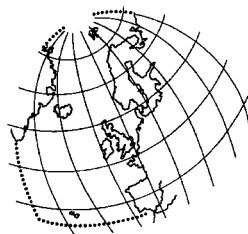


# Tetrabromobisphenol-A



OSPAR Commission  
2005 Update

The Convention for the Protection of the Marine Environment of the North-East Atlantic (the “OSPAR Convention”) was opened for signature at the Ministerial Meeting of the former Oslo and Paris Commissions in Paris on 22 September 1992, The Convention entered into force on 25 March 1998. It has been ratified by Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Luxembourg, Netherlands, Norway, Portugal, Sweden, Switzerland and the United Kingdom and approved by the European Community and Spain.

*La Convention pour la protection du milieu marin de l'Atlantique du Nord-Est, dite Convention OSPAR, a été ouverte à la signature à la réunion ministérielle des anciennes Commissions d'Oslo et de Paris, à Paris le 22 septembre 1992. La Convention est entrée en vigueur le 25 mars 1998. La Convention a été ratifiée par l'Allemagne, la Belgique, le Danemark, la Finlande, la France, l'Irlande, l'Islande, le Luxembourg, la Norvège, les Pays-Bas, le Portugal, le Royaume-Uni de Grande Bretagne et d'Irlande du Nord, la Suède et la Suisse et approuvée par la Communauté européenne et l'Espagne.*

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## Executive summary

Tetrabromobisphenol-A (CAS No. 79-94-7) is a brominated organic compound (C<sub>15</sub>H<sub>12</sub>Br<sub>4</sub>O<sub>2</sub>), and is primarily used as a reactive intermediate in the manufacture of flame-retarded epoxy and polycarbonate resins. It may also be used as an additive flame retardant, for example in the manufacture of acrylonitrile-butadiene-styrene resins and phenolic resins, or in the manufacture of derivatives, although there is presently no evidence of this latter use in the EU. Tetrabromobisphenol-A was added to the OSPAR List of Chemicals for Priority action in 2000.

Tetrabromobisphenol-A is produced in the USA, Israel and Japan but not in the EU. The current total amount of tetrabromobisphenol-A produced is estimated in the order of 120 000 to 150 000 tonnes/year. The amounts of tetrabromobisphenol-A imported into the EU both as the substance itself and in partly finished and finished products are estimated to be in the order of 40 000 tonnes/year.

Tetrabromobisphenol-A is not considered to fully meet the PBT criteria as its liability to bioaccumulate is below the threshold set by OSPAR. It is, however, persistent and toxic. The preparation of a risk assessment for tetrabromobisphenol-A is on-going under the EC existing substances regulation. For the marine environment this indicates a potential risk to water and sediment from the manufacture of flame-retarded epoxy and polycarbonate resins, for processing in acrylonitrile-butadiene-styrene and phenolic resins as an additive flame retardant. There appears to be no significant risk from the processing of epoxy and polycarbonate resins and secondary poisoning. However at this stage the results of the risk assessment are preliminary as further exposure information is needed to refine the assessment. The potential for tetrabromobisphenol-A to degrade under anaerobic conditions to form bisphenol-A is also still being investigated within the ESR process. Tetrabromobisphenol has been detected in freshwater, freshwater sediments and estuarine sediments but there are no available measured levels in marine waters. It has been detected in marine biota.

Actions so far have been limited. EC Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE Directive) requires Member States to set up separate collection schemes and ensure the proper treatment, recovery and disposal of WEEE and this will encourage producer responsibility for separation of plastic containing brominated flame retardants from collected WEEE.

The actions recommended are: to support the ongoing development of the EC ESR Risk Assessment Report and provide new information, which would enable the PEC/PNEC values to be refined; to ensure that the information in this background document and the conclusions reached by OSPAR are generally taken into account in the approach of the European Community; to encourage the substitution of tetrabromobisphenol-A through the development and identification of safer substitutes which pose less risk; to invite the relevant industries to work with Contracting Parties to improve the estimates of emissions, and if necessary, the estimation of PNEC values, to re-evaluate the risks posed by tetrabromobisphenol-A releases when further information has been collected; to communicate this background document to other international agreements that deal with hazardous substances.

A monitoring strategy for tetrabromobisphenol-A is attached to this background document.

## Récapitulatif

Le tétrabromobisphénol-A (N° CAS. 79-94-7) est un composé organique bromé ( $C_{15}H_{12}Br_4O_2$ ), et est principalement employé comme intermédiaire réactif dans la fabrication des résines époxy et de polycarbonates ignifuges. Il peut aussi servir d'adjuvant retardateur de flammes, par exemple dans la fabrication des résines acrylonitriles-butadiènes-styrènes et des résines phénoliques, ou dans la fabrication de produits dérivés, bien qu'à l'heure actuelle l'on ne dispose d'aucun indice prouvant cette dernière application dans l'Union européenne. Le tétrabromobisphénol-A a été inscrit en 2000 sur la liste OSPAR des produits chimiques devant faire l'objet de mesures prioritaires.

Le tétrabromobisphénol-A est fabriqué aux Etats Unis, en Israël et au Japon, mais pas dans l'Union européenne. La quantité totale fabriquée à l'heure actuelle est estimée se situer entre 120 000 et 150 000 tonnes/an. La quantité de tétrabromobisphénol-A importée dans l'Union européenne, que ce soit sous la forme de la substance elle-même, ou dans les produits finis ou en partie finis, est destinée être de l'ordre de 40 000 tonnes/an.

Le tétrabromobisphénol-A n'est pas considéré comme répondant pleinement aux critères de PBT, car sa faculté de bio-accumulation est inférieure au seuil fixé par OSPAR. Il est cependant persistant et toxique. Une évaluation du risque suscité par le tétrabromobisphénol-A est en cours en vertu du règlement communautaire relatif aux substances existantes. Dans le cas du milieu marin, cette évaluation indique que la fabrication des résines époxy et aux polycarbonates ignifuges présente un risque potentiel pour l'eau et les sédiments, de même que la transformation des résines acrylonitrile-butadiène-styrène et phénoliques, en adjuvants retardateurs de flammes. Il semble qu'il n'y ait aucun risque significatif qui serait dû au traitement des résines époxy et aux polycarbonates, ni d'intoxication secondaire. Toutefois, au stade actuel, les résultats de l'évaluation des risques sont préliminaires car de plus amples renseignements sur l'exposition sont nécessaires pour raffiner l'évaluation. Le potentiel de dégradation du tétrabromobisphénol-A en milieu anaérobie, qui se transforme ainsi en bisphénol-A, fait aussi encore l'objet d'une étude dans le contexte du processus ESR. Du tétrabromobisphénol a été décelé dans les eaux douces, les sédiments des eaux douces et les sédiments estuariens, mais en revanche l'on ne dispose d'aucune mesure qui aurait été faite dans les eaux marines. Il a été décelé dans le milieu vivant marin.

Jusqu'à présent, les actions ont été limitées. La Directive 2002/96/CE sur les déchets de matériel électronique et électrique (Directive WEEE) exige que les Etats membres mettent sur pied des régimes de collecte séparée, et fasse en sorte que les déchets de matériel électrique et électronique soient convenablement traités, récupérés et éliminés, ce qui renforcera la responsabilité qu'ont les fabricants de séparer les matières plastiques contenant des retardateurs de flammes au brome dans les déchets de matériel électrique et électronique qui auront été ainsi recueillis.

Les actions recommandées sont les suivantes : apporter son soutien à l'élaboration, en cours, du rapport d'évaluation des risques ESR de la CE, et fournir de nouveaux éléments d'information qui permettront de raffiner les valeurs PEC/PNEC ; faire en sorte que les renseignements figurant dans le présent document de fond ainsi que les conclusions tirées par OSPAR soient généralement pris en compte dans l'approche adoptée par la Communauté européenne ; encourager la substitution du tétrabromobisphénol-A, ceci par la création et l'identification de substituts moins dangereux, présentant un risque moindre, inviter les industries concernées à travailler avec les Parties contractantes afin d'améliorer les estimations des émissions, et, si nécessaire, l'estimation des valeurs PNEC, ceci afin de réévaluer les risques présentés par les émissions de tétrabromobisphénol-A lorsque de nouveaux éléments d'information auront été recueillis ; communiquer le présent document de fond aux autres accords internationaux traitant des substances dangereuses.

Une stratégie de surveillance sur le tétrabromobisphénol-A est jointe à ce document de fond.

## 1. Basis and rationale for action

The objective stated in the OSPAR Strategy with regard to Hazardous Substances ('the Strategy'), which was adopted in Sintra in 1998, updated at the 2003 Ministerial Meeting and endorsed by Ministers 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".*

The Strategy also includes a timeframe which states that:

*"every endeavour will be made to move towards the target of cessation of discharges, emissions and losses of hazardous substances by the year 2020".*

Tetrabromobisphenol-A (CAS No. 79-94-7) is on the OSPAR List of Chemicals for Priority Action (cf. Annex 2 of the Strategy), and the OSPAR Action Plan for 1998 - 2003 shows that the UK is the lead country for drawing up a background document on tetrabromobisphenol-A.

This background document addresses this obligation and has the following aims:

- identifying the main sources of tetrabromobisphenol-A and its various pathways into the marine environment;
- reviewing the various controls to limit discharges, emissions and losses of tetrabromobisphenol-A;
- assessing the extent of the risk posed by tetrabromobisphenol-A to the marine environment;
- assessing what further activities should be undertaken by OSPAR, or other relevant international organisations, in order to achieve the various OSPAR commitments.

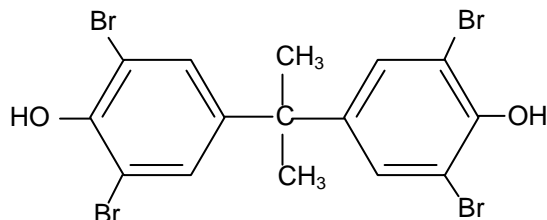
This background document takes into account the "Interim Guidance on how to address Hazardous Substances for Priority Action" agreed at OSPAR 1999 (cf. Annex 7 of the Summary Record OSPAR 99/15/1) and follows the structure for OSPAR background documents outlined in that document<sup>1</sup>.

## 2. Identification of all sources of the substance and pathways to the marine environment

### 2.1 Properties of tetrabromobisphenol-A

This assessment considers the following commercial substance:

CAS No:	79-94-7
EINECS No:	201-236-9
IUPAC Name:	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol-A)
Molecular formula:	C <sub>15</sub> H <sub>12</sub> Br <sub>4</sub> O <sub>2</sub>
Molecular weight:	543,9 g/mole
Structural formula:	



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<sup>1</sup> Much of the information is taken from the December 2003 draft risk assessment produced by the UK under the EU Existing Substances Regulation. This draft assessment resulted in a testing programme designed to clarify particular data gaps, and the results are expected later in 2005. These results, and their implications, will be reported to OSPAR through the background document update and review process.

Tetrabromobisphenol-A is very toxic to aquatic organisms, it does not degrade readily in the environment and shows a high accumulation in fish (BCF>100). The detailed properties of tetrabromobisphenol-A, including numerical values for toxicity, persistence and bioaccumulation are set out in the fact sheet at Appendix 2. This fact sheet includes the more recent values which have come to light in the RAR. TBBPA has demonstrated no endocrine disrupting effects in any of the tests available.

## 2.2 Identification of sources of tetrabromobisphenol-A

The primary use of tetrabromobisphenol-A is as a reactive intermediate in the manufacture of flame-retarded epoxy and polycarbonate resins. It may also be used as an additive flame retardant, for example in the manufacture of acrylonitrile-butadiene-styrene (ABS) resins and phenolic resins. Where tetrabromobisphenol-A is used as an additive flame retardant, it is generally used with antimony oxide for maximum performance (Hakk, 2001). Antimony oxide is generally not used in conjunction with tetrabromobisphenol-A in reactive flame retardant applications (Industry Consortium, 2002).

Tetrabromobisphenol-A is also used in the manufacture of derivatives. The main derivatives produced from tetrabromobisphenol-A are tetrabromobisphenol-A dimethylether, tetrabromobisphenol-A dibromopropylether, tetrabromobisphenol-A bis(allylether), tetrabromobisphenol-A bis(2-hydroxyethyl ether), tetrabromobisphenol-A brominated epoxy oligomer, and tetrabromobisphenol-A carbonate oligomers (IPCS, 1995). The main use of these derivatives is as flame retardants, usually in niche applications. As far as is known, tetrabromobisphenol-A is not currently used to manufacture any derivatives within the EU.

## 2.3 Pathways to the marine environment

Tetrabromobisphenol-A is likely to reach the marine environment largely through industrial waste waters from land-based industrial activities. A smaller contribution to releases to water comes from particulate losses from products containing the substance over their lifetime. Emissions to air are smaller than those to water, and most such emissions are expected to be deposited close to the sources of emission. There are however some indications of possible transport over longer distances, possibly adsorbed to particulate matter, which could lead to a contribution to the marine environment through this route.

# 3. Quantification of sources

## 3.1 Manufacture of tetrabromobisphenol-A

Tetrabromobisphenol-A is produced in the USA, Israel and Japan but not in the EU. The current total amount of tetrabromobisphenol-A produced is estimated at >120 000 tonnes/year (Hakk, 2001) and 150 000 tonnes/year (Arias, 2001).

For the ESR Risk Assessment, the amounts of tetrabromobisphenol-A imported into the EU have been estimated. Tetrabromobisphenol-A is imported as the substance itself. It is also imported as partly finished products (in the form of masterbatch, epoxy resins) and in finished products and components. Table 1 summarises the estimated amounts for each of the routes. It should be noted that there are a number of assumptions involved in the derivation of these figures, particularly for the amounts imported as partly finished or as finished products. These assumptions are described in the risk assessment report.

**Table 1. EU imports of tetrabromobisphenol-A**

Route	Amount (tonnes/year)
Tetrabromobisphenol-A imported into the EU as the substance	13 800
Tetrabromobisphenol-A imported into EU as partly finished products (e.g. masterbatch, epoxy resins)	6 000
Amount of tetrabromobisphenol-A imported into the EU in finished products and components	20 200
Total	40 000

## 3.2 Quantification of uses

A breakdown of use world-wide was provided by Leisewitz et al. (2000), who indicated that around 70% is used for epoxy resins in printed circuit boards, 15% is used additively in HIPS for casing materials, 10% is used for the production of derivatives and 5% is used as additives for other polymers such as ABS and thermoplastic polyesters. Industry has questioned the figures given above by Leisewitz et al. (2000) for the

use of tetrabromobisphenol-A as an additive flame retardant in HIPS (Industry Consortium, 2003). They indicated that they are unaware that tetrabromobisphenol-A is or has ever been used as an additive in HIPS, and indicated that in their experience, tetrabromobisphenol-A is not an effective flame retardant for HIPS. The Technical Meeting 1 03 for the RAR agreed to take out the HIPS scenario from the assessment.

Private information from Industry indicates that the ratio between reactive and additive flame retardant use in the EU is around 9:1, with ABS being the main additive use of tetrabromobisphenol-A. Hence the amount of tetrabromobisphenol-A used as a reactive flame retardant in the EU is taken as 12 420 tonnes per year, and the amount as an additive flame retardant is 1 380 tonnes per year. At the moment the situation with regards to production of derivatives of tetrabromobisphenol-A in the EU is unclear, although the Industry Consortium for tetrabromobisphenol-A have indicated that none of its members currently manufacture such derivatives in the EU (Industry Consortium, 2003).

## 4. Monitoring data on discharges, emissions and losses

### 4.1 Aquatic inputs to the marine environment

No data are available on loads of tetrabromobisphenol-A entering the OSPAR Convention Waters and the Greater North Sea.

### 4.2 Atmospheric inputs

No data are available on atmospheric inputs of tetrabromobisphenol-A but considering its low vapour pressure and tendency to adsorb to soils and sediments it can be expected that atmospheric concentrations will be extremely low. Available measurements in air relate to indoor and workplace situations. The available information on the long-range atmospheric transport of this substance indicates that the substance has a low, but not zero, potential to be transported over long distances via the atmosphere. The substance is thought to adsorb strongly onto atmospheric particulates and that it is the transport behaviour of these particulates that effectively governs the transport behaviour of tetrabromobisphenol-A itself. Tetrabromobisphenol-A has been found in samples of moss from Norway and this may provide an indication that transport via the environment may occur for tetrabromobisphenol-A by the mechanism outlined above.

### 4.3 Concentrations in the marine environment (and other waters/sediments)

There are no available measured levels of tetrabromobisphenol-A in marine waters, but there are measurements in estuarine sediments, as well as in freshwaters, freshwater sediments and waste waters. A summary of these data<sup>2</sup> is included in Tables 2 to 4.

**Table 2. Measured levels of tetrabromobisphenol-A in surface water**

Location	Concentration	Reference
Creek, Finland	<0,2 µg/l	Peltola (2002)
Baden-Wurtenburg, Germany	0,81 – 20,4 ng/l (7 of 30 samples)	Kuch et al (2001)

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<sup>2</sup> Further reports have been published since the draft risk assessment was produced. These will be reviewed for the revision of the assessment. A provisional analysis indicates that recent data from Sweden and Norway show similar levels in sediments to those included here.

**Table 3. Measured levels of tetrabromobisphenol-A in sediments**

Location	Concentration	Reference
<b>Rivers</b>		
Elbe, Germany (2001)	0,5 – 4,6 µg/kg dwt (7 of 30 samples)	Heemken et al (2001)
Various rivers, Germany	0,17 – 1,83 µg/kg dwt	Kuch et al (2001)
River, UK (1998)	2,3 mg/kg wwt	CEFAS (2002)
River, Ireland	<2,4 – 3,7 µg/kg dwt (3 of 4 samples)	de Boer et al (2002)
Tees, Tyne, Skerne (UK)	<2,4 – 9753 µg/kg dwt	de Boer et al (2002)
Berlin area, Germany	0,16 – 19 µg/kg dwt	Kemmlin (2000)
<b>Estuarine</b>		
Scheldt, Netherlands	<0,1 – 32 µg/kg wwt (13 of 19 samples)	de Boer et al (2002)
Western Scheldt, Netherlands	<0,1 – 1,3 µg/kg wwt (14 of 19 samples)	de Boer et al (2002)
Dublin Bay, Ireland	ND (<2,4 µg/kg dwt) (8 samples)	de Boer et al (2002)
Humber, Mersey, Clyde (UK)	ND (<2,4 µg/kg dwt)	de Boer et al (2002)
<b>Coastal</b>		
Finnish Gulf, Finland	<0,2 µg/kg dwt (3 samples)	Peltola (2002)

Most of the positive measurements cover a similar range of values. There are two reported values which are much higher, from the UK (CEFAS, 2002, and de Boer et al, 2002), which relate to sites close to potential sources of release.

**Table 4. Measured levels of tetrabromobisphenol-A in waste waters**

Country	Influent/ effluent	Concentration	Dissolved/ particulate	Reference
UK	Influent	2,6 – 85,2 ng/l (4 of 5 samples)	Dissolved	de Boer et al (2002)
	Effluent	ND (<15 ng/l)	Dissolved	
		21,7 µg/kg dwt (1 of 5 samples)	Particulate	
	Effluent	ND (< 3,9 µg/kg dwt)	Particulate	
Netherlands	Influent	ND (< 1-3,8 µg/kg dwt)	Particulate	
	Effluent	37 – 62 µg/kg dwt	Particulate	
Germany	Influent	0,81 – 17,4 ng/l (5 of 5 samples)	Dissolved	Kuch et al (2001)

#### 4.4 Concentrations in biota

The available data<sup>3</sup> on the levels of tetrabromobisphenol-A in aquatic biota are summarised in Table 5.

**Table 5. Measured levels of tetrabromobisphenol-A in aquatic biota**

Sample	Comment	Concentration	Reference
Baltic salmon	Blood sample from 1995.	Detected but not quantified	Asplund et al., 1999
	Ten muscle samples from the River Kymijoki and River Simojoki, Finland, 1993-1999.	Detected in 2 samples at 2,0 and 5,0 µg/kg fresh weight	Peltola, 2002
Eel	Two samples from Berlin area from 1998/1999.	0,045 and 0,10 µg/kg fresh weight	Kemmlin, 2000
	Samples from Scheldt basin, 2000. Detected in 6 out of 18 samples (detection limit 0,1 µg/kg wet weight).	<0,1-2,6 µg/kg wet weight	de Boer et al., 2002
	Samples from rivers in the Netherlands. Detected in 3 out of 11 samples (detection limit 0,1 µg/kg wet weight).	<0,1-0,2 µg/kg wet weight	de Boer et al., 2002
Perch	Sample from Berlin area from 1998/1999.	0,033 µg/kg fresh weight	Kemmlin, 2000
Pike	Sample from Berlin area from 1998/1999.	0,021 µg/kg fresh weight	Kemmlin, 2000
	Three muscle samples from Finland, 1997.	Not detected	Peltola, 2002
Cod liver	Samples from North Sea. Detected in 1 out of 2 samples. Detection limit 0,1 µg/kg wet weight.	<0,1-0,8 µg/kg wet weight	de Boer et al., 2003
Hake liver	Not detected in 1 sample. Detection limit 0,1 µg/kg wet weight.	Not detected	de Boer et al., 2003
Whiting (fillet)	North Sea, 1999. Detected in 2 out of 3 samples. Detection limit 97 µg/kg lipid.	<97-245 µg/kg lipid	de Boer et al., 2002
Whiting muscle	UK Sea Estuaries. Detected in 1 out of 2 samples. Detection limit ~ 4,8 µg/kg wet weight.	<4,8-3,3 µg/kg wet weight	de Boer et al., 2002
Cod liver	Samples from around Norway. Detected in 6 out of 6 samples.	0,08-0,16 µg/kg wet weight	SFT (2002)
Gudgeon	Western Scheldt. Not detected in 1 sample. Detection limit 0,1 µg/kg wet weight.	Not detected	de Boer et al., 2002
Blue mussel	Samples from around Norway. Detected in 6 out of 6 samples.	0,01-0,03 µg/kg wet weight	SFT (2002)
Hermit crab (abdomen)	North Sea, 1999. Detected in 5 out of 9 samples. Detection limit 1 µg/kg lipid.	<1-35 µg/kg lipid	de Boer et al., 2002
Mysid shrimp	Western Scheldt. Not detected in 1 sample. Detection limit 0,1 µg/kg wet weight.	Not detected	de Boer et al., 2002
Sea star (pyloric caeca)	North Sea, 1999. Detected in 2 out of 3 samples. Detection limit 1 µg/kg lipid.	<1-10 µg/kg lipid	de Boer et al., 2002
Moss	Samples from Norway. Detected in 11 out of 11 samples.	0,019-0,089 µg/kg wet weight	SFT (2002)

<sup>3</sup> Further data on levels in fish in Norway has been received since the draft assessment was produced; these are similar to those included in the table.

Sample	Comment	Concentration	Reference
Star fish	UK Estuaries. Detected in 1 out of 1 sample.	4,5 µg/kg wet weight	de Boer et al., 2002
Whelk (whole body)	North Sea, 1999. Detected in 3 out of 3 samples.	5-96 µg/kg lipid	de Boer et al., 2002
Harbour porpoise (blubber)	North Sea. Not detected in 5 samples (detection limit 18 µg/kg lipid).	Not detected	de Boer et al., 2002
	North Sea estuaries. Detected in 5 out of 5 samples. (CEFAS, 2002 reports the results as detected in 8 out of 25 samples; and Law et al. (2003 report the results as detected in 4 out of 25 samples).	0,05-376 µg/kg wet weight	de Boer et al., 2002; CEFAS, 2002; Law et al., 2003
Harbour seal (blubber)	North Sea. Not detected in 5 samples (detection limit 14 µg/kg lipid).	Not detected	de Boer et al., 2002
Harbour seal (liver)	North Sea. Not detected in 5 samples (detection limit 231 µg/kg lipid).	Not detected	de Boer et al., 2002

## 5. Assessment of the extent of the problem

### 5.1 Introduction

In order to assess the extent of the problem, the UK has carried out a marine risk assessment based on the guidance developed by OSPAR and the EC in recent years. The Marine Risk Assessment involved two steps. Firstly, the preparation of a PBT assessment to ascertain whether the substance is so hazardous that measures should be developed solely on the basis of the information available on sources and pathways to the marine environment. This was followed by a more traditional risk assessment approach where the predicted environmental concentrations were compared with the predicted no effect concentrations to give a PEC/PNEC ratio for various scenarios. The PEC/PNEC ratios give a numerical indication of the degree of risk. The details of the marine risk assessment are given in Appendix 1 of this document. The marine risk assessment draws heavily on data and information in the UK RAR, which will be published in due course when it has been finalised. It is clear that the marine risk assessment would be greatly improved with the provision of better quality information.

### 5.2 PBT Assessment

The classification of tetrabromobisphenol-A against the EC Technical Guidance Document PBT criteria gave the following results:

**Persistence:** tetrabromobisphenol-A is not considered to be readily biodegradable in the risk assessment, hence it meets the screening criteria for P or vP.

**Bioaccumulation:** the highest measured BCF value for fish is 1 234 l/kg, and there are several other determinations below this value. This value is below the cut-off value of 2 000, and so tetrabromobisphenol-A does not meet the B criterion.

**Toxicity:** the toxicity criterion used in the marine risk assessment guidance is a chronic NOEC <0,01 mg/l. There is some uncertainty over the actual NOEC for tetrabromobisphenol-A but the currently available data indicate that the NOEC for tetrabromobisphenol-A is around 0,0026 mg/l. Based in this result, it can provisionally be concluded that tetrabromobisphenol-A meets the toxicity criterion.

#### **Conclusion of the PBT assessment**

Tetrabromobisphenol-A meets two of the three criteria for the PBT assessment. Although the measured BCF value is around 60% of the threshold value, it is considered to be a maximum value as it may include accumulation of metabolites. There are also indications for some degradation of tetrabromobisphenol-A under both aerobic and aerobic conditions. Overall, tetrabromobisphenol-A is not considered to meet the PBT criteria.

### 5.3 PEC/PNEC ratios for the local marine risk assessment

The PEC/PNEC ratios for the local marine risk assessment are given in Table 6. For details of the derivation of the PECs and PNECs and the various assumptions which have been used, see Appendix 1.

**Table 6. Estimated PEC/PNEC ratios for tetrabromobisphenol-A for the local marine risk assessment**

Scenario	Step	PEC/PNEC ratio water	PEC/PNEC ratio sediment
Reactive flame retardant use	Manufacture of epoxy and/or polycarbonate resins	3,5	4,2
	Processing of epoxy resins	$9,0 \times 10^{-4}$	0,011
	Processing of polycarbonate resins	$9,0 \times 10^{-4}$	0,011
Additive flame retardant use - ABS	Compounding	96,2	115
	Conversion	4,4	5,3
	Compounding/conversion	100	120
Additive flame retardant use - phenolic resins	Compounding	19,2	23,2
	Conversion	0,87	1,02
	Compounding/conversion	21,2	24,6

### 5.4 Conclusion of the Risk Assessment for the marine compartment

The risk assessment for the marine environment<sup>4</sup> indicates a potential risk to water and sediment from some uses of tetrabromobisphenol-A, although processing of epoxy and polycarbonate resins (for water and sediment), and the conversion step for phenolic resins (for water), do not appear to present a risk. It would be possible to revise the PECs for the other endpoints by collection of further exposure information<sup>5</sup>.

It would also be possible to revise the PNEC for water and sediment by carrying out further testing to a) define better the actual long-term NOEC for tetrabromobisphenol-A in aquatic species and b) investigate the toxicity of tetrabromobisphenol-A to marine sediment organisms.

The conclusions of the marine risk assessment above are in agreement with those for the freshwater environment in the risk assessment.

The risk from secondary poisoning appears to be low for all scenarios – the ratios (not shown here) are all  $< 2,2 \times 10^{-3}$ .

The risk assessment also considers the possible degradation of tetrabromobisphenol-A in sediments. A study in estuarine sediments has indicated that tetrabromobisphenol-A has the potential to degrade through debromination under anaerobic conditions to form bisphenol-A. There are also studies on contaminated freshwater sediments and on soil which show degradation under anaerobic conditions. Bisphenol-A is stable under anaerobic conditions; it has recently been the subject of an ESR assessment and is thought to have adverse effects at low concentrations. These adverse effects are currently the subject of testing programmes within the ESR process. The information on this aspect of degradation is limited in terms of applicability to the environment, and so the risk assessment recommends that further testing be carried out to investigate this possible degradation mechanism. The results of such work will be potentially of relevance to the marine risk assessment.

<sup>4</sup> This risk assessment methodology has been formally agreed by the EC in April 2003 and has been adopted by the OSPAR Commission in June 2003 as the common EU/OSPAR risk assessment methodology for the marine environment.

<sup>5</sup> The PECs for manufacturing of resins are based on default emission factors but with more specific information on amounts used on sites. All other emissions are estimated using the Emission Scenario Document on Plastics, where the emission factors are based on those for other substances (largely diethylhexyl phthalate). Hence all areas could be refined with substance-specific information.

## 6. Achieving the desired reductions

### 6.1 OSPAR targets

The OSPAR Strategy with regard to Hazardous Substances sets out that the OSPAR objective with regard to hazardous substances 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.*"

The timeframe given in the Strategy states that "every endeavour will be made to move towards the target of cessation of discharges, emissions and losses of hazardous substances of concern by the year 2020."

At OSPAR 2002, OSPAR adopted guidance on the role of marine risk assessment, which gives, in particular, advice on the urgency of taking measures based on particular PEC/PNEC ratios (cf. Annex 6 of OSPAR 2002 Summary Record). The UK has attempted to apply this guidance and reached the following conclusions. However, these conclusions are considered to be provisional, and could change in the light of further information which is needed to get realistic estimations of a number of emissions.

The estimated PEC/PNEC ratios for tetrabromobisphenol-A for the marine environment are greater than 1 for the manufacture of epoxy or polycarbonate resins, for processing in ABS as an additive flame retardant, and for most processing in phenolic resins as an additive flame retardant. The assessment of secondary poisoning in the marine environment does not give rise to any PEC/PNEC ratios above one.

The guidance recognises, however, that where the uncertainties are high in the estimation of risk, this should be taken into account by the Contracting Parties when considering the actions necessary to achieve OSPAR's objectives.

In this instance, default values have been used in the calculation of emissions from the various processes, and further exposure information is needed to refine the PEC assessments. There is also a lack of long term toxicity information on seawater species, and some uncertainty over the effects data for freshwater organisms. Further long term testing for the freshwater environment has been recommended in the draft UK risk assessment. The assessment notes that the need for further toxicity data on marine organisms should be re-evaluated once the results of the testing on freshwater organisms are available. There is also a need (endorsed by Sweden) to investigate further the potential degradation of tetrabromobisphenol-A to bisphenol-A under anaerobic conditions. Hence at this stage the results of the risk assessment are considered to be preliminary.

Nevertheless, although it does not meet the PBT assessment in the EC Technical Guidance Document, tetrabromobisphenol-A may pose a risk to the marine environment (either as itself or through its possible breakdown products), and it is therefore imperative from OSPAR's point of view that appropriate actions, commensurate with the estimated risks, and taking account of the uncertainties in their estimation, should be taken to achieve the OSPAR objectives on hazardous substances.

### 6.2 OSPAR's role in achieving the desired targets

In order to meet the targets specified in the OSPAR objective and timeframe, it will be necessary to:

- assess the need for further reductions from the various sources and the practicability of such reductions;
- review existing regulations and controls in the light of the need for further reductions;
- decide which organisation is responsible and/or best placed for carrying out detailed assessments and/or implementing controls;
- inform the relevant organisation (if OSPAR sees fit) of the OSPAR Ministerial commitments with regard to hazardous substances and the need for action to address OSPAR concerns;
- set up mechanisms for monitoring the compliance with measures adopted in the relevant forum;
- set up mechanisms to monitor inputs to the marine environment and concentrations in the marine environment and biota to check that levels are falling at a satisfactory rate.

For a number of the sources of tetrabromobisphenol-A, OSPAR may not be the most appropriate international body to instigate further controls or to assess whether the controls are practicable or necessary. Therefore, setting and achieving the desired reduction targets will need to be carried out through close co-operation with other international forums.

It will also be possible, through appropriate assessment and monitoring activities, to consolidate the values obtained in Tables 2, 3 and 4 and to determine whether tetrabromobisphenol-A occurs in the marine

environment at significant levels, and to assess whether the levels are falling due to the implementation of agreed actions, and whether values are approaching near to zero concentrations.

## 7. Identification of possible measures

### 7.1 Review of existing OSPAR, EU and national measures

#### 7.1.1 Measures in OSPAR

No measures have been taken to date.

#### 7.1.2 Ongoing activities within the European Union

Tetrabromobisphenol-A is undergoing risk assessment under the Existing Substances Regulation in the EU (Regulation 793/93). The UK is leading this work.

Directive 2002/96/EC<sup>6</sup> on Waste Electrical and Electronic Equipment (WEEE Directive) entered European law on the 13<sup>th</sup> February 2003 and should be implemented by Member States by the 13<sup>th</sup> August 2004. The Directive contains the following elements:

- Member States shall set up separate collection schemes and ensure the proper treatment, recovery and disposal of WEEE;
- The treatment, recovery and disposal of WEEE shall be financed by producers to create economic incentives to adapt the design of electrical and electronic equipment to the prerequisites of sound waste management;
- Consumers shall have the possibility to return their equipment free of charge. They need to be informed about the possibilities of return WEEE.

The Directive encourages producer responsibility for waste management, separate collection of WEEE, improved treatment and reuse/recycling, and improved dissemination to users. In implementing the Directive, producers are required to set up systems to treat WEEE which would include, amongst other things, separation of plastic containing brominated flame retardants from collected WEEE (RPA, 2001).

#### 7.1.3 National initiatives within some Contracting Parties

In Denmark regulations are already in place on the management of waste from electrical and electronic products (Danish Environmental Protection Agency, 2001). According to the Ministry of Environment and Energy's Statutory Order No. 1067 of 22 December 1998, flame-retarded plastic has to be separated out from other waste from electrical and electronic equipment and this plastic has to be recycled, incinerated or deposited at approved facilities. In the case of recycling, the plastic has to be used for products for which special requirements apply for fire safety reasons. There are around 25 companies that separate electronic waste in Denmark.

## 7.2 Alternatives

One of the guiding principles of the OSPAR Strategy on Hazardous Substances is the principle of substitution (the substitution of hazardous substances or preferably non-hazardous substances where such alternatives are available).

Substitution has been discussed by various OSPAR subsidiary bodies in the 1999/2000 inter-sessional period. The substitution of hazardous substances used offshore has been addressed in OIC and is an essential element of the measures adopted at OSPAR 2000 with respect to the use and discharge of offshore chemicals.

The UK assessment has not yet revealed any definitive substitutes or alternatives which have been used for tetrabromobisphenol-A. It should be noted that tetrabromobisphenol-A is itself considered as an alternative to octabromodiphenyl ether as a additive flame retardant in ABS.

Substitution of tetrabromobisphenol-A by another substance requires consideration of the following:

- that the substitute is less harmful and poses a lower risk;

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<sup>6</sup> Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE). Official Journal of the European Union, L37, 13/2/2003, pp24-38.

- the physical behaviour of the substance and thus the nature of the processes used to produce these substances;
- the price differential between these substances and tetrabromobisphenol-A, based on these processes and resulting performance of the product;
- the efficacy of substitutes and the volumes required.

## **8. CHOICE FOR ACTION/MEASURES**

### **8.1 General considerations**

When considered in the light of the guidance on the role of risk assessment, the initial results from the risk assessment indicate that there should be concern over some uses of tetrabromobisphenol-A as a flame retardant.

However, it should be noted that the majority of the PEC values are derived from default emission estimates and this should be taken into account in the consideration and timing of measures. The current draft risk assessment recommends that better exposure information be obtained to improve the estimates of exposure. It also recommends further long-term tests on aquatic organisms to reduce the uncertainties over the existing data. A proper evaluation of the appropriate choices for action can only be made when all the relevant information has been collected and the UK risk assessment has been finalised later in 2004, and the relevant risk reduction scenarios have been developed. Assessment will be required of possible additional measures, examining options against key criteria such as effectiveness, practicability and economic impact. In particular, there needs to be a better understanding of the availability and risks posed by substitutes which are available to replace tetrabromobisphenol-A. However, the following actions are already thought to be justified.

### **8.2 Action in the EC**

Contracting Parties who are also EU Member States should support the ongoing development of the Risk Assessment Report and provide new information, if available, on exposure and discharges, emissions and losses, which would enable the PEC/PNEC values to be refined.

To support this process and to ensure that the information in this background document and the conclusions reached by OSPAR are generally taken into account in the approach of the European Community, OSPAR should communicate this background document to the European Commission.

### **8.3 Action within OSPAR**

The substitution of tetrabromobisphenol-A with safer substitutes which pose less risk to the environment should be encouraged. However, the UK assessment has not yet revealed any definitive substitutes or alternatives which have been used for tetrabromobisphenol-A. Therefore Contracting Parties should encourage the development of substitutes for tetrabromobisphenol-A where adequate substitutes are not currently available.

In recognition of the large uncertainties in the estimations of risk made, the relevant industries should be invited to work with Contracting Parties to improve the estimates of emissions, and if necessary, the estimation of PNEC values, to ensure the most effective risk reduction measures can be adopted.

OSPAR should re-evaluate the risks posed by tetrabromobisphenol-A releases when further information has been collected. Any associated measures which might be justified in the light of new findings should be addressed through the background document review process.

### **8.4 Action in other forums**

To ensure that the information in this background document can be considered in the context of other international agreements which deal with hazardous substances, and with which Contracting Parties are associated, OSPAR should send copies of this background document to the appropriate bodies dealing with those agreements and invite Contracting Parties who are parties both to OSPAR and those other agreements to promote action to take account of this background document by those other international bodies in a consistent manner.

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## Appendix 1: Marine risk assessment

### 1. Introduction

This Annex considers the risks to the marine environment from the production, use and disposal of tetrabromobisphenol-A. The methodology used is based on the marine risk assessment chapter of the Technical Guidance Document<sup>7</sup> for EU Regulation 793/93.

### 2. Marine exposure assessment

The methodology outlined in the marine risk assessment guidance essentially assumes that the adsorption/desorption, degradation and accumulation behaviour in the marine environment can, in the absence of specific information for the marine environment, be adequately described by the properties of the substance relevant for the freshwater environment. The relevant properties for tetrabromobisphenol-A are summarised in Table A2.1.

**Table A2.1. Adsorption and accumulation properties for tetrabromobisphenol-A used in the marine assessment**

Property	Value
Log Kow	5,90
Water solubility	1,26-2,34 mg/l
Organic carbon - water partition coefficient (Koc)	49 726 l/kg
Solid-water partition coefficient in suspended matter (Kp <sub>susp</sub> )	7 299 l/kg
Suspended matter - water partition coefficient (K <sub>susp-water</sub> )	1 826 m <sup>3</sup> /m <sup>3</sup>
Fish bioconcentration factor (BCF <sub>fish</sub> )	485 l/kg (tetrabromobisphenol-A alone) 1 234 l/kg (tetrabromobisphenol-A plus metabolites)
Biomagnification factor in fish (BMF <sub>1</sub> ) <sup>a</sup>	1
Biomagnification factor in predators (BMF <sub>2</sub> ) <sup>a</sup>	1

Note: a) Taken from the marine risk assessment guidance using the BCF<sub>fish</sub> as the trigger value. Actual biomagnification factors for tetrabromobisphenol-A appear to be <1 based on feeding studies.

As the pH of seawater is around 8, tetrabromobisphenol-A is expected to be present in an ionised form in the marine environment. The effect of pH on the partition coefficients and water solubility of the substance is considered in Section 1 and Section 3.1.0 of the draft UK RAR and the values reported in Table A2.1 are considered to be those most appropriate for the pH conditions likely to be found in the marine environment. The one possible exception to this is the log Kow, where the pH of the water used in the determination was not given. However, as suitable values for Koc and BCF<sub>fish</sub> are available from elsewhere, the log Kow is not vital to the assessment.

The starting point for the local marine assessment is the concentration of tetrabromobisphenol-A in effluent from the site of discharge. This effluent from industrial sites is assumed to enter into the marine environment without further waste water treatment.

As all the emissions are estimated on a mass/day basis, in order to estimate these concentrations, knowledge of the total aqueous effluent volume discharge from generic sites is needed. These data are not available. In this situation the Technical Guidance Document indicates that it can be assumed that the amount emitted per day is diluted into a volume of 200 000 m<sup>3</sup>, with adsorption onto suspended matter also being taken into account.

The emissions used as the starting point for the marine risk assessment are shown in Table A2.2. Table A2.2 also shows the resulting concentrations in seawater, marine sediment and marine biota. These have been estimated using the methods outlined in the Technical Guidance Document and the properties shown in Table A2.1 for the adsorption and accumulation behaviour of tetrabromobisphenol-A.

<sup>7</sup> Available from ECB web-site – <http://ecb.jrc.it/existing-chemicals>.

It should be noted that neither the production of tetrabromobisphenol-A nor the use of tetrabromobisphenol-A as an intermediate currently occur in the EU. The calculations of the PEC values for these scenarios are based entirely on default values and are included for illustration only. They are not taken on to the risk characterisation.

For secondary poisoning, the concentrations in predators and top predators have been estimated using the following equations.

$$PEC_{oral, predator} = 0,5 * (PEC_{local, seawater, ann} + PEC_{regional, seawater, ann}) * BCF_{fish} * BMF_1$$

$$PEC_{oral, top predator} = (0,1 * PEC_{local, seawater, ann} + 0,9 * PEC_{regional, seawater, ann}) * BCF_{fish} * BMF_1 * BMF_2$$

The  $PEC_{regional, seawater}$  is estimated as  $2,6 \times 10^{-4}$  µg/l using the EUSES 2.0 program.

**Table A2.2. Estimated PECs for tetrabromobisphenol-A for the local marine risk assessment**

Scenario	Comment	Daily emission to water (kg/day)	No. of days of release	$C_{local, seawater}$ ( $\mu\text{g/l}$ ) <sup>c</sup>	$C_{local, seawater, ann}$ ( $\mu\text{g/l}$ )	$PEC_{local, seawater}$ ( $\mu\text{g/l}$ ) <sup>d</sup>	$PEC_{local, seawater, ann}$ ( $\mu\text{g/l}$ ) <sup>d</sup>	$PEC_{local, sed}$ (mg/kg wet wt.)	$PEC_{oral}^{predator}$ (mg/kg) <sup>d</sup>		$PEC_{oral, top predator}$ (mg/kg) <sup>d</sup>	
									a	b	a	b
Production of tetrabromobisphenol-A	Example calculation	13,6	300	61,3	50,4	61,3	50,4	97,3	31,1	12,2	6,2	2,4
Use as an intermediate in the production of derivatives	Example calculation	17,5	200	78,9	43,2	78,9	43,2	125	26,7	10,5	5,3	2,1
Reactive flame retardant use	Manufacture of epoxy and/or polycarbonate resins	0,041	300	0,18	0,15	0,18	0,15	0,29	0,093	0,036	0,019	$7,4 \times 10^{-3}$
	Processing of epoxy resins	$5,0 \times 10^{-5}$	32	$2,3 \times 10^{-4}$	$2,0 \times 10^{-5}$	$4,9 \times 10^{-4}$	$2,8 \times 10^{-4}$	$7,8 \times 10^{-4}$	$3,4 \times 10^{-4}$	$1,3 \times 10^{-4}$	$3,2 \times 10^{-4}$	$1,3 \times 10^{-4}$
	Processing of polycarbonate resins	$5,0 \times 10^{-5}$	28	$2,3 \times 10^{-4}$	$2,0 \times 10^{-5}$	$4,9 \times 10^{-4}$	$2,8 \times 10^{-4}$	$7,8 \times 10^{-4}$	$3,4 \times 10^{-4}$	$1,3 \times 10^{-4}$	$3,2 \times 10^{-4}$	$1,3 \times 10^{-4}$
Additive flame retardant use - ABS	Compounding	1,1	171	5,0	2,3	5,0	2,3	7,9	1,4	0,56	0,28	0,11
	Conversion	0,05	171	0,23	0,11	0,23	0,11	0,36	0,068	0,026	0,013	$5,3 \times 10^{-3}$
	Combined compounding/ conversion	1,15	171	5,2	2,4	5,2	2,4	8,2	1,5	0,59	0,30	0,12
Additive flame retardant use - phenolic resin	Compounding	0,223	48	1,0	0,13	1,0	0,13	1,6	0,082	0,032	0,017	$6,4 \times 10^{-3}$
	Conversion	0,010	48	0,045	$5,9 \times 10^{-3}$	0,045	$6,3 \times 10^{-3}$	0,072	$4,0 \times 10^{-3}$	$1,6 \times 10^{-3}$	$1,1 \times 10^{-3}$	$4,2 \times 10^{-4}$
	Combined compounding/ conversion	0,233	48	1,1	0,14	1,1	0,14	1,7	0,086	0,034	0,017	$6,8 \times 10^{-3}$

- Notes: a) Calculations assuming  $BCF_{fish} = 1\ 234$  l/kg.  
b) Calculations assuming  $BCF_{fish} = 485$  l/kg.  
c) Assumes the daily emission is diluted into  $200\ 000\ \text{m}^3$  of water and the concentration of suspended matter in the seawater is 15 mg/l.  
d) Calculations use a  $PEC_{regional, seawater}$  of  $2,6 \times 10^{-4}$   $\mu\text{g/l}$  calculated with EUSES 2.0 and a Koc of 49 726 l/kg.

### 3. Predicted no effect concentration (PNEC) for the marine compartment

#### 3.1 Water

The Technical Guidance recommends that the pooled data for both freshwater and marine organisms are considered in the PNEC derivation. As discussed in Section 3.2.1.7.1 of the draft UK RAR, there are some uncertainties as to the actual NOEC values for some of the more sensitive species tested. The lowest value reported is an extrapolated EC<sub>10</sub> of 2,6 µg/l for shell regrowth in the marine species *Crassostrea virginica* in an acute test, and this result will be considered here for the marine environment. It should be noted that this value was extrapolated below the lowest concentration tested, and the control response in the test was slightly lower than is recommended in current test guidelines, and so is uncertain.

The overall data set for tetrabromobisphenol-A consists of NOEC values for freshwater fish (NOEC 0,16 mg/l), two species of freshwater invertebrates (lowest NOEC 0,12 mg/l), two species of marine invertebrates (lowest NOEC/EC<sub>10</sub> = 0,0026 mg/l for shell regrowth in *Crassostrea virginica*), and one freshwater algal species (NOEC ≥5,6 mg/l). In addition acute EC<sub>50</sub> values (but no NOEC values) are available for one freshwater algal species and three marine water algae (lowest EC<sub>50</sub> is 0,09 mg/l). The substance has been shown to have little or no estrogenic activity in the fish, invertebrates and amphibians tested so far. There is some evidence that the toxicity of tetrabromobisphenol-A to marine algae may increase with decreasing pH in the range pH 7,6 to 8,2, but, given that natural seawater is effectively buffered at around pH 8 such trends in toxicity are not likely to be important in reality.

From the Technical Guidance Document an assessment factor of 50 could be applied to the available data as there are NOECs from freshwater/marine species covering three trophic levels (algae, fish and crustaceans) with in addition a long-term NOEC from an additional marine taxonomic group (molluscs). As marine as well as fresh water species have been tested in two of the trophic levels (algae and crustaceans) it could be considered to reduce the assessment factor to a value of 10. However, there is some uncertainty over the actual NOECs for some of the species tested (see main risk assessment report) and no NOEC has been determined for marine algae. The uncertainty over the NOECs means that it is not currently possible to derive a reliable PNEC for the aquatic compartment.

Therefore an assessment factor of 50 will be used on the extrapolated EC<sub>10</sub> of 0,0026 mg/l for *Crassostrea virginica* to derive an indicative value of 0,052 µg/l for the marine risk assessment.

#### 3.2 Sediment

Reliable long-term toxicity tests have been carried out with the freshwater sediment oligochaete *Lumbriculus variegatus* for two sediment types. The NOEC values for the two sediments from this study, normalised to the Technical Guidance Document default organic carbon content of 5%, were 69 and 83 mg/kg wet weight. In addition, a 14-day partial life-cycle test was carried out with the freshwater midge (*Chironomus tentans*) but the control and solvent control responses in this study were poor in some replicates and the results are therefore uncertain and not used to derive a PNEC.

According to the Technical Guidance Document, for marine risk an assessment factor of 1 000 should be applied to the results of long term tests for one species<sup>8</sup>. Therefore, applying an assessment factor of 1 000 to the NOEC value of 69 mg/kg wet weight gives a PNEC<sub>marine sediment</sub> of 0,069 mg/kg wet weight.

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<sup>8</sup> The assessment factor for (freshwater) the PNEC for freshwater sediment was discussed at TMI'03. In view of the fact that the species tested, *L. variegatus*, feeds on the sediment, and that the results of the tests in two sediment types show that the toxicity seen is expressed mainly as a result of exposure via the sediment pore water, it could be considered that an assessment factor of 500 (normally only applied to two long term NOECs for species representing different living and feeding conditions) may be appropriate in this case. However, at present there is insufficient information available on the toxicity of tetrabromobisphenol-A to other species to identify *L. variegatus* as a sensitive species and so to warrant lowering the assessment factor. The assessment factor for the PNEC for marine sediment should be revisited once the results of the further sediment toxicity tests currently being undertaken are available.

## 4. Marine risk assessment

### 4.1 PBT assessment

The first part of the draft marine risk assessment procedure requires a screening of the properties of a substance to see if it is considered as a persistent (P), bioaccumulative (B) and toxic (T) substance. Where substances meet the PBT criteria, the standard PEC/PNEC assessment is considered to be uncertain.

#### 4.1.1 Persistence

The persistence criteria currently laid down in the marine risk assessment guidance require a half-life >60 days in marine water (or >40 days in fresh water) or >180 days in marine sediment (or >120 days in freshwater sediment).

The available screening studies, although showing that primary biodegradation does occur under some situations, indicate that tetrabromobisphenol-A is unlikely to be considered as readily biodegradable or inherently biodegradable. The half-life for primary degradation in freshwater aerobic sediments is estimated to be of the order of 50 to 70 days at 25°C, but no mineralization was observed over 56 days. It can therefore be assumed that tetrabromobisphenol-A is potentially persistent or potentially very persistent under the criteria used.

The degradation of tetrabromobisphenol-A has been studied under anaerobic conditions. In particular, one study has been carried out in estuarine sediment. This showed that tetrabromobisphenol-A was degraded and the main product formed was bisphenol-A, which was stable under the anaerobic conditions used. This is an important finding for the marine risk assessment for tetrabromobisphenol-A as the substance is predicted to adsorb strongly onto sediment. Thus, if tetrabromobisphenol-A is transported to the marine environment, it is expected that it will degrade to bisphenol-A in anaerobic sediments, which will itself persist under anaerobic conditions.

#### 4.1.2 Bioaccumulation

The criterion used in the marine risk assessment for bioaccumulation is a bioconcentration factor (BCF) >2 000 l/kg. The highest measured BCF value for (freshwater) fish with tetrabromobisphenol-A is around 1 234 l/kg. This value was based on <sup>14</sup>C measurements and so may represent accumulation of metabolites as well as tetrabromobisphenol-A. There are several other fish bioconcentration factors below this value. No BCF data are available for marine fish species, but a BCF value of 780 l/kg has been determined for a marine mollusc *Crassostrea virginica*. Therefore, the available BCF data indicates that tetrabromobisphenol-A does not meet the bioaccumulation criterion. However, it should be noted that the available data indicate that the substance is present at low levels in the tissues of a range of marine organisms, including top predators.

#### 4.1.3 Toxicity

The toxicity criterion used in the draft marine risk assessment guidance is a chronic NOEC <0,01 mg/l. There is some uncertainty over the actual NOEC for tetrabromobisphenol-A but the currently available data indicate that the NOEC for tetrabromobisphenol-A is around 0,0026 mg/l for the short-term shell regrowth of the marine species *Crassostrea virginica*. This value is extrapolated below the lowest concentration tested, but significant effects were seen in this study at 0,018 mg/l which is close to the toxicity criterion cut-off. Therefore, based in this result, it can provisionally be concluded that tetrabromobisphenol-A meets the toxicity criterion. It should be noted that further toxicity tests are being carried out for tetrabromobisphenol-A in order to determine a more reliable NOEC for this substance.

#### 4.1.4 Summary of PBT assessment

For the PBT assessment, tetrabromobisphenol-A can be considered to be potentially persistent (P) or potentially very persistent (vP) based on its ultimate mineralisation. The substance has been shown to degrade in aerobic and anaerobic sediments, but only primary biodegradation was shown to occur. Furthermore, experimental data show that tetrabromobisphenol-A can be expected to degrade in anaerobic marine sediments to bisphenol-A, which itself has been shown to persist under anaerobic conditions. The available information on bioaccumulation shows that tetrabromobisphenol-A does not meet the B criterion. The T criterion appears to be met for tetrabromobisphenol-A. Therefore tetrabromobisphenol-A is considered as very persistent (vP) and toxic (T).

## 4.2 Risk characterisation for the marine environment

The provisional risk characterisation ratios for water, sediment and predators/top-predators are shown in Tables A2.3, A2.4 and A2.5 respectively. The indicative concentration for marine water, and the PNECs for sediment and predators/top-predators are respectively 0,052 µg/l, 0,069 mg/kg wet weight and >667 mg/kg food respectively.

**Table A2.3. Risk characterisation ratios for marine water**

Scenario	Step	PEC (µg/l)	Risk characterisation ratio
Reactive flame retardant use	Manufacture of epoxy and/or polycarbonate resins	0,18	3,5
	Processing of epoxy resins	$4,7 \times 10^{-4}$	$9,0 \times 10^{-4}$
	Processing of polycarbonate resins	$4,7 \times 10^{-4}$	$9,0 \times 10^{-4}$
Additive flame retardant use - ABS	Compounding	5,0	96,2
	Conversion	0,23	4,4
	Compounding/conversion	5,2	100
Additive flame retardant use - phenolic resins	Compounding	1,0	19,2
	Conversion	0,045	0,87
	Compounding/conversion	1,1	21,2

**Table A2.4. Risk characterisation ratios for marine sediment**

Scenario	Step	PEC (mg/kg wet weight)	Risk characterisation ratio
Reactive flame retardant use	Manufacture of epoxy and/or polycarbonate resins	0,29	4,2
	Processing of epoxy resins	$7,5 \times 10^{-4}$	0,011
	Processing of polycarbonate resins	$7,5 \times 10^{-4}$	0,011
Additive flame retardant use - ABS	Compounding	7,9	115
	Conversion	0,37	5,3
	Compounding/conversion	8,3	120
Additive flame retardant use - phenolic resins	Compounding	1,6	23,2
	Conversion	0,071	1,02
	Compounding/conversion	1,7	24,6

**Table A2.5. Risk characterisation ratios for secondary poisoning in the marine environment**

Scenario	Step	Risk characterisation ratio for predators		Risk characterisation ratio for top predators	
		a	b	a	b
Reactive flame retardant use	Manufacture of epoxy and/or polycarbonate resins	$<1,4 \times 10^{-4}$	$<5,4 \times 10^{-5}$	$<2,8 \times 10^{-5}$	$<1,1 \times 10^{-5}$
	Processing of epoxy resins	$<4,6 \times 10^{-7}$	$<1,8 \times 10^{-7}$	$<4,5 \times 10^{-7}$	$<1,8 \times 10^{-7}$
	Processing of polycarbonate resins	$<4,6 \times 10^{-7}$	$<1,8 \times 10^{-7}$	$<4,5 \times 10^{-7}$	$<1,8 \times 10^{-7}$
Additive flame retardant use - ABS	Compounding	$<2,1 \times 10^{-3}$	$<8,4 \times 10^{-4}$	$<4,2 \times 10^{-4}$	$<1,6 \times 10^{-4}$
	Conversion	$<1,0 \times 10^{-4}$	$<4,0 \times 10^{-5}$	$<2,1 \times 10^{-5}$	$<8,1 \times 10^{-7}$
	Compounding/conversion	$<2,2 \times 10^{-3}$	$<8,7 \times 10^{-4}$	$<4,5 \times 10^{-4}$	$<1,8 \times 10^{-4}$
Additive flame retardant use - phenolic resins	Compounding	$<1,2 \times 10^{-4}$	$<4,8 \times 10^{-5}$	$<2,4 \times 10^{-5}$	$<9,6 \times 10^{-6}$
	Conversion	$<5,8 \times 10^{-6}$	$<2,2 \times 10^{-6}$	$<1,5 \times 10^{-6}$	$<6,0 \times 10^{-7}$
	Compounding/conversion	$<1,3 \times 10^{-4}$	$<5,1 \times 10^{-5}$	$<2,7 \times 10^{-5}$	$<1,0 \times 10^{-5}$

Notes: a) Based on  $BCF_{fish} = 1\,234$  l/kg.  
b) Based on  $BCF_{fish} = 485$  l/kg.

The risk assessment for the marine environment indicates a potential risk to water and sediment from some uses of tetrabromobisphenol-A, although processing of epoxy and polycarbonate resins (for water and sediment), and the conversion step for phenolic resins (for water), do not appear to present a risk. It would be possible to revise the PECs for the other endpoints by collection of further exposure information.

It would also be possible to revise the PNEC for water and sediment by carrying out further testing to a) define better the actual long-term NOEC for tetrabromobisphenol-A in aquatic species and b) investigate the toxicity of tetrabromobisphenol-A to marine sediment organisms.

These conclusions are in agreement with those obtained for the freshwater environment in the draft UK RAR.

The risk from secondary poisoning appears to be low for all scenarios.

### 4.3 Other issues relevant to the risk assessment<sup>9</sup>

A study in Norway has detected tetrabromobisphenol-A in the eggs of a number of predatory bird species. No information is available about possible trends, and the route of exposure of these birds is unknown (it could be from sources other than food), and so the levels can not be linked with any particular source at present.

The presence of a synthetic substance in the tissues of top predators is clearly undesirable, but does not by itself necessarily constitute a risk. However, tetrabromobisphenol-A is expected to be highly persistent in the environment, and a single study has been performed involving exposure of birds' eggs that demonstrates toxicity. The presence of tetrabromobisphenol-A in the eggs of top predators is therefore an important and serious finding that cannot be overlooked.

Since the normal PEC/PNEC comparison methods described in the Technical Guidance Document do not apply to this situation, it is proposed to derive an indicative estimate of the significance of these levels as follows:

- It is not possible to estimate a 90th percentile concentration in eggs. The maximum concentration was 0,013 µg/kg wet weight for Osprey.
- A dose of tetrabromobisphenol-A of 45 µg/g egg caused 80% mortality in quail and 96% mortality in chicken. These mortality rates were statistically significantly different from the mortalities seen in the control populations (13% in quail and 8% in chicken). No statistically significant mortalities

<sup>9</sup> The analysis in this section has been provided by The Netherlands based on the data in the assessment.

occurred in the 15 µg/g egg treatment groups compared to control populations. No other significant effects were observed at this dose in either of two studies.

- When the lower of these two doses is compared to the highest concentration in Osprey eggs, the ratio obtained is >106.

Such a large 'margin of safety' suggests that the significance of the levels detected in predatory bird eggs is low. There is therefore currently no reason for concern, even in the absence of information on trends. It should be noted that no significant effects have been observed in mammals (including in studies that were designed to examine neurotoxic effects).

#### **4.4 Result for marine compartment**

There is a need for further information and/or testing.

The risk characterisation ratios for the marine environment indicate a possible risk from some applications. Further exposure information is needed to refine the PEC estimates. The need for further toxicity data with marine organisms should be evaluated once the results of the further testing suggested for the freshwater aquatic compartment are available.

Tetrabromobisphenol-A does not meet all of the PBT criteria (it is vP and T). However, the substance has been shown to break down in estuarine sediments to another substance (bisphenol-A) that is known to be toxic and shows effects on the endocrine system. Thus this indicates that tetrabromobisphenol-A may have the potential to cause long-term adverse effects on marine ecosystems if sufficient exposure occurs. It is not clear how this finding fits in with the current Marine Risk Assessment Technical Guidance. The effects of bisphenol-A itself on aquatic organisms are currently being investigated further, and this should also be considered in any further discussion of this endpoint.

**Appendix 2: Fact Sheet from List of Substances of Possible Concern modified to include values from the risk assessment**

	<b>NAME</b>	phenol, 4,4'-(1-methylethylidene)bis[2,6-dibromo-		<b>VERSION: 2004-09-09</b>
<b>1</b>	<b>IDENTIFICATION</b>			
1.1	<i>CasNo</i>	79947		
1.2	<i>EINECS/ELINCS</i>	201-236-9		
1.3	<i>Synonym</i>	tetrabromobisphenol A (TBBP-A)		
1.4	<i>Group/Function</i>	Phenol, halogen		
1.5	<i>Initial selection</i>	PBT NSDB(I), QSAR-DK(III),		
1.6	<i>Prioritised for action</i>	Date: OSPAR 2000; Lead Country: United Kingdom; Background document: OSPAR 2003		
	<b>Parameter</b>	<b>Value</b>	<b>Source/Reference</b>	<b>Remarks</b>
<b>2</b>	<b>PHYSICAL/CHEMICAL PROPERTIES</b>			
2.1	<i>Molecular weight, g/mole</i>	543,9	EU - RAR	
2.2	<i>Water solubility, mg/l</i>	0,148 1,26 2,34	EU - RAR	Measured value at 25oC and pH 5 Measured value at 25oC and pH 7 Measured value at 25oC and pH 9
2.3	<i>Vapour pressure, Pa</i>	0,00000624	EU - RAR	Measured value at 25oC
<b>3</b>	<b>ABIOTIC/BIOTIC DEGRADATION PROPERTIES</b>			
3.1	<i>Abiotic OH-oxidation t½ d</i>	5,4	EU - RAR	Estimated value for half-life 130 hours. Based upon rate constant of 2,96e-12 cm3/molecule/s estimated using AOPWIN 1.88.

3.2	<i>Photolysis t<sub>1/2</sub>d</i>			EU - RAR	The available information suggests that tetrabromobisphenol-A is susceptible to direct photodegradation using UV radiation leading to a variety of products (significance for the environment not clear).
3.3	<i>Ready Biodegradability</i>	No		EU - RAR	
3.4	<i>Halflife</i>			EU - RAR	TBBPA can undergo primary biodegradation to form several products. Based upon the available data ultimate degradation occurs around 64 days.
3.5	<i>Inherent Biodegradability</i>	No		EU - RAR	
3.6	<i>Biodeg-QSAR</i>				
<b>4</b>	<b>BIOACCUMULATION/ BIOCONCENTRATION</b>				
4.1	<i>logKow</i>	5,9		EU - RAR	Measured value.
4.2	<i>Bcf</i>	1234		EU - RAR	Representative value for fish based upon measured data.
<b>5</b>	<b>AQUATIC TOXIC PROPERTIES</b>				
5.1	<i>Acute toxicity algae IC50, mg/l</i>	>= 5,6		EU - RAR	In the experiment no effects observed at solubility limit.
5.2	<i>Acute toxicity daphnia EC50, mg/l</i>	0,96		EU - RAR	Measured 48hr LC50
5.3	<i>Acute toxicity fish LC50, mg/l</i>	0,5		EU - RAR	Measured 96hr LC50 for Pimephales promelas
5.4	<i>Chronic toxicity daphnia NOEC, mg/l</i>	0,3		EU - RAR	Measured 21 day NOEC
5.5	<i>Chronic toxicity fish NOEC, mg/l</i>	0,16		EU - RAR	Measured 35 day NOEC (Larval survival) for Pimephales promelas
5.6	<i>Aquatox-QSAR</i>				
5.7	<i>Aquatic toxicity - other species</i>	0,0066		EU-RAR	EC10 for shell regrowth in Crassostrea virginica, some uncertainties associated with this test
<b>6</b>	<b>HUMAN TOXIC PROPERTIES</b>				
6.1	<i>Acute toxicity</i>				
6.2	<i>Carcinogenicity</i>				
6.3	<i>Chronic toxicity</i>				
6.4	<i>Mutagenicity</i>				
6.5	<i>Reprotoxicity</i>				

7 EXPOSURE				
7.1	<i>Production Volume</i>	HPVC	EU-RAR	150000 (global production - not produced in Europe)
7.1	<i>Production Volume</i>	50000	Industry	
7.2	<i>Use/Industry Category</i>	The primary use of TBBPA is as a reactive intermediate in the manufacture of flame-retarded epoxy and polycarbonate resins. It may also be used as an additive flame retardant and in the manufacture of derivatives.		Source: EU-RAR
7.3	<i>Use in articles</i>			
7.4	<i>Environm.Occur. Measured</i>		Surface water: <0,001 – 0,02 ug/l	EU-RAR
7.4			Sediment: <0,2 -9752 ug/kg wwt	EU-RAR
7.5	<i>Environm.Occur. Modelled</i>		Surface water: Local PEC 0,0006 – 9,2 ug/l	EU - RAR
7.5			Sediment: Local PEC 0,005 - 43 mg/kg wet wt	EU - RAR
7.5			Agricultural soil: Local PEC 0,002 – 19,5 mg/kg wet wt	EU - RAR
7.5			Air: Local PEC < 1e-5 mg/m3.	EU - RAR
8 EU-LEGISLATION				
8.1	<i>Dir 67/548/EEC (Classification)</i>		:Annex1, Dir 67/548/EEC	
8.2	<i>Reg 793/93/EEC (Existing substances)</i>	4(UK)		
8.3	<i>Dir 2000/60/EEC (WFD)</i>			
8.4	<i>Dir 76/769/EEC (M&amp;U)</i>			
8.5	<i>Dir 76/464/EEC (water)</i>			
8.6	<i>Dir 91/414/EEC (ppp)</i>			
8.7	<i>Dir 98/8/EEC (biocid)</i>			

9	ADDITIONAL INFORMATION			
9.1	<i>Hazard assessment-OECD</i>	YES		<a href="http://www.oecd.org/ehs/sidstable/">www.oecd.org/ehs/sidstable/</a>
9.2	<i>Other risk assessments</i>			

### Appendix 3: Monitoring Strategy for Tetrabromobisphenol-A (TBBPA)

As part of the Joint Assessment and Monitoring Programme (*reference number 2003-22*), OSPAR 2005 adopted a revised Agreement on Monitoring Strategies for OSPAR Chemicals for Priority Action (*reference number 2005-?*) to implement the following monitoring for tracking progress towards the objectives of the OSPAR Hazardous Substances Strategy (*reference number 2003-21*) with regard to tetrabromobisphenol-A. The monitoring strategy for tetrabromobisphenol-A will be updated as and when necessary, and redirected in the light of subsequent experience.

The primary use of TBBPA is as a reactive intermediate in the manufacture of flame-retarded epoxy and polycarbonate resins. It may also be used as an additive flame retardant, for example in the manufacture of acrylonitrile-butadiene-styrene (ABS) resins and phenolic resins. It is also used in the manufacture of other flame retardant derivatives.

TBBPA is likely to reach the marine environment largely through industrial waste waters from land-based industrial activities. A smaller contribution to releases to water comes from particulate losses from products containing the substance over their lifetime. Emissions to air are smaller than those to water, and most such emissions are expected to be deposited close to the sources of emission. There are, however, some indications of possible transport over longer distance, possibly adsorbed to particulate matter, which could lead to a contribution to the marine environment through this route.

The Background Document reported that there were no available measured levels of tetrabromobisphenol-A in marine waters, but recorded a number of measurements of TBBPA in estuarine sediments, as well as in freshwaters, freshwater sediments and waste waters. It is therefore apparent that analytical methodologies are available, although these may need to be adapted to marine conditions.

TBBPA is undergoing risk assessment under the Existing Substances Regulation in the EU (Regulation 793/93). The UK is leading this work which is not likely to be finalised until the middle of 2005. Depending on the conclusions of the risk assessment, appropriate risk reduction measures, such as marketing and use restrictions, will be developed and agreed at EU level.

In the light of the factors listed above, and the fact that TBBPA is a flame retardant, and as such should have a similar approach to the monitoring strategy on flame retardants which has already been agreed (cf. appendix 1 to the Background Document on Brominated Flame Retardants, OSPAR publication number 135/2001), the two main components of the monitoring strategy for TBBPA are as follows:

- a. keeping a watching brief on the implementation of any measures on TBBPA, particularly in relevant EC legislation arising from the risk assessment which would enable sales and use of the chemical to be tracked;
- b. assessing the need for further monitoring to determine whether concentrations of TBBPA in marine sediments and biota are significant. In this respect, Contracting Parties are encouraged to extend their monitoring programmes to cover TBBPA and submit information to the UK who will assess whether concentrations in marine sediments and biota are significant, and whether there are gaps in knowledge which OSPAR should fill prior to the 2010 Quality Status Report. If sufficient information is not obtained in this way, a one-off exploratory survey will be considered, which might also monitor for the endocrine disruptor bisphenol-A in order to investigate whether there is a relationship between the two chemicals.

<b>TETRABROMOBISPHENOL-A MONITORING STRATEGY</b>	
<b>Implementation of actions and measures</b>	<ul style="list-style-type: none"> <li>Examination of progress in the implementation of regulations on marketing and/or use or emission and/or discharge which have been agreed, or are endorsed, by the Background Document (on-going by lead country as any EC measures develop)</li> </ul>
<b>Maritime area:</b>	
<b>Concentrations in sediments</b>	<ul style="list-style-type: none"> <li>Contracting Parties are encouraged to extend their monitoring programmes as soon as possible to cover TBBPA and to report results on a voluntary basis to the lead country and also through the data-handling mechanism operated by ICES for the CEMP.</li> <li>Before 2006 the lead country will collate information on concentrations of this substance in the marine environment in order to assess whether there is a gap in knowledge which OSPAR should fill prior to the 2010 QSR. If the information obtained through this mechanism is insufficient, the feasibility of carrying out a one-off survey should be considered<sup>10</sup>. In the light of these steps, OSPAR will decide whether the CEMP should be expanded to include monitoring for tetrabromobisphenol-A.</li> <li>The review of the CEMP in 2005-2006 will review the availability of monitoring guidelines, quality assurance procedures and assessment tools in the marine environment.</li> <li>The need for EACs and BRCs will be considered in 2006-2007</li> </ul>
<b>Concentrations in biota</b>	<ul style="list-style-type: none"> <li>Contracting Parties are encouraged to extend their monitoring programmes as soon as possible to cover TBBPA and to report results on a voluntary basis to the lead country and also through the data-handling mechanism operated by ICES for the CEMP.</li> <li>Before 2006 the lead country will collate information on concentrations of this substance in the marine environment in order to assess whether there is a gap in knowledge which OSPAR should fill prior to the 2010 QSR. If the information obtained through this mechanism is insufficient, the feasibility of carrying out a one-off survey should be considered<sup>10</sup>. In the light of these steps, OSPAR will decide whether the CEMP should be expanded to include monitoring for tetrabromobisphenol-A.</li> <li>The review of the CEMP in 2005-2006 will review the availability of monitoring guidelines, quality assurance procedures and assessment tools in the marine environment.</li> <li>Any proposal for inclusion should take into account the possible need for monitoring in relation to any relevant EcoQOs adopted by OSPAR (organohalogen concentrations in seabird eggs)</li> </ul>
<b>Biological effects</b>	<ul style="list-style-type: none"> <li>Before 2006 the lead country will collate information available on any biological effects of this substance in order to assess whether this is a gap in knowledge which OSPAR should fill prior to the 2010 QSR</li> </ul>

<sup>10</sup> The UK believes that if possible, it would be sensible to include the parallel analysis of bisphenol-A in this survey to investigate the possible links between these substances.