STRATEGY FOR LIMITING RISKS

HEXABROMOCYCLODODECANE (HBCDD)

(2nd Priority List)

CAS no. 25637-99-4 and 3194-55-6

EINECS no. 247-148-4 and 221-695-9

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Executive summary

HBCDD poses risks for human health when handled in certain work-place activities. There is a local concern for repeated dose toxicity for humans exposed via food near certain industrial sites using HBCDD. Furthermore there is a need for further information with regard to reproductive toxicity and developmental neurotoxicity.

The risk assessment has concluded that Hexabromocyclododecane (HBCDD) has PBT properties according to the criteria of the Technical Guidance Document, TGD. Experiences at international level show that substances with characteristics rendering them persistent, liable to bioaccumulate and toxic present a very high concern. More specifically there are concerns that hazardous substances may accumulate in parts of the marine environment and that the effects of such accumulation are unpredictable in the long-term and that such accumulation would be practically difficult to reverse. A conventional risk characterization cannot be carried out and subsequently environmental concentrations where no effects will appear cannot be predicted with sufficient reliability for PBT substances. Risk management measures must therefore minimise exposures for humans and emissions to the environment that result from manufacture and uses throughout the lifecycle of the substance. There are also concerns for the environment near sites using HBCDD in various industrial processes and for sewage treatment plants receiving releases from certain industrial processes using HBCDD. The measures presented above will also manage the local concerns to the environment and to humans exposed via food.

Based on these conclusions this report presents a risk reduction strategy for HBCDD with an overview and a discussion of the possibilities for substitution.

Taking into account the criteria of effectiveness, practicability, economic impact and monitorability, the rapporteur therefore proposes:

Workers

- the legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to workers to the extent needed and shall apply

Environment and man via the environment:

- to impose restrictions on the marketing and use of HBCDD in general, i.e. in textiles, HIPS, EPS and XPS under the Limitations directive (76/769/EEC)
- to consider the need for time limited exemptions for certain uses of HBCDD in EPS and XPS under the Limitations directive;
- to impose compulsory marking of exempted uses of HBCDD in EPS and XPS products under the Limitations Directive
- to classify used material and products containing HBCDD as hazardous waste under the hazardous waste directive
- to include HBCDD as a priority hazardous substance in Annex X of the Water framework directive
- to develop a proposal for the inclusion of HBCDD in the Stockholm convention on POPs

The use of HBCDD in materials provides improved fire protection. This is one of several ways to reach a high level of fire safety. Further analysis and conditions set under the limitations directive should ensure that a high level of fire safety is maintained.

Restricting the use of HBCDD could lead to increased costs, e g in more expensive materials and development costs. The severe risks identified justify certain costs for market actors. The proposed measures would stimulate innovation and the development of substitutes.

1 BACKGROUND

1.1 Introduction

Hexabromocyclododecane, HBCDD (CAS-no 25637-99-4 or 3194-55-6), is used as a flame-retardant to increase the resistance to fire of building materials, textiles and electric and electronic equipment. The use of flame-retardants is often a consequence of national or international standards, legislation or insurance companies requirements on fire protection. These are formulated as functional requirements, such as improved resistance to ignition by a glowing cigarette or an open flame. The manufacturer has to satisfy these demands, while at the same time taking into account the risks for human health and the environment from any use of flame retarding chemical substances.

HBCDD is on the second priority list (Commission regulation EC 2268/95) of substances for assessment within the European Union's Existing Substances Regulation 793/93. Sweden is the rapporteur for HBCDD and the Swedish Chemicals Agency is designated as the Competent Authority. As rapporteur, Sweden is responsible for assessing the risks associated with HBCDD and for preparing a risk reduction strategy for areas where the risk assessment concludes that further risk reduction measures are needed.

The risk assessment has concluded that HBCDD has PBT properties according to the criteria of the TGD. There are immediate concerns for the environment near sites using HBCDD in various industrial processes and for sewage treatment plants receiving releases from certain industrial processes using HBCDD. The substance also poses risks for human health when handled in certain work-place activities. Based on these conclusions this report presents a risk reduction strategy for HBCDD.

The structure of this report follows the recommendation of the Technical Guidance Document (TGD) on Developing a Risk Reduction Strategy in combination with experience gained in the Community work. Where no other reference is given, information is taken from the risk assessment report (RAR) for HBCDD, draft for final written approval, April 2007. Written comments received on this version of the RAR during the period for comments, and the likely changes in the RAR, have been considered when developing the strategy for limiting the risks. Note that in some local scenarios the conclusions for environment and man exposed via the environment, the conclusions may be changed. This may for some local scenarios remove the need for measures to reduce the risks. The conclusion of the PBT-assessment and most of the conclusions for the local scenarios will however <u>not</u> be changed. The changes will therefore not have an impact on the proposed risk reduction strategy.

In addition, the report includes a reference to the demands in Annex XV in REACH[1], in order to ensure an efficient follow through of the proposed strategy.

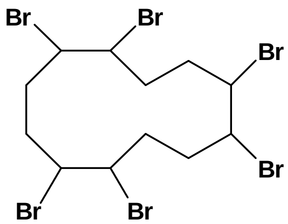
[1] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

1.2 General Substance information

Identification and physical-chemical data

Two different CAS numbers can describe Hexabromocyclododecane (HBCDD):

CAS No.	EINECS	Name
25637-99-4	247-148-4	Hexabromocyclododecane, and
3194-55-6	221-695-9	1,2,5,6,9,10- Hexabromocyclododecane



HBCDD is generally synthesised through bromination of cyclododecatriene of various conformations and isomer mixtures. Independently of the starting material and synthetic pathway used, the end product HBCDD could be described by either CAS No. 25637-99-4 or 3194-55-6, where the latter is the most specific due to the numbering of brominated carbon atoms and is used in the risk assessment. There are no differences in molecular structure or properties recorded for these CAS numbers.

In theory, 16 stereoisomers, 4 meso-forms and 6 pairs of enantiomers of HBCDD can be found. Compounds that are identical except for the spatial disposition of the atoms are called stereoisomers. Stereoisomers that form a pair of mirror images are called enantiomers and stereoisomers that are not enantiomers are called diastereomers. Some diastereomers are identical to their own mirror image; these are called meso-compounds.

The technical HBCDD product is a white odourless solid with a melting point between 175 and 195°C, a melting point of 190 ^{o}C has been used in the RAR. No boiling point has been measured due to decomposition at higher temperatures. The vapour pressure has been calculated to 6,4 * 10^{-6} Pa at 10°C and 1,7 * 10^{-4} Pa at 50°C. The water solubility of HBCDD ranges from 0.0024 to 0.066 mg/l at 20^{o}C depending on how the water solubility is measured. In the risk assessment, the higher value has been used as an environmentally realistic worst case.

The main stereoisomers in technical hexabromocyclododecane are alpha-, beta- and gamma-HBCDD. Separate CAS-numbers have been reported for these different stereoisomers. The technical product of HBCDD contains approximately 80% of the gamma isomer and 10% each of alpha and beta isomers. The composition varies between different market suppliers.

CAS No.	Name
134237-50-6	alpha-Hexabromocyclododecane
134237-51-7	beta-Hexabromocyclododecane
134237-52-8	gamma-Hexabromocyclododecane

The occurrence of three main stereoisomers has complicated the risk assessment since different stereoisomers can have different physical and chemical properties. There is scarce information on the properties of the three isomers, apart from information on melting point, water solubility and transformation between isomers.

Studies presented in the risk assessment indicate that the three main isomers of HBCDD are rearranged at higher temperatures. Thermal conversion of gamma to alpha-HBCDD at temperatures prevalent in some industrial processing of material with HBCDD has been shown. The gamma isomer dominates in abiotic samples, whereas the alpha isomer dominates in biological samples. The reason for the transformation between isomers may be differences in metabolism and/or bioisomerization of the isomers.

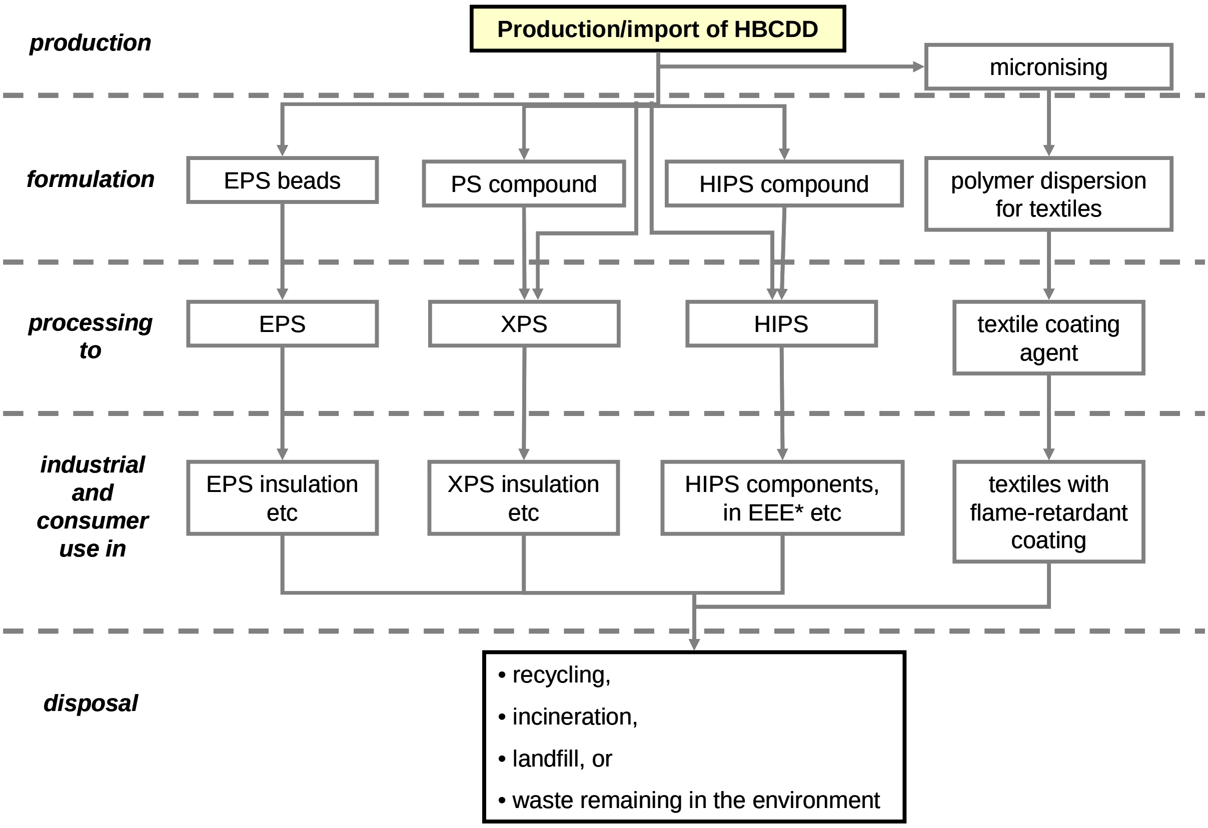
1.3 Production and use

Introduction

HBCDD is presently only produced at one site in EU15. Two other production sites were closed for production in the autumn of 2003 and June 1997 respectively. HBCDD is imported to and probably exported from EU, both as a chemical (on its own or in formulations) and in articles. The total consumption of HBCDD in EU15 (1999) is estimated to nine to ten thousand tons. HBCDD is also extensively used in several of the countries that joined EU in 2004.

The main part (90 %) of HBCDD is used as flame retardant in polystyrene (PS). PS-containing HBCDD, in the form of Expanded PS (EPS) or Extruded PS (XPS), is mainly used as rigid insulation panels/boards for buildings and for road and railway constructions to prevent frost heaves and provide a lightweight load-spreading construction material. HBCDD is also used to flame-retard textiles (for furniture, automobile interiors etc) and in smaller quantities in High Impact PS (HIPS). The latter polymer material is typically used in electronic and electrical equipment. Some other minor uses have been reported, but it is not clear whether they are relevant for EU, and they are not included in the current work.

An overview of the life-cycle stages of HBCDD is shown in Figure 1. A summary of the number of sites and quantities relevant for the various stages is shown in Table 1.1.



* Electrical and Electronic Equipment

Figure 1 Overview of life-cycle stages for HBCDD

Production

The production of HBCDD is a batch-process. Elementary bromine is added to cyclododecatriene in the presence of a solvent. The process temperature is 20 to 70°C, and the reaction takes place in closed systems. The suspension obtained is filtered, the solvent is removed with water, and the product is dried, stored in a silo and packed. The product is delivered as powder or pellets.

Micronising (grinding to smaller particles)

The HBCDD particles in some applications (e.g. for use in textile back-coating) need to be very small. Therefore some quantities of HBCDD are micronised through a grinding process. No information on where micronising takes place is available but it is assumed to be at a very limited number of sites.

Use in EPS

EPS beads are produced in a batch process by suspension polymerisation of styrene in water. HBCDD and other additives are added to the organic phase prior to combining it with the water phase. HBCDD is typically supplied in bags that are emptied in an intermediary storage container from which the substance is transported via pipes to the styrene. In the final EPS beads, HBCDD is incorporated as an integral and encapsulated component within the polymer matrix with uniform concentration throughout the bead. The decanted water from the process is typically re-used and exchanged annually or less frequently. The maximum concentration of HBCDD in EPS beads is assumed to be 0.7 %. After drying and treatment, the EPS beads (typically 0.01 to 0.5 mm) are packed in bins, bags or transported in bulk to EPS-converters.

Twelve sites in EU15 that are members of the trade organisation APME represent about two thirds of the number of sites producing EPS, and more than 80 % of the HBCDD used for flame-retarding EPS.

EPS foam is produced from EPS beads via pre-expansion of the beads with dry saturated steam, drying with warm air and shaping in shape moulds or in a continuous moulding machine. The foam can then be further formed by cutting, sawing or other machine operations.

The number of sites producing EPS foam flame-retarded with HBCDD in EU15 is not known, but it is likely that there is a fairly large number of such sites.

Nearly all EPS containing HBCDD is used in the building and construction industry, with smaller quantities used in (non-food) packaging. In Europe some 420 000 tonnes of EPS is used for construction applications, 170 000 of this is used in Eastern Europe. In Western Europe approximately 70 % of this EPS is flame-retarded grades, in Eastern Europe more than 99 %. Packaging uses some 250 000 tonnes of EPS in Western Europe of which approximately 10 % is flame-retarded grade.

After its service life, EPS products may be: re-used by grinding clean EPS waste and adding it to virgin material during production; or melting EPS and extruding it to make compact polystyrene; incinerated with energy recovery; or as landfill. EPS packaging is collected via national waste management schemes in increasing volumes. In buildings and construction, the service life of the EPS products is likely to be long. No information on the collection of EPS used in building and construction is available. HBCDD, if present, is not separated from the EPS.

Use in XPS

HBCDD is supplied to the manufacturer of XPS articles as a powder, as pellets (compacted powder) or as a granulate compound (concentrate of HBCDD in polystyrene).

Formulation of PS compound with HBCDD can be made at the same site as the following processing stage or at a separate site. HBCDD as powder or low-dust granulated form is emptied into hoppers (designed to minimise dusting) and transported via metering equipment to be mixed with polystyrene. It is then extruded in a heated process. The extruded compound is either air-cooled or cooled in a water-bath.

To manufacture XPS materials polystyrene is mixed with additives (including HBCDD on its own or as compound) and continuously fed into a heated extruder. A blowing agent is mixed with the melted polymer and a “foamable gel” is formed. The gel is cooled before it exits through an orifice, where the blowing agent volatilises, leaving a foam structure with a large number of closed cells. The XPS material is trimmed into the desired shape and stored for curing for about a week. Some 25 % of material from the manufacturing is recycled to the extruder. The content of HBCDD in XPS varies but is typically 1 to 3 %.

XPS with HBCDD is used in the construction industry as rigid insulation boards in constructions and in road and railway embankments to protect against frost damage and as insulation. It is also used as insulation in sandwich constructions in vehicles such as caravans and lorries for cold or warm transport of goods.

After its service life XPS products may be re-used, recycled, used as landfill or incinerated. In buildings and constructions the XPS products are likely to remain in use for a long time.

Use in HIPS

HBCDD is supplied to the manufacturer of HIPS articles as a powder or as a PS granulate compound (concentrate of HBCDD in polystyrene).

Formulation of PS compound with HBCDD can be made at the same site as the following processing stage or at a separate site. HBCDD as powder or low-dust granulated form is emptied into hoppers (designed to minimise dusting) and is then transported via metering equipment to where it is mixed with polystyrene. It is then extruded in a heated process and is then cooled, normally in a water bath.

To manufacture flame-retarded HIPS, HIPS is mixed with additives (including HBCDD on its own or as compound) and fed into a heated extruder. There it is further mixed, homogenised and granulated. Cooling may be by air or in water bath. After drying the HIPS pellets are packed into bags or into bulk storage.

Other brominated flame-retardants, as well as synergistic agents such as antimony trioxide, are sometimes used together with HBCDD. The content of HBCDD in flame-retarded HIPS varies but is typically below 7 %. HIPS-containing HBCDD is used mainly in electronic and electrical equipment such as video and stereo equipment, distribution boxes in electrical lines, and refrigerator lining.

Use in textiles

HBCDD is formulated to polymer-based dispersions (e.g. acrylic or latex) in water. This dispersion is then applied to the textile. The dispersion also contains other ingredients than HBCDD. The formulation step is usually done at another site than the application to the textile. The dispersion contains 5 to 48 % HBCDD, typically 10 to 15 %. The water used for cleaning is collected and reused in the process at some, but not all sites. The HBCDD used in this application must be a very fine powder (3 to 4 µm).

The dispersion is applied to the textile by back coating, either as a paste which is applied to the textile and a scratch knife defines the final thickness, or as a foam layer which is pressed on the textile through a rotating screen. The coating is dried and fixated at 140 to 180°C.

Textiles flame-retarded with HBCDD are typically technical textile and furniture fabric, based on cotton and cotton polyester blends. Typical end products are upholstered furniture, draperies, interior textiles and automobile interior textiles. The content of HBCDD in the final layer can be up to 25 %, or 6 to 15 % with about 4 to 10 % of antimony trioxide that has a synergistic flame-retardant effect.

Service-life and disposal

Waste containing HBCDD is generated at each life-cycle step. In some cases the waste material can be recycled into the process. Wasted end products are incinerated, put on landfill, left in the environment or recycled. Waste ending up in the municipal waste streams is likely to be incinerated or put on landfill. Construction material on or under ground may be left in the environment after use or be part of wasted construction material used as filling material. Recycling of EPS occurs in several European countries. Wasted EPS boards are ground and put back into the moulding process together with virgin EPS to form new boards. The percentages of HBCDD that is part of incinerated, landfill or recycled material is not known.

The service time for many products containing HBCDD is long, in some cases, e g roads and railways up to 100 years and for buildings typically 30 to 100 years. Thus the amount of HBCDD in the society is accumulating.

Table 1-1 Summary of production and use (EU15 data from 2002 in RAR)

	number of sites	quantity handled tons / year	typical HBCDD content in end-product	typical form of HBCDD (note 1)
Production of HBCDD in 2005	1	6 000	100 %	powder or granulate
Micronising of HBCDD	few	1 000 (assumption)	100 %	micronised
Formulation of flame-retarded EPS beads	> 18	3 400	0.7 % (in EPS beads)	powder
Formulation of flame-retarded PS compound for HIPS	4	> 200	not available	powder
Formulation of flame-retarded PS compound for XPS	> 14	1 700	40 % (in compound)	powder, granulate
Formulation of polymer dispersion for textile back-coating	16	1 100 (assumption)	10 to 15 % (in the dispersion)	micronised
Industrial use of EPS beads to produce flame-retarded EPS	hundreds	3 400	0.7 % (in the EPS)	embedded in EPS
Industrial use of HBCDD in PS compound to produce flame-retarded HIPS	not available	> 200	1 to 3% (in the XPS)	powder or embedded in compound
Industrial use of HBCDD in PS compound to produce flame-retarded XPS	17	1 700	1 to 3% (in the XPS)	embedded in compound
Industrial use of HBCDD as powder to produce flame-retarded XPS	18	3 200	0.5 to 3 % (in the XPS)	powder
Industrial use of HBCDD in polymer dispersion for textile back-coating	24	1 000	25 % or 6 to 15 % (in final layer) (note 2)	micronised, in a dispersion
Disposal	not known, widely spread	not known	varying	varying

Notes to table:

(1) micronised typically 3 to 4 μm, powder typically 50 to 250 μm; granulates typically > 500 μm
(2) the lower span is if used together with antimony trioxide, which is a synergistic flame-retardant

2 CONCLUSIONS FROM THE RISK ASSESSMENT

Section 2.1 and 2.2 presents an overview of the conclusions from the risk assessment. Sections 2.3 and 2.4 are taken from section 5.2 and 5.1 in the draft risk assessment report for final written approval (April 2007) with only editorial changes, and give more detailed information. Note that in some local scenarios the conclusions for environment and man exposed via the environment may be changed based on comments received. This may for some local scenarios remove the need for measures to reduce the risks. The conclusion of the PBT-assessment and most of the conclusions for the local scenarios will however not be changed. The changes will therefore not have an impact on the proposed risk reduction strategy.

2.1 Proposed classification

The proposed classification for the environment is:

N; R50-53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Concentration limits:

According to the proposal on specific concentration limits for very toxic substances (ECBI/65/99 Add.10), the reported L(E)C50 range of 10-100 µg/l will give rise to the following concentration limits of preparations:

Concentration limits of substance	*Classification of preparation*
C ≥2.5 %	N; R50-53
C ≥0.25 %	N; R51-53
C ≥0.025 %	R52-53

2.2 Overview

HBCDD poses risks for human health when handled in certain work-place activities. There is a local concern for repeated dose toxicity for humans exposed via food near certain industrial sites using HBCDD. Furthermore there is a need for further information with regard to reproductive toxicity and developmental neurotoxicity.

The risk assessment has concluded that Hexabromocyclododecane (HBCDD) has PBT-properties according to the PBT-criteria of the TGD. There are also concerns for the environment near sites using HBCDD in various industrial processes and for sewage treatment plants receiving releases from certain industrial processes using HBCDD.

Table 2-1 Overview of conclusions* from the risk assessment

Human health

General	**(i) on hold**	*with regard to:* - *a multi-generation reproduction study in a rodent species* - *a developmental neurotoxicity study*
Workers	**(iii)**	*for repeated dose toxicity for workers during filling HBCDD fine grade powder in production*
	(ii)	for other scenarios
Consumers	**(ii)**	for all scenarios
Man via the environment	**(iii)**	*for repeated dose toxicity in the following local scenarios: one textile backcoating (site-specific), one XPS industrial use (site-specific) and textile industrial use (generic)*
	(ii)	for other scenarios
Physico-chemical properties	**(ii)**	for all scenarios

Environment		
Aquatic	**(iii)**	*locally for:* - *EPS formulation (some sites and generic),* - *XPS formulation (all sites and generic),* - *formulation of polymer dispersions for textiles (one site and generic),* - *industrial use of HIPS,* - *sites involved in industrial use of XPS including the generic scenario (however, the relevance of the conclusions for intermittent release is questionable) and* - *sites involved in textile back-coating including the generic scenario.*
	(ii)	for other scenarios
Sewage treatment plant	**(iii)**	*locally for:* - *some sites with industrial use of XPS having intermittent releases to waste water and* - *for one textile back-coating site including the generic textile back-coating*
	(ii)	for other scenarios
Terrestrial	**(iii)**	*locally for:* - *the generic scenario for the industrial use of XPS compound, If an alternative half-life study is used, the conclusion (iii) only remains for the textile back-coating site and the generic textile back-coating scenario.* - *one site involved in textile back-coating and the generic textile back-coating scenario.*
	(ii)	for other scenarios
Atmosphere	**(ii)**	for all scenarios
Non-compartment specific effects relevant for the food chain **(**Secondary poisoning)	**(iii)**	*for the aquatic and marine food chains for:* - *some sites involved in EPS formulation including the generic scenario,* - *some sites involved in XPS formulation including the generic scenario,* - *one site involved in formulation of polymer dispersions for textiles including the generic scenario,* - *industrial use of EPS,* - *industrial use of HIPS,* - *some sites involved in industrial use of XPS including the generic scenario, and* - *sites involved in textile back-coating including the generic scenario.*
	(iii)	*for terrestrial predators for:* - *one site involved in industrial use of XPS including the generic scenario; if an alternative half-life study is used, the conclusion for the site and the generic scenario involved in industrial use of XPS changes from conclusion (iii) to conclusion (ii); and* - *one site involved in textile back-coating including the generic scenario.*
	(ii)	for other scenarios
Marine	**(iii)**	*locally for:* - *some sites involved in EPS formulation including the generic scenario,* - *all sites involved in XPS formulation including the generic scenario,* - *one site involved in formulation of polymer dispersions for textiles including the generic scenario,* - *industrial use of HIPS,* - *sites involved in industrial use of XPS including the generic scenario (however, the relevance of the conclusions for intermittent release is questionable) and* - *sites involved in textile back-coating including the generic scenario.*

	(ii)	for other scenarios
PBT	**(iii)**	

* Presented as:

(i) There is a need for further information and/or testing; or

(ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already; or

(iii) There is a need for limiting the risks; risk reduction measures that are already being applied shall be taken into account

2.3 Human health

Exposed human populations include workers, consumers, and humans via the environment. In the case of HBCDD measured data from occupational, consumer and indirect exposure exists. The endpoint of concern is repeated dose toxicity for which a NOAEL/BMD-L of 22.9 mg/kg/day based on an increased liver weight is deduced from an 28 days oral study using a benchmark model design. Worst-case exposures are assumed for all exposure scenarios.

Conclusion (i) on hold There is a need for further information and/or testing.

The TC NES subgroup on PBT assessment has decided that HBCDD is a PBT-substance according to the TGD criteria. The uncertainties thus arising with regard to human health effects relating to bioaccumulation of HBCDD, excretion of HBCDD to breast milk and possible effects on reproduction after life-time exposure needs to be addressed. Therefore, a conclusion (i) is reached with regard to a properly designed multi-generation reproduction study in a rodent species. This applies to all exposure scenarios. However, results from a one generation reproduction toxicity study performed by Lilienthal et al. (2006) will soon be available. In addition, according to information from industry a two generation reproduction toxicity study will be conducted in Japan. While awaiting these results and taking into account that HBCDD is a PBT substance and the exposure will be restricted by relevant regulations, a **conclusion (i) on hold** with regard to a properly designed multi-generation reproduction study in a rodent species applies.

There are indications of developmental neurotoxicity in adult mice exposed to HBCDD as pups. However, this study by Eriksson et al (2006) is not performed according to current guideline and GLP and therefore this potential developmental neurotoxicity needs to be examined further and conclusion (i) is reached for all exposure scenarios.

However, similar results on developmental neurotoxicity have been published for decabromodiphenyl ether by the same authors using the same method. For decabromodiphenyl ether it has been agreed to perform a new toxicokinetics/developmental neurotoxicity study according to a modified OECD guideline and GLP. The results from this new decabromodiphenyl ether study will serve as a guidance on how to interpret the data from the Eriksson study, and may also serve as a basis on how to proceed with further testing of neurotoxicity. While awaiting these results and taking into account that HBCDD is a PBT substance and the exposure will be restricted by relevant regulations, a **conclusion (i) on hold** with regard to a developmental neurotoxicity study applies.

Workers assessment

Conclusion (iii) There is a need for limiting the risks; risk reduction measures that are already being applied shall be taken into account

There are three occupational exposure scenarios; exposure during filling (production), adding (industrial use), and sewing (end use by professionals).

The results of the occupational assessment are presented in Table 2-2. There is concern for repeated dose toxicity for workers during filling HBCDD fine grade powder in production. Therefore it is considered that risk reduction measures are required and **conclusion (iii)** applies.

Table 2-2 Overview of conclusions with respect to occupational risk characterisation

End point	Conclusions for the occupational scenarios					
	Production		Industrial use		End use, professional	
	MOS	conclusion	MOS	conclusion	MOS	conclusion
Repeated dose toxicity; fine grade powder						
-inhalation	16	(iii)	52	(ii)	286	(ii)
-dermal	10	(iii)	327	(ii)	382	(ii)
-multiple exposure	6	(iii)	45	(ii)	164	(ii)
Repeated dose toxicity; standard grade powder						
-inhalation	85	(ii)	64	(ii)		
-dermal	47	(ii)	458	(ii)		
-multiple exposure	30	(ii)	56	(ii)		
Repeated dose toxicity; granules/masterbatch						
-all routes and multiple	≥458	(ii)	≥739	(ii)		

Consumers assessment

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those, which are being applied already

One exposure scenario for consumers has been considered; mouthing of textile. The results of the consumer assessment are presented in Table 2-3. There is no concern with respect to repeated dose toxicity.

Table 2-3. Overview of conclusions with respect to risk characterisation for consumers.

Endpoint	Mouthing of textile (both sides)	
	MOS	Conclusion
Repeated dose toxicity	760	(ii)

Humans exposed via the environment assessment

Conclusion (iii) There is a need for limiting the risks; risk reduction measures that are already being applied shall be taken into account

The EUSES modelling predicts rather high concentrations of HBCDD in root crops and fish locally around plants formulating or using HBCDD. There is concern for repeated dose toxicity in one site-specific local scenario relating to textile backcoating, one site-specific local scenario relating to XPS Industrial Use and the generic textile industrial use scenario, but not for the regional scenario or for exposure of infants via breast milk.

Combined exposure

No calculations have been performed.

Human health (physico-chemical properties)

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already

Flammability, explosive and oxidising properties are not considered to be of concern.

2.4 Environment

Aquatic compartment

Sewage treatment plant (STP)

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to most of the sites and life cycle stages.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to some sites with industrial use of XPS having intermittent releases to waste water and for 1 textile back-coating site including the generic textile back-coating scenario.

Surface water

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those, which are being applied already.

Conclusion (ii) applies to production and micronising, industrial use of EPS and HIPS and for individual sites in the other use areas.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to some sites involved in EPS formulation including the generic scenario, all sites involved in XPS formulation including the generic scenario, one site involved in formulation of polymer dispersions for textiles including the generic scenario, sites involved in industrial use of XPS and sites involved in textile back-coating including the generic scenario.

Freshwater sediment

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, micronising and industrial use of EPS and for individual sites in the other use areas.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to some sites involved in EPS formulation including the generic scenario, all sites involved in XPS formulation including the generic scenario, one site involved in formulation of polymer dispersions for textiles including the generic scenario, industrial use of HIPS, sites involved in industrial use of XPS including the generic scenario (however, the relevance of the risk characterisation ratios resulting from intermittent release is questionable) and sites involved in textile back-coating including the generic scenario. A general conclusion (iii) is drawn for textile back-coating. based on measured concentrations in sediment downstream three different locations giving RCRs (risk characterisation ratios) >1.

Terrestrial compartment

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to most sites and life cycle stages.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to one site site involved in industrial use of XPS including the generic scenario, and one site involved in textile back-coating including the generic scenario. However, if the DT50 (disappearance time 50%) from simulation study 1 is used the conclusion for the site and the generic scenario involved in industrial use of XPS changes from conclusion (iii) to conclusion (ii).

Atmosphere

Conclusion (ii) There is at present no need for further information and/or testing and for risk reduction measures beyond those, which are being applied already

This conclusion applies to all life cycle stages and scenarios.

Secondary poisoning

Aquatic predators

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, micronising and for individual sites in the other use areas.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to some site involved in EPS formulation including the generic scenario, some sites involved in XPS formulation including the generic scenario, one site involved in formulation of polymer dispersions for textiles including the generic scenario, industrial use of EPS, industrial use of HIPS, some sites involved in industrial use of XPS including the generic scenario, and some sites involved in textile back-coating including the generic scenario. A general conclusion (iii) is drawn for textile back-coating based on measured concentrations in fish from water courses associated textile industry.

Terrestrial predators

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, micronising, EPS formulation, XPS formulation, formulation of polymer dispersions for textiles, industrial use of EPS and HIPS and for individual sites in the other use areas.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to one site involved in industrial use of XPS including the generic scenario, and one site involved in textile back-coating including the generic scenario. However, if the DT50 from simulation study 1 is used the conclusion for the site and the generic scenario involved in industrial use of XPS changes from conclusion (iii) to conclusion (ii).

Marine predators

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, micronising and industrial use of EPS and HIPS and for individual sites in the other use areas.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to some sites involved in EPS formulation including the generic scenario, one site including the generic scenario for XPS formulation, one site involved in formulation of polymer dispersions for textiles including the generic scenario, some sites involved in industrial use of XPS including the generic scenario, and for some sites involved in textile back-coating including the generic scenario.

Marine top predators

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, micronising and industrial use of EPS and HIPS and for individual sites in the other use areas.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to the generic scenario for EPS formulation, all sites including the generic scenario for XPS formulation, one site involved in formulation of polymer dispersions for textiles including the generic scenario, one site involved in industrial use of XPS including the generic scenario, and some sites involved in textile back-coating including the generic scenario.

Marine environment

Marine Surface water

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, micronising and industrial use of EPS and HIPS and for individual sites in the other use areas.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to some sites involved in EPS formulation including the generic scenario, and both sites and the generic scenario for XPS formulation, one site involved in formulation of polymer dispersions for textiles including the generic scenario, some sites involved in industrial use of XPS including the generic scenario, and some sites involved in textile back-coating including the generic scenario.

Marine Sediment

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to production, micronising and industrial use of EPS and HIPS and for individual sites in the other use areas.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to some sites involved in EPS formulation including the generic scenario, and both sites and the generic scenario for XPS formulation, one site involved in formulation of polymer dispersions for textiles including the generic scenario, some sites involved in industrial use of XPS including the generic scenario, and some sites involved in textile back-coating including the generic scenario. In addition, measurements in marine sediment associated to a producer of EPS beads gives a RCR >1 which indicates that there are concerns for this site and that there may be a general concern for this use area.

PBT-assessment

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

HBCDD does not unequivocally fulfil the specific P-criterion, with some reliable studies indicating that biodegradation can occur. It does however not degrade rapidly and monitoring data indicate a significant degree of environmental transport and overall stability. The BCF of HBCDD is 18 100 and thus the vB criterion is fulfilled. Also the T-criterion is fulfilled according to available data. HBCDD is ubiquitous in the environment, being also found in remote areas far away from point sources. The highest concentrations of HBCDD are detected in marine top-predators such as porpoise and seals showing that HBCDD bioaccumulates up the foodchain. Based on an overall assessment the TCNES subgroup on identification of PBT and vPvB substances have concluded that HBCDD has PBT properties according to the PBT criteria of the TGD.

3 CURRENT CONTROLS FOR HBCDD

3.1 Community and national legislation

A request for information regarding existing risk management measures was sent to the representatives from member states competent authorities to the risk reduction meetings. The replies received (UK, PL, NL, DK, DE, SE) gave the following information. In general HBCDD is covered by national environmental and worker protection legislation (including provisions adopted to comply with community legislation), but without specific provisions for HBCDD.

For the production site in the Netherlands, a permit defining the maximum permitted release of HBCDD will be set.

The Norwegian government has proposed a ban on the use of HBCDD and 17 other substances in consumer products. The proposal was sent for hearing recently. [SFT 2007]

3.2 International conventions

OSPAR is the Convention for the Protection of the Marine Environment of the North-East Atlantic. In 1998 the first OSPAR List of Substances for Priority Action was established. The objective is to prevent pollution of the maritime area by continuing to reduce discharges, emissions and losses of hazardous substances 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. Every endeavour should be made by contracting parties to move towards the target of cessation of discharges, emissions and losses of hazardous substances by the year 2020.

Brominated flame retardants were given priority in the 1992 OSPAR Action plan and HBCDD is included, together with a number of other brominated flame-retardants, in the list of Chemicals for Priority Action established 1998. [OSPAR 2004]

The **Helsinki Commission** (or HELCOM) is the governing body of the Convention on the protection of the Marine Environment of the Baltic Sea area (also known as the Helsinki

Convention) and works to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental co-operation between Denmark, Estonia, the European Community, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden. HELCOM unanimously adopts recommendations for the protection of the marine environment, which governments of the Contracting parties must act on in their respective national programmes and legislation. Among the priorities are hazardous substances, defined as contaminants that are ecologically harmful. Similar to OSPAR, HELCOM is working towards the target of cessation of discharges, emissions and losses of hazardous substances by the year 2020. Brominated flame retardants are included as a group in List of substances which are candidates for selection, assessment and prioritisation according to section 3.1 of the Strategy to Implement HELCOM Objective with Regard to Hazardous Substances. [HELCOM 1998]

3.3 Voluntary agreements

A Voluntary Emissions Control Action Programme (VECAP) has been established by the brominated flame retardant industry. It was set up to manage, monitor and minimise industrial emissions of brominated flame retardants into the environment through partnership with the supply chain including Small and Medium-sized Enterprises (SMEs).

HBCDD is not included in the first annual progress report (2006), but it is mentioned that it will be included in the near future and that a similar programme, SECURE, for the use of HBCDD in expanded and extruded polystyrene will be launched soon. [Vecap]

4 MEASURES NEEDED TO EFFECTIVELY REDUCE THE RISKS

4.1 Workers

There is a need to reduce the exposure via dermal contact and inhalation for workers filling fine grade HBCDD in packaging. Such filling takes place at few sites. To minimise the inhalation exposure in the working environment the concentrations of HBCDD in the air should be minimised, and to minimise the dermal exposure in the working environment the potential for skin contact with HBCDD must be minimised. Both can be achieved through substitution of HBCDD, or through organizational and technical measures, e g more closed processes, improved local exhaust ventilation, or through the use of protective gloves and clothing for the individual.

4.2 Environment and humans exposed via the environment

Findings at international level show that substances with characteristics rendering them persistent, liable to bioaccumulate and toxic present a very high concern. Specifically there is:

a) the concern that hazardous substances may accumulate in parts of the marine environment and that: (i) the effects of such accumulation are unpredictable in the long-term; (ii) that such accumulation would be practically difficult to reverse;

b) the concern that remote areas of the oceans should remain untouched by hazardous substances resulting from human activity, and that the intrinsic value of pristine environments should be protected.

Of these additional concerns (a) above may be seen as the main concern. This is characterised by a spatial and temporal scale not covered by the inland risk assessment approach. It is a concern that chemical substances which can be shown both to persist for long periods and bioaccumulate in biota, can give rise to toxic effects after a greater time and at a greater distance than chemicals without these properties. While this is also true for the freshwater environment, the additional concern in the marine environment is that once the chemical has entered the open seas, any cessation of emission will not necessarily result in a reduction in chemical concentration and hence any effects become difficult to reverse. Equally, because of the long-term exposures and long-life-cycle of many important marine species, effects may be difficult to detect at an early stage.

To meet these concerns, which principally relate to substances that are considered as Persistent, Bioaccumulative and Toxic (PBT), or have other properties which give rise to a similar level of concern, an assessment approach that gives special consideration to this new protection goal has been included in the TGD.

It has been concluded that HBCDD has such properties according to the PBT criteria in TGD. A conventional risk characterization comparing the predicted environmental concentration to the predicted no-effect concentration cannot be carried out with sufficient reliability for substances fulfilling the PBT criteria. Risk management measures must therefore minimise exposures and emissions to humans and the environment that result from manufacture or uses throughout the lifecycle of the substance. This will also manage the identified local risks to the environment by reducing local releases as well as reducing the background concentration of HBCDD.

Because HBCDD has characteristics rendering it persistent, liable to bioaccumulate and toxic, the continuous feed into society raises very high concern. Even if it can be shown that emissions of HBCDD from uses are limited and that HBCDD is used in products with long service-life, it still needs to be considered that the substance may eventually enter the environment, e g during the waste stage. As the quantity in use in society increases, the quantity released will also increase and accumulate in living organisms.

5 POTENTIAL LEGISLATIVE TOOLS

5.1 Introduction

The following section summarises relevant legislation and other instruments in as much as they relate to the identified risks with HBCDD. There is a need for immediate measures. Therefore only legislation that will produce decisions possible to coming into force in a relative near future has been considered. Among others, authorisation under Reach[2] is not considered.

5.2 For the protection of workers

Chemical Agents at Work 98/24/EEC[3]

The directive lays down general provisions for safety and health relating to workplace chemicals, including procedures for setting Community level occupational exposure limit (OEL) values.

[2] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
[3] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work

To ensure that risks from hazardous chemical agents are eliminated or reduced to a minimum, employers are requested to conduct a risk assessment of such substances. The risk assessment must be documented. The employers, applying a set of general principles, should take action to reduce or remove identified risks. The effectiveness of the preventive measures should be monitored and the assessment should be reviewed. The Directive sets a hierarchy for exposure controls to be applied if a risk assessment reveals risks.

The general principles are substitution, prevention, protection and control. If it is not possible to substitute the chemical agent or process that poses a risk, the next steps to be taken are engineering controls, use of adequate equipment or general protection measures such as ventilation. The last option should be to use individual personal protective equipment.

The directive also gives provision for the Commission to draw up practical guidelines to assist compliance with the directive. These guidelines will be non-binding but should relate to development of standardised methods for measuring and evaluating air concentration at workplace, determination and assessment of risk and preventative and protective measures to control risk.

Member States were to implement the Chemical Agents Directive by the 5^{th} of May 2001. Thereafter a report should be given to the Commission every five years on its practical implementation.

An OEL could be established for HBCDD under this directive.

5.3 For the protection of the environment and humans exposed via the environment

The Water Framework Directive (2000/60/EC)[4]

The Water Framework Directive (WFD) establishes a wide framework for Community action in the field of water policy. The aim of the directive is to maintain and improve the aquatic environment. The directive covers inland surface waters, transitional waters, coastal waters and groundwater. The aquatic environment of surface waters includes the water column, its sediments and biota.

The WFD recognises that individual substances or groups of substances may present a significant risk to or via the aquatic environment and require action against pollution caused by these substances. Substances that present a significant risk to, or via the aquatic environment, will be prioritised for action on the basis of risk (“priority substances”).

Article 16(2) of the directive introduces a scientifically based methodology for selecting “*priority substances”* on the basis of their significant risk to or via the aquatic environment. “*Priority hazardous substances*” will be identified among the priority substances. For *priority substances*, the proposed controls shall aim at progressive reduction of discharges, emissions and losses and for *priority hazardous substances* cessation or phasing out of discharges, emissions and losses within 20 years. Member states shall ensure that controls or emission limit values set out in the directive are established and/or implemented.

Within the framework of this directive, a list of 33 priority substances or groups of substances has been established but HBCDD is presently not included. Final decisions will be taken in the review of the list of priority substances as foreseen under Article 16(4) “The Commission

[4] Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy

shall review the adopted list of priority substances at the latest four years after the date of entry into force of this Directive and at least every four years thereafter, and come forward with proposals as appropriate.”

HBCDD could be put forward as a priority hazardous substance in the WFD.

The Directive on Integrated Pollution Prevention and Control (96/61/EC)[5]

The aim of the IPPC directive is to lay down measures designed to prevent or control emissions in order to achieve a high level of protection of the environment. The instruments for risk reduction in the directive are permit requirements, including emission limit values (ELV) and the creation of reference documents on best available techniques, BREFs.

BREFs are the result of an exchange of information between member states and industry on best available techniques (BAT), organized by the commission. The results are published as IPPC BAT Reference Documents (BREFs). The means to reduce emissions as well as achievable emission limit values have to be described in the BREFs. BREFs must be taken into account when the competent authorities of Member States determine conditions for IPPC permits. Brominated flame-retardants are mentioned as one of the relevant categories of chemicals for the BREF of “Organic Fine Chemicals” of August 2006[6].

New medium-sized and large industrial installations, covered by the IPPC Directive, have to obtain a permit from the competent national authority before they are put into operation. Existing installations of the same kind should obtain a permit at the latest 2007.

Installations for industrial production of chemicals such as HBCDD are within the scope of the IPPC directive. The production of polymers such as EPS, XPS and HIPS is also within the scope of the IPPC directive. The inclusion of a brominated flame-retardant in EPS is specifically mentioned in the BREF for polymers[7]. The industrial use of EPS, XPS and HIPS and the formulation and application of textile-back-coating is not within the scope of the directive.

The IPPC directive can be used to manage the releases of HBCDD from industrial sites covered by the directive (production of HBCDD, EPS, XPS and HIPS) either by introducing emission limit values and/or by including information on HBCDD in the relevant BREF:s.

Council Directive on hazardous waste (91/689/EEC)[8]

The objective of the directive on hazardous waste is to approximate the laws of the Member States on the controlled management of hazardous waste.

For the purpose of this Directive ‘hazardous waste’ means:

- Wastes featuring on a list drawn up in commission decision 2000/532/EC[9]. These types of waste must have one or more of the properties listed in Annex III to the directive on hazardous waste.

[5] Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control

[6] Integrated Pollution Prevention and Control Reference Document on Best Available Techniques for the Manufacture of Organic Fine Chemicals, August 2006

[7] Integrated Pollution Prevention and Control Reference Document on Best Available Techniques in the Production of Polymers; Dated October 2006

[8] Council Directive 91/689/EEC of 12 December 1991 on hazardous waste

- Any other waste which is considered by a Member State to display any of the properties listed in Annex III to the directive on hazardous waste. Such cases shall be notified to the Commission and reviewed in accordance with the procedure laid down in Article 18 of Directive 75/442/EEC with a view to adaptation of the list.

Examples of properties listed in Annex III to the directive are: Irritant, Harmful, Toxic, Carcinogenic and Ecotoxic.

Domestic waste is exempted from the provisions in the directive. The directive lays down general rules for the handling of hazardous waste (recording and identification of hazardous waste, mixing of hazardous waste with other types of waste, packaging and labelling for collection, transport and temporary storage of hazardous waste etc.).

Article 2 of commission decision 2000/532/EC states characteristics for properties listed in annex III of the directive. If a waste is identified as hazardous by a specific or general reference to dangerous substances (any substance that has been or will be classified as dangerous in directive 67/548/EEC), the waste is to be classified as hazardous only if the concentrations of those substances are such (i.e. percentage by weight) that the waste presents one or more of the properties listed in Annex III to the directive. The commission decision provides concentration limits for several different properties concerning toxicity to human health.

For example, wastes classified as ***Toxic*** are considered to display one or more of the properties listed in Annex III to Directive 91/689/EEC and one or more of the following characteristics:

- One or more substances classified as very toxic at a total concentration ≥ 0,1 %,
- One or more substances classified as toxic at a total concentration ≥ 3 %,

For the property ***Ecotoxic*** no specification is given, therefore each case requires an assessment of the waste’s properties in comparison with the general definition in Annex III which is:

- ‘Ecotoxic’: substances and preparations which present or may present immediate or delayed risks for one or more sectors of the environment.

In the absence of general regulations for the classification of waste as hazardous based on content of PBT/vPvB substances, material containing HBCDD could be classified and listed as hazardous waste under this directive.

The Construction Products Directive (89/106/EEC)[10]

Under the construction products directive, Member States shall take all necessary measures to ensure that construction products which are intended for use in works, may be placed on the market only if they are fit for this intended use, that is to say they have such characteristics that the works in which they are to be incorporated, assembled, applied or installed, can, if properly designed and built, satisfy, the essential requirements of the directive.

The essential requirements for the works are:

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[9] 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

[10] Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products

1. Mechanical resistance and stability
2. Safety in case of fire
3. Hygiene, health and environment
4. Safety in use
5. Protection against noise
6. Energy economy and heat retention

According to requirement 3, the construction work, must be designed and built in such a way that it will not be a threat to the hygiene or health of the occupants or neighbours, in particular as a result of any of the following:

- the giving-off of toxic gas,

- the presence of dangerous particles or gases in the air.

- the emission of dangerous radiation- pollution or poisoning of the water or soil,

- faulty elimination of waste water, smoke, solid or liquid wastes,

- the presence of damp in parts of the works or on surfaces within the works.

Products which fulfil the requirements of the directive, including the essential requirements, can bear the CE marking. The manufacturer or his authorized representative established within the Community is responsible for affixing the CE marking on the product itself, on a label attached to it, on its packaging, or on the accompanying commercial documents.

The construction product directive is currently under revision. Construction products containing HBCDD could possibly be marked under this directive to simplify the identification and proper disposal of construction waste. To the extent possible, the presence of HBCDD in buildings could be kept in a record to facilitate handling in future. Depending on the result of ongoing revision, that could be ruled under the Construction Product Directive. It is also a measure that could be encouraged by member state national authorities.

The Sewage Sludge directive (86/278/EEC)[11]

The Sewage Sludge directive seeks to encourage the use of sewage sludge in agriculture and to regulate its use in such a way as to prevent harmful effects on soil, vegetation, animals and man. The directive specifies rules for the sampling and analysis of sludge and soils. Limit values for concentrations of heavy metals in sewage sludge intended for agricultural use and in sludge-treated soils are given in Annexes I A, I B and I C of the directive. The inclusion of limit values also for organic contaminants is discussed in the Environment DG working document on sludge [DG ENV 2000].

A limit value for HBCDD in sludge for agriculture use could be introduced under this directive.

[11] Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture

The RoHS[12] and WEEE[13] directives (2002/95/EC and 2002/96/EC)

Under the WEEE directive producers will be responsible for taking back and recycling electrical and electronic equipment. In order to prevent the generation of hazardous waste, the RoHS Directive requires the substitution of various heavy metals (lead, mercury, cadmium, and hexavalent chromium) and some brominated flame retardants (polybrominated biphenyls (PBB) or polybrominated diphenyl ethers (PBDE)) in new electrical and electronic equipment put on the market from 1 July 2006.

Restrictions of HBCDD in electrical and electronic equipment could be imposed under RoHS.

Limitations directive (76/769/EEC)[14]

The objective of the Limitations Directive is to protect the human health and the environment, and to improve the quality of life, and to remove obstacles to trade by harmonising restrictions on the marketing and use of certain dangerous substances and preparations on the European market. Substances and preparations regulated under the Limitations Directive are listed in the Annex I to that Directive which also specifies details on the marketing and use restriction applying in each particular case.

The Commission has the sole right to propose restrictions, while the initiatives can be taken e g through the existing substances programme or national notification. Where a "new" substance is proposed to be restricted by the Commission, the proposal shall be scrutinised and decided by the Council and the Parliament. Where a substance is restricted under the directive, and the proposal is to change the limitations already in place, this is handled through a Commitology Procedure, where a decision to adapt actual restrictions to technical progress can be taken.

Restrictions on the marketing and use of HBCDD for some or all uses could be introduced under this directive. Compulsory marking of material containing HBCDD could also be included in order to facilitate the identification and relevant handling of waste.

Voluntary agreements

Voluntary actions can be suitable in situations with a limited number of uses of a substance and a small number of parties involved, as the performance is dependent of commitment and co-operation within industry. A limited number of organisations can verify that members fulfil their commitments and ensure monitoring of the results of the commitments. Commitments can be made at national or Community level. As the commitments are not legally binding, the impact of such voluntary actions may vary. Agreements should preferably be combined with the assumption that regulatory measures will be taken if they are not fulfilled.

Industry has already communicated their intention to include the use of HBCDD in textiles in Vecap and the use in building products in a similar programme, Secure (see section 3.3).

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[12] Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment

[13] Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE)

[14] Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

The Stockholm convention on persistent organic pollutants (POPs)

The Stockholm Convention is a global treaty to protect human health and the environment from persistent organic pollutants (POPs). POPs are chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of living organisms and are toxic to humans and wildlife. In implementing the Convention, governments will take measures to eliminate or reduce the release of POPs into the environment. HBCDD has not been evaluated against the criteria of the convention, but available information indicates that HBCDD is a potential POP. The European Community has signed (23/05/2001) and approved (16/11/2004) the convention.

A proposal for inclusion of HBCDD in the convention could be developed.

6 EVALUATION AND SELECTION OF RISK MANAGEMENT MEASURES

6.1 Introduction

The previous chapters show that current controls for HBCDD are far from sufficient, but also that existing legislation and international agreements can be used to address identified risks of HBCDD. They may however require that measures are taken under separate legislative acts, taking account of both the severity of risks and the different uses of HBCDD.

6.2 Measures protecting workers

To reduce the risks identified in the risk assessment there is a need to reduce the exposure via dermal contact and inhalation in the filling of fine grade HBCDD in packaging. The need for further risk reduction measures is based on worst-case exposure estimates and is limited to very few sites. The setting of and maintaining a community-wide OEL is therefore deemed to require resources out of proportion to the prevalence of identified risks**.**

The legislation for workers' protection currently in force at Community level is considered to give an adequate framework to limit the risks of the substance to workers to the extent needed. This measure will be taken forward to the proposed measures to manage the risks.

6.3 Measures protecting consumers and the environment

Measures to reduce releases at the source

Restrictions under the **Limitations Directive** (76/769/EEC) are effective and practical by addressing the marketing and use of a hazardous substance, and thereby hindering risks to appear mainly during industrial and consumer use and waste handling. The directive also provides good opportunities for monitoring. Being restrictions having impact on the competition on the internal market, the proportionality of the advantages and drawbacks between on the one hand the effects on health and environment and the other those of the internal market, are of certain importance. The severe risks identified will however justify certain costs for market actors Restrictions under the Limitations Directive will therefore be included in the strategy to manage risks related to the use of HBCDD in textiles and polymer applications like HIPS, EPS and XPS. The **RoHS** Directive might apply for HIPS containing HBCDD used in certain electrical and electronic equipment. Other areas of application will be proposed to be restricted under the limitations directive, hence it will be more, practical, cost-effective and facilitate monitoring to restrict marketing and use of HBCDD under the same directive.

Appropriate alternatives to HBCDD do not seem to be commercially available for uses in EPS and XPS. There are commercially available alternative insulation materials on the market. To ascertain to what extent these materials, technically and economically, can replace fire protected EPS and XPS in EU as a whole, studies are needed that go beyond the aim of this report. Most certainly, the economic impact will vary among member states. Therefore, the use of HBCDD in certain applications under certain circumstances must be allowed at least for some time. Thus, there is a need to manage releases from any continued use.

Including information on HBCDD in the BREF:s in the **IPPC** directive will help managing the local environmental risks if this information is used when setting permits. To manage the universal risks of a PBT-substance permits based on local environmental conditions is however not adequate. Binding community wide emission limit values, ELV:s, under IPPC may be an alternative in this case, and such ELV:s will also manage the local risks.

The legal framework for setting a community wide ELV for some of the relevant industrial installations is in place and monitoring requirements should be included in permits under IPPC. It is therefore a practical, effective measure with monitoring. For installations without proper release controls there will be costs to install and manage such controls. These costs will have to be borne by the polluter and will prevent unfair cost-advantages for polluting companies. Measures under the IPPC directive will however cover only part of the installations using HBCDD, and not the usage outside industrial installations. As measures proposed under the limitations directive and the water framework directive (see below) will cover a wider range of usage, measures under the IPPC directive will not be brought forward to the proposed measures to manage the risks.

Including HBCDD as a priority substance in the **Water framework directive** means that measures to minimise pollution from the concerned point sources can be enforced on a river basin district level. This may be done under community legislation or legislation adopted on a national level. Including HBCDD as a priority substance ensures that the information on HBCDD is made available to those responsible for the relevant river basin management plans. Measures under the Programme of Measures on a river basin district level (national legislation) are hard to assess because of lack of information on national legislation in all the relevant countries. However it is reasonable to assume that controls under national legislation are effective, practicable and that the economic impact will be limited. The main part of the costs (investments etc to reduce release) will be borne by the polluter. Monitoring should be part of the river basin management. This measure will therefore be included as a proposed measure to manage the risks.

Voluntary agreements have a potentially important role to play in handling risks from the use of chemicals. For PBT-substances, where potentially severe adverse effects will take a very long time to reverse, voluntary actions are deemed not suitable to ensure rapid action leading to properly controlled risks. The wide use of HBCDD, many parties involved and the long service-life of material and products containing HBCDD, makes it difficult to make such actions practical, effective and possible to monitor. Voluntary agreements for HBCDD should be encouraged to complement, but not replace, legislative measures. Thus it will not be included in the proposed measures to manage the identified risks.

The inclusion of HBCDD in the **Stockholm convention on POPs** would mean that also releases outside the Community are managed. The inclusion of new substances in the convention is foreseen and information from the EU reports on risk assessment and risk reduction strategy are a good starting point for developing a proposal. Measures to monitor progress are also included in the convention. Thus it will be included in the proposed measures to manage the identified risks.

Measures to reduce exposure downstream

Setting a limit value for the concentration of HBCDD in **sewage sludge** for agricultural use under the sewage sludge directive is possible under the current legislation. It will only be effective in managing the local risks for humans exposed via the environment. It will help to reduce the general background exposure only to a very limited extent, since HBCDD enters the environment mainly via other routes. As the levels of HBCDD in sludge would be analyzed, monitoring would be included in this measure. In general analytical procedures for organic substances in sludge are complicated and expensive. [JRC 2001] These costs and the costs for disposing of sludge with HBCDD content above the limit value, would be borne primarily by the operator of the sewage treatment plant (STP). In some cases this would be the polluter (for on-site industrial STP), but in most cases it would probably be the local or regional community. Although HBCDD has been found in sewage sludge in several cases, the costs for community-wide regulations is not deemed to be justified in terms of the effectiveness of such measures.

It is crucial that waste containing HBCDD is handled in a way that prevents emissions to the environment. The waste legislation does not have a general classification of waste as hazardous based on content of PBT/vPvB substances. Therefore defining the waste as hazardous in accordance with directive 91/689 on **hazardous waste** is needed to ensure that it is correctly handled and disposed of. To enable identification of waste containing HBCDD all products containing HBCDD could be marked during manufacture. Such a measure could be introduced through the limitations directive or possibly the construction product directive. Such a measure would be practical (the existing legislation is in place), effective and possible to monitor, at least for building materials. For textiles, the practicality and effectiveness of this measure is more doubtful. Handling of hazardous waste is more costly than the handling of none hazardous waste (both the transport and the final handling). For materials used in building and construction the increased costs would be borne by the party handling the removal of the insulation. This measure will be taken forward to the proposed measures to manage the risks.

6.4 Fire protection and fire properties of products in general

When considering the risk management measures for substances used as flame retardants, it is necessary to also take fire safety into account. According to Swedish experts [KemI R1/06], fire safety is considered to be dependent on:

- how individuals behave
- how organisations behave
- the vulnerability of the people exposed to the fire
- the fire properties of products
- the technical fire safety in the building
- the fire brigade’s ability to respond to a fire

If all these points are covered then fire safety can be maintained at a high level. Focusing on any one of these points and neglecting the others will lead to suboptimal safety. The benefits from the use of flame retardants therefore need to be discussed in a wider context.

A study of fire statistics in the Nordic countries reached the conclusion that it was not possible to quantify the benefits of flame retardants based on available information. In an analysis of historical data there are a number of confounding factors such as trends in smoking, alcohol and drug abuse, increased use of smoke detectors etc, which are difficult to quantify. In case studies the exact cause of the fire is rarely reported in enough detail to determine the consequences had the fire properties of a certain material been different.

Flame retardants are used to make ignition more difficult and to slow down the initial fire growth. They can make the initial fire develop more slowly or even make it go out. However, experts point out that if a source of ignition gives a large exposure to radiation then flame retardants will be less important. They are also of less effect if the fire spreads or grows to a certain size. All the interviewed experts (KemI R1/06) would like to see more research done on the importance on flame retardants for fire protection. In particular how they function and what effects they have in preventing ignition and on fire growth. The effects that flame retardants have for fire safety should be quantified. Flame retardants should be set in a larger context, together with other protection measures.

6.5 Conclusion on selected risk reduction measures

6.5.1 Conclusion on measures protecting workers

When selecting measures to manage the risks, the measure shall not go beyond what is necessary to achieve a high level of protection for health, safety, environment and consumer. Priority should be given to intervention at the source, in compliance with the polluter pays principle and the principle of pollution prevention. The proposed strategy for limiting the risks for workers is therefore:

The legislation for workers' protection currently in force at Community level is generally considered to give an adequate framework to limit the risks of the substance to workers to the extent needed and shall apply

6.5.2 Conclusion on measures protecting consumers and the environment

When selecting measures to manage the risks, the measure shall not go beyond what is necessary to achieve a high level of protection for health, safety, environment and consumer. Priority should be given to intervention at the source, in compliance with the polluter pays principle and the principle of pollution prevention. Pollution prevention is particularly important for substances likely to bioaccumulate and persist in the environment for long periods of time. The proposed strategy for limiting the risks for the environment and humans exposed via the environment is:

- ***to impose restrictions on the marketing and use of HBCDD in general, i.e. in textiles, HIPS, EPS and XPS under the Limitations directive (76/769/EEC)***
- ***to consider the need for time limited exemptions for certain uses of HBCDD in EPS and XPS under the Limitations directive;***
- ***to impose compulsory marking of exempted uses of HBCDD in EPS and XPS products under the Limitations Directive***

- ***to classify used material and products containing HBCDD as hazardous waste under the hazardous waste directive***
- ***to include HBCDD as a priority hazardous substance in Annex X of the Water framework directive***
- ***to develop a proposal for the inclusion of HBCDD in the Stockholm convention on POPs***

7 ADVANTAGES AND DRAWBACKS OF SELECTED RESTRICTIONS

7.1 Introduction

Scope

An analysis of advantages and drawbacks of the selected risk reduction measures under 76/769/EEC and of the availability of replacement substances is included in this report since marketing and use restrictions are proposed. Since any legislative proposal will be elaborated and processed by the Commission this appraisal of advantages and drawbacks is of a pre-analytical nature.

In this chapter the advantages and drawbacks of restricting the use of HBCDD in referred applications are discussed, considering the technical and health and environmental aspects of identified commercially available alternative substances and technologies. Because of lack of appropriate information, no attempt has been made to quantify or monetarise the discussed advantages and drawbacks of selected restrictions on HBCDD.

7.2 Availability of alternative technologies or substances

Substitution is not just the replacement of one chemical substance by another one whose use poses less risk to human health and environment, but also other technological and/or organisational changes. A key parameter is functional equivalence, in the case of HBCDD, primarily flame-retardant properties of a material or product. The product can be anything from a TV-set to part of a building. It is not possible to fully evaluate alternative technologies for the substitution of HBCDD within the scope of this risk reduction strategy, but some possibilities have been described to give examples. The examples should not be taken as endorsements of particular alternatives.

It has to be considered that each flame retarded application is unique concerning its mechanical and fire retarded properties, which have to be assessed for each individual application vis a vis the appropriate quality and fire requirements on the market.

The diverse set of regulations and standards that impose the extent of fire protection of textiles and polymer applications do not stipulate the use of a certain flame-retardant to manage particular fire requirements for a specific application. Therefore substitution is potentially an alternative for managing the identified risks for HBCDD.

In this section the technical and health and environmental aspects of some alternative substances and technologies are briefly discussed.

HBCDD in textile applications

Tightened legislation and more restricted fire requirements are the major forces that have driven forward development towards functionally better and more effective flame retardants. This trend is particularly clear in the English-speaking countries. The United Kingdom, Ireland and the United States, especially California, have carried out extensive large-scale risk-benefit studies. In the light of this trend, a large number of specific fire standards with unique fire requirements have been developed internationally for various widely differing situations.

Reported alternative substances in this application include: Reactive phosphorous constituents; Ammonium polyphosphates; Diammonium phosphate; and Intumescent systems. The intumescent systems are described as alternatives to HBCDD, but there are doubts about the technical qualities in particular the durability and effectiveness in certain applications. [KemI 1/06]

The environmental and health hazards of some potential alternatives to HBCDD have been evaluated, for example: The conclusion from the UBA study is that the use of ammonium polyphosphate and red phosphorous as flame-retardants are unproblematic. [UBA 2001] Despite the lack of a complete database the NRC study concludes that ammonium polyphosphates can be used on residential furniture with minimal risk to consumer health, even under worst-case assumptions. [NRC 2000]

The relative costs of using the various flame retardants have not been assessed. Nor has the possibilities and consequences of optimising the choice of materials in the textiles for fire protection been explored.

For the use of HBCDD in textiles, there seems to be alternatives available that are technically viable and pose less risk to human health and the environment.

HBCDD in high impact polystyrene (HIPS)

Traditionally brominated flame-retardants (BFr) have been applied for housing of business electronics and TV sets from HIPS. HBCDD is one brominated flame-retardant used. Other halogenated flame-retardants used in this application together with antimony trioxide (as synergistic flame-retardant) includes Decabromodiphenylether; Decabromodiphenylethane; Ethylenebis(tetrabromophtalimide); Brominated epoxies; Chlorinated paraffins. [KemI 1/06]

Various alternatives to brominated flame-retardants have been investigated, for example: A copolymer of HIPS and polyphenylene oxide (PPO) with a suitable flame-retardant can in many cases substitute HIPS with HBCDD, though it will not exactly match all the properties, e g UV stability. However the addition of PPO improves flame retardancy. Triphenyl phosphate (TPP) is one flame-retardant that could be used in PPO/HIPS. The cost of substitution is dependent on the price of the raw materials, research and development costs, and possible changes of moulds and other tools. The latter, if necessary, may be a significant part of the costs. These costs can be lowered if the introduction of substitutes takes place when the moulds are changed along with periodic design changes. As an indication of raw material prices it is estimated that going from HIPS with a brominated flame-retardant (other than Deca-BDE) to PPO/HIPS with a halogen-free flame-retardant would increase the raw-material price with about 4-5 EUR for a full enclosure of an average TV-set. [Danish EPA 2006]

There is insufficient data for a firm conclusion on the health and environmental aspects of TPP, but there is no evidence of concern with respect to CMR. TPP is not considered persistent or bioaccumulative according to the PBT criteria, but data are inconclusive on the T-criteria. [Danish EPA 2007]

For the use of HBCDD in HIPS, there seems to be alternatives available that are technically viable and pose less risk to human health and the environment.

HBCDD in building and construction materials

In Europe a system for fire testing and classification has been introduced. It is called the Euroclasses system. Testing according to the Euro class system is carried out through a number of harmonised European testing methods (EN) that have been issued by the European standardisation organisation CEN.

The Euro class-system for construction products affects mainly surfaces and floorings. There are seven main classes of reaction to fire for construction products except flooring. Which class that is required in the various EU countries is the provision of their national building legislation.

For EPS and XPS, mainly used in construction products for insulation in buildings, there are no commercially available alternatives found in the publications studied in the review. There are some examples described in literature, where boron and metal salts have been used, but there are doubts about their commercial applicability. In cases where flame protection is required according to the so called Euroclasses, the only flame retardant commercially available is HBCDD. [KemI 1/06]

Other materials than EPS and XPS are also used as insulation in buildings. The other major materials are PUR, polyurethane rigid foam (used with added flame-retardants) and mineral-based products (inherently non-flammable). The materials have different technical properties, for example in insulation performance, mechanical properties, weight and sensitivity to humidity. A comparison of relative costs of material per area unit insulated to a specific insulation performance has been done. If EPS = 1, mineral wool = 1.3, PUR = 2.8 and XPS = 3 [UBA 2000]. It should be emphasized that this is the cost of the material only, other effects such as the need for more or less supporting construction material is not included. Insulation materials are therefore not universally interchangeable, but rather serve specific applications segments, for which they provide substance specific advantages. The substitution of one for the other is either not possible, or only possible under certain circumstances. [UBA 2001] The various materials potential effects on human health and the environment have not been assessed.

The need for improved flame retardant properties of EPS and XPS is being deemed differently in different countries. In for example Sweden and Denmark most of the EPS and XPS used in the building sector do not contain any flame retardant. The functionality is instead reached by encasing the insulation with fire-proof materials or if this is not possible by using alternative insulation materials. [Brandforsk 2000] [KemI 2007] Other countries, for example Poland and Germany have come to a different conclusion, and here most of the EPS and XPS contain a flame-retardant. Some have also pointed on the need for flame-retardant properties during transport, storage and construction (before the insulation material is encased), and also when transported stored and handled as waste. [KemI 2007]

Different views have been given on the economic impact of introducing a restriction on the use of HBCDD in EPS and XPS. Producers of EPS/XPS, building industry and authorities in countries with little use, e g Sweden and Denmark indicate little or no consequences, whereas in countries with a large use, e g Poland and Germany, respondents indicate potentially severe consequences, in particular on small and medium sized enterprises (SMEs). Because of the relatively high costs of transport it is unlikely that import from outside EU would be relevant except fairly close to the borders. [KemI 2007]

In conclusion for HBCDD in building and construction materials:

- *there currently seems to be no substance that can substitute HBCDD in EPS and XPS*
- *non-flammable insulation materials are being used in buildings; their potential effect on man and the environment have not been assessed here, nor has it been possible to conclude on the practical and economical possibility of switching to such materials in the various applications*
- *the need for fire-retardant properties in XPS/EPS has been deemed differently in different member states, in some it is a legal requirement, in other there are no such requirements*
- *the need for fire-retardant properties in XPS/EPS is linked to the ignition source (e g sparks or an established fire) that the material should be able to resist and how the material is exposed (e g open during transport or encased in non-flammable material in a building)*

7.3 Overall conclusion

The use of HBCDD gives an improved fire protection to materials. Reaching a high level of fire safety is in itself an important goal. The further analysis and the conditions set under the limitations directive should accordingly ensure that a high level of fire safety is maintained.

HBCDD has been assessed to have PBT properties; therefore it poses severe and probably irreversible risks to the environment and to man via environment. The main strategy for substances with PBT properties is therefore a complete phasing out. However, an overall ban might not always be proportional, i.e. when no technical and economically viable substitutes are commercially available. This RRS does not include quantified and monetarised analysis of eventual impacts of considered and selected restrictions. Still it can be stated that the severity of impacts will vary for different applications.

HBCDD being a PBT substance, the starting point for a risk reduction strategy should be general restrictions on the marketing and use under 76/769. Taking into account the proportionality of such a measure, certain applications could be exempted temporarily. A general ban with exemptions will hinder the use of HBCDD in applications not identified in the RAR as well as other future uses. Uses identified in the RAR and selected for market restrictions are discussed below.

<u>Textiles</u>

Alternatives to HBCDD for the use in the textile industry, that are both technically suitable and which pose less risk to the environment and man via environment, are commercially available. Though not being able to present actual costs for substitution, it is assumed that it is proportional not to exempt any use in the textile industry, where the use of loose and micronised HBCD powder seems to be most frequent. This when taking into account the availability of viable and less dangerous alternatives and the relatively high market price for HBCDD related to the severe risks posed by HBCDD. In addition, the relatively wide spread use in textiles will hardly make it economical or technically possible to organise separate waste handling or recycling.

HIPS

The main use of HBCDD in HIPS seems to be in electric and electronic applications. It is confirmed that technically viable and less harmful alternatives are available. Dependent on how diversified that use is, i.e. range of applications, the ROHS Directive could apply. However, if the use in HIPS goes beyond what is covered by ROHS, and where other areas of application are considered to be restricted by 76/769/EEC, it will be most effective to restrict all uses of HBCDD under the same directive. Considering available information, it is assumed to be proportional not to exempt any uses of HIPS,

EPS and XPS

According to the findings in the RAR, about 90 per cent of the HBCDD used in EU 15 is used in EPS and XPS. At that point in time, there seemed to be no commercially available alternatives for flame retarding EPS and XPS. There are however alternative materials for the flame retarding or fire protecting of buildings. The latter will require that non-flammable insulation materials are used in buildings, or that EPS and XPS insulation is covered by other, non-flammable materials like steel or concrete. A current study has confirmed an extensive and still growing use of EPS and XPS along with technical and economic advantages, and also a diverse flora of standards and national rules stipulating fire protection of buildings in general or of EPS and XPS specifically. Considering those findings, thorough research has to be done to formulate proportional restrictions and time frames for exemptions and to assess their advantages and drawbacks.

Still, being a PBT, the ultimate aim should be to phase out the use of HBCDD. Hence to protect the environment, exemptions should be compensated by a compulsory labelling of marketed products containing HBCDD. The appropriateness of exemptions will depend on how flame retarded EPS and XPS is handled in the demounting of e g buildings. Also the spread in use might cause problems concerning supervision. Therefore, such a measure should be combined with mandatory rules for waste handling to give expected result.

7.4 Sources of information

A report has been commissioned by the Swedish Chemicals Agency in order to learn more about Swedish and Nordic fires including their causes and consequences. The study of fire statistics was carried out by the National Centre for learning from Accidents at the Swedish Rescue Services agency. An analysis of fire protection strategies as described by leading Swedish experts was also performed. The report was published in 2006. [KemI R1/06]

The Danish Environmental Protection Agency has published a study to identify and describe suitable alternatives to the brominated flame-retardant Deca-BDE primarily in electrical and electronic equipment, and to determine whether substitution with the alternative substances is possible from a scientific or technical point of view. [Danish EPA 2006] A second study has been published with a health and environment assessment of selected alternatives from the first study. [Danish EPA 2007] These studies are also relevant to this report, since some of the alternatives to Deca-BDE are also relevant for HBCDD in certain applications.

The German Umwelbundesamt (UBA) has published a report examining the status, trends and alternatives (substitution and reduction potentials) in the use of flame retardants in selected product sectors: construction; electronics and electrical engineering; rail vehicles; textiles/upholstery. In addition, the study characterizes thirteen flame retardants in terms of material flows, applications and toxicology/ecotoxicology. A first part presents the results and a summary overview [UBA 2001]. More comprehensive background materials were published as volume II and III of this report. [UBA 2000]

The U.S. National research council (NRC) has made a study reviewing toxicological and exposure data on 16 selected flame-retardant chemicals to assess potential health risks to consumers and the general population resulting from potential exposure to these chemicals in residential furniture. [NRC 2000] The study was requested by the U.S. Consumer Product Safety Commission as part of the consideration of a possible flammability standard for upholstered furniture.

The Swedish fire research board (Brandforsk) initiates, conducts and follow fire research. It is financed by the insurance industry, municipalities, industry, organisations and the government. Brandforsk is part of the non-profit organisation The Swedish Fire Protection Association (Brandskyddsföreningen). It has made a survey of the occurrence of brominated flame retardants in building products sold on the Swedish market. [Brandforsk 2002]

On behalf of the Swedish Chemicals Agency, IFP Research has surveyed a technical assessment of tetrabromobisphenol – A (TBBPA) and hexabromocyclododecane (HBCDD) and possible alternatives, from a quality and a fire protective perspective, that are commercially available on the market. The sources for the review were public and open references from authorities and scientific literature as it was very hard to get enough relevant technical information from the market. [KemI 1/06]

The Swedish chemicals agency commissioned a consultant to interview producers of EPS/XPS, building companies, industry organizations and authorities on their use of HBCDD and alternatives. The purpose of the study was to increase the understanding of the use of flame retardant materials, in particular those containing HBCDD, in the building and construction sector in EU. Companies and authorities from five countries, Denmark, UK, Germany, Spain and Poland were chosen. The result has been presented in a report. [KemI 2007]

Annex I – References

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Danish EPA 2006	Deca-BDE and alternatives in electrical and electronic equipment; Environmental project no 1141, 2006; Danish environmental protection agency
Danish EPA 2007	Health and environmental assessment of alternatives to Deca-BDE in electrical and electronic equipment; Environmental project no 1142, 2007; Danish environmental protection agency
DG ENV 2000	Working document on sludge, 3rd draft; European Commission DG Environment; ENV.E.3/LM; Brussels, 27 April 2000; available from http://ec.europa.eu/environment/waste/sludge/workingdoc3.htm
HELCOM 1998	HELCOM RECOMMENDATION 19/5 Adopted 26 March 1998, having regard to Article 13, Paragraph b) of the Helsinki Convention; www.helcom.fi visited 2007-06-26
JRC 2001	Organic contaminants in sewage sludge for agricultural use; European Commission, JRC; 18 October 2001; available from http://ec.europa.eu/environment/waste/sludge/index.htm
KemI 1/06	Survey and technical assessment of alternatives to TBBPA and HBCDD; KEMI PM 1/06; May 2006; available from www.kemi.se
KemI R1/06	Fire and fire protection in homes and public buildings – An analysis of Swedish fire statistics and fire protection strategies; KemI report 1/06; January 2006; available from www.kemi.se
KemI 2007	A European industry perspective of the use of HBCDD in insulation material; Vega Systems AB on behalf of the Swedish Chemicals Agency, 29 June 2007
NRC 2000	Toxicological risks of selected flame-retardant chemicals; National research council; 2000; National academy press Washington
OSPAR 2004	Certain Brominated Flame Retardants – Polybrominated Dipehnylethers, Polybrominated Biphenyls, Hexabromo Cyclododecane; OSPAR Priority Substances Series; OSPAR Commission 2001 (2004 update)
RAR	Risk assessment report draft for final written procedure, April 2007
SFT 2007	www.sft.no Høringer og kunngjøringer 31.05.07 (in Norwegian, Draft of new chapter concerning consumer products in the Norwegian Product Regulations available in English); visited 2007-06-26
UBA 2001	Substituting environmentally relevant flame retardants: Assessment fundamentals results and summary overview; Umweltbundesamt Texte 40/01; Berlin June 2001
UBA 2000	Erarbeitung von Bewertungsgrundlagen zur Substitution umweltrelevanter Flammschutzmittel – Band II Flammehemmende Ausrüstung ausgewählter Produkte, anwendungsbezogene Betrachtung, Stand der Technik, Trend Alternativen; Umweltbundesamt Texte 26/01; December 2000; in German
Vecap	Vecap Europe – Annual progress report 2006; EBFRIP and BSEF; available from http://www.bsef.com/product_stew/vecap/; visited 2007-05-29

ANNEX II – PARTIES CONTACTED

Europe	*Lawrie McLaren, Consultant to the European Brominated Flame Retardant Industry Panel, www.ebfrip.com*
	Cefic - European Chemical Industry Council, Styrenics, PlasticsEurope
Denmark	*Sundolitt A/S*
	NCC A/S
	Miljöstyrelsen
Germany	*Umweltbundesamt*
	NCC Deutschland GmbH
Great Britain	*Springvale Ltd*
	British Plastics Federation
Poland	*Dwory A.S.*
	Chemikalia, Biuro do spraw substancji preparatów chemicznych
	Skanska S.A.
Spain	*Drace S.A*

ANNEX III – CREATING AN ANNEX XV DOSSIER FOR HBCDD

It is foreseen in the Reach regulation (article 136) that work initiated under the Existing substances legislation may need to be taken over to the Reach regulation. Although the strategy for limiting the risks of HBCDD is presented well in advance of the stipulated deadline of 1 June 2008, an outline of how such a transition could be done has been included below. Authorisation under Reach has not been proposed as a risk reduction measure for HBCDD, but it has been included here for the sake of completeness.

Restrictions

The requirements of a dossier for restrictions of manufacture, placing on the market or use of a substance within the Community is set out in Annex XV II(3). Such a dossier should include: a **proposal** including the **identity of the substance**, the **restrictions proposed** for the manufacture, placing on the market or use(s) and a summary of justifications; **information on hazards and risk**; evidence that **implemented risk management measures** are not sufficient; **information on alternatives**; **justification of community-wide action**; information from **stakeholder consultation**; and may include a **socio-economic assessment**.

The **identity of the substance** and **information on hazards and risk** are included in the risk assessment report (RAR) and summarised in this risk reduction strategy (RRS). As the risk assessment has been done based on the actual current situation, including any risk management measures in place, it also gives evidence that **implemented risk management measures** are not enough.

The actual **restrictions proposed** would have to be elaborated based on the information in this RRS and the RAR.

Information on alternatives, **justification of community-wide action** and some information useful as a starting-point for a **socio-economic assessment** are included in this RRS.

Information on **consultation of stakeholders** and how their views have been taken into account is included in this RRS.

Other measures

The documentation of other measures than restrictions and authorisation under Reach that are proposed to address the identified risks, have been presented in this RRS.

Authorisation

The requirements of a dossier for the identification of PBTs, vPvB, or a substance of equivalent concern is set out in Annex XV II(2).

The dossier should include a **proposal** including the identity of substance(s) concerned and whether it is proposed to be identified as a CMR according to Article 57(a), (b) or (c), a PBT according to Article 57(d), a vPvB according to Article 57(e), or a substance of equivalent concern according to Article 57(f); and a **justification**; and **information on exposures, alternative substances and their risks**.

The **proposal** would be to include HBCDD as a PBT-substance in the candidate list for eventual inclusion in Annex XIV as outlined in article 59 of Reach. The identity of the substance is set out in the relevant parts of the RAR and summarised in this RRS.

The **justification** and **information on exposures** are set out in the relevant parts of the RAR and summarised in this RRS.

An overview of **information on alternative substances and techniques** are included in this RRS and could be further elaborated if needed.

ANNEX IV – GLOSSARY OF ACRONYMS

BAT	Best available technique
BMD-L	Bench mark dose low
BREF	Reference Document on Best Available Techniques
CAS	Chemical abstract services
CEN	European Committee for Standardisation
CMR	Carcinogenic, mutagenic, toxic for reproduction
Deca-BDE	Decabromodiphenyl ether
DT50	Disappearance time 50%
EC50	Median effect concentration
ECHA	European Chemicals Agency
EINECS	European inventory of existing commercial chemical substances
EN	European standard
ELV	Emission limit value
EPS	Expanded Polystyrene
HIPS	High impact polystyrene
IPPC	Integrated pollution prevention and control
LOEC	Lowest observed effect concentration
LOAEL	Lowest observed adverse effect level
NOAEL	No Observed Adverse Effect Level
NOEC	No observed effect concentration
OEL	Occupational exposure limit
PBT	Persistent, bioaccumulating, toxic
POP	Persistent organic pollutant
PPO	Polyphenylene oxide
PS	Polystyrene
PUR	Polyurethane rigid foam
RAR	Risk assessment report (in the Existing substances programme)
RCR	Risk characterisation ratio
RoHS	Restriction of the use of certain hazardous substances in electrical and electronic equipment
RRS	Risk reduction strategy
RRSM	Risk reduction strategy meeting
SME	Small and medium sized enterprise
STP	Sewage treatment plant
TGD	Technical guidance document
TPP	Triphenyl phosphate
WEEE	Waste electrical and electronic equipment
WFD	Water framework directive
WWTP	Waste water treatment plant
XPS	Extruded Polystyrene