECD monograph was published [OCDE/GD(94)96] which discussed the commercial and environmental life cycle of these substances as well as risk reduction measures implemented in Member countries and these countries' positions on the perceived risk from these substances (OECD, 1995).

Discussions were held, in 1995, between Member countries and industry on possible activities that could be taken to further reduce risk. The result of these discussions was a proposed commitment, made by the major global producers of brominated flame retardants, to take certain risk management actions on tetrabromobisphenol A, polybrominated biphenyls (PBBs), and PBDEs.

This commitment was formally presented to OECD's 23rd Joint Meeting of the Chemicals Group and Management Committee in June 1995. The Joint Meeting agreed to oversee such actions and industry agreed to report to OECD every two years regarding their implementation of this initiative. At the 24th Joint Meeting in February 1996, a similar voluntary industry commitment, proposed by the Japanese manufacturers of these brominated flame retardants, was presented. The Joint Meeting agreed to incorporate this commitment with the one developed by the U.S. and European brominated flame retardant manufacturers.

These voluntary measures have been undertaken by members of the US Chemical Manufacturers Association (CMA), the Brominated Flame Retardant Industry Panel (BFRIP) and the CEFIC European Brominated Flame Retardant Industry Panel (EBFRIP).

Within this framework and with particular regard to decaBDE, BFRIP and EBFRIP committed to (OECD, 1995):

- Co-operate with polymer producers and end user manufactures (such as original equipment and textile manufacturers) on the safe disposal and recycling of polymers containing brominated flame retardants
- Co-ordinate toxicity studies
- Not manufacture or import/export the non-commercial brominated diphenyl oxide congeners as individual flame retardants, except when they are present as part of the commercial decaBDE. The non-commercial congeners are Nona-, Hepta-, Hexa-, Tetra-, Tri-, Di- and MonoBDE
- Use BAT without incurring in expensive costs, to improve the purity of decaBDE, 97% or greater
- Minimise environmental exposure of brominated flame retardants through the appropriate treatment of effluents and emissions from the manufacturing process
- Continue to issue and regularly update product literature to educate customers on the safe use of decaBDE. This is to prepare Material Data Sheets according to national standards, describing the product and its uses, and summaries of the toxicology data available on the product
- Use the best information available to regularly evaluate the risks of brominated flame retardants. Using any new information, BFRIP and EBFRIP member would seek to minimise risks that are identified by such evaluation.

BSEF Product Stewardship Programme (VECAP)

The Voluntary Emissions Control Action Programme (VECAP) is a voluntary initiative run by BSEF under the Responsible Care Initiative to set high standards for chemicals management in the workplace, both at manufacturing sites and along the value chain.

The aim of the programme is to reduce potential emissions of flame retardants to the environment through the promotion of manufacturing best practice among those involved along the value chain. This is achieved by increasing an understanding of chemicals management in the value chain, promoting dialogue between industry, regulators and stakeholders and by implementing best practices.

BSEF established the Product Stewardship Programme in 2002 which identified:
- The applications of concern
- The processes used by the downstream users
- The consumption patterns
- The geographical spread of the consumption of decaBDE in the EU.

For the evaluation of the above parameters, a number of stakeholders were identified so as to cover all known applications and provide a sufficient coverage of consumption across the EU.
The scheme was initiated in 2004 by the UK textile coating industry that began to take action to reduce emissions of decaBDE. Over subsequent years, VECAP has extended its scope to include other flame retardants, namely HBCD and TBBPA.

VECAP currently operates under the European Flame Retardant Association (EFRA), a sector group of the European Chemical Industry Council (Cefic).
For the decaBDE Stewardship Programme, nine companies (downstream users) from four countries (Belgium, Germany, Italy and the United Kingdom) agreed to participate, including:
- Two textile formulations compounders
- One textile finisher
- Two producers of polymers (rubber foam insulation)
- Four polymers masterbatchers/compounders.

EU Ecolabel

The EU Ecolabel criteria indicate that no use of flame retardants or flame retardant preparations is permitted where substances concerned are assigned one of a number of specified risk phrases and are present at more than 0.1% by weight.

Additionally, Green Public Procurement criteria have been developed for 20 product groups[48], of which the following are relevant to decaBDE:
- Textiles: decaBDE (along with pentaBDE, octaBDE and PBBs) should not be present in the textile. It is mentioned that if the product is certified according to a Type 1 ecolabel (e.g. EU-ecolabel), it is considered to comply with the criteria.
- Furniture: They include the criteria for textiles as described above.
- Transport: The criteria on passenger cars or public transport (bases) focus mainly on the emissions and fuel consumption of the vehicle. The main concern about materials is the share of recycled materials in the vehicle.

Other “green labels” such as the Japanese ECO Mark, Nordic Swan, German Blue Angel and

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[48] Available at: http://ec.europa.eu/environment/gpp/eu_gpp_criteria_en.htm

Swedish TCO, had restricted halogenated flame retardants in IT products since the early 1990s.

B.9.2 Human Exposure

This section includes a summary of relevant human health exposure data for decaBDE. The PBT status of decaBDE is associated with the toxicity of its breakdown products. Notwithstanding these properties, decaBDE has also been associated with adverse effects in its own right. Exposure data for humans may usefully considered during discussions on the proportionality/cost-effectiveness of any proposed restriction in addition to considerations of potential PBT/vPvB impacts mediated through breakdown products.

Different sources and pathways have to be considered for the assessment of human exposure to decaBDE, such as exposure from food, drinking water, inhalation of air, ingestion of dust as well as dermal exposure. Further, the foetus is exposed to decaBDE through transport across the placental barrier, and breast-fed children are exposed through consumption of breast milk. There are two ways of assessing the exposure: by evaluating the external or internal dose. The external dose is calculated by multiplying measured or modelled concentrations of decaBDE in different exposure media (e.g. food, air and drinking water) with exposure factors (e.g. inhalation rate or volume/amount consumed). The internal dose is based on measured concentrations of decaBDE in a suitable biological matrix (e.g. blood or breast milk), which further can be used to calculate the body burden based on knowledge on distribution in the human body. The internal dose reflects an integrated exposure over time comprising various sources and pathways. Biomonitoring data (e.g. blood concentrations) will also take individual differences into consideration (e.g. age and gender). However, biomonitoring does not give any information on the relative importance of different exposure pathways, which is highly relevant when selecting appropriate risk management to minimize exposure. Therefore, the methods using internal and external doses are considered complementary in exposure estimation.

B.9.2.1 Worker exposure

Earlier studies on occupational exposure are all from either Scandinavia or Asia, where high-exposure occupational groups like electronic dismantlers have been the main focus. In Sweden, the median decaBDE blood level in electronic dismantling workers and computer technicians was reported to be 4.8 and 1.53 ng/g lipids, respectively (Sjödin et al., 1999; Jakobsson et al., 2002), while a median of 35 ng/g lipids were reported among rubber workers (Thuresson et al., 2005). Whilst not directly relevant to risk management in the EU, the widespread recycling and dismantling of e-waste under primitive conditions in China has received increasing attention and examples of biomonitoring studies thereof are given in Table 60. The median decaBDE concentration in Guiyu (Bi et al., 2007) was 50-200 times higher than that previously reported in the occupationally exposed populations in Sweden. A strong relationship between highly brominated PBDEs (except BDE-197) in Guiyu and Haojiang were seen, implying that individual residents in Haojiang may have had exposures arising from Guiyu through transport of PBDEs by particles in the atmosphere or through other environmental processes across the 50 km separating both regions. The highest concentration of decaBDE in human tissue ever reported arose in the study by Qu et al. (2007), i.e. 3436 ng/g lipids, while the maximum in the above mentioned study by Bi et al. (2007) was 3100 ng/g lipids, about 3000 times higher than usually observed in general populations. However, in the most recent study (Yang et al., 2013), no significant difference was seen between the residents in an e-waste recycling area and the reference group and the blood concentrations were considerably lower. Equally, elevated PBDE concentrations have recently been reported in serum from firefighters in California. The decaBDE level ranged from 4 to 88 ng/g lipids (median 24 ng/g lipids) and contributed >50% of the total

PBDE concentration in four individuals, implying continuous occupational exposure to c-decaBDE (Shaw et al., 2013).

Zennegg et al. (2014) measured the total PBDF content in plastic materials produced from the recycling of plastics containing known amounts of PBDEs. DecaBDE was usually the dominant compound, but the samples contained also octa- and penta-BDE. The authors concluded that the resulting PBDF contents (~1x10^3 µg kg^{-1}) do not pose a risk for consumers under normal conditions, but warned that toddlers should avoid contact with decaying recycling materials that have been stored prior to recycling and highlighted the need for the protection of workers at recycling plants.

Table 60: Examples of biomonitoring studies on workers and non-workers living in areas at or close to primitive e-waste recycling in China (ng/g lipids)

N	Location	Subjects	Year	Mean	Median	Min	Max	Reference
26	Guiyu	residents in typical e-waste recycling site	2007	340	310	<64	3100	Bi et al., 2007
21	Haojiang	residents in a district with fishing industry 50 km east of Guiyu		130	86	<64	370	
20	Guangdong	workers in typical e-waste recycling site			83.5	<1	3436	Qu et al., 2007
15		residents in a farmer district 50 km away of Guangdong			13.5	<1	377	
20	Guangzhou	referents. no known occupational exposure			5.7	<1	63.2	
27	Luqiao	residents in typical e-waste recycling site	2006	87.2	64.5	17.16	378.9	Zhao et al., 2010
24[a]	Wenling	residents in typical e-waste recycling site		210.48	171.6	84.52	555.76	

N	Location	Subjects	Year	Mean	Median	Min	Max	Reference
239	Taizhou	workers in typical e-waste recycling site	2008	57.78	40.65	<	458.54	Wang et al., 2010
93		residents in typical e-waste recycling site		92.61	53.31	<	1708	
116		farmers in neighbouring town (controls)		41.35	27.96	<	336.47	
35	Tianjin	residents in typical e-waste recycling site	2009-10	4.52[b]	5.73	1.8[c]	12.3[c]	Yang et al., 2013
21		residents living 40 km away from the recycling site		4.00[b]	5.87	0.64[c]	25.9[c]	

[a] Results based on 12 samples due to contamination
[b] Geometric mean
[c] Inter quartile range

B.9.2.2 Consumer exposure

Consumer exposure includes exposure from house dust, indoor air as well as dermal or oral contact with consumer products. C-decaBDE is used in many consumer products including plastics, textiles and foam furniture and might leach from the products into house dust as well as both indoor and outdoor air. Thus ingestion of house dust and inhalation of airborne particulates are potential exposure sources for decaBDE, as well as direct contact with consumer products.

It is not well documented whether decaBDE migrates out of the products and finds its way onto dust or comes from the breakdown (abrasion) of the product matrix itself. It has been suggested that decaBDE is transferred to dust via physical processes such as abrasion or weathering (Webster et al., 2009). Debromination of decaBDE to lower brominated congeners has been observed in house dust experimentally exposed to sunlight (Stapleton and Dodder, 2008).

The fate of c-decaBDE in the products during use is still unclear. One aspect that has been under focus is the possibility of degradation of decaBDE during common use of products to lower brominated congeners as well as formation of polybrominated dibenzofurans (PBDFs) under natural sunlight conditions (see section B.4 and SVHC support document for more information).

Children’s toys manufactured in China, specifically hard plastic toys, have been identified as a potential source of exposure of young children to c-decaBDE (Chen et al., 2009). Although BFRs are not mandatory additives in children’s toys, they are widely used in plastic, rubber, textile, or polyurethane foam, which may be used in children’s toys. According to a survey performed in this study, a large quantity of recycled plastics could be used as raw materials in products, including electronics, mattresses, and toys, which may therefore contain high concentrations of flame retardants. This study also suggested that elevated concentrations of octa- and nonaBDEs arise from the decomposition of c-decaBDE during the manufacturing processes of the toys. Another study screening for the presence of recycled polymers from waste electric and electronic equipment, revealed the occurrence of brominated flame retardants, and decaBDE in particular, in black thermo cups and selected kitchen utensils purchased on the European market (Samsonek and Puype, 2013). The results indicated that polypropylene–polyethylene copolymers and mainly styrene-based food-contact materials, such as acrylonitrile-butadiene-styrene had the highest probability of containing brominated flame retardants (mainly technical decaBDE was detected in the samples).

The indoor environment has recently been recognized as an important exposure pathway for PBDEs, as emphasized in the review by Harrad et al. (2010). This compilation of data showed decaBDE concentrations in the indoor air ranging from <LOQ (limit of quantification) to 651 pg/m^3. In European house dust, the decaBDE concentrations ranged from 63 to 10000 ng/g in dust from Germany, Sweden and the UK (Fromme et al., 2009). The sum of the lower brominated PBDEs (BDE-47, 99, 100, 153, 154 and 183) measured in the same samples was substantially lower and ranged from 26 to 170 ng/g dust. The concentration of decaBDE in North American house dust were comparable to those in Europe (<500-2000 ng/g) (Fromme et al., 2009). According to several extensive reviews, most studies on PBDEs in dust from the indoor environment show decaBDE to be the dominating congener (Frederiksen et al., 2009a; EFSA, 2011; Besis and Samara, 2012).

There is growing evidence that occupancy in cars and, potentially, aeroplanes may be a significant source of PBDE exposure (Besis and Samara, 2012). While the average time spent in cars is considerably less than time spent indoors, the median levels of decaBDE in dust from cars were about 20 times higher than in house dust, although the levels varied substantially between the studies. This is in line with a recent German study where the mean decaBDE concentration in car, house, and office dust samples were 940, 45 and 120 ng/g, respectively (Brommer et al., 2012). However, a recent risk assessment, based on international literature, concluded that exposure to BDEs (including decaBDE) in air and dust arising from child car seats and automotive upholstery is unlikely to cause adverse health effects in infants and toddlers (Fowles and Morgott, 2013).

B.9.2.3 Indirect exposure of humans via the environment

Indirect exposure via the environment includes exposure from food and beverages, drinking water and inhalation of outdoor air. DecaBDE is widely present in food and is reported in concentrations ranging from ~2 to >50,000 pg/g wet weight as reviewed by Frederiksen et al. (2009a). The highest concentrations were generally measured in fish and shellfish. Measurements of decaBDE in Norwegian food in the period 2002-2006 has been reviewed by Knutsen et al. (2008) and the upper bound[49] concentrations ranged from 45 to 1964 pg/g wet weight. The highest concentrations were observed in the eggs of seagulls, followed by fish and dairy products, which included milk, cheese and butter. Domingo (2012) also reviewed the presence of PBDEs in food and estimated daily intakes. He concluded that despite differences in methodologies used, decaBDE contributes significantly to the total dietary intake of PBDEs.

Following the advice of the EFSA Panel on Contaminants in the Food Chain (CONTAM), a monitoring program was carried out in the EU starting in 2006. The results comprised up to 19 PBDE congeners analysed in 3971 food samples from 11 European countries covering the period 2001-2009. DecaBDE was reported in 1300 samples. The concentration of decaBDE was the highest among the measured PBDEs in almost all the food samples, except for "Fish and other seafood" and "Food for infants and small children". The mean lower bound (upper

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[49] Upper bound: values < LOD/Q has been assigned the LOQ/Q-concentration. Lower bound: values < LOD/Q has been assigned 0 concentration.

bound in parentheses) concentration across eight broad food categories ranged from 0.021 (0.11) pg/g wet weight in milk and dairy products to 2.22 (2.73) pg/g wet weight in products for special nutritional use.

The influence of cooking conditions on the PBDE content in food is not well characterised. However, one study showed that fish containing decaBDE that was heated at typical cooking conditions (200 °C, in plant oil) led to the formation of lower brominated congeners. Low amounts of one hexabromodibenzofuran and a heptabromodibenzofuran isomer were also detected. However, penta- and tetrabrominated diphenyl ethers were not observed (Bendig et al., 2012). Recently, Vetter et al. (2014) measured the amounts of PBDFs that were formed in fish contaminated with decaBDE, during cooking. They identified the presence of hepta- and hexaBDFs, but also observed the formation of lower brominated congeners (nona- to heptaBDEs). In addition, and based on previously established tolerable weekly intake limits for dioxin-like compounds, and realistic assumptions regarding concentrations of decaBDE in fish and cooking time, they calculated that fish contaminated with decaBDE could contribute between 6.4 – 15 % of the tolerable intake. They concluded that decaBDE concentrations that would not exceed residue limits of POPs in food can be linked to the formation of amounts of PBDFs that can raise concern. More data are needed to evaluate the potential risk associated with formation of these more toxic compounds during the preparation of food.

Due to the extremely low water solubility of decaBDE, any contribution from drinking water to exposure is considered negligible.

In outdoor air, decaBDE concentrations have been reported in the range of <limits of detection (LOD) to 105 pg/m^3 (Harrad et al., 2010). In most cases where decaBDE was included in the measurement, this was the prevalent congener, with the exception of studies from the US where BDE-47 and 99 are more prevalent (Besis and Samara, 2012).

B.9.2.4 Combined human exposure assessment

B.9.2.4.1 General information

The combined human exposure assessment considers exposure from all sources (both sources of consumer exposure and indirect exposure of humans via the environment as described in section B.9.2.2 and 9.2.3). The internal dose, e.g. assessed using biomonitoring data, reflects an integrated exposure over time comprising various sources and pathways.

Of the PBDEs, the tetra- to octaBDEs have the highest stability and persistence (EFSA, 2011), and are prone to bioaccumulation in human tissues. The bioaccumulative properties of decaBDE appear to be species-dependent, and there is evidence that it is capable of bioaccumulation in human tissues (Frederiksen et al., 2009a). For this reason, levels measured in breast milk, serum, blood and placenta can give a reflection of internal exposures received through all relevant routes, including food and inhalation/ingestion of air/dust. However, there is evidence of considerable binding of decaBDE to proteins (Hakk et al., 2002), which means that analyses of levels in lipids may underestimate the body burden of decaBDE. However, tissues or body fluids representative of protein-bound fractions of decaBDE have not been the focus for human biomonitoring studies.

As presented in the following paragraphs, a vast number of scientific studies have shown decaBDE to be frequently detected in human matrices, proving that humans are extensively exposed to c-decaBDE. Further, the presence of decaBDE in placenta and samples of cord blood confirms prenatal exposure. Median levels are generally in the range of 0.5 to 5 ng/g lipids for adults with no known occupational exposure. The levels on lipid basis seem to be quite similar in foetuses, children and adults throughout the world, while significantly higher concentrations are seen in occupationally exposed persons. In many of the studies, decaBDE was the PBDE congener present in highest amounts, particularly in breast milk.

B.9.2.4.2 Placenta and cord blood

The foetus may be exposed to decaBDE through trans-placental transfer from the mother (US EPA, 2009). DecaBDE has been measured in placental samples in concentrations ranging from 0.05 to 8.4 ng/g lipids in a Danish and Spanish study, the median were 1.14 and 1.0 ng/g lipids, respectively (Frederiksen et al., 2009b; Gomara et al., 2007). Both studies reported decaBDE to be the dominating PBDE, representing around 50% of the total PBDEs. Whilst not directly relevant to risk management in the EU, a similar congener pattern was observed in a recent study from China, where pre-natal placental concentrations were in the range of 1.33 to 8.84 ng/g lipids (median 2.64 ng/g lipids) (Zhao et al., 2013).

Analysis of cord blood is well suited to indicate the internal dose in neonates. An overview of biomonitoring studies presenting cord blood concentrations of decaBDE is presented in Table 61. DecaBDE was in general making a large contribution to the sum of the PBDEs, and was even the most abundant compound (by weight) in several of the studies (Wu et al., 2010; Antignac et al., 2009; Wang et al., 2012). The greatest maximum concentration was observed in cord blood collected in a contaminated e-waste recycling area in China. However, the mean and median values obtained from the French study were higher than median values reported in the data from China. No explanation for this difference is available.

Table 61: Overview of studies presenting concentrations of decaBDE in cord blood worldwide (ng/g lipids)

Location	*N*	Area	Year	Det. Freq.[a]	Mean	Median	Min	Max	Reference
Europe									
Spain	44	Vallecas	2003-4			2.2	<1.1	11	Gomara et al., 2007
	48	Getafe				1.4	<1.1	24	
Spain	174	Valencia	2003-5	18	2.60	<1.2	<1.2	40	Vizcaino et al., 2011
France	90		2004-6	40	78.1	27.11	3.46	363.2	Antignac et al., 2009
Sweden	10		2005-6	60		<4.9	<1.6	9.9	Jakobsson et al., 2012
Other									
China	102	Guiyu	2007			4.2	ND[b]	483.5	Wu et al., 2010
	51	Chaonan				2.5	ND[b]	361.4	
China	65		2010		0.50[b]		ND[b]	2.0[b]	Wang et al., 2012

[a] Percentage of measurements above LOD/Q
[b] Not detectable
[c] ng/mL

B.9.2.4.3 Breast milk

Breast milk is an easy to obtain, non-invasive medium for biomonitoring and any contamination of this medium is of great concern as this contamination is directly passed on to the next generation. PBDEs have been widely measured in breast milk throughout the world, but only some few studies have included decaBDE. The extensive review by Frederiksen et al. (2009a) covered studies published until 2007 and showed that decaBDE was reported in the concentration range of 0.1 to 2.9 ng/g lipids (medians). Of the nine studies presenting decaBDE concentrations breast milk, three were from Europe. Only one study from the Faroe Islands assessed temporal trends and found approximately the same levels in 1987, 1994-5 and 1999 (0.51-0.60 ng/g lipids) (Fängström et al., 2005). The fraction of decaBDE in the studies varied from 0.1% in US samples to 48% in the Spanish samples (She et al., 2007; Gomara et al., 2007). EFSA recognized seven European studies (of which five are not included in the review by Frederiksen et al., 2009a) presenting decaBDE levels in breast milk, the mean concentrations were between 0.21 and 2.9 ng/g lipids. An overview of the most recent studies of decaBDE in breast milk is presented in Table 62. The mean/median concentrations are in the same range as previously reported, but the maximum values vary considerably within and between geographical regions. decaBDE was the most prominent congener of all PBDE congeners measured, in about half of the studies.

There are significant changes in the composition of breast milk during the period of lactation and these changes have been shown to have impact on the BDE congener profile. Jakobsson et al. (2012) have shown that colostrum, which is secreted during the first five days after birth, is enriched in higher brominated BDEs, including BDE-197, 207 and decaBDE, relative to mature breast milk. Depending on the congener, the levels in colostrum were by a factor of 3 (BDE-207), 7 (decaBDE) or 9 (BDE-197) higher than in mature breast milk. This means that exposure estimates for neonates based on the congener levels in mature breast milk may underestimate the intake. Unfortunately, measurement of BDEs in colostrum is not commonly undertaken.

Table 62: Overview of recent studies presenting concentrations of decaBDE in breast milk worldwide (ng/g lipids)

Location	*N*	Year	Det. Freq.[a]	Mean	Median	Min	Max	Reference
Europe								
Norway	46	2003-5	76	0.61	0.32	<0.2	5.8	Thomsen et al., 2010
Spain	9	2005	100	2.5	2.7	0.2	5.7	Gomara et al., 2011
Sweden	10 (colostrum)	2005-6	80		1.7	<0.23	4.6	Jakobsson et al., 2012
	9 (mature)		78		<0.23	<0.23	0.93	
Belgium	84	2009-10	57.1		0.65	0.22 (P10[b])	1.84 (P90[b])	Croes et al., 2012
Ireland	109[c]	2010	100	1.5	0.77	0.37	7.19	Pratt et al., 2013

Location	*N*	Year	Det. Freq.[a]	Mean	Median	Min	Max	Reference
Other								
Taiwan	42 (C. Taiwan)	2000-1	86	0.558	0.485	0.173 (P25[b])	0.668 (P75[b])	Shy et al., 2012
	147 (S. Taiwan)	2007-10	100	0.9	0.346	0.237 (P25[b])	0.739 (P75[b])	
US	82	2003-5		3.67	1.41	0.28	55.3	Park et al., 2011
China	20 (Shijiazhuang)	2006-7	55		0.57	0.16	14	Sun et al., 2010
	20 (Tianjin)		80		0.3	0.3	2.5	
	20 (Shi)		80		0.22	0.12	0.5	
China	48	2007	100	2.2	1.8	0.2	8.6	Ma et al., 2012
Taiwan	46	2007-8	91	0.471	0.346	0.305[d]	0.598[d]	Chao et al., 2010
Taiwan	70	2007-10	99	0.468	0.295		1.7	Chao et al., 2011
New Zealand	37	2008	97	0.354	0.19	0.065	3.14	Mannetje et al., 2013b
Philippines	30	2008		0.5	<0.05	<0.05	3.4	Malarvannan et al., 2013
Ghana	16 (Accra)	2009		0.83	0.55	<0.01	4	Asante et al., 2011
	14 (Kumasi)			1.4	0.39	<0.01	11.2	
	12 (Tamale)			0.84	0.95	<0.01	1.7	
India	55	2009						Devanathan et al., 2012
China	103	2011	78	9.85	1.95	<	131.05	Shi et al., 2013

[a]Percentage of measurements above LOD/Q
[b]P: percentile
[c]11 pooled samples
[d]95% confidence interval (CI)

B.9.2.4.4 Blood

The most common matrix used for biomonitoring purposes of PBDEs, applicable for both genders and all ages, is blood. DecaBDE concentrations in populations with no known occupational exposure were shown to range from 1 to 18.5 ng/g lipids in the review by Frederiksen et al. (2009a). Examples of more recent data are presented in Table 63, which shows similar levels, except from the strikingly high levels reported from Laizhou (2011) in China, a production area of halogenated flame retardants (He et al., 2013). The subjects in this study were living within 10 km of the main chemical production sites and some of them may have been factory workers. One study from Sweden has assessed the concentration of decaBDE in serum from first time mothers living in Uppsala sampled from 1996 to 2010 (Lignell et al., 2011). The mean of the 36 serum pools were 1.3 ng/g lipids and no significant temporal trend was seen, which is in accordance with the lack of trend for breast milk.

The few studies in which decaBDE have been measured in children, show similar concentrations as in adults, with some exceptions. In the US study by Fischer et al. (2006) which was a case study of a family of four, the highest decaBDE as well as the other PBDE levels were measured in the children. Two samples were taken some months apart, and the decaBDE concentration varied tenfold. Another US study on paired serum samples from 20 mothers and their firstborn children whose ages ranged from 1.5 to 4 years, revealed that decaBDE were detected more often in children than mothers (13 vs 9), but the levels were not significantly higher as was observed for most of the other PBDEs (Lunder et al., 2010). A recent study from New Zealand assessing 747 individual serum samples divided into 49 pools according to age, showed that of the quantified PBDEs, the highest serum concentrations were observed for decaBDE, for the youngest age group (19-24 years) (weighted mean 3.57 ng/g lipid) (Mannetje et al., 2013a).

Table 63: Overview of recent studies presenting blood concentrations of decaBDE in adults and children worldwide (ng/g lipids) (no known occupational exposure)

Location	***N***		**Year**	**Det. Freq.**[a]	**Mean**	**Median**	**Min**	**Max**	**Reference**
Europe									
Spain	*731*	44% men	2002	82.8	3.5[b]	3.7	0.45	50	Gari et al., 2013
Spain	*174*	women	2003-5	33	2.0	<0.7	<	40	Vizcaino et al., 2011
Norway	*25*	women	2004-5	96	2.3	1.5	< 1	14	Thomsen et al., 2008
	41	men	2004-5	85	2.4	1.7	< 1	11	
France	*91*	women	2004-6	70	9.47	5.78	0.79	34.43	Antignac et al., 2009
Other									
USA	*20*	women	2006-7	45	1.7	1.4	<1.88	3.20	Lunder et al., 2010
Japan	*31*	women	2007-8	94	1.0	0.9			Uemura et al., 2010
	41	men	2007-8						
Korea	*720*	49% men	2009-10	9	0.91	<3.68	<3.68	39.8	Kim et al., 2012
China	*305*	10 pools	2011		220		62	740	He et al., 2013
Children									
Europe									
Faroe Islands	*42*	7 yrs	2000-1	57		1.0	<0.3	6.4	Fängström et al., 2005
Other									
USA	*94*	2-5 yrs.	2003-5		4.4	2.6			Rose et al., 2010
USA	*1*	5 yrs.	2004				9.00	143	Fischer et al., 2006
	1	18 mont.					19.00	233	
USA	*20*	1.5-4 yrs.	2006-7	65	3.5	1.7	<1.8	19.	Lunder et al., 2010
China	*58*	9-12 yrs.	2008	56		1.73	1.73	13.3	Zhang et al., 2011

[a] Percentage of measurements above LOD/Q
[b] Geometric mean

B.9.2.5 Estimated intakes

The characterisation of human exposure is based on intake estimates. The main routes of human exposure to PBDEs include food consumption, ingestion of house dust and to a lesser extent inhalation of indoor and outdoor air as well as skin uptake. The exact contribution of each pathway may vary substantially on a compound-specific basis, between individuals and within different populations.

B.9.2.5.1 Adults

The estimated mean dietary intake of decaBDE for average consumers in European countries ranged from 0.35 (minimum Lower Bound) to 2.82 ng/kg bw per day for decaBDE (maximum Upper Bound) (median: 0.61 – 1.69 ng/kg bw day)(EFSA, 2011). Animal and vegetable fats and oils and milk and dairy products contributed most to the overall intake, 43.5 and 41.7 % respectively (maximum UB). The dietary intake of decaBDE estimated by EFSA was in close agreement with intakes reported in previous European studies ranging from 0.26 to 1.4 ng/kg bw per day, respectively (Knutsen et al., 2008; Thomsen et al., 2008; Zeilmaker et al., 2008). Based on a daily intake of 50 mg dust and a body weight (bw) of 70 kg, EFSA estimated the exposure of adults to be in the range of 0.045 to 7 ng/kg bw per day. The contribution from outdoor and indoor air is comparably low and was not included in EFSAs assessment. Similarly, Fromme et al. (2009) estimated the daily intake of dust for German adults to be 0.26 ng/kg bw. The minor contribution of indoor and outdoor air to decaBDE exposure was proven in this study.

Lorber (2008) reviewed exposure to PBDEs in the US and showed that for decaBDE, soil/dust ingestion with 104.8 ng/day by far made the largest contribution to the exposure, followed by soil/dust through dermal contact (25.2 ng/day). The total exposure was estimated to 147.9 ng/day, of which food and drinking water contributed only 16.3 and 0.09 ng/day, respectively. The total exposure corresponds to 2.11 ng/kg bw per day given a body weight of 70 kg as used by EFSA.

Based on reported concentrations of decaBDE in ambient and indoor air, dust, water, various foodstuffs and human breast milk, upper-bound estimates of total daily intake of decaBDE were determined to be 9.3 ng/kg bw for Canadian adults (20-59 years) (Health Canada, 2012). Food and indoor dust were the dominant sources of exposure, contributing 51 and 45% to the total intake, respectively.

B.9.2.5.2 Infants

The exposure of breast-fed neonates and infants is strongly determined by PBDE levels in colostrum and mature breast milk, which may vary considerably within and between geographical regions.

A recent report (Kortenkamp et al., 2014) assessed the ranges of mean daily intake values for breastfed infants up to the age of three months across various regions in Europe, Africa and Asia (Table 64). In estimating these intakes, it was assumed that an infant weighing 6.1 kg consumes 800 ml (average consumption) or 1200 ml (high consumption) of breast milk with a fat content of 3.5% every day (EFSA, 2011). Due to the scarcity of analyses of colostrum, it was not possible to assess the true exposure to decaBDE and other higher brominated congeners in the first few weeks of life. This means that exposure estimates for neonates based on the congener levels in mature breast milk may underestimate the real intake.

Table 64: Mean intake of decaBDE in breast-fed infants across regions (ng/kg bw per day) (reproduced from Kortenkamp et al., 2014)

	Europe[a]		**Africa (Ghana)**	**Asia (India)**	**Asia (China, Taiwan)**		**Asia (Philippines, Vietnam)**	
Consumption	**LB[b]**	**UB[c]**			**LB**	**UB**	**LB**	**UB**
800 ml	1.01	13.3	4.6	3.82	2.2	13.8	2.3	7.8
1200 ml	1.52	19.95	6.9	5.73	3.3	20.7	3.45	11.7

[a] LB Occurrence data reported in studies carried out in different European countries and reported in the literature (EFSA, 2011)
[b] LB lower bound
[c] UB upper bound

Breast milk was also considered in the EFSA survey, and for breast fed infants three months of age with an average consumption of breast milk (800 ml) a similar mean daily exposure to decaBDE of 0.96 to 13.3 ng/kg bw day was estimated (EFSA, 2011). High consumers (1200 ml) had a daily intake ranging from 1.4 to 20 ng/kg bw.

Health Canada (2012) estimated the total intake of decaBDE of breast fed infants up to 6 months to be in the range 50-187 ng/kg bw per day, the contribution of dust was 40 ng/kg bw per day.

B.9.2.5.3 Toddlers

Several studies have established that toddlers and young children show higher levels of PBDEs than adults (Frederiksen et al., 2009a), which has also been shown for decaBDE (Fischer et al., 2006; Lunder et al., 2010). While there is no evidence for a diminished capacity of young children and toddlers to eliminate PBDEs, it appears that small children, as a result of their behaviour receive considerable PBDE doses from house dust. Lorber (2008) estimated that the total PBDE exposure of US children of age 1-5 years is 7-fold higher than for adults, on a body weight basis. He attributed this to higher dust ingestion by children and concluded that the pathways of soil/dust ingestion and dermal contact overwhelm the exposure of children (and adults) to PBDEs. DecaBDE alone contributed more than half of the total PBDE exposure. Webster et al. (2005) estimated that more than half of a child's PBDE exposure via dust is dermal.

As children are likely to ingest higher amounts of dust than adults, EFSA assumed a daily ingestion of 100 mg. The exposure for 1-3 years old children (12 kg) in Europe were estimated to range from 0.53 to 83 ng/kg bw per day, which is considerably higher than the corresponding calculated median dietary intake ranging between 2.59 and 6.4 ng/kg bw (EFSA, 2011). The dietary exposure of decaBDE was four times higher in children than in adults.

Health Canada (2012) estimated the daily decaBDE intake for the age group 0.5 to 4 years to be 89 ng/kg bw, of which diet and dust contributed 24 and 64 ng/g kg bw, respectively. Children's toys manufactured in China, specifically hard plastic toys, have recently been identified as a potential source of exposure of young children to c-decaBDE (Chen et al., 2009). This exposure was modelled in the assessment of oral intake of decaBDE of Canadian children for the 0.5- to 4-year age group (Health Canada, 2012). The upper-bound estimate was 120 ng/kg bw per day, which was twice the exposure estimate from soil (dust) for this age group.

The combined exposure estimates are summarised in Table 65.

Table 65: An overview of estimated intakes of decaBDE in ng/kg bw per day

	Europe (EFSA 2011[a])		**US (Lorber 2008[b])**		**Canada (Health Canada 2012[c])**	
Infants					**0 - 0.5 years**	
	Food	0.96 - 13.3			Food	16-187
					Dust	40
Toddlers	**1 - 3 years**				**0.5 - 4 years**	
	Food	2.59 - 6.4			Food	24
	Dust	0.53 - 83			Dust	64
					Mouthing	120
Adults						
	Food	0.61 - 1.69	Total	2.11	Food	4.7
	Dust	0.045 - 7.00			Dust	4.2
					Total	9.3

[a] Dust ingestion: 50 mg for adults and 100 mg for toddlers. Values are median LB – UB.
[b] Dust ingestion: 50 mg
[c] Dust ingestion: adults 25-59 years 30 mg, toddlers 100 mg

Human decaBDE exposure depends strongly on the life stage. On an amount per body weight basis, children of age 1 – 3 years are the age group with the highest exposures. Breastfed infants are also quite highly exposed. With increasing age, the intake (on a body weight basis) declines somewhat. As pointed out by Health Canada (2012) the assessment of human health risks through exposure estimates is limited by a scarcity of inhalation and/or dermal exposure data as well as by insufficient data on toxicokinetics of decaBDE in humans.

B.9.3 Environmental exposure

Measurements of decaBDE in the environment were first published during the late 1980s (Kortenkamp et al., 2014). Early studies were associated with uncertainty in terms of analytical sensitivity and, in some instances, reproducibility of measurements (EC, 2002). However, the sensitivity and reproducibility of analytical techniques are considered to have improved over time, particularly in the last 10 years (Leonards and Duffek, 2008, after Kortenkamp et al., 2014) and have confirmed the widespread occurrence of decaBDE across environmental compartments and in wildlife (EA, 2009; Kortenkamp et al., 2014). Equally, temporal trends and changes in the use patterns of decaBDE (and other BDE congeners) that have occurred since the 1980s are likely to have modified decaBDE exposure in the environment. Based on these observations, whilst early studies were instrumental in raising awareness of the presence of decaBDE in the environment, more recent studies should be considered to more accurately reflect current environmental exposure to decaBDE. With this in mind, Kortenkamp et al. (2014) based a mixtures risk assessment for PBDEs on a "snapshot" of more recent environmental monitoring studies for decaBDE obtained from the scientific and grey literature.

B.9.3.1 EU RAR conclusion (i) monitoring programme

A key outcome of the risk assessment of decaBDE carried out under the ESR (EC, 2002; ECB, 2004 and 2007) was a ten-year monitoring programme (known as the conclusion (i) monitoring programme, or DECAMONITOR) requested by the EU Member States under Commission Regulation (EC) No 565/2006[50]. The monitoring programme, funded by industry[51], was to investigate the long-term trends in levels of decaBDE in four matrices: sewage sludge (total of 12 wastewater treatment plant sites from the UK, Ireland and the Netherlands), sediment (total of 10 EU sites, in 5 different countries), biota (predatory birds eggs from the UK and Norway) and air (UK). Sediments and sewage sludge were sampled bi-annually, whilst biota was sampled annually. Interim results of the programme were reported previously in ECB (2007) and in the Annex XV report for the identification of decaBDE as an SVHC (ECHA, 2012). In addition, De Boer et al. (2010) reviewed the first five years of the monitoring programme where they conclude that there were insufficient data available to establish reliable time trends, but the graphical illustrations in the paper did not suggest substantial changes in the concentrations being detected. EBFRIP (European Brominated Flame Retardants Industry Panel) in a presentation to CARACAL[52] also stated that levels of decaBDE have not changed significantly during the first four years of the monitoring study.

Further to these previous data, the conclusions from the first six sampling years (2005 – 2010) of the sediment, sewage sludge and biota sampling programme are now available (Leslie et al., 2012):

- The concentration of decaBDE in the eggs of sparrowhawk (*Accipitier nisus*) collected between 2005-2010 ranged from 0.07 to 12 ng/g w/w. The majority of sparrowhawk eggs had detectable decaBDE (4 non-detects out of 47 eggs in total). No increasing or decreasing trend in decaBDE levels in sparrowhawk eggs was observed over the 2005-2010 period.
- The concentration of decaBDE in the eggs of glaucous gull (*Larus hyperboreus*) from a remote northern island in the Barents Sea (Bear Island, Norway) collected between 2005-2010 ranged between 0.1 and 1.0 ng/g wet weight (i.e. up to 10 ng/g lipid). Glaucous gull eggs have decaBDE concentrations that are consistently lower than found in the sparrowhawk eggs. 23 of the 72 eggs collected had no detectable decaBDE (32% of all eggs collected). No increasing or decreasing trend in decaBDE levels in glaucous gull eggs was observed over the 2005-2010 period.
- DecaBDE concentrations in sludge from Dutch sites sampled in the first three sampling rounds has average levels between 473 and 1600 µg/kg OC (organic carbon). DecaBDE concentrations at sites from the UK over the same period were consistently higher (by more than an order of magnitude), ranging from 9740 to 55,700 µg/kg OC. This may reflect differences in decaBDE usage patterns between the two countries. The most recent sewage sludge samples from Liverpool (Shandon Docks) and Burnham-on-Crouch in the UK had approximately double the concentrations of decaBDE compared to previous sampling years. Other sewage treatment sites showed neither decreasing or increasing levels.

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[50] O.J. No L 99, 07/04/2006 p. 003 - 005.

[51] Bromine Science and Environmental Forum

[52] 4th Meeting of Competent Authorities for REACH & CLP, 3rd of February 2010

- Low concentrations of decaBDE (<500 µg/kg organic carbon) observed in the Elbe, Ems, Seine and Outer Humber sites appear stable throughout the first six years of the study. Dublin Harbour sediments exhibited higher organic carbon normalised decaBDE concentrations in 2009 compared to previous sampling years (2005 and 2007), which may be due to the low levels of organic carbon present in this sediment.
- Sediments sampled from sites in the Western Scheldt (~40 mg/kg organic carbon), Liverpool Bay (20-40 mg/kg organic carbon) and River Mersey (40-120 mg/kg organic carbon) have the highest concentrations of decaBDE included in the study. The concentrations are at least an order of magnitude higher than in the sediments from the Elbe, Ems, Seine and Outer Humber. Notably, in the Dublin Harbour and River Mersey sediments collected in 2009, approximately twice the decaBDE concentrations were measured compared to previous sampling rounds. No explanation for this result has been proposed.

Air sampling was undertaken at a single (semi-rural) site in the UK during 2007. The site had previously been used to monitor decaBDE in 2005, prior to the EU RAR conclusion (i) monitoring programme (Thomas and Jones, 2007; EA, 2009). The geometric mean concentration measured in 2007 was 18 pg/m^3, which was not statistically significantly different from the geometric mean concentration found in 2005 (15 pg/m^3).

The lack of any clear decreasing trend in the data from this programme is important, because the VECAP scheme has been in place since 2004. If VECAP were having a significant impact on emissions of decaBDE across its lifecycle the monitoring data would be expected to reflect this. The absence of any downward trend in the levels of decaBDE observed in the environment and wildlife suggests that the VECAP either does not affect the most significant emissions from the decaBDE lifecycle (e.g. service life and waste in the environment), or has yet to reduce emissions sufficiently so that a reduction in the environmental burden can be detected.

B.9.3.2 Monitoring data submitted by MSCA during consultation

Table 66 summarises monitoring information on decaBDE that was submitted by MSCAs during consultation (responses were received from Austria, Germany, Netherlands, Norway and Sweden). Most of the information comes from Central European or Nordic countries. Monitoring data from some major importing countries, such as Belgium and Italy, are missing. Most of the member states have not reported any observable trends during their measurements.

B.9.3.3 Monitoring data from the literature

B.9.3.3.1 Aquatic compartment

Studies reporting decaBDE exposures in the aquatic compartment (including surface water, sediments and wastewater treatment influents/effluents) were initially collated and summarised in the ESR risk assessment for decaBDE (ECB 2002, 2004 and 2007). Subsequently, additional recent data have been collated from the scientific and grey literature by the Environment Agency of England and Wales (2009) and Kortenkamp et al. (2014). These studies report decaBDE concentrations in the aquatic compartment measured in Europe and elsewhere. Key studies and general trends are outlined briefly below.

B.9.3.3.2 Surface and waste water

In Europe, decaBDE concentrations in surface water are generally close to, or below, analytical limits of detection, i.e. <0.06 - <2.5 µg/l. Monitoring of marine surface waters in the Netherlands using semi-permeable membrane devices detected decaBDE in surface waters at concentrations between <0.1 pg/l and 4 pg/l (Booij et al., 2000). Breivik et al. (2005) report that decaBDE was not detectable in four surface water samples from Lake Mjøsa, Norway (limit of detection was <~20 pg/l), although decaBDE was detected in samples of effluents from nine sewage treatment plants in the area. DecaBDE is present in urban stormwater as well as industrial and sewage treatment effluents (EC, 2002; ECB, 2004; ECB, 2007; EA, 2009). Kortenkamp et al. (2014) based their PBDE mixtures risk assessment for freshwater on dissolved (67.0 and 52.0 pg/l decaBDE) and suspended particulate (5.7 ng/l and 3.9 ng/L decaBDE) data from typical cultured fish ponds in South China (Zhang et al., 2010, as reported in Kortenkamp et al., 2014).

Table 66: Summary of MSCA environmental concentration data on decaBDE, collected through consultation

Compartment	Austria[(a)]	Germany	Netherlands	Norway	Sweden
Ambient air	Rural-urban: n.d. – 100 pg/m^3 (2011) Alpine: n.d. - 73 pg/m^3 (2005 - 2007)	0.97 – 56 pg/m^3 (2002 - 2009)	-	<0.01 – 2.409 pg/m^3 (2010 – 2012)	0.2 pg/m^3 (2009 - 2010)
Deposition	Rural-urban: n.d. – <45 ng/m^3 (2011) Alpine: n.d. - 232 ng/m^3 (2005 - 2007)	-	-	-	-
Surface water	n.d. – 0.24 µg/L (2011) n.d. - <18 µg/L (2012)	-	-	<0.02 µg/L (2012)	-
Groundwater	n.d. - <18 µg/L (2012)	-	-	-	-
Sediments	-	-	-	Salt water: 0.25 – 1,555 µg/kg dw (mean 110) (2003 – 2012) Fresh water: 0.04 – 415 µg/kg dw (mean 15) (2003 – 2008)	-
Sewage sludge	-	Sewage sludge: 97 – 2,200 µg/kg dm (2002 – 2003)	-	44 – 2,000 µg/kg dw (mean 269) (2006 – 2011)	-

Compartment	Austria[(a)]	Germany	Netherlands	Norway	Sweden
Indoor air	House dust: 3.8 – 170 µg/kg (2003)	Air: 0.66 – 190 pg/m^3 (2002 – 2009) Dust: 19 – 19,000 µg/kg (2001 – 2003) Dust (12 cars): 220 – 3,100 µg/kg (2010 - 11) Dust (12 offices): 28 – 310 µg/kg (2010 – 11) Dust (1 home): 21 – 72 µg/kg (2010 – 11)	-	-	-
Soil	Mineral, rural: n.d. – 2.3 µg/kg dw (2008) Mineral, rural: n.d. – 1.7 µg/kg dw (2011) Humus layer: 0.6 – 11 µg/kg dw (2004)	Humus*: 0.35 – 8.9 µg/kg dw (2002) Humus*: <0.01 – 81 µg/kg dm (2006) Humus (alpine)*: 0.61 – 11 µg/kg dw (2004) Forest top soil*: "*Some to several 10*" µg/kg dw (2006 – 2007)	-	Soil: 0.17 – 4.34 µg/kg dw (2005) Moss (wet): 0.03 – 0.66 µg/kg ww (2002) Moss (dry): 0.43 – 8.64 µg/kg dw (2005)	-
Solid waste	-	Parts of used devices: 100 – 7,800 mg/kg Municipal sewage sludge: 0.012 – 8.5 mg/kg SLF: 0.76 – 75 mg/kg Municipal solid waste: 0.008 – 0.13 mg/kg	-	Landfill leachate: 0.09 µg/l (2006 – 2010) Landfill (sediment): 0.05 µg/l (2006 – 2010)	-

Compartment	Austria(a)	Germany	Netherlands	Norway	Sweden
Biota	Spruce needles: n.d. – 1.2 ng/kg dm (2004)	Eggs of herring seagulls: 3 – 198 µg/kg lw (1998 – 2008) Bream muscle: 0.46 – 663 µg/kg lw (1995 – 2009) Deer liver*: 0.47 – 29 µg/kg lw (2001 – 2007)	-	0.01 – 10.51 µg/kg w/w (1993 – 2012)	2 eggs of herring seagulls: 0.21; 0.28 µg/kg fw
Food	-	-	<1 – 311 ng/kg (2006)	(c)	Fats: 89 ng/kg fat (2010)
Human tissue	-	-	-	(c)	Serum (1st time mothers): 0.95 µg/kg lw (2010)
Maternal milk	n.d. – 13 µg/kg fat (2008)	0.1 – 4.5 µg/kg milk fat (2001 – 2004)		(c)	1.5 µg/kg lw (2007)

*: total PBDE concentration

[a]: A total of 14 grassland sites under extensive use were selected in the federal provinces of Burgenland (BGL), Carinthia (KTN), Upper Austria (OÖ) and Styria (STM), and soil samples were taken at depths of 0–5 cm and 5–10 cm. The contents of 25 congeners of the possible 209 PBDE compounds were analysed within the framework of this study. It appears that the verifiability and magnitude of PBDE levels vary considerably in the congeners. Highest levels (up to 3,900 ng/kg DS) have been found for decaBDE (BDE-209). The total values from the sum of all 25 analysed PBDEs are between 14.3 and 5,283.9 ng/kg DS.

[b]: Monitoring information from Denmark has been submitted through (Danish EPA, 2013) and was incorporated in the main body of this report.

[c]: These will be described by the Norwegian CA in the chapter on human biomonitoring data in Part B of the restriction dossier.
Source: Consultation (specific sources can be found in the respective questionnaire)

B.9.3.3.3 Aquatic sediments

DecaBDE is detected much more frequently in aquatic sediments compared to surface waters, which is consistent with its physico-chemical properties, and is frequently reported as the most abundant PBDE congener present (Law et al., 2006; Ross et al., 2009). Extensive data on decaBDE concentrations in European Member States are available in the scientific literature and have been collated and summarised in detail across previous reviews (EC, 2002; ECB, 2004 and 2007; EA, 2009). Therefore this section is limited to an overview describing the breadth of relevant studies that have been published rather than attempting to summarise individual studies in detail. Additional information on methodology or results should be obtained from previous reviews or original manuscripts.

DecaBDE concentrations in UK sediments have been found to range from below the limit of detection (<0.6 µg/kg dry weight) to 3,190 µg/kg dry weight (associated with a local emission source), although the majority of sites have much lower concentrations (Environment Agency, 2002; Law et al., 1996; Allchin et al., 1999; Cefas, 2006).

Concentrations of decaBDE in the 63 µm fraction of 22 European estuarine sediments from the UK, France, the Netherlands and Germany are reported by van Zeijl (1997) and range from less than the limit of detection (~<0.5 µg/kg dry weight) at a reference site to 200 µg/kg dry weight in the Scheldt and 1,700 µg/kg dry weight in the Mersey (UK). All other sites sampled had decaBDE concentrations <50 µg/kg dry weight.

DecaBDE concentrations in surface sediments (0-2 cm) from eight locations in Sweden ranged from <20 – 12,000 µg/kg dry weight (ignition loss basis), with greatest concentrations generally being found downstream from industry (Sellström, 1998).

De Boer et al. (2001) report the results of a detailed investigation into the levels of decaBDE in sediments from the Western Scheldt (NL) and the river Tees (UK). In the Western Scheldt (19 samples) the mean level of decaBDE was 172 µg/kg dry weight and the highest concentration observed was ~1,000 µg/kg dry weight. In the Tees (50 samples) decaBDE was not generally detected in the upper Tees stretches (<0.2 µg/kg dry weight), but was observed at a mean concentration of 170 µg/kg dry weight and 240 µg/kg dry weight in the lower Tees and Tees estuary, respectively. The levels of decaBDE in sediments in and around the Scheldt basin were further elaborated on by de Boer et al. (2003). DecaBDE was found in 17 out of 19 samples (detection limit was 0.1 µg/kg wet weight) at concentrations of 0.7 to 700 µg/kg dry weight. Vethaak et al. (2002) report decaBDE concentrations of <9.0 – 510 µg/kg in sediments collected from various locations in the Netherlands, with the greatest concentrations observed in samples from the Scheldt.

Sawel et al. (2002) report that decaBDE was found in 32 of 33 sediment samples from the River Danube and its main tributaries. The concentration of decaBDE was found to range from 0.032 – 83.8 µg/kg dry weight, with a median concentration of 3.30 µg/kg dry weight. DecaBDE was detectable in 93% of samples and the levels found were generally lower in rural regions than in industrialised areas. The highest concentration (83.8 µg/kg dry weight) was found at the Moson Danuber arm in an industrialised region with textile, electronics, plastics and automotive industries.

Additional data on decaBDE in aquatic sediments are reported for Denmark (Christian and Platz, 2001), The Netherlands (Klamer et al., 2005; Verslycke et al., 2005), Norway (SFT 2005), Belgium (Voorspoels et al., 2004; Covaci et al., 2005), Spain (Eljarrat et al., 2004, 2005 and 2007) and Switzerland (Kohler et al., 2008). SFT (2002) report concentrations of decaBDE of 0.49 – 91 µg/kg wet weight in sediments associated with effluents from six waste sites in Norway. However, Kilemade et al. (2004) did not detect decaBDE in surface sediments for sites in Cork Harbour, Ireland. The detection limit in this study was 0.1 – 0.11 µg/kg dry weight.

De Boer (2001) and Kemmlein (2000) report that polybrominated diphenyl ethers (PBDEs) are present in European sediments from the 1960s onwards with decaBDE generally detected from around the 1970s. Temporal trends of decaBDE concentrations in sediment cores from Europe have also been reported by Zegers et al. (2000 and 2003), Kohler et al. (2008) and Vane et al. (2010). These studies generally show a trend of increasing concentrations of decaBDE in sediments since it was first detected (EA, 2009). Zegers et al. (2000 and 2003) observed that decaBDE levels in sediments from sites in Norway, the western Wadden Sea and Lake Woserin (Germany) had peaked between ~1985 to 1998. De Boer (2001), meanwhile, report a general trend of increasing concentrations of decaBDE since 1995 (by around 50-100%).

DecaBDE has also been detected in sediment samples outside of Europe with levels up to 6 mg/kg dry weight measured in Japan (Environment Agency Japan, 1991) and up to 14 mg/kg in the United States (Zweidinger et al., 1979). Choi et al. (2003) report the concentration of total polybrominated diphenyl ether in sediment cores (decaBDE being the major congener found) from Tokyo Bay, Japan. Low concentrations were observed in cores corresponding to 1904-1941, with a rapid increase in concentration from 1946-1948 onwards, peaking at 78.1 µg/kg dry weight in 1992-1993. Concentrations in the core from 1998-1999 were similar to 1992-1993 data, at 76.6 µg/kg dry weight. Based on a comparison with data on use the authors conclude that a lag of around 10 years between peak use and deposition in the sediments is present. Ohta et al. (2002) also report decaBDE concentrations in sediments in Japan. DecaBDE was detected at 7.8 – 350 µg/kg dry weight in the coastal area around Osaka Bay. Chen et al. (2007a) report that decaBDE concentration in the Pearl River Delta in China remained constant until 1990 and thereafter increased exponentially with doubling times of 2-6-6.4 years. Similarly, Kwan et al. (2014) reported rapid increase in decaBDE concentrations in sediments from Thailand corresponding to 1980-1990 equivalent to a doubling time of 6-7.5 years. Concentrations are reported to have peaked in the mid 1990s.

Marvin et al. (2013) investigate the spatial and temporal trends of PBDEs in suspended sediments the Detroit River, US. Concentrations of decaBDE ranged from 4 µg/kg to 60-180 µg/kg and were dependent on the proximity to large urban areas, which can act as a diffuse source of PBDEs.

Kortenkamp et al. (2014) based their PBDE mixtures risk assessment for freshwater sediment on decaBDE concentrations for South China fish ponds of 8.5 and 16.1 µg/kg (Zhang et al., 2010, as reported by Kortenkamp et al., 2014) and for the Detroit river of 24.7 and 59.1 µg/kg dry weight (Marvin et al., 2013, as reported in Kortenkamp et al., 2014). Marine sediment mixtures risk assessment was based on decaBDE concentrations of 3.6 and 75.1 µg/kg dry weight from South China (Yu et al., 2011, as reported by Kortenkamp et al., 2014) and 2.5 µg/kg dry weight from Vancouver Island, Canada (deBruyn et al., 2009, as reported by Kortenkamp et al., 2014).

B.9.3.3.4 Soil

In Europe, Sellström et al. (2005) detected decaBDE in a farm soil from southern Sweden at a concentration of 2,200 µg/kg dry weight. The farm had previously received sewage sludge from a wastewaster treatment works that treated waste from the textile industry. The concentrations of decaBDE at a local reference site was 0.75 µg/kg dry weight. Eljarrat et al. (2008) determined the levels of decaBDE in samples of soils from Spain. The sites chosen were used for the cultivation of winter crops and had been amended with sewage sludge since 1997. DecaBDE was present in all soils, with concentrations in the sewage sludge amended soils in the range of 24.6 – 655 µg/kg dry weight compared to 14.6 µg/kg dry weight in the control soil. The greatest concentration was measured in soils that had received repeated additions of sewage sludge since 1997, suggesting that decaBDE can build up in soils following repeated additions of sewage sludge.

Offenberg et al. (2006) detected decaBDE in 26 out of 22 soil samples from across the US (detection limit was 0.21 µg/kg dry weight). The mean concentration was 21.1 µg/kg dry weight (range 0.3 – 342 µg/kg dry weight).

The mean, median and range of decaBDE in 30 soil samples from Japan have been reported by Hirai and Sakai (2004) as 10 µg/kg, 0.4 µg/kg and 0.06-195 µg/kg, respectively. Similarly, Hayakawa et al. (2004) measured decaBDE at a concentration of 6.9 µg/kg in a sample from Kyoto University. Wang et al. (2005) report a decaBDE concentration of 1,026 µg/kg dry weight in soil from an open waste electronics treatment site in Japan. Additional data on decaBDE concentrations in soils in China are reported by Duan et al. (2010), Gao et al (2011), Li et al. (2013), Meng et al. (2011), She et al. (2013) and Wang 2011). Concentrations of decaBDE in Pakistan are reported by Syed et al. (2013).

Kortenkamp et al. (2014) based their mixtures risk assessment for soil on data reported by Li et al. (2011), Yang et al. (2008), Jian et al. (2010), Zhang et al. (2010) and Yu et al. (2011). All studies were from China and reported soil concentrations of decaBDE between 0.48 (urban soil) and 3,288.1 (soil from e-waste site) µg/kg (based on data reported by Kortenkamp et al., 2014). DecaBDE was the dominant congener in soils.

B.9.3.3.5 Sewage sludge

DecaBDE has been measured in sewage sludge from Sweden (de Wit, 1999; Öberg et al., 2002; Kierkegaard et al., 2004), Germany (Weisser, 1992; Hamm, 2004; Knoth et al., 2004), the UK (Environment Agency, 2002), Spain (Elijarrat et al., 2008), the Netherlands (de Boer et al., 2002) and Norway (SFT, 2005). The concentrations observed ranged from <0.05 mg/kg dry weight to 57.8 mg/kg dry weight, although in general measured concentrations are in the region of up to a few milligrams per kilogram dry weight (EA, 2009).

Hale et al. (2001) report decaBDE concentrations from <0.075 to 9.12 mg/kg dry weight in 11 sewage sludge samples from the United States. DecaBDE was reported in ten sewage sludge samples from six sites in Canada at concentrations of 360 – 830 µg/kg dry weight (Kolic et al., 2003). Wang et al. (2007) report decaBDE concentrations up to 1,109 mg/kg dry weight (mean of 68.5 µg/kg dry weight) in sewage sludge from sites across China. Ran et al. (2013) report additional data for China with concentrations of decaBDE ranging from 9.85 and 5,010 µg/kg dry weight (mean of 1,092 µg/kg dry weight). Mean concentrations of decaBDE in rural and urban sewage sludge from Australia were 490 and 880 µg/kg dry weight, respectively (Clark et al., 2008).

Kortenkamp et al. (2014) base their PBDE mixtures assessment for sewage sludge on data reported by Hwang et al. (2012) for sewage sludge samples from China.

B.9.3.3.6 Biota

As discussed previously for the sediment compartment, extensive data on decaBDE concentrations in biota from European Member States are available in the scientific literature and have been collated and summarised in detail across previous reviews (EC, 2002; ECB 2004 and 2007; EA, 2009; Environment Canada, 2010). Therefore, this section is limited to an overview describing the breadth of relevant studies that have been published rather than attempting to summarise individual studies in detail. Additional information on methodology or results should be obtained from these previous reviews or original manuscripts.

Many of the reported concentrations of decaBDE in biota are normalised to lipid content (see also sections B.4.3 and B.9.6.7). However, metabolism studies have shown that decaBDE is generally associated with blood and blood rich tissues (e.g. liver) rather than lipid, which is supported by evidence from studies with rodents. Care should therefore be taken when interpreting biota biomonitoring data expressed on the basis of lipid content, or studies that specifically target adipose tissues.

Within Europe, decaBDE has been detected in tissue samples obtained from fish, shellfish, other aquatic invertebrates, marine mammals, birds (and their eggs), terrestrial invertebrates and terrestrial mammals (including polar bear).

Vethaak et al. (2002) report decaBDE concentrations in fish muscle from the Netherlands of <0.3 – 0.9 µg/kg dry weight, although decaBDE was not consistently detected. De Boer et al. (2002) report decaBDE concentrations in samples of yellow eels from the Scheldt basin between 0.4 and 0.5 µg/kg wet weight (limit of detection 0.1 µg/kg wet weight). However, decaBDE was not found in the majority of eel or in two samples of cod liver from the North Sea and one sample of hake liver from Southern Ireland that were also included in the analysis. Voorspoels et al. (2003) report decaBDE in pooled liver samples for sole (*Solea solea*), bib (*Trisopterus luscus*) and whiting (*Merlangius merlangus*) at concentrations between 3.4 µg/kg wet weight and 37.2 µg/kg wet weight. SFT (2005) report concentrations of decaBDE in freshwater and marine fish (cod liver) from Norway of 0.02 – 0.08 µg/kg wet weight (3 out of 9 samples) and 0.4 – 3.0 µg/kg wet weight (4 out of 8 samples), respectively.

DecaBDE was detected in the blubber and liver of harbour seals and harbour porpoises, and in the liver of white-beaked dolphin from the North Sea at concentrations of up to 318 µg/kg lipid (de Boer et al., 2001). Vorkamp et al. (2008) report decaBDE concentrations in 57 samples of ringed seal (*Phoca hispida*) blubber from Greenland collected between 1982 and 2006. DecaBDE was detected in 8 out of the 57 samples: one individual from 1982 (3.3 µg/kg lipid), one individual from 1994 (5.6 µg/kg lipid), one individual from 2000 (2.0 µg/kg lipid) and five out of twenty samples from 2006 (0.93-3.3 µg/kg lipid).

RIVO (2003, after ECB, 2004) report the results of an extensive baseline study of the occurrence of decaBDE in tissues (liver and muscle) and eggs from a large number of predatory bird species native to the UK, including terrestrial and aquatic species. Samples were mainly from the UK tissue archive maintained by the Centre for Ecology and Hydrology, but the study also included a small number of samples from the Netherlands and Sweden. Widespread occurrence of decaBDE was observed, irrespective of tissue type and proximity to potential sources. DecaBDE was detected in samples from 10 of the 14 species included in the study. Similarly, Herzke et al. (2003) report the presence of decaBDE in the eggs of predatory birds from Norway, including white-tailed eagle (*Haliaeetus albicilla*), peregrine falcon (*Falco peregrinus*), merlin (*Falco columbarius*), golden eagle (*Aquila chrysaetos*), osprey (*Pandion haliaetus*) and northern goshawk (*Accipiter gentilis*).

A trend-analysis of the concentration of decaBDE in peregrine falcon and sparrowhawk samples from the UK tissue archive from the 1970s to 2003 found that concentrations were clearly higher in 2003 compared to 20 years ago, although this conclusion is based on a relatively small dataset (ECB, 2004).

Knudsen et al. (2005) investigated spatial and temporal trends of decaBDE in eggs from seabirds in northern Norway and Svalbard. The species sampled included herring gulls (*Larus argentatus*), Atlantic puffins (*Fratercula arctica*), black-legged kittiwakes (*Rissa* *tridactyla*) and glaucous gulls (*Larus hyperboreus*). DecaBDE was detectable in 64% of herring gull eggs, 10% of puffin eggs and 32% of black-legged kittiwake eggs. DecaBDE was found in all samples of glaucous gull eggs. However, there were no statistically significant temporal or spatial relationships observed for any species. Knusden et al. (2007) collected liver and brain tissue samples from glaucous gulls in Bjørnøya (Svalbard). decaBDE was detected in 24% of glaucous gull brain tissue samples (mean concentration of 2.9 µg/kg lipid) and 95% of glaucous gull liver samples (186 µg/kg lipid). Fangström et al. (2005) determined the concentration of decaBDE in tissue and egg samples from northern fulmars (*Fulmarus glacialis*) from the Faroe Islands. DecaBDE was not detected in eggs or in samples from juvenile birds, but was present in almost all of the muscle samples from adults at a concentration of up to 62 µg/kg lipid. These data are supported by those of Karlsson et al. (2006) who also report an absence of decaBDE in the eggs of northern fulmars from Faroe.

A similar study was conducted by Verreault et al. (2004) on levels of decaBDE in tissue and eggs samples from glaucous gulls collected from Bear Island (Bjørnøya). DecaBDE was found to be present in 15% of the egg samples (23.2 – 52.5 µg/kg lipid) and 30% of plasma samples (2.76 – 14.7 µg/kg wet weight). Verreault et al. (2005) also collected blood samples from adult glaucous gulls from Svalbard in the Norwegian Arctic. DecaBDE was detected in 50% of blood samples from males (up to 0.21 µg/kg wet weight and 36% of samples from females (0.33 µg/kg wet weight).

Jaspers et al. (2006) investigated the levels of decaBDE in tissue samples (liver and muscle) from terrestrial and aquatic predatory birds from Flanders including, grey heron (*Ardea cinerea*), great crested grebe (*Podiceps cristatus*), barn owl (*Tyto alba*), long-eared owl (*Asio otus*), common buzzard (*Buteo buteo*), kestrel (*Falco tinnunculus*) and sparrowhawk (*Accipiter nisus*). DecaBDE was only detected in samples from terrestrial species (59 µg/kg lipid in barn owl liver, 68 µg/kg lipid in barn owl muscle, 66 µg/kg lipid in long-eared owl liver, 52 µg/kg lipid in sparrowhawk liver, 85 µg/kg in kestrel liver. Voorspoels et al. (2006a) also investigate the levels of decaBDE in birds of prey in Belgium. DecaBDE was not found in samples from the three species of owls sampled (*Asio otus, Tyto alba and Strix aluco*), but was detected in liver samples from buzzards (*Buteo buteo* – 3 out of 29 samples: 19 – 190 µg/kg lipid) and sparrowhawks (*Accipitier nisus* – 2 out of 8 samples: 16 – 19 µg/kg lipid). DecaBDE was detected in the serum of owls (one out of three samples: 9 µg/kg lipid), buzzards (16 out of 20 samples: 2 - 58 µg/kg lipid) and sparrowhawks (2 out of 2 samples: 16 – 36 µg/kg lipid).

Johansson et al. (2009 and 2011) report the occurrence and temporal trends of PBDEs, including decaBDE, in the eggs of peregrine falcon (*Falco peregrinus peregrinus*) in Sweden. Concentrations of decaBDE in eggs were reported to have increased from 1974 to 2007, with an average yearly increase of 15%. Fliedner et al. (2012) report that the concentrations of decaBDE in the eggs of herring gull (*Larus argentatus*) increased over the period of 1998 to 2008 at two rural sites in Germany, although decaBDE was not the dominant PBDE congener. Muños-Arnaz et al. (2011) report that decaBDE was the detected in 100% of samples (and was the dominant PBDE congener) in white stork (*Ciconia ciconia*) from urban Madrid. Bustenes et al. (2007) report temporal trends (1968-2004) in the eggs of tawny owl (*Strix aluco*) in northern Europe. DecaBDE was detected in 63.5% of samples. Mean concentrations in eggs were 1.25 ng/g and 1.28 ng/g for the periods 1986-1995 and 1998-2004, respectively. D. Chen et al. (2010) review global PBDE contamination in birds.

In relation to terrestrial species other than birds, CSL (2005, after ECB, 2007) report decaBDE concentrations for earthworms in central England (4 sites, 4 samples) of <0.06 – 0.52 µg/kg whole weight. Sellstrøm et al. (2005) report maximum decaBDE concentrations of 5200 µg/kg lw in earthworms from agricultural soil treated with sludge contaminated with decaBDE. Voorspoels et al. (2006b) report decaBDE concentrations in samples of muscle

(33 samples), liver (30 samples) and adipose (27 samples) tissue from red fox (*Vulpes vulpes*) from the south of Belgium. DecaBDE was detected in 40% of liver samples (<9.1 – 760 µg/kg lipid), 21% of muscle samples (<3.9 – 290 µg/kg lipid) and 15% of adipose tissues (<3.7 – 200 µg/kg lipid). Concentrations in urban foxes were considered by the authors to be slightly higher than rural foxes, but this could not be confirmed statistically. Voorspoels et al. (2007) investigated the concentration of polybrominated diphenyl ethers in small rodents form the diet of foxes and birds of prey in the studies described above (Voorspoels et al. 2006a/2006b). However, decaBDE was not detected above the limit of quantification (7.3 – 17 µg/kg lipid) in any of the rodent samples (collected from around Antwerp). Mariussen et al. (2008) report decaBDE in the liver of Moose (*Aices alces*) and Lynx (*Lynx lynx*) from Norway, although it was not present in all samples. Paepke et al. (2011) report decaBDE concentrations of 0.47 – 29 ng/g in deer liver from Germany sampled between 2001 and 2007.

Several studies have investigated the concentration of decaBDE in polar bears (*Ursus maritimus*). Gabrielsen et al. (2004) analysed the adipose tissue of 15 bears from Svalbard (Sampled 2002) and decaBDE was not detected (limit of detection was 0.1 µg/kg wet weight). Verreault et al. (2005), presumably as part of the same project, reported the concentration of decaBDE samples of plasma from 15 samples of polar bears from Svalbard (Sampled 2002). DecaBDE was detected in a single individual (0.1 µg/kg wet weight). The limit of quantification was 0.06 µg/kg wet weight. Sørmo et al. (2006a and 2006b) report a mean decaBDE concentrations in polar bears of 0.022 µg/kg whole body weight (~0.09 µg/kg lipid in adipose). Two recent BDE-monitoring studies focusing on mammals with the aim to provide an overview of the BDE body burden for certain species and exposure scenarios, but not specifically focusing on decaBDE, were identified. Guo et al. (2012) analysed the BDE pattern in household cats and found their pattern quite similar to the congener composition of household dust, and clearly different from the typical BDE burden of humans. This led the authors to conclude that dust is the major uptake route of BDEs into cats. Christensen et al. (2013) investigated the uptake and elimination of BDEs in grizzly bears. The authors identified a clear seasonality of the BDE sources. In spring decaBDE originated mainly from vegetation, whilst in autumn salmon were the main source of decaBDE intake.

DecaBDE has also been reported for to be detected in moss from Norway (SFT, 2002; Mariussen et al., 2008; Norwegian Climate and Pollution Agency, 2012).

Analysis of decaBDE in biota has also been undertaken outside Europe, including the US (Dodder et al., 2002; Oliaei and Hamilton, 2003; Gauthier et al., 2008; Park et al., 2009), Canada (Ikonomou et al., 2000 and 2002; Chen et al., 2007b and 2012a/b; Plourde et al., 2013; Chabot-Giguere et al., 2013), Japan (Akutsu et al., 2001; Hori et al., 2000; Mizukawa et al., 2013) and China (Mo et al., 2012/2013; He et al., 2012; Wu et al., 2008/2009).

B.9.3.3.7 Air

DecaBDE in outdoor air has been reported at concentrations of up to 105 pg/m^3 in Ontario, Canada (as reviewed by Harrad et al., 2010). However, decaBDE has also been detected in outdoor air in Europe, i.e. Italy (Vives et al., 2007), Spain (Quintana et al., 2006), Austria (Gans et al., 2007) and France (Castro-Jiménez et al., 2011) as well as the Arctic (de Wit et al., 2010; Konoplev et al., 2012). The highest reported levels in remote regions were measured in air-aerosols over the Arctic Ocean (41 pg m^{-3}, Wang et al., 2005). DecaBDE concentrations in the air in arctic regions are increasing, with doubling times in the range of 3.5-6.2 years (Su et al., 2007; Hung et al., 2010).

Where concentrations of multiple congeners were reported, decaBDE is often the prevalent PBDE congener. However, in some studies other PBDE congeners (i.e. BDE-47 and 99) were more prevalent than decaBDE, e.g. studies from the US (as reviewed by Besis and Samara, 2012). DecaBDE has been shown to be the dominant PBDE in air samples from Alert on Ellesmere Island (Muir & de Wit, 2010) and Zeppelin mountain on Spitsbergen, Norway (Norwegian Environment Agency, 2012/2013). DecaBDE in indoor environments has also been found to be a significant source of decaBDE to urban outdoor air (Björklund, 2012; Cousins, 2014).

B.9.3.4 Summary of environmental exposure

In older studies decaBDE was initially detected infrequently in aquatic species (i.e. fish, invertebrates and marine mammals) sampled within the EU. These results were associated with issues surrounding analytical sensitivity and, in some instances, reproducibility of measurements. However, over the past 10 years, improved analytical methods have been developed to measure decaBDE with good accuracy and precision. With the use of these methods, reliable data on the presence and concentration of decaBDE in the environment and wildlife have been generated. It can be concluded that decaBDE is present almost ubiquitously in the European environment and in European wildlife, albeit in low concentrations in some species (i.e. marine mammals).

DecaBDE has been found over a wide scale at low (parts per billion) levels in a variety of predatory and other bird species, including their eggs, across Europe and elsewhere (i.e. arctic regions). Given these findings it can be anticipated that other bird species would also accumulate decaBDE, and this is confirmed by detection of decaBDE in samples of glaucous gull from polar regions. Terrestrial species (especially bird-eating species) appear to have the highest levels in relative terms, i.e. Eurasian sparrowhawk and peregrine falcon.

The exact route of decaBDE into these organisms is not clear, but could be occurring via diet, water and air as well as through ingestion of contaminated sediment or soil.

Conclusions:

- DecaBDE can be found widely in sediments and sewage sludge, where it is frequently the dominant PBDE congener present. Based on the available data, decaBDE should be considered as ubiquitous in these environments in some parts of Europe.
- Sewage sludge is a potentially major source of decaBDE to agricultural land because of sludge spreading. The levels of decaBDE found in sludge in the EU in recent studies are generally around 0.1 mg/kg dry weight up to a few mg/kg dry weight. It is expected that decaBDE will be persistent in agricultural soils once applied, and indeed Sellstrøm et al. (2005) detected levels of a few mg/kg dry weight in a farm soil in Sweden that had last received an input from sludge around 20 years before.
- DecaBDE can be detected in a wide variety of biota, including aquatic organisms. It is frequently detected in invertebrates, fish, predatory birds and some mammals. There is some indication that levels in terrestrial species might be higher than those in the aquatic organisms. Its presence in the tissues of so many species is a cause for concern.

B.9.4 Other sources (for example natural sources, unintentional releases)

The EU RAR (2002) for decaBDE indicated that a number of brominated compounds structurally similar to the brominated diphenyl ethers have been found in some marine species, especially marine sponges, many of the compounds demonstrating antimicrobial properties. Compounds with 4 to 6 bromine atoms/molecule have been detected in some tropical species and green alga from a variety of marine and freshwaters, including the Baltic Sea. Overall, there is a wide range of chemical substances formed naturally in some marine species, similar to the polybrominated diphenyl ether flame retardants. Some of the naturally occurring compounds may cause interferences in analytical methods used to detect the polybrominated diphenyl ether flame retardants in the marine environment. However, such interference is unlikely in the determination of decaBDE, since the natural substances generally have 4 to 6 bromine atoms/molecule.

B.9.5 Analytical challenges and possible uncertainties

The determination of decaBDE has historically been affected by analytical difficulties (Alcock et al., 2011; de Boer and Wells, 2006; Stapleton et al., 2006; Björklund et al., 2004; Covaci et al., 2003; Tollbäck et al., 2003). Loss and degradation may arise during sample preparation and instrumental analysis by gas chromatography-mass spectrometry (GC/MS). Problems reported in the analysis cover the tendency of decaBDE to degrade in UV-light (Söderström et al., 2004; Päpke et al., 2004; Christiansson et al., 2009; Shih and Wang, 2009). In addition, decaBDE has a strong tendency to be adsorbed onto glassware due to its limited solubility in most organic solvents. Further, decaBDE is thermally labile and may partially degrade in hot and dirty GC-injection ports as well on GC-columns at temperatures above 300°C.

All these factors will lead to an underestimation of the decaBDE content in environmental and human samples. However, if ^{13}C-labelled decaBDE is used as an internal standard these possible losses are compensated for (Björklund et al., 2003; de Boer and Wells, 2006).

These issues were underlined in several interlaboratory comparison studies which frequently have resulted in rather high standard deviations of up to 100% (De Boer et al., 2002; De Boer and Wells, 2006; Alcock et al. 2011). Hence Alcock et al. (2011) pointed out that the problems in the analysis of decaBDE were widespread and data on the environmental fate of decaBDE has to be treated with caution in view of the versatile difficulties associated with its correct chemical analysis.

However, over the past 10 years improved methods have been developed to measure decaBDE with good accuracy and precision. With the use of these methods, reliable data on decaBDE have been generated. Recommendations can be summarized as follows (de Boer and Wells, 2006; Bendig and Vetter, 2013):

- Use of ^{13}C-labelled decaBDE together with electron capture negative ionization MS or electron impact high-resolution MS,
- Avoidance of exposure to UV-light during sample handling and storage,
- Use of moderate temperature for GC injectors or programmed temperature vaporizer,
- Short capillary GC column length (10-15 m) and thin stationary phase film.

Due to these particular requirements, it is recommended that the instrumental analysis of DecaBDE is performed separately from the lower brominated PBDEs and other BFRs for which higher separation power is required.

A further critical factor in the determination of decaBDE is due to its high abundance in indoor particulate matter (De Boer and Wells, 2006; Harrad et al., 2008). This results in considerable concentrations of decaBDE in solvent blank samples which lead to much higher limits of detection. For decaBDE to be positively detected in a sample extract, its concentration must be significantly higher than in the corresponding blank samples which have been treated the same way as the sample. Blank values for decaBDE may vary considerably, and it is therefore mandatory to carry out blank analyses more frequent than usual (Frederiksen et al., 2010a). To reduce blank values, laboratories should be kept as clean as possible, all glassware used should be carefully cleaned, heated to > 450°C and stored wrapped in aluminium foil. All solvents and reagents should be checked for their purity before use, and samples handling in the laboratory should be minimized (Päpke et al., 2004).

Finally, there is a disagreement between research groups of how to report concentrations of decaBDE in environmental biota and human samples. Most papers report concentrations on mass basis, e.g. ng/g. However, Thuresson et al. (2005) pointed out that when compounds of highly variable masses, such as decaBDE (MW 959) and BDE-47 (MW 486), are compared, the most correct way is to present concentration on a molar basis (pmol/g). This is also reasonable from a toxicological view as it is molecules in a given matrix that interact with biological macromolecules (e.g. DNA, enzymes, and receptors) leading to potential toxic effects.

Further, concentrations of lipophilic compounds in biological material are often normalised to the lipid content in order to compare concentrations between tissues and species. However, the lipid adjustment of the highest brominated congeners, e.g. decaBDE, has been critically discussed (Frederiksen, 2010c). A study of body distribution in rodents showed that the tri- to hexaBDEs were fairly uniformly distributed within body lipids, but the hepta- to decaBDEs accumulated primarily in highly perfused tissues such as liver and kidney (Huwe et al., 2008). Therefore, it seems most meaningful to report concentrations of highly brominated BDEs, in particular decaBDE, both on lipid and wet weight basis in biological material.

In general, reliable measurements depend critically on validated and tested methods, comprehensive quality systems, and traceability to appropriate measurement references. Today, such methods for the determination of decaBDE are available and taking all the measures listed above, reliable determinations of trace levels of decaBDE in environmental media and human tissues are possible.

B.9.6 Overview of human biomonitoring data on tetra- to heptabrominated diphenyl ethers

The basis for the identification of decaBDE as a PBT/vPvB was its potential to degrade into lower brominated PBDEs with PBT/vPvB properties. Therefore, the available exposure data for tetra- to heptabrominated PBDEs compliments exposure data for decaBDE and is likely to be useful when considering the cost-effectiveness and proportionality of the proposed restriction for decaBDE. It should be noted that because of historic and contemporary releases of lower PBDEs there is uncertainty with regards to the exact proportion of lower PBDEs detected in humans and the environment that are present as a consequence of the degradation of decaBDE i.e. they may have been released to the environment as lower PBDEs.

PBDEs have been marketed as flame retardants as three technical mixtures named Penta- Octa- and c-decaBDE after the dominating congeners present (La Guardia et al., 2006).

The volumes of usage and product patterns have varied greatly between geographical regions and over time (de Wit et al., 2010). Some of the strictest fire safety regulations are in North America, and this has resulted in an extensive use of particularly pentaBDE in the region. In Europe, UK has very high fire safety standard, and primarily c-decaBDE has been used (Harrad et al., 2008). Although penta- and octaBDE mixtures have been banned and voluntarily phased-out, human exposure continues due to the occurrence of these flame retardants in products in use and release from secondary sources such as contaminated

soils and sediments.
Compared to c-decaBDE many more exposure studies have been performed on tetra- to heptaBDEs, and the literature on external and internal exposure has been thoroughly reviewed (Hites, 2004; Frederiksen et al., 2009a).

B.9.6.1 External exposure

Tetra- to heptaBDEs are recognized as hydrophobic, highly persistent and bioaccumulative compounds (Stockholm Convention). They accumulated in lipid-rich tissues of animals at all stages of the food chain. Diet has therefore been considered as a major source to human exposure (Sjödin et al., 1999). Market basket studies on PBDEs have been performed in Europe (Knutsen et al., 2008) and the USA (Schecter et al., 2004). Calculations from market basket studies have shown an approximate daily intake of 23-88 ng PBDEs for both Europe and North America (Frederiksen et al., 2009a). Fish and other sea food was often found to be the main dietary source in Europe (Knutsen et al., 2008), while in the USA, the equally high or even higher PBDE intake was associated with meat and dairy products (Schecter et al., 2008). Although indications of higher PBDE levels were observed in US food compared to Europe, these differences cannot explain the large differences in human tissue levels, being about an order of magnitude higher in the US (Frederiksen et al., 2009a). In addition, poor correlations between PBDEs and PCBs in human tissues indicate different or additional sources of exposure (Bradman et al., 2007).

Relatively high concentrations of PBDEs in indoor air and in house dust have suggested a "missing link" in exposure analysis (Jones-Otazo et al., 2005). A number of studies in different countries have produced data on the occurrence of PBDEs in indoor environments. These studies give evidence of geographical differences in PBDE levels, probably due to different application patterns. PentaBDE was predominantly used in North America, which is reflected in the highest dust concentration in a global perspective, while European concentrations were lower than those from the USA and similar to each other.

In conclusion, diet and the indoor environment are recognized as main sources for human exposure in terms of daily intake rates (Vorkamp, 2012). However, the contribution of these sources to the total PBDE exposure varies. Exposure estimates from North America generally conclude that unintentional house dust ingestion contributed most to the overall exposure for all life stages except infants (Allen et al., 2007; Lorber, 2008). Mainly owing to lower concentrations in dust, but also differences in diet, most European studies have identified food as the main source of PBDE exposure (Knutsen et al., 2008; Fromme et al., 2009).

Several exposure scenarios have reached the conclusion that the highest daily PBDE intake is that of the breast-fed infant (de Winter-Sorkina et al., 2003; Jones-Otazo et al., 2005; EFSA, 2011). Concentrations of 2-3 ng/g lipid was stated as typical level in breast milk from European countries, while median concentrations for the US were an order of magnitude higher (Daniels et al., 2010).

B.9.6.2 Internal exposure

Breast milk has been widely used for biomonitoring the internal dose of PBDEs. In fact, the first time trend study of Swedish breast milk from 1972 to 1997 revealed an exponential increase in PBDE levels in that period (Meironyté et al., 1999). This raised high concerns about the human exposure to this class of pollutants and started a wealth of research studies. Later studies (Lind et al., 2003; Fängström et al., 2008) showed that breast milk levels reached a plateau at the end of the 1990s and decreased thereafter. This trend is ascribed to the ban and phase-out of the use of penta- and octaBDE.

In contrast to breast milk, blood samples can be obtained from a larger range of the population to assess levels and trends in PBDE body burdens. The typical sum PBDE level (excluding BDE-209) found in studies from Europe is in the range of about 2 to 8 ng/g lipids, which is similar to the concentrations observed in blood samples (Vorkamp 2012). This is one order of magnitude below the US levels which are approximately 30-60 ng/g lipids (Vorkamp 2012).

Several time trend studies on blood exist. A Norwegian study found an increase from 0.44 ng/g lipids in 1977 to 3.79 ng/g lipids in 2003 (sum PBDE excl. decaBDE). Maximum concentrations were observed in the late nineties and concentrations seem to be levelling off after that (Thomsen et al., 2007). A significant increase in PBDE concentrations was also observed in US citizens between 1985 and 2002, ranging from 9.6 to 61 ng/g lipids (median sum PBDE (excl. decaBDE)(Sjödin et al., 2004).

Several studies have documented the presence of PBDEs in umbilical cord blood and have thus demonstrated that placental transfer does take place, and the foetus is exposed to PBDEs. Lipid normalised umbilical cord values are lower than the maternal blood, but in the same order of magnitude. Maternal and umbilical cord levels are generally highly correlated (Mazdai et al., 2003; Frederiksen et al., 2010a). In addition to direct analysis of umbilical cord blood and placenta tissue, the kinetics and the extent of placental PBDE transfer have been studied in a human *ex vivo* placenta perfusion system (Frederiksen et al., 2010b). It was found that the placental transfer increases with decreasing degree of bromination. The foetal/maternal ratio for BDE-47 was determined to 0.47, i.e. about one third of the PBDEs in the maternal circulation are transferred to the foetus.

B.9.6.3 Congener patterns

Early studies have focused on measuring BDE-47, which has been the most abundant congener of the tetra- to heptaBDEs in human tissues and body fluids. While the pattern of these congeners in house dust is similar to that of the technical pentaBDE mixture, in breast milk and blood, the ratio between BDE-47 and -99 strongly increased as well as the fraction of BDE-153. This shift in congener composition from abiotic to biotic matrices is not unexpected and explained by differences in persistence, bioaccumulative properties as well as metabolic transformation of the individual congeners (Stapleton et al., 2004). Further, a temporal trend with decreasing proportion of BDE-47 and increasing proportion of BDE-153 has been observed (Fängström et al., 2005). The reason for this development is not completely understood, but is likely to be connected with the longer half-life of BDE-153 (Knutsen et al., 2008). Whether or not a debromination of decaBDE is involved in the increase in BDE-153, is not yet known.

B.10 Risk Characterisation

B.10.1 General introduction

In general, due to the high uncertainties regarding long-term exposure and effects, the risks of PBT/vPvB substances, such as decaBDE, to the environment or to humans via the environment cannot be adequately addressed in a quantitative way, e.g. by derivation of PNECs (or DNELs). Therefore a qualitative risk assessment should be carried out. Risks to workers as a result of direct exposure to a PBT/vPvB substance may be assessed quantitatively if a suitable threshold based on another hazardous property can be derived (ECHA 2012). In these cases the application of a higher margin a safety (i.e. risk quotient of workplace exposure / DNEL <<1) is considered appropriate to take account of the PBT/vPvB nature of the substance. However, quantitative assessment is undertaken principally to guide the selection of appropriate risk management measures and operational conditions commensurate with the minimisation of exposure, rather than the derivation of an exposure that could be considered not to pose a risk. Irrespective of these considerations, the human health effects of decaBDE in section B.5 are presented to aid discussions on the proportionality and cost-effectiveness of the proposed restriction, and are not considered to be the principal motivation for the development of this Annex XV dossier, which is primarily concerned with emissions to the environment. As such, quantitative risk assessment of the human health risks of decaBDE to workers has not been undertaken as part of this restriction proposal.

Consequently, this section summarises the sources, releases and likely routes of exposure of decaBDE to humans and the environment and therefore its PBDE transformation products. Exposure, in the case of a PBT/vPvB, can also be usefully considered as a proxy for risk i.e. during considerations of the proportionality of the proposed restriction).

B.10.2 Summary of information on releases

In the EU decaBDE is no longer manufactured but is imported as a substance (on its own or in mixtures), and in articles. It is released from the formulation and processing stage ("production"), the service life of articles and from the waste stage (recycling, landfilling and incineration). The total releases are estimated to be in the range 0.06% (low emission scenario) and 0.17% (high emission scenario) of the total tonnage of decaBDE used every year.

The industrial use of decaBDE is wide dispersive. As a general purpose flame retardant decaBDE is assumed to be used and released at many professional and industrial sites. The Annex XV SVHC report (2012) indicates more than 100 sites of compounders/formulators, master batchers, injection moulders and finishers in the EU. VECAP data (2013) are used as a basis for emissions from all EU "production" in the low emissions scenario. However, VECAP does not cover all production but mainly polymer processing and textile finishing and not all companies in this sector are members of VECAP. No information is available regarding releases from the use of decaBDE in adhesives, sealants, coating and inks. In order to take into account potential higher releases from these uses and from companies which are not members of VECAP, the OECD ESD methodology (RPA, 2014) was used for the high emissions scenario.

The article service life appear to be the major factor for describing releases of decaBDE (83% and 84% of the total releases for the low and high emission scenario, respectively). DecaBDE is used in a number of plastic and textile articles and in adhesives, sealants, coatings and inks for both professionals and consumers. It is also found in imported and exported articles. The amount of decaBDE imported in articles is not known but in this assessment it is assumed to be 10 % of the amount imported as a substance. However, there is considerable uncertainty is this estimate.

It appears that the ultimate fate of the vast majority of products containing decaBDE is landfill. The emissions from the waste stage are estimated to be between 2% and 7% of the total for the low and high emission scenario, respectively. The long-term emission potential of decaBDE in the landfills is poorly known although there is a potential for a release to the environment of decaBDE, or its degradation products, at a later stage.

B.10.3 Human Health

B.10.3.1 Human exposure to decaBDE

Commercial decaBDE is used in many consumer products including plastics, textiles and furniture (foam) and might leach from the products into house dust and indoor air. Most studies on PBDEs in dust from the indoor environment show decaBDE to be the dominant congener and the indoor environment has recently been recognised as an important exposure pathway. Humans are exposed to decaBDE in indoor air through inhalation of decaBDE bound to particulates and through ingestion of dust contaminated with decaBDE. In European house dust, the decaBDE concentration ranged from 63 to 10000 ng/g in dust samples from Germany, Sweden and the UK (Fromme et al., 2009). Dust in cars may also be a significant source of PBDE exposure. For example, a recent German study found mean decaBDE concentrations in car, house and office dust samples of 940, 45 and 120 ng/g, respectively (Brommer et al., 2012).

The main routes of human exposure to decaBDE include food consumption (indirect exposure via the environment), ingestion of house dust and to a lesser extent inhalation of particulate bound decaBDE in indoor and outdoor air and via skin uptake. The exact contribution of each pathway may vary substantially between individuals and within different populations. In addition, direct contact with consumer products may be a source of exposure, however more detailed information to this end is lacking. Further, the foetus is exposed to decaBDE through transport across the placental barrier and infants are exposed through the consumption of breast milk.

Human exposure to decaBDE on a body weight basis depends strongly on the life stage. Young children appear to be the age group with the highest exposures. Breastfed infants are also quite highly exposed on a body weight basis. However, exposure to decaBDE has been found to decline somewhat with increasing age.

The internal dose as measured in biomonitoring data (e.g. blood concentrations) reflects an integrated exposure over time comprising various sources and pathways and also takes individual differences into consideration (e.g. age and gender). A large number of scientific studies have shown decaBDE to be frequently detected in human blood and breast milk, proving that humans are extensively exposed to decaBDE. Further, the presence of decaBDE in placenta and samples of cord blood confirms prenatal exposure. In many of the studies, decaBDE was the PBDE congener present in highest amounts, particularly in breast milk.

Median blood levels in Europe of decaBDE are generally in the range of <0.7 to ~5 ng/g lipids for adults with no known occupational exposure (reported values range from < 0.45 to 50 ng/g lipids). The levels reported on a lipid basis seem to be quite similar in foetuses, children and adults throughout the world. However, significantly higher concentrations are seen in occupationally exposed persons.

B.10.3.2 Human exposure to lower brominated congeners

The historical use of commercial mixtures of penta- and octaBDE (which also contain other PBDE congeners) were the major sources of tetra- to heptaBDEs to the environment and biota. Despite controls on these mixtures, exposure from these sources continues due to the occurrence of these flame retardants in products still in use and from the waste stage, as well as release from secondary sources such as contaminated soils and sediments.

Debromination of decaBDE is considered to constitute an additional source of exposure of humans to tetra- to heptaBDE congeners indirectly via the environment due to a combination of abiotic and biotic debromination in the environment, as well as biotransformation in organisms.

For the tetra- to heptaBDEs diet has been considered as a major source to human exposure in Europe. Calculations from market (food) basket studies have shown an approximate daily intake of 23-88 ng PBDEs (Frederiksen et al., 2009a). Fish and other sea food were often found to be the main dietary source in Europe. The indoor environment is also recognised as a significant source for human exposure mainly due to ingestion of house dust.

B.10.4 Environment

B.10.4.1 Environmental exposure to decaBDE

In the EU, decaBDE is released from all life cycle stages except manufacture, which no longer takes place. Article service life appears to be the major source of release to the environment although significant amounts of decaBDE are also predicted to be present in landfills from the disposal of end-of-life articles. The long-term emission potential of decaBDE once in landfill is poorly understood.

DecaBDE is present almost ubiquitously in the European environment and in European wildlife, albeit in low concentrations in some species (i.e. marine mammals). DecaBDE can be found widely in sediments and sewage sludge, where it is frequently the dominant PBDE congener present. During wastewater treatment decaBDE partitions to sewage sludge, which can subsequently be incinerated, landfilled or used for soil “improvement”. The levels of decaBDE found in sludge in the EU in recent studies are generally around 0.1 mg/kg dry weight up to a few mg/kg dry weight. In air, decaBDE is principally associated with particulates and has the potential for long-range atmospheric transport during dry periods (as demonstrated by its occurrence in environmental media and wildlife in remote areas). Some studies indicate that the levels of decaBDE in the Arctic atmosphere are increasing.

DecaBDE is present in many aquatic and terrestrial species across trophic levels, including top predators and in the tissues of sensitive life stages such as bird eggs. Small amounts of decaBDE can cross the blood-brain barrier in rodents and birds. The exact routes of decaBDE into organisms are not always clear, but could occur via diet, water and air as well as through ingestion of contaminated sediment or soil. Terrestrial species (especially bird-eating species) appear to have the highest levels in relative terms, i.e. Eurasian sparrowhawk and peregrine falcon. DecaBDE is also detected in samples of glaucous gull from Polar Regions. Its presence in the tissues of so many species remains a cause for concern.

Monitoring of the environment through the DECAMONITOR programme over the last six years has failed to demonstrate a change in environmental levels (including in wildlife) over time despite efforts to reduce emissions during the production of articles treated with decaBDE. This suggests that the measures introduced to reduce emissions e.g. via the industry VECAP initiative have not affected the most significant emissions from the decaBDE lifecycle or the emissions have not been reduced sufficiently.

B.10.4.2 Environmental fate and transformation to other PBDE congeners

In the atmosphere decaBDE may undergo phototransformation to several per cent w/w nonaBDEs. Also, small amounts of other PBDEs such as octa- and heptaBDEs might be formed. In aquatic environments, decaBDE has the potential to photodegrade to nona-, octa-, hepta- and hexaBDE congeners, but only a very small fraction of the total decaBDE present in aquatic environments is assumed to be available for photodegradation. Biotic degradation by microbes under environmentally realistic conditions in sediments and in aerobic soil in the presence of plants have been shown to lead to the formation of tetra- to nonaBDEs.

In the SVHC SD it was concluded that, based on the available evidence, there is a high probability that decaBDE is transformed in soil and sediments to form tetra- to heptaBDEs, (or to the higher congeners that can act as precursors) in individual amounts greater than 0.1% w/w over timescales of a year.

Biotransformation of decaBDE into lower PBDEs in biota, including congeners with well-demonstrated neurotoxic properties, have been shown to occur in a number of species, i.e. in fish, birds and mammals.

Most of the transformation studies with biota lack information about the exact percentage of decaBDE transformed to lower PBDE-congeners. However, studies on rats provide good evidence that decaBDE is biotransformed to lower brominated PBDE congeners, including heptacongeners, and these data are of relevance to wild mammals as well. In a recent high quality study with a bird species (kestrels) it was estimated that the half-life of decaBDE in plasma was approximately 14 days and that at least 80% of the non-decaBDE concentrations (including hepta- and hexacongeners) in the kestrel tissues and plasma originated from decaBDE debromination (Letcher et al., 2014).

The high persistence of decaBDE combined with its wide distribution in the environment creates a high potential for lifetime exposure and uptake in organisms. Hence a pool of decaBDE in many localities will act as a long-term source of lower brominated PBDEs through both abiotic and biotic transformation in sediment, soil, water and air and through diet as result of metabolism of decaBDE in biota.

Annex C

C. Available information on alternatives

C.1 Identification of potential alternative substances and techniques

The assessment of technical and economic feasibility of alternatives to decaBDE is primarily focused on the use of alternative **substances**, i.e. chemicals that have flame retardant properties that can be substituted directly for decaBDE in articles. However, alternative **techniques** to improve fire safety also exist and these are described in this section.

This approach was considered appropriate for the following reasons:

- None of the consultees identified during the stakeholder consultation (section G) mentioned that they would use alternative techniques in preference to alternative substances in the event that the use of decaBDE was restricted. For the purposes of the development of this report it was therefore considered most plausible that the industry using decaBDE would switch to a "drop-in" alternative substance rather than adopt an alternative technique. Focussing on this scenario for the assessment of alternatives is therefore of greatest relevance.
- Even if articles produced using the alternative techniques identified could be considered as technically feasible alternatives to articles produced using decaBDE from a fire safety perspective (i.e. they meet fire safety standards), the assessment of economic feasibility is very difficult or impossible to conduct in a meaningful way. This is because the characteristics of articles produced using alternative techniques (e.g. function and aesthetics) may be very different to articles manufactured using decaBDE.

Therefore, alternative techniques have limited relevance for the SEA reported in Part F. This does not exclude the possibility that some companies may move to non-chemical alternatives in the event that the use of decaBDE is restricted, such as those described below.

C.1.1 Alternative techniques

C.1.1.1 Plastics

Various techniques that could be used to replace decaBDE in plastics are described below[53].

- **Intumescent systems**: The mechanism of FRs based on intumescent technologies is to cause the plastic, when heated, to swell (intumesce) into a thick, insulating char that protects the underlying material from burning, by providing a physical barrier to heat and mass transfer. For intumescent technologies, the Danish EPA (2006) suggests that solutions for polypropylene (PP) have been commercially available for many years, but

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[53] Some of the techniques could be categorized also under the section C.1.2 "Alternative substances". However their way of functioning to achieve flame retardancey is based on a different "technique" and/or they need to be used in combination with some other "main" flame retardant substance to achieve the required flame retardancy.

they face both technical and economic viability challenges. The substances concerned often belong to nitrogen-containing or organophosphorous flame retardants (e.g. phosphorous/nitrogen compounds, ethylenediamino phosphate etc.)

- **Nanocomposites**: Mesoporous silicate particles (MSP) are porous silica beads, which when compounded with polymers can form a physically cross-linked polymer-particle network. During combustion, the network provides a char barrier that reduces flame intensity while simultaneously improving the mechanical performance of the polymer. When used on their own, they will not typically result in achieving flame retardancy, but by replacing a portion of the flame retardant loading with about 2 to 8% by weight MSPs, flame retardancy may be reached (US EPA, 2014). According to the UK HSE (2012), research into the use of nanocomposites has focused on plastics like polymethyl-methacrylate (PMMA), polypropylene, polystyrene, and polyamides, and they require special processing. For the time being, PINFA (Phosphorus, Inorganics and Nitrogen Flame Retardants Association) does not consider nanocomposites are viable standalone flame retardants.

- **Expandable graphite**: On exposure to fire, the graphite expands to over 100 times its original size producing a barrier effect. It has been used in thermoplastics and can be used in polyolefins in combination with another FR such as ammonium polyphosphate, magnesium hydroxide, chloroparaffins or red phosphorous (UK HSE, 2012). According to industry, expandable graphite is used in plastics, rubbers (elastomers), coatings, polymeric foams and also in textiles. However, use of synergists is necessary to achieve the required flame retardancy. In some cases, process condition as well as equipment should also be modified (NYACOL, 2014).[54]

- **Smoke suppressants**: In the event of fire these systems lead to the formation of glassy coatings or intumescent foams or dilution of the combustible material, which prevents further formation of pyrolysis products and hence smoke (KemI, 2005). Such systems are of particular relevance to transportation applications of decaBDE. Molybdic oxide is one such substance and common FRs used alongside it include aluminium hydroxide and magnesium hydroxide (KemI, 2005).

- **Polymer blends**: Readily flammable polymers (e.g. HIPS or ABS) may be blended with less readily flammable polymers such as PC, PPO or polyphenylene sulphide (PPS).This enables lower flame retardant loadings to be used with limited impact on other technical properties (UK HSE, 2012). The replacement of decaBDE in EEE enclosures stipulated by the RoHS Directive provide examples of the implementation of such solutions. More expensive polymers such as PC, PPO and PPS (possibly in the presence of a fluorinated polymer (as synergist) so that halogen-free FR options also become possible) may also be used as substitutes to the combination of HIPS/decaBDE/ATO or ABS/decaBDE/ATO while achieving an acceptable processability and recycling properties (JRC, 2007).

  Another option is layering where an article is produced using layers of highly flame retardant filled polymer and low or non-flame retarded polymer. This apparently gives a similar level of fire performance as would be achieved if the entire polymer had been treated, while helping to retain the mechanical properties of the polymer (UK HSE, 2012).).

- **Use of inherently flame retardant materials**: Halogenated polymers such as PVC have flame retardant properties because they release halogen radicals, which have the same effect during combustion as halogen radicals released from halogenated FRs. This

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[54] Available at http://www.nyacol.com/exgraphadv.htm.

effect can be enhanced by the addition of synergists such as ATO to halogenated polymer blends. Polymers that char such as polyimides, polyaramides, liquid crystal polyesters, polyphenylene sulphide, polyarylenes and many thermosets also tend to have a greater resistance to fire. Where the base polymer has flame retardant properties, depending on the end use, a sufficient level of fire performance may be achieved without the need for chemical flame retardants or much lower loadings may be required (UK HSE, 2012).

The following are polymer materials that are inherently flame-retardant and which might be considered as a substitute to decaBDE-based polymers like PBTE or PA (Danish EPA, 2006):

- Halogen-free polyketone (this is considerably more costly than PBTE and PA)
- High performance thermoplastics such as polysulphone, polyaryletherketone (PAEK) or polyethersulphone (PES)

Some examples of new inherently FR materials are mentioned in literature or in commercial web-sites, and these are often promoted as replacements for decaBDE (UK HSE, 2012) (Albemarle, 2013) (Great Lakes, 2013) (PR Newswire, 2010). It may be necessary to change product designs to adopt these alternative materials and their implementation would require higher level of research and development activities than the substitution of decaBDE with an alternative flame retardant.

- **Product redesign:** these options are specifically relevant to EEE (Lowell Center for Sustainable Production, 2005) and they can be:

  - Replacement of the original polymer material with another in combination with shielding of power supplies (this has been the case with a move from HIPS to ABS and additional shielding in printers and related equipment)
  - Removal of the power supply from the product thus reducing the fire retardancy requirements of the electronic enclosure

  Like for the inherently flame retardant materials, it may be necessary to change product designs and their implementation would require higher level of research and development activities than the substitution of decaBDE with an alternative flame retardant.

C.1.1.2 Textiles

Various techniques that could be used to replace decaBDE in textiles are described below:

- **Replacement surface treatments:** There are two types of surface treatments – finishes and coatings. A finish is applied by impregnating the fabrics with an aqueous solution of the chemical. A coating, on the other hand, is the application of a layer on the surface of the fabric generating a heterogeneous fabric/polymer composite (Gnosys, University of Bolton, & Oakdene Hollins, 2010). There are alternative flame retardant substances and potential new variants based on different synergistic combinations that could be used as substitutes for decaBDE. These include intumescent and surface-active fibre systems, as well as systems with graft copolymers (RPA 2014, and references therein).

- **Copolymerisation and fibre blending:** Copolymerisation refers to the inclusion of an additive in the fibre melt spinning process; FRs are added into the molten plastic during the spinning process and become physically part of the fibre matrix (e.g.

organophosphorous added to viscose fibres). This approach is applicable to synthetic fibres only where either one of the monomer/homopolymer can be fire retarded or the FR molecules can be attached to the polymer chain during polymerisation, or FR additives can be in the polymer melt or in solution prior to extrusion (Gnosys et al., 2010). Fibre blending is a very common method of reducing the flammability of flammable fibres. Polyester is usually blended with cotton and this 'poly-cotton', if it has lower than 50% polyester content, can pass the simple vertical strip flammability test. Cotton-nylon blends are also quite commonly used to reduce the flammability of cotton (Gnosys et al., 2010).

- **Fire barriers and composite textile assemblies:** Fire barriers are fire-resistant materials placed either between the exterior cover fabric of the product and the first layer of cushioning materials, or beneath one or more "sacrificial layers" of cushioning. These sacrificial layers are close to the product's exterior surface and provide a desirable aesthetic feel or look (Lowell Center for Sustainable Production, 2005). Fire barriers are made from inherently fire-resistant fibres such as para-aramids, melamines, modacrylics, or glass, and, therefore, do not rely on the use of FR chemicals (Lowell Center for Sustainable Production, 2005).

- **Use of inherently flame retardant materials or materials:** Several materials which are used in textile applications, like natural leather and wool, have inherently fire-resistant properties. Depending on the tightness of the weave (tightly woven heavy wool fabrics, leather with a dense fibre interweaving) they can meat fire safety requirements without any additional flame retardant treatment or in other cases additional substances are used to increase flame retardancy. Flame retardants may also be applied where leather is used for transport applications (e.g. trains) and exceptionally may be applied to safety shoes and safety gloves. However, leather is unlikely to be acceptable in domestic upholstery for consumers who object to the use of animal derived materials. (UK Annex XV SVHC). Inherent Flame Retardant Fibres based on viscose, aramids and polyamides have extensive applications in public places (contract textiles), in the transport sector, in bed mattresses and in protective clothing (e.g. for firefighters and military) (RPA, 2014). In some cases these materials might limit the choice of covering or filling materials, or may produce a less durable product in the case of personal protective equipment (Gnosys et al., 2010). Comments received by industry during the preparation of the Risk Reduction Strategy for decaBDE (RPA, 2003) had suggested that inherently fire-resistant fibres find applications mainly in polyester materials and to a lesser extent in polypropylene and acrylic fabrics. They have poor aesthetics (they are difficult to dye) and are not relevant to the uses of decaBDE. Trials made with inherently fire-resistant acrylics and a phosphorous-based backcoat showed that it might be necessary to use around three times as much FR (for instance, microencapsulated ammonium polyphosphate) to achieve the same flame retardancy as with decaBDE (RPA, 2003).

C.1.2 Alternative substances

The literature includes a long list of substances that might be alternatives to decaBDE. Not all of them are assessed here in detail, since the necessary information for a full analysis is not available and because many of the identified substances would be unlikely to be selected by industry as a suitable replacement for decaBDE. Different considerations are relevant when selecting a replacement for decaBDE. An alternative substance needs to be technically and economically feasible, and be available for the user. In addition, users of decaBDE may be concerned about the hazard profile of the alternatives. For example, they would be unlikely to choose a replacement which is subject to regulatory risk management (i.e. SVHC under REACH) or which may later on become the target of regulatory risk management. However, these decisions will depend on when a possible further regulatory action is envisaged and the ease with which the alternative can be used to substitute decaBDE.

C.1.2.1 Screening

Because of the high number of potential substitutes to decaBDE a screening exercise was carried out to identify the most relevant alternatives for more detailed assessment:

Step 1 – Identification of potentially relevant alternatives

All the alternatives mentioned in the literature or identified by the consultees during the stakeholder consultation were considered as potentially relevant. This includes almost 200 substances.

Step 2 – Screening of technical feasibility of alternatives

(a) alternatives that have been identified by consultees were automatically assumed to be technically feasible (for the applications identified by each consultee), and

(b) the literature was assessed to establish how frequently the identified alternatives were mentioned as suitable replacements for decaBDE in a particular use. The aim of this step was to eliminate substances that would not be among the most likely choices of industry stakeholders as far as the substitution of decaBDE is concerned. The following information sources were considered:

- KemI (2004, 2005, 2009)
- Danish EPA (2006)
- Washington State (2006)
- JRC (2007)
- US EPA (2012)
- Illinois EPA (2007)
- Troitzsch (2011)
- UK HSE (2012)
- Lowell Center for Sustainable Production, (2005)
- EFRA (2012, 2012b)
- PINFA (2013, 2010, 2010b, 2010c)
- DecaBDE manufacturers (Albemarle (2013b) Chemtura (2013), ICL Industrial Products (2013b))
- Member State authorities questionnaire responses for the purposes of this study

The results of this screening step are presented in full in RPA (2014). This step results in a list of 21 substances. It should be noted that this step provides only an indicative estimate of the ‘popularity’ of each alternative.

Step 3 – Screening of economic feasibility of alternatives

The rationale behind this step was to identify which of the alternatives are potentially too costly in comparison to decaBDE and the therefore less likely to become the preferred choice of industry should decaBDE be restricted. The information collected from consultation on the cost of alternatives is very limited, thus it has been complemented by information from the open literature. It should be noted that the previous step already considers economic feasibility to a certain extent.

There is considerable uncertainty in the data used for this step (price per tonne, loading, other changes in formulations and operating costs). Based on the information available none of the alternatives can be assumed to be too costly, and thus unlikely to be used by industry. Therefore, no exclusion of any alternative was undertaken and all 21 alternatives were taken to next screening step.

Step 4 – Screening for hazards

This step was undertaken to screen out potential alternative substances that, if adopted, would not result in a net reduction in risk to either human health or the environment relative to the use of decaBDE. This was based on an assumption that downstream users would not adopt an alternative that had a similar or worse hazard profile than decaBDE (e.g. an SVHC listed on either Annex XIV of REACH or the Candidate List).

Screening was undertaken based on an analysis of the hazard properties of potential alternatives, rather than a comparison of any risk or impacts associated with their use relative to decaBDE. This was because information on potential exposures of alternatives, when used as an alternative to decaBDE, were not available. In addition, as PNEC or DNEL values for the PBT properties of a substance cannot be derived (exposure is consistent with a risk/impact), comparision of the risks posed by alternatives relative to decaBDE based on conventional risk characterisation is of limited usefulness and a simple comparison of hazard should be sufficient to identify a potentially acceptable alternative.

The hazard profiles of potential alternatives have been considered based all endpoints where data are available i.e. the assessment was not limited to a consideration of PBT/vPvB or other SVHC properties.

One substance was screened out in this step because of its classification. Additionally, a proprietary product was also screened out as the information available on its hazard was very limited precluding a meaningful assessment. In total 19 substances were taken forward to next screening step

Step 5 – Market availability of alternatives

Market availability was assessed by checking if substances were registered under REACH. Alternatives for which registration had been completed were considered further and substances without a registration were screened out. However, it cannot be excluded that alternatives that were screened out in this assessment may become available in the future. There is currently no other information from the literature on the availability of alternatives.

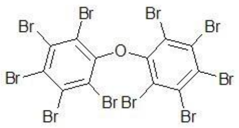
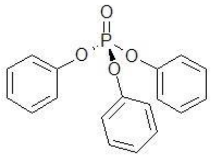
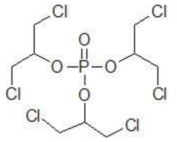
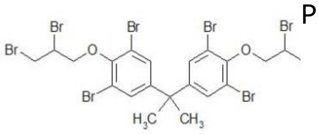
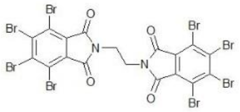
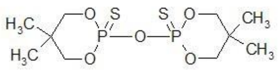
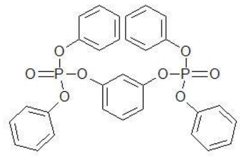
This screening step identifies those alternatives that are readily available on the market and can serve a significant proportion of users. This step excludes seven alternatives from the more detailed assessment.

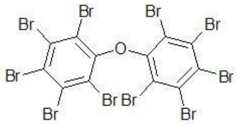
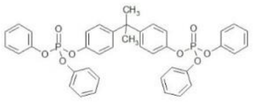
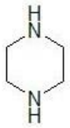
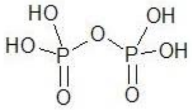
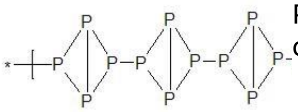
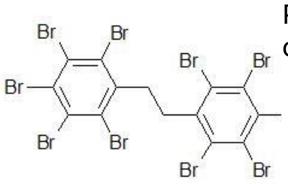
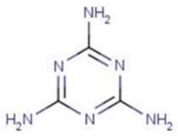
C.1.2.2 Conclusions from screening

The initial screening identified almost 200 potential alternative substances. Of these, 12 substances were prioritised for further assessment, using the screening criteria described above. The detailed results of the screening of alternative substances can be found in RPA (2014). In addition, alternative 13: 1,3,5-triazine-2,4,6-triamine (melamine), was added to the list based on information received from industry.

Table 67 presents the 13 potential alternative substances that were subject to detailed assessment. Whilst the aim of the screening exercise was to identify the most relevant alternatives from the perspective of technical and economic feasibility, hazard and availability, this does not exclude the possibility that other alternatives may be also relevant for some users, especially in very specific applications.

Table 67: Shortlist of potential alternatives for decaBDE for further assessment as identified from the screening exercise

decaBDE		**CAS No**	**Structure**	**Primary use**
Bis-(pentabromophenyl) ether (decaBDE)		1163-19-5		Polymers, textiles, coatings, adhesives
No	**Potential alternative substance**	**CAS No**	**Structure**	
1	Triphenyl phosphate (TPP)	115-86-6		Polymers
2	Magnesium hydroxide (MDH)	1309-42-8	$Mg(OH)_2$	Polymers, textiles, coatings/adhesives
3	Tris(1,3-dichloro-2-propyl) phosphate (TDCPP)	13674-87-8		Polymers, textiles
4	Aluminium trihydroxide (ATH)	21645-51-2; 8064-00-4	$Al(OH)_3$	Polymers, textiles, coatings/adhesives
5	Tetrabromobisphenol A bis (2,3-dibromopropyl ether)	21850-44-2		Polymers (textiles)
6	Ethylene bis(tetrabromophthalimide) (EBTBP)	32588-76-4		Polymers, textiles, coatings/adhesives
7	2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide	4090-51-1		Textiles
8	Resorcinol bis(diphenylphosphate) (RDP)	57583-54-7; 125997-21-9		Polymers (textiles)

decaBDE		**CAS No**	**Structure**	**Primary use**
Bis-(pentabromophenyl) ether (decaBDE)		1163-19-5		Polymers, textiles, coatings, adhesives
No	**Potential alternative substance**	**CAS No**	**Structure**	
9	Bisphenol A bis(diphenyl phosphate) (BDP/BAPP)	5945-33-5; 181028-79-5		Polymers (textiles)
10	Substituted amine phosphate mixture (P/N intumescent systems)	66034-17-1	 	Polymers (textiles, coatings/ adhesives)
11	Red phosphorous	7723-14-0		Polymers, textiles, coatings/adhesives
12	Ethane-1,2-bis(pentabromophenyl)(EBP)	84852-53-9		Polymers, textiles, coatings/adhesives
13	1,3,5-triazine-2,4,6-triamine (melamine)	108-78-1		Textiles

C.2 Assessment of shortlisted alternatives

A further assessment of each of the shortlisted alternatives is presented in sections C.2.1 to C.2.13 and each one comprises four sub- sections:

1. Human health information
2. Environmental information
3. Technical and economic feasibility
4. Conclusions on suitability

The information on human health and environment is presented according to the following structure:

- Information from government or other regulatory authority[55]
- Information from scientific literature
- Other reports
- Information from Registrations, C&L and Industry[56]
- Bio-monitoring *or* Environmental monitoring
- Conclusions for Human Health *or* Conclusions for Environment

The assessment of net reduction of risk is limited to an assessment of hazard. This is because information on exposures associated with use of substances as an alternative to decaBDE are not available. Equally decaBDE has PBT/vPvB properties that cannot be assessed using conventional risk assessment approaches. Where information on the risks of alternatives are described it is important to consider that the uses associated with these risks may be different to the use of a substances as an alternative to decaBDE. Therefore any conclusions of previous risk assessments should be interpreted accordingly.

The assessment of technical feasibility focuses on the identification of applications and materials where the substance has been reported to be used. The alternative is considered to be technically feasible in these applications. When available, this includes information on the effectiveness of an alternative to meet relevant flame retardancy requirements/standards.

The assessment of economic feasibility comprises information on the required loadings (again often linked to certain flame retardancy requirements) and prices of the alternatives. These are compared with typical loadings and prices for decaBDE. According to RPA (2014), decaBDE is incorporated in the plastic at a loading of roughly 12%. Information from consultation suggests loadings of decaBDE between 9 and 19% depending on the plastic. In textile backcoating, which is the most common application in textiles, the loading will usually be in the range of 7.5 – 20% depending on the weight of the fabric (ECB, EU RAR decaBDE, 2002). It is clear that also the loadings of the alternative flame retardants vary significantly between the applications and desired level of flame retardancy performance.

In the comparison of the loadings of decaBDE and the alternative, and later on in the substitution cost and cost-effectiveness calculations a loading of 12% is assumed. Furthermore decaBDE is used typically with an additional 4% of antimony trioxide (ATO) as a synergist. However, this is also the case for some of the alternative substances. This cost element is not considered in the assessment of the economic feasibility in this section. However, it is briefly discussed in Annex F.2 where substitution costs are calculated.

For the purposes of comparing the prices of decaBDE and alternative substances, the price of one kg of decaBDE is assumed to be €4, based on the information from the stakeholder consultation. The information on prices of alternatives is either from the consultation, literature or internet market places (mainly alibaba.com). It has not been possible to confirm the prices presented in the internet market places for all the substances. However, the available information on price differences between decaBDE and alternatives is reported in RPA (2014). The price assumed for decaBDE is somewhat higher than that suggested by Alibaba.com.

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[55] Some information is from outside the EU. This information should be considered as indicative since it cannot be directly extrapolated to the EU.

[56] This information is taken directly from industry submissions (in registrations and in C&L inventory) or during consultations made in RPA (2014), and has not been assessed for its quality.

Information on the potential need to change a production process to adopt an alternative substance is mentioned, when available. The substitution cost calculations and cost-effectiveness estimates (€ per kg of emission reduced) are presented in section F.2 Economic impacts.

In the end of the analysis of each alternative, its suitability as an alternative to decaBDE is summarised considering the information on human health and environment, as well as technical and economic feasibility.

C.2.1 Alternative 1: Triphenyl phosphate (TPP)

C.2.1.1 Human health information

TPP is currently in the CoRAP list for Evaluation under REACH and will be assessed in 2015 (rapporteur UK). The concern being related to potential endocrine disruptor properties and environmental exposure.

C.2.1.1.1 Information from government or other regulatory authority

US EPA (2014) evaluated the effects at repeated dose based on weight of evidence including reduced body weight in male rats administered TPP in the diet for 28 days. *The NOAEL of 23.5 mg/kg-day and the LOAEL of 161.4 mg/kg-day span across the High and Moderate hazard designation ranges (the US Department for the Environment criteria are for 90-day repeated dose studies; criteria values are tripled for chemicals evaluated in 28-day studies making the High hazard range < 30 mg/kg-day and the Moderate hazard range between 30 and 300 mg/kg-day)*.

C.2.1.1.2 Information from registrations, C&L and industry

Self-notified classifications for human health in the C&L Inventory include H332 Harmful if inhaled and Eye Irrit. 2 H319

C.2.1.1.3 Information from scientific literature

- House dust containing TPP was associated with decreased sperm concentration in men (n=50) (Meeker & Stapleton, 2010);
- Altered prolactin levels were associated with increased levels of TPP in dust (Meeker & Stapleton, 2010);
- TPP was listed among other chemicals that are believed to be neurotoxic to humans (Grandjean & Landrigan, 2006);
- TPP decreased human glucocorticoid receptor activity by 20% and decreased human androgen receptor activity by 40-50 (Honkakoski et al., 2004);
- TPP had moderate binding affinity for the androgen receptor (Fang, Tong, Branham, & Moland, 2003).

C.2.1.1.4 Other reports

Arcadis & EBRC (2011) analysed three sub-scenarios for: indoor air (monitoring data), service life of furniture and airborne particulates (monitoring data). *A first tier dermal* *exposure assessment to TPP using the ECETOC TRA Consumer tool showed that the service life of furniture was associated with an RCR above 1. During a second consultation period it was explained by industry that the concentration of the flame retardant in the final matrix (artificial leather) used for the dermal exposure assessment refers to a mixture of FRs, whereas TPP is only present to a small extent in this mixture. Taking the new figure given by industry a reduction in the dermal exposure estimate led to a RCR < 1. No risk was identified for the inhalation route using measured exposure data*.

C.2.1.1.5 Bio-monitoring

The available monitoring data indicate that TPP was detected in:

- human milk, adipose tissue and human plasma (US EPA, 2014);
- breast milk in Sweden (pooled samples) with a median concentration of 8.5 ng/g lipid (Krowech, 2012).

Furthermore, a TPP metabolite, diphenyl phosphate was identified in urine (USA: 9 samples, median: 1.8 µg/L, range: 0.569-63.8 µg/L; Germany: 19 samples, median: 1.3 µg/L, 95th percentile: 28.6 µg/L).

C.2.1.1.6 Conclusions for human health

Overall, neurotoxicity and suspected endocrine disruption effects should be considered as areas of potential concern for TPP.

C.2.1.2 Environmental information

C.2.1.2.1 Information from government or other regulatory authority

The Danish EPA reports: "*TPP has been studied extensively and it is clearly persistent, bioaccumulative, and toxic (PBT)*" (Danish EPA, 2013). . They also stated earlier in 2007 that TPP is highly toxic to algae, invertebrates and fish with typical L(E)C50 values <1 mg/l. Two studies of the chronic toxicity in fish report NOEC values in the range 0.014-0.23 mg/l. (Danish EPA, 2007)

The Illinois EPA (2007) characterised *TPP as a potentially problematic alternative for decaBDE. They report that there was 'high' concern over its acute and chronic aquatic toxicity: algal inhibition* EC_{50}*=0.26-2.0 mg/L; Daphnia* LC_{50}*=1.0-1.2 mg/L; fish* LC_{50}*=0.36-290 mg/L; chronic Daphnia NOEC=0.1 mg/L(estimated); fish NOEC for survival and growth=0.0014 mg/L). They report 'low' concern for other effects based on existing data and professional judgement, but also identify key data deficiencies on carcinogenicity and two-generation reproductive/developmental studies.*

The Environment Agency for England and Wales: *TPP could enter the environment from its production and use, and from the use of articles made from materials containing it. Based on the available information, potential risks were identified for all of the life cycle steps for one or more of the protection goals* (Environment Agency (2009b)). However, the substance does not meet any of the PBT criteria based on its intrinsic properties.

US EPA (2014) concluded "high" or "very high" concerns for the following endpoints:

- Acute aquatic toxicity: *evaluation based on experimental fish 96-hour LC50 values of 0.4 and 0.85 mg/L;*

- Chronic aquatic toxicity: *evaluation based on an experimental fish 30-day LOEC = 0.037 mg/L. No chronic experimental data were available for daphnia or algae;*

C.2.1.2.2 Information from registrations, C&L and industry

The following self-classifications for environment are available in the C&L Inventory: Aq ac. 1 H 400; H 332; Aq Chr 1H400/H410; Aq Chr 4/413.

C.2.1.2.3 Other reports

Arcadis & EBRC (2011) has used information from the Environment Agency 2009 evaluation of the substance and concluded that the PEC/PNEC rations were below one.

With regard to human health risk assessment, three sub-scenarios were identified for which a risk characterisation has been performed: indoor air (monitoring data), service life of furniture and airborne particulates (monitoring data). A first tier dermal exposure assessment to TPP using the ECETOC TRA Consumer tool showed that the service life of furniture was associated with an RCR above one. During a second industry consultation period it was explained by industry that the concentration of the FR in the final matrix (artificial leather) used for the dermal exposure assessment refers to a mixture of FRs, whereas TPP is only present to a small extent in this mixture. Taking the new figure given by industry a reduction in the dermal exposure estimate led to a RCR < 1. No risk was identified for the inhalation route using measured exposure data

C.2.1.2.4 Conclusions for Environment

TPP has a self-notified classification for aquatic toxicity (H400/H410). However, based on several reviews (EA 2009, Danish EPA 2007) the substance does not fulfil the PBT criteria (based on its intrinsic properties).

C.2.1.3 Technical and economic feasibility

C.2.1.3.1 Technical feasibility - relevant applications

There are several literature sources describing the applicability of TPP as a flame retardant.

A summary is provided in Table 68 below.

Table 68: Applications of TPP as a flame retardant

Application	Material - substrate	Source
Profiles- Trim	*ABS, PC blends, Polycarbonate*	*PINFA* (2013)
Castings, Coatings, RIM parts	*Polyurethane (PU)*	*PINFA* (2013)
Flooring	*Phenolic resins*	*PINFA* (2010b)
Ceiling *Sidewalls* *Panels*	*Phenolic resins*	*PINFA* (2010b)

Application	Material - substrate	Source
Structural parts		
Automotive parts (dashboard instruments, etc.)	ABS, PC/ABS	PINFA (2010b)
Sealants (flame-retarded and/or fire-resistant)	*PUR, acrylics, epoxy, elastomers, PVC*	*PINFA* (2010b)
Cables	*Used in fire-resistant coatings for cables*	*PINFA* (2010b)
Electrical cables *PV cables* *Control cables* *Lift cables* *Fire alarm cables*	*Polyolefins* *Elastomers* *Thermoplastic Elastomers (TPE)* *Polypropylene (PP)*	*PINFA* (2013)
Films: Tarpaulins	*Flexible PVC*	*PINFA* (2013)
Sheets: Roofing, Glazing, Lighting	*Polycarbonate and blends*	*PINFA* (2013)
Thin films: roofing underlay	*TPU*	*PINFA* (2013)
E&E – UL94V0	PC, PC/ABS, PPE/HIPS	Troitzsch (2011)
Printed circuit boards, Thermoplastic/styrenic polymers Thermosets and epoxy resins Photographic film		Environment Agency (2009b)
Not specified	HIPS/PPO, PC/ABS	JRC (2007)
E&E Enclosures V-0	PC/ABS, PPE/HIPS, phenolic	Danish EPA (2006)
Not specified	PC/ABS, HIPS/PPO, epoxy resins, phenolic resins	UK HSE (2012)
Electronics	HIPS/PPO, PC/ABS	US EPA (2014)
Hydraulic fluids, PVC, electronic equipment such as video display units cables, casting resins, glues, engineering thermoplastics, phenylene-oxide-based resins, phenolic resins		van der Veen & de Boer (2012)

Note: entries in italics refer to "phosphate esters" in general, rather than specifically to TPP.

TPP can be used in polymer applications. However, using TPP as a replacement for decaBDE in polymers would require manufacturers to switch to different resins, e.g. from HIPS to HIPS/PPO plastic (Department of Ecology State of Washington, 2008). It is also mentioned in literature that TPP is a constituent of products (made of HIPS/PPO and PC/ABS) containing RDP (alternative 8) at approximately <5-6% (Washington State, 2006).

C.2.1.3.2 Economic feasibility

Loading
Information on the loading of the substance in its applications is summarised in Table 69.

Table 69: Loadings for TPP

Loading (bw)	Material	Notes	Source
8-12%	PC/ABS	UL94 V-0 grade	Danish EPA (2006)
14%	PC/ABS	UL94 V-0 grade	PINFA (2010)
30%	HIPS/PPO		Department of Ecology State of Washington (2008)

Price

HELCOM (2013) suggests that the price of TPP is €6/kg, which would make it 50% more expensive than decaBDE. In addition, the loading of TPP could be higher than decaBDE making the total cost of using TPP as an alternative to decaBDE even greater. Nevertheless, it has been reported that producers would face minimal or no affordability issue if TPP was to be used in HIPS/PPO or PC/ABS resins (HELCOM, 2013).
By way of comparison, information from the Alibaba.com online marketplace would suggest that TPP might be less expensive than decaBDE by ca. 20%.

C.2.1.4 Conclusions

The following table summarises the conclusions from the above information on the feasibility and suitability of TPP as a replacement for decaBDE.

Table 70: Conclusions on suitability and feasibility of TPP

Category	Conclusion	Notes
Hazard	TPP does not meet the PBT criteria based on its intrinsic properties. However, it shows some aquatic toxicity . It is listed on the CoRAP for REACH Evaluation, based on potential concern as an endocrine disrupting substance.	
Technical feasibility	TPP can feasibly be used in polymer applications only. Typical applications include: HIPS/PPO, PC/ABS, phenolic resins and epoxy resins	For UL94 V-0 grade
Economic feasibility	Available information would suggest that TPP could be more expensive than decaBDE because of the higher loading of the substance needed, and potentially higher price. Nevertheless, literature describes TPP as affordable.	
Overall conclusion	**TPP is a technically and economically feasible alternative to decaBDE for certain applications . It has some hazardous properties, notably aquatic toxicity, and has been identified as a potential endocrine disrupting substance**	

C.2.2 Alternative 2: Magnesium hydroxide (MDH)

C.2.2.1 Human health information

C.2.2.1.1 Information from government or other regulatory authority

The Illinois EPA (2007) concluded that MDH could be a safer alternative based on no cancer or reproductive/developmental data were found and an estimated '*low' concern for other effects*. The conclusion was based on existing data and professional judgement (human exposure data from food, medicinal, and cosmetic uses) and considering key data deficiencies that included cancer, reproductive/developmental, and chronic aquatic toxicity studies .

US EPA (2014) confirms the limited concerns surrounding the substance. The "High" concern regarding persistence purely reflects the inorganic nature of the compound. MDH is not expected to biodegrade, oxidise in air, or undergo hydrolysis under environmental conditions. As a naturally occurring compound, it may participate in natural cycles and form complexes in environmental waters

C.2.2.1.2 Other reports

More recently, Arcadis & EBRC (2011) analysed one sub-scenario (service life of textiles for carpets or furniture) for which a risk characterisation was performed and concluded no human health concerns for consumers.

C.2.2.1.3 Information from Registrations, C&L and Industry

The following self-classifications are published on the ECHA website: Skin irrit.2 H315; Eye irrit.2 H319; STOT SE 3 H335 (eye, skin, lung); Ac. Tox 4 H 302; Eye dam. 1 H318; STOT RE 1 H372 (GI tract, CNS,…) (oral)

C.2.2.1.4 Conclusions for human health

Overall, and based on these limited information, it appears that MDH does not raise immediate concern for human health.

C.2.2.2 Environmental information

Due to its inorganic nature, a PBT assessment is not considered relevant for MDH.

C.2.2.2.1 Information from government or other regulatory authority

The US EPA assessment from 2014 confirms limited concerns for the environment.

C.2.2.2.2 Information from Registrations, C&L and Industry

No relevant information.

C.2.2.2.3 Conclusions for Environment

Overall, based on the limited available information, MDH seems not to raise any significant concern for the environment.

C.2.2.3 Technical and economic feasibility

C.2.2.3.1 Technical feasibility - relevant applications

There are several literature sources describing the applicability of magnesium hydroxide (MDH) as a flame retardant. A summary is provided in Table 71 below.

Table 71: Applications for magnesium hydroxide (MDH)

Application	Material - substrate	Notes	Source
Not specified	PP/PE, PS, PVC, ABS, UPR, PUR		KemI (2005)
Not specified	PP/PE, PS, PVC, ABS, PC, UPR, PUR, Rubber		KemI (2009)
	Textiles	.	
Profiles- window, doors, trim	Rigid PVC		PINFA (2013)
Pipes	HDPE, PP		PINFA (2013)
Cable trays, skirting boards	PP		PINFA (2013)
Facade decoration	Aluminium Composite Panels (ACP) – inner layer made of PE, PE/EVA, Ethylene-co-polymers		PINFA (2013)
Flooring (incl. linoleum)	PE/PP, Elastomers		PINFA (2010b) PINFA (2013)
Electrical cables	LDPE, EVA, Polyolefins, Elastomers, silicone rubbers (SiR)		PINFA (2010b)
Low voltage			PINFA (2013)
Medium voltage			
PV cables			
Emergency lighting			
Control cables			
Fire alarm cables			
Information cables			
LAN cables			
Telephone cables			

Application	Material - substrate	Notes	Source
Rigid sheets: Aluminium Composites Panels, building scaffolds (walk ways)	Polyolefins (mostly HDPE, PP)		PINFA (2013)
Water-proofing membranes	Tar bitumen, EPDM, TPO, HDPE		PINFA (2010)
E&E – UL94V0	Polypropylene (PP)		Troitzsch (2011)
Not specified	PA, PP, PE		JRC (2007)
E&E V-0 connectors and wires	PA (connectors), PP (wires), Thermoplastic polyester and elastomers, PVC, EPDM, PE/EVA		Danish EPA (2006)
Not specified	EVA copolymers, thermoplastic elastomers, PE, PP, PA, PE/EVA, flexible PVC, EPDM, TPU, acrylic resins, silicone		UK HSE (2012)
Wire and Cables, Electrical connectors, TPO for roofing, Foils and sheets, LD and HDPE, PP, Soft PVC, PA			ICL Industrial Products (2013b)
Wire and cable	PP, PE, EVA, Elastomers		US EPA (2014)
Public buildings	PP, PE, EVA, Elastomers		
Construction materials	PP, PE, EVA, Elastomers		
Automotive	PP, PE, EVA, Elastomers		
Aviation	PP, PE, EVA, Elastomers		
Shipping pallets	PP, PE		
Waterborne emulsions and coatings	PP		

MDH and ATH (alternative 4) act in the same way, partly based on the "heat sink" effect and partly based on the dilution of combustible gases by the water formed as a result of dehydroxylation. However, MDH thermally decomposes at slightly higher temperatures than ATH, at around 325 °C. Combinations of ATH and MDH function as efficient smoke suppressants in PVC (SFT, 2009). A potential use of MDH in technical textiles was identified during consultation. However, the consultation also described the use of MDH in technical textiles as problematic. MDH is only expected to be a technically suitable alternative to decaBDE for less demanding applications i.e. those with less stringent fire safety requirements. (RPA 2014)

C.2.2.3.2 Economic feasibility

Loading
Limited information is available on loadings of MDH. In a document on halogen-free FRs for EEE, MDH is reported to require high filler levels of about 45 to 50% to reach UL 94 V-0[57].

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[57] Flammability standard

Because of its limited temperature stability, it is mainly used in low glass fibre (PINFA, 2010). Consultation has suggested a 5 times higher loading compared to decaBDE in special textiles with FR performance still lagging behind that of decaBDE formulations.

Price
Information from the Alibaba.com online marketplace would suggest that MDH might have lower price than decaBDE by ca. 75%. The substance does not require the presence of ATO.

C.2.2.4 Conclusions

Table 72 summarises the conclusions on the feasibility and suitability of MDH as a replacement for decaBDE.

Table 72: Conclusions on suitability and feasibility of MDH

Category	Conclusion
Hazard	MDH is not classified as a PBT, as it is not an organic substance. It does not seem to raise any significant concern based on other hazardous properties
Technical feasibility	MDH can in principle be used in almost the full range of applications that are relevant to decaBDE. However, there seem to some problems in its technical feasibility when applied in textiles..
Economic feasibility	MDH requires high loadings compared to decaBDE but it is likely to have a price per tonne lower than decaBDE
Overall conclusion	**MDH is likely to be an affordable and rather benign alternative to decaBDE for a wide range of applications. However, due to its limited fire retardant properties it is unlikely to be widely adopted.**

C.2.3 Alternative 3: Tris(1,3-dichloro-2-propyl) phosphate (TDCPP)

C.2.3.1 Human health information

C.2.3.1.1 Information from government or other regulatory authority

The risk assessment carried out under the Existing Substances Regulation (ECB, 2008)revealed the following unacceptable risks:

- *The reasonable worst case dermal exposure during the manufacture of the substance (worker scenario 1), manufacture of flexible PUR foam – stabstock (worker scenario 2a) and manufacture of flexible PUR foam – moulded (worker scenario 2b) in relation to repeated dose toxicity and carcinogenicity*
- *A conclusion (i) "on hold" applied to effects on female fertility for both regional and local exposures.*

Kemi (2009) also highlighted TDCPP's classification as carcinogenic category 2, mentioning the suggestions of the recent EU risk assessment (ECB, 2008) for classification as carcinogenic category 2 and toxic for reproduction category 2.

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http://www.ul.com/global/eng/pages/offerings/industries/chemicals/plastics/testing/flame/

The US Consumer Product Safety Commission from 2006, concluded that TDCPP is a probable human carcinogen based on sufficient evidence in animals and its structural similarity to TRIS and tris(2-chloroethyl)phosphate, both listed as causing cancer under Proposition 65 (OEHHA, 2011).

The US Legislation of relevance to TDCPP (CTT, 2013) included restrictions on the use of TDCPP and other FRs introduce in some US states in the following applications (for more information see RPA, 2014):
- *plastic foam building insulation materials*
- *children's products and residential upholstered furniture*

C.2.3.1.2 Information from scientific literature

A more recent study (Gnosys et al., 2010) revealed possible female fertility effects.
A 2011 review of the hazard profile of TDCPP reported *in vitro* neurotoxicity, similar to chlorpyrifos (Dishaw et al., 2011): *TDCPP was described as a potent neurotoxicant as the pesticide chlorpyrifos in rat neuronal cells in vitro and TDCPP exposure in zebrafish embryos affects survival and induces developmental abnormalities, similar to chlorpyrifos* (Stapleton, 2011).

C.2.3.1.3 Other reports

Arcadis & EBRC (2011) analysed three sub-scenarios (PUR foam in furniture and consumer exposure by inhalation, dermal exposure and oral exposure (hand to mouth contact, child)) and concluded no risks to human health from consumer products.

Furthermore, the US Consumer Product Safety Commission (2006), concluded that TDCPP is a probable human carcinogen based on sufficient evidence in animals and its structural similarity to TRIS and tris(2-chloroethyl)phosphate, both listed as causing cancer under Proposition 65 (OEHHA, 2011).

C.2.3.1.4 Information from Registrations, C&L and Industry

TDCPP is classified as Carcinogenic category 2 H 351 in the registration dossier and as (low) acute toxic (Acute tox. 4 (H302); Skin Irrit.2 H315; Ac tox 3 H331; STOT RE 2 H373; Ac tox 4 H 332 self-classifications.

C.2.3.1.5 Conclusions for Human Health

Overall, based on the available information, there are concerns for TDCPP human health hazards for the following endpoints:
- carcinogenicity Cat 2 (REACH registration);
- (low) acute toxicity (Acute Tox. 4 / H302, (C&L inventory self-classification);
- neurotoxic properties shown in recent studies;
- potential female fertility effects were identified under ESR.

C.2.3.2 Environmental information

C.2.3.2.1 Information from government or other regulatory authority

Kemi (2009) concludes that TDCPP does not meet the PBT criteria (BCF less than 120), but highlights its aquatic toxicity.

C.2.3.2.2 Information from scientific literature

Gnosys et al. (2010) also concluded that TDCPP does not meet all of the PBT criteria, but potentially criteria for P or vP.

C.2.3.2.3 Information from Registrations, C&L and Industry

TDCPP is related with chronic aquatic toxicity 2 with H411 (registration dossier), persistence (but no vP).

C.2.3.2.4 Conclusions for Environment

Overall, TDCPP is not considered as a PBT, but it is persistent and toxic to the aquatic environment.

C.2.3.3 Technical and economic feasibility

C.2.3.3.1 Technical feasibility - relevant applications

There are few literature sources describing the applicability of TDCPP as a flame retardant. A summary is provided in the Table 73.

Table 73: Applications for tris(1,3-dichloro-2-propyl) phosphate (TDCPP)

Application	Material - substrate	Notes	Source
Not specified	Flexible PU foam, epoxy resin and phenolics, unsaturated polyesters	Excellent processing, good thermal and hydrolytic stability, low fogging	ICL Industrial Products (2013b)
Automotive industry and furniture	An additive FR in resins, latexes and foams, textiles		van der Veen & de Boer (2012)

US sources indicate that TDCPP has been the main FR used in automotive foam cushioning for many years and is frequently used in upholstered furniture foam. TDCPP has been referred to as one of the primary FRs replacing pentaBDEs in polyurethane foam (NRDC, 2010). In the 1970s, TDCPP was briefly used in children's sleepwear after tris(2,3-dibromopropyl)phosphate (TRIS) was banned. The use of TDCPP in sleepwear in the USA was withdrawn in 1977 (OEHHA, 2011).

Although banned from children's pyjamas in 1977, TDCPP continues to be in widespread use in baby nursery items, strollers, nursing pillows, and other children's products, as well as other foam padded furniture, such as couches, chairs, and sofa beds (NRDC, 2010). In addition, recent research in the USA suggests that TDCPP could be detected in baby product foam used in car seats, changing table pads, sleeping wedges, portable mattresses, baby walkers, high chairs, rocking chairs, baby carriers, nursing pillows and infant bath slings (Stapleton, 2011). TDCPP is used in the same kind of products as TCPP (an alternative rejected from a more detailed assessment due risk profile), but because of the higher price of TDCPP, it is only used in applications where a more effective FR is required (van der Veen & de Boer, 2012).

Consultation suggests that the substance is promoted by some formulators as alternative to decaBDE-based formulations for textile backcoating. However, it is not suitable for all fabrics.

C.2.3.3.2 Economic feasibility

Loading
Consultation with actors in the textiles industry suggest that TDCPP may need to be used at a loading ca. 5% higher than decaBDE. On the other hand, foam samples from the USA sampled between 2003 and 2009 were analysed and the most frequently detected flame retardant, detected in 15 samples, was TDCPP with a concentration of 1–5% (w/w) (van der Veen & de Boer, 2012). The reasons for varying information on loadings are not known but may relate e.g. to different applications requiring different flame retardancy.

Price
Consultation suggests that TDCPP may have 20% lower price than decaBDE for textile applications. On the other hand, information from the Alibaba.com online marketplace would suggest that TDCPP might have significantly lower price than decaBDE by ca. 75% ; this value is unlikely to be a reliable indicator. The substance does not require the presence of ATO.

C.2.3.4 Conclusions on alternative 3

The following table summarises the conclusions from the above information on the feasibility and suitability of TDCPP as a replacement for decaBDE.

Table 74: Conclusions on suitability and feasibility of TDCPP

Category	Conclusion
Hazard	TDCPP is not a PBT; however, it is toxic to the aquatic environment (H411) (with higher water solubility) and a Carc Cat 2 (H351). Recent research raises concerns about its potential neurotoxicity and female fertility effects
Technical feasibility	TDCPP can be used in textile backcoating, however, it is not applicable in all fabrics where decaBDE is used. In addition, it can be used in foam applications which are generally of limited significance to decaBDE.
Economic feasibility	TDCPP seems to require marginally higher loadings compared to decaBDE but it is likely to have a price per tonne lower than decaBDE. It does not require ATO.
Overall conclusion	**TDCPP does not have a favourable hazard profile. It can only be used in a limited range of relevant applications, mainly in backcoating of some fabrics for textiles.**

C.2.4 Alternative 4: Aluminium trihydroxide (ATH)

C.2.4.1 Human health information

C.2.4.1.1 Information from government or other regulatory authority

The Illinois EPA (2007) characterised ATH as a potentially unproblematic alternative for decaBDE, as no cancer data were found, and risks were considered low, based on professional judgement. '*Low' concern was identified for other effects based on existing data and professional judgement (human exposure data from antidiarrheal and antacid uses); key data deficiencies included cancer, neurological effects, and chronic aquatic toxicity studies*.

US EPA's assessment (2014) highlighted moderate neurological and repeated dose hazards, confirming the limited reason for concern.

C.2.4.1.2 Information from scientific literature

Shaw et al. (2009) report that "the demonstrated neurotoxicity of aluminium hydroxide and its relative ubiquity as an adjuvant suggest that greater scrutiny by the scientific community is warranted." More information on neurotoxicity can be found in the Hazardous Substances Data Bank (HSDB)

C.2.4.1.3 Other reports

Arcadis & EBRC analysed in 2011 one scenario - inhalation exposure to aluminium hydroxide vapour and identified no risks to human health from airborne particles. The scenario was considered not relevant due to the ionic nature of the substance. The dermal exposure was not assessed, as it was not considered a relevant exposure pathway *due to the negligible dermal absorption of aluminium and no systemic/local effects expected for aluminium cations following exposure to skin*.

C.2.4.1.4 Information from Registrations, C&L and Industry

The only information is available from self-notifications: Skin Irrit.2 H315; Eye Irrit.2 H319; STOT SE 3 H335 (respiratory system)(inhalation); H 319; H 315; H 335; H319

C.2.4.1.5 Conclusions for Human Health

Overall, there is insufficient information to conclude whether ATH poses a risk to Human Health~~.~~

C.2.4.2 Environmental information

There is no PBT assessment performed by authorities, as ATH is an inorganic substance.

C.2.4.2.1 Information from government or other regulatory authority

The Illinois EPA highlighted that acute aquatic toxicity was likely only at very low pH (Daphnia LC_{50}=2.6-3.5 mg/L).

The recent US EPA's assessment (2014) confirms the limited reason for concern, it identifies as medium the acute and chronic aquatic toxicities and gives to the persistence criterion a high score due to the substance's inorganic nature (*biodegradation or oxidation not expected under typical environmental conditions*) .

C.2.4.2.2 Information from Registrations, C&L and Industry

No relevant information.

C.2.4.2.3 Conclusions for Environment

Overall, there is insufficient information to conclude whether ATH poses a risk for Environment.

C.2.4.3 Technical and economic feasibility

C.2.4.3.1 Technical feasibility - relevant applications

ATH has been used as a flame retardant and smoke suppressant since the 1960s and it is available in a variety of particle sizes as commercial products. Flame retardation by ATH has been shown to be partly due to the "heat sink" effect and partly due to the dilution of combustible gases by the water formed as a result of dehydroxylation. Alumina which is formed as a result of thermal degradation of ATH slightly above 200 °C has been shown to form a heat-insulating barrier on the surface that prevents further fire propagation of the matrix material (SFT 2009).

There are several literature sources describing the applicability of ATH as a flame retardant. A summary is provided Table 75 below.

Table 75: Applications for aluminium trihydroxide (ATH)

Application	Material - substrate	Notes	Source
Upholstery, blinds, blackout curtains, automotive textiles	Not specified	In-expensive filler, relatively insoluble. Little real flame retardant effect, potentially poor fabric handle	RPA (2003)
Not specified	PE/PP, PS, PVC, ABS, UPR, Epoxy, PU		KemI (2005)
Not specified	PE/PP, PS, PVC, ABS, PC, UPR, Epoxy, PU, Textiles		KemI (2009)
Cables and wires	PVC, Silicone rubber, EPDM, EVA, LDPE		EFRA (2011)

Application	**Material - substrate**	**Notes**	**Source**
Semi-durable textile finishes	Cotton, polyester		EFRA (2012)
Solid thermoplastics	EVA copolymer, PP, PE, Thermoplastic elastomers		PINFA (2010c) PINFA (2010b)
Foams	PE foam, PVC/nitrile foam, Rubber (elastomer)		
Thermosets	Epoxy, Phenolic, Unsaturated Polyester, Vinyl esters, Acrylic		
Wires & cables	Silicone, PVC flexible, EPDM, PE/EVA, PP (boehmite)		
Textiles	Textile backcoating		
Coatings/Adhesives	Hot melts, Paints		
Transportation flooring	PVC, PE/PP, Epoxy, Elastomers		PINFA (2010b)
Transportation ceiling, sidewalls, panels, structural parts	Unsaturated Polyesters (UP), Vinylester (VE), Acrylate resin, Polyurethane (PU)		
Dashboard	RIM, UPR		
Instruments			
Instrument panels			
Instrument cluster housing, etc.			
Transportation coatings	2K-PU, epoxy, acrylates		
Sealants (flame-retarded and/or fire-resistant)	PUR, acrylics, epoxy, elastomers, PVC		
Transportation textiles		Back-coating or added to polymer melt	
Films: Tarpaulins	Flexible PVC		PINFA (2013)
Sheets	Unsaturated polyester		
Rigid sheets: Aluminium Composites Panels, building scaffolds (walk ways)	Polyolefins (mostly HDPE, PP)		
Flooring	PVC, linoleum		
Profiles- window, doors, trim	Rigid PVC		

Application	**Material - substrate**	**Notes**	**Source**
Pipes	HDPE, PP		
Cable trays, skirting boards	PP		
Facade decoration	Aluminium Composite Panels (ACP) – inner layer made of PE, PE/EVA, Ethylene-co-polymers		
Water-proofing membranes	Tar bitumen, EPDM, TPO, PVC, EVA, PU, EPR, UPR, Acrylates		PINFA (2010)
E&E – UL94 V-0	Epoxy resins (EP), Unsaturated polyester resins (UP)		Troitzsch (2011)
Electronics	Thermosets		US EPA (2014)
Wire & cable	PP, EVA, elastomers		
Public buildings	PP, EVA, elastomers, thermosets		
Construction materials	PP, EVA, elastomers, thermosets		
Automotive	PP, EVA, elastomers, thermosets		
Aviation	PP, EVA, elastomers, thermosets		
Textiles	Emulsions		
Waterborne emulsions and coatings	Thermosets		
Not specified	EVA copolymers, PE, thermoplastic elastomers, rigid and flexible PVC, rubbers/elastomers, hot melts, epoxy resins, phenolic resins, unsaturated polyester, vinyl esters, acrylic resins, silicone, EPDM, TPU, PE/EVA		UK HSE (2012)

Application	Material - substrate	Notes	Source
Printed circuit boards, Electronic components encapsulations, Technical laminates, Electrical Encapsulating & Casting	Epoxy resins		Anonymous (undated)
Wire and cable	EVA		
Thermoplastics	PE/Copolymers Elastomers PVC		Albemarle (2013)
Foams	Polyolefin foams, PVC/Nitrile foams, Elastomer foams		
Wire and cable	Silicone, EPDM, PE/EVA, XL PE/EVA, TPU, PVC		
Thermosets	Epoxy, phenolic, UPR, vinyl esters, SMC/BMC, PU/CASE, Latex		

The table suggests that ATH finds a wide range of applications; however, its performance generally does not match that of decaBDE formulations. For instance, consultees have identified possibilities for use of ATH in some polymer and technical textile applications for which, however, its performance would be inadequate (RPA, 2014).

C.2.4.3.2 Economic feasibility

Loading

ATH needs to be used at loadings significantly higher than decaBDE. The stakeholder consultation has suggested loadings five times greater than decaBDE in polymer applications and three times greater in textile applications. The substance has been described as a "cheap filler" in previous reviews of decaBDE alternatives which cannot meet the performance of decaBDE/ATO formulations (RPA 2003).

ATH loading levels can be reduced with a correct choice of particle size, surface modification and proper dispersion in the matrix material. A Norwegian report refers to recently developed coated filler products (e.g. ZHS-coated ATH) which offer the possibility of equivalent or better flame retardancy and smoke suppression at significantly reduced incorporation levels (SFT 2009).

Price

Robust information on the price of ATH is not available. Limited information from the stakeholder consultation would suggest that ATH is marginally more expensive than decaBDE. On the other hand, information from the Alibaba.com online marketplace would suggest that ATH might have a price which is only a small fraction of decaBDE's cost.

C.2.4.4 Conclusions

The following table summarises the conclusions from the above information on the feasibility and suitability of ATH as a replacement for decaBDE.

Table 76: Conclusions on suitability and feasibility of ATH

Category	Conclusion
Hazard	Insufficient information to conclude whether ATH pose a risk to Human Health and the Environment
Technical feasibility	ATH can be used in a wide range of applications that are relevant to decaBDE but it does not necessarily perform as efficiently or effectively as decaBDE formulations
Economic feasibility	ATH requires very high loadings compared to decaBDE and the information on price per tonne is contradicting from different sources.
Overall conclusion	**ATH has a wide range of applications, but it requires high loadings in order to achieve acceptable performance. It is expected to be technically suitable for less demanding applications. The available information on prices is contradicting.**

C.2.5 Alternative 5: Tetrabromobisphenol A bis (2,3-dibromopropyl ether)

C.2.5.1 Human health information

C.2.5.1.1 Information from government or other regulatory authority

Reports published by authorities highlight some concern on carcinogenicity: suspected of (Kemi, 2009) and mutagenic concerns by the US National Toxicology Program (NTP) over its carcinogenic potential as cited in (EU RAR, 2007). In addition, EU RAR (2007) highlighted a low acute toxicity (LD_{50} = 20g/kg, oral) and a relatively low sub-chronic toxicity NOAEL of 200 mg/kg bw/day.

US EPA (2014) assessment concludes with regard to tetrabromobisphenol A bis (2,3-dibromopropyl ether) that its carcinogenicity, reproductive and developmental effects might be of concern, based on the potential for alkylation and professional judgement. Mutagenicity to *Salmonella typhimurium* but not in other assays in *S. Typhimurium* and *E. coli* and studies in mouse lymphoma cells. Genotoxic potential may be also estimated based on the alkylation potential. Other negative results for tetrabromobisphenol A bis (2,3-dibromopropyl) ether were registered in vitro in Chinese hamster ovary (CHO), *in vivo* in a micronucleus assay in mice but not in unscheduled DNA synthesis in rats.

C.2.5.1.2 Other reports

Three sub-scenarios were identified in the review of Arcadis & EBRC (2011), for which a human health risk characterisation was performed: saturated vapour concentration (inhalation), service life of textiles used for carpets (dermal) and service life of textiles used for carpets (inhalation). *First tier exposure assessments were performed using the ECETOC TRA Consumer tool with some simple refinements like the saturated vapour concentration for a more plausible inhalation exposure assessment. This tentative risk assessment using conservative exposure estimations showed a risk with respect to the dermal exposure to textiles used for carpets. However, this application was questioned as* *being relevant for the domestic environment. No risk was identified for the inhalation of vapour or airborne particulates*.

C.2.5.1.3 Information from registrations, C&L and industry

No relevant information

C.2.5.1.4 Conclusions for human health

Tetrabromobisphenol A bis (2,3-dibromopropyl ether) may have CMR properties, although no conclusions have been reached.

C.2.5.2 Environmental information

C.2.5.2.1 Information from government or other regulatory authority

Reports published by authorities highlighted the very limited data (Kemi, 2009) and the relatively low degradability EU RAR, 2007). Also the environmental fate of derivatives of TBBPA has been much less studied.

The ESR RAR for tetrabromobisphenol-A TBBPA considered that some of the simple ether derivatives of TBBPA, including the bis (2,3-dibromopropyl ether), appear, at least theoretically, to have some potential to form TBBPA in the environment through a (bio)degradation process but the significance of this is unknown.

Danish EPA (2013) also reported TBBPA as a degradation product in some of the samples of tetrabromobisphenol-A bis (2,3-dibromopropyl ether).

The persistence of tetrabromobisphenol A bis (2,3-dibromopropyl ether) in a sediment mesocosm has recently been investigated by De Jourdan et al. (2013). This study found that the median dissipation time for tetrabromobisphenol A bis (2,3-dibromopropyl ether) was around 32 days in the particulate phase and 102 days in the sediment phase.

The US EPA agrees that *it is not evident that TBBPA will be released from tetrabromobisphenol-A bis (2,3-dibromopropyl) ether and the conditions necessary for such degradation are not known. If TBBPA is released through the degradation, the associated hazard profile would be influenced by any toxicity associated with TBBPA* (US EPA, 2014).-

Bergman et al. (2012) estimated LogK_{ow} values and K_{oc} values for several derivatives of TBBPA. All derivatives have relatively high LogKow and Koc values, indicating their preferentially partition onto sediment and soil in the environment. For tetrabromobisphenol A bis (2,3-dibromopropyl ether) the values were 8.51 and 1.01×10^6 respectively (also cited by Danish EPA, 2013).

US EPA (2014) identified tetrabromobisphenol A bis (2,3-dibromopropyl) ether as being of "High" or "Very High" concern with regard to :

- Persistence: *high persistence of tetrabromobisphenol A bis (2,3-dibromopropyl) ether is expected as a result of located biodegradation studies and the absence of other expected likely removal processes under environmental conditions. In the course of a 28-day Japanese Ministry of International Trade and Industry (MITI) test, only 1% of tetrabromobisphenol A bis (2,3-dibromopropyl) ether was degraded. Tetrabromobisphenol A bis (2,3-dibromopropyl) ether will exist primarily in the particulate phase in the atmosphere and is not expected to undergo removal by gas phase oxidation reactions. It is also not anticipated to undergo removal by* *hydrolysis.*

- Bioaccumulation: *based on an estimated bioaccumulation factor of 12,000 and its detection in Great Lakes Herring gull eggs, Tetrabromobisphenol A Bis (2,3-dibromopropyl) Ether's potential for bioaccumulation is high*.
- US EPA also agrees that *it is not evident that TBBPA will be released from tetrabromobisphenol A bis (2,3-dibromopropyl) ether and the conditions necessary for such degradation are not known. If TBBPA is released through the degradation, the associated hazard profile would be influenced by any toxicity associated with TBBPA*.

C.2.5.2.2 Information from registrations, C&L and industry

The information available indicates persistence properties, with half-life more than 1 year, non-readily biodegradability, but no T and B properties.

C.2.5.2.3 Conclusions for environment

Overall, based on the limited knowledge, although is not a recognised as a PBT, tetrabromobisphenol A bis (2,3-dibromopropyl) ether may raise concerns based on its persistence and bioaccumulation. Equally, the vPvB properties of its breakdown product TBBPA are of concern.

C.2.5.3 Technical and economic feasibility

C.2.5.3.1 Technical feasibility - relevant applications

There are several literature sources describing the applicability of tetrabromobisphenol A bis (2,3-dibromopropyl ether) as a flame retardant. A summary is provided in the table below.

Table 77: Applications for tetrabromobisphenol A bis (2,3-dibromopropyl ether)

Application	Material - substrate	Notes	Source
Fabricated plastic sheets for electrical cabinets, textiles, paints, and hot melts, pipes, water barriers, kitchen hoods, household, and in TV, hifi-audio, and electronics	PP, HDPE, LDPE, HIPS Textiles		NIEHS (NIEHS, 2002)
Not specified	HIPS, PP, PE, Crystalline PS		KemI (2009)
E&E UL94 V-0	PP		Troitzsch (2011)
Not specified	PP		JRC (2007)

Application	Material - substrate	Notes	Source
Not specified	HIPS, PP	This chemical is marketed for use in HIPS, but is mainly used in other polymers including polypropylene	Washington State (2006)
Enclosures	HIPS (UL94 V-0)	A supplier claims that it is very effective in PP and in HIPS at low dosage. Along with the melting characteristics of SAYTEX HP-800A flame retardant, this results in minimal impact on mechanical properties of the resin; good thermal stability; usually used with antimony trioxide for maximum flame retardant performance	Danish EPA (2006)
Wires	PP (UL94 V-0)		
Not specified	PE, crystal PS		
E&E equipment, textiles, construction materials	PP, PE, PS, HIPS		Arcadis & EBRC (2011)
Not specified	HIPS, PP, PE, PS, TPU		UK HSE (2012)
Not specified	PP, HIPS, ABS	Good FR efficiency and thermal stability	ICL Industrial Products (2013b)
Electronics	PP, Elastomers		US EPA (2014)
Public buildings	PP, Elastomers		
Construction materials	PP, Elastomers		
Automotive	PP, Elastomers		

The table indicates that tetrabromobisphenol A bis (2,3-dibromopropyl ether) can find applications mainly in polymers and less so in textiles. Process changes that would be required for its use are not known but are likely to be limited (as it is a brominated flame retardant).

C.2.5.3.2 Economic feasibility

Loading

To achieve a V-0 fire rating in HIPS, a low loading of 5% is referred to in combination with a “styrenic based resin”, and 5% ATO. Additional detail is available from the Existing Substances Regulation Risk Assessment Report (RAR) for TBBPA. In polypropylene, the substance may be used at a loading of 8-10% to meet the UL94 V-0 rating and the minimum amount necessary to meet the UL94 V-2 rating and Glow Wire rating is 1.5% of the flame retardant with 0.5% ATO and 1% of the flame retardant with 0.33% ATO respectively. Additionally, 12% of the flame retardant with 4% ATO and 14.5% of the flame retardant with 5.2% ATO are used in formulations to meet the UL94 V-0 rating in PP homopolymers and block copolymers respectively. It is also reported that the UL94 V-2 rating is met using formulations containing 3% of the flame retardant with 1% ATO and 4.5% of the flame retardant with 1.5% ATO in polypropylene homopolymers and block copolymers respectively (EU, 2006).

Price
Information on prices of this alternative is generally not available. Data from the Alibaba.com online marketplace would suggest that tetrabromobisphenol A bis (2,3-dibromopropyl ether) may have a price which is ca. 50% that of decaBDE. In electronics, its price is suggested in the literature as lower than decaBDE but this assertion is not supported by consultation.

C.2.5.4 Conclusions

The following table summarises the conclusions from the above information on the feasibility and suitability of tetrabromobisphenol A bis (2,3-dibromopropyl) ether as a replacement for decaBDE.

Table 78: Conclusions on suitability and feasibility of tetrabromobisphenol A bis (2,3-dibromopropyl) ether

Category	Conclusion
Hazard	Tetrabromobisphenol A bis (2,3-dibromopropyl) ether is not a recognised PBT. However, it may show high persistence and there are concerns over its bioaccumulation. It may break down to TBBPA in the environment but how this may occur and what its significance is, are uncertain. Some concerns have been raised about its carcinogenicity but no conclusive results appear to be available in the literature
Technical feasibility	Tetrabromobisphenol A bis (2,3-dibromopropyl) ether can be used in HIPS, PP, PE, crystalline PS and potentially also in some textiles
Economic feasibility	Tetrabromobisphenol A bis (2,3-dibromopropyl) ether may require similar loadings to decaBDE. Information on prices from literature, Alibaba.com and consultation is conflicting.
Overall conclusion	**Tetrabromobisphenol A bis (2,3-dibromopropyl) ether raises some concerns over its environmental fate and potential CMR properties and may only be used in a modest range of relevant applications. It requires similar loadings to decaBDE but information on prices is contradictory.**

C.2.6 Alternative 6: Ethylene bis(tetrabromophthalimide) (EBTBP)

C.2.6.1 Human health information

C.2.6.1.1 Information from registrations, C&L and industry

The information indicates no human health hazards.

C.2.6.2 Environmental information

C.2.6.2.1 Information from government or other regulatory authority

Reports published by authorities (Kemi, 2009) and Danish EPA, as cited in (EU RAR, 2007) concluded based on the available information the substance does not meet all the PBT criteria, being only very persistent.

A recent review by the European Food Safety Authority (EFSA, 2012) considered for the substance LogKow and Koc to be 6.63 and 96,500 L/kg respectively, which indicate that the substance will adsorb strongly to sediment and soil. The BCF in fish was reported to be low (<33 L/kg) but EFSA considered the potential for accumulation in mammals to be high, based on modelling. They also considered the substance TEBP-Anh and ethylenediamine product, fully brominated on the aromatic rings, being expected to undergo reductive debromination in the environment. Tetrabromophthalic acid is a possible degradation product.

The overall environmental persistence (Pov) estimated by modelling was >500 days (Danish EPA, 2013).

US EPA provided in their 2014 assessment information on:

- Persistence: *the very high persistence for ethylene bis(tetrabromophthalimide) is based on limited experimental data and quantitative structure activity relationship (QSAR) estimates. No degradation observed in activated sludge during a MITI test, indicating it is not biodegradable under the stringent test conditions. Results from biodegradation models provided similar results and indicate that it will be recalcitrant under aerobic conditions. Anaerobic degradation under methanogenic conditions is not considered probable. The atmospheric half-life of ethylene bis-tetrabromophthalimide is estimated to be 3.3 hours, although it is expected to exist primarily in the particulate phase in air. Resistance to most environmental fate processes indicates that ethylene bis-tetrabromophthalimide is expected to be persistent in the environment*

- Bioaccumulation: *the potential for bioaccumulation of ethylene bis(tetrabromophthalimide) is high based on the estimated bioaccumulation factor. The BAF estimate is consistent with that anticipated for high molecular weight chemicals with a high degree of bromination*.

C.2.6.2.2 Information from registrations, C&L and industry

The information indicates that EBTBP is very persistent, will partition predominantly to soil, but is non-bioaccumulative and has no toxic properties.

C.2.6.2.3 Conclusions for environment

Overall, ethylene bis(tetrabromophthalimide) can be concluded as being very persistent, raising concerns on its bioaccumulation, but not meeting all the criteria for a full PBT. Another concern it in relation to its potential for debromination in the environment to PBT substances (as per decaBDE).

C.2.6.3 Technical and economic feasibility

C.2.6.3.1 Technical feasibility - relevant applications

There are several literature sources describing the applicability of ethylene bis(tetrabromophthalimide) as a flame retardant. A summary is provided in Table 79 below.

Table 79: Applications for ethylene bis(tetrabromophthalimide)

Application	Material - substrate	Notes	Source
E&E UL94 V-0	PE, PP, HIPS, ABS, PET, PBT, PC, PC/ABS, PPE/HIPS, epoxy, UPR, thermoplastic styrene-block copolymers (TPE-S), thermoplastic polyurethanes (TPU)		Troitzsch (2011)
Wires and cables – VW 1	Thermoplastic polyester elastomers (TPE-E)		
Not specified	HIPS, ABS, PBT, PP, PE, PC/ABS, HIPS/PPO		JRC (2007)
Not specified	HIPS, ABS, PC/ABS, HIPS/PPO		Washington State (2006)
Enclosures	HIPS, ABS, PC/ABS, PPE/HIPS	Compared to decaBDE, it may display better bloom resistance, thermal stability and UV stability. Claimed to be a popular choice for resins used in office automation equipment, such as photocopiers and printers where UV stability is an important performance criterion	Danish EPA (2006)
Connectors	PA, PET/PBT		
Wires	PP, PP		
Not specified	ABS, HIPS, PBT/PET, PC, PP, PE, PC/ABS, HIPS/PPO, thermoplastic elastomers, silicone, PVC, EPDM, TPU, PE/EVA, thermosets (epoxy and phenolic resins, unsaturated polyesters)		UK HSE (2012)
Thermoplastics	ABS, HIPS, Polyester, PC, PP, PE, SAN, PC/ABS, HIPS/PPO, Elastomers, PVC		Albemarle (Albemarle, 2013)
Foams	Polyolefin, PVC/Nitrile, Elastomers		
Wire & cable	Silicone, EDPM, PP, PE/EVA, TPU, PVC		
Thermosets	Epoxy, phenolic, UPR, VE, SMC/BMC, PU, Latex		
Electronics	PP, PE, HIPS, Thermoplastics		US EPA (2014)
Wire & cable	CPE, PP, PE		
Public buildings	PP, PE		
Construction materials	PP, PE, Elastomers		

Application	Material - substrate	Notes	Source
Automotive	PP, PE		
Shipping pallets	PP, PE		
Not specified	HIPS, PE, PP, thermoplastic polyesters, PA, EPDM, rubbers, PC, ethylene co-polymers, ionomer resins, textiles		Consultation with Norway (NIEHS, 1999)

Ethylene bis(tetrabromophthalimide) is one of the substances with the widest range of applications as a decaBDE replacement and can be used both in polymers and textiles.

C.2.6.3.2 Economic feasibility

The Danish EPA (2006) suggests that ethylene bis(tetrabromophthalimide) can be used at the same loading as decaBDE, i.e. 12-13% with 4-5% ATO in order to achieve a V-0 fire rating in HIPS.

Information from the Alibaba.com would suggest that ethylene bis(tetrabromophthalimide) might has a higher price than decaBDE by ca. 40%.

C.2.6.4 Conclusions

The following table summarises the conclusions from the above information on the feasibility and suitability of ethylene bis(tetrabromophthalimide) as a replacement for decaBDE.

Table 80: Conclusions on suitability and feasibility of ethylene bis(tetrabromophthalimide) (EBTBP)

Category	Conclusion
Hazard	Ethylene bis(tetrabromophthalimide) is very persistent, , may bioaccumulate and could potentially undergo debromination in the environment. Its human health hazard profile does not appear to raise concerns
Technical feasibility	Ethylene bis(tetrabromophthalimide) can be used in a wide range of applications that are relevant to decaBDE at similar loadings to decaBDE and in the presence of ATO
Economic feasibility	Ethylene bis(tetrabromophthalimide) requires similar loadings to decaBDE but it is likely to have a price per tonne higher than decaBDE.
Overall conclusion	**Ethylene bis(tetrabromophthalimide) is an alternative compatible with a wide range of applications. However, it seems to be more expensive to use due to its higher price.**

C.2.7 Alternative 7: 2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide

C.2.7.1 Human health information

C.2.7.1.1 Information from registrations, C&L and industry

No relevant information

C.2.7.1.2 Conclusions for human health

Overall and based on the limited information, this alternative does not appear to raise any significant concern for human health..

C.2.7.2 Environmental information

C.2.7.2.1 Information from registrations, C&L and industry

The information indicates that the substance is not readily biodegradable and the hydrolysis under environmental conditions is assumed to be slow and classification as Aq Chr 4 H413; H413 . Based on the limited available information, no conclusions could be triggered for its bioaccumulation and toxic potential.

C.2.7.2.2 Conclusions for environment

Overall, the substance does not appear to fulfil the PBT criteria.

C.2.7.3 Technical and economic feasibility

C.2.7.3.1 Technical feasibility - relevant applications

Information from the relevant industry association that represents manufacturers of phosphorous and nitrogen-based FRs (PINFA) confirms that the substance may only find uses as a FR in viscose textiles (PINFA, 2010c). This certainly limits the scope of the substance to act as a widespread replacement for decaBDE. Information from consultation confirms its role as a FR additive in this context. It is probably used mainly in clothing, so its share in decaBDE-related products is expected to be very low.

A supplier of viscose fibres that are flame-retarded with the substance has provided information during consultation and this is presented in the Confidential Annex of the RPA report (2014). In summary, the supplier has claimed that the technical characteristics of their fibre are equivalent or better than decaBDE-backcoated textiles, while offering better aesthetics and lifetime.

C.2.7.3.2 Economic feasibility

Loading
A recent patent describes the use of the substance in making FR viscose fibres. It is used at a concentration of no lower than 15% by weight of dry yarn and is accompanied by 5% by weight TBBPA (Tozzi-Spadon, Seghizzi, & Patritti, 2011). The information obtained from consultation suggests a lower loading, ca. 10%, which is lower than for decaBDE.

Price
The price of 2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide has been described as several times higher than decaBDE. Often also the final article (textile) is considerably more expensive than decaBDE-backcoated articles. This price difference has more to do with the use of more expensive raw materials (because of the more costly fibres that need to be used) rather than increased operating costs (additional detail is provided in the Confidential Annex to RPA (2014)).

C.2.7.4 Conclusions

The following table summarises the conclusions from the above information on the feasibility and suitability of 2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide as a replacement for decaBDE.

Table 81: Conclusions on suitability and feasibility of 2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide

Category	Conclusion
Hazard	2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide is persistent, however, it is not a PBT (based on screening information) and its human health hazard profile does not appear to raise concerns
Technical feasibility	2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide appears to be suitable for replacing decaBDE in textile applications when used as a FR for a specific fibre type (viscose)
Economic feasibility	2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide requires the same or lower loadings than decaBDE. However it has a higher price and requires the use of more expensive raw material fibres. As a result, the price of the textile articles are considerably higher than with decaBDE.
Overall conclusion	**2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide is persistent in the environment. It can find limited application as a decaBDE replacement and is considerably more expensive to use due to higher price and requirement for more expensive raw material.**

C.2.8 Alternative 8: Resorcinol bis(diphenylphosphate) (RDP)

C.2.8.1 Human health information

C.2.8.1.1 Information from government or other regulatory authorities

The recent US EPA (2014) assessment of alternatives to decaBDE, considered the carcinogenic, developmental, neurological and repeated dose hazard posed by RDP to be moderate.

The German Federal Environmental Agency (Umweltbundesamt) recognised in 2001 the lack of data on RDP.

C.2.8.1.2 Other reports

An assessment of human health risks from the use of consumer products (EEE) that contained RDP was carried out by Arcadis & EBRC (2011) and did not identify any unacceptable risks.

C.2.8.1.3 Information from registrations, C&L and industry

The information indicates no PBT properties and self-classifications as Aq Chr 3 H412; Aq Chr 2 H411; Aq Ac 1 H400.

C.2.8.1.4 Conclusions for human health

The very limited data available is not sufficient to conclude if RDP poses significant risks for human health.

C.2.8.2 Environmental information

C.2.8.2.1 Information from government or other regulatory authorities

Assessments performed by authorities for this substance by Kemi (2009), and JRC (EU RAR, 2007) conclude that it does not meet the PBT/vPvB criteria. The same conclusions were triggered by an ENFIRO project (2014).

The evaluation of RDP's environmental risks, performed by The Environment Agency for England and Wales in 2009, identified potential risks for all of the life cycle steps for one or more of the so-called "protection goals". EA (2009) concludes that the substance meets one of the criteria on the basis of screening data (P and vP), but does not meet the other two criteria and so is not a PBT/vPvB substance. Tetraphenyl resorcinol diphosphate is considered to be inherently biodegradable but it is not possible to determine if the specific criteria are met (Section 3.1.1). The substance undergoes hydrolysis in water with a half-life at 10°C shorter than the criteria. However, this is for primary degradation, and the results also indicate that the reaction may reach equilibrium after one or two half-lives. This is not considered sufficient evidence that the substance does not meet the criteria. Hence, the substance is considered to meet the first stage screening criteria for P and vP.

The US EPA recent assessment of alternatives to decaBDE (2014) identified the following high and very high concerns regarding environmental endpoints for RDP:

- *Acute toxicity: based on measured EC50 values for daphnia. Measured values for fish and algae are higher than the water solubility limit, suggesting no effects at saturation (NES)*
- *Chronic aquatic toxicity: based on an experimental 21-day NOEC 0.021 mg/L in Daphnia magna. Estimated chronic values suggest a high hazard with the n = 1 oligomer (CAS No: 57583-54-7) of 0.0093 mg/L for fish*
- *Bioaccumulation: the estimated BCF value for the n=1 component (CAS No. 57583-54-7) has high potential for bioaccumulation. The higher molecular weight oligomers that may be found in this mixture (n=2, 3, 4...) are expected to have moderate or low potential for bioaccumulation based on their large size and low solubility according to the polymer assessment literature*.

In addition, US EPA (2014) highlighted that *hydroxy-RDP, dihydroxy-RDP, resorcinol diphenyl phosphate, and hydroxyl-resorcinol diphenyl phosphate, resorcinol, resorcinol conjugates, resorcinyl glucuronide and resorcinyl sulphate were identified as metabolites. Environmental degradation of RDP has been demonstrated in experimental studies; however, the degradation products have not been identified. Degradation of RDP by sequential dephosphorylation could produce phenol, diphenyl phosphate or resorcinol. The importance of dephosphorylation relative to possible competing pathways has not been demonstrated in a published study*.

The commercial RDP contains up to 5% TPP. TPP raises concerns of aquatic toxicity but it is assumed a generally low presence of TPP in the commercial product.

C.2.8.2.2 Information from Registrations, C&L and Industry

The information indicates no PBT properties and self-classifications as Aq Chr 3 H412; Aq Chr 2 H411; Aq Ac 1 H400.

C.2.8.2.3 Conclusions for environment

Overall, this alternative does not meet the PBT criteria but it shows signs of persistence in the environment and its biodegradation is yet unclear. In addition, there is uncertainty about its bioaccumulation and aquatic toxicity.

C.2.8.3 Technical and economic feasibility

C.2.8.3.1 Technical feasibility - relevant applications

Commercial RDP is a mixture of chemicals (State of Hawaii Department of Health):

- 65-80% phosphoric acid, 1,3-phenylene tetraphenyl ester (CAS No 57583-54-7)
- 15-30% phosphoric acid, bis[3-[(diphen-oxyphosphinyl)oxylphenyl] phenyl ester (CAS No 98165-92-5), and
- <5% triphenyl phosphate (TPP).

According to the US EPA (2014), the material used by industry for FR applications is most likely the polymeric material with CAS number 125997-21-9, although the CAS number for the discrete organic where n=1, 57583-54-7 (Phosphoric acid, P,P'-1,3-phenylene P,P,P',P'-tetraphenyl ester), has been used interchangeably with 125997-21-9 in the publicly available literature.

There are several literature sources describing the applicability of RDP as a flame retardant. A summary is provided in the table below.

Table 82: Applications for resorcinol bis(diphenylphosphate) (RDP)

Application	Material - substrate	Notes	Source
Enclosures	PC/ABS, PPE/HIPS	Superior flammability performance and lower volatility than is obtainable with conventional triaryl phosphates	Danish EPA (2006)

Application	Material - substrate	Notes	Source
Transportation: Dashboard Instruments Instrument panels Instrument cluster housing And other parts	ABS, PC/ABS		PINFA (2010b)
Automotive foams	Not specified		PINFA (2010b)
Automotive E&E components	HIPS/PPO, PC/ABS (4:1)		PINFA (2010b)
E&E – UL94V0	PC, PC/ABS, PPE/HIPS, TPU		Troitzsch (2011)
Electronics	PC/ABS, PPE/HIPS		US EPA (2014)

RDP is an aryl phosphate, which is used as a substitute for halogenated FRs as well as for TPP because it has a lower volatility, a higher thermal stability, and a higher P-content in comparison to TPP. This would not be of influence on the FR efficiency if RDP were only working in the solid phase of burning materials. The primary mechanism of RDP is the solid phase mechanism, but in addition, a (weaker) gas phase mechanism is also assumed. The active substance content lies between 10 and 11% of phosphorus weight, depending on the product. RDP is used as a substitute for TCPP as it is less volatile, and therefore less likely to be released into the environment (van der Veen & de Boer, 2012).
RDP cannot be used in HIPS as a direct replacement for decaBDE. In order to use RDP, the manufacturer must use a different plastic to achieve the same fire rating. Other plastic blends using RDP such as HIPS/PPO or PC/ABS have been identified as viable alternatives to decaBDE/HIPS TV enclosures. RDP is used instead of other phosphate FRs like TPP, because the amount of phosphate in the RDP is higher and therefore would lead to the higher total phosphorus loading (Department of Ecology State of Washington, 2008).

C.2.8.3.2 Economic feasibility

Loading
RDP is added to plastic at up to 20% by weight. For a given amount of plastic, more RDP must be added compared to decaBDE to maintain fire safety, that is, to achieve UL94 V-0 rating. Recent information however indicates that fire safety and the UL94 V-0 rating can be maintained with much lower levels of RDP, for example in PC/ABS blends as little as 9% RDP (Department of Ecology State of Washington, 2008).

Also several other literature sources refer to the loadings of RDP:
- 10% in V-0 grade PC/ABS and PPE/HIPS (Danish EPA, 2006)
- 17-20% in PPE and polystyrene blends (Takamura, Todt, & Sharma, 2013)
- 8-13% in a blend of poly(2,6-dimethylphenylene ether), polyphenylethylene-poly(ethylene/butylene)-polyphenylethylene block copolymer and a styrene-(ethylene/propylene-styrene)-styrene copolymer (Kosaka, 2006)
- 9% in V-0 PC/ABS (PINFA, 2010).

Price
Information from HELCOM (2013) suggests that the price of RDP is below €3.5/kg. The cost

to producers has been described as "affordable". No other source of information is available.

C.2.8.4 Conclusions

The following table summarises the conclusions from the above information on the feasibility and suitability of RDP as a replacement for decaBDE.

Table 83: Conclusions on suitability and feasibility of RDP

Category	Conclusion
Hazard	RDP raises some concern about its persistence and bioaccumulation, but is not recognised as a PBT. It may show chronic and acute aquatic toxicity. Its degradation products are not known with certainty.
Technical feasibility	RDP appears to be suitable for replacing decaBDE in plastic blends, primarily for EEEs where the use of decaBDE has been eliminated under the RoHS Directive
Economic feasibility	RDP may nowadays require lower loadings than decaBDE and it appears to have lower price per kg than decaBDE. However, the changes to the resins (e.g. from HIPS to a blend) and any other changes to the process may have a notable impact on costs, which literature has described as "affordable"
Overall conclusion	**RDP's hazard profile raises concerns with regard to persistence, bioaccumulation, degradation and aquatic toxicity, yet the substance appears to have been a successful replacement for decaBDE in polymer EEEs**

C.2.9 Alternative 9: Bisphenol A bis(diphenyl phosphate) (BDP/BAPP)

C.2.9.1 Human health information

C.2.9.1.1 Information from government or other regulatory authority

The US EPA assessment of alternatives report (2014) indicates moderate carcinogenic hazard for BDP/BAPP.

C.2.9.1.2 Other reports

Arcadis & EBRC (2011) assessed the risks to human health of BDP/BAPP from consumer uses scenarios including service life of clothes, PVC, flooring and furniture. *First tier exposure assessments to BDP/BAPP have been performed using the ECETOC TRA Consumer tool with a simple refinement for a more plausible inhalation exposure assessment using the saturated vapour concentration. This tentative risk assessment using conservative exposure estimations showed a risk with respect to the dermal and oral exposure to textiles and the dermal exposure to PVC flooring and furniture. It was stated by industry that the latter two applications are not relevant for the domestic environment. Additionally, the use in textiles was confirmed as being a niche application. No risk was identified for the other applications and routes considered*.

Information from registrations, C&L Inventory and Industry
No relevant information available

C.2.9.1.3 Conclusions for human health

The available information does not allow to conclude on a human health concern.

C.2.9.2 Environmental information

C.2.9.2.1 Information from government or other regulatory authority

The assessments performed by authorities (Kemi, 2009; EU RAR, 2007) support the conclusion that BDP/BAPP does not fulfil the PBT criteria.

The US EPA assessment of alternatives to decaBDE (2014) provided information on parameters identified as being of "High" or "Very High" concern:

- *Persistence: experimental studies were on the commercial mixture, which is estimated to contain approximately 85% BAPP. BAPP is not readily biodegradable. In a Japanese Ministry of International Trade and Industry (MITI)-I (OECD Test TG 301C) test 6% biodegradation occurred over 28 days in sewage sludge. BAPP does not contain chromophores that absorb at wavelengths >290 nm, and therefore is not expected to be susceptible to direct photolysis by sunlight. The atmospheric half-life of BAPP is estimated to be 5.5 hours, although it is expected to exist primarily in the particulate phase in air. Enzymatic or basic hydrolysis leading to the production of phenol (CAS No 108-95-2), diphenyl phosphate (CAS No 838-85-7), and bisphenol A (CAS No 80-05-1) through sequential dephosphorylation is theoretically possible but has not been demonstrated;*

- *Bioaccumulation: although measured BCF values for the components of the polymeric mixture result in a Moderate bioaccumulation hazard designation, the overall bioaccumulation designation for BAPP is high based on an estimated BAF value. The estimated BAF of 1,100 for the predominant component of the mixture with a MW <1,000 daltons, suggests that BAPP may bioaccumulate in higher trophic levels;*

- *degradation of BAPP has been demonstrated in experimental studies. The importance of dephosphorylation relative to possible competing pathways has not been demonstrated in a published study. Therefore, the hazards of the theoretical degradation products were not considered in this hazard assessment.*

The ENFIRO assessment (ENFIRO, 2014) concluded low to high ecotoxicity and persistence.

C.2.9.2.2 Information from registrations, C&L and industry

The information indicates classification as aquatic chronic 2 and 4, H411 and respectively H413, and no PBT properties.

C.2.9.2.3 Conclusions for environment

Overall, although BDP/BAPP shows uncertain persistence, it is not considered a PBT substance. There are concerns on its degradation products (bisphenol A and phenol, with concerning hazard profiles), but this has not been proven.

C.2.9.3 Technical and economic feasibility of alternative 9

C.2.9.3.1 Technical feasibility - relevant applications

BAPP is a mixture of three components, two components with bisphenol A as a major constituent (>97%) and TPP (3%) (Department of Ecology State of Washington, 2008). There are several literature sources describing the applicability of BDP/BAPP as a flame retardant. A summary is provided in the table below.

Table 84: Applications for bisphenol A bis(diphenyl phosphate) (BDP/BAPP)

Application	Material - substrate	Notes	Source
Enclosures	PC/ABS, PPE/HIPS	Superior flammability performance and lower volatility than is obtainable with conventional triaryl phosphates	Danish EPA (2006)
Transportation: Dashboard Instruments Instrument panels Instrument cluster housing Speaker grilles Gear knobs And other parts	ABS, PC/ABS		PINFA (2010b)
Automotive foams	Not specified		PINFA (2010b)
Automotive E&E components	PC/ABS (4:1)		PINFA (2010b)
E&E – UL94V0	PC, PC/ABS, PPE/HIPS, TPU		Troitzsch (2011)
Wire & cable, E&E housings	HIPS, PC, PU		Arcadis & EBRC (2011)
Textiles, furniture		Textiles is a niche application	
Flooring			
Electronics	PC, PC/ABS, PPE/HIPS		US EPA (2014)

A comparison between the technical characteristics of BDP/BAPP and decaBDE in polymer applications has been provided by a consultee and this is presented in detail in the Confidential Annex of the RPA report (2014).

C.2.9.3.2 Economic feasibility

Loading

Several literature sources refer to the loadings of BDP:

- 10-14% in V-0 grade PC/ABS and PPE/HIPS (Danish EPA, 2006)
- 15-16% in PPE and polystyrene blends (Takamura, Todt, & Sharma, 2013)
- 12-13% (with an upper limit of 15%) for PPE/HIPS blends achieving a UL94 V-0 fire rating (Landa, 2009)
- 12.3% in V-0 PC/ABS (PINFA, 2010).

Consultation suggests that the substance's loading does not differ to that of decaBDE in PC/ABS and mPPE. However, it does not require the presence of ATO.

Price

Information from the Alibaba.com online marketplace would suggest that BDP/BAPP may have a market price ca. 50% lower than decaBDE, but this is not supported by information from consultation. By way of comparison, HELCOM (2013) presents the price of bisphenol A at €4.5/kg, that is, ca. 10% more expensive than decaBDE.

Some additional information on how investment and operating costs may change from a transition from decaBDE to BDP/BAPP in polymer formulation is provided in the Confidential Annex to RPA report (2014). It can be disclosed that investment costs is an important consideration when comparing the two substances.

C.2.9.4 Conclusions

The following table summarises the conclusions from the above information on the feasibility and suitability of BDP/BAPP as a replacement for decaBDE.

Table 85: Conclusions on suitability and feasibility of BDP/BAPP

Category	Conclusion
Hazard	BDP/BAPP raises some concern about its persistence, but is not recognised as a PBT. A classification for chronic aquatic toxicity is made in the registration dossier and the C&L Inventory. Degradation of the substance by dephosphorylation may generate substances of unfavourable hazard profile (bisphenol A, phenol), but this has not been proven.
Technical feasibility	BDP/BAPP appears to be technically feasible for replacing decaBDE in plastic blends, with textiles being a niche application
Economic feasibility	BDP/BAPP appears to be used at loadings similar to decaBDE and its price per tonne is assumed to be comparable to decaBDE. However, its use may require a change to different resin and notable investment costs
Overall conclusion	**The hazard profile of BDP/BAPP may raise concerns due to its persistence, aquatic toxicity and potential degradation products. Its use in polymer applications may increase production costs**

C.2.10 Alternative 10: Substituted amine phosphate mixture (P/N intumescent systems)

C.2.10.1 Human health information

C.2.10.1.1.1 Information from government or other regulatory authority

The US EPA assessment (2014) identified for mixtures of substituted amines "Moderate" concern for carcinogenicity, genotoxicity, reprotoxicity and repeated dose endpoints, law for neurological and "High" concerns for the acute toxicity, with regard to the acute toxicity of piperazine contained in the mixture.

C.2.10.1.1.2 Information from registrations, C&L and industry

This product is a mixture of piperazine pyrophosphate and a substituted amine phosphate. Only for the former is a REACH registration available and its limited contents show classification as Eye Irritant 2 H319: Causes serious eye irritation

C.2.10.1.2 Conclusions for human health

Overall, due to the limited information available, no concerns can be raised. Nevertheless, the acute toxicity has been highlighted as potentially problematic.

C.2.10.2 Environmental information

C.2.10.2.1.1 Information from government or other regulatory authority

The US EPA assessment (2014) identified the following parameters of "High" or "Very High" concern for mixtures of substituted amines :

- *Acute mammalian toxicity: using a conservative approach, acute toxicity hazard potential for the substituted amine phosphate mixture is estimated based on toxicity for inhalation exposure to the piperazine moiety in rats. The hazard is estimated to be low for oral and dermal routes of exposure to the substituted amine phosphate and piperazine components of the mixture;*

- *Persistence: the substituted amine phosphate mixture is estimated to show high persistence in the environment based on experimental data for the organic components. The persistence of the inorganic phosphate components of this mixture were not considered a factor in the assignment of this hazard designation. The organic component of the confidential substituted amine phosphate undergoes biodegradation according to measured results; however, the rates of removal are slow. The organic portion of the substituted amine phosphate component is considered inherently biodegradable, not readily biodegradable.*

C.2.10.2.1.2 Information from registrations, C&L and industry

Only for substituted amine phosphate there is a REACH registration available and its limited contents show Aquatic Chronic 3 (H412)

C.2.10.2.2 Conclusions for Environment

Overall, due to the limited information available, this alternative appears to raise only persistence concerns.

C.2.10.3 Technical and economic feasibility

C.2.10.3.1 Technical feasibility issues - relevant applications

There are several literature sources describing the applicability of this mixture as a flame retardant. A summary is provided in the table below.

Table 86: Applications for substituted amine phosphate mixture (P/N intumescent systems)

Application	Material - substrate	Source
Wires & cables	PP, PE	Danish EPA (2006)
E&E – UL94 V-0	PP, PE, Thermoplastic styrene-block copolymers (TPE-S)	Troitzsch (2011)
Not specified	PP, PE, EVA copolymers, thermoplastic elastomers, UPE, EPDM, TPU, PE/EVA	UK HSE (2012)
Electronics	Elastomers, PP, PE, TPU	US EPA (2014)
Wires & cables	Elastomers, EVA, PP, PE, TPU	
Public buildings	Elastomers, EVA, PP, PE, TPU	
Construction materials	Elastomers, EVA, PP, PE, TPU	
Automotive	Elastomers, EVA, PP, PE, TPU	
Aviation	Elastomers, EVA, PP, PE, TPU	
Storage and distribution	Elastomers, PP, PE	

Consultation suggests that this alternative may find applications in (unspecified) polymers used in electronics (including the housing of electrical appliances), wire and cable, public buildings, construction materials, automotive, aviation, storage and distribution products. Consultation with a supplier (shown in the Confidential Annex) appears to suggest that the alternative may perform to a similar or better performance level as decaBDE.

C.2.10.3.2 Economic feasibility

Loading
Information from consultation suggests that in PE/PP the loading of this alternative may be 20-30% higher than for the decaBDE.

Price
The substance is reported to have a price notably higher than that of decaBDE, however, it does not require the presence of ATO. The overall price increase for the final article is estimated at considerable compared to decaBDE-based articles. Certain operating costs are also likely to change, as described more in detail in the Confidential Annex to RPA (2014).

C.2.10.4 Conclusions

The following table summarises the conclusions from the above information on the feasibility and suitability of the substitute amine phosphate mixture as a replacement for decaBDE.

Table 87: Conclusions on suitability and feasibility of substituted amine phosphate mixture (P/N intumescent systems)

Category	Conclusion
Hazard	Limited information is available; persistence concerns and acute toxicity has been highlighted as potential problematic areas
Technical feasibility	Technically feasible for polymer applications in a variety of areas; example resins include elastomers, EVA, PP, PE, TPU
Economic feasibility	Higher loadings and price per kg combined with changes to operating costs
Overall conclusion	**Only limited information on hazards is available. It is technically feasible in many polymer applications, but seems to introduce higher production costs due to higher prices, loadings and increased production costs.**

C.2.11 Alternative 11: Red phosphorous

C.2.11.1 Human health information

C.2.11.1.1 Information from government or other regulatory authority

Kemi (2009) highlighted that red phosphorous is often contaminated with yellow and white phosphorus, which are considerably more toxic forms.

The US EPA (2014) assessment of Deca BDE's alternatives only identified a moderate concern for the genotoxicity of red phosphorous.

C.2.11.1.1.1 Information from scientific literature

During combustion and long-term storage of red phosphorus the formation of toxic phosphine gas occurs (SFT, 2009). *The disproportionation of red phosphorus to phosphine and phosphoric acids occurs in the presence of moisture at elevated temperatures. Significant disproportionation can only take place in the injection moulding process if the residual moisture content in the polymer is too high (Uske & Ebenau, 2013). Industry claims that phosphine is very reactive and is readily oxidised in the environment, leading to the production of harmless phosphates (Gatti, 2002).* Improved techniques and increased expertise in the production and compounding of red phosphorous allow a proper control of degradation problems (Gatti, 2002, PINFA, 2010, Uske & Ebenau, 2013).

C.2.11.1.2 Information from Registrations, C&L Inventory and Industry

Self-notifications indicate: Ac Tox 2 H330; Ac Tox 1 H300; Skin Corr.1A H 314; Eye Dam. 1 H 318; STOT SE 1 H 370; STOT RE 2 H 373 and for the phys-chem: Flam. Sol. 1 H 228; Pyr. Sol.1 H 250; Self heat. 1 H251;

C.2.11.1.2.1 Conclusions for human health

From the available information, during properly controlled manufacturing and use, no significant concerns for human health appear to exist.

Its flammability (for the solid state) does not pose concerns, as long as red phosphorous can be stabilised in masterbatches and by this, the flammability hazard is addressed.

C.2.11.2 Environmental information

C.2.11.2.1 Information from government or other regulatory authority

A study published in 2001 by the German Federal Environmental Agency (Umweltbundesamt) described red phosphorous as unproblematic in its main applications, the polymer articles (including electrical and electronics such as insulation, printed circuit boards and enclosures for electrical appliances, as well as textiles for upholstered furniture), on the basis of environmentally relevant properties (toxicity and ecotoxicity) data.

The US EPA assessment from 2014 identified as being of "high" concern its persistence: *red phosphorus is estimated to display high persistence in the environment. Elemental red phosphorus is relatively non-reactive under typical environmental conditions. Measured data indicate that red phosphorus will slowly undergo hydrolysis under environmental conditions (<3% in 4 months) and will eventually convert to phosphine and hypo phosphorous acid. Subsequent oxidation of these hydrolysis products will lead to the formation of phosphoric oxides and acids.*

C.2.11.2.2 Information from registrations, C&L and industry

The informations indicates classification as Aquatic Chronic 3 with H412 and Aq Ac. 1 H 400; and persistence in the environment. Its water solubility is low.

C.2.11.2.3 Conclusions for environment

Red phosphorus, as an inorganic compound isis not a PBT, but it may be considered persistent in the environment. It is also classified for aquatic toxicity.

C.2.11.3 Technical and economic feasibility

C.2.11.3.1 Technical feasibility - relevant applications

There are several literature sources describing the applicability of red phosphorous as a flame retardant. A summary is provided in the table below.

Table 88: Applications for red phosphorous (CAS No. 7723-14-0)

Application	Material - substrate	Source
Automotive textiles	Cotton-based and cotton-rich	RPA (2003)
Unspecified	PE/PP, PS, PVC, ABS, UPR, Epoxy, PU	KemI (2005)
Connectors	PA	Danish EPA (2006)
Wires	PE	
Unspecified	PP/PE, PS, PVC, ABS, PA, PC, SAN, UPR, Epoxy, PU, rubber	KemI (2009)
Transportation insulation materials	PIR	PINFA (2010b)
Sealants (flame-retarded and/or fire-resistant)	PUR, acrylics, epoxy, elastomers, PVC	
Cables	Used in fire-resistant coatings for cables	
	Polyolefins	
	Elastomers	
	Thermoplastic Elastomers (TPE) Polypropylene (PP)	
E&E components	PA 6,6 + glass fibre	
E&E – UL94V0	PE, PET, epoxy resins	Troitzsch (2011)
Unspecified	PA, PE	UK HSE (2012)
Semi-durable finishes	Cotton, polyester	EFRA (2012)
Electronics	Epoxy, PA, PA6,6 GF, PP	US EPA (2014)
Wires & cables	Elastomers, PA, PP	
Automotive	Emulsions, epoxy resins	
Aviation	Epoxy resins, PA	
Waterborne emulsions and coatings	Emulsions, epoxy resins	
Small parts for electronic appliances	PBT, PET, PA	German MSCA

Red phosphorous is an active FR as a single additive in nitrogen and/or oxygen containing polymers such as polyamides (particularly glass-filled PA), polyesters, polyurethanes, epoxies, polyisocyanates, polycarbonates and ethylene-vinyl acetate, while it has to be applied with spumific and carbonific agents and/or with inorganic hydroxides in polyolefins, styrenics and rubbers. Its use is restricted on the basis of colour – it cannot be used for white or light coloured final articles, but is widely applicable for items from black to medium grey (Gatti, 2002).

Another drawback with the use of red phosphorus is the formation of toxic phosphine gas during combustion and long-term storage (SFT, 2009). Precautions against degradation

have to be taken (PINFA, 2010). The disproportionation of red phosphorus to phosphine and phosphoric acids. Improved techniques(Gatti, 2002) like for example, efficient pre-drying can be used as a counter-measure (Uske & Ebenau, 2013).
The red phosphorous market has been historically limited mainly because of product flammability and has been regulated as potentially hazardous material in transportation, feeding and processing. In order to improve the safe handling of red phosphorous powder at the workplace, it is usual to stabilise it, microencapsulate the surface with thermoset resins and add dust suppressant agents. However, even when stabilised and coated, red phosphorous powder is still flammable and always represents a hazard in handling and transportation. Consequently, the safest and most convenient way of handling and processing red phosphorous is the use of concentrates/masterbatches in a wide range of polymers (Gatti, 2002).

C.2.11.3.2 Economic feasibility

Loading
Red phosphorous is the most concentrated source of phosphorus; therefore, it is an effective FR additive at a concentration ranging from 2-10% by weight (Gatti, 2002).
In glass fibre reinforced PA 6,6, red phosphorous is used at 5 to 8% addition level, where its high efficiency at low loading guarantee to maintain the mechanical and electrical properties of the polymer while obtaining the highest flame proofing characteristics (PINFA, 2010).

Price
Information from the Alibaba.com online marketplace would suggest that red phosphorous might have a price lower than decaBDE by ca. 20%.

C.2.11.4 Conclusions

The following table summarises the conclusions from the above information on the feasibility and suitability of red phosphorous as a replacement for decaBDE.

Table 89: Conclusions on suitability and feasibility of red phosphorous

Category	Conclusion
Hazard	It may be considered persistent in the environment but as an inorganic compound cannot be subject to the PBT criteria. It is accompanied by an Aquatic Chronic 3 classification (but test data could suggest a more severe classification might be warranted) With the exception of irritant properties and some uncertainty over genotoxicity and hepatoxicity, no significant concerns for human health appear to exist. Its physico-chemical hazards and the risk of disproportionation products are reduced through encapsulation and stabilisation
Technical feasibility	Suitable for polymer applications (PA, PE/PP, Epoxy, etc.) in dark colours and semi-durable finishes on cotton-rich textiles, generally unsuitable for man-made fibres
Economic feasibility	Limited information available indicates lower loadings and lower price per tonne than decaBDE
Overall conclusion	**Generally of limited concern as regards hazards and strong FR properties make it suitable for a number of specific applications. Limited information indicates lower loadings and prices per kg.**

C.2.12 Alternative 12: Ethane-1,2-bis(pentabromophenyl) (EBP)

C.2.12.1 Human health information

C.2.12.1.1.1 Information from government and other regulatory authority

In its 2009 assessment, Kemi informed on studies in rats and rabbits indicating low toxicity. The lack of human health data did not allow, in 2001, the German Federal Environmental Agency (Umweltbundesamt) to trigger a recommendation on its safe use.

US EPA (2014) considered EBP to have medium concern for carcinogenicity and high concern for developmental effects.

C.2.12.1.2 Other reports

In 2011, Arcadis & EBRC identified no risk by analysing one consumer exposure scenario (vapour inhalation).

C.2.12.1.3 Information from Registrations, C&L Inventory and Industry

According to the updated information in the registration dossier provided by Albemarle, (2013), the substance is not classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2 or 3) according to Directive 67/548/EEC (or the DSD) or carcinogenic (category 1A or 1B), germ cell mutagenic (category 1A or 1B), or toxic for reproduction (category 1A, 1B or 2) according to Regulation EC No 1272/2008 (or CLP Regulation).
No other evidence of chronic toxicity, as identified by the classifications: T, R48, or Xn, R48 according to Directive 67/548/EEC or specific target organ toxicity after repeated exposure (STOT RE category 1 or 2) according to Regulation EC No 1272/2008

C.2.12.1.4 Conclusions for human health

Based on the available data, at this stage, no definitive conclusion can be reached for the human health hazard of EBP.

C.2.12.2 Environmental information

EBP is currently subject to Evaluation under REACH by the UK Competent Authority based on concerns regarding its wide dispersive use and PBT properties.

C.2.12.2.1 Information from Governmental reports

UK HSE (2012) highlighted that EBP breaks down to PBT/vPvB substances and is considered to act as a long-term source of degradation products through both abiotic and biotic transformation. Its partition coefficient may have values from 3.55 measured by generator column method, and varies when calculated, between 7.8 and 14.

US EPA in its 2014 assessment considered as of "high" or "very high" the following endpoints:

- *Persistence: very high persistence of EBP is expected based on experimental biodegradation data. EBP was determined to not be readily biodegradable in a 28-day MITI test nor was it inherently degradable in a 90-day aerobic sewage/soil test using pre-exposed inoculum. It is not expected to undergo hydrolysis since it does* *not contain hydrolysable functional groups. The atmospheric half-life of EBP is estimated to be 4.5 days, although it is expected to exist primarily in the particulate phase in air. Laboratory studies have demonstrated photolysis of EBP, although the rate of this process under environmental conditions has not been established;*

- *Bioaccumulation: the bioaccumulation hazard designation is estimated based on EBP monitoring data reporting detections in many different species, including those higher in the food chain. Although the estimated bioaccumulation factor is low, the persistence of EBP and its detection in many species from different habitats and trophic levels indicates high potential for bioaccumulation hazard in aquatic or terrestrial species.*

C.2.12.2.2 Information from registrations, C&L and industry

The information indicates a classification as Aquatic Chronic 4 with H413. It is considered very persistent(vP) , but not B and T.

C.2.12.2.3 Conclusions for Environment

Based on the available data, no conclusions can be reached on the environmental hazard of EBP. However, it is noteworthy that it is currently undergoing Evaluation under REACH based on PBT concerns.

C.2.12.3 Technical and economic feasibility

C.2.12.3.1 Technical feasibility - relevant applications

There are several literature sources describing the applicability of EBP as a flame retardant. A summary is provided Table 90 below.

Table 90: Applications for ethane-1,2-bis(pentabromophenyl) (EBP)

Application	Material - substrate	Notes	Source
Enclosures	HIPS, ABS, PC/ABS, PPE/HIPS	EBP is claimed to have better bloom resistance, UV stability and physical properties	Danish EPA (2006)
Connectors	PA, PBT/PET		
Wires	PP, PE		
E&E – UL94V0	PE, PP, HIPS, ABS, PET, PBT, PC, PC/ABS, PPE/HIPS, Epoxy resins, Unsaturated polyester resins (UP), Thermoplastic styrene-block copolymers (TPE-S) Thermoplastic polyurethanes (TPU) Thermopolyolefins (TPO)		Troitzsch (2011)
Wires and cables – VW 1	Thermoplastic polyester elastomers (TPE-E)		
Not specified	ABS, HIPS, PA, PBT/PET, PC, PP, PE, SAN, PC/ABS, HIPS/PPO, thermoplastic elastomers, silicone, PVC, EPDM, TPU, PE/EVA, thermosets (epoxy and phenolic resins, unsaturated polyesters)		UK HSE (2012)
Thermoplastics	ABS, HIPS, PA, Polyester, PC, PP, PE/copolymer, SAN, PC/ABS, PPO/HIPS, Elastomers, PVC		Albemarle (2013)
Foams	Polyolefin, PVC/Nitrile, Elastomers		
Wire & cable	Silicone, EPDM, PP, PE/EVA, TPU, PVC		
Thermosets	Epoxy, phenolic, UPR, vinyl esters, PU/CASE, latex		

Application	Material - substrate	Notes	Source
Adhesives, sealants and coatings			Chemtura (2013)
Automotive			
Aviation			
Public, mass transit			
Wire and cable			
Roofing membrane and flooring			
Textile backcoating			
HIPS, PE, PP, ABS,		FR efficiency, exceptional thermal stability and multi-purpose	ICL Industrial Products (2013b)
PBT, UPE, Epoxy, Nylon 6, Textiles			
Electronics	CPE, PP, PE, Elastomers, HIPS, Engineering thermoplastics, thermosets		US EPA (2014)
Wire & cable	CPE, PP, PE, Elastomers, Engineering thermoplastics		
Public buildings	Elastomers, PE, thermosets		
Construction materials	Elastomers, PP, thermosets		
Automotive	Elastomers, engineering thermoplastics, PP, PE		
Storage and distribution products	Elastomers, PP, PE		
Textiles	Emulsions		
Waterborne emulsions and coatings	CPE, emulsions, engineering thermoplastics		

According to consultation, EBP is being marketed as a direct “drop-in” replacement of decaBDE. In other words, it does not require changes in the process to be implemented. One supplier of the substance confirmed that it can be used in a wide variety of plastics, including thermoplastics (HIPS, ABS, polyolefins, TPU, polyesters (PBT), PA), thermosets and in coatings. Available information shows that technical parameters, such as strength properties and flame resistance performance (LOI), are very similar and can be achieved with the same loading. Also ATO is used at the same loading as with decaBDE. An example application in technical textiles where EBP may act as a replacement for decaBDE without process changes and with the same FR performance is shown in the Confidential Annex of RPA (2014). Some processing issues associated with the use of EBP as a replacement for decaBDE have been reported, but no further clarification was given other than that those can generally be overcome. Several industry representatives have confirmed that they see EBP as the obvious choice, as it is technically compatible with the processes used in the industry, especially now that its price is comparable to that of decaBDE.

The assertion that EBP is becoming/will become the main replacement for decaBDE has also been supported by information provided during consultation by the US EPA (2014b) and Environment Canada (2014).

C.2.12.3.2 Economic feasibility

Loading

The following table replicates information presented by the Danish EPA (2006) on the relative loading of decaBDE and EBP in different matrices. This information suggests that the two substances require identical loading (including the loading of the ATO synergist). This was also confirmed in the consultation.

Table 91: DecaBDE and EBP loading rates in different matrices

Material/Fire rating	decaBDE content	ATO content	EBP content	ATO content
HIPS V-0	12-13%	4-5%	12-13%	4-5%
PBT V-0	10.4%	4%	10.4%	4%
PA V-0	16-18%	6-7%	16-18%	6-7%
ABS V-0	13-15%	5%	N/A	N/A
Polyolefins V-0	20-30%	6-10%	20-30%	6-10%

Price

Information from the Alibaba.com online marketplace would suggest that EBP might have a cost, which is ca. 20% higher than that of decaBDE. Consultation would appear to be in some agreement with this figure. A price difference of 5-20% was suggested which, based on an assumed price for decaBDE of €4/kg, would mean that EBP may cost €4.2-4.8/kg.

C.2.12.4 Conclusions

The following table summarises the conclusions from the above information on the feasibility and suitability of EBP as a replacement for decaBDE.

Table 92: Conclusions on suitability and feasibility of EBP

Category	Conclusion
Hazard	EBP is highly persistent. There have been analyses on its bioaccumulation and reductive degradation and industry asserts that EBP does not behave like decaBDE and has provided information in support of this. Yet, the substance has been detected in many species from different habitats and trophic levels. While substance evaluation is under way, no conclusion can be reached on whether EBP is a suitable replacement for decaBDE
Technical feasibility	EBP is marketed as a drop-in replacement for decaBDE across its entire range of applications
Economic feasibility	EBP needs to be used at the same loading as decaBDE and with the same presence of ATO. Its price is estimated to be 5-20% higher than decaBDE’s. Its use might require some minor process changes (which have not been explained during the consultation in detail)

Category	Conclusion
Overall conclusion	**EBP is a drop-in replacement for all applications of decaBDE. It is used at the same loadings and the price is moderately higher than decaBDE. It seems to be the most obvious choice for the industry to switch to. However, its hazard profile is unclear and still under investigation**

C.2.13 Alternative 13: Melamine

C.2.13.1 Human health information

C.2.13.1.1 Information from or other regulatory authority

The OECD SIDS (1998) considered the toxicity of melamine to mammals to be low, not irritating to skin and eye, not sensitising and not teratogenic and not genotoxic with a low exposure of workers and consumers with an estimated margin of safety for workers of at least 210, and for consumers of at least 6000. The repeated exposure resulted in urinary bladder stones and other lesions of the urinary tract was also mentioned, and the bladder tumours only in male rats were considered to occur after prolonged irritation of the epithelium by the bladder stones, melamine acting only indirectly as a non-genotoxic carcinogen and they can be regarded in relation to the oral exposure. Therefore, melamine was considered of low potential risk and low priority for further work.

Melamine is classified as Giftklasse 4 in the German List of Toxic poisons GDL (2014), a hazardous material information system for the safe handling of chemical substances in the workplace, corresponding to an acute oral lethal dose (rats) of 500 to 2000 mg/kg (the class 1 the highest, the 5 grade the lowest).

The IARC Working Group noted in 1999 that a non-DNA reactive mechanism by which melamine produced urinary bladder tumours in male rats occurred only under conditions in which calculi were produced and concluded that melamine is not classifiable as to its carcinogenicity to humans (Group 3) (IARC, 1999).

C.2.13.1.2 Information from Registrations, C&L and Industry

Fourteen (14) companies fully registered the substance indicating various uses, including PROCs like mixing to milk, milk products or other food and feed and addition to pet food and baby milk as a nitrogen source. These might justify the various classifications notified: Acute Tox.4 H 312 and H 332, Skin Corr. 1C H314, Skin Sens.1 H317, Skin Irrit. 2 H315, Eye Irrit.2 H319, STOT RE 2 H373 (kidney/urinary…, bladder), STOT SE 3 H335 (lungs(inhalation), Carc.2 H351(oral).

C.2.13.1.3 Information from scientific literature

There is a large amount of information available on melamine, however it is not relevant for the concerned uses and exposure. It is mostly related to its use as a non-protein nitrogen source to cattle foodstuffs (sometimes illegally added to falsely elevate the protein contents determined in assays), the contamination of pet food ingredients associated with renal disease and deaths of pets and ending with tainting formula milk powders that caused the death of at least six infants and the hospitalization of 290,000 infants receiving therapy for kidney calculi or renal failure in China in 2008.

Gavin et al. (2008) reported MFR (melamine formaldehyde resins) contact allergic dermatitis with a negative reaction to formaldehyde in a worker on a melamine paper (a basic material used in the furniture industry for home and office interiors) impregnation line.

The findings of Kuo et al. (2013) study suggest that melamine increased inflammation and oxidative stress via activation of NOX/ROS pathway, and further suggested the potential inhibitor role of NOX (NADPH oxidase) against melamine toxicity in melamine-induced ROS (Reactive Oxygen Species) production, revealing the molecular target of melamine toxicity.

Wang et al. (2011) indicated that melamine influences the growth and morphology of eukaryotic cells, and that it affects the cellular protein expression levels but concluded that further research is needed.

Exposure to lower levels of melamine did not induce gene expression changes according to Camacho et al. (2011).

Zhang et al. (2011) investigated the long-term effect of low dose melamine on malignant transformation of normal human liver cell line L02 by Ames test, in vitro mammalian chromosome aberration test, mouse micronucleus test and sperm abnormality test and concluded that melamine has the ability to increase sperm deformity rate and DNA damage although it has no mutagenic function in prokaryotes and eukaryotes in vitro and in vivo and does not have ability to induce malignant cell transformation after long-term treatment.

Yin et al. (2013) concluded based on the TUNEL assay (method for detecting DNA fragmentation by labelling the terminal end of nucleic acids), that mice treated with high dose of melamine (50 mg/kg/day) had a significant increase in apoptotic index of spermatogenic cells ($p < 0.05$) compared with the control group. Sperm abnormality test indicated that melamine alone resulted in abnormal sperm morphology.

C.2.13.1.4 Conclusions for human health

Based on the data available and relevant for the types of exposure involved, melamine seem to raise no significant human health concern.

C.2.13.2 Environmental information

C.2.13.2.1 Information from government or other regulatory authority

The UK EPA assessments from 2003 concluded a low concern for melamine and no aquatic and PBT/vPvB.

The OECD SIDS highlighted its low toxicity to aquatic organisms, PEC/PNEC ratios based on realistic worst case conditions and on monitored concentrations below 1, low n-octanol/water partition coefficient, not readily biodegradable but effectively degraded in adapted waste- water treatment plants. Therefore melamine was considered of low potential risk and low priority for further work.

C.2.13.2.2 Information from registrations, C&L and industry

According to the registrants' information, melamine is hydrolysed by mineral acid or inorganic alkali. Hydrolysis proceeds stepwise, with loss of one, two, or all three amino groups, i.e. producing ammeline, ammelide and cyanuric acid. It is not readily biodegradable, and it appears to have a hydrolytic degradative pathway under anaerobic conditions by three successive deaminations to cyanuric acid, which is further metabolized. In soil up to ca. 18% of the nitrogen of its molecule are converted to nitrate within 24 weeks.

The adsorption of Melamine onto soil is not important. A soil sorption coefficient (Koc) of 53 was calculated.

CL notifications for melamine include Aquatic Acute 1 H400 and Aquatic Chronic 1 H410.

C.2.13.2.3 Information from scientific literature

The results of the Waaijers et al. (2013) study, part of the EU project ENFIRO (KP7-226563), revealed that melamine exhibited no acute toxic effect at their water solubility (EC50 > water solubility) and that no effects were observed at high concentrations.

In the Xu et al. (2013) study melamine appeared not to be easily biodegradable in two activated sludge treatment systems seeded with the sludge from a local municipal WWTP in China, even after a 100 days of sludge adaptation.

C.2.13.2.4 Conclusions on environment

This alternative does not meet the PBT criteria.

C.3 Conclusions on the analysis of alternatives

C.3.1 Alternative techniques

A variety of potential alternative techniques to the use of decaBDE exist and some of these are already currently used by industry, albeit in different applications. However, the available data does not allow their technical and economic feasibility as an alternative to the uses of decaBDE to be confirmed. Furthermore, there are no indications from the stakeholder consultation that users of decaBDE would switch to an alternative technique if decaBDE was not available. Because of this, alternative techniques have limited relevance for the SEA carried out in Part F. However, Inherent Flame Retardant Fibres (IFRF), which do not require flame retardant chemicals, were mentioned in the consultation by textile associations. Based on this, it should not be excluded that some of the users of decaBDE may switch to an alternative technique rather than to an alternative chemical should the use of decaBDE be restricted.

C.3.2 Alternative substances

Table 67 summarises the analysis of shortlisted alternative flame retardant substances and indicates which of them could make suitable replacements for decaBDE. Currently, only brominated FRs would appear to be able to act as drop in replacements for a wide range of applications, and indeed EBP (alternative 12), from a technical and economic perspective, is widely regarded as the substance most feasible for the industry to replace decaBDE. Nevertheless, many substances have a role to play and may act as technically feasible, reasonably priced alternatives for specific uses of decaBDE. Notwithstanding the conclusion above, it cannot be excluded that some users of decaBDE would switch to non-chemical alternatives.

For example, ethylene bis(tetrabromophthalimide) [EBTBP - alternative number 6] is another bromine-containing FR which is promoted as suitable to replace decaBDE in many of its applications. However, information from Alibaba.com suggests that ethylene bis(tetrabromophthalimide) is more expensive than both decaBDE and EBP. Therefore, it may be a less attractive alternative than EBP.

C.3.2.1 Plastics

Information has also been sought from non-EU administrations where the use of decaBDE has been under regulatory scrutiny, namely the USA and Canada. The US EPA has noted, "*Anecdotal information suggests* [a switch from decaBDE to EBP] *is likely happening/will happen in the US*" (US EPA, 2014b). Environment Canada has also confirmed a similar trend, "*Canada has seen an increased commercial interest for this substance as a direct drop-in replacement for decaBDE (…) Based on a recent study on PBDEs in products* (…), *the primary substitute that is being used by manufacturers in Canada appears to be EBP. Further, it seems that this compound is a cost-effective replacement for decaBDE applications relevant to Canadian manufacturers*" (Environment Canada, 2014).

There is a large variety of polymer materials which are currently flame-retarded with decaBDE. Therefore, there are opportunities for using different alternative substances, depending on the particular needs of products. Based on the frequency by which different alternatives appear in the literature, most potential choices appear to be:

- BDP/BAPP (alternative 9)
- RDP (alternative 8)
- ethylene bis(tetrabromophthalimide) (alternative 6)
- MDH (alternative 2)
- TPP (alternative 1)
- ATH (alternative 4)
- red phosphorous (alternative 11)

Some of these alternatives have a better hazard profile than EBP, irrespective of the outcome of the present Evaluation, and may offer a more sustainable long-term alternative to decaBDE that EBP.

C.3.2.2 Textiles

Several industry representatives have confirmed that they consider EBP as the obvious choice of alternative, as it is technically compatible with the processes used in the industry. Nevertheless, other alternatives may also be used, should decaBDE be restricted. These include:

- ATH
- MDH
- TDCPP
- ethylene bis(tetrabromophthalimide)
- 2,2'-oxybis[5,5-dimethyl-1,3,2-dioxaphosphorinane] 2,2'-disulphide (for viscose)
- red phosphorous

Some of these alternatives provide the possibility for industry to switch to less hazardous alternatives than EBP.

Annex E

E. Justification why the proposed restriction is the most appropriate Union-wide measure

E.1 Identification and description of potential risk management options

E.1.1 Options for restrictions

E.1.1.1 Preliminary screening of the options

This annex presents a preliminary screening of restriction options in terms of their potential to reduce emissions (effectiveness) and their cost-effectiveness. The effectiveness of a restriction option corresponds to its capacity to reduce emissions relative to total emissions. The cost effectiveness of a restriction is the cost to realise this emissions reduction. Effectiveness and cost-effectiveness considerations can be used to prioritise candidate restriction options. However, additional considerations of enforceability and proportionality will influence the final preferred restriction option.

The candidate restriction options considered (Table 93 and Table 94) were developed based on the information on emissions (low and high scenarios) and substitution costs presented in Section F (Table 12). Several of the candidate restriction options (1-4) are structured according to the type of material that decaBDE is used in (plastics or textiles) and where manufactured articles are used (indoors or outdoors, see section B.8.2.3.2))[58]. A further set of candidate restriction options (5-7) focus simply on the life-cycle stage of decaBDE use, i.e. production, service-life or waste, with no consideration of article type.

To correctly interpret the results (see sections E.1.1.1.1 to E.1.1.1.4), note that:

$$Cost\ effectiveness\ \left(\frac{€}{kg}\right) = \frac{Substitution\ Costs\ (€)}{Amount\ of\ decaBDE\ emission\ reduced\ (kg)} = \frac{\Delta pq}{\Delta fq}$$

p: price of flame retardant (€/kg), q: quantity used (kg), f: emission factor

- high emission factors lead to improved cost-effectiveness (the cost per kg of reducing decaBDE emissions is low)
- low emission factors lead to reduced cost-effectiveness (the cost per kg of reducing decaBDE emissions is high)
- consequently, the high emissions scenario gives systematically better cost effectiveness (lower cost per kg of reducing decaBDE emissions) than the low emissions scenario.
- For simplicity, only a single substitution scenario is considered in the screening

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[58] This is a consequence of how the emission estimations and subsequent cost calculations were made (see section B.8.2 and F.2).

analysis i.e. Approach A based on the total replacement of decaBDE with EBP (from section F.2)

- The analysis is based on information on the use of decaBDE in plastic and textile articles and it is assumed that all uses of decaBDE are covered with that approach. This is because very limited information was collected on other potential uses (e.g. inks and coatings, adhesives and sealants).

Table 93: Risk management options

Options	**Reference to matrix** (Table 94)
Restriction on plastics used indoors	1
Restriction on plastics used outdoors	2
Restriction on textiles used indoors	3
Restriction on textiles used outdoors	4
Restriction on production	5
Restriction on placing on the market	6
Impose conditions on waste management	7

Note 1: the proposed RMO is a combination of option 1, 2, 3 and 4 (or options 5 + 6). For emissions and cost figures of a total ban see Table 95.

Note 2: for a full description of each of the options see dedicated paragraph below

Table 94: Risk management option matrix

		1	**2**	**3**	**4**	
Production	Indoor plastics	x				**5**
	Outdoor plastics		x			
	Indoor textiles			x		
	Outdoor textiles				x	
Service Life	Indoor plastics	x				**6**
	Outdoor plastics		x			
	Indoor textiles			x		
	Outdoor textiles				x	
Waste	Indoor plastics	x				**7**
	Outdoor plastics		x			
	Indoor textiles			x		
	Outdoor textiles				x	

Coloured area: total emissions to be abated
1 – 7: risk management options
x: emissions that can be abated by the corresponding risk management option

Table 95: Emissions from plastics and textiles used indoors and outdoors

Production of plastic and textile articles (t)	0.31
Service life of plastic and textile articles (t)	4.15
Waste from plastic and textile articles (t)	0.28
Total (t)	4.74
Emissions Factor	1.1E-03
Substitution costs (€/year)	2 200 000
Cost-effectiveness (€/kg)	464

Source: section F.2
Note: Figures might not agree due to rounding.

E.1.1.1.1 Restriction on plastics used indoors (option 1)

A restriction on the production and placing on the market of plastics containing decaBDE for indoor use would lead to an abatement of 1.37 t of decaBDE emissions and display a cost effectiveness of 773 €/kg (Table 96). This restriction option is the least cost-effective of all considered.

Table 96: Emissions from plastics used indoors

Production of indoor plastic articles (t)	0.15
Service life of indoor plastic articles (t)	1.08
Waste from indoor plastic articles (t)	0.14
Total (t)	1.37
Emissions Factor	6.5E-04
Substitution costs (€/year)	1 054 944
Cost-effectiveness (€/kg)	773

Source: section F.2
Note: Figures might not agree due to rounding.

E.1.1.1.2 Restriction on plastics used outdoors (option 2)

A restriction on the manufacture or placing on the market of plastics containing decaBDE for outdoor uses would lead to an abatement of 0.04 t of decaBDE emissions and a cost-effectiveness of 30 €/kg (Table 97).

Restriction of the manufacture and placing on the market of plastics continuing decaBDE for use outdoors is the most cost-effective option. This is because the emission factors employed for outdoor uses are based on conservative assumptions. However, the total contribution of outdoor uses to total decaBDE emissions is very low, because only a very small percentage of plastics is used in outdoor applications. Therefore, whilst cost-effective, this option would not reduce emissions of decaBDE significantly.

Table 97: Emissions from plastics used outdoors

Production of outdoor plastic articles (t)	0.00
Service life of outdoor plastic articles (t)	0.03
Waste from outdoor plastic articles (t)	0.00

Total (t)	0.04
Emissions Factor	1.7E-02
Substitution costs (€/year)	1 056
Cost-effectiveness (€/kg)	30

Source: section F.2
Note: Figures might not agree due to rounding.

E.1.1.1.3 Restriction on textiles used indoors (option 3)

A restriction on the manufacture and placing on the market of textiles containing decaBDE for indoor uses would lead to an abatement of 1.44 t of decaBDE emissions and a cost effectiveness of 756 €/kg (Table 98).

Restriction of textiles used indoors displays the second least cost-effective option. This is because this scenario uses a low emission factor for a relatively high proportion of the total tonnage.

Table 98: Emissions from textiles used indoors

Production of indoor textile articles (t)	0.15
Service life of indoor textile articles (t)	1.14
Waste from indoor textiles (t)	0.14
Total (t)	1.44
Emissions Factor	6.6E-04
Substitution costs (€/year)	1 086 800
Cost-effectiveness (€/kg)	756

Source: sections B.8.2 and F.2
Note: Emissions are given as % of total emissions. Figures might not agree due to rounding.

E.1.1.1.4 Restriction on textiles used outdoors (option 4)

A restriction on the manufacture and placing on the market of textiles containing decaBDE for outdoor uses would lead to an abatement of 1.9 t of decaBDE emissions and a cost effectiveness of 30 €/kg (Table 99).

Table 99: Emissions from textiles used outdoors

Production of outdoor textile articles (t)	0.01
Service life of outdoor textile articles (t)	1.89
Waste from outdoor textiles (t)	0.01
Total (t)	1.90
Emissions Factor	1.7E-02
Substitution costs (€/year)	57 200
Cost-effectiveness (€/kg)	30

Source: section F.2
Note: Figures might not agree due to rounding.

E.1.1.2 Restriction on production (option 5)

Under this option the production of plastic and textile articles (and mixtures) within the EU would be prohibited but the placing on the market of articles would still be allowed. Meaning that imports of articles (and mixtures) from outside the EU would continue. This option would abate all emissions of decaBDE from the production, service life and waste stages of articles originally produced in the EU. However, emissions occurring during the service life or waste stage of any imported articles containing decaBDE would continue. Under this option the amount of imported articles could potentially remain the same as the baseline (where it is assumed that EU production of articles using alternatives to decaBDE directly replaces production of articles using decaBDE), or could increase (if replacement with articles using alternatives to decaBDE is less) (see Figure 12). For these reasons, no estimate of the imported tonnage of decaBDE associated with articles is made.

This restriction option, in isolation, may not reduce EU emissions of decaBDE effectively or with certainty. This is primarily because of the emissions associated with the service life of any imported articles that contain decaBDE (which is the most significant life-stage in terms of emissions). In addition, risks at a global level, i.e. those associated with the long range transport of decaBDE are not addressed by this restriction option.

It is difficult to estimate a corresponding cost-effectiveness for this restriction option because of the uncertainty associated with potential imports. If it is assumed that imports of articles remain the same as the baseline, the cost/effectiveness of this option is estimated at 461 €/kg in the low emissions scenario (464 €/kg for total ban, see Table 95). However if imports of articles increase the cost of production moving outside of the EU would need to be quantified, in order to estimate cost-effectiveness. These costs would then need to include those related to potential shutdown of production lines and temporal unemployment of the workers.

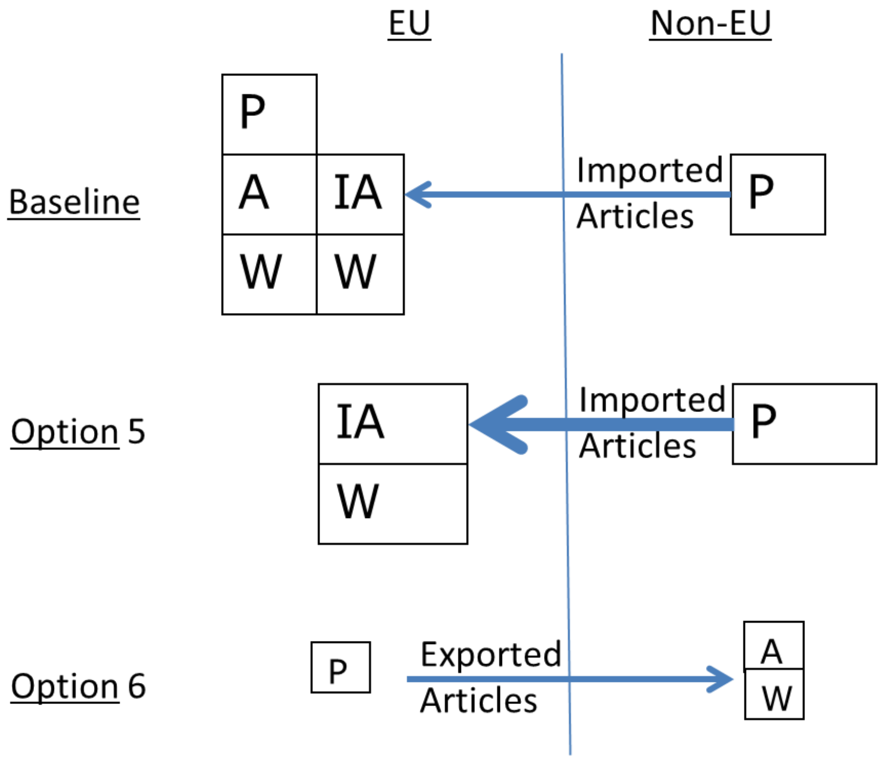

Figure 12: Schematic effects of options 5 and 6

Legend: P: Production, A: Articles, IA: Imported Articles, W: Waste. The surface of the boxes represents the amount of the emissions.
Note: option 5 increases imports of articles, option 6 increases exports of articles

E.1.1.3 Restriction on placing on the market (option 6)

This option would prevent the placing on the market of articles containing decaBDE, irrespective of if they were produced in the EU or imported. It would effectively mean that production of articles (and formulation of mixtures) in the EU could continue. However, the products could only be exported. It is expected that production in the EU (with the accompanying emissions) will be reduced, but not necessarily to zero (see Figure 12). The magnitude of these emissions cannot be estimated with the information we currently have (as it is not possible to estimate how much of the baseline EU production would remain). This option would have a very similar risk reduction capacity (and cost-effectiveness) to a total ban. This is because the current exports are assumed to be zero, and it might be challenging for EU producers to find new markets outside the EU (if these markets were profitable they would have been exploited already). In addition, as above, this option is not considered adequate to deal with risks at a global level, i.e. those associated with the long range transport of decaBDE. Furthermore, it is not straightforward to reliably calculate the cost-effectiveness of this restriction option if exports are assumed to increase. This is because, the profits from increased production for exports should be taken into account in the substitution cost calculations.

E.1.1.4 Discussion and conclusions of the preliminary screening

Overall, with the exception of a restriction on the use of plastics outdoors, all of the various restriction options considered would result in an abatement of decaBDE related emissions to an appreciable extent (see Table 96 to Table 99). As would be expected, some of the restriction options are more cost-effective or reduce a greater proportion of current emissions than others.

The cost-effectiveness of two of the restriction options (5 and 6) could not be assessed quantitatively because of uncertainty in the underlying data or response of the supply chain to the proposed restriction. As such, they cannot be considered in a quantitative assessment. However, their potential as restrictions options will be discussed qualitatively. Figure 13 shows an abatement cost curve for restriction options 1 to 4. Restricting outdoor uses would result in ~40% of emissions (see also Table 100) at a cost-effectiveness of 30 €/kg (predominantly via an abatement of emissions from textiles rather than plastics). Abatement of the remaining 60% of indoor emissions has a higher cost-effectiveness (from 756 to 773 €/kg).

Based on the differences observed between the relative importance of indoor and outdoor sources, it cannot be concluded that a targeted restriction in either the indoor or outdoor compartment would completely remove emissions. In addition a targeted restriction on e.g. outdoor uses alone would be very difficult to enforce. Therefore a restriction combining both outdoor and indoor uses would appear to be necessary.

Similarly, based on the available information, a restriction on either only the production life cycle stage (option 5) or article use (option 6) would be unlikely to result in sufficient emissions reduction whilst also resulting in significant uncertainty in terms of likely consequences, both for EU emissions and the global risk of decaBDE. However, the effect of combining options 5 and 6, is the same as combining options 1 to 4.

In conclusion, based on the analysis described above, from an effectiveness perspective a restriction of the manufacture and use of both plastics and textile articles for both indoor and outdoor uses is considered as the most appropriate restriction option, and will be assessed further in section E.1.1.

Cost effectiveness of the various options range from 30 to 773 € per kg. To assess the proportionality of the estimated cost-effectiveness estimates, it would be desirable to have a comparator. This comparator can be a "benchmark" (see Part F), e.g. based on the cost-effectiveness of the existing restrictions for similar substances. As cost-effectiveness of the restriction options are in the same order of magnitude with the cost-effectiveness of previous restrictions under REACH (see section F.1), none of the proposed options would appear to be disproportionate.

Table 100: Achieved Emission abatement from restriction on outdoor and indoor uses

	tonnes	%
Outdoor use	1.94	41%
Indoor use	2.80	59%
Total	4.74	100%

Source: Table 96, Table 97, Table 98, Table 99

E.1.1 Other Union-wide risk management options than restriction

E.1.1.1 Assessment of the need for a specific derogation for recycling

This document was drafted by ECHA as Dossier Submitter, to aid the discussion in the Committees.

Discussion Document

What is the issue – waste streams with high decaBDE concentrations: The Annex XV restriction proposal does not contain a specific derogation for recycling. All articles placed on the market (made from recycled or virgin material) need to respect the proposed concentration limit of 0.1 % w/w.

It was found that some batches of waste streams exhibit concentrations which are higher than the proposed restriction limit (up to 0.33 % w/w, shredder plastic from WEEE, IVM, 2013)[59]. If this material is considered to be a mixture, and is used to produce new articles without further dilution, it will breach clause no 1 for the proposed restriction (use/placing on the market of mixture with $\geq$ 0.1 % w/w decaBDE). If new articles are produced from this material with no blending/dilution with materials not contaminated with decaBDE then clause no 2 of the proposed restriction is also breached. Nevertheless, all measurements in the IVM (2013) study, both on recycled plastic pellets and on new products made from recyclate, reveal concentrations of decaBDE far below 0.1 % w/w. No comments were

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[59] In fact, this specific batch (0.33 % w/w) was routed to incineration. There were 4 batches out of 8 which exhibited decaBDE concentrations > than 0.1 % w/w. Two of them (0.11 % w/w and 0.2 % w/w were destined to recycling, but only after a further float-sink separation. No more details on this further processing are available in the study). The other two (0.33 % w/w and 0.12 % w/w were destined to incineration). Finally, all batches from automotive shredder residue, mixed shredder residue (Automotive + WEEE) and shredder WEEE from a different company, had decaBDE concentrations far below the 0.1 % w/w limit.

received from recyclers that the concentration limit would be a problem[60].

<u>EU POP regulation – derogation for recycling of the old PBDEs:</u> "Articles and preparations containing concentrations below 0.1 % by weight of PBDE"[61].

<u>Difference with decaBDE – it is used a lot more than the "old" POPs:</u> The global consumption of c-decaBDE is considerably bigger than the consumption of c-pentaBDE and c-octaBDE, indicating a larger pool of material that could be directed to recycling (see Table 1). In addition, c-pentaBDE was used typically at concentrations of 4 % w/w and c-octaBDe at concentrations of 10 – 18 % w/w (IVM, 2013).

Table 101: Estimated total production of PBDE commercial mixtures (1970 to 2005)

	Tonnes
c-DecaBDE	1,100,000 to 1,250,000
c-OctaBDE	102,700 to 118,500
c-PentaBDE	91,000 to 105,000

Source: UNEP (2010)

<u>RoHS directive – 0.1 % limit for PBDEs:</u> Waste plastic intended to be recycled and subsequently used for electronic equipment have to comply with the RoHS Directive (0.1 % for PBDEs including decaBDE).

<u>Techniques to separate waste with PBDEs:</u> IVM (2013) reports that "…the separation of plastics with and without BFRs is currently often based on differences in their densities. A rough distinction is made between plastics containing BFRs, assumed to have densities ca. 1.20 tonnes/m^3 or more, and plastics with densities of maximum 1.05 tonnes/m^3 which are considered unlikely to contain BFRs. The high density fraction containing BFRs is often exported or incinerated". A detailed analysis of available techniques can be found in UNEP (2014). As an additional example, DE and SE do not recycle waste containing PBDEs (specifically WEEE is mentioned), it is mostly incinerated in authorised facilities (Lindner, 2012 as cited in RPA, 2014).

Important considerations

The following considerations need to be taken into account in the decision-making:

1. DecaBDE is used in similar concentrations in articles as c-octaBDE (c-pentaBDE was used in lower concentrations). At a first approximation this seems to indicate that a similar concentration limit would be appropriate. The EU POP regulation stipulates a limit of 0.1% for recycling for the listed POPs, which is the same with the all-purpose limit (both recycled and virgin materials), put forward by the restriction proposal and the limit specified in the RoHS Directive. On the other hand, c-decaBDE was used in considerably

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[60] The RETF observed that: 'In case there is little information on costs submitted during public consultation, it can be inferred that the concern is low, unless information about the process did not reach the adequate audience'.

[61] The Stockholm Convention (tetra to hepta BDEs) stipulates a time limited derogation for recycling (need for the exemption reviewed periodically, and the exemption will in any case expire in 2030).

bigger quantities. This signifies that there is a considerably bigger volume to be potentially recycled <u>and</u> a bigger potential for emissions, if these volumes are recycled (instead of being e.g. incinerated).

2. If it is allowed to dilute decaBDE by using recycled material in 'new' articles, it will be very difficult or impossible to identify which articles contain decaBDE and treat later on. This conclusion is reached by analogy to the listed POPs[62].

3. To some extent, it seems that it is common practice to separate and incinerate (or landfill) waste with high PBDE concentrations. Meaning that in such cases a higher limit would either not make a difference, or actually allow the recycling of contaminated waste. Also, it has to be considered that currently it is common practice to incinerate also non-contaminated plastic waste from e.g. shredder fractions (at least in Member States with a large incineration capacity, e.g. DE), because it is not profitable to recycle this material. Hence, the supply of plastic waste is actually higher than the demand for recycling meaning that the minor decrease in supply triggered by the proposed restriction is unlikely to have a significant economic impact.

4. Not all non-EU countries are phasing out decaBDE. If high concentrations in recycled articles are allowed, there is a risk to receive, in the EU, imported recycled articles with high concentrations of decaBDE. In addition, it is considered as a challenge for enforcement to differentiate articles made from recyclate (allowed) from articles made from virgin materials (forbidden).

5. During the public consultation, originally stakeholders from the automotive sector have requested a derogation for recycling (which after further clarification is not needed, because according to information from the European Automobile Manufacturers Association (ACEA) waste streams from end-of-life vehicles (ELV) do comply with a limit value of 0.1 %)[63]. No information from recycling companies has been received[64].

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[62] UNEP (2010): Finally it must be noted that the concentrations of POP-BDE in first use articles are at levels where their identification, at least on the basis of bromine content, is straightforward using relatively cheap techniques. If the concentrations of POP-BDE are diluted by recycling then their subsequent identification for collection and treatment becomes much more difficult, the identification of the waste streams likely to be contaminated becomes more challenging – and much larger volumes of material would then have to be treated. In practical terms, therefore, if recycling of articles containing POP-BDE is allowed then future recovery of these POPs is likely to be much more difficult and may be impossible. In these circumstances widespread human and environmental contamination would be inevitable.

[63] <u>Extract from e-mail sent to ECHA on 01/04/2015:</u>
DecaBDE can still be found in several applications in automobiles – resulting in decaBDE concentrations in the shredder output as well. The relevant question is how the shredder output can be valorised and how these processes might be suitable to manage decaBDE constituents.
The preferred option to treat shredder outputs is to use advanced post shredder treatment (PST). Various applications are available and used in practise (e.g. EMR/Chinook, VW-Sicon).
As one part of the process the heavy-fraction (containing flame retardant, filled & PVC materials) is separated and assigned for energy recovery (thermal treatment) ensuring decaBDE destruction. Separation processes ensure the remaining polymeric fraction meets the requirements for recycling (e.g. as a carbon donor in iron manufacturing or for secondary polymer recycling). In some cases fibre fractions are used for the enhancement of sewage sludge filtration and are incinerated after usage.
All material flows to thermal treatment, energy recovery or incineration are ensuring the destruction of halogenated substances – including decaBDE.
Some material containing decaBDE remains but will decrease in the following years due to phase-out efforts in all OEMs advanced PST can also treat this residue.
Regarding the percentage of decaBDE in the entire waste stream decaBDE is only a minor constituent. Either if the entire vehicle is considered as a homogeneous material (100%) or only the non-metal fraction (25% of the vehicle) the decaBDE content will stay way below 0.1 % w/w. Considering the treatment methodologies described above (PST) the remaining amount of decaBDE will drop significantly again.

[64] E-mails were sent to the European Plastics Converters and the European Plastics Recyclers Association

Information gaps

Construction sector: there is no information available from the construction sector. However it seems unlikely that only articles containing decaBDE in high concentrations would be selectively collected and subsequently recycled, thereby leading to high concentration of decaBDE in the recyclate. Instead, it seems more plausible (similarly to the information from the automobile and WEEE sectors) that these articles will be mixed with others (not flame retarded with decaBDE), leading to lower concentrations in the final recyclate.

Uncertainty regarding final fate of waste: waste with high concentrations of decaBDE, which is currently recycled, might end up in landfill (the least environmentally preferred option), instead of incineration, due to lack of incineration capacity in the EU.

Conclusions

Based on a limited evidence base (only some measurements in one EU country) there are some indications that some recycling activities could be affected by the proposed restriction. However no information was provided from the recycling sector during the public consultation, indicating the absence of a problem. In addition, techniques to effectively separate waste containing PBDEs, and treat them separately, are available.

A concentration limit for mixtures and articles placed on the market is necessary to ensure that a) the majority of plastic articles can be recycled and b) decaBDE is not present in high concentrations in articles made from recyclate.

If the limit is too high, there will be less incentive to separate articles/mixtures with high PBDE concentrations. This situation has the potential to diminish the risk reduction to be achieved by the proposed restriction.

If the limit is too low, articles which contain PBDEs in low concentrations (presumably because the separation did not take place or was ineffective) would not be allowed to be placed on the market. This situation has the potential to negatively affect recycling operations at a larger scale.

The proposed limit of 0.1 % w/w seems to be a good compromise as indicated by the available measurements. Alternatively, a higher limit could be proposed, for example 0.5 % w/w which is higher than the highest measurement from IVM (2013). However this would need to be better substantiated with information from industry (perhaps by asking a specific question in the SEAC PC).

References

- UNEP (2010), Technical Review of the Implications of Recycling Commercial Pentabromodiphenyl Ether and Commercial Octabromodiphenyl Ether, DRAFT, August 2010

http://chm.pops.int/Portals/0/download.aspx?d=UNEP-POPS-POPRC.6-2-Annex.English.pdf

- IVM (2013), POP-BDE waste streams in the Netherlands: analysis and inventory, Report R13-16, 17 December, Institute for Environmental Studies (IVM), VU University

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(27/11/2014, reminder on 04/02/2015).

- UNEP (2014), Guidance on best available techniques and best environmental practices for the recycling and disposal of articles containing polybrominated diphenyl ethers (PBDEs) listed under the Stockholm Convention on Persistent Organic Pollutants, Draft, Revised March 2014

http://chm.pops.int/Implementation/NIPs/Guidance/GuidancefortheinventoryofPBDEs/tabid/3171/Default.aspx

E.1.1.2 Waste management (option 7)

The most effective among the assessed options to abate emissions from waste is incineration, for which it is assumed zero emissions in the low emissions scenario (and very limited emissions compared to the other options in the high emissions scenario). Consequently, a mandatory incineration scheme could be considered as a risk management option for waste containing decaBDE. However, this option would encounter implementation challenges: harmonisation of waste management practices in the EU, identification of plastics and textiles which contain decaBDE in order to be incinerated (and not landfilled or recycled). Even if implementation was possible, this option would reduce only 0.28 t of the emissions (Table 95). This option will not be assessed further. Despite that re-use and recycling are considered as better in the waste management "hierarchy", in the specific case of abatement of decaBDE emissions, incineration is considered as the best available waste management option and should be promoted for the products which are currently in service, and will reach the waste stage at the end of their service life.

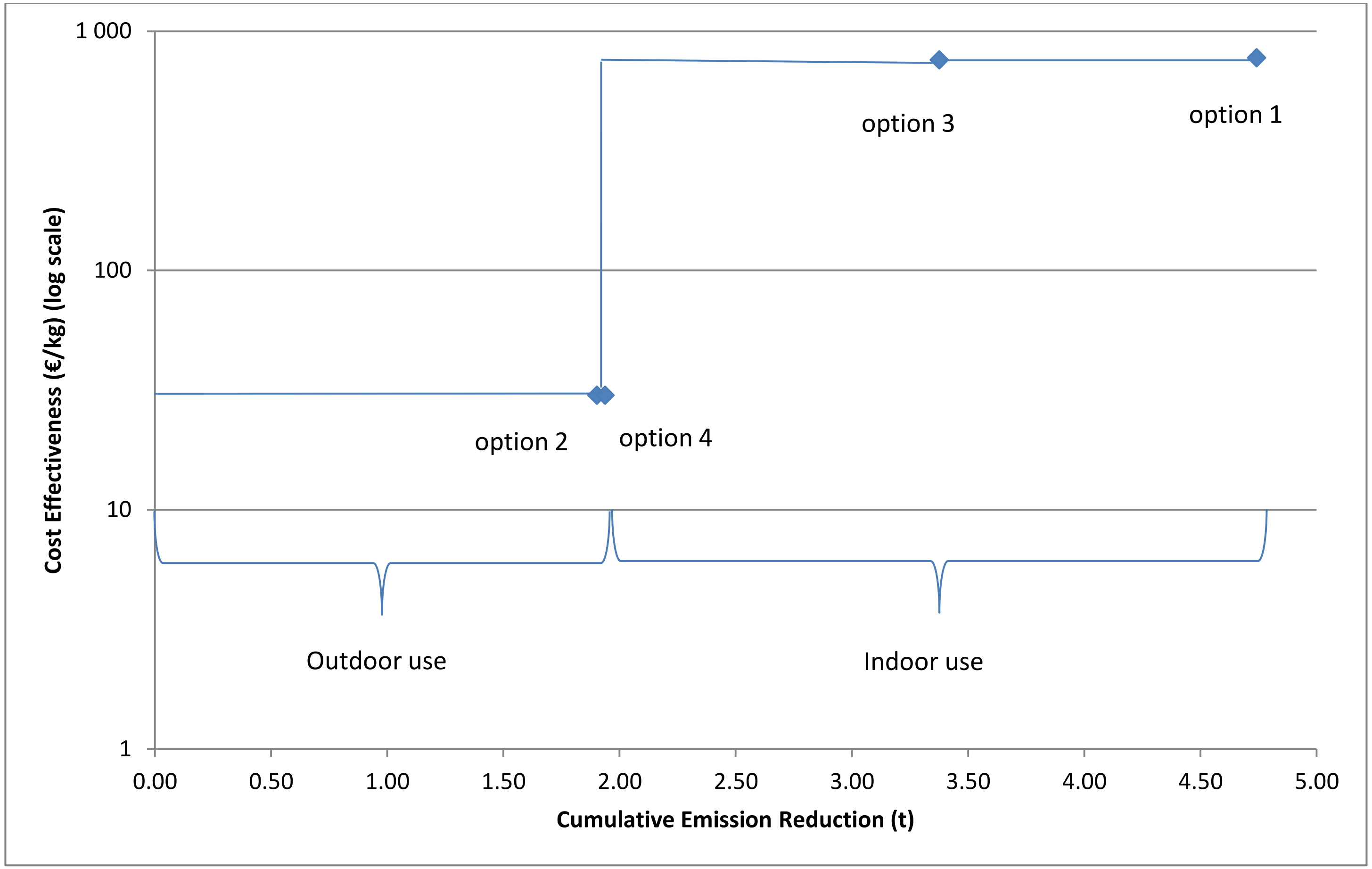

Figure 13: Abatement Cost curves for decaBDE (options 1-4)

Annex F

F. Socio-economic Assessment of Proposed Restriction

This annex presents additional information on the approach to describe the benefits and on the calculations of compliance cost and cost-effectiveness to what is presented in the main report.

F.1 Human health and environmental impacts

The following section discusses the statements in section F.1 of the main report more in detail.

F.1.1 DecaBDE is a PBT and a vPvB substance, and thus a substance of very high concern

In November 2012 decaBDE was identified as a substance meeting the criteria of Article 57 (d) as a substance which is persistent, bioaccumulative and toxic and of Article 57 (e) as a substance which is very persistent and very bioaccumulative, both in accordance with the criteria and provisions set out in Annex XIII of Regulation (EC)1907/2006 (REACH).

The Member State Committee concluded that primary degradation half-lives in sediment and soil significantly exceed 180 days, indicating that decaBDE is 'very persistent' according to the Annex XIII criteria.

On the basis of the available data, it was concluded that there is a high probability that decaBDE is transformed in soil and sediments to form substances which either have PBT/vPvB properties, or act as precursors to substances with PBT/vPvB properties. Transformation to such substances within biota provides an additional pathway for the exposure of organisms. High persistence combined with wide distribution in the environment creates a high potential for lifetime exposure and uptake in organisms, and a pool of the substance in many localities that will act as a long-term source of degradation products through both abiotic and biotic transformation.

The PBT/vPvB nature of the principal transformation products of deca BDE, i.e. tetra-, penta-, hexa- and heptaBDE congeners, has already been recognised by their inclusion as persistent organic pollutants (POPs) in Annex A of the Stockholm Convention, implemented in the Regulation (EC) No 850/2004 as Commission Regulation (EU) No. 757/2010.

F.1.2 Why are risks with and impacts of PBT/vPvB substances not assessed by quantitative methods?

According to ECHA guidance on PBT assessment (ECHA, 2012), PBT/vPvB substances may have the potential to contaminate remote areas that should be protected from further contamination by hazardous substances resulting from human activity because the intrinsic value of pristine environments should be protected. However, the monetary valuation of this intrinsic value is not currently possible.

The impacts of PBT/vPvB chemicals may be difficult to detect in either the laboratory or the environment because of the long-term low-level exposures involved in combination with the long life-cycles of species at the top of the food chain. In the case of vPvB chemicals, there is concern that long-term effects might be possible since high but unpredictable levels may be reached in man or the environment over extended time periods. However, the uncertainty in the likelihood of any impact, as well as in the actual damage the releases would cause, makes it impossible to quantify the impacts.

It can be concluded that the properties of the PBT/vPvB substances lead to a high degree of uncertainty in the estimation of risk to human health and the environment when applying quantitative risk assessment methodologies. For that reason, a "safe" concentration in the environment cannot be established with sufficient reliability, using the methods currently available[65]. Therefore, a separate PBT/vPvB assessment is required under REACH (Art. 14(3d)) in order to take these specific concerns into account.

According to Annex I(4) of the REACH Regulation, the objective of the PBT/vPvB assessment is to determine if the substance fulfils the criteria given in Annex XIII, and if so, to characterise the potential emissions of the substance to the different environmental compartments. In addition, it is necessary to identify the likely routes by which humans and the environment are exposed to the substance.

In practice, the PBT/vPvB assessment comprises 3 steps (1) comparison with the criteria, (2) emission characterisation and (3) risk characterisation, which are outlined in detail in section B of this report. Even if the procedure is partly quantitative in its approach its outcome is qualitative in nature and should not, due to the uncertainty explained above, be directly translated to a quantified risk. Instead PBT/vPvB substances are classified as substances of very high concern (art. 57(d) and (e) of the REACH Regulation), and their use and emission are subject to an array of measures to ensure risk reduction, such as substitution of the substance.

As discussed above, the quantitative risk assessment is not required for the PBT substances under REACH. This is because of the high uncertainties that would be inherently introduced in such an attempt. These uncertainties also explain why it is not possible to value the benefits via the assessment of impacts on environment and human health via the standard impact pathways approach. However, for some PBT substances, information allowing quantification of impacts may exist, but it always allows only a partial quantification and valuation.

Even if the standard impact pathway approach is not possible, it could be possible to use direct 'contingent' valuation of the benefits. This approach would involve surveys in which members of the public are provided with a qualitative (or otherwise) description of the possible benefits of reducing PBTs or vPvBs, and are asked to place a monetary value on that reduction. Survey respondents would therefore effectively be left to judge how to take account of the benefits uncertainty in their monetary valuation. Although contingent valuation studies have been undertaken for decades and are well established, very few such studies have so far been undertaken to value the benefits of PBT or vPvB reduction.

The results of some recent studies (undertaken on behalf of the UK Environment Agency) looking at the valuation of precautionary control of hazardous chemicals were presented at a workshop on PBT valuation at the Royal Society of Chemistry in 2013. One of the studies, which were carried out in the UK, was concerned with reducing emissions of DecaBDE. Using a 'choice experiment' valuation format, the study estimated the WTP to reduce

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[65] It should be noted that over the last years a number of methods have been proposed in the scientific literature that could eventually be used to reduce the uncertainty in the risk estimation (on either the exposure or effects side) of PBTs and hence may lead to a better understanding of the level of risk associated with these substances, in particular in a comparative sense.

environmental accumulation of DecaBDE in the environment. Since DecaBDE is a highly efficient flame retardant, respondent were asked to 'trade-off' between different levels of environmental accumulation of DecaBDE, different level of possible human health risks associated with DecaBDE, different levels of fire risk (related to the efficacy of DecaBDE in this respect) and increases in household expenditures related to the higher price of alternatives to decaBDE. It is important to note that the reductions in environmental accumulation and human health concerns from DecaBDE were based on precautionary control of these risks in general and not to changes in specific risk outcomes (since these are unknown given the present state of scientific knowledge). Although the results of the study are not directly applicable to the proposed restriction, the study indicates a clear and potentially substantial willingness-to-pay amongst the general public for precautionary reductions in environmental accumulation and human health concerns for decaBDE. The study reports that "…perhaps an average British person have a 'fixed' WTP of between £129.14 and £145.02 for precaution to switch away from Deca-BDE/PBT substances if it means lower risks to the environment and human health" (Yun, 2013).
A second option would be to provide only a qualitative, narrative argumentation in favour or against the proportionality. However, there are no agreed criteria by which such argumentation could be made and the approach would not provide much information to assess the proportionality of the proposed restriction.

Because of the challenges in quantifying the impacts, the estimated amount of avoided emissions of decaBDE is used as a proxy of the benefits of the proposed restriction in the SEA.

Emissions as a proxy of the benefits and cost-effectiveness approach

As described above, the reduced emissions are used as a proxy of the benefits from the proposed restriction. In section F.2 Economic impacts summarises the emissions, as well as the tonnages of decaBDE imported to EU as a substance and in the articles. These values are used in the SEA to estimate the economic impacts of the proposed restriction. As emissions are used as a proxy of the benefits, the cost-effectiveness is estimated as a cost of reducing a kg of decaBDE emission. As described above, emission of decaBDE will lead to exposure to the environment and humans to decaBDE as well as to lower brominated PBDEs.

To assess the proportionality of the estimated cost-effectiveness estimates, it would be desirable to have a comparator. This comparator can be a "benchmark" or a range of "benchmarks" on the level of costs and could be based e.g. on:

- studies on abatement or avoidance costs for PBTs and vPvBs, including information on the cost of past regulations,
- data on remediation or clean-up costs for PBTs and vPvBs, and
- economic valuation studies on benefits of reducing emissions from PBTs and vPvBs.

Information on other PBTs and PBT like substances is considered relevant, as they reflect similar concern (to decaBDE) that cannot be quantified. Consequently, a kg of emission of any PBT substance could be considered the same in terms of the potential damage to human health and environment.

Relevant available information is limited, and no estimates on decaBDE were found in addition to WWTP estimates from UK Environment Agency (forthcoming, 2014) mentioned above. However, some information exists on other PBTs, PBT like substances, as well as on air pollutants. This includes:

- Cost estimates for PCBs (an overview is presented in Annex E.8),
- Cost estimates for mercury[66] (an overview is presented in Table 105),
- Damage costs to health and the environment resulting from pollutants emitted from industrial facilities (this information is presented in a report by European Environment Agency (EEA, 2011)[67]).

The existing studies on PCBs and mercury are mostly based on historical cases of emissions that occurred in a given geographical area during a given period of time. The studies may estimate the adverse socio-economic impacts (costs) of such specific pollution occurrences, but do not establish general damage cost functions. Ex-ante costs (i.e. the cost of avoiding emissions in the first place, for example by substituting a PBT substance with a less hazardous alternative) can differ a lot from a more specific ex-post costs (i.e. the cost of cleaning up or repairing damage from emissions that have already occurred), even for the same substance. Furthermore, some of the cost-effectiveness estimates are for the reduced amounts of substance used, instead of amounts emitted. It is also very challenging to use the damage cost from other type of pollutants (reported in EEA, 2011) to derive a benchmark level on costs for a PBT substance like decaBDE. Specifically, based on the available information, mercury (as methylmercury) would appear to biomagnify within ecosystems to a significantly greater extent than decaBDE. Equally, the relative toxicity of decaBDE and mercury (as methylmercury) are different (methylmercury is more toxic) (ECHA BD 2011b). Together, this may suggest that the impact (per kg) of decaBDE and mercury substances may be different.

Even if it is not straight forward to establish benchmarks for acceptable level of costs with the available information, it can be used to support the assessment of the proportionality. Especially the information on the cost-effectiveness of restrictions on mercury in measuring devices and phenylmercury compounds is considered relevant, as it indicates the level of costs for a PBT-like substance, that has been considered acceptable in the context of REACH. This does not exclude the possibility that even higher cost-effectiveness estimate could be considered proportionate. The cost-effectiveness of the mercury in measuring devices restriction was estimated to be €4,100/kg of mercury used (ECHA, 2011a, see Annex 1). The estimates varied between the measuring devices from €0/kg to €19,200/kg. For phenylmercury compounds, the estimated cost-effectiveness was €649/kg mercury emitted (ECHA, 201, see Annex 1). This is more cost-effective than the measuring devices restriction considering the fact that the figure is for a kg emitted, not used. In this restriction report, the cost-effectiveness estimates are also for a kg of decaBDE emitted. The estimated cost of €464/kg of decaBDE emission reduced fits into this same range of cost-effectiveness (see Annex F.2 for details on cost calculations).

F.2 Economic impacts

The economic impacts are estimated by assessing substitution costs for the industry. The assessment is based on the work of RPA (2014).

F.2.1 Introduction to approach

As discussed in Part F, the assessment of economic feasibility of alternatives in Part C

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[66] Even if mercury is not a PBT substance, it has similar properties that makes the comparison meaningful.

[67] EEA (2014), Revealing the costs of air pollution from industrial facilities in Europe. AvailableAvailable at http://www.eea.europa.eu/publications/cost-of-air-pollution.

focused on the use of alternative **substances**. This does not mean that some companies may move to non-chemical alternatives.

The available information to estimate substitution costs is limited. Some information is available on the prices and loadings of the flame retardants, however, quantified information on possible R&D activities and investments costs is often missing. This limits the possibilities for the substitution costs calculations for most of the alternative substances discussed in Part C.

In the main report, the economic impact assessment for both textiles and plastics focuses on EBP which, as discussed in Part C, is assumed to be the primary replacement for decaBDE. The available information supports the assumption that EBP is a drop-in substitute for decaBDE allowing cost calculation simply based on prices and loading, excluding R&D and potential changes in the process. However, there are reasons to assume some variety in the substitution strategy of the users of decaBDE, especially in plastics. The large variety of polymer materials provides opportunities for using different alternative substances, depending on the substrate and the particular needs of products. Because of this, and the fact that for plastics information on the prices of the polymers is available, an additional approach is adopted in this Annex to estimate the substitution costs for plastics.

In this Annex, the approach in the main report is referred to as A, and the additional approach as A+B.

Approach A: Replacement of decaBDE by EBP in textile and plastic applications

Approach A assumes that the entire consumption of decaBDE would be replaced by EBP. This is the most `convenient’ alternative as it does not require alteration of formulations and it is not much more expensive than decaBDE.

Information from a website of online purchases[68] indicates that EBP is about 18% more expensive than decaBDE. However, information from the industry suggests that EBP is 5% to 20% more expensive than decaBDE. The prices of substances vary and price differences that are valid today may not be valid tomorrow. The consultation suggests that the price difference between decaBDE and EBP used to be higher in the past. For the purposes of the calculation of substitution costs, the price of decaBDE is assumed to be €4/kg and the price of EBP is €4.5/kg. In other words, EBP is €0.5/kg (12%) more expensive than decaBDE.

Approach A+B: Replacement of decaBDE by a range of alternatives in plastic applications (full transition to EBP in textiles)

In addition to price difference between decaBDE and EBP, Approach A+B uses information on the prices of different resins (flame-retarded with and without decaBDE) to estimate by how much the production costs of the polymers currently flame-retarded with decaBDE would increase following reformulation. Such information can be obtained from the 2006 Danish EPA report. No consultees in the polymers industry provided quantified information for the purposes of this analysis in the stakeholder consultation.

Approach A+B makes assumptions on the extent to which different types of alternatives would be preferred by the users of plastics (see Table 102).

Table 102: Assumptions used for the calculation of substitution costs in approach B

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[68] http://www.alibaba.com/

Alternative	Assumed market share
EBP	50%
BFRs (e.g. ethylene bis(tetrabromophthalimide, Tetrabromobisphenol-A bis (2,3-dibromopropyl ether))	10%
Halogen Free Flame Retardants (e.g., RDP, BDP/BAPP, TPP, RP)	40%

The above assumptions are based on informed guesses by RPA on the understanding that:

- EBP would still dominate the alternatives market,
- BFRs other than EBP would find limited use (given that EBP would be the 'number one' choice among BFRs),
- The remainder of the decaBDE tonnage would be replaced by a range of Halogen free flame retardants (HFFRs).

Based on the analysis and results in RPA (2014), it can be calculated that this combination of alternatives would lead to an average increase of €4[69] (100% increase compared to the price of decaBDE) in the production costs per kg of decaBDE substituted in plastics. However there are big differences in the costs between different types of alternatives. RPA (2014) provides more detailed information on these differences and the methodology. The impact of these assumptions is also discussed briefly in section F.7.

F.2.2 Compliance costs and cost-effectiveness

The annual compliance costs and cost-effectiveness to reduce emissions of decaBDE are calculated based on the estimated amounts of decaBDE used and emitted (see section B). As described in Section E, it is not possible to confirm any trend in the future emissions of decaBDE without the restriction. Consequently, no trend (0 trend) is assumed and these results are representative for all the years after the proposed restriction becomes effective. Table 103 summarises the annual compliance costs and costs-effectiveness estimates with different assumptions. It presents results both based on the approach A (full transitions to EBP in all applications) and A+B (full transition to EBP in textiles and variety of alternatives, including EBP, in plastics).

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[69] Annual substitution cost (€) / annual avoided amount of decaBDE used (kg)= €20,000,000 / 5,000,000 kg = 4 €/kg. The calculation in RPA (2014) and here, is based on a price difference of 5% between decaBDE and EBP (instead of 12% used in approach A).

Table 103: Substitution costs (€/year) and costs-effectiveness estimates (€/kg) for low and high emissions scenarios

		Textiles		**Plastics**		**Total**		
		Indoor	**Outdoor**	**Indoor**	**Outdoor**	**Textiles**	**Plastics**	**All**
Low Emissions Scenario	Substitution costs (€/year) A	1 086 800	57 200	1 054 944	1 056	1 144 000	1 056 000	2 200 000
	Substitution costs (€/year) A+B	1 086 800	57 200	8 439 552	8 448	1 144 000	8 448 000	9 592 000
	Cost-effectiveness (€/kg) A	7 663	30	10 582	30	563	7 846	1 015
	Cost-effectiveness (€/kg) A+B	7 663	30	84 657	242	563	62 769	4 427
High Emissions Scenario	Substitution costs (€/year) A	1 086 800	57 200	1 054 944	1 056	1 144 000	1 056 000	2 200 000
	Substitution costs (€/year) A+B	1 086 800	57 200	8 439 552	8 448	1 144 000	8 448 000	9 592 000
	Cost-effectiveness (€/kg) A	398	30	401	30	246	396	301
	Cost-effectiveness (€/kg) A+B	398	30	3 208	239	246	3 168	1 311

Note: the assumptions behind the low and high emission *scenarios are presented in* section *B.8.2.*

F.2.3 Conclusions on substitution costs and cost-effectiveness based on approach A+B

As presented in the main report, the compliance costs are estimated to be €2,200,000 per year and cost-effectiveness 464 €/kg, when all the decaBDE would be substituted with EBP (Approach A).

However, the substitution costs and the related cost-effectiveness vary a lot between different alternatives. This is demonstrated by the differences in the results from the two approaches applied to plastics. Furthermore, the variety in the cost-effectiveness is explained by the differences in emission factors for different applications.

Using approach A+B, the annual compliance costs are estimated to be between €9,6 million. It is not possible to confirm to what extent EBP would be used, but available information from stakeholder consultation (RPA, 2014) suggests that decaBDE has already to a great extent been replaced by it. Unless the prices change, it seems reasonable to assume that EBP will continue to remain the main alternative. As companies will decide which alternative to use, they will avoid alternatives with unreasonable high costs. In case they decide to switch to something else than the cheapest alternative (EBP), there must be a reason for that. These additional benefits that companies consider relevant are not quantified in this report. The cost-effectiveness estimates based on approach A+B vary between €1,300 per kg (high emission scenario) and €4,400 per kg (low emission scenario).

F.3 Social impacts

No additional information to what is presented in the main report.

F.4 Wider economic impacts

No additional information to what is presented in the main report.

F.5 Distributional impacts

No additional information to what is presented in the main report.

F.6 Main assumptions used and decisions made during analysis

No additional information to what is presented in the main report.

F.7 Uncertainties

In addition to the sensitivity scenarios presented in the main report, Table 104 presents a simple one parameter sensitivity analysis. It provides the assumptions used in the calculation, describes the direction in which the uncertainty will influence and the level of impact that may occur.

Table 104: Assumptions made in the SEA and related uncertainties

Parameter	Assumption	Direction in which the uncertainty influences	Level of estimated impact of the uncertainty
Costs			
Price difference between decaBDE and EBP	Average additional cost: €0.5/kg	The higher the difference, the higher the cost of reducing 1 kg of emissions	Moderate. If the price difference increases to €1/kg instead of €0.5/kg (for EBP), the substitution costs and the cost effectiveness will double. If the price difference decreases to €0.25/kg, the substitution costs and cost-effectiveness will halve.
Drop-in nature of EBP	One-to-one drop-in substitute, i.e. no need for R&D activities or process investments	If R&D activities or investments are needed, the substitution costs and cost-effectiveness estimate would be higher	Small. Even if R&D activities or investments are needed, they should be fairly limited.
Alternative flame retardant to which industry substitutes (see also discussion in Annex F.2)	Full transition to EBP	The more substitution with e.g. halogen free alternative the higher the cost. The more substitution with EBP, the lower the cost.	Significant. The cost with substituting only with halogen free alternative suggests almost two orders of magnitude higher costs[70] compared with substituting with EBP.
Trend in the amounts used	No trend. Same amount in the future (trend =0)	Increasing trend suggest increasing substitution costs. Decreasing trend decreasing costs. No impact on cost-effectiveness.	Moderate. If the use will decrease to 50% of what it is today, the cost will decrease to 50% by that year as well.
Emissions			
Emission factors (central/high/low scenario)	Total emission factors: Central scenario: 0.11% High scenario: 0.17% Low scenario: 0.05%	Emissions (emission factors) do not affect the substitution costs. The higher the emission factor the lower the cost of reducing 1 kg of emissions	Significant. The low emission estimate gives around 3 times higher cost of reducing 1 kg of emission.

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[70] According to RPA (2014), the costs of reducing 1 kg emission are below €10 for EBP, below €100 for other brominated flame retardants, and below €500 for non halogenated flame retardants. Please note that these figures are based on different emission factors than what is estimated in this report, and consequently cannot be directly compared with costs-effectiveness estimates reported here.

Table 105: Overview of cost estimates for PCBs

Source (link)	Type of cost estimate	Original estimate	Guesstimated cost per kg
Lower Fox River/Green Bay (WI) Natural Resource Damage Assessment			
Bishop 2000	WTP for ongoing PCB-caused losses (346,700 households in 10 Wisconsin counties)	USD 254 – 610 million	USD 2,240 – 5,379/kg (based on release of 113 tons)
Breffle 1999	Damages from Recreational Fishing Service Losses Resulting from Fish Consumption Advisories (combined revealed and stated preference model)	USD 106 – 147.7 million	USD 935 – 1,302/kg (based on release of 113 tons)
EPA 2013	Removal or containment of 8 million cubic yards of contaminated sediments in Fox River and Green Bay area, consisting of 5 operable units (OU)	USD 701 million	USD 7,538/kg (based on 93 tons of PCB content)
EPA 2013	Dredging and disposal of 370,000 cubic yards of contaminated sediments in OU 1	USD 100 million	USD 116,000/kg (based on 860 kg of PCBs removed)
New Bedford (MA) Harbor Site			
McConnell 1984	Damages to recreational activity, including beach use (WTP for access to beaches) and recreational fishing (travel costs incurred by fishermen)	USD 9.53 million	USD 79/kg (based on release of 120 tons)
Mendelsohn 1986	Damages by PCB contamination to New Bedford harbour amenities using residential property values	USD 27.3 – 39.7 million	USD 228 – 331/kg (based on release of 120 tons)
EPA 1998	Dredging and containment of approximately 450,000 cubic yards of PCB-contaminated sediment	USD 120 – 130 million	USD 1,000 – 1,080/kg (based on release of 120 tons)

Source (link)	**Type of cost estimate**	**Original estimate**	**Guesstimated cost per kg**
Ban under US Toxic Substances Controls Act (1979)			
EPA 1979	Rule banning the manufacture of polychlorinated biphenyls (PCBs) and phasing out most PCB uses	USD 58 – 105 million (first year), USD 34 million (annual cost)	USD 3.2 – 5.7/kg (first year cost) USD 1.9/kg (annual cost) (based on 18 tons produced in 1974)
MacArthur/ Nagy 1976	Economic impact of a ban, including primary ("red tape", disposal, plant rebuild, salary) and secondary impact (new plant rebuilds for increasing capacitor output, disposal, increased cost of substitutes)	USD 13.7 million (one-time), USD 110 million (annual cost)	USD 0.7/kg (one-time cost) USD 6/kg (annual cost) (based on 18 tons produced in 1974)
Other information			
Stackelberg/ Hammitt 2005	Aggregate WTP of 300,000 households to avoid HH and ENV damages from PCBs in Hudson River (NY)	USD 37.5 – 90 million	USD 64 – 153/kg (based on release of 590 tons)
TemaNord 2004	Costs due to the use of PCB in Sweden, including research, PCB in buildings, handling of waste, clean up of soil and sediment and Project Sea Eagle	EUR 330 million	EUR 70 - 140/kg (based on 4,000 – 5,000 tons used in Sweden)
NYCSA 2012	Building exterior remediation (soil remediation) Building exterior remediation (caulk encapsulation) Building interior remediation (caulk removal) Building interior remediation (light ballast and fixture removal and replacement)	USD 950 – 1,267 per ton of soil USD 22 – 29 per lf caulking USD 172 – 207 per lf caulking USD 1,594 – 1,743 per ballast/fixture	USD 38,000,000 – 51,000,000/kg (assumed 25 ppm concentration) USD 8,800 – 11,600/kg (assumed 2.5g PCB per lf caulking) USD 68,800 – 82,800/kg (assumed 2.5g PCB per lf caulking) USD 39,850 – 43,575/kg (assumed 40g PCB content)
Envio 2004	Cost of PCB transformer replacement with new transformer per kg of total weight of transformer Cost of decontamination of PCB transformer for re-use per kg of total weight of transformer	USD 4.85 per kg USD 2 per kg	USD 8/kg (assumed 600,000 ppm content) USD 3.3/kg (assumed 600,000 ppm content)

F.8 Overview of cost estimates for mercury

Table 106: Costs for strategies avoiding Hg pollution and their potential to reduce Hg pollution, expressed in the classes: small, medium, and large

Activity	Place and year	Cost (US$/kg Hg)[a]	Reduction potential	Reference
Return of Hg thermometers	Sweden, 1992–1996	950–1,200[b]	Large	Rein and Hylander, 2000
Replace mercury-containing items	Minnesota, estimated 1999	20–2,000[c]	Large	Jackson et al., 2000
Collect Hg and Hg compounds in school labs	Sweden, 1995–1999	70–400[b]	Small	Rein and Hylander, 2000
Collect metallic Hg in school laboratories	Minnesota, estimated 1999	20[c]	Large	Jackson et al., 2000
Collect Hg compounds in school laboratories	Minnesota, estimated 1999	1,400[c]	Small	Jackson et al., 2000
Replacing Hg cells at chlor–alkali plants	USEPA, estimated 1996	10,100[d]	Large	USEPA, 1997
Increase recycling of chairside traps in dentistry	Minnesota, estimated 1999	240	Medium	Jackson et al., 2000
Install amalgam separators	Minnesota, estimated 1999	33,000–1,300,000	Medium/ Large	Jackson et al., 2000
Replace dental amalgam fillings at dentists	Sweden, estimated 2004	129,000	Large	Hylander and Goodsite, 2006
Remove dental amalgam fillings at death	Sweden, estimated 2004	400	Large	Hylander and Goodsite, 2006
Flue gas cleaning with carbon at crematoria	Sweden, estimated 2004	170,000–340,000	Medium/ Large	Hylander and Goodsite, 2006
Flue gas cleaning with carbon at crematoria	UK, estimated 2004	29,000	Medium/ Large	Hylander and Goodsite, 2006; BBC News, 2005
Medical waste incinerators with scrubber	USEPA, estimated 1996	4,400–8,800	Medium/ Large	USEPA, 1997
Carbon injection into flue gases at waste	USEPA, estimated	465–1,900	Medium/ Large	USEPA, 1997

Activity	Place and year	Cost (US$/kg Hg)[a]	Reduction potential	Reference
incinerators	1996			
Combined technologies at waste incineration	Uppsala, Sweden, 2004	40,000	Large	Hylander and Goodsite, 2006
Coal cleaning, conventional, chemical or both	Minnesota, estimated 1999	100,000–128,000	Large	Jackson et al., 2000
Carbon injection into flue gases at power plants	USEPA, estimated 1996	31,000–49,000[e]	Large	USEPA, 1997
Carbon injection into flue gases at power plants	US Dep. Energy, estimated 1996	149,000–154,000 [e]	Large	Brown et al., 2000
Carbon injection into flue gases at power plants	Minnesota, estimated 1999	20,000–725,000	Large	Jackson et al., 2000
Combined technologies at power plants	USEPA, estimated 1996	11,000–61,000[e]	Large	USEPA, 1997
Combined technologies at power plants	US Dep. Energy, estimated 1996	56,000–85,000[e]	Large	Brown et al., 2000
Wind as replacement for energy from coal	Minnesota, estimated 1999	1,200,000–2,000,000	Large	Jackson et al., 2000

Source: Hylander and Goodsite (2006)
Notes:
[a] Values in a range reflect differences across facilities of different sizes or at different recovery rates e.g. 90% or >95% of Hg recovered from flue gases, or other site-specific conditions.
[b] Cost calculated per kilogram Hg collected and includes costs for information, reimbursement for thermometers, and additional costs for collecting, transport and deposition, while costs for additional working time of shop assistants, municipal officials, etc. are excluded.
[c] Total cost per unit of Hg not emitted.
[d] Capital and electrical costs. Indirectly reduced Hg emissions caused by lower consumption of electricity from Hg emitting power plants have not been included. The costs increase if pollution occurred earlier needs extensive remediation.
[e] 90% reduction in mercury emissions. The EPA figures are based on a lower flue gas temperature when carbon is injected, thereby using the sorption capacity better, resulting in that only 2–34% active carbon is used compared to the DOE estimates.

Table 107: Cost-effectiveness of restriction proposals on mercury in measuring devices and phenylmercury compounds

Restriction report	Device	Cost-effectiveness (€/kg)
Mercury in measuring devices	Sphygmomanometers*	1,300
	Thermometers (including hygrometers) *	19,200**
	Barometers	0
	Manometers (including tensiometers)	0
	Strain gauges	9,600
	Pycnometers***	not available
	Metering devices***	not available
	Total*	**4,100**
Phenyl mercury compounds		**649**

Source: Background documents for mercury in measuring devices (ECHA BD, 2011a) and Phenylmercury compounds (ECHA BD, 2011b).
Note: The cost-effectiveness estimates for measuring devices are for the reduced amounts of mercury used. For phenylmercury compounds the estimates are for reduced amounts emitted.

Table 108: Health benefits from reducing mercury emissions measured in € per kg of removed mercury, 2010 price level

Option		Scenario 1 (19.1 tonnes of Hg removed)	Scenario 2 (26.7 tonnes of Hg removed)	Degree of certainty
1	Cost of Illness estimates for persistent IQ deficits in children exposed above the reference dose in utero	€4,926 *($3,900)*	€5,684 *($4,500)*	Highest
2	As 1 but effects occur also below the reference dose	€12,883 *($10,200)*	€13,641 *($10,800)*	Fairly high
3	As 2 but also “males that consume non-fatty freshwater fish”, are assumed to have cardiovascular effects	€16 041 *($12,700)*	€17,683 *($14,000)*	Lower
4	As 3 but also all individuals are assumed to have cardiovascular effects	€229,873 *($182,000)*	€245,660 *($194,500)*	Lowest

Source: Page 193 in Rice and Hammitt (2005)
Note: The estimates in the study were given in US dollars 2000 price level and are given in (italics). They have been converted to euros in 2010 price level by first converting the dollars to euros (i.e. ECUs) in 2000 and then using the EU’s GDP deflator to bring them to 2010 price level. End note 1 gives the deflators and exchange rates used.

Annex G

G. Stakeholder consultation

G.1 Call for Evidence on the challenges in substituting decaBDE

A call for evidence was advertised on the ECHA website from 16/10/2013 to 15/12/2013 and focussed on the following topics:

- Information on uses for which substituting decaBDE is challenging.
- Potential alternatives and reasons why they are not currently used including information on the technical difficulties and economic impacts of switching.
- For the uses and alternatives identified: time needed to adapt the processes/make the substitution.

In total, eight responses were received. Respondents included companies and industry associations. The role of the responding companies in the supply chain were varied, and included: manufacturer of alternatives, former importer of decaBDE and downstream user of decaBDE. The industry associations represented the flame retardant industry and the aviation industry. All comments were taken into account in the development of the report and, more specifically, in the analysis of alternatives.

The background note for the call for evidence gives more information:

http://echa.europa.eu/documents/10162/13641/bd_call_for_evidence_decabde_en.pdf

G.2 Targeted Consultation

In addition to the call for evidence, two targeted consultations were conducted, one focussing on industry and one on MSCAs. Further information on the consultation can be found in the sections below and in RPA (2014).

G.2.1 Industry consultation

The consultation was held from 11/11/2013 to 15/12/2013 and questionnaires were sent to around 300 selected stakeholders (51 associations and 252 companies including registrants, SiA and C&L notifiers, EU-wide or national associations and their members, non-EU manufacturers of decaBDE and producers of articles flame retarded with decaBDE). Ten responses were received and analysed (1 importer, 1 downstream user, 2 distributors, 3 former users including 1 former manufacturer and 3 suppliers of alternatives). Apart from the questionnaires, a total of 56 additional stakeholders provided feedback to the consultation (e-mails and telephone meetings).

Different versions of the questionnaire were developed and tailored towards different actors of the decaBDE supply chain, including versions intended for manufacturers, suppliers and users of alternative substances, materials and techniques.

The questions focussed on the following topics:

- Uses and related tonnages including uses in articles.
- Releases and exposure in the EU.
- Technical and economic feasibility of alternatives.
- Market availability of alternatives.

The information was used in several sections of the restriction report, including uses of decaBDE, information on alternatives and cost calculations.

The questionnaires can be found at (currently in RPA site): http://www.rpaltd.co.uk/news-deca.shtml

G.2.2 MSCAs consultation

The consultation was held from 22/11/2013 to 10/01/2014. Questionnaires were sent to all MSand 11 responses were received. The questions focussed on the following topics:

- Relevant legislation at national level, including fire safety standards.
- Information on imported quantities and information on decaBDE contained in imported or produced articles and number of companies involved.
- Emissions during life-cycle.
- Environmental monitoring and bio-monitoring data.
- Waste management practices.
- Alternative substances and techniques.

The information received was used in the relevant sections of the report.

G.2.3 Consultation with non-EU authorities

US EPA and Environment Canada provided information on alternatives. Environment Canada provided further information on their national regulations related to decaBDE.

G.2.4 ECHA request to provide latest tonnage information

The registrants of decaBDE were contacted by ECHA and asked to updated tonnage information (letters sent on 21/03/2014). Five companies have provided recent tonnages imported. The updated information was used in the estimation of emissions of decaBDE and the estimation of trends on imports of the substance.

G.3 ECHA consultation of EU agencies

Relevant EU agencies (railway, aviation, maritime and space sectors) were contacted by

ECHA and asked to provide information on the impact of the restriction on their respective sectors and any need for derogation (e-mail sent on 08/05/2014). Three agencies have provided information, however only the European Aviation Safety Agency (EASA) highlighted the need for a derogation and provided related information.

G.4 Consultation on the Annex XV dossier for identification of decaBDE as an SVHC

The consultation was held during October 2012. Although the scope and the objectives of this consultation are different from the consultations related to the restriction proposal, some aspects are relevant to the preparation of an Annex XV dossier for a restriction and consultation responses were reviewed for this purpose. The SVHC consultation focussed on:

- The SVHC proposal and its justification.
- Uses, exposures, alternatives and risks.