

ROHS Annex II Dossier for TBBP-A Restriction proposal for substances in electrical and electronic equipment under RoHS

Report No. 2
Substance Name: Tetrabromobisphenol A
(TBBP-A, flame retardant)
(2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol)
EC Number: 201-236-9
CAS Number: 79-94-7

Version 3
27/03/2020

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Abbreviations

ABS	Acrylonitrile Butadiene Styrene
BAUA	German Federal Institute for Occupational Safety and Health
bw	Body Weight
C&L	Classification and Labelling inventory
CAS number	A CAS Registry Number, also referred to as CASRN or CAS Number, is a unique numerical identifier assigned by Chemical Abstracts Service (CAS) to every chemical substance described in the open scientific literature
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH)
CoRAP	Community Rolling Action Plan
DecaBDE	Decabromodiphenylether
DEPA	Danish Environmental Protection Agency
DNEL	Derived No Effect Levels
EC number	The European Community number (EC Number) is a unique seven-digit identifier that was assigned to substances for regulatory purposes within the European Union by the European Commission
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECETOC TRA	ECETOC's Targeted Risk Assessment
ECHA	European Chemical Agency
ED	Endocrine Disruption
EEE	Electrical and Electronic Equipment
EFRA	European Flame Retardants Association
EFSA	European Food Safety Authority
ESIA	European Semiconductor Industry Association
EU RAR	EU Risk Assessment Report
FR4	Flame resistant epoxy resin binder for glass-reinforced epoxy laminate materials used in rigid printed wiring boards
GADSL	Global Automotive Declarable Substance List
HBCDD	Hexabromocyclododecane
HIPS	High Impact Polystyrene
IARC	International Agency for Research on Cancer
IPA	Fraunhofer-Institute for Manufacturing Engineering and Automatisations

ITEM	Fraunhofer-Institute for Toxicology and Experimental Medicine
Koc	Soil Adsorption Coefficient: Concentration of chemical in soil/Concentration of chemical substance in water * 100/ % organic carbon
MSDS	Material safety data sheet
n.d.	Not defined
OctaBDE	Octabromdiphenylether
OEL	Occupational Exposure Limit
OSPAR	Oslo and Paris Conventions; to protect the marine environment of the North-East Atlantic
PBT	Persistent, bioaccumulative and toxic (properties of a chemical)
PC	Polycarbonate
PET	Poly Ethylene Terephthalate
PNEC	Predicted no effect concentration
PWB	Printed Wiring Board (=printed circuit boards)
REACH	Regulation (EU) No 1907/2006 on the Registration, Evaluation, Authorisation and restriction of Chemical substances
SIN	SIN (Substitute it Now!) List of the NGO ChemSec
TBBP-A / TBBPA	Tetrabrombisphenol A
UBA	German Umweltbundesamt (Federal Environment Agency)
UK	United Kingdom
US EPA	United States Environmental Protection Agency
VECAP	Voluntary Emissions Control Action Programme
WEEE	Waste of Electrical and Electronic Equipment

CONTEXT and SCOPE of the Substance Assessment

The substance assessment of 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol or tetrabromobisphenol A (TBBP-A, flame retardant), respectively, is being performed as part of the “*Study on the review of the list of restricted substances and to assess a new exemption request under RoHS 2 – Pack 15*”. With contract No. 07.0201/2017/772070/ENV.B.3 implementing Framework Contract No. ENV.A.2/FRA/ 2015/0008, a consortium led by Oeko-Institut for Applied Ecology has been assigned by DG Environment of the European Commission to provide technical and scientific support for the review of the list of restricted substances and to assess a new exemption request under RoHS 2. This study includes an assessment of seven substances with a view to the review and amendment of the RoHS Annex II list of restricted substances. The seven substances have been pre-determined by the Commission for this task. The detailed assessment is being carried out for each of the seven substances in line with a uniform methodology.¹

In the course of the substance assessment, the 1st stakeholder consultation was held from 20 April 2018 to 15 June 2018 to collect information and data for the seven substances under assessment. Information on this consultation can be found at Oeko-Institut’s project webpage at: <http://rohs.exemptions.oeko.info/index.php?id=289>.

For TBBP-A, a total of 11 contributions were submitted by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at <http://rohs.exemptions.oeko.info/index.php?id=295>.

Among these contributions, a study from the Fraunhofer Institutes ITEM and IPA has been submitted, which is an assessment of TBBP-A performed according to the “Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS 2 Directive, thus in the format of a RoHS dossier which was mandated and funded by BSEF, the Bromine Science and Environmental Forum.² Though no date on when the study was conducted is indicated, it is understood as a very recent data compilation. In August 2018, after the stakeholder consultation was closed, the BSEF provided an updated version of this assessment. It is understood that the update overall covers the DNELs retrieved from the ECHA Registered Substance Database that has been lowered in the last years. In the following, this updated assessment is referred to as Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018).³

Nine different stakeholder contributions were received during the 2nd stakeholder consultation which was held from 05th December 2019 to 13th February 2020. The contributions can be viewed at <http://rohs.exemptions.oeko.info/index.php?id=333>.

¹ This methodology includes a dossier template for substance assessment which had been prepared by the Austrian Umweltbundesamt GmbH in the course of a previous study. The methodology for substance assessment has been revised based on various proposals from and discussions with stakeholders. Among others, revisions have been made to clarify when the Article 6(1) criteria are considered to be fulfilled and how the precautionary principle is to be applied. The methodology has also been updated in relation to coherence to REACH and other legislation and publicly available sources of relevance for the collection of information on substances have been updated and added. The methodology is available at <https://rohs.exemptions.oeko.info/index.php?id=341>

² Fraunhofer ITEM & IPA, Hesse, Susanne; Wibbertmann, Axel; Hahn, Stefan; Miehe, Robert; Müller, Sebastian (no year): Assessment of TBBP-A (tetrabromobisphenol-A) according to the “Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS2 Directive”. Update August 2018. Fraunhofer ITEM, Fraunhofer IPA, Stuttgart; submitted as part of the contribution submitted by BSEF, aisbl – The International Bromine Council during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018

³ Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018): Assessment of TBBP-A (tetrabromobisphenol-A) according to the “Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex III) under the RoHS2 Directive”. Update August 2018. Fraunhofer ITEM, Fraunhofer IPA, Stuttgart.

Areas on which stakeholders commented during the second stakeholder consultations are summarised in the order in which these issues are addressed in the dossier and include:

- The conclusions drawn from the structural comparison of BPA and TBBP-A;
- DEPA conclusions on PBT and endocrine disrupting properties are used as a basis;
- The presentation of waste management and sorting techniques;
- The references on exposure data;
- The analysis of hazards of alternatives proposed;
- The data basis of the socio-economic analysis;

A number of stakeholders have criticized the consideration in the assessment of possible impacts that the presence of a substance in EEE may have on WEEE management that takes place outside the EU, in cases where second hand EEE is exported from the EU and in cases of illegal waste exports. Recital 7 of the RoHS Directive states that despite the measures implemented through the WEEE Directive, *“significant parts of waste EEE will continue to be found in the current disposal routes inside or outside the Union”* and that even were such waste collected separately and submitted to recycling processes its contents of certain substances *“would be likely to pose risks to health or the environment, especially when treated in less than optimal conditions”*. Consideration of adverse impacts of WEEE management that take place outside the EU are thus considered to be of relevance to this review, particularly when there is evidence that EEE originally placed on the European market may be handled at end-of-life outside the EU.

One contribution explicitly stated its general agreement with the dossier and its recommendations.

Version 3 represents the final version of the RoHS Annex II dossier for TBBP-A.

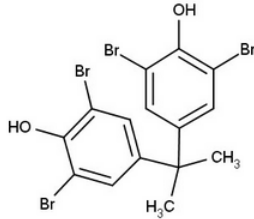
1. IDENTIFICATION, CLASSIFICATION AND LABELLING, LEGAL STATUS AND USE RESTRICTIONS

1.1 Identification

1.1.1. Name, other identifiers, and composition of the substance

The 'ECHA information on substances database' lists Tetrabromobisphenol-A (TBBP-A) and its synonymous names. The following Table 1-1 shows information on the substance identity of TBBP-A as listed in the ECHA database information on substances⁴ and the European Risk Assessment Report (EU RAR).⁵

Table 1-1: Substance identity and composition of TBBP-A and its derivatives

Chemical name	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol
EC number	201-236-9
CAS number	79-94-7
IUPAC name	2,6-dibromo-4-[2-(3,5-dibromo-4-hydroxyphenyl)propan-2-yl]phenol
Index number in Annex VI of the CLP Regulation	604-074-00-0
Molecular formula	C ₁₅ H ₁₂ Br ₄ O ₂
Bromine content	58.8 % by weight
Molecular weight (range)	543.9 g/mole
Synonyms	2,2',6,6',-tetrabromo-4,4'-isopropylidenediphenol 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol 2,6-dibromo-4-[2-(3,5-dibromo-4-hydroxyphenyl)propan-2-yl]phenol 4,4'-Isopropylidenebis(2,6-dibromophenol) 4,4'-propane-2,2-diylbis(2,6-dibromophenol) FR-1524 Tetrabromobisphenol A, TBBP-A, TBBP-A, TBBA
Structural formula	
Degree of purity	98.5 %
Remarks	-
Derivates	Tetrabromobisphenol-A dimethyl ether: CAS No. 37853-61-5 Tetrabromobisphenol-A dibromopropyl ether: CAS No. 21850-44-2 Tetrabromobisphenol-A bis(allyl ether): CAS No. 25327-89-3 Tetrabromobisphenol-A bis(2-hydroxyethyl ether): CAS No. 4162-45-2 Tetrabromobisphenol-A brominated epoxy oligomer: CAS No. 68928-70-1 Tetrabromobisphenol-A carbonate oligomers: CAS No. 94334-64-2 and 71342-77-3

Source: EU RAR 2008

⁴ ECHA Brief Profile: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2019); <https://echa.europa.eu/de/brief-profile/-/briefprofile/100.001.125>, last viewed 19.04.2018

⁵ EU RAR – European Risk Assessment Report (2008): 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol-A or TBBP-A). Final Environmental RAR of February 2008;

1.1.2. Physico-chemical properties

Physico-chemical properties of TBBP-A are summarised in Table 1-2 below and were extracted from the ECHA database information on substances⁶ and from the EU RAR.

Table 1-2: Overview of physico-chemical properties of TBBP-A

Property	Value
Physical state at 20°C and 101.3 kPa	Solid (white crystalline powder)
Melting/freezing point	178°C; 181-182°C
Boiling point	316°C (decomposes at 200-300°C)
Vapour pressure	<1.19*10 ⁻⁵ Pa at 20°C
Water solubility	0.148 mg/l at 25°C (pH 5) 1.26 mg/l at 25°C (pH 7) 2.34 mg/l at 25°C (pH 9)
Partition coefficient n-octanol/ water (log KOW)	5.90 at 25°C
Dissociation constant	9.37 - 9.43 at 20°C
Relative density	2.17
Specific gravity	-

Source: ECHA Brief Profile: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2018) and <https://echa.europa.eu/de/brief-profile/-/briefprofile/100.001.125>; RAR (2006)

1.2. Classification and labelling status

The Classification, Labelling and Packaging (CLP) regulation⁷ ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the European Union through classification and labelling of chemicals. Annex VI of Regulation No 1272/2008 lists substances where a harmonised classification exists based on e.g. human health concerns.

Annex VI of the CLP regulation is continuously adapted by engagement of Member State Competent Authorities and ECHA as far as new information becomes available, where existing data are re-evaluated or due to new scientific or technical developments or changes in the classification criteria.⁸

Further explanation on the human and environmental hazards is provided in sections 3 and 3.3.

Classification in Annex VI Regulation No 1272/2008

The harmonised classification according to Annex VI Regulation No 1272/2008 of tetrabromobisphenol A attributes the following environmental hazards to TBBP-A (see Table 1-3):

- Aquatic Acute 1 (Hazardous to the aquatic environment) – H400 (very toxic to aquatic life)
- Aquatic Chronic 1 (Hazardous to the aquatic environment) – H410 (very toxic to aquatic life with long lasting effects)

⁶ Opt. cit. ECHA Brief Profile for TBBP-A (2019)

⁷ Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

⁸ For further information, see <https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling>, last viewed 19.04.2018

Table 1-3: Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008

Index No.	International Chemical ID	EC No.	CAS No.	Classification		Labelling			Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)		
604-074-00-0	Tetrabromobisphenol-A; 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol	201-236-9	79-94-7	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09 Wng	H410	-	-	-

Source: Annex VI Regulation No 1272/2008; <https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp>, last viewed 19.04.2018

Self-classification(s)

Manufacturers, importers or downstream users are obliged to (self-)classify and label hazardous substances and mixtures to ensure a high level of protection of human health and the environment. If a harmonised classification is available, it should be applied by all manufacturers, importers or downstream users of such substances and of mixtures containing such substances.

However, mostly, suppliers decide independently as to the classification of a substance or mixture, which is then referred to as self-classification. Therefore, self-classification might indicate an e.g. additional hazard which is so far not reflected by the harmonised classification. The following assessment of the self-classification therefore emphasises cases where self-classifications differ and where additional hazards were notified in the self-classification.

According to the ECHA database 'C&L Inventory', which contains classification and labelling information on notified and registered substances received from manufacturers and importers, there is a total number of 501 notifications for tetrabromobisphenol A (as of September 2019).⁹ Most notifications refer to the harmonised classification and specify TBBP-A as very toxic to aquatic life (Aquatic Acute 1, H400) and as very toxic to aquatic life with long lasting effects (Aquatic Chronic 1, H410). The joint classification (16 notifiers) and an additional 29 notifiers also refer to TBBP-A as suspected of causing cancer (Carc. 2, H351).

1.3. Legal status and use restrictions

1.3.1. Regulation of the substance under REACH

TBBP-A was included in the Community Rolling Action Plan (CoRAP) by the Danish EPA (Danish Ministry of the Environment). The inclusion was motivated by the following concerns:¹⁰

- Suspected reprotoxicity;
- Potential endocrine disruptor;
- Suspected persistent, bioaccumulative and toxic (PBT/vPvB);

⁹ ECHA Registered Substances Database (2019): Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol; <https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.125> (visited on 10.10.2019)

¹⁰ ECHA Substance Evaluation CoRAP (2019): Entry for TBBP-A (last viewed 10.10.2019)

- Use in large amounts of consumer products;
- Exposure of environment;
- Exposure of workers;
- High (aggregated) tonnage; and
- Wide dispersive use.

In March 2017, the ECHA requested the provision of further information concerning the endocrine disruptive properties of TBBP-A and the exposure and PBT properties (particularly persistency / environmental fate of methylated transformation products of TBBP-A (e.g. bismethyl ether TBBP-A and monomethyl ether TBBP-A)). The requested information is to be provided until 4 January 2021 (ECHA 2017).¹¹

1.3.2. Other legislative measures

WEEE shall be collected separately from household waste, according to the collection targets specified WEEE Directive, and then recycled. Directive 2012/19/EU (WEEE Directive) stipulates that plastics-containing brominated flame retardants have to be removed from separately collected WEEE. That plastic fraction shall be disposed of or recovered in compliance with Waste Framework Directive 2008/98/EC. In the EU, collection and recycling of WEEE, containing TBBP-A, shall be implemented according to the following standards:

- EN 50625-1: Collection, logistics & treatment requirements for WEEE - Part 1: General treatment requirements;
- TS 50625-5: Collection, logistics & treatment requirements for WEEE -- Part 5: Specification for the end-processing of WEEE fractions- copper and precious metals.

1.3.3. Non-governmental initiatives

The OSPAR Convention of 1992 sets out to prevent and eliminate pollution and to take necessary measures to protect the maritime environment against the adverse effects of human activities. It aims to safeguard human health and to conserve marine ecosystems and, when practicable, to restore marine areas which have been adversely affected. TBBP-A was included in the OSPAR List of Chemicals for Priority Action in 2000. TBBP-A is considered to meet all three of the OSPAR criteria for the PBT (persistent, bioaccumulative and toxic) assessment, though it is noted that TBBP-A is a borderline case regarding the bioaccumulation criterion (OSPAR 2011).¹² Despite the OSPAR listing, TBBP-A does not meet the criteria for a PBT or a vPvB substance under REACH.

Another compilation of potential substances of concern – the so-called “SIN List” – has been developed and regularly updated by the independent non-profit organisation Chemsec (International Chemical Secretariat). The SIN list is meant to put pressure on legislators to assess substances listed therein and enact chemical legislation where necessary. TBBP-A was added to the SIN List for the reason that it is potentially persistent and bioaccumulative and that endocrine effects have been reported. It has been frequently found in humans and the environment.”¹³

¹¹ ECHA Substance Evaluation Decision (2017)

¹² OSPAR (2011): Background Document on tetrabromobisphenol-A.

¹³ ChemSec (2019)

Various eco-label schemes address the substance group of halogenated flame retardants. The voluntary application of eco-labels requires their users to comply with the environmental safety precautions prescribed in the respective award criteria. TBBP-A is not allowed in products under the following eco-label schemes: The German Blue Angel label for hair dryers and TV sets requires that *“halogenated polymers shall not be permitted. Neither may halogenated organic compounds be added as flame retardants. Moreover, no flame retardants may be added which are classified pursuant to Table 3.1 or 3.2 in Annex VI to Regulation (EC) 1272/2008 as very toxic to aquatic organisms with long-term adverse effect and labelled with Hazard Statement H 410 or Risk Statement R 50/53.”* Process-related, technically unavoidable impurities; fluoroorganic additives used to improve the physical properties of plastics (provided that they do not exceed 0.5 percent weight) and plastic parts less than 25 grams in mass are exempt from this rule (DE-UZ 145 and DE-UZ 175). The Nordic Swan requires that a variety of organic halogenated flame retardants and other flame retardants that are assigned one or more hazard statements (H340–360) must not be added to products (Oeko-Institut 2014a).¹⁴

The harmonised classification of TBBP-A does not include any of these hazard classifications (i.e. H340–360), however, TBBP-A has been specified in self-classifications as suspected of causing cancer.

In 2009, the International Electronics Manufacturing Initiative (iNEMI) published a position statement proposing a threshold for the presence of bromine in EEE components specified to be “low halogen.”¹⁵ The position paper supports the following definition of “low halogen” (BFR-/CFR-/PVC-free) electronics: *“A component* must meet all of the following requirements to be Low Halogen (“BFR/CFR/PVC-Free”):*

- *All printed board (PB) and substrate laminates shall meet Br and Cl requirements for low halogen as defined in IEC 61249-2-21 and IPC-4101B (refer to International Electrochemical Commission’s (IEC) and Association Connecting Electronics Industries (IPC) standards for actual requirements) saying that for non-halogenated epoxide with a glass transition temperature of 120°C degree minimum, the maximum total halogens contained in the resin plus reinforcement matrix is 1,500 ppm with a maximum chlorine of 900 ppm and maximum bromine being 900 ppm.*
- *For components* other than printed board and substrate laminates: Each plastic within the component contains < 1,000 ppm (0.1 %) of bromine [if the Br source is from BFRs] and < 1,000 ppm (0.1 %) of chlorine [if the Cl source is from CFRs or PVC or PVC copolymers].”*

iNEMI member companies endorsing this position statement are: Cisco, Dell Inc., Doosan Corporation, HP, Intel Corporation, Lenovo, Nan Ya Plastics Corporation, Senju Comtek Corp. Sun Microsystems, Inc. and Tyco Electronics.

Moreover, TBBP-A is on several other substance lists (e.g. at member state level the List of Undesirable Substances of the Danish EPA¹⁶ and at industry level on the Global Automotive Declarable Substance List (GADSL)).¹⁷ The European brominated flame retardant industry has included TBBP-A in its Voluntary Emissions Control Action Programme (VECAP) which is a voluntary product

¹⁴ Oeko-Institut (2014a): Osmani, D.; Dodd, N.; Wolf, O.; Graulich, K.; Bunke, D.; Groß, R.; Liu, R.; Manhart, A.; Prakash, S.; Development of European Ecolabel and Green Public Procurement Criteria for Desktop and Notebook Computers and Televisions, prepared by JRC-IPTS and Oeko-Institut e.V. – Institute for Applied Ecology for the Joint Research Centre (JRC) — Institute for Prospective Technological Studies (IPTS), Sevilla

¹⁵ iNEMI (2009), iNEMI Position Statement on the Definition of “Low-Halogen” Electronics (BFR/CFR/PVC-Free)

¹⁶ Danish Ministry of the Environment (DEPA) (2011): List of Undesirable Substances 2009

¹⁷ GADSL (2018) Global Automotive Declarable Substance list

stewardship scheme.¹⁸ The VECAP progress report of 2017 declares that 90 % of TBBP-A was handled according to the best practices as specified by VECAP “gold standard”.¹⁹ That code of conduct aims to control emissions during handling and use of brominated flame retardants.

¹⁸ <https://www.vecap.info>, last viewed 04.09.2019

¹⁹ The European brominated flame-retardant industry (2017) The European Progress Report VECAP; referred to as VECAP (2017)

2. USE IN ELECTRICAL AND ELECTRONIC EQUIPMENT

2.1. Function of the substance

The primary use of TBBP-A is as a precursor in the production of brominated epoxy resins that function as reactively flame-retarded substrate in printed wiring boards (PWB). It is also used as an additive flame retardant in thermoplastic EEE components, for example housings that consist of ABS plastic. The most recent available data (2014) on proportions for the different types of application indicate that ~90 % of TBBP-A are used for the production of FR4 PWB in form of a reactive flame retardant, while only 10 % are used as an additive flame retardant.²⁰ However, according to Fraunhofer ITEM IPA, Wibbertmann & Hahn (2018), the available literature data on uses varies widely (~70-90 % reactive use).²¹

The following sections outline the two different forms of use in EEE products.

2.2. Types of applications / types of materials

Reactive flame retardant

As outlined in earlier works (Oeko-Institut, 2014b)²² and confirmed by stakeholders (e.g. AEM 2018; ZVEI, 2018)^{23 24} more recently, the primary use of TBBP-A is as a reactive intermediate in the manufacture of flame-retarded epoxy and polycarbonate resins.

In almost all epoxy-based PWBs of the FR4 type, TBBP-A – together with an epoxy-group containing di-carboxylated monomer – is a precursor for the epoxy resin material. After the polymerisation, this structure of the epoxy resin alternately consists of the two former monomers covalently linked via ester or ether bonds. Therefore, reacted TBBP-A lacks its original chemical signature and the substance is unlikely to be liberated from PWBs in its original substance identity. In these uses, the substance is chemically bound to the polymer and becomes thus an integrated part of the polymer matrix. Hence, the chemical identity of TBBP-A is altered during the production process of EEE components.

Regarding the chemical transformation of TBBP-A within the epoxy or polycarbonate resin formation, it is understood from stakeholder contributions as well as from other literature that the formation of these polymers requires (beside the epoxides and carbonates) a di-hydroxyl substituted counterpart as a reacting agent. By default, bisphenol-A (BPA) is used as a precursor, but TBBP-A can partly substitute the BPA in order to act as a carrier of bromine which provides the resin with flame retardant

²⁰ Oeko-Institut (2014b): Study for the Review of the List of Restricted Substances under RoHS 2. Analysis of Impacts from a Possible Restriction of Several New Substances under RoHS 2 by Gensch, C.-O., Baron, Y. Blepp, M., Bunke, D., Moch, K.

²¹ Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

²² Op cit. Oeko-Institut 2014b

²³ Association of Equipment Manufacturers (AEM; 2018): Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

²⁴ Zentralverband Elektrotechnik- und Elektroindustrie e.V. (ZVEI; 2018) –Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

properties. As mentioned above, the intrinsic substance characteristics of TBBP-A no longer exist in these polymers as the functional OH-groups are changed into C-O-C-ether or ester-bonds firmly fixed in the polymer matrix.^{25 26 27}

As a reactive flame retardant, TBBP-A is applied in printed wiring boards (PWBs), but also in epoxy resin sealants, adhesives and encapsulations. Thus, the two main applications for epoxy resins that contain reacted TBBP-A as a flame retardant in EEE are:

- Laminated printed wiring boards PWB (designated FR4-type): rigid FR4-PWBs are used in nearly all types of EEE. It can be understood from Rakotomalala et al. (2010) that PWB containing reacted TBBP-A in form of epoxy resins have been used widely in the past and up to now. At present, FR4-PWBs are still the most common type of printed wiring board in the EEE sector. Industry stakeholders such as TMC report that TBBP-A-based FR4-PWBs are used in “*the entire portfolio of products*”²⁸. Though market surveillance data provided by DEPA shows that TBBP-A concentrations are found mainly in polymer or composite product parts, in a few cases they have also been found in PWBs of commercial products.²⁹

These uses have also been mentioned by stakeholders in the 1st consultation of this substance evaluation program (BSEF, ZVEI, TMC, MedTech, JEITA, ASD and AEM, all 2018, as can be seen from concrete contributions linked in the Appendix).

- Epoxy resins are also used to encapsulate certain electronic components mounted directly on printed wiring boards. Examples are: plastic / paper capacitors, integrated circuits (e.g. microprocessors), bipolar power transistors, IGBT (Integrated Gate Bipolar Transistor) power modules, ASICs (Application Specific Integrated Circuits) and metal oxide varistors. This use of TBBP-A has been described by Oeko-Institut (2008), but has not been confirmed recently by any of the stakeholder contributions.

Additive flame retardant

TBBP-A is also used as an additive flame retardant in thermoplastic EEE components. The substance is non-covalently included in the polymer matrix. Non-covalent bonds are generally weaker than chemically reacted bonds, and therefore TBBP-A remains principally unchanged during the normal product use phase and enters the WEEE treatment processes in its original form. Where used as an additive flame retardant, TBBP-A is reported to be used in combination with antimony oxide for maximum performance.^{30 31} According to Fraunhofer ITEM IPA, Wibbertmann & Hahn

²⁵ Test and Measurement Coalition (TCM) (2018): Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

²⁶ Alaei, M.; Arias, P.; Sjödin, A.; Bergman, Å. (2003): An overview of commercially used brominated flame retardants, their applications, their use patterns in different countries/regions and possible modes of release. Environ. Int. 29, 683-689.

²⁷ Buekens A. and Yang J.: Recycling of WEEE plastics: A Review in J Mater Cycles Waste Manag (2014): 16:415–434

²⁸ Op. cit. TCM (2018)

²⁹ Danish Environmental Protection Agency (DEPA; 2018): Contribution submitted (Part II) during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

³⁰ Op. cit. TMC 2018

³¹ MedTech Europe (2018): Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted

(2018),³² the thermoplastic which is of relevance concerning additive use of TBBP-A is acrylonitrile-butadiene-styrene (ABS). The material is considered to be the predominant plastic type in EEE products housings and packaging of electronic components. TBBP-A levels in ABS are usually 12 % to 16 % with a maximum of up to 22 %. Levels of ~14 % have been reported for HIPS which is the other polymer material that TBBP-A is used with (but to a lesser extent).³³

As an additive flame retardant, TBBP-A is applied in EEE products. Examples of RoHS-relevant EEE products are computer monitors, tablets, notebook computers, printers, office machines, TV sets, other consumer electronics (electric toothbrush and straightener), medical and industrial electronics and small household appliances (electric plugs). Computer housings seem to be the most relevant application area.^{34 35} According to EMPA (2010),³⁶ ~30 % of housings of IT-appliances made of ABS are treated with TBBP-A, while the remaining housings use different flame retardants.

In their contributions to the 1st consultation, the stakeholders mention additive use of TBBP-A e.g. that “*relatively small amounts of TBBP-A [are] added to ABS (and possibly other polymers)*”.³⁷ JEITA (2018) summarise that “*TBBPA may be contained in EEE when it is used as additive flame retardant*”, however, they “*don’t have exact information of resulted compounds*”³⁸ According to ZVEI (2018), any additive use of TBBP-A as flame retardant in Electric and Electronic equipment, e.g. in housing, is not known in Europe. In imported articles, however, the use of TBBP-A as an additive flame retardant needs to be further taken into account.

It is noteworthy that TBBP-A can also be found in a wide range of non-EEE applications that do not fall in the scope of RoHS, presumably construction materials and textiles. However, recent innovation trends point towards an integration of smart electronic functions in all sorts of technical artefacts and formerly non-EEE products. This poses concern over a possible growth in numbers of goods and mass flow of additively flame retarded materials falling newly under the scope of RoHS due to the integration of EEE parts into these products. However, this issue is not specific to TBBP-A.

Intermediate (e.g. for the production of other flame retardants)

In the EU RAR (2008), the use of TBBP-A in the manufacture of derivatives is mentioned; however, it is also mentioned as being a less relevant type of application. The main derivatives are TBBP-A dimethyl ether, TBBP-A dibromopropyl ether, TBBP-A bis(allyl ether), TBBP-A bis(2-hydroxyethyl ether), TBBP-A brominated epoxy oligomer, and TBBP-A carbonate oligomers. The main use of these derivatives is also as flame retardants, usually for the purpose of tuning the reactive properties

substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

³² Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

³³ BSEF (2020): Contribution submitted during the TBBP-A stakeholder consultation conducted from 5 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (Pack 15); see the link to the contribution in the Annex.

³⁴ Op. cit. Oeko-Institut (2014b)

³⁵ Op. Cit. DEPA 2018, Part II: Six of the tested components containing both TBP (tribromophenol) and TBBP-A had concentrations above 1000 ppm.

³⁶ Wäger, P., et al. (2010) RoHS Substances in Mixed Plastics from Waste Electrical and Electronic Equipment. Swiss Federal Laboratories for Materials Science and Technology (EMPA). September 17, 2010.

³⁷ Op. cit. AEM (2018)

³⁸ Japan Electronics and Information Technology Industries Association (JEITA; 2018) : Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

of the flame retardant according to special desired properties of the polymer matrix.³⁹ In this case, TBBP-A is used as an intermediate chemical and will not be present in final products.

2.3. Quantities of the substance used

Different data on TBBP-A tonnages have been published, but the most recent data, as cited by e.g. Fraunhofer Institute ITEM and IPA (2018),⁴⁰ originate from already five years ago (Oeko-Institut 2014b) except for the ECHA Registered Substance Database. The stakeholder consultation did not yield more contemporary information on amounts.

The information from the joint submission of the TBBP-A registration at ECHA indicates a total tonnage band of 1,000 to 10,000 tonnes per annum for manufactured and/or imported TBBP-A.⁴¹ The quantities for the use of TBBP-A as reactive flame retardant were indicated to be approximately 5,850 tonnes per year.⁴² Compared to earlier research, this seems to be a clear decrease. Data for 2003/2005 indicated ~ 40,000 tonnes of TPPB-A per year found in WEEE in the EU.^{43 44} However, it remains unclear whether the reported tonnage also accounts for the reacted TBBP-A that are part of flame retarded epoxy resins. Additionally, to the basic chemical, the import of TBBP-A-containing articles or half-finished products to the EU is most likely to happen in relevant quantities and needs to be taken into account as in such cases quantities would not be covered in the ECHA registration data.

An overall increasing trend of the global market volume of TBBP-A was reported since the 1990s.⁴⁵ Based on data from 2001, the EU RAR⁴⁶ refers to a global consumption of ~ 120,000 t/a. A very similar estimation was independently reached by Morose (2006),⁴⁷ who estimated a worldwide market demand for TBBP-A of 119,700 t/a in 2001. Covaci et al.⁴⁸ reported 170,000 t/a in 2004 globally of which ~ 18 % were used to produce derivatives and oligomers, the other 82 % went into ABS or laminates for PWBs. According to a report by the German Umweltbundesamt from 2008,⁴⁹ 145,000t/a TBBP-A were used globally (with 7,000 t/a being used in the EU).

³⁹ Op. Cit. EU RAR (2008)

⁴⁰ Op. Cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

⁴¹ Op. Cit. ECHA Registered Substances Database (2019)

⁴² Op. Cit. Oeko-Institut (2008)

⁴³ Op. Cit. Oeko-Institut (2008)

⁴⁴ Thereof, 6,600 t/a in form of a basic chemical, 6,000 t/a as partly finished products (in the form of master batch, epoxy resins etc.-) and 27,500 t/a in form of finished products and components).

⁴⁵ International Agency for Research on Cancer IARC (2015): Some Industrial Chemicals. IARC Monographs on the evaluation of carcinogenic risks to human. Section on tetrabromobisphenol A, p. 247 – 290.

⁴⁶ Op. cit. EU RAR on TBBP-A (2008)

⁴⁷ Morose, G., An Overview of Alternatives to Tetrabromobisphenol A (TBBP-A) and Hexabromocyclododecane (HBCD) (2006): Lowell, MA, USA

⁴⁸ Cited by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

⁴⁹ UBA (2008): Bromierte Flammschutzmittel –Schutzengel mit schlechten Eigenschaften.

Table 2-1: Summary of reported annual amounts of TBBP-A used in the EU

Application	Different specifications of the use amounts
Epoxy resins in printed wiring boards (reactive component)	<ul style="list-style-type: none"> • 900 – 2,250 t/a (90 % of the EU sales numbers of TBBP-A according to a stakeholder contribution of the European Flame Retardants Association EFRA in 2014)⁵⁰ • 5,850 t/a (Oeko-Institut, 2008)
Others <ul style="list-style-type: none"> • Epoxy resins to encapsulate certain electronic components (reactive component)⁵¹ • Polycarbonate and unsaturated polyester resins (reactive component) • ABS thermoplastic (additive flame retardant) 	<ul style="list-style-type: none"> • 100 – 250 t/a (10 % of the EU sales numbers of TPPBA according to a stakeholder contribution of the European Flame Retardants Association EFRA in 2014)
Total	<ul style="list-style-type: none"> • 1,000 to 10,000 t/a (ECHA Registered Substance Database, 2019) • 1,000 – 2,500 t/a (EU sales volume of TPPBA according to a stakeholder contribution of the European Flame Retardants Association EFRA in 2014) • 7,000 t/a (German UBA, 2008) • 40,000 t/a (Oeko-Institut, 2008)

Source: ECHA Registered Substances Database: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2018); EFRA 2014, Oeko-Institut 2008, Oeko-Institut 2014b, UBA (2008).

Aside from the use of TBBP-A in the manufacture of flame retarded printed wiring boards, there is a lack of detailed data for any other applications. The European brominated flame retardant industry (2017) states that only 59 % of TBBP-A traded on the EU market could be accounted for while the rest end up in unknown destinations.⁵² This may create the impression that the demand of TBBP-A used in Europe has recently decreased down to between 1,000 to 2,500 tonnes (EFRA 2014),⁵³ compared to the quantity reported by Oeko-Institut in 2008 and the submitted data to the ECHA registration system. Thus, these data as well as sales numbers of EFRA must also be viewed with caution, as these numbers only represent TBBP-A manufactured or imported for use in manufacture taking place in the EU. However, the amount of TBBP-A being incorporated in imported goods that are placed on the EU market is unknown. For example, it remains unclear whether the use of TBBP-A as additive flame retardant is more usual in the manufacturing of housings and enclosures outside the EU, and thus EEE with additive TBBP-A enter the market in imported articles. The majority of such goods containing PWBs and flame retarded ABS housings are imported from China. Hence,

⁵⁰ Op. Cit. Oeko-Institut (2014b)

⁵¹ Plastic/paper capacitors, microprocessors: used in plastic/paper capacitors, microprocessors, bipolar power transistors, IGBT (Integrated Gate Bipolar Transistor) power modules, ASICs (Application Specific Integrated Circuits) and metal oxide varistors)

⁵² Op. cit. VECAP (2017)

⁵³ European Flame Retardants Association EFRA (2014): Contribution submitted during stakeholder consultation on 04.04.2014 by Oeko-Institut in the course of the study for the Review of the List of Restricted Substances under RoHS 2. Analysis of Impacts from a Possible Restriction of Several New Substances under RoHS 2 (Oeko-Institut 2014)

an unknown quantity of TBBP-A may enter the EU in form of imported final goods as well as intermediate products and components (e.g. master-batch plastic granulate, epoxy resins).⁵⁴ This means that the figures mentioned in Table 2-1 are most likely an underestimation.

⁵⁴ Op. cit. Oeko-Institut (2014b)

3. HUMAN HEALTH HAZARD PROFILE

According to the harmonised classification in Annex VI of the CLP Regulation, TBBP-A is not classified for human health hazards. However, 13 notifiers, among them a joint submission of a REACH registration dossier, classify TBBP-A as carcinogenic Category 2 (H351 - Suspected of causing cancer). In summary, the C&L brief for TBBP-A, provided by ECHA, states that *“this substance is suspected of causing cancer”*.⁵⁵

The most recent report of DEPA (2015),⁵⁶ which was prepared for the purpose of justifying the selection of TBBP-A for CoRAP inclusion, summarised that there is potential for endocrine disrupting effects and toxic effects on reproduction and development (see explanation in the following section).

The concerns about TBBP-A, being suspected PBT, are summarised in the section on environmental hazards (section 3.3).

3.1. Endpoints of concern

On the potential endocrine disrupting effect of TBBP-A, DEPA⁵⁷ summarises the following:

“In vitro studies have demonstrated that TBBP-A has a high potency in competing with T4 for binding to transthyretin (TTR) in animals, however no firm conclusions regarding the affinity of TBBP-A for TTR in vivo can be drawn from the limited data available. The main target for TBBP-A human toxicity is thyroid hormone homeostasis, and most of the studies indicated a decrease in serum T4. In addition, weak estrogenic potency has been found, but TBBP-A did not induce CYP1, CYP2B1 or CYP3A mRNA, protein and respective monooxygenase activities. The BMDL₁₀ of 16 mg/kg bw for changes in circulating thyroid hormone levels could, in principle, be used as the basis to derive a human health-based guidance value.

Furthermore, Environment Canada/Health Canada reported that there is some recent evidence to suggest that TBBP-A may be capable of disrupting normal functioning of the thyroid system in amphibians and fish, and enhancing immune system activity in marine bivalves. This may further support the findings already described.”

The acute toxicity of TBBP-A is reportedly rather low by all routes of exposure (oral, dermal, inhalation) as well as for repeated dose toxicity. Information on effects is not available. Furthermore, the EU RAR (2008) stated that there was no data on carcinogenicity nor information that indicated toxicologically significant effects on fertility or reproductive performance at doses of up to 1,000 mg/kg.

The consultants note however that the EU RAR is older (2008) and based on data generated prior to its publication. It thus needs to be assumed that the statements of Environment Canada/Health Canada cited by DEPA (2015) regarding human toxicity and endocrine properties may be based on more recent data. The current substance evaluation under REACH based on DEPA (2015) anyhow aims to generate current data regarding endocrine disruption and PBT properties.

In its contribution to the 2nd stakeholder consultation, the Norwegian Environment Agency indicated their notification to ECHA’s Registry of Intention (RoI) that it will develop a proposal for classification

⁵⁵ Opt. cit. ECHA Brief Profile: Entry for TBBPA (2019)

⁵⁶ Danish Environmental Protection Agency DEPA (2015): Justification for the selection of a substance for CoRAP inclusion, 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol

⁵⁷ Opt. cit. DEPA (2015)

with Denmark. The foreseen classification is “Carc 1B” (H350 “May cause cancer”) and is to be submitted on 1 June 2020.⁵⁸ Here too, the consultants assume that the last efforts of DEPA and the Norwegian Environment Agency have allowed gathering more recent test results that support a classification of TBBP-A as “Carc 1B” (H350 “May cause cancer”).

3.2. Existing Guidance values (DNELs, OELs)

Information regarding existing guidance values in the form of derived no effect levels (DNELs) and occupational exposure levels have been extracted from the publicly available ECHA databases, which are based on information from the REACH registration dossiers. It should be stressed that information provided by registrants has not been subject to scrutiny by ECHA or any EU expert group. It should be further noted that the pending evaluation of TBBP-A as a potential endocrine disrupter would result in a repeal of these DNELs.

The DNELs for TBBP-A extracted from the ECHA Brief Profile are summarised in the table below.

Table 3-1: Derived no effect levels (DNELs) for TBBP-A

Population	Local / systemic effect	Effects	Threshold: DNEL
Workers	Inhalation Exposure	Systemic Effect Long term	17.6 mg/m ³
	Dermal Exposure	Systemic Effect Long term	250 mg/kg bw/day
General Population	Inhalation Exposure	Systemic Effect Long term	4.3 mg/m ³
	Dermal Exposure	Systemic Effect Long term	125 mg/kg bw/day
	Oral Exposure	Systemic Effect Long term	2.5 mg/kg bw/day

Source: ECHA Brief Profile: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2018)

3.3. Non-testing information opposing existing DNELs

TBBP-A molecules exhibit a notable structural similarity to bisphenol A (BPA) molecules and furthermore there is “*some evidence that TBBP-A can degrade to give bisphenol A under certain anaerobic conditions, and that bisphenol-A is stable under these same conditions*”, according to the EU RAR (2008). Bisphenol A has been identified as a substance of very high concern (SVHC) because of its endocrine disrupting properties (article 57(f)). BPA causes probable serious effects to the environment, which give rise to an equivalent level of concern to those of CMR and PBT/vPvB properties.⁵⁹ The SVHC identification of bisphenol A (and other structurally derived compounds)

⁵⁸ Norwegian Environment Agency (2020), Contribution of the Norwegian Environment Agency submitted during the stakeholder consultation conducted from 05 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15), see the link to the contribution in the annex; Link to the Registry of Intent: <https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e184330ec8> (last accessed 17.03.2020)

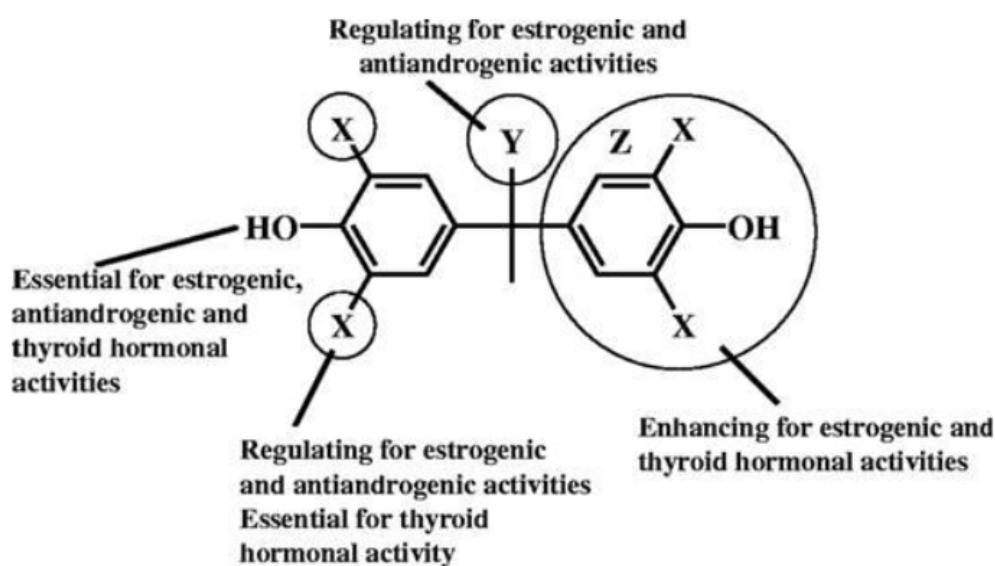
⁵⁹ European Chemicals Agency ECHA (2017): SVHC SUPPORT DOCUMENT - 4,4'-ISOPROPYLIDENEDIPHENOL

signals structural alerts that call for different modes of necessary actions to be taken. They are summarised as follows (structural abbreviations correspond to Figure 3-1):

“To exert estrogenic activity, an unhindered hydroxyl group (OH-) on an aryl ring and a hydrophobic group on the para-position to the hydroxyl group (-C(-Y)₂-) is required. The hydroxyl group on one phenyl ring is also essential for an anti-androgenic activity of bisphenols. [...] Kitamura et al. (2005)⁶⁰ demonstrated that a 4-hydroxyl group and double substitution by a halogen or methyl group at the 3,5-positions (X) of the A-phenyl group are essential for thyroid hormone activity of bisphenol.”

As shown in Table 1-1, TBBP-A has the chemical structure presented in Figure 3-1 with the substituent X being bromine atoms and Y being methyl groups. Given the structural similarity of TBBP-A with BPA, it can be inferred that TBBP-A exhibits similar endocrine disrupting properties.

Figure 3-1: Structural alerts in phenols important to exert different hormonal activities



Source: Kitamura et al. (2005) cited by European Chemicals Agency ECHA (2017)

⁶⁰ Kitamura et al. (2005). Comparative study of the endocrine-disrupting activity of bisphenol A and 19 related compounds. *Toxicological sciences: an official journal of the Society of Toxicology* 84, 249-259.

According to Alaei et al (2003), “the key concern with TBBPA is its similarity in chemical structure to thyroxine (T4). It was shown that in in vitro T4-TTR assay TBBPA has stronger affinity for binding with the thyroid hormone transport protein transthyretin (TTR) than the natural ligand T4”. Since then, several peer-review studies report endocrine disrupting properties of TBBP-A such as Fini et al. (2007) or Shaw et al. (2010).^{61 62} Although, opposing studies exist such as a review by Colnot et al. (2014) that state “adverse effects might be considered to be related to disturbances in the endocrine system. Therefore, in accordance with internationally accepted definitions, TBBPA should not be considered an “endocrine disruptor”.⁶³

The following thresholds for the DNELs for BPA have been published in its ECHA brief profile. Comparing the DNELs of BPA (Table 3-2) with those of TBBP-A in Table 3-1 leads to the conclusion that thresholds are much lower for BPA. With regard to the structural similarity of BPA and TBBP-A, it can be anticipated that both substances show similar PBT & ED properties. Thus, DNELs of BPA might be applied for TBBP-A ad interim until the results of the ongoing substance evaluation led by the Danish EPA (Danish Ministry of the Environment) (see section 1.3.1) are available; requested test results for the endocrine disruptive property of TBBP-A should become available presumably in 2021. Since the ED expert group of ECHA is currently reviewing TBBP-A concerning its possible endocrine disrupting properties, the upcoming results of that assessment should be heeded for in the RoHS substance evaluation.⁶⁴

Table 3-2: Derived no effect levels (DNELs) for BPA

Population	Local / systemic effect	Effects	Threshold: DNEL
Workers	Inhalation Exposure	Systemic Effect Long term	2 mg/m ³
	Dermal Exposure	Systemic Effect Long term	31 µg/kg bw/day
General Population	Inhalation Exposure	Systemic Effect Long term	1 mg/m ³
	Dermal Exposure	Systemic Effect Long term	1.9 µg/kg bw/day
	Oral Exposure	Systemic Effect Long term	4 µg/kg bw/day

Source: ECHA Brief Profile: Entry for 4,4'-isopropylidenediphenol (2019)

⁶¹ Fini, J.-B., Le Mével, S., Turque, N., Palmier, K., Zalko, D., Cravedi, J.-P., and Demeneix, B.A. (2007). An In Vivo Multiwell-Based Fluorescent Screen for Monitoring Vertebrate Thyroid Hormone Disruption. *Environmental Science & Technology* 41, 5908-5914.

⁶² Shaw, S.; Blum, A.; Weber, R.; Kannan, K.; Rich, D.; Lucas, D.; Koshland, C.; Dobraca, D.; Hanson, S.; Birnbaum, L. (2010). "Halogenated flame retardants: do the fire safety benefits justify the risks?". *Reviews on Environmental Health*. 25 (4): 261–305.

⁶³ Colnot, T., Kacew, S. & Dekant, W. Mammalian toxicology and human exposures to the flame retardant 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (TBBPA): implications for risk assessment; *Arch Toxicol* (2014) 88: 553

⁶⁴ Endocrine disruptor assessment list: <https://echa.europa.eu/de/ed-assessment/-/dislist/details/0b0236e180932f8a> (last viewed on 29.10.2019)

4. ENVIRONMENTAL HAZARD PROFILE

According to the harmonised classification and labelling, TBBP-A is very toxic to aquatic life and is very toxic to aquatic life with long lasting effects.

The environmental hazard evaluation process for TBBP-A, which concerns the endocrine disruptive as well as the PBT properties, is still ongoing⁶⁵ and will be pending until at least 2021.⁶⁶

Nevertheless, some preliminary information on adverse impacts on biota has been gathered as a result of various studies:

- The endocrine disruptive properties of TBBP-A may cause effects on the thyroid hormone system of aquatic organisms by possible interference with oestrogen signalling. This concern was expressed by the Danish EPA and is based on various studies including both *in vitro* and *in vivo* assays. This concern is currently being analysed by means of a Larval Amphibian Growth and Development Assay (LAGDA) (test method: OECD 241).
- The persistency of one transformation product of TBBP-A, monomethyl ether TBBP-A (Phenol, 4,4'-(1-methylethylidene)-bis[2,6-dibromo-]) is under evaluation. Further information will be requested in respect to the bioaccumulation potential and potentially hereafter on the chronic toxicity towards aquatic organism and/or mammalian species.

The following sections on the environmental properties are based on data of the EU RAR (2008)⁶⁷ and from the ECHA Registered Substance Database.⁶⁸

4.1. Environmental fate properties

The EU RAR (2008) concludes that TBBP-A is persistent or potentially very persistent according to the criteria used under REACH. It is understood that primary biodegradation occurs only under specific environmental circumstances, e.g. under anaerobic conditions. The main degradation product found was bisphenol-A (BPA), which is persistent under anaerobic conditions (EU RAR 2008). BPA is recognised as SVHC for endocrine disrupting properties for the environment as well as for human health.

According to the ECHA Decision on Substance Evaluation (2017), TBBP-A transforms in natural sediments to monomethyl ether TBBP-A, a substance that is also suspected of meeting PBT criteria.

McCormick et al. (2010)⁶⁹ examined the relative toxicity of TBBP-A and its two known degradation products BPA and TBBP-A DME using the exposure model of embryonic zebrafish. Their data showed “*an increase in embryo or larval mortality following developmental exposure to TBBP-A or BPA. TBBP-A DME exposure, however, did not result in death as compared to control embryos after one-week post-fertilization. TBBP-A proved to be 10 times more potent than BPA or TBBPA DME exposure.*”

⁶⁵ Op. cit. ECHA Substance Evaluation Decision (2017)

⁶⁶ The test results have to be submitted by 04.01.2021; thereafter the MSCA have to review the submission.

⁶⁷ Op. cit. EU RAR 2008

⁶⁸ Op. cit. ECHA Registered Substances Database: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2019)

⁶⁹ McCormick et al. Embryonic exposure to tetrabromobisphenol A and its metabolites, bisphenol A and tetrabromobisphenol A dimethyl ether disrupts normal zebrafish (*Danio rerio*) development and matrix metalloproteinase expression *Aquatic Toxicology* 100 (2010) 255–262

4.2. Endpoints of concern

The US EPA (2015) estimated the distribution of TBBP-A in the environment as follows: Air = 0 %, Water = 1.4 %; Soil = 64 %; and Sediment = 35 % (Estimated with Level III Fugacity Model).

In soil, TBBP-A is attributed a low mobility based on its calculated soil adsorption coefficient K_{oc} . Therefore, leaching of TBBP-A from soil into groundwater is not expected to be an important transport mechanism. Estimated volatilization half-lives for a model river and lake indicate that it will have low potential to volatilise from surface water. In the atmosphere, TBBP-A is expected to exist primarily in a particulate phase (dust). Particulate TBBP-A will be removed from air by wet or dry deposition.

According to the EU RAR (2008), TBBP-A may cause long-term adverse effects to organisms in the aquatic environment. This conclusion is based on the toxic effects seen in acute toxicity assays with fish and daphnia ($L(EC)_{50} < 1$ mg/l), the lack of biodegradation seen in standard ready biodegradation tests and the high bioconcentration factors ($BCF > 100$) measured in fish (ibid).

It is noted that stakeholders argued that a $BCF > 100$ is not high and this is correct in relation to fulfilment of the bioaccumulation-criterion according to REACH, which requires a BCF above 2000. However, the EU RAR perceived the BCF as being high at that time and TBBP-A is still under assessment for being bioaccumulative. See also discussion in the following section 4.3.

4.3. Potential for secondary poisoning and bioaccumulation

Secondary poisoning is a phenomenon related to toxic effects, which might occur in higher members of the food chain. It results from ingestion of organisms from lower trophic levels in which substances of concern have bio-accumulated. Chemicals which have bioaccumulation and bio-magnification properties within the food chain may particularly pose a danger to predatory species.

As for bioaccumulation, the highest measured bioconcentration factor (BCF) value for (freshwater) fish with TBBP-A is around 1,234 l/kg according to the EU RAR (2008), which is below the cut-off value for the REACH criterion for bioaccumulation at $BCF > 2,000$ l/kg. It should be noted here, that according to the ECHA Registered Substances Database (2018), in the registration dossier a much lower BCF in aquatic species (fish) was indicated: "*The BCF of the parent TBBP-A molecule was approximately 150. The majority of the ^{14}C -activity detected in fish tissue was not associated with the parent molecule. The whole-body half-life of ^{14}C -activity was < 24 hours.*"

Monitoring data as presented in the EU RAR (2008) are available in a limited amount from remote regions, including the Arctic. However, a more extensive database of monitoring data in aquatic organisms exists. "*The data show that tetrabromobisphenol-A has been detected at low levels in a number of aquatic species, including some top predators such as harbour porpoise, but most of these data were collected from sites that may be influenced by local or regional sources of emission and so are difficult to interpret in terms of the PBT assessment. In addition, it should be noted that there are a significant number of samples analysed where tetrabromobisphenol-A was not detectable. Tetrabromobisphenol-A has been detected in a single sample of human breast milk from the Faroe Islands.*" (ibid)

DEPA (2015) states that there is no sufficient evidence to conclude that TBBP-A meets the bioaccumulation criteria for B or vB but that it is possible that it fulfils Article 57(f) as quasi PBT on the basis of its environmental toxicity and persistency.

4.4. Guidance values (PNECs)

The predicted no effect concentration (PNEC) is the concentration below which exposure to a substance is not expected to cause adverse effects to species in the environment. Therefore, the knowledge of these values is important for further characterisation of possible risks.

The following PNEC values for TBBP-A for different compartments are extracted from the EU RAR (2008), the ECHA Registered Substances Database: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2018) as well as values compiled in a collection of references provided by the Norwegian Environmental Agency as a contribution to the first stakeholder consultation.⁷⁰

Table 4-1: Predicted No-Effect Concentration (PNEC) for TBBP-A

Fact	Compartment	PNEC value ECHA Registered Substances Database 2018	PNEC value EU RAR 2008	PNEC value Norwegian Environment Agency 2014
Hazard for Aquatic Organisms	Freshwater	16 µg/l	1.3 µg/l	6.6 µg/l
	Marine water	0.34 µg/l	0.25 µg/l	0.05 µg/l
	Sewage treatment plant (STP)	1.5 mg/l	-	-
	Sediment (freshwater)	9 mg/kg sediment dw	2.7 mg/kg wet weight In some cases, a higher PNEC is applied for a sediment where TBBP-A may show a stronger adsorption.	0.24 dw
	Sediment (marine water)	1.8 mg/kg sediment dw	0.54 mg/kg wet weight	0.063 dw
Hazard for Air	Air	No hazard identified	long-range transport to the Arctic could occur	-
Hazard for Terrestrial Organism	Soil	0.031 mg/kg soil dw	0.012 mg/kg wet weight	-
Hazard for Predators	Secondary poisoning	222.22 mg/kg food	>667 mg/kg food	-

Source: EU RAR (2008), ECHA Registered Substances Database: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (2018), Norwegian Environment Agency (2018)

⁷⁰ Norwegian Environment Agency (2018): Contribution submitted during the TBBP-A stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); see the link to the contribution in the Annex

5. WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT

5.1. Description of waste streams

According to BSEF, TBBP-A is produced mainly in Israel, the United States, Jordan, Japan and PR China.⁷¹ Thus, releases of the substance from primary production processes are not expected to occur in Europe. Certain amounts of TBBP-A are imported as a commoditised intermediate chemical (see 2.3), which is used for the manufacturing of various EEE products. Notably, TBBP-A is used as a reactant in the manufacturing of FR4 printed wiring boards (PWB). However, wastes emerging during the PWB production do not fall under the scope of the RoHS directive.

RoHS relevant waste encompasses post-consumer WEEE, which contains TBBP-A mainly in form of an additive flame retardant in plastic components (such as ABS-parts). Reacted TBBP-A occurs in rigid FR4 PWB but does no longer exist in its original substance identity (see 2.2). Hence, TBBP-A cannot be analytically identified in PWB fractions of WEEE except for unreacted TBBP-A from the original PWB production. TBBP-A detected otherwise in WEEE cannot be attributed to the PWB.

It must be noted, that the literature does not always clearly distinguish the difference between reacted and not reacted TBBP-A in WEEE. Moreover, accounts on the TBBP-A contents, found in WEEE categories are at odds with the figures on TBBP-A used, reported in section 2.3.

Taverna et al. (2017)⁷² for instance, examine typical EEE flame retardants as part of the material flows in the Swiss WEEE treatment system. In this study, 220 tons of WEEE with a typical composition with regard to the WEEE categories⁷³ was examined based on the statistical WEEE composition of Switzerland in the year 2009. This study found that, out of the 18 flame retardants examined, TBBP-A was the most abundant one with a mean concentration of > 600 mg/kg waste in composite samples from all output streams of WEEE processing. With focus on TBBP-A, the following three output streams (out of 13 examined in total) are important:

- PWBs (representing 2 % of the total WEEE output mass flow),
- polymer components from dismantled EEE housings (5 % of the total WEEE output mass flow),
- polymer particle fraction generated by shredding of WEEE (23 % of the total output mass flow).

In these three outputs, TBBP-A was always found to be the most abundant flame retardant. For the PWB output stream, TBBP-A was found with an average concentration of 390 mg/kg by far more than from other FR (next followed by DecaBDE with 110 mg/kg). In computer and notebook housings made from polymeric material, TBBP-A was present with 4,000 mg/kg (next followed by DBDPE with 1,400 mg/kg); and finally, an average concentration of 1,700 mg/kg was detected in the polymer particle fraction with diameters < 25 mm (next followed by DBDPE 1,100 mg/kg).

From the distribution of TBBP-A in the examined output streams it can be concluded that > 90 % of additively applied TBBP-A content in WEEE ends up in the polymer fraction (housings + polymer particles) as can be seen from Figure 5-1. The PWB output stream holds a share of only 1 % of the TBBP-A. This result proves the assumption that the release of unreacted TBBP-A from poly epoxy

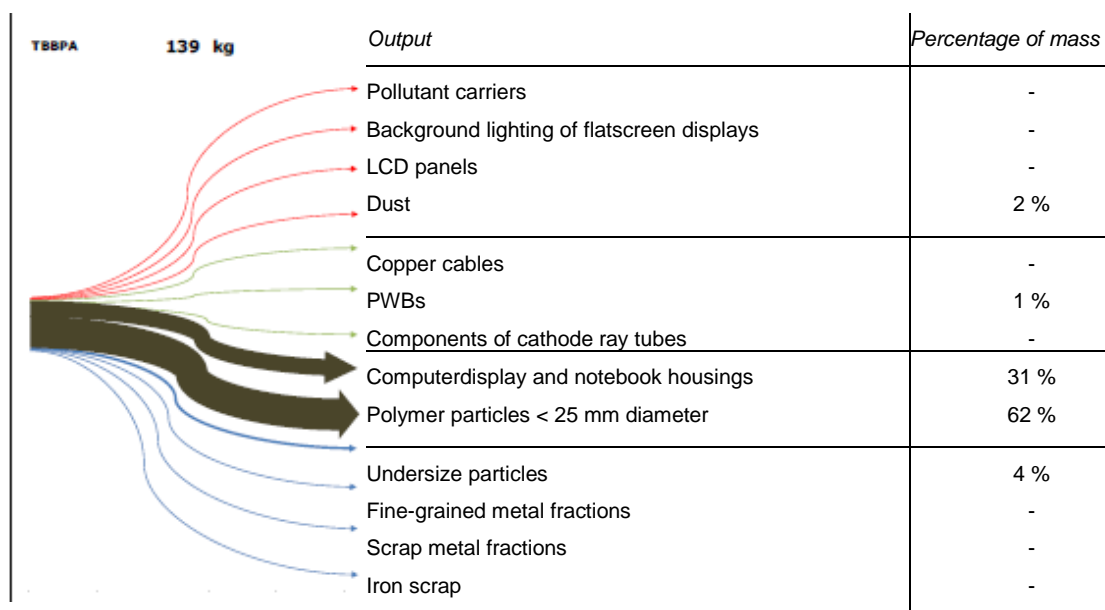
⁷¹ BSEF, Fact sheet TBBP-A: Tetrabromobisphenol A for Printed Circuit Boards and ABS plastics. 2007: Brussels, Belgium

⁷² Taverna, R. et al. (2017): Stoffflüsse im Schweizer Elektronikschrott. Metalle, Nichtmetalle, Flammschutzmittel und polychlorierte Biphenyle in elektrischen und elektronischen Kleingeräten. Bundesamt für Umwelt, Bern. Umwelt-Zustand Nr.1717

⁷³ Based on Taverna (2017): Figure 5, pg. 30, the investigated composition included: 25% IT equipment without monitors; 1% laptops; 3% LCD monitors; 9% CRT monitors; 3% communications equipment; 7% mixed consumer electronics without TVs; 9% LCD TVs; 14% CRT TVs; and 27% small household appliances.

resins is only a very small source for this substance in the waste stream. Moreover, the findings suggest a focus for this chapter on the waste management of TBBP-A containing plastic fractions.

Figure 5-1: Distribution of TBBP-A in the examined output waste streams



Source: Taverna et al. 2017.

5.1.1. Main materials where the substance is contained

As explained in section 2.2, there are two main application forms for TBBP-A in EEE:

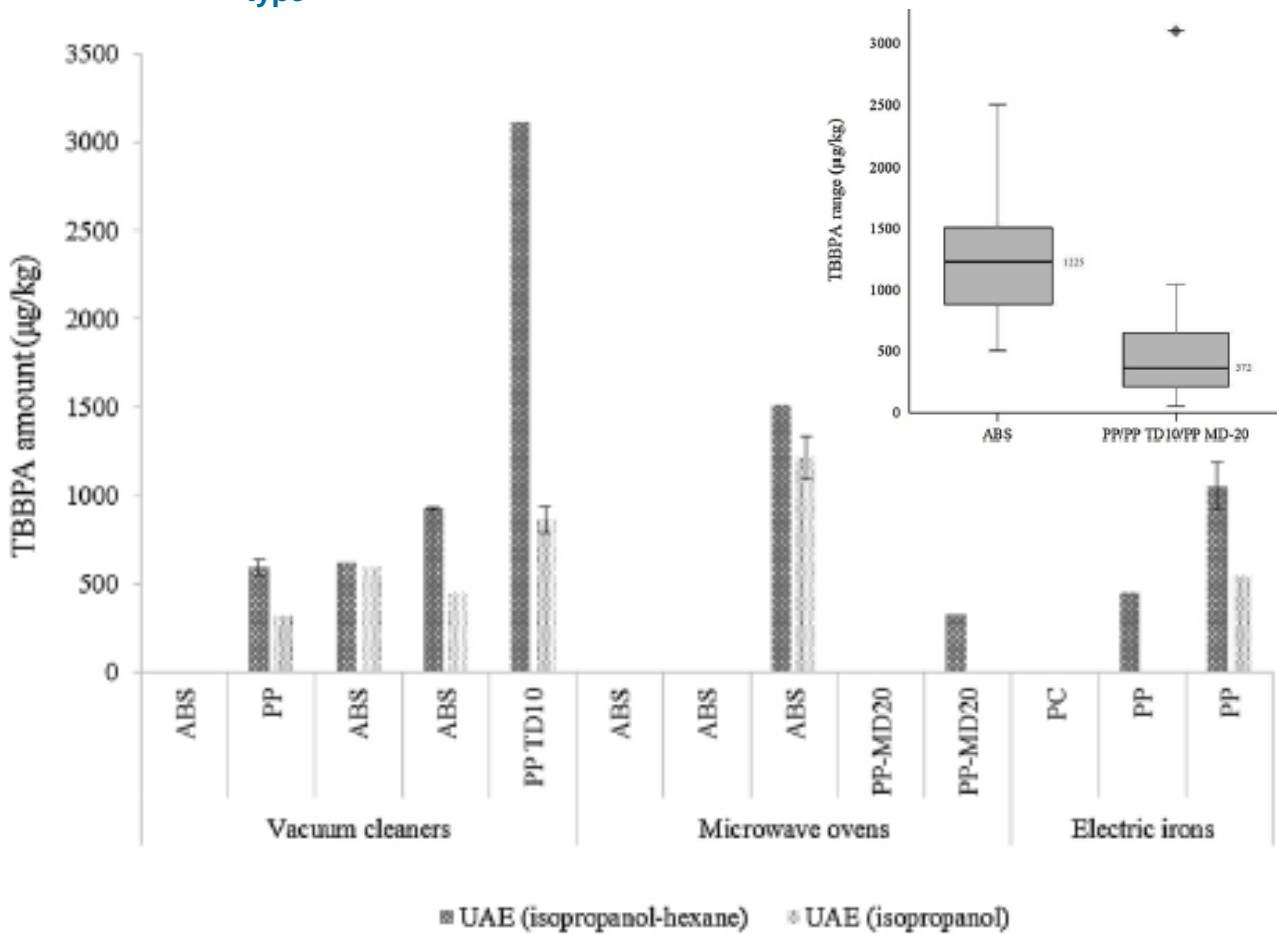
- 1) Covalently bound TBBP-A in epoxy and polycarbonate resins that form the main constituent of rigid (FR4) PWB.
- 2) Additive TBBP-A (non-covalently bound) in ABS based plastic components, mainly EEE housings. Small amounts of non-covalently bound TBBP-A may occur in rigid (FR4) PWB as a residue from their production.

Kousaiti et al. (2020)⁷⁴ evaluated the TBBP-A content per polymer type⁷⁵: The range of TBBP-A per polymer type varies among ABS and PP and PP blends, as the following Figure 5-1 shows. It was not detected in PC and PC blends. Amongst the same type of polymer, values varied significantly (see the error bars in the boxplot below). The highest average value was found in ABS-containing samples (1.2 mg/kg), followed by PP (0.4 mg/kg). Kousaiti et al. explain that the reason for not detecting TBBP-A in PC and PC/ABS blends is possibly due to different kinds of FRs in those PC-containing polymers, in addition to high uncertainties due to a limited number of PC samples tested (n=2). HIPS samples were not evaluated in this study.

⁷⁴ Kousaiti et al. (2020): Assessment of tetrabromobisphenol-A (TBBPA) content in plastic waste recovered from WEEE. Journal of Hazardous Material, 390, 121641

⁷⁵ (1) ABS; (2) Polypropylene and blends (PP-TB10, PP-MD20); and (3) Polycarbonate and PC blends (PC/ABS)

Figure 5-1: Mean and range values of TBBP-A content in plastic matrices per polymer type



Source: Kousaiti et al. (2020)⁷⁶

5.1.2. WEEE categories containing the substance

WEEE, containing reacted TBBP-A

FR4-type PWBs consist of reacted TBBP-A. PWBs are found in a multitude of EEE products that contain electronic components. This is true for almost all modern appliances that are equipped with electronics to provide “smart” functions (e.g. Internet / cloud connectivity). Also, EEE products without smart functions are likely to be equipped with PWBs if they provide any kind of functions that go beyond a simple on/off switch. Examples of PWB mounted electronic components in EEE are LED indicator lights, sensors, control units, displays, speakers, buzzers, digital data ports (e.g. USB), wireless connectivity etc.

⁷⁶ Op. cit. Kousaiti et al. (2020)

Table 5-1: Annex I categories of WEEE containing reacted TBBP-A

No.	Categories name	Examples
1	Large household appliances	Fridges, freezers, air conditioners, white goods
2	Small household appliances	Coffee machines,
3	IT and telecommunications equipment	Personal computers, printer, notebooks, tablets, mobile phones
4	Consumer equipment	TV Sets
5	Lightning equipment	Surface mounted LED on PWBs including controllers
6	Electrical and electronic tools	PWBs in different products of the category
7	Toys, leisure and sports equipment	PWBs in different products of the category
8	Medical devices (except all implanted and infected products)	Imaging systems, monitors, infusion pumps
9	Monitoring and control instruments	Navigation, sensors, control systems
10	Automatic dispensers	PWBs in different products of the category

Source: adopted from Fraunhofer ITEM IPA⁷⁷

Noteworthy, the reacted TBBP-A resides solely in rigid FR4 PWBs whereas flexible PWBs are not expected to contain the substance. Consequently, EEE that do not contain FR4 PWBs is unlikely to contain reacted TBBP-A with the exception of encapsulated EE components.

However, rigid FR4 PWBs are not considered to contain TBBP-A in its original substance identity, because reacted TBBP-A becomes an inherent building block of covalently bound epoxy resins. PWBs may contain residues of not-reacted TBBP-A in traces only. According to Rachmilevich (2015), to which several stakeholders refer to (e.g. MedTech 2018, JEITA 2018), the unreacted residues of TBBP-A in epoxy based PWBs can be considered as very low: TBBP-A concentrations in samples at different production stages of PWBs (CCL, unclad laminates, prepregs) from four different manufacturers were found to be lower than the methods' detection limits of either 10 or 20 ppm⁷⁸ which is estimated to be less than 0.006 % of the original used TBBP-A⁷⁹. Sellstrom and Jansen (1995) found 0,7 mg residual TBBP-A per gram of PWB, thus 0.7 ppm, which in 2015 was the only published concentration of TBBP-A in laminate material according to US EPA (2015). From the bromine and the TBBP-A concentrations found in the separated PWB output stream investigated by Taverna et al. (2017), the amount of unreacted TBBPA was in a comparable order of magnitude, though understood to relate to the complete PWB and not necessarily to the homogenous material (see calculations in footnote⁸⁰).

⁷⁷ With information from inter alia obt cit. Wibbertmann, Axel and Hahn, Stefan (2018)

⁷⁸ Rachmilevich, Y., Determination of unreacted TBBP-A in different production stages of printed circuit boards. 2015, ICL Industrial Products

⁷⁹ Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018

⁸⁰ The total Br from reactive and additive use in PWB was found to be $m(\text{Br}_{\text{total}}) = 89,000 \text{ mg/kg}$ which corresponds to $n(\text{Br}_{\text{total}}) = 1.11 \text{ mol/kg}$; while the $m(\text{TBBP-A}) = 390 \text{ mg/kg}$ (assumed to be the unreacted TBBP-A) corresponds to $n(\text{TBBP-A}) = 0.0007 \text{ mol/kg}$. With $n(\text{Br from TBBP-A}) = 4 \times n(\text{TBBP-A}) = 2.87 \times 10^{-3} \text{ mol/kg}$, the ratio of $n(\text{Br from TBBP-A})/n(\text{Br}_{\text{total}}) = 0.00258$ --> deviation with 4 as $4 \times \text{Br}$ per TBBPA results in a concentration of 0.000645 (based on data from Taverna et al. 2017).

Hence, it has to be noted that **WEEE containing reacted TBBP-A in its polymeric backbone is not considered relevant for the further analysis**. In other words, epoxy-based PWBs that are found in WEEE are not considered to contain TBBP-A in relevant amounts.

WEEE, containing non-covalently bound TBBP-A

Additive TBBP-A is likely to be found in WEEE items that contain plastics housing parts of ABS. Such components are to be expected in a multitude of products. Müller et al. (2012)⁸¹ studied TBBP-A concentrations in WEEE categories 1 to 4, which are known to contain cover parts made from ABS polymer. TBBP-A was detected in most samples with average concentration levels typically ranging from 1 to 10 g/kg. The highest concentrations were found in mixed plastics from CRT monitors⁸² with an average concentration of 37 g/kg and a maximum level of 63 g/kg. The lowest detected value, namely 0.1 g/kg, was found in a single sample of mixed plastics from small appliances for high-temperature applications. The results suggest that TBBP-A has to be expected in concentrations between 1 and 10 g/kg or above in mixed plastics from WEEE categories 2–4, whereas there are indications that they do not occur in mixed plastics from WEEE category 1.

Kousaiti et al. (2020)⁸³ review ten additional studies from 2005 to 2014 that report measurements of TBBP-A concentrations in different waste streams of categories 1 to 4 as well as different types of polymers. The study confirms the trends identified by Müller et al. (2012). According to Gallen et al. (2014), maximum values exceeded 140 g TBBP-A per kg WEEE in toys, leisure and sports equipment, small appliances and ICT equipment.⁸⁴

Table 5-2: Annex I categories of WEEE containing additive TBBP-A

No.	Categories name	Examples
1	Large household appliances	Fridges, freezers, microwave ovens, white goods
2	Small household appliances	e.g. Coffee machines
3	IT and telecommunications equipment	e.g. personal computers, printer, notebooks, tablet, mobile phones
4	Consumer equipment	e.g. TV Sets
8	Medical devices (except all implanted and infected products)	e.g. imaging systems, monitors, infusion pumps

Source: adopted from Fraunhofer ITEM IPA⁸⁵

⁸¹ E. Müller, M. Schluep, P. Wäger and P. Leroy: "RoHS - regulated substances in mixed plastics from waste electrical and electronic equipment," *2012 Electronics Goes Green 2012+*, Berlin, 2012, pp. 1-6

⁸² Cathode ray tube monitors and TV had been legacy WEEE back in 2012 but were still found abundantly in WEEE at the time of that study. Nowadays, the number of CRT devices in WEEE has declined substantially.

⁸³ Op. cit. Kousaiti et al. (2020)

⁸⁴ Gallen et al. (2014) Towards development of a rapid and effective non-destructive testing strategy to identify brominated flame retardants in the plastics of consumer products. *Science of the Total Environment* 491-492, 255-265 cited by Kousati et al (2020)

⁸⁵ With information from inter alia obt cit. Wibbertmann, Axel and Hahn, Stefan (2018)

Overall, WEEE categories 2 to 4 play the major role concerning housings (additive use), whereas all WEEE categories are relevant for printed wiring boards (reactive use), since these are present in almost all pieces of equipment.

5.2. Applied waste treatment processes

According to the WEEE directive, waste electric and electronic equipment is to be collected and treated separately from household waste. The WEEE collection target level in the EU, in effect since 2019, is 65 percent of EEE placed on the market during the three previous years. This applies for all WEEE regardless of the presence and the form of TBBP-A (reacted or additive) in the respective WEEE items.

5.2.1. Initial treatment processes

Following the separate collection of WEEE from households, general handling processes of WEEE waste encompass pre-treatment (e.g. removal of specific hazardous components), manual or mechanical dismantling (e.g. shredding) sorting, recovery, processing, incineration or landfilling of residues. WEEE that was not separately collected is likely to be co-processed as part of municipal solid waste. The following assessment applies under the condition of separate collection and treatment of current operational conditions in the EU. WEEE that is exported outside the EU might be recycled by means of crude process technologies (see 5.5).

Separately collected WEEE undergoes the following principal treatment processes:⁸⁶

- Transport of mixed WEEE to processing plants,
- Manual pre-dismantling of parts containing hazardous materials (e.g. batteries),
- Manual dismantling has been applied in the past⁸⁷ and is increasingly being replaced by mechanical dismantling (shredding / crushing). Manual work is still an option for niche applications although semi-automatic options are available too,⁸⁸
- Screening and separation: a series of physical treatment methods e.g. sieving, magnetic and electrostatic separation, gravimetric separation, air separation), TBBP-A will most likely end up in the plastics fraction (separated whole ABS parts and shredded polymer flakes).

5.2.2. Subsequent treatment processes of secondary wastes

Under current operational conditions in the EU, further waste treatment processes for products and components with additive TBBP-A are:

- Storage and transports of intermediate recycling fractions (including shredded polymer flakes),
- Gravimetric sorting of shredded polymer flakes,
- Plastics recovery: ABS, originating from plastic parts that are free of flame retardants is recovered to a certain extent. ABS, containing flame retardants with a bromine content above 2,000 ppm⁸⁹,

⁸⁶ Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

⁸⁷ Op. cit. Oeko-Institut (2008)

⁸⁸ Op. cit. Fraunhofer ITEM IPA Wibbertmann and Hahn (2018)

⁸⁹ The threshold is specified in the WEEE CEN standard series 50625 technical specification TS 50625-3-1, under Section 8.3 for CRT display appliances, but also referring to its applicability to "*plastic fractions that can contain Brominated*

is usually incinerated and recycling processes for TBBP-A-contaminated plastic housings have not been reported (as far as the concentration is > 2,000 ppm),^{90 91}

- Incineration of residues in municipal waste incinerators,
- Co-incineration of bromine-free plastic waste as substitute fuel in cement kilns⁹²

The WEEE Directive⁹³ requires that plastics containing brominated flame-retardants have to be removed from any separately collected WEEE. Recycling of polymers (epoxy resins or ABS) containing TBBP-A is usually not practiced in the EU. Though, there would be a market for plastics with TBBP-A, recycling technologies cannot make a distinction between the different brominated flame retardants in the polymers.⁹⁴ Hence, additive TBBP-A expected to be found in WEEE that contains ABS parts (such as inner and outer plastic housing, front or rear cover plates) need to be separated and disposed of.

In this respect, in their contribution to the consultation, EuRIC (2020)⁹⁵ states that *“total bromine content is useful for separating low brominated fraction from high brominated fractions, according to standard CEN TS 50625-3-1. Both antimony (Sb) and bromine (Br) are used by state-of-the-art recycling techniques to separate flame retardant from non-flame-retardant plastics”*. XRF sensors and density separation are mentioned in this respect.

EuRIC (2020)⁹⁶ raises concern whether XRF and density separation techniques can properly deal with phosphorus-based flame retardants which may be used as substitutes for TBBP-A. It is explained that XRF sensors cannot detect phosphorus-based flame retardants and density-based separation may not allow the correct separation of plastics containing phosphorus-based flame retardants (PFR) from “clean” plastic fractions, because of the density overlap between PFR and non-PFR plastic fractions. EuRIC are concerned that a restriction could *“lead, via the substitution by PFRs, to a higher residual fraction of non-recycled plastics (if a restriction is implemented), and of lesser quality of recycled plastics, containing PFR”*.

KU Leuven (2018) also refer to this point, explaining that *“With post-shredder sorting techniques plastics containing bromine/antimony-based flame retardants can be separated with a high efficiency from other non-flame-retardant plastic types, as the density is significantly higher and the bromine content is sufficient for good detection by XRF. However, with these techniques it is today not economically viable to separate bromine/antimony containing plastics for mechanical recycling, as further sorting of these plastics to obtain the required purity is not possible post-shredder, as no*

Flame Retardants (i.e. plastics from all categories of WEEE except large appliances and cooling and freezing appliances)”

⁹⁰ Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

⁹¹ <http://www.recplas.co.uk/abs-recycling.html> (last viewed 08.10.2019)

⁹² Op. cit. BSEF (2020)

⁹³ Annex VII on the selective treatment for materials and components of waste electrical and electronic equipment referred to in Article 8(2) of the Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast); <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32012L0019&from=EN>, last viewed 02.07.2018

⁹⁴ EERA (2020) Contribution submitted during the TBBP-A stakeholder consultation conducted from 5 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (Pack 15); see the link to the contribution in the Annex.

⁹⁵ EuRIC (2020) The European Recycling Industries' Confederation. Contribution submitted during the TBBP-A stakeholder consultation conducted from 5 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (Pack 15); see the link to the contribution in the Annex

⁹⁶ Op. cit. EuRIC (2020)

techniques exist to sort for example ABS BrFR and HIPS BrFr post shredder. It should also be considered that the same issues are valid for phosphor-based flame-retardant plastics".⁹⁷

In the consultant's view, though this argumentation may show that the waste management sector may be challenged by the possible content of phosphorus-based flame retardants in EEE polymer fractions, it does not support the further use of TBBP-A as a flame retardant in additive applications, should this be found to fulfil the criteria for restriction. To begin with, it is noted that there is a time lag between when EEE products are placed on the market and the time they arrive at end-of-life, i.e. at waste management facilities. It is also assumed that should TBBP-A be restricted under RoHS, a transition period would be specified and would provide additional time for the sector to develop suitable separation and recycling techniques. This conclusion is furthermore supported by the understanding that phosphorus-based flame retardants as well as other substitutes are already in use by some manufacturers and are expected to enter the waste stream to some degree regardless of the future use of TBBP-A (see section 8.3). Whether such substitutes may also result in impacts in the use phase or the waste phase and in the fulfilment of the RoHS criteria for restriction is of relevance for considering whether additional substances should be addressed by RoHS to avoid regrettable substitution.

PWBs are usually sent to copper smelters for metal recovery. The reacted TBBP-A, contained in epoxy resin based PWBs, is usually co-incinerated in process of metal smelting where waste gas cleaning devices are expected to be installed.⁹⁸ The bromine is thus removed as a salt, which is disposed of in landfills.

5.3. Waste treatment processes relevant for assessment under RoHS

While reacted TBBP-A, being part of FR4 PWBs, is unlikely to be liberated in its original chemical signature, the additive form of application as a flame retardant in thermoplastic ABS parts may be released during abrasive and thermal recycling and disposal processes. Releases of TBBP-A during WEEE treatment are to be expected above all during the **shredding of mixed WEEE**, which takes place at several stages of the overall treatment chain at a large number of installations. Shredding residues that contain polymers are likely to contain various brominated flame retardants, with TBBP-A among them. Such residues are to be incinerated. The importance of the different subsequent treatment processes for the assessment under RoHS will be commented on in the following sections.

The following WEEE treatment processes are considered of low relevance regarding TBBP-A releases:

- Manual dismantling of WEEE (e.g. housings) is unlikely to cause airborne emissions due to the high vapour pressure of TBBP-A. However, dermal contact of workers to TBBP-A bearing plastic parts could be a possible exposure pathway if personal protection equipment (gloves) is insufficiently used.

⁹⁷ KU Leuven-University of Leuven (2018): Contribution submitted by Jef Peeters, Department of Mechanical Engineering, Faculty of Engineering & Engineering Technology, KU Leuven-University of Leuven on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_KU_LEUVEN_Diantimony_Trioxide_20180615.pdf, last viewed 26.06.2018

⁹⁸ Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

- Manual dismantling of PWBs seems to be of low relevance due to chemically bound state of TBBP-A in the polymeric resin. Yet, dermal contact of workers to un-reacted TBBP-A (concentrations below 0.006 % see 5.1.1) cannot be ruled out.
- Uncontrolled heating and burning of TBBP-A bearing plastics can lead to the formation of dibenzo-p-dioxins and furans,⁹⁹ in particular in the presence of copper. However, this risk is not specific to TBBP-A, but applies to all species of brominated flame retardants in WEEE.

5.4. Releases from (relevant) WEEE treatment processes

In its contribution, AEM¹⁰⁰ states on behalf of their members that in the EU, waste management and WEEE recycling processes are carried out by professional waste treatment companies that comply with EU waste treatment legislation. Thus, emissions of brominated pollutants from WEEE are thought to be under control in the EU.

In relation to emissions, EERA (2020)¹⁰¹ further states that *“the BAT/BREF requirements for shredder processes, ensure that the shredder dust is captured, and that this shredder dust is incinerated, hence the shredder processes do not pose a risk for human health or the environment. For CRT appliances a manual separation of the plastics is state of the art. At the workstations of the manual dismantling, dust extraction systems ensure the reduction of any human health and environmental risks to an absolute minimum”*.

Other stakeholders do not provide information on waste phase or, as JEITA,¹⁰² focus on exposure of TBBP-A during the use phase rather than during the WEEE processing.

Though approaches concerning releases of TBBP-A and its degradation products have been published (e.g. EU RAR), quantitative exposure estimations for WEEE treatment are rarely found and mainly based on a limited number of monitoring data.¹⁰³

In terms of suspected pathways of TBBP-A release, shredding of mixed WEEE and pre-sorted ABS fractions are the most relevant processes as they may cause TBBP-A bearing dust emissions at the working place and into the environment. In particular, polymer particles with diameters below 25 mm are seen of high relevance for TBBP-A releases (Taverna et al. 2017).

Shredding processes may differ with regard to the composition of WEEE feedstock, the shape and particle size distribution of shredded materials and residues, dustiness and emission prevention appliances, ventilation conditions, the grade of automatisation, and the work pace situation (indoor or outdoor), just to name some aspects. This leads to the conclusion that the occupational and environmental exposure risk to TBBP-A differs per shredding site.¹⁰⁴

Fraunhofer ITEM and IPA conclude from an extrapolation for a – in their opinion – typical WEEE shredding site (throughput of 250 t WEEE/day) a diffuse release of 130 g TBBP-A per day. Out of this amount, a release rate of 0.52 g TBBP-A per ton WEEE treated in such a site can be calculated.

⁹⁹ Op. cit. Oeko-Institut. 2008,

¹⁰⁰ Op. cit. AEM (2018)

¹⁰¹ EERA (2020) Contribution submitted during the TBBP-A stakeholder consultation conducted from 5 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (Pack 15); see the link to the contribution in the Annex

¹⁰² Op. cit. JEITA (2018)

¹⁰³ Ob cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

¹⁰⁴ Op. cit. Environmental Agency Austria (2008), see the chapter „Workplace description of mechanical treatment of WEEE”

This extrapolation is based on data from 2004 and may therefore be considered outdated. No more recent publicly available data could be found in this study, nor did the stakeholders in the second consultation provide information on actual TBBP-A releases from WEEE in Europe. Against this background, the assumption that emissions of brominated pollutants from WEEE in Europe are under control is not supported.

Regardless the poor information on environmental entry pathways, inter-compartment transport and transformation, TBBP-A has been detected in various environmental compartments related to the disposal phase (see chapter 6.3.3).

Releases of toxic degradation products

Thermal waste treatment processes, applied to plastic parts containing additive TBBP-A, are suspected to result in a release of bromine in form of chemical compounds of low molecular weight, specifically hydrobromic acid (HBr). That substance can act as a precursor to the formation of brominated dioxin species if the WEEE undergoes crude thermal treatment processes in presence of copper (which is almost certainly the case if PWBs are combusted in open fire). However, the aforementioned pathway to the formation of brominated pollutants is not specific to TBBP-A. It can occur with any brominated compound that has been added to EEE during their manufacturing.

5.5. Crude WEEE treatment in non-OECD countries

This includes mechanical treatment of residual waste, incineration in municipal waste incinerators but also landfilling or transboundary movements outside the EU cannot be ruled out. WEEE, exported towards non-OECD countries is likely to be subjected to all sorts of informal recycling and waste treatment processes, such as uncontrolled combustion, grilling, desoldering, uncontrolled dumping of residues, and generally uncontrolled treatment under crude circumstances. Due to their content of precious metals, PWBs are particularly prone to crude recycling treatment, including open burning, roasting, and hydro chemical acid leaching. The presence of reacted TBBP-A in FR4 PWB does impose special precautions to be applied in informal recycling businesses. The fate of plastic parts containing additive TBBP-A is uncertain. Some ABS plastic parts might be landfilled or burned while others are subjected to manual sorting and recovery of ABS. The latter pathway poses a risk of cross-contamination, which means an uncontrolled pollution of recycled ABS feedstock with a mixture of additives, among them TBBP-A. There is a risk of re-imports of products (not only EEE) containing cross-contaminated plastic recyclates into the EU.

6. EXPOSURE ESTIMATION DURING USE AND DURING WEEE TREATMENT

6.1. Basis of exposure estimation

Before becoming WEEE, products containing covalently bound TBBP-A as part of epoxy or polycarbonate resin based PWBs are not thought to release the substance to the environment.¹⁰⁵ The stakeholder contribution of ZVEI (2018) underpins this claim by referring e.g. to the status report of the ICL. JEITA and AEM stress the fact that no TBBP-A emissions from PWCs could be detected although evidence was not provided.¹⁰⁶ The presence of unreacted TBBP-A as a production residue in finished epoxy-based printed wiring boards is negligible according to information provided by stakeholders from industry. The FR4 laminates contain TBBP-A at levels of less than the detection limits of either 10 or 20 ppm. Therefore, the unreacted residue levels can be considered as very low (see also section 2.1).

The possibility of TBBP-A exposure resulting from additive use in polymers is higher than from residues of unreacted TBBP-A residues in PWBs. In its form as an additive, TBBP-A is non-covalently and therefore more loosely bound to the polymer than in its reacted form. Therefore, the substance has a higher likelihood to be released from products in the use phase and when WEEE is recycled or disposed of. However, as the volatility of TBBP-A is negligible air emissions will be extremely small (US EPA 2015). TBBP-A may be released in the form of dust particles in the process of shredding, crushing, and milling of flame retarded ABS plastics contained in WEEE.

6.2. Human exposure estimation

6.2.1. Exposure of workers of EEE waste processing plants

Modelled data

According to the waste streams examined in chapter 5.3 and 5.4 exposition of workers in WEEE processing plants to TBBP-A can occur during the processes of dismantling and shredding. The exposure can occur through inhalation of dust and dermal contact. The exposure route via inhalation is assumed to be the more relevant one.

Exposure estimation for workers was modelled in the course of the preparation of the dossier at hand by using the ECETOC's Targeted Risk Assessment (TRA)¹⁰⁷ tool. It helps calculating the risk of exposure from chemicals to workers, consumers and the environment. The ECETOC TRA tool is intended for manufacturing and formulation processes, therefore no appropriate processes to describe the exposure conditions of waste treatment processes are available so far.

The process category 24: "*high (mechanical) energy work-up of substances bound in materials and/or articles*" has been selected to calculate the exposure of workers of EEE waste processing plants. This approach has been first introduced by the Austrian Umweltbundesamt for the RoHS assessment of the phthalates DEHP, DBP and BBP; it has also been used by KEMI for the MCCP

¹⁰⁵ Op. cit. Alaei, M., et al. 2003 and Buekens A. and Yang J. (2014)

¹⁰⁶ Op. cit. ZVEI, JEITA and AEM (2018)

¹⁰⁷ <http://www.ecetoc.org/tools/targeted-risk-assessment-tra/>

dossier¹⁰⁸ and was used by the Fraunhofer ITEM IPA in this case as well.¹⁰⁹ In contrast to the modelling carried out by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018), the lowest possible default value concentration for the substance in preparation of <1 % was chosen, based on measured concentration of TBBP-A in Taverna et al. (2017) as follows:

- Dust from pre-shredding and from the impact mill: 300 mg TBBP-A / kg;
- TBBP-A content in screen and notebook enclosures: 4,000 mg TBBP-A / kg;
- Fine-grained plastic fraction: 1,700 mg TBBP-A / kg.

The input parameters for the exposure estimation are shown in Table 6-1.

Table 6-1: Input parameters used in ECETOC TRA for worker exposure

Scenario name	Shredding of WEEE plastic and cables
Treatment setting	Professional
Duration of activity	>4 hours/day
Use of ventilation	Outdoors
Respiratory protection	No
Substance in preparation	<1 %

Source: Own compilation based on ECETOC TRA 3.1

Within the process category 24 (PROC 24), subcategories a (Process temperature < melting point: Low fugacity), thus, PROC24a with a low fugacity was chosen. This leads to the following exposure values, concentrations are given in mg/m³:

Table 6-2: Exposure estimates with ECETOC TRA for TBBP-A in PROC 24a

Process Category (PROC)	Long-term Inhalative Exposure Estimate [mg/m ³] c= <1 %	Long-term Dermal Exposure Estimate [mg/kg/day] c= <1 %
PROC 24a	2.10E-01	2.83E-01

Source: Own compilation based on ECETOC TRA 3

The exposure estimation with ECETOC TRA was made with rather conservative assumptions. The results give a rough indication on whether risk management measures at the workplace are necessary. As a rule, the DNEL for workers is taken to compare the estimated exposure to the identified limits to decide whether there is a risk expected for workers. The actual DNEL provided by the REACH registrants is 17.6 mg/m³ for inhalation exposure and 250 mg/kg bw/day for dermal exposure. The significance of these DNELs will be discussed in the section on impact and risk evaluation (section 7.2).

¹⁰⁸ Swedish Chemicals Agency KEMI (2018): ROHS Annex II Dossier M CCP, Proposal for a restriction of a substance in electrical and electronic equipment under RoHS; <https://www.kemi.se/global/rapporter/2018/report-4-18-rohs-annex-ii-dossier-mccp.pdf>, last viewed 24.07.2018

¹⁰⁹ Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

Monitoring data

In Sweden and Norway, serum samples of recycling plant employees have been analysed regarding TBBP-A concentrations. As presented in Table 6-3, mean concentrations were found between 0.64 and 4.0 ng/g lipid weight.

Table 6-3: Concentrations of TBBP-A reported in serum of workers

Species	No of samples	Location	Mean concentration (range) or range [ng/g lipid weight]	Reference
Workers in electronics dismantling	4	Sweden	< 1.1 - 4.0	Hagmar et al. (2000)
Workers in electronics dismantling ¹¹⁰	5	Norway	1.3 (0.64 – 1.8)	Thomsen et al. (2001)
Associated workers				
Computer technicians	19	Sweden	0.54 – 1.85	Jakobusson et al.(2002)
Wiring board producers	5	Norway	0.54 (<0.1 – 0.8)	Thomsen et al. (2001)
Laboratory personnel	5	Norway	0.34 (<0.1 – 0.52)	Thomsen et al. (2001)

Source: Data collected in IARC 2015

Various TBBP-A concentrations in indoor dust and air at recycling facilities in European countries were collected from different studies by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) as shown in the following table.

¹¹⁰ Work included manual dismantling of WEEE. Dust protection masks occasionally on a voluntary basis, Shredder located outdoor.

Table 6-4: TBBP-A concentrations in indoor dust and air in European WEEE treatment sites

Type of sample	Location		Results	Reference
Indoor dust	Switzerland	Recycling site	653 µg/ g dust	Morf et al. (2003)
	Sweden	Electronics dismantling facility, removal area	31 µg/g	Pettersson et al. (2001) cited in EU RAR 2008
	Sweden	Electronics dismantling facility, dismantling hall	4.1 µg/g	Pettersson et al. (2001) cited in EU RAR 2008
Air	Finland	Four different WEEE recycling sites	Nd – 1.1 µg/m ³	Rosenberg et al. (2011)
	Sweden	Electronic recycling plant, dismantling hall	0.014 µg/m ³	Tollbäck et al. (2006)
	UK	Mean from 16 individual measurements at 2 PWB shredding sites	4.58 µg/m ³ (0.019 – 20.8)	DEPA (2015)

Source: compilation of studies carried out by Fraunhofer ITEM IPA, for concrete references see Appendix

Even if maximum values were found for dust samples from WEEE treatment facilities, TBBP-A concentrations in dust ranged in a similar order of magnitude compared to indoor dust samples, e.g. from offices. The authors conclude that not all processed WEEE items contain TBBP-A in significant amounts while additively incorporated TBBP-A might be released from office equipment.

The comparison of TBBP-A concentrations in air samples is misleading because air sampling strategies differed from case to case. The same applies for parameters such as protective measures, ventilation and exact WEEE treatment processes. Thus, comparing measured values with estimated data, concentrations of TBBP-A in measured air samples were two orders of magnitude (factor ~ 100) smaller than the estimation results derived from ECETOC TRA.

The potential formation of dibenzo-p-dioxins and furans¹¹¹ from TBBP-A during incineration of plastics is not further assessed. It is assumed, that in the EU, municipal waste incinerator plants and metal smelters are equipped with state-of-the-art waste gas treatment so that emissions of these pollutants into the environment are below the allowed thresholds.

In contrast, WEEE exported in non-OECD countries (e.g. in Nigeria, Ghana) is likely to be processed under very crude conditions, e.g. open burning of PWBs and plastic parts in presence of copper. Therefore, brominated dibenzo-p-dioxins and furans are likely to be released in considerable amounts. Since emission monitoring and exposure control equipment as well as the use of protective gear by workers are almost absent, the TBBP-A contained in exported WEEE is likely to contribute significantly to occupational and environmental exposure in the respective countries. Systematic exposure measurement data is not available for these countries.

¹¹¹ Op. cit. Oeko-Institut (2008)

6.2.2. Exposure of neighbouring residents of EEE waste processing plants

No information could be identified in the course of this project about measured TBBP-A concentrations related to neighbouring residents of WEEE processing plants.¹¹²

6.2.3. Consumer exposure

Exposure of the general population predominantly may occur through oral uptake (e.g. via food) and through ingestion of indoor dust.

A scientific opinion of the European Food Safety Authority (EFSA) on TBBP-A and its derivatives in food¹¹³ arrives at the conclusion that the exposure scenario based on average human milk consumption and the reported range for TBPP-A in human milk (0.06 to 37.3 ng/g fat) results in daily exposures of 0.28 to 171 ng TBBP-A/kg body weight. For infants with high human milk consumption the respective daily exposures ranged from 0.41 to 257 ng/kg bodyweight. The hypothetical worst-case dietary exposure for the specific group of adult high fish consumers¹ was 2.6 ng/kg bodyweight per day. Categorising the TBBP-A containing food samples (n=652), “Fish and other seafood” was the dominant category (~71 %), followed by “meat and meat products” (~8 %) and “milk and dairy products” (~6 %).

The inhalation of TBBP-A vapour is rather unlikely, given its low vapour pressure. Sjödin et al. (2011) confirmed that airborne TBBP-A exists primarily in a particulate phase rather than in the vapour phase. Generally, very young children will predominantly be affected via ingestion of dust compared to adults.¹¹⁴ As an example, in the United Kingdom, average estimated daily intakes of TBBP-A from the ingestion of dust were 1.6 and 4.4 ng/day for adults and toddlers, respectively,¹¹⁵ contributing 34 % and 90 % of their overall daily intake from air, dust and diet (Abdallah et al., 2008).

As for dust, a compilation of relevant peer-reviewed studies was reviewed by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018). Building upon a number of similar primary studies (see Table 6-5), the conclusion can be drawn that the exposure to TBBP-A would not pose elevated concern for the health of the general population. On the other hand: An evaluation by the International Agency for Research on Cancer (IARC 2015) mentioned several affirmative proofs for indoor dust being a relevant exposure route basing their opinion on the similar primary studies. In contrast to EFSA & Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018), the majority of the IARC Working Group on TBBP-A considered that the strong mechanistic evidence that TBBP-A can operate through some key characteristics of carcinogens and that these can be operative in humans. This fact – together with the ubiquitous occurrence in almost all biotic and abiotic compartments worldwide – finally lead to considerations to propose an upgrade of TBBP-A to the Cancer Group 2A.

EFSA (2011) summarises that dust in homes, classrooms and cars can be an additional source of exposure to TBBP-A, particularly for children. A typical exposure scenario would be 1.2 ng/kg bw per day.¹¹⁶ Comparing the exposure resulting from this scenario with the BMDL₁₀ of 16 mg/kg bw results in an MOE of about 1.3×10^7 that indicates that exposure of children to TBBP-A from dust does not raise a health concern. Based on the large MOEs derived for both dietary exposure and

¹¹² Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

¹¹³ EFSA Panel on Contaminants in the Food Chain (CONTAM); Scientific Opinion on Tetrabromobisphenol A (TBBPA) and its derivatives in food. EFSA Journal 2011; 9 (12):2477.

¹¹⁴ Op. cit. IARC report 2015; and Abdallah et al. (2016), Emerging Contaminants, 2, 73-79

¹¹⁵ Not with regard to the body weight!

¹¹⁶ Considering the 95th percentile TBBP-A concentration of 460 ng/g in dust.

airborne exposure through dust, the EFSA expert group concluded that it is unlikely that combined exposure through food and dust would result in a health concern.

Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) refer to the results from EFSA (2011) concerning the daily intake of TBBP-A via food (2.6 ng/kg bw) per day); and sum up their literature review on TBBP-A in house dust with the conclusion that – with some exemptions - mostly all values were below 600 ng/g dust. In their study, EU and non-EU countries were addressed while in this report only EU data is shown (Table 6-5) where in total concentrations were measured with a highest median concentration of 79 ng/g. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) used as inhalation DNEL of 300 mg/m³ and the oral DNEL of 2.5 mg/kg/day; applying these DNELs, Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) concludes that no risk could be expected for consumers. It should be noted that the actual DNEL for the general population for inhalative exposure according to the ECHA Brief profile on TBBP-A¹¹⁷ is 4.3 mg/m³.

The following table summarises studies reporting TBBP-A concentrations in dust from consumer environments such as houses, cars and offices, carried out in different European countries.

Table 6-5: Median concentrations (range) of TBBP-A in dust samples from consumer environments in several EU countries

Country (year of sampling)	Environment (no. of samples)	Concentration median (range) [ng/g]	Reference ¹¹⁸
France (2008)	Homes (9)	44 (7-165)	Abdallah et al. 2016
	Offices (11)	79 (32-1,255)	
	Cars (7)	47 (9-66)	
UK (2007)	Homes (35)	62 (<LOD-382)	Abdallah et al. 2008
	Offices (28)	36 (<LOD-140)	
	Cars (20)	2 (<LOD-25)	
Germany (not reported)	Homes (20)	28 (3-233)	Fromme et al. 2014
Belgium (2007/08)	Homes (16)	10 (1-1,481)	Geens et al. 2009
Belgium (2008)	Offices (10)	70,4 (<LOD-212)	D'Hollander et al. 2010
	Homes (45)	11,7 (<LOD-141)	
Greece (not reported)	House dust (28)	11 (<1-630)	Wang et al. 2015
Romania (not reported)	House dust (23)	6 (<1-380)	

Sources: as indicated in the table, compilation of Wibbertmann and Hahn 2018, EFSA 2011 and IARC 2015; LOD: Limit of detection

TBBP-A was also measured in all umbilical cord samples from 16 Japanese mothers in concentrations of 16 +/- 5.5 pg/ g wet weight (IARC 2015). Therefore, it has to be assumed that prenatal exposure occurs. In this period of its development the human embryo is very vulnerable towards exposure to hazardous chemicals.

The exposure of consumers is addressed in several review studies based on similar information, but different conclusions are drawn by the reviewers.

¹¹⁷ Op. cit. ECHA Brief Profile: Entry for 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol

¹¹⁸ See the details of these references in the list of references

6.3. Environmental exposure estimation

Environmental exposure estimation for TBBP-A is based on modelling of environmental concentrations (see section 6.3.1) and on monitoring data. A large amount of monitoring data has been published. Specific data is available for concentrations found near waste processing sites (see section 6.3.3). TBBP-A has also been found in remote regions and in a large number of biota (see 6.3.2).

6.3.1. Exposure modelling

Modelling of environmental concentrations has been done for TBBP-A within the EU RAR (2008). Results of modelling based on more recent data has been published by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018). They used the ECETOC TRA model, the most frequently used model under REACH for Tier 1 exposure estimates. Modelling has been performed for two different Koc values to take into account the variability and uncertainty within the assessment parameter. The following two tables show the predicted concentrations in water. For further predicted concentrations (for air, soil and secondary poisoning) see Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018).

Table 6-6: Predicted Environmental Concentrations (PECs) in water for TBBP-A, Koc = 49,726 l/kg

Information	PEC
Local PEC in surface water during emission episode (dissolved)	3.62E-07 [mg.l-1]
Annual average local PEC in surface water (dissolved)	3.62E-07 [mg.l-1]
Local PEC in fresh-water sediment during emission episode	5.74E-04 [mg.kgwwt-1]
Local PEC in seawater during emission episode (dissolved)	4.69E-08 [mg.l-1]
Annual average local PEC in seawater (dissolved)	4.69E-08 [mg.l-1]
Local PEC in marine sediment during emission episode	7.45E-05 [mg.kgwwt-1]

Source: Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018

Table 6-7: Predicted Environmental Concentrations (PECs) in water for TBBP-A, Koc = 147,360 l/kg

Information	PEC
Local PEC in surface water during emission episode (dissolved)	9.56E-08 [mg.l-1]
Annual average local PEC in surface water (dissolved)	9.56E-08 [mg.l-1]
Local PEC in fresh-water sediment during emission episode	3.06E-04 [mg.kgwwt-1]
Local PEC in seawater during emission episode (dissolved)	1.78E-08 [mg.l-1]
Annual average local PEC in seawater (dissolved)	1.78E-08 [mg.l-1]
Local PEC in marine sediment during emission episode	5.72E-05 [mg.kgwwt-1]

Source: Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018

6.3.2. Monitoring data: remote regions, biota

TBBP-A has been first detected in the environment 1983 in sediments from the Neya River in Japan, in concentrations at a level of 20 ng/g in sediments (Watanabe et al. 1983). In a large number of

studies TBBP-A has been found in various biotic and abiotic matrices from different parts of the world over the past few years (IARC 2015).

Recently, Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) summarised the findings of general monitoring data of TBBP-A in abiotic matrices in areas which have not been used for waste treatment (see the following table).

Table 6-8: Environmental Exposure/ monitoring data for TBBP-A not related to waste treatment (dw: dry weight; LOD: Limit of detection; n.d.: not detectable)

	Matrix	Minimum	Maximum	Unit
1	STP sludge (Italy, Korea, Spain, Sweden, Germany, NL, UK, Ireland, Finland, Canada)	<0.01	617	ng/ g
2	Sediment (Arctic environment, China, Norway, Czech Republic, Germany, Japan, UK, NL, Asia (general), USA)	n.d.	330,000	ng/ g dw
3	Air (Arctic environment, Northeast Atlantic, Russia, US, Japan, China, UK, Sweden, Germany, "8 EU countries")	< LOD	1,800	ng/m ³
4	Soil (Israel, US, China, Switzerland, Spain)	5	45,000	ng/g
5	Water (France, Germany, Japan, Finland, NL, UK, Canada, China, Belgium, Sweden)	< LOD	130	ng/l

Source: Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018

Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) conclude that the available monitoring data suggest that WEEE treatment facilities are not the main sources of release for TBBP-A. More relevant sources are manufacturing plants (BFR manufacturing or EEE manufacturing). They further conclude that usually the measured data are below the PNEC for the respective environmental compartment:

“Usually, all water samples are below the PNECs for fresh and marine water (0.0013, 0.00025 mg/l). However, one study in China results in values in lake water up to 4.87 µg/l in the summer month. All other studies from China results in significantly lower values, The highest values in Europe were found in river and lake water in Poland with values between 0.26 and 0.49 µg/l[37].

For soil and sediment some values are found as well which are above the corresponding limit values (sediment 12.4 mg/kg dw (freshwater), 2.48 mg/kg dw (marine water), 0.055 mg/kg dw (soil)). Again the covered range is large for all compartments, going over several orders of magnitude.

For sediment, two values are above the PNEC (see details in the Annex of Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)): One measured in 1977 in the US near a BFR manufacturing site (330 mg/kg dw) and one from the UK (9.8 mg/kg dw), all other values are below 1 mg/kg dw.

For soil also two values are affected: One from Israel measured near a contaminated site (450 mg/kg dw) and one from China, measured near a BFR manufacturing site (up to 7.76 mg/kg dw; mean 0.672 mg/kg dw). All other values are below the PNEC.

Again this indicates that safe use, including manufacture of TBBP-A, is in general possible. However, under uncontrolled conditions without appropriate.”

A summary of monitoring data from biota is given in IARC (2015). Accordingly, TBBP-A has been found in humans (in serum, adipose tissue, breast milk, cord serum) as well as in animals (common whelk, sea star, hermit crab, fish (e.g. whiting, cod, hake, eel, vendace trout, bull shark), African penguins, cormorant, eggs of predatory birds, seals and dolphins). Examples for concentration ranges found in different species of animals are given in the following table.

Table 6-9: Environmental exposure: TBBP-A in animals. Unit: nanogram / g lipid weight

	Species, matrix, location	Concentration mean / range	Unit
1	Common whelk, whole body, North Sea	5,0 - 96	ng/g lip.w.
2	Sea star, whole body, Tees estuary, UK	205	ng/g lip.w.
3	Fish, muscle, Czech Republic	5 - 203	ng/g lip.w.
4	Bull shark, muscle, Florida USA	0,03 – 35,6	ng/g lip.w.
5	Predatory birds, egg, Norway	<0,003-0,013	ng/g lip.w.
6	Harbour porpoise, blubber, North Sea	83 / 0,1 – 418	ng/g lip.w.
7	Bottlenose dolphin, blubber, Florida, USA	0,05 – 8.48	ng/g lip.w.

Source: IARC 2015

6.3.3. Monitoring data: waste management

A recent summary of monitoring data of TBBP-A in environmental compartments near waste-treatment sites and landfill sites has been given by Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018). Accordingly, most concentrations are not significantly higher than the range of values found at other points of the environment: e.g. in water, one concentration could be found (68 pg/l). In sediments, concentrations range between 0 and 21 ng/g dw (up to 44.4 ng/g ww). In soil, concentrations have been found in the range from < 0.025 – 1800 ng/g dw.

Taken together, this data indicates that disposal and treatment of WEEE can lead to release of TBBP-A if emission control is not properly implemented. If such standards are not met, high TBBP-A emissions can take place. Leaching studies with extractions of housings and printed wiring boards show that TBBP-A can be leached out from WEEE with a leaching rate of usually less than 1 % (Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018):

“Available leaching studies show that the leaching rate of TBBP-A is depending on the pH of the extracting liquid, with higher pH values obviously giving higher leaching rates. However, all studies indicate comparably low leaching rates of usually less than 1 %. Concentrations in extraction liquid go up to 0.012 mg/l which is above the PNECs for fresh and marine water as suggested by the EU RAR (0.0013 and 0.00025 mg/l). However, concentrations in laboratory extraction studies on only one product type (printed wiring boards, housings) are not representative for actual concentrations found in leachate. Concentrations found in landfill leachate go up to 0.00062 mg/l. This is still above the PNECs, however, the measured concentrations include values before waste water treatment, which usually happens before leachate is released into a water compartment (see ECHA guidance R18). After on-site treatment and dilution happening during the release concentrations are expected to be below the applicable PNECs.

Particulate, “leachate sediment” and sludge concentrations are in the ng/g region and thus, all below the PNECs for soil and sediment.”

7. IMPACT AND RISK EVALUATION

The substance evaluation of the human health and environment hazards of TBBP-A under REACH is currently ongoing. EU wide, no conclusion is reached so far on whether TBBP-A has endocrine disruptive properties and whether it is to be considered as PBT, respectively. Any evidence regarding one of these properties may affect the impact and risk evaluation here at hand because as a result of both properties, the current DNELs and PNEC may no longer be applicable:

- As pointed out in section 3.3, there are substantial structural similarities of TBBP-A and bisphenol A. In the document on the identification of bisphenol A as an SVHC due to its endocrine disrupting properties, the structural alerts have been described that are necessary for the different modes of action for BPA, the estrogenic activity, the anti-androgenic activity and the thyroid hormone activity. Having in mind that TBBP-A is currently under review by the ED expert group of ECHA concerning its possible endocrine disrupting properties, it is suggested here that similar hazards are to be expected for TBBP-A as for BPA.
- Substances with PBT properties have the potential to persist and accumulate in the environment. ECHA (2017b) emphasises that the effects of such accumulation are unpredictable in the long-term and that such accumulation is in practice difficult to reverse as cessation of emission will not necessarily result in a reduction in chemical concentration. They circulate in the global environment for long times and if further released the environmental concentration is constantly increasing.

As explained below, workers and consumers as well as the environment are subjected to exposure, which, however, on the basis of the threshold values, is not assessed as posing a risk. However, the risk characterisation ratios provided by the study of the Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) would no longer be valid if TBBP-A were to be recognised as endocrine disrupter and as a type of PBT substance.

As for human health it should further be noted that according to the Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018), the DNELs available come from the REACH registrants, thus from industry. These DNELs however have substantially decreased in the last years and have not been officially scrutinised by ECHA or any EU expert group.

As pointed out earlier, exposure is mainly due to the additive use of TBBP-A in plastic enclosures and housings. Stakeholders, e.g. the ZVEI (2018) pointed out that the manufacture of EEE containing additive applications of TBBPA would not take place in Europe. Based on this information, it is assumed that plastic containing additive TBBP-A occurs solely in imported goods.

7.1. Impacts on WEEE management as specified by Article 6(1)a

Article 6(1)a demands for a potential Annex II candidate the assessment of whether a substance/ substance group *“could have a negative impact during EEE waste management operations, including on the possibilities for preparing for the reuse of WEEE or for recycling of materials from WEEE”*.

As according to the WEEE Directive¹¹⁹ plastics used in EEE containing brominated flame-retardants have to be removed from any separately collected WEEE according to Annex VII on the selective treatment for materials and components of waste electrical and electronic equipment referred to in

¹¹⁹ Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) (recast)

Article 8(2), any brominated flame retardant is understood to render the recycling of the plastic non-feasible.

Standard procedures, especially semi-automatic treatment processes, may not be able to distinguish TBBP-A treated ABS polymers from other, possibly restricted polymer additives (e.g. OctaBDE). This was the reason for DEPA (2010) to conclude that the presence of additively used TBBP-A plastic parts may hinder the recycling of the corresponding plastic. Recyclers¹²⁰ oppose that this would not seem to be of relevance currently as ABS housings were usually not recycled (but incinerated) due to not economically relevant volume streams and chemical contamination.

It is therefore concluded that TBBP-A used as additive flame retardant poses a negative impact on the recycling of WEEE.

As earlier pointed out the residual TBBP-A concentration in wiring board resins is low so that TBBP-A does not contribute to its classification as hazardous waste according to the Commission's decision 2014/955/EU.¹²¹

7.2. Risks for workers and neighbouring residents

According to section 5, shredding of WEEE and the further processing of plastic waste are the most relevant TBBP-A exposure scenarios.

Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) compared the modelled data for exposure according to ECETOC TRA to the DNELs as provided by the REACH registrants that result in a risk characterization ratio (RCR) value below 1. Assuming additionally that not all shredded material contains housings and not all housings have been treated with TBBP-A as a flame retardant, Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) do not expect risks for workers.

It is stressed again that this conclusion is based on DNELs that do not take into account potential endocrine disrupting properties. Workers of EEE waste processing plants are exposed to TBBP-A which is suggested by exposure estimations, by measurements of TBBP-A in EEE waste streams (see Taverna et al. 2017) and results from human biomonitoring (concentrations of TBBP-A reported in serum of workers) (for details see section 6.2.1). Based on these considerations and in contrast to Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018), an impact on worker in EEE waste processing plants is seen here.

If DNEL values of BPA are taken into account as suggested in section 3.3, in order to reflect the potential endocrine disrupting properties of TBBP-A, the estimated exposure by ECETOC TRA rather indicates a risk for workers via dermal exposure than via inhalation.

For workers in third countries where crude WEEE treatment takes place, additional health concerns arise from hazardous transformation products in uncontrolled combustion, grilling, desoldering, uncontrolled dumping of residues, and generally uncontrolled treatment under crude circumstances.

7.3. Risks for consumers

As mentioned above, the risk assessments conducted by Fraunhofer ITEM IPA, Wibbertmann and Hahn, (2018) as well as previous assessments (EFSA, 2015), all referring to quite the same set of

¹²⁰ <http://www.recplas.co.uk/abs-recycling.html>; and <https://eu-recycling.com/Archive/14043> (both visited at 25.10.2019)

¹²¹ 2014/955/EU: Commission Decision of 18 December 2014 amending Decision 2000/532/EC on the list of waste pursuant to Directive 2008/98/EC of the European Parliament and of the Council Text with EEA relevance

literature data, concluded that the exposure via indoor dust does not pose a risk to the general population. Nonetheless, IARC (2015) draws a contradictory conclusion.

Based on assumptions on the house dust ingestion and inhalation as documented by Oomen et al. (2008)¹²² and the identified maximum concentration of TBBP-A in house dust (1,480 ng/g) a daily exposure via dust has been estimated as shown in the following table.

Table 7-1: Worst case exposure to TBBP-A via house dust (ingestion + inhalation)

Population	Exposure
Child	0.015 mg/day/kg
Adult	0.0013 mg/day/kg

Source: Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018

If DNEL values of BPA are taken into account as mentioned in section 3.3, in order to reflect the potential endocrine disrupting properties of TBBP-A, a risk characterisation ratio of > 1 is reached for children that indicates a risk. The DNEL for bisphenol A for oral exposure is at 4 µg/kg body weight per day.

7.4. Risks for the environment

The exposure modelling for PECs of Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) does not indicate a risk for the different environmental compartments if the PNECs as presented in section 4.4 are taken into consideration. The highest risk characterisation ratios are reached for the soil compartment which reflects the adsorption behaviour of TBBP-A to particles. However, these considerations do not take into account the persistent properties of TBBP-A.

The monitoring data in biota can be summarised in a way that TBBP-A is frequently detected and can be seen as a ubiquitous contaminant. This indicates that it is continuously released into the environment. The presence of TBBP-A in the Arctic is an indication for its ability to undergo long-range transport and contaminate also remote and pristine areas.

It is an indication for its persistency and thus an indication that the normal risk assessment, by means of the ratio of the expected environmental concentration (Predicted Environmental Concentration, PEC) and an estimated non-effect threshold (Predicted No-effect concentration, PNEC), is not applicable. Substances with PBT properties have the potential to persist and thereby accumulate in the environment. ECHA (2014) emphasises that the effects of such accumulation are unpredictable in the long-term and that such accumulation is in practice difficult to reverse as cessation of emission will not necessarily result in a reduction in chemical concentration. They circulate in the global environment for long times and if further released the environmental concentration is constantly increasing.

For third countries, where informal recycling of WEEE take place, Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018) note that *“exposure to TBBPA and its decomposition products may be higher. Available monitoring data suggest that soil will probably be the most critical compartment*

¹²² Oomen, A.G.; Janssen, P.J.C.M.; Dusseldorp, A.; Noorlander, C.W. (2008): Exposure to chemicals via house dust; <https://www.rivm.nl/bibliotheek/rapporten/609021064.html>

Also cited in: European Chemicals Agency ECHA (2015): Guidance on Information Requirements and Chemical Safety Assessment Chapter R.15: Consumer exposure estimation; Draft (Public) Version 3.0 October 2015; https://echa.europa.eu/documents/10162/23047722/draft_201510_r15_peg_infreq_uses_en.pdf/4c52b39e-ca5e-4cb2-a6e3-b8020dc8d047

for TBBPA exposure in these cases. Concerning degradation products information cited in the previous section concerning PCDD/F levels as well as further information published e.g. by Hu et al. [149] also suggests that other environmental compartments will show increased concentrations of these contaminants. However, it is not possible to quantify the influence of TBBPA on the overall exposure to these potential decomposition products.”

8. ALTERNATIVES

The discussion on alternatives addresses the two application areas - reactive applications in PWBs and additive applications in plastic housings.

In relation to epoxy resins (**reactive use of TBBP-A in PWBs**), it is understood that industry is actively investigating substitution strategies for brominated flame retardants. The stakeholder contributions to support this study mention that halogen-free PWB laminate materials were available.¹²³ However, no concrete alternatives are proposed as they would not have all necessary safety approvals and greater percentages of the substitutes would be required within the products. In addition, ASD state that “*the substitutes are unlikely to perform sufficiently well when subjected to heat and vibration in high-stress environments*” and TMC points out that “*they do not exist for all applications, especially in high-frequency circuitry.*”

Nonetheless, the most successful and already applied alternatives to TBBP-A in PWBs are phosphorus compounds like DOPO (9,10-Dihydro-9-oxa-10-phosphaphenanthrene-10-oxide), poly phosphates or metal phosphinates, from time to time in combination with inorganics synergists like ATH or silica, bound to epoxy resins. Concerning DOPO, moderate human health concern is assumed but this compound and its derivatives are expected to be highly environmental persistent.

Commonly used substitutes for **TBBP-A in housings** for EEE (additive use) also include halogen-free organic phosphorus compounds. The human health hazards of the organophosphate esters are estimated to be lower than those of TBBP-A though some substitution candidates still meet the PBT criteria regarding the environmental risks.

In this area elimination is also possible through the substitution of polymers such as ABS and HIPS with polymers such as PC and PPE.¹²⁴

8.1. Availability of substitutes / alternative technologies

In the following information is specified summarising the potential substitutes separately presented for reactive (see also Table 8-1) and additive (see also Table 8-2) TBBP-A applications.

Alternatives to TBBP-A in reactive applications

In relation to epoxy resins, it is understood that industry is actively investigating substitution strategies for brominated flame retardants. In some cases, this may only entail a substitution of one brominated flame retardant by other types rather than by bromine free alternatives. However, it is also clear that non-halogenated flame retardants are in development for such purposes. Rakotomalala et al.¹²⁵ mention that since disputable additives can leach out of a polymer while being processed and/or while being used, there is always a potential health risk when such systems are used. In addition, the environmental and end-of-life issues have led to strong efforts in replacing halogenated systems.

¹²³ Op. cit. TCM (2018)

¹²⁴ Op. cit. UBA (2008): This source specifies “*this goes hand in hand with the substitution of polymers such as PC and PPE for ABS and HIPS, or the use of polymer blends*”. Semantically PC and PPE are referred to as alternatives for both ABS and HIPS using TBBP-A. As current data suggests that only ABS is a housing material in which TBBP-A is used, this data has been reformulated here in this respect.

¹²⁵ Rakotomalala, M.; Wagner, S.; Döring, M.: Recent Developments in Halogen Free Flame Retardants for Epoxy Resins for Electrical and Electronic Applications. *Materials* 2010, 3, 4300-4327; Data presented by Rakotomalala et al show that bromine-based flame retardants account for only 10% market share of flame retardants used for EEE. Non-halogenated substitutes account for a larger market share: metal hydroxide-based flame retardants (56%), non-halogenated phosphorus ones (9%) and melamine-based ones (3%).

Table 8-1: Existing alternatives for reactively used TBBP-A in epoxy resins

Category	Functional principle	Name/specification	Advantages and limitations in application	Hazardous properties
Nitrogen components		Melamine polyphosphate based products		May show moderate concerns for human health effects, high concerns for reproductive effects and a high tendency for persistence (modelled data).
		Melamine cyanurate	Advantage of cheap and high availability but poor flame retardancy and high dosages required.	
Non-halogenated phosphorus FR	Function as a mono- or bifunctional cross-linking agent and in combination with aluminium-hydroxide. ¹²⁶ Converted into a phosphorus-containing epoxy material.	Non-halogenated PFR in general	Have a higher moisture absorption than TBBP-A based.	The inorganic part of phosphorus containing flame retardants "is not harmful and does not tend to form toxic gases since phosphorus is mostly locked into the char." ¹²⁷
		DOPO (9,10-Dihydro-9-oxa-10-phosphaphenanthrene-10-oxide); Derivates: <ul style="list-style-type: none"> • DOPO-HQ • DOPO-PEPA¹²⁸ • EDA-DOPO¹²⁹ • Ethylen-(DOP)2 	<ul style="list-style-type: none"> • Compared to TBBP-A, this substitute has higher costs which can be lowered with ATH or silica as fillers, or in combination with metal phosphinates; • is monofunctional, meaning that there is more potential for releases from products compared to bifunctional alternatives (such as TBBP-A). 	<ul style="list-style-type: none"> • According to REACH Registration data, causes allergic skin reactions and irritation of the eye¹³⁰. Furthermore, the US EPA identifies: • moderate hazard concerning carcinogenicity, developmental and neurological effect; • moderate concern for aquatic toxicity; • a high tendency for persistence.
		FyrolPMP: phosphorus content of 17.5 % ¹³¹	Hazardous properties <ul style="list-style-type: none"> • moderate hazard for reproductive, developmental, neurological and repeated dose effects (estimated); • high concerns for acute/chronic aquatic toxicity (estimate); • a very high tendency for persistency and bioaccumulation¹³². 	
		Dow XZ-92547: reaction product of an epoxy phenyl novolak with DOPO	Hazardous properties Related from the structure of the components <ul style="list-style-type: none"> • phosphinate esters: environmental toxicity; • epoxy groups/epoxides: dermal sensitization, cancer, reproductive effects, developmental toxicity; • organophosphorus compounds: neurotoxicity. 	
		Poly 2-(6-oxido-6H-debenzo(c,e)(1,2)oxaphosphorin-6-yl)- 1,4-benzenediol (POBPP) (no further information available)		

¹²⁶ Op. cit. Rakotomalala, M. et. al 2010

¹²⁷ Under thermal stress, the major part of phosphorus is oxidised to phosphorus pentoxide (P₂O₅) which then hydrolyses to polyphosphoric acid (H_xP_yO_z). Polyphosphoric acid in particular plays an important role in creating carbonaceous char." The PO and PO₂ derivates that are formed when phosphorus FR react via the gas phase can be rapidly oxidised to P₂O₅ which in turn forms polyphosphoric acid (Rakotomalala et al, 2010).

¹²⁸ Yan Zhang, Bin Yu, Bibo Wang, Kim Meow Liew, Lei Song, Chengming Wang, and Yuan Hu: Industrial & Engineering Chemistry Research 2017 56 (5), 1245-1255

¹²⁹ N.M. Neisius, M. Lutz, D. Rentsch, P. Hemberger, S. Gaan: Synthesis of DOPO-based phosphonamidates and their thermal properties. In: Ind. Eng. Chem. Res. Band 53, Nr. 8, 2014

¹³⁰ REACH registration on ECHA website

¹³¹ A reaction product of Phosphonic acid, P-methyl-, diphenyl ester, polymer with 1,3-benzenediol (= Aryl alkylphosphonate)

¹³² Environmental degradation of this polymer by hydrolysis or direct photolysis is not expected to be significant as the functional groups present do not tend to undergo these reactions under environmental conditions. Possible degradation products from sequential dephosphorylation are phosphinates, phenol or resorcinol. Op. cit. US EPA 2015

Fillers	Applicable in combination with other flame retardants	Aluminium diethylphosphinate and silica	(no further information available)	
Metal-based substitutes	Will not be covalently integrated in the surrounding polymer matrix.	Metal-based FR in general	Are to be considered rather as additives and may also distort the technical performance (e.g. dielectric properties) of PWB.	
		Red phosphor in combinations with ATH or MDH	Red phosphor can form phosphine (PH ₃) and acidic oxides under hot and humid conditions.	Highly flammable and handling is difficult until it is incorporated into the polymer. Traces of phosphine and corrosive phosphorus acids are generated under moist conditions. Moreover, red phosphorus is toxic to aquatic organisms. ¹³³
		Metal hydroxides	<ul style="list-style-type: none"> • Cheap and easy to obtain; • High loadings are a condition for effective flame-retardant effect; • Looking at ATH, the use is only possible under low temperature conditions. In contrast, MDH is usable at ~330 °C due to an endogenic reaction under water release. 	are understood to be non-toxic and environmentally friendly

Source: Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018, US EPA 2015 and Morose, G. 2006 ;other sources are cited in the footnotes

In addition, on the material level, alternative epoxy resin material could be applied aiming to phase out halogenated flame retardants (elimination) e.g. non-flammable resins or those materials with which halogen free flame retardants are applicable. According to Morose:

- for low-end applications of wiring boards, less expensive resins such as phenolics, melamines, vinyl esters, and polyesters may be used;
- while for high frequency applications, poly(tetrafluoroethylene) (PTFE) are applicable;
- for high temperature applications, PTFE, other fluoropolymers, cyanates and epoxy-PPE blends or even ceramics are an alternative whereas cyanates, PTFE, and inorganic substrates are usually inherently flame retardant.”¹³⁴

In general, estimations made by Bergendahl et al.¹³⁵ suggest, that costs will increase by approximately 35-50 % for the manufacture of printed wiring boards if a switch to halogen free resins is performed. In addition, the cycle time, i.e. the maximum time allowed at each workstation in the assembly line to complete its assembly tasks on the board, may increase.

¹³³ Weil, Edward D., and Levchik, Sergei, A.: Review of Current Flame Retardant Systems for Epoxy Resins, Journal of Fire Sciences, Vol. 22, January 2004 (cited by Morose, 2006)

¹³⁴ Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

¹³⁵ Bergendahl, C.G., et al.: Environmental and economic implications of a shift to halogen-free printed wiring boards. Electronics Goes Green 2004 (Plus): Driving Forces for Future Electronics, Proceedings, 2004: p. 783-788.

Alternatives to TBBP-A in additive applications

Whereas **additively used TBBP-A** was substituted by (organo-)phosphorus or nitrogen FR in polyurethane foams – to name one example,¹³⁶ this cannot be adapted directly to EEE applications because the functional requirements may differ from case to case.

From the available data, it can be understood that for obtaining flame retardancy in additive applications either other brominated flame retardants are applied or various non-halogenated flame retardants.

- Alternative brominated compounds include e.g. Decabromodiphenylether or brominated epoxy oligomers (BEOs).¹³⁷ Nevertheless, substituting TBBP-A with those will not be expedient to phase out halogenated FR as such. Decabromodiphenylether is furthermore prohibited under various legislation including RoHS (as part of the prohibition of polybrominated diphenyl ethers), Annex A of the Stockholm Convention, and thus POP regulation, and would thus not be relevant as a potential substitute. This is why these substitution candidates are not further addressed here.
- As for non-halogenated substance substitutes, these include halogen-free organic phosphorus compounds. The human health hazards of the organophosphate esters are estimated to be lower than those of TBBP-A though some substitution candidates still meet the PBT criteria regarding the environmental risks.

¹³⁶ According to Zevenhoven (2004), the use of brominated flame retardants (BFRs) in polyurethanes in form of an additive FR has been in decline already back in 2004. The reasons for decreasing use were environmental and health concerns. Moreover, flame retardants based on (organo-)phosphorus or nitrogen alternatives were becoming more common. PU foams are often flame-retarded using phosphate polyols, which contain ~10 %-wt phosphorus. The open cell structure of PUF foams makes flame retardation difficult, and increasing the tendency of the foam to char is an important effect. For PUR foams additive flame retardants are used.

¹³⁷ Posner, S.: Survey and technical assessment of alternatives to TBBPA and HBCDD. 2006, KEMI: Sweden; and op. cit. DEPA 2010

Table 8-2: Possible alternatives for the additive use of TBBP-A in housings

Category	Functional principle	Name/ specification	Advantages and limitation in application	Hazardous properties
Metal hydroxides	Often used as synergists with phosphorus based flame retardants	<ul style="list-style-type: none"> Aluminium hydroxide (ATH) Magnesium hydroxide (MDH) 	Very high loadings (~30–60 %) are required to obtain flame retardancy. Thus, it cannot be used in applications where the high loadings may affect processing and required material properties.	Are understood to be non-toxic and environmentally friendly.
Zinc borate	Halogen-free application with silica ¹³⁸	Tradename <i>Firebrake</i> , is described as <i>“combines the best of zinc and boron oxides with water release”</i> . ¹³⁹	Only applicable in low temperature environments.	Toxic to aquatic organisms, but is not expected to bio-concentrate. However, at high concentrations, it can be harmful to boron sensitive plants ¹⁴⁰
Non-halogenated organophosphorus FR	In combination with PPE/PS or PC/ABS blends, in parts accompanied by ATH	<ul style="list-style-type: none"> Resorcinol-bis-diphenylphosphat (PBDPP); Resorcinol-diphosphat; Bisphenol-A-bis-diphenylphosphat (BPA-BDPP); Bisphenol-A-diphosphat; Triphenylphosphat (TPHP); Diphenyl-cresylphosphat; Aluminium-diethylphosphinate; 		<p>The inorganic part of phosphor containing flame retardants <i>“is not harmful and do not tend to form toxic gases since phosphorus is mostly locked into the char.”</i>¹⁴¹</p> <p>Structural alerts:¹⁴²</p> <ul style="list-style-type: none"> Phosphinate esters - environmental toxicity (aquatic toxicity); Organophosphorus compounds – neurotoxicity; Phenols (for the hydrolysis product) – neurotoxicity. <p>Further specific hazardous properties can be read in Table 8-3.</p>

Source: US EPA 2015, DEPA 2015 and Morose, G. 2006

UBA (2008) mentions that PC and PPE could be used as alternatives on the material level for ABS so as to eliminate the use of TBBP-A¹⁴³. For now, it is not yet clear to which extent, housing materials used for other equipment could substitute ABS/TBBP-A systems.¹⁴⁴

8.2. Hazardous properties of substitutes

In general, when substituting one brominated flame retardant for another, the change in hazardousness shall be determined by the substance to be applied as an alternative, resulting in

¹³⁸ Op. cit. Morose (2006)

¹³⁹ <https://www.borax.com/products/firebrake> (last access 24-10-2019)

¹⁴⁰ HDP User Group International, Inc., Design for Environment – Phase II, January, 2004; Gardner, Donald, et al, Toxicological Risks of Selected Flame-Retardant Chemicals, National Academy Press, Washington D.C., 2000 (cited by Morose, 2006)

¹⁴¹ See footnote 127

¹⁴² Op. cit. US EPA (2015)

¹⁴³ Op. cit. UBA (2008)

¹⁴⁴ Op. cit. Morose (2006)

either a higher, similar or lower toxicity. Detailed information on hazardous properties of substitutes categories are presented in the tables above.

In a report published by US EPA 2015, **ten flame-retardant** chemicals and resins for **FR4 laminate materials for PWBs** were evaluated in relation to their hazardous properties. It is explained that the level of available information on human health and environmental toxicity varies widely between flame-retardant chemicals. Little information exists concerning many of the alternative flame-retardant materials evaluated and thus EPA used the tools and expertise developed for the New Chemicals Program to estimate the potential impacts of flame retardants for which no experimental data were available. Unfortunately, the evaluation of the chemicals and resins relates mainly to trade names, which makes it impossible to interpret and assess the results in the dossier at hand.

On the environmental fate of DOPO and its hydrolysis product [2-(2'-hydroxyphenyl)phenyl] phosphonic acid, US EPA (2015) explains that they are expected to be found primarily in soil and to a lesser extent, in water. Both are expected to be highly mobile in soil based on an experimental Koc value. These compounds have the potential to migrate from soil into groundwater. In the atmosphere, DOPO is expected to exist in both the vapour and particulate phase, based on its vapour pressure and [2-(2'-hydroxyphenyl)phenyl] phosphonic acid is expected to exist primarily in the particulate phase. Vapor-phase DOPO is expected to have limited potential for photodegradation. Particulates will be removed from air by wet or dry deposition.

In the consultants' perspective, seeing as DOPO is monofunctional and has a higher potential for release than TBBP-A, the environmental fate could be a reason for concern where DOPO emits into the environment. Looking at the specified hazardous properties also raises concern in this regard, though certainty is not clear given that there is currently no harmonized CLP classification¹⁴⁵: The REACH registration data refers to possible skin reactions and eye irritations. The US EPA identifies DOPO as a moderate hazard in relation to cancer, neurological effects and aquatic toxicity, while also referring to its high tendency for persistence. Though additional studies on the toxicity of DOPO may be needed, this suggests that DOPO may also be associated with hazardous concerns.

As it comprises one of the more promising alternatives for **TBBP-A applied in additive uses**, the category of the **organophosphates** is further addressed as follows:

According to REACH¹⁴⁶, from this group the following classifications are specified

- Triphenylphosphate is classified as:
 - very toxic to aquatic life;
 - toxic to aquatic life with long lasting effects; and
 - potential endocrine disruptor.
- Tricresylphosphate is classified as
 - toxic to aquatic life with long lasting effects;
 - suspected as mutagenic and skin sensitising.

¹⁴⁵ The REACH Registration dossier submitted refers to H317 (may cause an allergic skin reaction) but does not specify further classification. See <https://echa.europa.eu/de/information-on-chemicals/cl-inventory-database/-/discli/details/104051>

¹⁴⁶ Op. cit. ECHA Registered Substance Database: Entry for Tricresylphosphate & Triphenylphosphate

The following table summarises the persistence, bioaccumulation potential and toxicity information for other selected alternatives of the organo-phosphorus group.¹⁴⁷

Table 8-3: Human health and environmental impact indicators for different organo-phosphorus based FR as compared to TBBP-A

Substance	Human health					A/M ecotoxicity. Acute or chronic	Persistence	Bioacc.	PBT
	Cancer hazard	Non-cancer effects	Mutagenity	Amount of tox info	Inf on potential routes of exposure				
TBBPA	L	M	L	M	Yes	M-H	Yes	Yes	Yes
Resorcinol bis (diphenyl-phosphate) (RDP)	NI	L	L	L	NI	M-H	No	No	No
Bisphenol A diphosphate (BAPP, BPADP) or Bisphenol A bis(diphenyl phosphate) (BDP)	NI	L	L	L	NI	L-M	Yes	NI	NI
Diphenyl cresyl phosphate (DCP)	NI	M	L	L-M	Yes	M-H	Yes	Yes	Maybe (NI)
Triphenyl phosphate (TPP)	L	L-M	L	L-M	Yes	M-H	No	No	No

NI : No Information/insufficient information

A/M : Aquatic and microbial

PBT: whether the alternative meets Washington State Department of Health's PBT criteria,

Ranking: H = high, M = medium, L = low concern based on available information: Ranking is based on US EPA, 2005.

Source: Danish EPA 2010

8.3. Data basis for alternatives and uncertainties

It is understood that alternatives exist and are also applied in some cases. Though data is not always detailed there are indications that alternatives are already in use by certain manufacturers, particularly among manufacturers of ICT products.

¹⁴⁷ **Data** from Washington State (2006): Polybrominated Diphenyl Ether (PBDE). Chemical Action Plan: Final Plan. Department of Ecology Publication No. 05-07-048. Washington State Department of Health. **Layout:** Danish EPA 2010 Inclusion of HBCDD, DEHP, BBP, DBP and additive use of TBBPA in annex IV of the Commission's recast proposal of the RoHS Directive - Socioeconomic impacts

Some companies restrict the use of halogenated substances in all materials and components on a voluntary base. For example, companies like Apple¹⁴⁸, Dell¹⁴⁹, Lenovo¹⁵⁰, HP¹⁵¹ and Samsung¹⁵² have TBBP-A on their supply chain specifications for use of restricted substances in products with thresholds of 900 ppm (HP, Apple, Samsung) or 1000 ppm (Lenovo, Dell). These thresholds are quite high for the case of unreacted traces of TBBP-A when applied in reactive uses (epoxy laminates in PWBs). It is thus not clear whether these companies use alternatives to TBBP-A in FP4 applications in PWBs, or whether the voluntary restriction is complied with given the very low amounts of unreacted TBBP-A left in the final product. In this respect, most companies do not specify the application form of TBBP-A and the restriction is understood to apply to all forms which result in higher concentrations in the final product. In contrast, Lenovo specifies reactive TBBP-A as an exemption to their TBBP-A threshold, whereas Samsung includes reactive TBBP-A in the restrictions. The 1000 ppm threshold corresponds to 0.1 % per weight which is the threshold applied for most RoHS restricted substances of Annex II. In addition, this threshold is in line with the thresholds for “low halogen” presented in an iNEMI statement from 2009 mentioned above. Apple states that the company “replaced brominated flame retardants [...] using safer metal hydroxides and phosphorus compounds in their place.”¹⁵³ DEPA 2010 present non-halogenated polymer-flame retardant combinations used by important European producers of TV-sets. The producers were mostly using different polymer blends (PC/ABS, PS/PPE, HIPS/PPO) in combination with non-halogenated flame retardants but the actual flame retardants were not reported.

An additional proof for the application of halogen-free housings is the fact that phosphorous based flame retardants in EEE enclosures (e.g. LCD TVs) are reported to be found in the waste stream.¹⁵⁴

The stakeholder contributions to support this study mention that halogen-free PWB laminate materials were available.¹⁵⁵ However, no concrete alternatives are proposed as they would not have all necessary safety approvals and greater percentages of the substitutes would be required within the products. In addition, ASD state that “the substitutes are unlikely to perform sufficiently well when subjected to heat and vibration in high-stress environments” and TMC points out that “they do not exist for all applications, especially in high-frequency circuitry.”

¹⁴⁸ Apple (2019): Environmental Responsibility Report 2019 Progress Report, covering fiscal year 2018; https://www.apple.com/environment/pdf/Apple_Environmental_Responsibility_Report_2019.pdf
Apple Regulated Substances Specification 069-0135-K, September 2018; https://www.apple.com/environment/pdf/Apple_Regulated_Substances_Specification_Sept2018.pdf (assessed 07.11.2019)

¹⁴⁹ Dell Specification, Materials Restricted for Use, Document Number: ENV0424 Revision:A03-00; <https://i.dell.com/sites/doccontent/shared-content/solutions/en/Documents/ENV0424-A02.pdf> (assessed 07.11.2019)

¹⁵⁰ Lenovo Engineering Specification 41A7731, Baseline Environmental Requirements for Lenovo Products, Materials and Parts; 01 May2019, Version 7.5; <https://www.lenovo.com/us/en/pdf/41A7731.pdf> (last assessed 07.11.2019)

¹⁵¹ HP Standard 011 General Specification for the Environment, HX-00011-00, 26-Jul-2018; (last assessed 07.11.2019)

¹⁵² Samsung Electronics, Standards for Control of Substances used in products (SEC Registration No. 0QA-2049), Revision 19, October 13, (2017); <https://www.samsung.com/us/smg/content/dam/samsung/sg/aboutsamsung/2017/environment/pdf/standard-substances-products-en.pdf> (last assessed 07.11.2019)

¹⁵³ Environmental Responsibility Report (2019), Apple

¹⁵⁴ KU Leuven-University of Leuven (2018): Contribution submitted by Jef Peeters, Department of Mechanical Engineering, Faculty of Engineering & Engineering Technology, KU Leuven-University of Leuven on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_KU_LEUVEN_Diantimony_Trioxide_20180615.pdf, last viewed 26.06.2018 and op. cit. ZVEI (2018)

¹⁵⁵ Op. cit. TCM (2018)

8.4. Conclusion on alternatives

The environmental fate in the case of alternatives may differ from case to case due to physico-chemical characteristics of the substitutes. It is inherently difficult to conclude as to actual impacts resulting from the application of alternatives. Nonetheless, conclusions on the most promising possibilities are drawn as follows:

For reactive use

The most successful and already applied alternatives to TBBP-A in PWBs are phosphorus compounds like DOPO. Concerning this substitution candidate, moderate human health concern is assumed and this compound and its derivatives are expected to be highly environmentally persistent. As DOPO is mono-functional compared to the bi-functional TBBP-A, a one-to-one substitution cannot take place. Furthermore, its use implies higher costs which can be reduced by using ATH or silica as fillers, or by combining it with metal phosphinates.

As PWBs are ubiquitous in EEE of all categories with TBBP-A being one of the most important flame retardants in this application, the question remains whether DOPO could substitute the large amount of TBBP-A used there and as to how this alternative would compare in terms of hazardous properties.

For additive use

Common substitutes for TBBP-A in housings are halogen-free organo-phosphorus compounds, while elimination of TBBP-A may also take place where ABS/TBBP-A systems are replaced with polymers such as PC and PPE, or other polymer blends.¹⁵⁶ This exchange in host material entails higher costs for manufacturers (typically 10-50 % higher). The costs may decrease over the years as a result of a larger market for the alternatives.¹⁵⁷ The human health hazards of the organophosphate esters differ depending on the side group of the phosphate. To sum it up, non-chlorinated alkylated organophosphates are registered without restriction under REACH; in contrast, some arylated and chlorinated organophosphates meet the PBT criteria or are suspected of being potential endocrine disruptors (triphenyl phosphate).

As outlined earlier, companies exist that have voluntarily phased out TBBP-A especially in additive use, thus substitution is concluded as possible here both from the technical perspective (substitutes comparable and reliable) as well as in terms of the economic perspective (additional costs, in conclusion, considered to be acceptable). The environmental and human health risks of several of the organophosphorus compounds suggest that additional data is needed concerning the available alternatives to allow conclusions to be drawn as to their level of hazardousness and as to the possible need for further restrictions to avoid regrettable substitution.

¹⁵⁶ Op. cit. UBA 2008, DEPA (2010)

¹⁵⁷ Op. cit. DEPA (2010)

9. DESCRIPTION OF SOCIO-ECONOMIC IMPACTS

9.1. Approach and assumptions

In this section, possible socio-economic impacts of a scenario in which TBBP-A is to be restricted are compared with the current situation (business as usual) in which TBBP-A is not restricted. In this respect, the section shall address the differences between two scenarios:

- a restriction scenario; and
- the current non-restriction scenario.

The essence of this analysis is based on the understanding as to which applications shall be affected by a restriction scenario. In principal, as presented in the above sections as well as in section 10, TBBP-A is applied in two application areas which could be affected from a restriction; reactively in epoxy resins of PWBs and additively in plastic housings and enclosures of EEE.

In reactive applications, TBBP-A undergoes a chemical reaction and is generally not present in the final component in its original form. On the condition of good practice, existing evidence suggests that the concentration of TBBP-A remaining in cases of its application in epoxy resins in PWBs is well below the proposed restriction threshold (see section 10). In such cases impacts are not expected and shall not be addressed in the sub-sections below. Cases of bad practice, where TBBP-A may remain at higher levels in the final component, may be affected if they exist. Since in such cases substitution of this substance may be avoided through the application of good practice, this sub-case shall also not be looked into separately: As in most cases, standard manufacture practices do not result in residual TBBP-A in concentrations above the proposed threshold, it must be assumed that the costs of improvements in production practices are acceptable and would be justified with the benefit of reducing the amount of residual TBBP-A and preventing possible emissions.

In the case of additive uses, it has been shown that these remain in the final product and may emit through use or at end-of-life, resulting in possible impacts on consumers and or on workers of waste management facilities. Emissions have shown up in the environment as well as in the Arctic, suggesting that TBBP-A is a persistent substance and its increasing presence could result in an impact on the environment (aquatic toxicity). Thus, other impacts related to a restriction are to be weighed against the benefits of removing TBBP-A from the plastic material cycle and thus to preventing (or decreasing) possible impacts on the environment and on health with which its presence and emissions are related.

9.2. Impact on chemicals industry

Manufacturers of flame retardants

In terms of the manufacture of TBBP-A, BSEF specify that it is produced mainly in Israel, Jordan, the United States, Japan and the PR of China.¹⁵⁸ These countries are understood to be the main countries where bromine is sourced and bromine-based chemicals are manufactured.

To understand how these industries shall be affected, it is necessary to know how the restriction shall affect the use of TBBP-A in articles placed on the EU market as well as in the global production of EEE. Generally, in a restriction scenario, it can be expected that the production of TBBP-A is to

¹⁵⁸ BSEF, Fact sheet TBBP-A: Tetrabromobisphenol A for Printed Circuit Boards and ABS plastics (2007): Brussels, Belgium

decrease, as it shall no longer be permitted in EEE to be placed on the EU market. It is, however, also possible that the EU restriction will affect EEE to be placed on other markets:

- In part, this can be attributed to the fact that many countries have established legislation similar to the RoHS Directive, and that these may adapt their legislation to include the proposed restriction. In the current context, this is observed to derive knowledge on the range of impacts on the manufacture and marketing of TBBP-A. However, proceeding from the assumption that the TBBP-A restriction shall result in environmental and health benefits; this should also be viewed as an added benefit of an EU restriction. In other words, the benefit of a restriction can be expected to extend beyond the European market (i.e. consumers and waste management can be expected to have environmental and health benefits also beyond the EU).
- Additionally, though in some sectors EEE is manufactured to some degree for specific markets, in others, equipment design targets the global markets, and substance restrictions that need to be complied with in one country shall often lead to compliance of all equipment. This is for example the case in the medical device sector and the monitoring and control sector, where equipment is manufactured in small annual volumes and thus models are developed for the most part for all markets.

In this sense, a restriction can be expected to lead to a decrease in the manufacture of TBBP-A somewhere in the range of the TBBP-A currently in use for EEE in the EU and for EEE globally. Subsequently, this may affect the total amounts of bromine sourced. The data presented in 2.3 suggests that a decrease in used quantities is already underway. The most recent data on global use originate from UBA¹⁵⁹ who estimated in 2008 that 145,000t/a TBBP-A were used globally (with 7,000 t/a being used in the EU). This number does not reflect the total amount that is placed on the EU market through EEE, nor the amounts relevant for additive applications. Additional data on this aspect is still being sought, but the existing data provides a first indication as to the potential decrease in the amount of TBBP-A produced globally.

In parallel, in terms of alternatives, it is observed that different types of substitutes exist, namely halogenated FR and non-halogenated ones. Of the first group, some of these can be expected to be brominated FRs, which shall also be manufactured by the bromine industry in the countries mentioned above. In this sense, though TBBP-A manufacture is expected to decrease, industries affected can also be expected to see a certain increase in the manufacture of other bromine-based FR which shall set off lost revenue to some degree.

In parallel, manufacturers of non-halogenated alternatives can be expected to see an increase in business. According to DEPA¹⁶⁰, three of the bromine manufacturers also manufacture different halogen-free flame retardants like organo-phosphorous compounds and magnesium hydroxide. In this sense, here too, TBBP-A losses could be expected to be set off by gains related to the marketing of non-halogenated alternatives. DEPA further quote a study by Lassen et al.¹⁶¹ and specify that *“halogen-free alternative flame retardants that may serve as alternatives to TBBPA in EEE are manufactured primarily by 6 European companies, of which 5 have headquarters within the EU”*.

Though it is difficult to estimate how the losses of TBBP-A manufacturers shall be set-off by the gains of manufacturers of alternatives, it is noted that at least some alternatives are currently more expensive and require higher concentrations to provide the same flame retardancy effect. It is thus

¹⁵⁹ Op. Cit. UBA (2008)

¹⁶⁰ Op cit. Depa (2010)

¹⁶¹ Cited by Depa (2010) as Lassen C., A. Leisewitz and P. Maxson. 2006. Deca-BDE and alternatives in electrical and electronic equipment. Environmental Project no. 1141, 2006. COWI, Öko-Recherche and Concorde East/West for the Danish Environmental Protection Agency. www.mst.dk.

assumed that within the chemical industry, losses of TBBP-A manufacturers shall be set-off by gains of manufacturers of other alternatives.

In this respect, it is also worth mentioning the possible decrease in the amount of bromine sourced. For example, both in Jordan and Israel, bromine is sourced from the Dead Sea. In both countries, these chemical industries provide a significant source of income and employment, while also having an impact on the surrounding environment.

Resin manufacturers

According to a DEPA¹⁶² study “*plastic resins are produced and formulated by relatively few large companies in Europe. The resins are mixed with additives (in so-called “masterbatches”) to form compounds, which are the raw materials for further processing. Compounding may take place by the resin manufacturer, by specialised compounders or by the company manufacturing the plastic parts”*.

Resin manufacturers can be expected to be affected in so far that they shall need to reformulate resins where TBBP-A is phased out. Nonetheless, stakeholder information suggests that EU manufacturers no longer use TBBP-A in their equipment (see ZVEI contribution¹⁶³) and in this sense, it is only resin manufacturers outside the EU (or EU manufacturers exporting to non-EU countries) that may be affected. Though some resin formulators who have been using TBBP-A may experience loss of business, some of these may revert themselves to alternatives to prevent such losses and others that are already applying alternatives may see an increase of business. Though resin reformulation may be associated with expenses, these costs are understood to be passed on to the manufacturer who, if needed, shall adapt the price of the product. In this sense, estimations were not made separately for this part of the value chain. Furthermore, as some EEE manufacturers have phased-out TBBP-A voluntarily, it needs to be assumed that this process did not have a severe effect on resin manufacturers and thus no adverse impacts are anticipated as a result of a TBBP-A restriction at present either.

9.3. Impact on EEE producers

A few of the stakeholder contributions refer to aspects of relevance for analysing socio-economic impacts of a restriction. For example, the Test and Measurement Coalition (TMC) stated that “restricting TBBP-A will lead to:

- Forced redesign and requalification testing of entire portfolio;
- Lost opportunity for introduction of new, cutting edge products;
- Withdrawal of products from EU market;
- Impacts on innovation of users unable to access withdrawn products.”¹⁶⁴

“And we anticipate that our entire portfolio of products will be impacted [...] (portfolio scale of 2,000 to 3,000 products (average of members) with tens of thousands of product plus option

¹⁶² Op cit. Depa (2010)

¹⁶³ ZVEI (2019): 1st Stakeholder Consultation–QuestionnairefortetrabromobisphenolA–TBBP-A(CAS79-94-7), submitted by Zentralverband Elektrotechnik- und Elektronikindustrie e. V. on 14.06.2018 available under : https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_TBBPA_ZVEI_Answers_RoHS_Pack_15_Fragebogen_TBBP-A.pdf, last viewed 19.11.2019

¹⁶⁴ Op. cit. TMC (2018)

combinations)¹⁶⁵. However, TMC neither provide estimations as to the range of such costs e. g. for third-party certification, nor does the contribution distinguish between additive and reactive use of TBBP-A. However, TMC mentions the need for a transition period for EEE Cat. 9 of 12 years. In the case of additive use, some manufacturers have already reverted to alternatives voluntarily, thus the relevance of these comments to additive applications is to be viewed with caution. Though manufacturers who still apply plastic with TBBP-A shall incur redesign costs, these must be assumed to be at an acceptable level, seeing as other manufacturers have already made a phase-out. From the availability of substitutes, it is also clear that higher costs are not to be expected in such applications for identifying suitable alternatives. Alternatives are understood to be suitable for consumer products. Should there be some cases with more challenging performance conditions, exemptions could be applied as to ensure that sufficient time is available to test existing alternatives and develop suitable formulations. In this sense, impacts referred to by TMC such as product withdrawal and lost opportunity for introducing new cutting-edge products cannot be followed in this area of application.

In terms of the actual expected costs, a DEPA¹⁶⁶ study looked into the costs of replacing ABS/TBBP-A systems in the case of a RoHS restriction. In this study, cost estimations initially prepared in relation to the phase-out of ABS/octa-BDE for other alternatives (ABS/TBBP-A as well as other alternatives) were used to estimate costs of a phase-out of TBBP-A in ABS housings. *“The total price increase of changing ABS with TBBPA by copolymers with halogen-free flame retardants can [...] roughly be estimated at 0.3-0.7 €/kg ABS including R&D costs distributed over 5 years. The price increase is based on European prices - as much of the TBBPA is imported with EEE from Asia the actual price difference may be lower, but European prices are used here for indication of the incremental costs”*. In this respect, DEPA also estimates that *“the prices of alternatives are typically 10-50 % higher than ABS/TBBPA/ATO systems and it is estimated that the total incremental costs at the production level of replacing additively used TBBPA in all EEE may likely be some 5-30 million €/year depending on the actual alternatives being introduced (European prices). The costs may decrease over the years as result of a larger market for the alternatives”*.

A cost estimation performed in the Fraunhofer ITEM IPA study¹⁶⁷ used this data as a basis for calculating the total costs of replacing ABS/TBBP-A with copolymers with non-halogenated flame retardants. For the estimated amount of ~8000 t/a TBBPA in ABS assumed in the DEPA study (i.e., 36,364 t/a ABS with ~22 % TBBPA content) this resulted in 11-25 million € additional costs per year. The range of 5-30 million €/year is explained to consider the uncertainties of the dEPA study assumptions.

As Fraunhofer ITEM IPA had assumed a lower tonnage in other estimations performed in their study, costs were also calculated for the lower amount of ~4800 t/a (applied in their exposure assessment), resulting in 6.5-15.3 million € per annum. After consideration of uncertainties, Fraunhofer ITEM IPA specify the range at roughly 3-20 million € per year. To take these costs into account, the study estimated the turnover of the EU electrical equipment industry to amount to 279 billion € in 2010 (Eurostat 2013), explaining that the costs for the TBBP-A phase-out from additive applications may be a small fraction of the industries' total turnover; however, there is concern that these costs could burden SMEs heavier than other companies.

¹⁶⁵ TMC (2020): Contribution submitted during the TBBP-A stakeholder consultation conducted from 5 Dec 2019 to 13 Feb 2020 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (Pack 15); see the link to the contribution in the Annex

¹⁶⁶ Op cit. Depa (2010)

¹⁶⁷ Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

Fraunhofer ITEM IPA¹⁶⁸ also assumes that the increased turnover in the flame retardant and plastic industry will probably lead to some additional jobs, however, this impact could not be finally quantified. In general, it can be assumed that this shall mainly affect the supply chain of EEE manufacturers: companies that produce TBBP-A-based components shall have increased costs where they need to substitute or will lose some of their business in some cases where they are too slow. Other companies already applying alternatives may benefit from an increase in business which can be expected to set off the latter.

9.4. Impacts on SME

DEPA¹⁶⁹ explain that “the market for plastic parts is characterized by many small and medium-sized enterprises (SMEs)”. A study is cited that looked into the market structure of plastic part manufacture in the UK¹⁷⁰. Here it was found that 5,260 companies from a total of 14,540 plastics manufacturers were to be considered as small companies (< 50 employees) and that the majority of these (3,365) were micro-enterprises (< 9 employees). The study also provided insight for the EU, estimating a total 55,000 companies manufacturing rubber and plastics in the EU with an average enterprise size of 25 employees. It is not clear how many of these companies supply EEE parts, or how many supply parts that are flame retarded with TBBP-A. Though such SMEs can be expected to be familiar with the RoHS Directive now, it is possible that they shall have a heavier burden in terms of identification of suitable alternatives and R&D connected with the introduction of alternatives. Nonetheless, it is also possible that some of these smaller companies have already moved to alternatives and that they will benefit from the restriction.

9.5. Impact on EEE users

Aside from the costs of a phase-in, impacts on consumers also need to take into consideration the benefits of phasing-out TBBP-A. According to the exposure estimations in Section 7.3, and assuming DNEL values of BPA according to the precautionary principle, results in a risk characterisation ratio of > 1 which is considered a risk for children. Though TBBP-A dust may be generated also from other than EEE products, the elimination of part of this equipment from consumer homes is expected to result in a health benefit against which additional costs are to be weighed.

In terms of the restriction for consumers, the DEPA¹⁷¹ study refers to the impact that the phase-out of TBBP-A shall have on consumer prices, basing estimations on what is understood to be conservative assumptions. The basis for the calculation is understood to be the additional costs of manufacture that shall be shifted to consumers.

“The total incremental costs to the consumers can be roughly estimated using the following assumptions:

- *Total volume of additively used TBBPA in EEE: 8,000 tonnes year.*
- *Total volume of ABS polymer assuming a maximum TBBPA load of 22 %: 36,000 tonnes/year.*
- *Total incremental costs assuming that all TBBPA is used in ABS and re-placed by copolymers with non-halogenated flame retardants: 11-25 million €/year.*

¹⁶⁸ Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018)

¹⁶⁹ Op cit. Depa (2010)

¹⁷⁰ Cited in DEPA (2010) as Corden, C. and M. Postle. 2002. Risk Reduction Strategy and analysis of advantages and drawbacks for octabromodiphenyl ether. RFA for U.K. Department for Environment, Food and Rural Affairs (DEFRA).

¹⁷¹ Op cit. Depa (2010)

Considering the uncertainties related to the assumptions the total incremental costs are roughly estimated to be in the range of 5-30 million €/year. The costs may decrease over the years as result of a larger market for the alternatives”.

As mentioned by the DEPA study, all TBBP-A is not assumed to be used in ABS and therefore the consultants understand these estimations to be conservative.

Fraunhofer ITEM IPA¹⁷² refers to a further estimation made as to the percentage increase in the average price of products for consumers. This estimation derived an increase of between 0.19 % and 0.30 % of the product costs, if the increased costs for a replacement of TBBPA in ABS were passed on to the consumer.

The latter estimation allows a more comprehensive assessment of how the total costs would affect the individual. Beyond the observation that an increase of between 0.19 % and 0.30 % in product costs is not expected to deter consumers from purchases, the fact that some companies have voluntarily phased-out TBBP-A further strengthens this conclusion, i.e., seeing as this voluntary phase-out was possible and seeing as losses in product quality have not been reported in this respect.

The above estimations, though applying in general to all EEE, are understood to be more relevant for consumer products, whereas for industrial and commercial equipment, often manufactured in lower volumes, delays in the time to market of some equipment may affect consumers to some degree.

In this respect the Association of Equipment Manufacturers (AEM)¹⁷³ point out the recertification needs of some equipment and how this may affect the time to compliance and subsequently the availability of equipment on the market. For example, they state that *“If TBBP-A were to be restricted before fully RoHS compliant equipment can be tested and gain EU NRMM Emissions Regulation approval from a Notified Body, many types of equipment could not be sold in the EU.”* The possibility that some equipment may require redesign and recertification that would extend beyond the initial transition period of a restriction could lead to impacts upon equipment users. Though for private consumers, it can be expected that relevant equipment (particularly ICT equipment, electric appliances) will either already be compliant for some manufacturers or will achieve compliance before the end of a transition period, this may differ for commercial and industrial users. For example, the medical facilities depend on medical equipment which can also be expected to require recertification in cases where changes to design shall be needed to substitute TBBP-A. The same is true for example for equipment using combustion engines which must be approved according to the Non-Road Mobil Machinery Regulation (Regulation (EU) 2016/1628), addressed by AEM.

Though in these cases additional time may be needed for a phase-out, this could be bridged through a longer transition period or, through the provision of an exemption in cases where relevant sectors can communicate the scope of equipment where phase-out of TBBP-A requires additional time. This approach would enable equipment still using TBBP-A to be placed on the market until the phase-in is accomplished, at least by some manufacturers.

¹⁷² Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn (2018): referred in the text as DEPA 2010, but cited epr footnote as Corden, C. and M. Postle. 2002. Risk Reduction Strategy and analysis of advantages and drawbacks for octabromodiphenylether. RFA for U.K. Department for Environment, Food and Rural Affairs (DEFRA). (cited by DEPA, 2010)

¹⁷³ Op. cit. AEM (2018)

9.6. Impact on waste management

According to chapter 5, shredding of WEEE and the further processing of plastic waste are the most relevant TBBP-A exposure scenarios. Such exposures provide part of the justification for this restriction. Thus, an important positive impact of the restriction scenario is attributed to the reduction of TBBP-A in EEE and thus also to the prevention of impacts linked to exposure of workers to its presence through inhalation or dermal contact (see Section 6.2.1). Additional positive impacts on the health of workers may be relevant in the recycling of WEEE in third world countries (for example where EEE is exported through secondary market operations or where WEEE is exported illegally), where crude treatment practices may result in additional transformation products that emit from treatments such as uncontrolled combustion and uncontrolled dumping of residues.

As has been pointed out in Section 7.1, the presence of TBBP-A in plastic parts (ABS housings) results in such parts being separated from other plastic streams and incinerated. This is in part related to the small volume of this stream, which would render its separate recycling as economically not feasible, but is also explained to be the practice so as to avoid contamination of other streams (ABS that is free of TBBP-A or other BFR). In this sense, a restriction of TBBP-A would result in a change in the plastic stream available for recycling as explained below. Given the lifetimes of typical products in which ABS/TBBP-A systems are still in use, it may take time until a restriction can be observed in the WEEE arriving at waste management. Once this change is noticeable, a few cases may exist:

- In cases where ABS shall be used with alternative halogen-based additives, though impacts of TBBP-A on workers are to be prevented, other additives may have similar impacts depending on their identity. In general, in this case, it is still to be expected that the ABS fraction in which BFRs are present is to be separated and sent to incineration, so aside from possible positive impacts where alternatives have lower impacts on health and/or environment, additional benefits described below would not be expected in terms of the volumes of recovered of ABS.
- In cases where ABS shall be used with alternative halogen-free additives, it is expected that once TBBP-A-free ABS parts arrive at End-of-life, an increase in the amounts of ABS available for recycling is to be expected. The Fraunhofer ITEM IPA study states that ABS / housings are usually not recycled but rather energy recovered in light of the small volumes, however suppliers are available with equipment for recycling ABS¹⁷⁴ and it is thus assumed that ABS recycling is already in place and that additional amounts are not expected to lead to a need for additional investments in equipment, but rather to an increase in ABS recovery and a subsequent increase in the use of recycled ABS. It should be noted that this positive impact may be limited in some cases, depending on the identity of alternative additives. This view has been supported by the waste management sector¹⁷⁵, who raise concerns as to whether current waste management techniques can properly deal with phosphorus-based flame retardant).
- In cases where ABS is to be substituted with other polymers, contributions to the amount of plastics recovered would depend on the new polymers to be used and possible systems for flame retardancy.

To summarise, though in some cases (halogenated alternatives) a restriction may not lead to significant benefits, in other (non-halogenated alternatives) benefits are expected in the form of additional secondary material, beyond the health benefits expected to arise from the phase-out of TBBP-A. Such impacts are however expected to incur in the mid- or long-term, seeing as it shall

¹⁷⁴ See for example: <https://www.schmaus-kunststoffaufbereitung.de/technische-kunststoffe/abs-kunststoffe.htm>

¹⁷⁵ Op. cit. EERA (2020) and op. cit. EuRIC (2020)

take time until EEE that has been affected from the restriction shall turn into waste and arrive at treatment facilities.

9.7. Impact on administration

DEPA¹⁷⁶ estimates that costs of companies already in compliance with RoHS are to be minimal. This is based on the understanding that such companies shall already have prepared similar compliance documentation in the past for parts where deca-BDE or octa-BDE were traditionally used as additive FR and where TBBP-A is used at present.

According to DEPA,¹⁷⁷ most administration costs are expected to be associated with checking the presence of TBBP-A in EEE (compliance monitoring). This applies to manufacturers, importers and regulators alike, who can be expected to perform testing in order to ensure that TBBP-A is not present in EEE to be placed on the market. In this regard DEPA explains that simple XRF screening only detects the presence of Br and Sb, whereas for TBBP-A detection, sampling, extraction and laboratory analysis shall be required, as however is already the case for other RoHS substances (e.g. octa-BDE or deca-BDE). In this sense, the additional costs would only be in relation to the need for additional laboratory analysis. *“The extra costs of an analysis for TBBPA in ABS in Denmark, if the sample is already analysed for PBDE, is reported to be about 40€ (excl. VAT). The extra costs of analysis of TBBPA and HBCDD in HIPS, if the sample is already analysed for deca-BDE is about 60€ (excl. VAT). All prices are per sample when more than 20 samples are analysed.”*

Fraunhofer ITEM IPA¹⁷⁸ refer to another source suggesting that the overall costs are between 150 and 500 €, depending on the availability/ level of standardisation of the technique and requirements such as good laboratory practice.¹⁷⁹ On this basis the Fraunhofer ITEM IPA study estimates total costs, assuming that for the EU as a whole 7000 tests per annum (250 tests per EU Member State/annum) are sufficient to control a ban of additively used TBBPA ban. In this case, the total costs for the EU would be 0.28 Mio € annually using the estimated 40 € per test as specified by DEPA. Assuming a higher cost of ~300 € per test would result in a total of approximately 2.1 Mio € for additive use. It is further stated in this respect that the administrative costs cannot be seen as lost costs, as they would increase the turnover of the chemical analysis sector.

Though this view can be followed, the consultants assume that the market surveillance and independent sampling efforts that are performed for a newly restricted RoHS substance are of a larger range than for substances that have been phased-out. In this sense, it would be expected that the costs related to surveillance and sampling of TBBP-A would be expected to be largest following the restriction and to decrease gradually. From the phase-out of the phthalates, the consultants are aware that these activities started well before the end of the transition period, with the aim of seeing where such substances are still used. Further surveillance and sampling shall still take place following the end of the transition period of a restriction, but can be expected to decrease to a lower “routine” level as it becomes apparent that the substance has been phased-out for the most part. In any case, such surveillance costs are understood to be an acceptable effect of substance restrictions, as can also be understood from past restrictions.

¹⁷⁶ Op cit. Depa (2010)

¹⁷⁷ Op cit. Depa (2010)

¹⁷⁸ Op. cit. Fraunhofer ITEM IPA, Wibbertmann and Hahn 2018: cited as S. Schuchardt, personal communication, 03. (2015)

¹⁷⁹ The difference between this estimation and the DEPA one may have to do in part with price changes throughout time or may reflect prices of single costs in comparison to the DEPA value which refers to the price of a single sample when multiple samples are analysed.

9.8. Total socio-economic impact

To summarise the above, though a restriction of TBBP-A under RoHS is likely to involve various costs, these, in conclusion, need to be accepted as costs necessary to bring about environmental and health benefits.

The restriction is expected to reduce the risks of exposure for consumer's (particularly for children) and for workers of waste management who may currently be exposed through inhalation or dermal contact. Further benefits may be relevant where TBBP-A is replaced with non-brominated alternatives, driving an increase in the amount of ABS to be available for recycling.

In terms of costs, both in the chemicals industry and in the EEE industry, though some manufacturers may incur loss of business or costs of substitution, others are understood to have already switched to alternatives voluntarily and may even experience a business growth. This last point also explains why the costs of a phase-out of TBBP-A are to be considered as acceptable. Though it can be understood that TBBP-A is still used additively in plastic parts, some EEE manufacturers have already phased-out this flame retardant voluntarily and it is also understood that additive use of TBBP-A as a flame retardant in EEE housings is no longer practiced in the EEE. It thus needs to be concluded that the available alternatives are suitable and will not lead to changes in product qualities and that costs of a restriction are acceptable. This applies to:

- the total costs estimated for the phase-in (5-30 million €/annum according to DEPA or 6.5-15.3 million €/annum according to newer estimations of Fraunhofer ITEM IPA);
- their implications for consumers (increase in product costs in a range of 0.19 % and 0.30 %); and
- the compliance monitoring and surveillance costs associated with a restriction (between 0.28 Mio €/annum based on DEPA data to 2.1 Mio € based on Fraunhofer ITEM IPA data).

10. RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

TBBP-A is used in relevant quantities in EEE. Despite some data gaps it can be stated that the largest part of the TBBP-A (about 90 %) is used as a reactive component in epoxy resins. Epoxy resins for their part are the essential component of PWB type FR4 and can be found in practically every type of EEE. In addition, epoxy resins can also be used as a sealing compound for electronic components. The remaining 10 % of the TBBP-A applied in EEE is used as an additive flame retardant, especially for plastic housings. On the basis of the data available and presented in this dossier, it is open whether the quantities used for these applications have actually decreased or whether this only applies to European manufacture, and whether the quantities of TBBP-A in imported EEE components and equipment have remained stable or even increased in view of the continuing consumption of EEE.

TBBP-A as a precursor for epoxy resins is the main application, however, releases of TBBP-A during waste phase can mainly be attributed to its second application, the additive use as a flame retardant in housings and encapsulations. This can be attributed to the fact that TBBP-A undergoes a chemical transformation when used as a reactive component and – apart from low residual monomer contents – is no longer present as such substance.

With regard to emissions of TBBP-A from WEEE treatment processes, it should be noted that the relevant exposure of TBBP-A by dust in shredding processes of plastic housings and enclosures is assumed to be the most relevant exposure scenario. No monitoring data is currently available, so it is not possible to determine whether effects occur in EU facilities in this stage or the opposite is the case.

With regard to risks for human health, there are some reasons in favour of a restriction of TBBP-A under RoHS:

- The current DNELs for TBBP-A do not take into account potential endocrine disrupting properties. Instead, based on an initial read-across approach, it is proposed that DNEL values of bisphenol A should be taken into account in order to reflect the potential endocrine disrupting properties of TBBP-A. In the case at hand, the read across approach is based on the structural similarity of TBBP-A and BPA and should be assessed in further depth to validate the suggested results.
- The observation that workers of EEE waste processing plants are exposed to TBBP-A is confirmed by exposure estimations, by measurements of TBBP-A in EEE waste streams and results from human biomonitoring suggesting that TBBP-A has been detected in the serum of workers. Based on these considerations, an impact on workers in EEE waste processing plants has been observed and the estimated exposure by ECETOC TRA rather indicates a risk for workers via dermal exposure than via inhalation.
- The general population is exposed to TBBP-A by house dust ingestion and inhalation; estimations on worst case exposure to TBBP-A via house dust (ingestion + inhalation) and taking the DNEL for bisphenol A for oral exposure at 4 µg/kg bw/day, a risk characterisation ratio of > 1 for children indicates a risk.
- As for the environment, according to monitoring data, TBBP-A is frequently detected and can thus be seen as a ubiquitous contaminant. This indicates that it is continuously released into the environment. The presence of TBBP-A in the Arctic is an indication for its ability to withstand long-range transport and to contaminate also remote and pristine areas and is an indication for its persistency. For persistent substances, the normal risk assessment, by means of the ratio of the expected environmental concentration (Predicted Environmental Concentration, PEC) and an

estimated non-effect threshold (Predicted No -effect concentration, PNEC) is not applicable. Substances with PBT properties have the potential to persist and thereby accumulate in the environment. ECHA (2014) emphasises that the effects of such accumulation are unpredictable in the long-term and that such accumulation is in practice difficult to reverse as cessation of emissions will not necessarily result in a reduction in chemical concentration. They circulate in the global environment for long periods of time and, if further released, the environmental concentration will increase constantly. Thus, it is concluded that TBBP-A has an impact on the environment.

With regard to Article 6(1) of RoHS 2, it should therefore be noted that TBBP-A meets the criteria for inclusion in the list of prohibited substances in several respects:

- *given its uses, could give rise to uncontrolled or diffuse release into the environment of the substance, or could give rise to hazardous residues, or transformation or degradation products through the preparation for reuse, recycling or other treatment of materials from waste EEE under current operational conditions, and*
- *could lead to unacceptable exposure of workers involved in the waste EEE collection or treatment processes.*

With regard to the disposability of alternatives, it should be noted that they are available when TBBP-A is used as an additive flame retardant:

- Alternatives seem readily available and are applied which is e.g. apparent in light of voluntary substance restriction lists of some companies including brominated FR as such. Resorcinol-bis-diphenylphosphat (PBDPP) and Resorcinol-diphosphat as well as some non-halogenated organophosphate esters present themselves as alternatives with a more favourable hazard profile. However, on the basis of risks already known and suspected several phosphorus compounds like DOPO and aryl-substituted organophosphate esters such as triphenyl phosphate and tricresylphosphate should be further evaluated concerning their risk potential before being applied as substitutes in the short term. If a restriction is considered, it may be relevant to assess these substances to ensure whether they are suitable substitutes or whether a regrettable substitution should be avoided through their simultaneous substitution. In such cases, it is noted that assessments under REACH are in some cases underway and necessary to ensure a first basis of information is available for an assessment in the context of RoHS. In addition, it should be noted that most of the non-halogenated phosphorus FR entail a shift from ABS polymers to PPE/PS or PC/ABS blends.
- Regarding the use of TBBP-A as a reactive component for the production of epoxy resins, including the pertinent use as a component of FR4 PWB, few alternatives are currently available. Since the residual levels of TBBP-A in these applications are very low due to the chemical reaction in the production of epoxy resin, they are not expected to be affected by the recommended restriction.

To summarise, it is proposed to amend Annex II through the addition of the following restriction:

Recommended substance restriction formulation

2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol or tetrabromobis-phenol A (TBBP-A) (0,1 % per weight)

Assuming good and controlled manufacturing conditions, reactive applications and in particular its use as a component of FR4 PWB would not be affected by this restriction, because the residual levels of TBBP-A would be below the proposed limit in this case.

Estimates on the severity of emissions rely on the read-across of endocrine properties from BPA to TBBP-A. These conclusions should be assessed in further depth to validate their suggested results. In addition, assessments of TBBP-A as endocrine disruptive and/or as PBT are underway. Additional information has been requested by ECHA in relation to both processes and is to be provided by January 2021. The validation of the read-across approach and/or results of the identification of TBBP-A as endocrine disruptive and/or as PBT (the first process to conclude), should be considered in the final decision on a RoHS restriction. In all cases, classification would render current guidance (no effect) as irrelevant and would be in favour of the restriction. This shall also provide some additional time for a further assessment of a few of the substitutes for TBBP-A, and for decisions on whether certain substitutes should be considered for restriction jointly with the restriction of TBBP-A.

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Appendix I: Contributions to 1st stakeholder consultation hold from 20 April 2018 to 15 June 2018

The following non-confidential contributions were submitted during the 1st stakeholder consultation (see also: <https://rohs.exemptions.oeko.info/index.php?id=291>):

Contribution of the **BSEF, aisbl – The International Bromine Council**, submitted on 23.04.2018: [PDF1](#), [PDF2](#), [PDF3](#), [PDF4](#), [PDF5](#)

Contribution of the **Swedish Chemicals Agency (KEMI)**, submitted on 11.06.2018: Report with information on TBBP-A in Swedish (summary in English): [PDF](#)

Contribution of the **Norwegian Environment Agency**, submitted on 14.06.2018
https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution_Norwegian_Environment_Agency_TBBPA_MCCPS_20180614.pdf

Contribution of the **Zentralverband Elektrotechnik- und Elektronikindustrie e. V. (ZVEI)**, submitted on 14.06.2018: [PDF](#)

Contribution of the **Danish Environmental Protection Agency (DEPA)**, submitted on 14.06.2018: Part 1: [PDF](#); Part 2: [PDF](#)

Contribution of **MedTech Europe**, submitted on 15.06.2018: [PDF](#)

Contribution of the **JBCE – Japan Business Council in Europe aisbl**, submitted on 15.06.2018: [PDF](#)

Contribution of the **Test and Measurement Coalition (TMC)**, submitted on 15.06.2018: [PDF](#)

Contribution of the **Association of Equipment Manufacturers (AEM)**, submitted on 15.06.2018: [PDF](#)

Contribution of the **Japanese electric and electronic (E&E) industrial associations**, submitted on 14.06.2018: [PDF](#)

Contribution of the **AeroSpace and Defence Industries Association of Europe (ASD)**, submitted on 14.06.2018: [PDF](#)

Appendix II: Contributions to 2nd stakeholder consultation hold from 05 December 2019 to 13th February 2020

The following non-confidential contributions were submitted during the 2nd stakeholder consultation (see also: <https://rohs.exemptions.oeko.info/index.php?id=333>):

Contribution of the **Norwegian Environment Agency**, submitted on 27.01.2020: [PDF](#)

Contribution of **COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry)**, submitted on 28.01.2020: Contribution: [PDF](#) and Annex 1: [PDF](#)

Contribution of the **Test and Measurement Coalition (TMC)**, submitted on 12.02.2020: [PDF](#)

Contribution of **MedTech Europe**, submitted on 12.02.2020: [PDF](#)

Contribution of **EuRIC – The European Recycling Industries' Confederation**, submitted on 12.02.2020: [PDF](#)

Contribution of **EERA – European Electronics Recyclers Association**, submitted on 12.02.2020: [PDF](#)

Joint Contribution of **Digital Europe** and the **JBCE – Japan Business Council in Europe** , submitted on 13.02.2020: [PDF](#)

Contribution of **ZEBRA Technologies**, submitted on 13.02.2020: [PDF](#)

Contribution of the **BSEF – The International Bromine Council**, submitted on 13.02.2020: Part 1: [PDF](#); Part 2: [PDF](#)