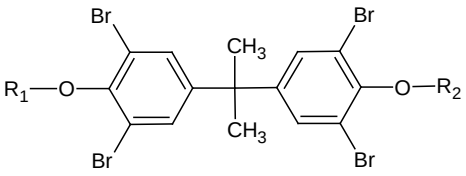
Assessment of regulatory needs

Authority: European Chemicals Agency (ECHA)

Date: 15 December 2021

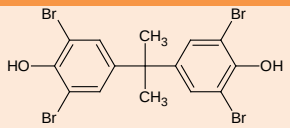
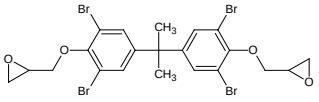
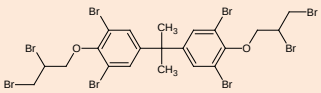
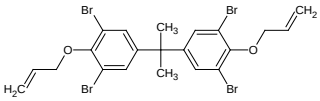
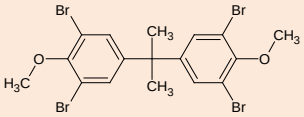
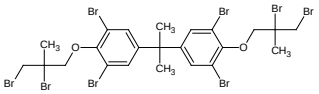
Group Name: Tetrabromobisphenol A (TBBPA) and its derivatives

General structure:

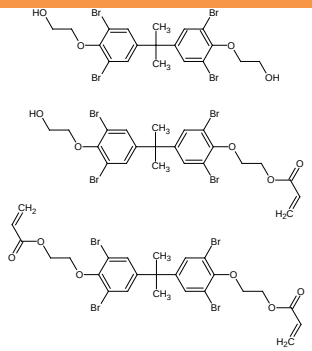
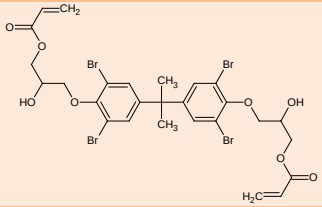
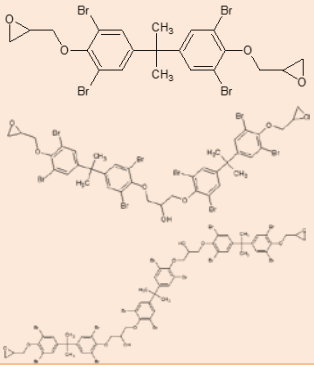


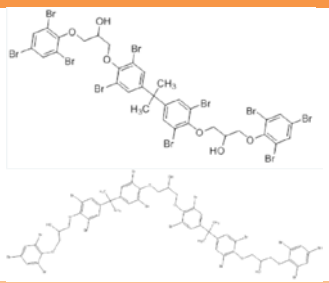
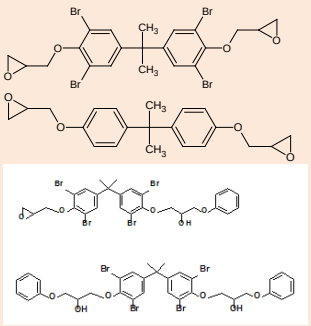
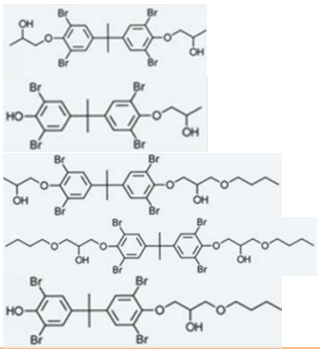
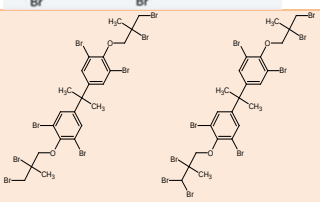
Revision history

Version	*Date*	*Description*
1.0	07.06.2022	

EC / List number	CAS number	Substance name [and/ or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
201-236-9	79-94-7	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol [TBBPA (tetrabromobisphenol A)]]l		Full, >1000 t/y
221-346-0	3072-84-2	2,2'-[(1-methylethylidene)bis[(2,6-dibromo-4,1-phenylene)oxymethylene]]bisoxirane [TBBPA-bGE]		Full, 10-100 t/y
244-617-5	21850-44-2	1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene] [TBBPA-bDiBPrE]		Full, 100-1000 t/y
246-850-8	25327-89-3	1,1'-isopropylidenebis[4-(allyloxy)-3,5-dibromobenzene] [TBBPA-bAE]		Full, Not (publicly) available
253-693-9	37853-61-5	4,4'-(isopropylidene)bis[2,6-dibromoanisole] m [TBBPA-bME]		Not registered
306-832-3	97416-84-7	1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromo-2-methylpropoxy)benzene]		Full, >1000 t/y
400-440-7		INTERSTAB FR 184	Not (publicly) available	NONS

[1] Note that the total aggregated tonnage band may be available on ECHA's webpage at https://echa.europa.eu/information-on-chemicals/registered-substances

EC / List number	CAS number	Substance name [and / or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
420-850-1		A mixture of: 2-ethyl-[2,6-dibromo-4-[1-[3,5-dibromo-4-(2-hydroxyethoxy)phenyl]-1-methylethyl]phenoxy]propenoate; 2,2'-diethyl-[4,4'-bis(2,6-dibromophenoxy)-1-methylethylidene] dipropenoate; 2,2'-[(1-methylethylidene)bis[[2,6-dibromo-4,1-phenylene)oxy]ethanol]]		NONS
436-220-2		2,2-bis(3,5-dibromo-4-(3-acryloyloxy-2-hydroxypropoxy)phenyl)propane		NONS
468-980-6		BB 331	Not (publicly) available	NONS
500-107-7	40039-93-8	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane	Representative structures: 	Full, >1000 t/y
500-399-6	158725-44-1	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric	Representative structures:	Not (publicly) available

EC / List number	CAS number	Substance name [and / or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
		reaction products with 1-chloro-2,3-epoxypropane and 2,4,6-tribromophenol		
600-581-6	1045809-53-7	Reaction product of Phenol, 2,2'-[(1-methylethylidene)bis[(2,6-dibromo-4,1-phenylene)oxymethylene]]bisoxirane and 4,4'-(1-methylethylidene)bis[phenol], Ph ethers with 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane	Representative structures: 	Full, Not (publicly) available
926-564-6		2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether	Representative structures: 	Full, Not (publicly) available
944-461-4		Reaction mass of 1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromo-2-methylpropoxy)benzene] and 1,3-dibromo-2-(2,3-		Full, 100-1000 t/y

EC / List number	CAS number	Substance name [and / or Substance name acronyms]	Chemical structures	Registration type (full, OSII or TII, NONS), highest tonnage band among all the registrations (t/y) [1]
		dibromo-2-methylpropoxy)-5-{2-[3,5-dibromo-4-(2,3,3-tribromo-2-methylpropoxy)phenyl]propan-2-yl}benzene		

This table does not contain group members that are only notified under the CLP Regulation. Should further regulatory risk management action on one or more substances in the group be considered, ECHA may make an additional search for related C&L notified substances to be included in the group and develop an assessment of regulatory needs for them.

Contents

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Foreword

The purpose of the assessment of regulatory needs of a group of substances is to help authorities conclude on the most appropriate way to address the identified concerns for a group of substances or a single substance, i.e. the combination of the regulatory risk management instruments to be used and any intermediate steps, such as data generation, needed to initiate and introduce these regulatory measures.

An assessment of regulatory needs can conclude that regulatory risk management at EU level is required for a (group of) substance(s) (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. While the assessment is done for a group of substances, the (no) need for regulatory action can be identified for the whole group, a subgroup or for single substance(s).

The assessment of regulatory needs is an important step under ECHA's Integrated Regulatory Strategy. However, it is not part of the formal processes defined in the legislation but aims to support them.

The assessment of regulatory needs can be applied to any group of substances or single substance, i.e., any type of hazards or uses and regardless of the previous regulatory history or lack of such. It can be done based on a different level of information. A Member State or ECHA can carry out this case-by-case analysis. The starting point is available information in the REACH registrations and any other REACH and CLP information. However, a more extensive set of information can be available, e.g. assessment done under REACH/CLP or other EU legislation or can be generated in some cases (e.g. further hazard information under dossier evaluation). Uncertainties associated to the level of information used should be reflected in the documentation. It will be revisited when necessary. For example, after further information is generated and the hazard has been clarified or when new insights on uses are available. It can be revisited by the same or another authority.

The responsibility for the content of this assessment rests with the authority that developed it. It is possible that other authorities do not have the same view and may develop further assessment of regulatory needs. The assessment of regulatory needs does not yet initiate any regulatory process, but any authority can consequently do so and should indicate this by appropriate means, such as the Registry of Intentions.

For more information on Assessment of regulatory needs please consult ECHA website[2].

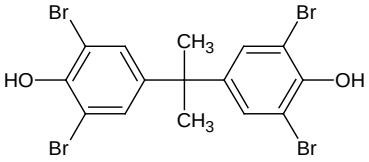
[2] https://echa.europa.eu/understanding-assessment-regulatory-needs

Glossary

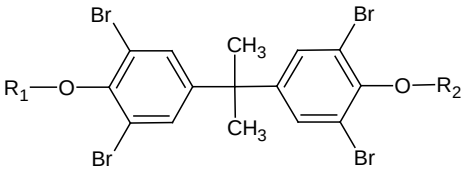
ARN	Assessment of Regulatory Needs
CCH	Compliance Check
CLH	Harmonised classification and labelling
CMR	Carcinogenic, mutagenic and/or toxic to reproduction
Dev	Dossier evaluation
ED	Endocrine disruptor
EDD	Ecodesign Directive
NONS	Notified new substances
OEL	Occupational exposure limit
OSH	Occupational Health and Safety Directive
OSII or TII	On-site isolated intermediate or transported isolated intermediate
PBT/vPvB	Persistent, bioaccumulative and toxic/very persistent and very bioaccumulative
RMOA	Regulatory management options analysis
RoHS	Restriction of Hazardous Substances
RRM	Regulatory risk management
SEv	Substance evaluation
STOT RE	Specific target organ toxicity, repeated exposure
SVHC	Substance of very high concern
TPE	Testing Proposal Evaluation
WHO/IPCS	World Health Organisation/International Programme on Chemical Safety

1 Overview of the group

ECHA has grouped together structurally similar substances based on the presence of a tetrabromobisphenol A-based moiety. The group consists of 15 brominated flame retardants, including tetrabromobisphenol A (TBBPA, EC 201-236-9), shown in figure (A) below, and 14 of its derivatives. The derivatives have constituents with the generic structure (B).



(A) Tetrabromobisphenol A (EC 201-236-9)



(B) Generic structure for the derivatives. R1 and R2: same/different substituents

The substances have in common the TBBPA-based moiety and the presence of bromine. The derivatives have the phenolic hydroxyl groups derivatised with various different types of groups such as brominated alkyl groups, and with groups including other functionalities e.g. epoxy groups. The group consists of mono- and multi-constituent and UVCB substances.

Based on the information reported in the REACH registration dossiers, TBBPA and its derivatives are used as flame retardants in the manufacture of polymers and plastics, either as part of the polymer or added to the polymer matrix. The uses are mostly as intermediates. Additive uses of TBBPA concern about 10% of the substances' production volume. The possible fraction of the TBBPA derivatives used as additive is less clear and cannot be quantified based on the information available in the registration dossiers. In addition to uses in polymers and plastics, some TBBPA derivatives are also registered for use in coatings, textile, leather and fur. Registered uses suggest that these substances may be interchangeable.

Exposure of workers (industrial and professional), consumers and the environment may be expected. Exposure of consumers may be expected also during article service life. Exposure is most likely for those applications where the flame retardants are used as additives to the material. In cases where the flame retardant reacts with the (polymer) matrix, exposure during article service life is expected to be much lower but cannot be excluded.

In September 2021 RAC has adopted its opinion to classify TBBPA as Carc. 1B (lack of genotoxicity and presumption of a threshold MoA), based on the CLH proposal submitted by the Norwegian (NO) and Danish Competent Authorities (DK CA)[3]. In November 2021 the NO CA notified its intention to prepare an SVHC dossier for

[3] https://echa.europa.eu/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e184330ec8

TBBPA on the basis of Art. 57(a)[4], expected to be submitted in August 2022. The DK CA is currently clarifying TBBPA's further potential ED[5] and PBT/vPvB[6] properties through Substance Evaluation.

The regulatory needs for other brominated flame retardants are assessed in other groups such as "Brominated flame retardants related substances (small groups)". Other bisphenols are assessed in the group "Bisphenols"[7]. ECHA will prepare an overall strategy on flame retardants by 2022, see section 3.

Note on the scope of ECHA's assessment of regulatory needs

Regarding hazards, the focus of ECHA's assessment is on CMR (carcinogenic, mutagenic and/or toxic to reproduction), sensitiser, ED (endocrine disruptor), PBT/vPvB or equivalent (e.g. substances being persistent, mobile and toxic), aquatic toxicity hazard endpoints and therefore only those are reflected in the table in section 3. This does not mean that the substances do not have other known or potential hazards. In some specific cases, where ECHA identifies a need for regulatory risk management action at EU level for other hazards (e.g. neurotoxicity, STOT RE), such additional hazards may be addressed in the assessment. An overview of classification is presented in Annex 1.

On the exposure side, ECHA is mainly using the information on uses reported in the registration dossiers (IUCLID) as a proxy for assessing the potential for exposure to humans and releases to the environment. The potential for release / exposure is generally considered high for "widespread" uses, i.e. professional and consumer uses and uses in articles. For these uses, normally happening at many places, the expected level of control is *à priori* considered limited. The chemical safety reports are not necessarily consulted, and no quantitative exposure assessment is performed at this stage.

[4] https://echa.europa.eu/registry-of-svhc-intentions/-/dislist/details/0b0236e186f70922

[5] Decreased thyroxine levels are reported in repeated-dose toxicity and reproductive toxicity studies. TBBPA does not bind to the progesterone or the estrogen receptors in an agonistic or antagonistic significant way (IARC, 2018), but the effects on estrogen homestasis, especially in rats, observed in the 2-year study, needs to be considered as well.

[6] PBT/vPvB properties are suspected to be caused by its degradation products monomethyl ether TBBPA (TBBPA-MME) and bismethyl ether TBBPA (TBBPA-DME).

[7] https://echa.europa.eu/documents/10162/3448017/GMT_109_Bisphenols_Report_public_23502_en.pdf/1bd5525c-432c-495d-9dab-d7806bf34312?t=1647590013566

2 Justification for the need for regulatory risk management action at EU level

Based on currently available information, there is a need for (further) EU regulatory risk management – Restriction for carcinogenicity, ED (human health and environment), and PBT/vPvB hazards due to the potential for release/exposure of TBBPA and all its derivatives in this group.

RAC supported the classification of TBBPA as Carc. 1B in its opinion from September 2021. TBBPA is intended to be identified as SVHC on the basis of Art. 57(a). In addition, potential ED and PBT/vPvB properties of TBBPA are being assessed through Substance Evaluation conducted by the DK CA.

It is suspected that the TBBPA derivatives may share at least some of the hazard profile of TBBPA. This is based on structural similarity to TBBPA and preliminary QSAR modelling suggesting that for all TBBPA derivatives in this group there may be some metabolisation to TBBPA.

There is some uncertainty with regard to the carcinogenicity potential of TBBPA derivatives since the available information (short-term and sub-chronic toxicity studies) raises no concern. However, in the absence of long-term toxicity studies to clarify carcinogenicity for TBBPA derivatives and based on the above considerations on structural similarity to TBBPA and preliminary QSAR modelling, it is concluded that there is a potential carcinogenicity hazard (see also section '*Uncertainties with regard to a carcinogenicity hazard for the TBBPA derivatives*').

Data to clarify the reproductive toxicity, ED and PBT/vPvB properties of TBBPA derivatives will be generated under Testing Proposal Evaluation (TPE) and/or Compliance Check (CCH) for EC/List 306-832-3, 221-346-0, 500-107-7, 500-399-6, and 926-564-6. For List 600-581-6 further data on aquatic toxicity and genotoxicity will be requested via CCH. This data generation will also inform on the possible formation of degradation or biotransformation products and may show whether TBBPA or its degradation or biotransformation products are formed. Whereas the carcinogenicity may have a threshold, this is not the case for PBT/vPvB properties.

Based on the information reported in the REACH registration dossiers, the substances of this group are mainly used as flame retardants in the manufacture of polymers and plastics. Some substances of the group are additionally used in coatings, textiles, leather and fur. Exposure of workers (industrial and professional), consumers and the environment is expected from using mixtures and during the article service life when these substances are used as an additive flame retardant. Exposure is expected to be less of a concern when the substances react with the polymer matrix (though some exposure from these reactive uses cannot be excluded, e.g. due to the residual presence of unreacted substances, as also indicated by EFSA in relation to TBBPA[8]).

The first step of the regulatory risk management action proposed, should the hazard exist, is the confirmation of hazard via harmonised classification (CLH) as

[8] EFSA Assessment of possible risks for consumers, EFSA Journal 2011;9(12):2477. The assessment of TBBPA and its derivatives is currently revisited (https://www.efsa.europa.eu/en/efsajournal/pub/2477).

Carc.1B or the confirmation of hazard via SVHC identification and inclusion on the Candidate List as PBT/vPvB or ED (human health and environment).

CLH i) will require company level risk management measures (RMM) under the OSH legislation for workers to be in place, ii) is needed or highly recommended for further regulatory processes under REACH and iii) is a prerequisite to restrict the presence of the substances in consumer mixtures, by means of restriction entry 28 (Carc. cat.1B).

CLH is also a prerequisite to restrict the presence of the substances in clothing, other textiles, and footwear articles, by means of the restriction entry 72 of REACH Annex XVII (this would require addition of the relevant substances to Appendix 12 by the Commission through Article 68(2)).

SVHC identification is highly recommended for further regulatory processes under REACH (restriction). In addition, SVHC identification brings immediate obligations for suppliers of the substances such as (i) supplying a safety data sheet and communicating on the safe use of the substances, (ii) responding to consumer requests within 45 days and (iii) notifying ECHA if the article they produce contains the substance above regulatory threshold.

TBBPA and its derivatives are already restricted for use in the enclosure and stand of electronic displays. Indeed, the Ecodesign Directive restricts the use of halogenated flame retardants in the enclosure and stand of electronic displays[9]. Specific for TBBPA, further restriction of its use in electronic equipment is ongoing under RoHS (Restriction of Hazardous Substances). The current version of the assessment report for TBBPA[10] recommends including this substance in the list of restricted substances with a limit value of 0.1 % per weight. This recommendation is based on risk of workers involved in the waste recycling of electronic equipment and the availability of alternatives. Assuming good and controlled manufacturing conditions, intermediate uses of TBBPA are concluded not a risk for workers and are therefore not proposed for restriction under RoHS.

ECHA proposes to consider further **restricting TBBPA and its derivatives in plastic articles** under REACH. Restriction would cover articles produced in Europe and those imported and should target those uses as well as uses in mixtures that cause EU wide risks. Based on the analysis conducted under RoHS it is expected that for TBBPA and its derivatives additive uses would be the main target. Reactive uses, however, should not *a priori* be excluded. Furthermore, restricting professional and consumer uses of polymer preparations should be considered. Based on the registration dossiers, exposure of professionals and/or consumers may be expected for EC/List 201-236-6, 221-346-0, 500-399-6 and 926-564-6. Exposure of consumers arising from uses of polymer preparations may already be addressed through the generic restriction REACH Annex XVII entry 28 once the substances are confirmed Carcinogens cat.1B. Authorisation seems to have little regulatory benefit for the remaining uses, as intermediate uses are exempt from the authorisation requirement under Article 56 (use as intermediate in the manufacture of polymers, polymer resins and epoxy resins).

[9] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0341&from=EN and https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02019R2021-20210501. The determined value for any homogeneous material should not exceed 0.1% by weight of halogen content. Use is currently restricted in cases and standings for digital screens.

[10] https://op.europa.eu/en/publication-detail/-/publication/ce50dc9c-6c19-11eb-aeb5-01aa75ed71a1/language-en

A restriction under REACH could be targeted to TBBPA and its derivatives, or to flame retardant uses in articles in more general terms.

For TBBPA, a restriction under REACH in plastic articles could already be based on carcinogenicity. Several elements should however be considered with regard to the scope and timing of such a restriction. First is that hazard assessment is still ongoing to clarify ED and PBT/vPvB properties of TBBPA. Should these confirm, these potential additional hazards are expected to impact the scope of a further restriction of TBBPA. Second is that TBBPA derivatives may have similar modes of action to TBBPA, on which data is or will be generated to clarify these. Should the properties be confirmed, a group restriction for TBBPA and its derivatives should be considered. And third is that the German Competent Authority (DE CA) is developing a proposal to restrict the use of bisphenols with ED effects on the environment, on their own, or as impurities in other substances, and in mixtures and articles. If TBBPA and its derivatives meet the WHO/IPCS criteria for endocrine disruptors and are identified as ED for the environment, these substances are also expected to be further regulated through this restriction.

For these reasons it is suggested to await the completion of the ED and PBT/vPvB assessment and hazard confirmation (through SVHC identification) of TBBPA before any specific restriction is initiated. Depending on the ongoing regulatory action and the eventual scope of the restriction prepared by the DE CA, regulatory needs to address possible remaining concerns for human health and the environment should be assessed, *e.g.* needs for further restriction, authorisation or action under the Occupational Safety and Health Directive (OSH).

Based on the information available for List 600-581-6 there is an additional concern for mutagenicity to be followed-up in a CCH. Since this substance is only registered at Annex VII for use as intermediate in industrial settings, self-classification may already sufficiently support safe work in case further data generation would confirm mutagenic properties. No further need for EU RRM is therefore foreseen for this specific hazard.

Uncertainties with regard to a carcinogenicity hazard for the TBBPA derivatives

In the recently adopted RAC opinion (September 2021) it was concluded that TBBPA induces uterine adenocarcinoma and testicular adenomas in rats, as well as hepatoblastoma, large intestine tumours and haemangiosarcoma in male mice. TBBPA is not mutagenic and one of the discussed mechanisms for the uterine cancer is a disruption of oestrogen homeostasis by TBBPA binding and inhibiting oestrogen glucuronosyltransferases and/or oestrogen sulfotransferases (competition) which may decrease the oestrogen excretion. This effect is reported in long-term (2-year) toxicity studies at high doses (500 and 1000 mg/kg bw/d). However, a lot of uncertainties related to the mode of action for TBBPA remain.

TBBPA derivatives may be carcinogenic themselves or due to biotransformation to TBBPA. The high threshold observed for TBBPA and uncertainty in the mode of action may give rise to uncertainty regarding the likeliness to expect TBBPA derivatives to be carcinogenic as well. In addition, TBBPA derivatives have higher molecular masses than TBBPA suggesting a possible lower bioavailability to humans. Together, this may suggest that the TBBPA derivatives might have less potential for carcinogenicity than TBBPA.

As discussed above, the absence of effects in the available carcinogenicity data on TBBPA derivatives (short-term and sub-chronic toxicity studies) cannot be seen as absence of hazard (which might only show *in vivo* at high doses and long exposure

durations). Insight in possible carcinogenic properties might be obtained from further information on degradation and hydrolysis products that may result from the ongoing data generation. Also, should ED and/or PBT/vPvB properties confirm, risk management action could already be initiated based on those hazards and confirmation of carcinogenic properties might not add value to the overall risk management. Because any further clarification of a carcinogenic hazard might involve chronic toxicity testing in animals, and because at present is considered that regulatory action might be possible without this additional animal testing, it is concluded for now to not pursue further carcinogenicity testing via Substance Evaluation.

3 Conclusions and actions

The conclusions and actions proposed in the table below are based on the REACH and CLP information available at the time of the assessment by ECHA. The main source of information is the registration dossiers. Relevant public assessments may also be considered. When new information (e.g. on hazards through evaluation processes, or on uses) will become available, the document will be updated, and conclusions and actions revisited.

As indicated in the Restrictions Roadmap[11] ECHA will prepare an overall strategy on flame retardants by 2022, which will support the Commission when it decides to request ECHA to prepare (a) restriction dossier(s). The substances in scope are in principle all flame retardants, and there will be particular focus on brominated flame retardants and their prioritisation for restrictions.

The overall strategy on flame retardants may bring new perspectives and may result in a need to revise some of the conclusions in this Assessment of Regulatory Needs (ARN).

Subgroup name, EC number, substance name	Human Health Hazard	Environmental Hazard	Relevant use(s) & exposure potential	Last foreseen action	Action
201-236-9 (TBBPA) 221-346-0 244-617-5 246-850-8 253-693-9 306-832-3 400-440-7	Known or potential hazard for carcinogenicity and ED for all substances in the group Inconclusive hazard for mutagenicity for 600-581-6	Known or potential hazard for aquatic toxicity, for PBT/vPvB and ED for all substances in the group	Use as flame retardant in polymers and plastics, mainly in electronic equipment, and additionally in coatings, textile, leather and fur for some substances. Exposure of industrial and professional workers,	**Need for EU RRM: Restriction** <u>Justification</u>: Restriction is proposed based on ED human health and environment, PBT/vPvB and/or Carc. to address risks of humans and the environment (once	**First step:** CCH For 221-346-0, 306-832-3, 500-107-7, 500-399-6, 600-581-6 and 926-564-6 Substance evaluation ongoing for TBBPA to clarify ED and PBT/vPvB properties.

[11] https://ec.europa.eu/docsroom/documents/49734

420-850-1 436-220-2 468-980-6 500-107-7 500-399-6 600-581-6 926-564-6 944-461-4			consumers and the environment, from use of mixtures and during article service life may be possible.	hazards confirm) from exposure during article service life and when using mixtures when these flame retardants are added to plastics, coatings, textile, leather and/or fur. Authorisation will be less effective for addressing risks from articles and will most likely not add value to protecting industrial workers in case of intermediate uses.	**Next steps (if hazard confirmed):** Restriction – It is suggested for TBBPA to await clarification of the ED and PBT properties and to develop the restriction in a group approach with the TBBPA derivatives.

Annex 1: Overview of classifications

Data extracted on 29.09.2021

EC/ List No	CAS No	Substance name	Harmonised classification	Classification in registrations	Classification in C&L notifications (*)
201-236-9	79-94-7	2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol	*Aquatic Acute 1 H400* *Aquatic Chronic 1 H410* *Carc. 1B* *H350 (adopted by RAC)*	Carc. 2 H351 Aquatic Acute 1 H400 Aquatic Chronic 1 H410	Eye Irrit. 2A H319 [1 out of 50] Aquatic Chronic 2 H410 [1 out of 50] STOT SE 3 H335, affected organs: Respiratory tract [1 out of 50] Skin Irrit. 2 H315 [1 out of 50]
246-850-8	25327-89-3	1,1'-isopropylidenebis[4-(allyloxy)-3,5-dibromobenzene]		-	Aquatic Chronic 4 H413 [1 out of 5] Eye Irrit. 2 H319 [3 out of 5]
926-564-6	-	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with Propylene oxide and n-butyl glycidyl ether		Acute Tox. 4 H302	-
468-980-6	-	468-980-6		Aquatic Chronic 4 H413	-
221-346-0	3072-84-2	2,2'-[(1-methylethylidene)bis[(2,6-dibromo-4,1-		-	Skin Sens. 1 H317 [3 out of 4]

		phenylene)oxymethylene]]bisoxirane			
500-107-7	40039-93-8	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane		-	Skin Irrit. 2 H315 [1 out of 23] Aquatic Acute 1 [1 out of 23] Aquatic Chronic 1 H410 [1 out of 23] Eye Irrit. 2 H319 [5 out of 23] Skin Sens. 1 H317 [7 out of 23]
600-581-6	1045809-53-7	600-581-6		Skin Irrit. 2 H315 Eye Irrit. 2 H319 Skin Sens. 1 H317 Aquatic Chronic 2 H411	-
944-461-4	-	Reaction mass of 1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromo-2-methylpropoxy)benzene] and 1,3-dibromo-2-(2,3-dibromo-2-methylpropoxy)-5-{2-[3,5-dibromo-4-(2,3,3-tribromo-2-methylpropoxy)phenyl]propan-2-yl}benzene		-	-
306-832-3	97416-84-7	1,1'-(isopropylidene)bis[3,5-		-	-

		dibromo-4-(2,3-dibromo-2-methylpropoxy)benzene]			
500-399-6	158725-44-1	2,2',6,6'-Tetrabromo-4,4'-isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane and 2,4,6-tribromophenol		-	-
244-617-5	21850-44-2	1,1'-(isopropylidene)bis[3,5-dibromo-4-(2,3-dibromopropoxy)benzene]		-	-

(*) the number in brackets indicates the number of notifications received. Each notification can represent a group of notifiers; therefore the number may differ from the C&L inventory which displays number of notifiers.

Annex 2: Overview of uses based on information available in registration dossiers

Data extracted on 29.09.2021

Main types of applications structured by product or article types	244-617-5	600-581-6	221-346-0	500-399-6	246-850-8	468-980-6	926-564-6	306-832-3	500-107-7	944-461-4	201-236-9
Polymer preparations and compounds	F, I, **A**		F, I, **P, C, A**	F, I, **P, C**	F, I		I, **P, A**	F, I, **A**	F, I	F, I, **A**	F, I, **P, C, A**
Coatings, paints, thinners, paint removes									F, I		
Dyes and impregnating products for textile leather and fur	F, I, **A**							F, I, **A**			
Intermediate		F, I				I		F, I	F, I		F, I

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life; P, C and A are highlighted in red to indicate widespread use with potential for exposure/release

Annex 3: Overview of completed or ongoing regulatory risk management activities

Data extracted on 26.08.2021

EC / List number	RMOA	Authorisation		Restriction*	CLH	Actions not under REACH / CLP
		Candidate list	Annex XIV	Annex XVII	Annex VI (CLP)	
201-236-9	YES				YES	EFSA[12], RoHS, EDD
221-346-0						EFSA, EDD
244-617-5						EFSA, EDD
246-850-8						EFSA, EDD
253-693-9						EFSA, EDD
306-832-3						EDD
468-980-6						EDD
500-107-7						EDD
500-399-6						EDD
600-581-6						EDD
926-564-6						EDD
944-461-4						EDD

*Some of the broad restriction entries in the Annex XVII of REACH are not represented in the overview, e.g. when the scope of the restriction is defined by its classification or the substance identification is broad (e.g. entries 3, 28-30 and 40).

4 References

EFSA: EFSA Assessment of possible risks for consumers, EFSA Journal 2011;9(12):2477. No risks were identified. However, limited information available was flagged. The assessment of TBBPA and its derivatives is currently revisited (https://www.efsa.europa.eu/en/topics/topic/brominated-flame-retardants).

RoHS: proposal to restrict additive uses of TBBPA in electronic apparatus (TBBPA_RoHS_Dossier_V2_final_20191204.pdf (oeko.info))

EDD: Ecodesign Directive 2019/2021 (https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0341&from=EN) and 2021/341 limiting the overall content of halogens from halogenated flame retardants in materials.

[12] Assessment of possible risks for consumers, EFSA Journal 2011;9(12):2477. No risks were identified. However, limited information available was flagged. The assessment of TBBPA and its derivatives is currently revisited.