ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S):

4,4'-isopropylidenediphenol (Bisphenol A) and bisphenols of similar concern for the environment

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TABLE OF CONTENTS

TABLE OF TABLES

TABLE OF FIGURES

Summary

The overarching aim of this restriction proposal is to minimise environmental exposure of endocrine disrupting bisphenols as much as technically and economically feasible. Since it is not possible, based on current scientific knowledge, to set sufficiently safe threshold values for endocrine disrupting chemicals in the environment, any exposure of endocrine disrupting bisphenols can be taken as a proxy for risk. It is assumed that every emission of endocrine disrupting bisphenols to the environment increases the likelihood of irreversible and adverse effects relevant at the population level, i.e. effects on reproduction, growth and survival. Therefore, current and future emissions of these bisphenols have to be minimised as much as technically and economically feasible.

Due to their technical properties, bisphenols A (BPA) and other bisphenols of similar concern, such as bisphenol S (BPS) and bisphenol B (BPB) are imported, produced and used in a wide range of mixtures and articles in large quantities in the EU. BPA is registered with a tonnage band of more than 1,000,000 t/a and BPS with a tonnage of ≥ 10,000 t/a. Although the remaining BoSC are used in smaller amounts (< 1000 t/a BPAF and < 100 t/a for a multiconstituent substance containing BPF and its isomers) or are not yet fully registered (as in case of BPB), it is expected that their use as a substitute for BPA and BPS in the EU would significantly increase if only the large scale bisphenols are restricted. In addition, monitoring data already shows the occurrence of bisphenols of similar concern in surface water or other environmental compartments in Europe. Thus, BPA and other bisphenols with endocrine disrupting properties in the environment are considered together in this restriction proposal.

To ensure that the group approach taken here comprises all relevant bisphenols the scope of the restriction proposal covers bisphenols already identified according to Article 57 (f) of the REACH Regulation as endocrine disruptors in the environment and bisphenols , meeting the WHO/IPCS criteria for an endocrine disruptor in the environment based on an EU wide agreement. Hence, this proposal for restriction covers the substances Bisphenol A and Bisphenol B as they are already identified as substances of very high concern (SVHC) under REACH based among others on their endocrine disrupting properties in the environment.

- 4,4'-isopropylidenediphenol ('Bisphenol A', BPA, EC 201-245-8)
- 4,4'-(1-methylpropylidene)bisphenol ('Bisphenol B', BPB, EC 201-025-1)

Furthermore, other bisphenols have been identified to be of similar concern for the environment ('BoSC') as they fulfil the WHO/IPCS criteria for an endocrine disruptor in the environment. BoSC covered in the actual scope of the proposed restriction are:

- 4,4'-sulphonyldiphenol ('Bisphenol S', BPS, EC 201-250-5)
- 4,4'-methylenediphenol ('Bisphenol F', BPF, EC 210-658-2)
- 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol ('Bisphenol AF', BPAF, EC 216-036-7) and its salts

Additionally, bisphenols that will be identified as substances of very high concern due to their endocrine disrupting properties for the environment according to Article 57 and Article 59 of the REACH Regulation, that are classified as endocrine disruptors for the environment

category 1 in Part 3 of Annex VI to Regulation (EC) No 1272/2008, that will be identified as endocrine disruptors for the environment according to Regulation (EC) No 528/2012 and that will be identified as endocrine disruptors for the environment according to Regulation (EC) No 128/2009 are covered by the scope of this restriction proposal.

The use pattern of BPA and the BoSC shows a lot of wide dispersive and wide spread uses and exposure of the environment cannot be excluded or is already demonstrated by monitoring data.

A large variety of emission sources contributes to the exposure of the environment and humans to BPA and other BoSC. Continuous and wide spreading via diffuse emissions into aqueous compartments potentially leads to spatial effects. Thus, adverse effects will not only occur at the point of release of BPA and BoSC but also far away from it. Additionally, BPA and BoSC may affect a very large number of species since the target endocrine pathways leading to adverse effects of these ED bisphenols are highly conserved among mammals, fish and amphibians. Furthermore, there are hints that also invertebrates might be affected by endocrine disrupting bisphenols.

The conclusion of the dossier submitter's (DS) assessment of the risk is hence that the use of Bisphenol A and the BoSC is not adequately controlled despite the fact that for BPA some sector specific regulations (EU-wide and national) are already in place. Therefore, an analysis of risk management options (RMOs) was conducted to identify the most appropriate measure to address these risks, including regulatory measures under REACH, existing EU legislation and other possible Union-wide RMOs.

To achieve an effective emission reduction the dossier submitter identified during RMO analysis the following aspects that need to be addressed:

- BPA and BoSC are originating from a very broad spectrum of wide dispersive and wide spread uses.
- A group approach must be taken to cover all bisphenols having endocrine disrupting properties for the environment and fitting specific structural group boundaries, since owing to the high structural similarity of ED bisphenols there is a high risk that these substances are used among each other as drop-in substitutes for restricted uses (*e.g.* as it could be observed in thermal papers, where BPA has been largely replaced by BPS). This would render any restriction approach focusing on single ED bisphenols disproportionate.
- Regrettable substitution must be avoided to achieve an effective measure.
- Additive and polymeric uses differ significantly in their emission potentials.
- The service life of products, the processing of mixtures and products as well as the end of life and waste phase have to be adressed either directly or indirectly.

With respect to this, national and/or sector specifc regulations (e.g. the restriction for BPA in thermal paper) are judged to be not adequate and an EU-wide and broad restriction is proposed to well balance the maximum that can be achieved for environmental emission reduction while keeping feasibility and proportionality. To address the specific differences of additive and polymeric uses of BPA and the BoSC three restriction options are described and analysed with respect to their economic and environmental impacts. 'Additive uses' in this case refers to uses of bisphenols in which they are not covalently bound to a matrix (i.e. via acting as a monomer in a polymer or a reactive cross-linker) but rather freely added (non-covalently bound) to a mixture or included in an article.

On the basis of an analysis of the effectiveness, practicality and monitorability of these RMOs, the following restriction option is proposed to minimise environmental exposure:

Proposed restriction

Bisphenols, HO-(R1)-R2-(R3)-OH with R1 and R3 being phenylene groups bearing any substituents at any ring position and R2 being a methylene group being unsubstituted or bearing any substituents or another bridging unit bearing unspecified substituents, which are listed in Appendix X and their salts.

Further bisphenols may be added to Appendix X if they fulfil one or more of the following conditions:

- They have been identified as substances of very high concern due to their endocrine disrupting properties for the environment according to Article 57 and Article 59 of this Regulation.
- They are classified as endocrine disruptors for the environment category 1 in Part 3 of Annex VI to Regulation (EC) No 1272/2008.
- They have been identified as endocrine disruptors for the environment according to the Biocidal Products Regulation (EU) No 528/2012.
- They have been identified as endocrine disruptors for the environment according to the Plant Protection Products Regulation (EC) No 1107/2009.

Conditions of restriction

1. Shall not be placed on the market in mixtures and articles in a concentration equal to or greater than 10 ppm (0.001 % by weight). This limit value refers to the sum of all substances subject to this Annex XVII entry which are present in the respective mixtures and articles.
2. Paragraph 1 shall not apply to mixtures and articles where the bisphenols listed in Annex X are either covalently bound to any type of matrix (e.g. via functioning as a cross-linker) or are used as intermediates in the manufacture of polymers, and for which
   i. contact to aqueous media in any form can be excluded during their reasonable and foreseeable use throughout their service life or
   ii. the migration limit in the respective mixtures and articles does not exceed 0.04 mg/L over the entire service life. Conditions for migration testing are described in Annex Z below.
3. Paragraphs 1 and 2 shall apply from [EiF + 18 months] for entries 1 to 5 of Appendix X. Specific derogations are listed in Appendix Y.
4. Appendices X and Y shall be amended in accordance with the procedure referred to in Article 133(4). Articles 69 to 73 shall not apply.

Appendix X

Substances	Index No	EC No	CAS No
4,4'-isopropylidenediphenol (Bisphenol A)	604-030-00-0	201-245-8	80-05-7
4,4'-(1-methylpropylidene)bisphenol (Bisphenol B)	N/A	201-025-1	77-40-7
4,4'-sulphonyldiphenol (Bisphenol S)	N/A	201-250-5	80-09-1
4,4'-methylenediphenol (Bisphenol F)	N/A	210-658-2	620-92-8
4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol (Bisphenol AF)	N/A	216-036-7	1478-61-1

Appendix Y

Substances	Derogations
(a) Bisphenol X CAS No XX EC No XXX	Use as X as defined by Regulation (EC) No XXX. The derogation shall apply until XXXX.

Uses proposed for derogation and inclusion in Appendix Y by the DS

Use	Proposed Derogation	Reasons
Recycling of paper	Concentration limit 150 ppm for 78 months	BoSC will be removed almost completely from the recycling loop within five years after a restriction on the use of BoSC in thermal paper becomes effective. However during that period no paper recycling would be possible in the EEA most likely leading to the demise of the paper recycling industry.
Fluoroelastomers	Concentration limit 50 ppm for 10 years	Stakeholder information suggests that BPAF concentrations in FKM are in the range 10 – 50 ppm. Stakeholders report on ongoing research to reduce the current concentrations
Polycarbonates (PC) and polycarbonate-based mixtures	Concentration limit 150 ppm	10 ppm concentration limit can only be met by less than 30% of the currently manufactured PC and polycarbonate-based mixtures. European manufacturers can meet 150 ppm concentration limit. Testing costs are deemed to be affordable and proportionate when considering that the concentration limit ensures a level playing field for EEA and non-EEA articles and mixtures.
Epoxy resins	Concentration limit 65 ppm for the placing on the market of articles	Stakeholders provided information that BPA and BPS residues in articles made of liquid epoxy resins amount to less than 10 ppm. Residues in articles

	manufactured with solid and semisolid epoxy resins. Concentration limit of 1 ppm for epoxy resin mixtures intended for consumer uses	made with solid epoxy resins contain less than 65 ppm residues. In order to minimize the emissions resulting from improper curing by consumers and from improper disposal by consumers, only epoxy resin mixtures with very limited emission potential shall be used by non-professionals.
Leather articles and mixtures used for the tanning of leather	Concentration limit 500 ppm for 5 years.	High uncertainty regarding current concentrations of BoSC in leather articles. Information available on R&D for syntans containing fewer amounts of BoSC. Limited costs expected when tanneries use new syntans. Information is lacking on whether even lower concentration limits can be met in the future.

Appendix Z: Description of conditions and methods for a tiered testing approach that can be used for migration testing to fulfil paragraph 2(ii) of this entry.

The release of BPA/BoSC from the samples shall be tested as a worst-case (tier 1) by exposure to hot water at selected worst case time and temperature conditions. For worst case outdoor use the water shall be at pH of 5-6. For remaining applications, water at pH 8 shall be used. The testing shall be performed in accordance with regulation EU 10/2011 for plastic food contact materials and following the relevant parts of the European standards for migration testing (CEN, 2004). Additional migration modelling[1] (e.g. with data from laboratory tests to model migration under field conditions) shall be used in cases where conducting full migration tests is considered not feasible based on technical or socioeconomic considerations. In this case, up-to-date technical guidance provided by the Joint Research Centre shall be considered when choosing the programs and parameters.

In case the worst-case testing according to tier 1 in combination with modelling reveals a migration above the maximum residue limit of 0.04 mg/L for the entire foreseen service life, a refined test taking into account the use conditions of the tested article shall be conducted.

As a tier 2 standardized method shall be used to simulate weathering conditions and thus the release potential from articles according to the reasonable and foreseeable use. The following methods for standardized simulation of weathering conditions are available (non-exhaustive list). An adequate method shall be chosen based on the foreseen use of the tested articles:

- DIN EN ISO 877-1:2011-03 Plastics - Methods of exposure to solar radiation - Part 1: General guidance (ISO 877-1:2009)
- DIN EN ISO 2810:2019-12 Paints and varnishes - Natural weathering of coatings - Exposure and assessment (ISO/DIS 2810:2019)
- DIN EN ISO 4892-1:2016-10 Plastics - Methods of exposure to laboratory light sources - Part 1: General guidance (ISO 4892-1:2016)
- DIN EN ISO 11341:2004-12 Paints and varnishes - Artificial weathering and exposure to artificial radiation - Exposure to filtered xenon-arc radiation (ISO 11341:2004)
- DIN EN ISO 11507:2007-05 Paints and varnishes - Exposure of coatings to artificial weathering - Exposure to fluorescent UV lamps and water (ISO 11507:2007)
- SAE J 1976:2012-04-16 Outdoor Weathering of Exterior Materials
- DIN EN 12224:2000-11 Geotextiles and geotextile-related products - Determination of the resistance to weathering
- DIN EN ISO 29664:2017-05 Plastics - Artificial weathering including acidic deposition (ISO 29664:2010)

[1] This is only necessary if a longer service life can be assumed or if an article is used outdoors.

- ISO/IEC 17025: 2005 to do migration testing and chemical analysis of food contact materials (FCM).
- ISO 11641 / UF 426 Leather - Tests for colour fastness - Colour fastness to perspiration (ISO 11641:2012)
- EN-ISO 2810:2020 Paints and varnishes - Natural weathering of coatings - Exposure and assessment
- DIN 75220 Ageing of automotive components in solar simulation units
- DIN EN 60068-2-38:2010-06 Environmental testing - Part 2-38: Tests - Test Z/AD: Composite temperature/humidity cyclic test (IEC 60068-2-38:2009)
- DIN EN ISO 2810:2019-12 Paints and varnishes - Natural weathering of coatings - Exposure and assessment (ISO/DIS 2810:2019)
- DIN EN ISO 11341:2004-12 Paints and varnishes - Artificial weathering and Exposure to artificial radiation - Exposure to filtered xenon-arc radiation (ISO 11341:2004)
- DIN EN ISO 11507:2007-05 Paints and varnishes - Exposure of coatings to artificial weathering - Exposure to fluorescent UV lamps and water (ISO 11507:2007)
- SAE J 1976:2012-04-16 Outdoor Weathering of Exterior Materials
- DIN EN ISO 12944-1:2019-01 Paints and varnishes - Corrosion protection of steel structures by protective paint systems - Part 1: General introduction (ISO 12944-1:2017)
- ISO 20345:2011 Personal protective equipment — Safety footwear

Explanatory notes on the proposed restriction entry:

Column 1 - Chemical structure

The bisphenol structural element is basically characterized by a number of chemical degrees of freedom that the restriction entry needs to map to delineate which substances fall under the restriction conditions. Since the extension mechanism cumulatively links the chemical structure to the fulfillment of the ED environmental status, from the dossier submitter's perspective it is considered necessary to describe the structural element by relatively generic terms, imposing no restrictions on phenyl ring substitution patterns, symmetry, or nature of the bridging unit.

Column 1 - "Core Set"

According to the assessment of the DS, a core set of five bisphenols is to be restricted directly on the basis of their endocrine-disrupting properties for the environment: These include the two substances already identified as SVHCs based on their ED properties for the environment, BPA and BPB, and the three other bisphenols of concern (BosC) BPF, BPAF and BPS. For the latter, an SVHC dossier has been submitted by the BE CA in August 2022. The Member State Committee (MSC) will decide on the SVHC identification of the substance based on the ED properties for humans and the environment in parallel to the submission of the restriction dossier. For BPF and BPAF, MSC decides on the environmental ED properties based upon a request by ECHA's executive director according to Art. 77(3)(c).

Extension mechanism for future BosC

In addition to the core set, the restriction should also include a mechanism to dynamically cover additional bisphenols for which ED properties for the environment are identified in the future. For this purpose, the reference to the identification as SVHC according to Art. 57 of

REACH, Part 3 of Annex VI to Regulation (EC) No 1272/2008, Regulation (EC) No 528/2012 and Directive No 128/2009/EC based on these ED properties for the environment has been implemented.

Direct adoption of identified/classified bisphenols after transition period (Y) vs. adoption via appendix mechanism (X)

A direct inclusion of substances identified or classified as ED environment, possibly after a transition period, would potentially be feasible. However, the dossier submitter considers a solution in analogy to entries 28-30 of Annex XVII for the restriction of the use of CMR substances by the general public as more appropriate. Here, substances that meet the appropriate requirements are included in an appendix to the restriction entry and only then become subject to the restriction. For the existing entries 28-30, Article 68(2) REACH provides that in this case the normal restriction procedure does not apply.

The wording proposed hierin provides for a corresponding analogous approach also for the extension mechanism for the bisphenol restriction. The extension mechanism would thus be laid down directly in the Annex XVII entry and refer to an appendix (X) for the listing of the bisphenols concerned and, if necessary, to a supplementary appendix (Y) for withdrawal exceptions or separate transition periods. Immediately upon entry of the restriction, Appendix X would already be populated with the five core bisphenols BPA, BPS, BPB, BPF and BPAF as indicated.

REACH

Currently, EDs are exclusively identifiable according to Art. 57 f). However, according to the Chemicals Strategy, the reorganisation of Art. 57 in the context of the REACH revision is foreseeable. There is a strong possibility that EDs may receive a separate, explicit letter in the future (apart from the current "Equivalent level of concern" procedure via Art. 57 f)). Therefore, the extension mechanism only refers to SVHC identification according to Art. 57-59 based on endocrine disrupting properties for the environment without further differentiation.

CLP

In addition, the CSS foresees the creation of new CLP hazard classes for EDs for human health as well as for the environment, so that EDs may also be included in Annex VI CLP in the future by a CLH procedure. It is therefore useful to include a reference directly to the CLP classification in the extension mechanism in order to cover bisphenols that meet the relevant CLP criteria for EDs. From the point of view of the dossier submitter, it would make sense here, in analogy to the established regulatory consequences for CMR substances, to refer to a classification as ED Cat. 1 for the environment and to exclude the "Suspected ED for the environment" category (ENV ED Cat. 2) from the restriction.

Identification via further legislation

Theoretically, a reference in the restriction entry to active substances and co-formulants identified as EDs for non-target organisms in the evaluation under the Biocidal Products (BPR) and Plant Protection Products (PPP) Regulations based on the ED criteria laid down therein would also be conceivable to allow the restriction of bisphenols not used as industrial chemicals and evaluated in the REACH context. Hence, a reference to the BPR and PPPR has also been included in the proposed restriction text.

Scope of the restriction regarding uses

The restriction is based on the need to reduce the release of BosC into the environment, in particular emissions into water. Although BosC may also be released into the environment in the form of dust through abrasion or grinding of articles, the dossier submitter considers this emission pathway as secondary to the release through contact with aqueous media.

The restriction entry comprises a general ban of the marketing of mixtures and articles that do not meet the maximum residue levels (MRL).

If an article does not meet the required MRL and does not qualify as an additive use, a migration test must be used to demonstrate that the sum of BosC released from the matrix of the article in the restriction entry does not exceed the migration limit.

Consideration of non-aqueous life cycle

However, as an exception to these two restriction conditions, substances, mixtures and articles should be exempted from the restriction for which it can be excluded that they will come into contact with aqueous media during their life cycle under realistic and foreseeable use.

This would apply, for example, to prepolymers with BosC contents above the MRL which are transported between industrial operators in an anhydrous and controlled manner, or to encapsulated components in complex articles. Substances, mixtures and articles meeting this condition would thus be exempt from the application of paragraph 1 (MRL) and by extension paragraph 2 (the necessity to provide a migration test to comply with the restriction).

Proposed residual and migration testing according to paragraph 2(i) and 2(ii)

Due to the large number of different uses of BPA/BoSC and the different products manufactured from them, suitable test methods do not yet exist for all areas of application. In this respect, the dossier submitter considers that activities for the development of test methods on the part of the manufacturers/industries concerned in the field of standardization (e.g. relevant technical committees of CEN (Comité Européen de Normalisation, European Committee for Standardization) would be desirable in order to close these gaps.

Furthermore, it is conceivable that for a certain group of articles a test is carried out on the basis of an overall use pattern in order to limit the testing effort for migration behaviour into the environment. In the same way, the number of necessary tests can be further minimized in the sense of a framework formulation (e.g. considering a relatively high residual content of BPA) and representation of a worst case. In this way, the dossier submitter assumes that effort and costs required to check the migration limit can be significantly reduced. Further considerations on testing for residuals and migration are contained in Annex E, section 7.1.

Identified hazard and risk

BPA, BPB, BPS, BPF and BPAF fulfil the scientific WHO/IPCS criteria for endocrine disrupting substances in the environment, i.e. they show adverse and population relevant effects on reproduction, survival and growth that can biologically plausibly linked to an endocrine mode of action. Environmental endocrine disruptors are, like PBT and vPvB substances, considered as non-threshold substances since, it is not possible to derive a safe level of exposure for such substances in environmental media that would be sufficiently protective for all possibly affected species. Therefore, any environmental emission of BPA and bisphenols of similar concern (BoSC) pose an unacceptable risk to the environment. Thus, the precautionary principle must be applied and emissions need to be minimised as much as possible.

The risk arising from additive uses of BPA and further BoSC is estimated to be much higher compared to the risk emenating from polymeric uses of these bisphenols. This is reflected in the proposed restriction scenarios aiming at a complete substitution of additive uses of BPA and BoSC as well as lowering the emissions from polymeric uses as much as possible with respect to proportionality aspects.

Justification that action is required on a Union-wide basis

A large variety of emission sources contributes to the exposure of the environment to BPA and other BoSC. Continuous and wide spreading via diffuse emissions into aqueous compartments potentially leads to spatial effects. Thus, adverse effects will not only occur at the point of release of BPA and BoSC but also far away from it. Monitoring data show that BPA and BPS are already ubiquitously present in the aqueous environment. Thus, co-exposure to BPA, other BoSC and other endocrine disrupting chemicals (e.g. alkylphenols and pharmaceuticals) in the environment acting via the same modes of endocrine action takes place potentially in all EU-Member States and synergistic effects cannot be excluded.

National regulatory actions will not adequately manage the risks of BPA and the BoSC. AnEU-wide restriction with a broad scope ensuring that emissions to the environment are as low as possible is proposed. An EU wide restriction will prevent and reduce the releases of BPA and BoSC within the EU in a harmonised manner. It may be the first step for global action. In addition, Union-wide action is proposed to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to action undertaken by individual Member States.

Effectiveness, Enforceability and Practicality

The cost-effectiveness of the proposed restriction is expected to be similar to REACH restrictions which have been decided and have entered into force previously. It is considered affordable for the impacted supply chains.

Analytical methods to enforce and/or to comply with the restriction and to monitor the effect are available. The costs for industry and enforcement agencies were assessed to be affordable.

The proposed restriction is practical because it is affordable, implementable, enforceable and manageable.

Report

1. The problem identified

BPA, BPB, BPS, BPF and BPAF fulfil the WHO/IPCS criteria for endocrine disrupting substances in the environment. Since it is not possible, based on current scientific knowledge, to set sufficiently safe threshold values for endocrine disrupting chemicals in the environment, any environmental exposure of endocrine disrupting bisphenols can be taken as a proxy for risk. Therefore, current and future emissions of these bisphenols have to be minimised as much as technically and economically feasible.

Due to their technical properties, BPA and other BoSc like BPS and BPB are imported, produced and used in a wide range of mixtures and articles in large quantities in the EU. BPA is registered with a tonnage band of more than 1,000,000 t/a and BPS with a tonnage of ≥ 10,000 t/a. Even if the remaining BoSC are used in smaller amounts (< 1000 t/a for BPAF and < 100 t/a in case of BPF and its isomers) or are not yet fully registered (as in case of BPB), it is expected that their use as a substitute for BPA and BPS in the EU would significantly increase if only the large scale bisphenols are restricted.

The use pattern of BPA and the BoSC shows a lot of wide dispersive and wide spread uses and exposure of the environment cannot be excluded or is already demonstrated by monitoring data.

A large variety of emission sources contributes to the exposure of the environment to BPA and other BoSC. Continuous and wide spreading via diffuse emissions into aqueous compartments potentially leads to spatial effects. Thus, adverse effects will not only occur at the point of release of BPA and BoSC but also far away from it. To date the sector and substance specific regulations in place are not adequate to minimise the risks emenating form the use of BPA and BoSC.

Thus, an EU-wide measure considering the group of endocrine disrupting bisphenols is needed to efficiently reduce environmental emissions while taking technical feasibility and economic proportionality into account.

1.1. Hazard, emissions and risk

1.1.1. **Identity of the substance(s), and physical and chemical properties**

This proposal for restriction covers the substances Bisphenol A and other Bisphenols of similar concern for the environment (‘BoSC’). BoSC covers the following additional substances:

- 4,4'-sulphonyldiphenol (‘Bisphenol S’, EC 201-250-5)
- 4,4'-methylenediphenol (‘Bisphenol F’, EC 210-658-2)
- 4,4'-(1-methylpropylidene)bisphenol (‘Bisphenol B’, EC 201-025-1)
- 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol (‘Bisphenol AF’, EC 216-036-7) and its salts

Table 1 summarizes chemical and regulatory identifiers of the substance Bisphenol A. Table 2 to 5 summarize chemical and regulatory identifiers of the other Bisphenols of concern included in this proposal for restriction.

Table 1: Substance identity of BPA

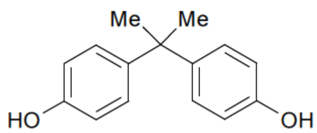
EC number:	201-245-8
EC name:	4,4'-isopropylidenediphenol
CAS number (EC inventory):	80-05-7
CAS number:	80-05-7
CAS name:	Phenol, 4,4'-(1-methylethylidene)bis-
IUPAC name:	2,2-bis(4-hydroxyphenyl)propane
Index number in Annex VI of the CLP Regulation	604-030-00-0
Molecular formula:	$C_{15}H_{16}O_2$
Molecular weight range:	228.28 g/mol
Synonyms:	Bisphenol A; Phenol, 4,4'-isopropylidenedi- (8CI); (4,4'-Dihydroxydiphenyl)dimethylmethane; 2,2-Bis(4-hydroxyphenyl)propane; 2,2-Bis(p-hydroxyphenyl)propane; 2,2-Di(4-hydroxyphenyl)propane; 2,2-Di(4-phenylol)propane; 2,2'-Bis(4-hydroxyphenyl)propane; 4,4'-(1-Methylethylidene)bisphenol; 4,4'-(Propane-2,2-diyl)diphenol; 4,4'-Isopropylidenebis[phenol]; 4,4'-Isopropylidenediphenol; 4,4'-Methylethylidenebisphenol; BPA; Bis(4-hydroxyphenyl)dimethylmethane; Bis(p-hydroxyphenyl)propane; Diphenylolpropane; Isopropylidenebis(4-hydroxybenzene); p,p'-Bisphenol A; p,p'-Dihydroxydiphenylpropane; p,p'-Isopropylidenebisphenol; p,p'-Isopropylidenediphenol; β,β'-Bis(p-hydroxyphenyl)propane
Structural formula:	

Table 2: Substance identity of BPS

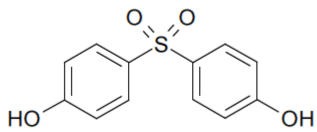
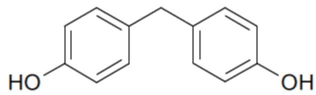
EC number:	201-250-5
EC name:	4,4’-sulphonyldiphenol
CAS number (EC inventory):	80-09-1
CAS number:	80-09-1
IUPAC name:	4-(4-hydroxybenzenesulfonyl)phenol
Index number in Annex VI of the CLP Regulation	N/A
Molecular formula:	$C_{12}H_{10}O_4S$
Molecular weight range:	250.27 g/mol
Synonyms:	Bisphenol S;1,1'-Sulfonylbis[4-hydroxybenzene]; 4,4'-Bisphenol S; 4,4'-Dihydroxydiphenyl sulfone; 4,4'-Sulfonylbisphenol; 4,4'-Sulfonyldiphenol; 4-Hydroxyphenyl sulfone; Bis(4-hydroxyphenyl) sulfone; Bis(hydroxyphenyl)sulfone; Bis(p-hydroxyphenyl) sulfone; Dihydroxydiphenyl sulfone; p,p'-Dihydroxydiphenyl sulfone; Phenol, 4,4'-sulfonylbis- (9CI); Phenol, 4,4'-sulfonyldi- (6CI, 8CI); Phenol, sulfonylbis-; Phenol, sulfonyldi-;Sulfonyldiphenol
Structural formula:	

Table 3: Substance identity of BPF

EC number:	210-658-2
EC name:	4,4'-methylenediphenol
CAS number (EC inventory):	620-92-8
CAS number:	620-92-8
IUPAC name:	4,4'-Dihydroxydiphenylmethane
Index number in Annex VI of the CLP Regulation	N/A
Molecular formula:	$C_{13}H_{12}O_2$
Molecular weight range:	200.23 g/mol
Synonyms:	Bisphenol F; BPF
Structural formula:	

Instead of disseminated data from a registration dossier on BPF itself, the following data is reported from the ECHA dissemination database on for a multi-constituent substance comprising BPF and two of its regioisomers, section “Physical & chemical properties”.[2]

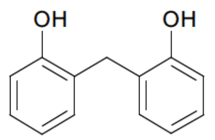
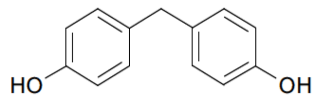
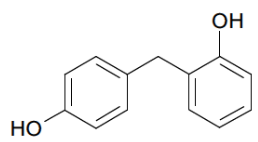
[2] Via https://echa.europa.eu/de/registration-dossier/-/registered-dossier/26309 accessed 25 April 2022

Table 4: Identity of the registered substance structurally related to BPF[3]

List number[4]:	908-912-9
SMILES:	See below
CAS number:	1333-16-0
Chemical name:	Reaction mass of 2,2'-methylenediphenol and 4,4'-methylenediphenol and o-[(4-hydroxyphenyl)methyl]phenol
Index number in Annex VI of the CLP Regulation	N/A
Molecular formula:	C13H12O2
Molecular weight range:	200.20 g/mol

Substance type: multi-constituent

The registered substance predominantly consists of a combination of the isomers ,4’-BPF, 2,4’-BPF and 2,2’-BPF.**Table 5: Constituents of the registered substance structurally related to BPF**

	EC Number	**CAS number**	**SMILES / structural formula**
2,2'-methylenediphenol	219-578-2	2467-02-9	Oc1ccccc1Cc2ccccc2O 
4,4'-methylenediphenol	210-658-2	620-92-8	Oc2ccc(Cc1ccc(O)cc1)cc2 
o-[(4-hydroxyphenyl)methyl]phenol	219-579-8	2467-03-0	Oc2ccc(Cc1ccccc1O)cc2 

[3] Based on the identifiers specified by the registrants of the substance
[4] Explanation on the role of LIST numbers is provided in the ECHA website at: https://echa.europa.eu/information-on-chemicals/registered-substances/information

Table 6: Substance identity of BPB

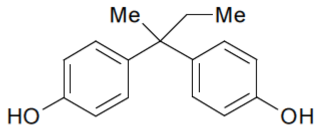
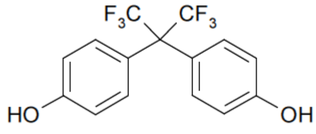
EC number:	201-025-1
EC name:	4,4'-(1-methylpropylidene)bisphenol
CAS number (EC inventory):	77-40-7
CAS number:	77-40-7
CAS name:	Phenol, 4,4'-(1-methylpropylidene)bis
IUPAC name:	4,4'-(1-Methylpropylidene)bisphenol
Index number in Annex VI of the CLP Regulation	N/A
Molecular formula:	$C_{16}H_{18}O_2$
Molecular weight range:	242.318 g/mol
Synonyms:	Bisphenol B; BPB; 2,2-Bis(4-hydroxyphenyl)butane; p,p'-sec-butylidenediphenol; p,p'-Dihydroxy-2,2-diphenylbutane; 4,4'-(1-Methylpropylidene)diphenol; 4,4'-(2,2-Butanediyl)bisphenol; 4,4'-(Methylethylmethylene)bisphenol; Phenol, 4,4'-sec-butylidenedi-; 4,4'-sec-Butylidenediphenol; Bis(4-hydroxyphenyl)methylethylmethane; Butane, 2,2-bis(4-hydroxyphenyl)-; 2,2-Bis(p-hydroxyphenyl)butane
Structural formula:	

Table 7: Substance identity of BPAF

EC number:	216-036-7
EC name:	4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol
CAS number (EC inventory):	1478-61-1
CAS number:	1478-61-1
IUPAC name:	2,2-Bis(4-hydroxyphenyl)hexafluoropropane
Index number in Annex VI of the CLP Regulation	N/A
Molecular formula:	$C_{15}H_{10}F_6O_2$
Molecular weight range:	336.23 g/mol
Synonyms:	Bisphenol AF; BPAF; 4,4'-(1,1,1,3,3,3-hexafluoropropane-2,2-diyl)diphenol; 4,4'-(Hexafluoroisopropylidene)diphenol; 4,4'-[2,2,2-Trifluoro-1-(trifluoromethyl)ethylidene]bisphenol; 4-[1,1,1,3,3,3-hexafluoro-2-(4-hydroxyphenyl)propan-2-yl]phenol
Structural formula:	

Besides BPAF itself, at least eight of its salts are registered under REACH.

These contain BPAF as a counter anion in their compositions, as presented in the table below:

Table 8: List of registered BPAF salts and BPAF: counter ion ratio

EC/List No	BPAF: counter ion ratio
278-305-5	1:1
479-100-5	1:1
943-265-6	Variable ratio (multi-constituent substance)
947-368-7	Variable ratio (multi-constituent substance)
443-330-4	1:1
468-740-0	1:1
425-060-9	1:2
469-080-6	Variable ratio (UVCB)

Under environmental as well as physiological conditions, dissociation of the substances to the respective cation and the anion (BPAF) takes place. In many of the registration dossiers data for phys-chem properties and aquatic toxicity have been given separately for the cation and the anion; in many cases aquatic toxicity data for BPAF has hence been submitted.

As these salts of BPAF are registered and expected to be sources of BPAF, they are also covered by the restriction proposal.

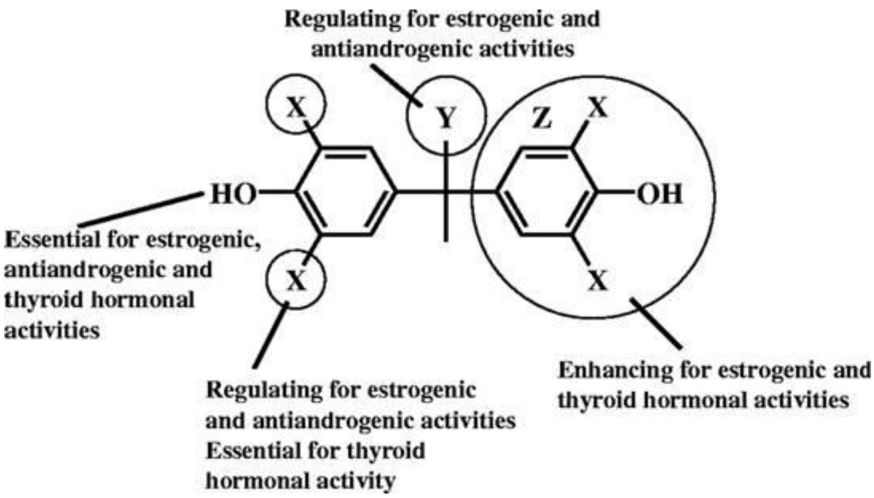
1.1.2. **Justification for grouping**

The overarching aim of this restriction proposal is to minimise environmental exposure of endocrine disrupting bisphenols. Since it is not possible, based on current scientific knowledge, to set sufficiently safe threshold values for endocrine disrupting chemicals in the environment, any exposure of endocrine disrupting bisphenols represent a risk. To minimise this risk the proposed restriction not only targets the specific uses of ED bisphenols but as well the issue of regrettable substitution. Owing to the high structural similarity of ED bisphenols there is a high risk that these substances are used among each other as drop-in substitutes for restricted uses (*e.g.* as it could be observed in thermal papers, where BPA has been largely replaced by BPS). This would render any restriction approach focusing on single ED bisphenols disproportionate. Hence, a group approach is taken in this restriction proposal to cover all bisphenols having endocrine disrupting properties for the environment and fitting the structural group boundaries described below.

To ensure that the group approach taken here comprises all relevant bisphenols the scope of the restriction proposal covers chemicals already identified according to Article 57 (f) of the REACH Regulation as endocrine disruptors in the environment or, based on an EU wide agreement, meeting the WHO/IPCS criteria for an endocrine disruptor in the environment. Additionally, bisphenols that will be identified as substances of very high concern due to their endocrine disrupting properties for the environment according to Article 57 and Article 59 of the REACH Regulation, that are classified as endocrine disruptors for the environment category 1 in Part 3 of Annex VI to Regulation (EC) No 1272/2008, that will be identified as endocrine disruptors for the environment according to Regulation (EC) No 528/2012 and that will be identified as endocrine disruptors for the environment according to Regulation (EC) No 128/2009 are covered by the scope of this restriction proposal.

The cases of BPA, BPB, BPS, BPF and BPAF demonstrate that specific molecular structures are needed in bisphenols as a prerequisite to act as endocrine disruptors. The essentials of these are presented in Figure 2 and discussed in detail by Kitamura et al. (2005) who summarized the structural alerts necessary for the different modes of action for BPA and other derivating compounds. Based on this the group boundaries for the bisphenols that fall or might fall under the scope of this restriction proposal are derived.

Figure 1: Structural alerts in phenols important to exert different hormonal activities (Kitamura et al., 2005)



The following tendencies regarding receptor binding potential and specificity are deduced by Kitamura et al. (2005):

To exert estrogenic activity, an unhindered hydroxyl group on an aryl ring and a hydrophobic group on the *para*-position to the hydroxyl group is required (Blair et al., 2000; Elsby et al., 2000; Fang et al., 2000; Hong et al., 2002; Nishihara et al., 2000). For bisphenol derivates, this means the phenolic hydroxyl group. A hydroxyl group on one phenyl ring is also essential for an anti-androgenic activity of bisphenols.

Experimental data suggest that the distance between para hydroxyl groups and also the nature of the bridging carbon substituent modulate the estrogenicity. Furthermore, increasing polarity reduces the estrogenicity (Molina-Molina et al., 2013).

The thyroid receptor protein shows a higher substrate specificity compared to the estrogen and androgen receptors, because of the relatively small size of the active site (Wagner et al., 1995; Wagner et al., 2001). Kitamura et al. (2005) demonstrated that a 4-hydroxyl group and double substitution by a halogen or methyl group at the 3,5-positions of the A-phenyl-group are essential for thyroid hormone activity of bisphenols.

Hence, substances in the scope of this restriction proposal are bisphenols, HO-(R1)-R2-(R3)-OH with R1 and R3 being phenylene groups bearing any substituents at any ring position and R2 being a methylene group being unsubstituted or bearing any substituents or another bridging unit bearing unspecified substituents, which are listed in Appendix X. Further bisphenols may be added to Appendix X.

The group approach also acknowledges the fact that BoSC already occur in environmental compartments in Europe as shown by monitoring data. Samples taken in the Ebro river in Spain in 2019 by Gil-Solsona et al. (2022) showed that BPS was ubiquitous in all the environmental compartmens with a detection frequency of 100% of water samples (similar to BPA). Detection rate of BPS and BPF in human urine has been found to even increase (Frederiksen et al., 2020), whereas there is evidence of BPAF in biota (Gil-Solsona et al., 2022; Oró-Nolla et al., 2021). Recent monitoring data demonstrates the presence of BPB in sea water as well as in biota of remote areas since abiotic degradation is negligible. Hence, BPB can reach habitats from various sources, and can be present in surface waters and other compartments (Lucia et al., 2016; Ruus, 2017; Ruus et al., 2015). Many organisms may therefore be exposed more or less continuously to BPB and potentially cannot avoid exposure (see Annex B4.2.5).

1.1.3. **Classification and labelling**

Bisphenol A is covered by index number 604-030-00-0 in part 3 of Annex VI to the CLP Regulation as follows, as amended by Commission Regulation (EU) 2016/1179 (9th ATP):

Table 9: Classification of BPA according to Annex VI, Table 3.1, CLP

Index No	International Chemical Identification	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)		
604-030-00-0	Bisphenol A 4,4'-isopropylidenediphenol	201-245-8	80-05-7	Skin Sens. 1 Eye Dam. 1 STOT SE 3 Repr. 1B	H317 H318 H335 H360F	GHS07 GHS05 GHS08 Dgr	H317 H318 H335 H360F		

A CLH proposal for adding environmental hazard classes to the Annex VI entry for BPA has been submitted by Germany in 2019 (BAuA, 2019).[5] It proposes to add the following hazard classes and hazard statements to the existing entry for BPA:

Table 10: CLH proposal for BPA

Index No	International Chemical Identification	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)		
604-030-00-0	Bisphenol A 4,4'-isopropylidenediphenol	201-245-8	80-05-7	Aquatic Acute 1 Aquatic Chronic 1	H400 H410	GHS09	H400 H410	M=1 M=10	

This CLH proposal was evaluated by RAC. The RAC opinion was published on the 8th of October 2020. RAC supported the proposed classification in its opinion.

As of October 2022, **Bisphenol S** is not covered by an Annex VI CLP entry. However, a CLH proposal for a harmonised classification for BPS has been submitted by Belgium in 2018 (FPS, 2019).[6] It proposes to add an entry with the following hazard classes and hazard statements for BPS:

Table 11: CLH proposal for BPS for a reprotoxic hazard class for Annex VI

Index No	International Chemical Identification	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)		
	Bisphenol S 4,4'-sulphonyldiphenol		80-09-1	Repr. 1B	H360FD	GHS08 Dgr	H360FD		

This CLH proposal was evaluated by RAC. The RAC opinion was published on the 10th of December 2020. RAC supported the proposed classification in its opinion.

Bisphenol AF is currently not covered by an Annex VI CLP entry. However, a CLH proposal for a harmonised classification for BPAF has been submitted by Sweden in 2018 (SCA, 2019). The CLH proposal covers 5 out of 9 substances from the BPAF group established by ECHA in

[5] CLH process on BPA: https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e18280184f

[6] CLH process on BPS: https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e182ed4414

the regulatory group strategy on BPAF and its salts.[7] It proposes to add the following hazard classes and hazard statements to the existing entry for BPAF:

Table 12: CLH proposal for BPAF for a reprotoxic hazard class for Annex VI

Index No	International Chemical Identification	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)		
	Bisphenol AF 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol	216-036-7	1478-61-1	Repr. 1B	H360F	GHS08 Dgr	H360F		

This CLH proposal was evaluated by RAC. The RAC opinion supporting the proposed classification was published on the 18th of March 2021.[8]

1.1.4. **Hazard assessment**

The scope of the present restriction covers all bisphenols where the available scientific data demonstrate a similar environmental concern compared to BPA and BPB. This section assesses the available data for BPS, BPF and BPAF with the focus on tests and endpoints that can be conclusive for their endocrine disrupting properties in the environment. Similarity of concern to BPA and BPB with respect to their intrinsic hazard properties is determined if the available data lead to the conclusion that the bisphenols under assessment fulfil, in accordance with the WHO/IPCS definition of an endocrine disruptor in the environment as interpreted by the EC ED EAG (JRC, 2013), all of the following criteria:

- They show an adverse and population relevant effect in organisms. All effects that impact the survival, the growth or the reproduction of an organism are considered to be adverse and of population relevance.
- They show an endocrine activity; and
- An endocrine mode of action, i.e. there is a biologically plausible link between the endocrine activity and the adverse effects observed.

To conclude if these criteria are fulfilled a weight of evidence approach is used. All relevant and reliable data available when compiling this dossier are considered. This comprises *in silico*, *in vitro* and *in vivo* data from standard as well as from non-standard exploratory studies. For analysis the data were grouped into three categories following the conceptual framework of

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[7] The substances covered by the CLH proposals are EC/List No 216-036-7 (BPAF), including EC No 278-305-5, EC No 479-100-5, List No 943-265-6 and List No 947-368-7

[8] CLH process on BPAF: https://echa.europa.eu/de/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e1830f8b24

the OECD Revised Guidance Document 150 (OECD, 2018) and the EU EDC guidance (ECHA et al., 2018): I) *in vitro* and *ex vivo* mechanistic parameters, II) *in vivo* mechanistic parameters and III) parameters providing information on adversity to create a "set of relevant information grouped to assess a hypothesis" (ECHA et al., 2018).

The relevance of a given study is assumed if the study design allows for answering questions regarding an endocrine mode of action and/or regarding adverse effects that are or can be mediated via an endocrine mode of action. To judge on the reliability of data, all studies were assessed according to the Klimisch scoring system (Klimisch et al., 1997).

1.1.4.1. Bisphenol A (BPA)

Bisphenol A is identified as an SVHC [according to article 57(f)] by giving rise to an equivalent level of concern compared to PBt/vPvB and CMR substances due to its endocrine modes of action and the type of effects caused by these modes of action in wildlife species (fish, amphibians).[9] The candidate list has been amended accordingly in January 2018.

BPA clearly acts as an oestrogen agonist in fish (with VTG induction in males, changes in gonadal staging and testis-ova, as well as a female biased phenotypic sex ratio and depression of male secondary sex characteristics in i.a. Medaka and Zebrafish) and as a thyroid antagonist in amphibians (with accelerated development *in vivo* and increased levels of thyroid hormones) (Bhandari et al., 2015; Chen et al., 2015; Goto et al., 2006; Hatef et al., 2012; Heimeier et al., 2009; Shioda and Wakabayashi, 2000; Sohoni et al., 2001; Tabata et al., 2001; Yokota et al., 2000). Endocrine-mediated effects occurred at lower concentrations than systemic toxicity.

BPA has also been identified as an SVHC according to article 57(f) for probable serious effects on human health due to its endocrine disrupting properties on the basis of data on mammals.

1.1.4.2. Bisphenol B (BPB)

Similar to BPA, BPB has been identified as a substance meeting the criteria of Article 57(f) of Regulation (EC) 1907/2006 (REACH) because it is a substance with endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in paragraphs (a) to (e) of Article 57 of REACH.[10]

BPB has estrogen-agonist properties and induces adverse effects on the male reproductive system in rodents and fish which are plausibly mediated by this endocrine activity (with VTG induction in males, reduced sperm count and fecundity as well as dereased embryo hatching in survival of F1 generation) (Rosenmai et al., 2014; Wang et al., 2014; Yamaguchi et al., 2015; Yamasaki et al., 2003; Yang et al., 2017). Supportive evidence is provided by the consideration that BPB possibly has androgen-antagonist properties. This endocrine activity could also plausibly contribute to the adverse effects on the male reproductive system in

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[9] Agreement of the Member State Committee on the Identification of 4,4'-Isopropylidenediphenol (Bisphenol A) as a Substance of Very High Concern According to Articles 57 and 59 of Regulation (EC) 1907/2006 Adopted on 14 December 2017: https://echa.europa.eu/documents/10162/81862f4e-92bc-6f64-9a01-42565b526022

[10] Agreement of the Member State Committee on the Identification of 4,4'-(1-methylpropylidene)bisphenol (Bisphenol B) as a Substance of Very High Concern According to Articles 57 and 59 of Regulation (EC) 1907/2006 Adopted on 3 June 2021: https://echa.europa.eu/documents/10162/b8baaee8-e3ae-64f6-371a-dd188c8d4268

rodents and fish. The effects in fish and rodents are relevant for the environment as an effect on reproductive function can have adverse consequences at a population level. Therefore, there is scientific evidence that BPB fulfils the WHO/IPCS definition of an endocrine disruptor in the environment.

The assessment shares similar lines of argumentation as previous SVHC identifications of BPA for its ED properties, for which a considerable amount of data is available. Due to the very close structural similarity between BPB and BPA, commonalities of effects and of modes of action of BPA an BPB are assumed.

1.1.4.3. Bisphenol S (BPS)

There is strong evidence that the adverse effects on reproduction and development seen in zebrafish after exposure to BPS are plausibly linked to the disturbance of the estrogen modality and the disrupted steroid hormones synthesis.

These effects result from conserved mechanisms across vertebrates and are in line with effects measured in rodent species. Indeed, there is strong evidence that the adverse effects on reproduction seen in rats after exposure to BPS and especially the decrease in fertility in females, are plausibly linked to the estrogen modality.

Adverse effects concerning development and reproduction are generally regarded as endpoints of particular relevance because such effects are likely to manifest themselves at the population level. Such changes in both fish and mammals associated with endocrine modalities pose unacceptable risks to the environment.

Based on this available scientific evidence for fish and mammals, it can be concluded that BPS fulfils the WHO/IPCS (2002) definition of an endocrine disruptor for the environment.

The findings for mammalian species, and particularly in rodents, support the findings seen for environmental species (fish). It should be noted that effects observed in rats are of particular concern for wildlife species with a natural low reproductive output, including top predators and other mammals (including endangered species) as negative effects on reproduction have an even higher potential for causing long-term negative effects at the population level for such taxa.

Adverse effects on environmental species (fish) were seen after BPS exposure leading to a significant decrease in egg and sperm production. As a consequence, BPS impacted hatchability by increasing the time to hatch and decreasing the hatching success. BPS also alters the sex ratio by leading to a feminisation. Sex ratio is considered as EATS-mediated effect, providing evidence for both endocrine activity and adverse effect. Several *in vitro* tests show a clear estrogenic activity of BPS, via ER binding and ER activation. BPS also disrupted steroidogenesis, impacts the production of testosterone and aromatase activity. Exposure to BPS impairs VTG levels in different fish studies and thus shows estrogenic mode of action.

Based on all available scientific evidence (environmental data, supported by human health data) it can be concluded that BPS fulfils the WHO/IPCS (2002) definition of an endocrine disruptor with regard to the environment:

- It shows clear adverse effects in zebrafish by a change in reproduction and development, supported by clear adverse effects on reproduction in rodents (Naderi et al., 2014; Qin et al., 2021; Shi et al., 2019)(Unpublished study report, 2000, 2017b and 2019). The reproductive endocrine system is highly conserved not only between mammals, but also between mammals and vertebrates like fish.

- It has endocrine mode of actions: clear estrogenic mode of action and disruption of steroidogenesis.

- The adverse effects are considered EAS-mediated effects and are thus a consequence of the endocrine mode of action.

In August 2022, the Belgian Competent Authority (CA) has submitted a dossier to identify BPS as an SVHC based on its reprotoxic properties (meeting the criteria of Article 57c)) as well as based on its endocrine disrupting properties for human health and the environment, thereby meeting the criteria of Article 57f).[11]

1.1.4.4. Bisphenol F (BPF)

Available data for BPF show clear and consistent adverse and population relevant effects on reproduction and sexual development in two zebrafish studies. The observed effects fit to an estrogenic and/or anti-androgenic mode of action and no indications of further non-ED mediated pathways were found in the two studies.

The available *in vitro* as well as *in vivo* mechanistic data clearly and consistently demonstrate an estrogenic and anti-androgenic activity of BPF. Additionally, *in vitro* and *in vivo* data from fish and amphibians point to an interference of BPF with the HPT axis. Two *in vitro* studies also show an interference with testosterone production in cellular assays.

BPF may have multiple modes of endocrine action (estrogenic, anti-androgenic, thyroidal activity and interference with steroidogenesis) that might interact and are difficult to distinguish from each other. However, the estrogenic and/or anti-androgenic effects of BPF in fish are consistently observed in the available studies showing significant effects on egg production, hatching and survival of F1 larvae, sex ratio and gonadal development. Estrogenic and anti-androgenic modes of action are well known to be involved in the regulation of sexual development and reproduction (AOP Wiki including examples therein,[12] e.g. AOP 345). Adverse effect such as feminization of fish, fertilization success, ability to produce viable offspring and gonadal development and their link to an estrogenic and/or anti-androgenic mode of action have been reviewed i.a. by (Jobling et al., 2002; Jobling et al., 1998; Miller et al., 2012).

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[11] Annex XV dossier in Bisphenol S submitted by the Belgian CA: https://echa.europa.eu/de/substances-of-very-high-concern-identification/-/substance-rev/70906/term

[12] Collaborative Adverse Outcome Pathway Wiki: https://aopwiki.org/aops

Considering the observed concomitant decrease in plasma testosterone levels and the increase in plasma estradiol levels as well as the increase in VTG levels and gene expression in male fish, the link between these endocrine activities and the observed adverse effects on fish is highly plausible.

In vitro and *in vivo* data from fish and amphibians point to an interference of BPF with the hypothalamic-pituitary-thyroid (HPT) axis.

Additionally, the available human health data support the conclusion for an estrogenic and/or antiandrogenic activity of BPF, even though the reliability of these studies have not been assessed here. Studies on rats show consistently a decrease in serum testosterone levels and a decrease in sperm motility in the offspring of treated female rats. An increase in uterus weight was observed in juvenile rats.

The link between the observed effects and the specific estrogenic and/or anti-androgenic activity of BPF is further supported by the analogy of BPF to BPA and BPB. BPA and BPB, both of which share very similar chemicals structures compared to BPF, show well defined adverse effects and modes of action that fit to an estrogenic mode of action in fish.

Overall, BPF has estrogen agonistic properties and induces adverse effects in fish that are plausibly mediated by this endocrine activity. Furthermore, in vivo and in vitro evidence shows that BPF has androgen antagonistic properties. This endocrine activity could also plausibly contribute to the observed adverse effects on reproduction and sexual development in fish. The effects observed in fish are relevant for the environment as an effect on the reproductive function and the sexual development can have consequences at a population level. Therefore, there is scientific evidence to conclude that BPF fulfils the definition of an endocrine disruptor in the environment.

In March 2021 the conclusion of a Regulatory Management Option Analysis (RMOA) prepared by the Swedish CA for BPF was published. The RMOA also addressed the ED concern with a focus on ED properties for human health. The Swedish CA concluded that the current evidence might not be strong enough to be used as basis for SVHC identification (ED HH) but might be used as the basis for a read-across to BPA to propose a classification of BPF as Repr. 1B. Evaluation of ED properties for the environment was not the focus of the Swedish CA's RMOA.[13]

In accordance with Article 77(3)(c) of the REACH Regulation, the MSC was requested to provide an opinion on the endocrine disrupting properties of BPF.[14] The dossier submitter prepared a report containing the available information on the environmental ED properties to support the opinion-making of the MSC.[15]

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[13] Risk Management Option Analysis Conclusion Document on 4,4'-methylidenediphenol (Bisphenol F) dated 24 March 2021: https://echa.europa.eu/documents/10162/785a51c1-3391-1b81-e532-cc83b665ea60

[14] Request to the Member State Committee (MSC) for an opinion on the endocrine disrupting properties for the environment of BPF, BPAF and for eight BPAF salts dated 5 May 2022: https://echa.europa.eu/documents/10162/8b189603-3b85-0f8b-f766-805ac1c234f3

[15] Article 77(3)(c) Request Supporting Information Report: Evaluation of endocrine disrupting properties for the environment for Bisphenol F, April 2022: https://echa.europa.eu/documents/10162/9fa94006-f703-4b22-cf28-4fec2975bd76

1.1.4.5. Bisphenol AF (BPAF)

The exposure of fish in a long-term study with BPAF showed an adverse effect on the reproduction capacity with a reduced fertilisation rate of spawned eggs. The same study documented effects for an estrogenic and/or anti-androgenic MoA in absence of indications for unspecific systemc toxicity.

BPAF shows significant endocrine activity in the nanomolar range in the available *in vitro* studies in a dose-dependent manner. Most prominent are estrogen agonistic effects, but also specific antagonistic activity to the ERβ receptor protein subtype was observed. These results are consistent across the different cell lines used in the available studies. *In vivo* studies with fish further show that BPAF impairs VTG levels and influences the spermatogenesis.

The salts of BPAF are expected to dissociate under environmental conditions to the respective cation and BPAF. In many of the registration dossiers of the BPAF salts data for physicochemical properties and aquatic toxicity have been given separately for the cation and the anion; in many cases aquatic toxicity data from BPAF has hence been submitted. Under physiological conditions, dissociation of the salts is also expected. Based on the nature of the substances, it is concluded that the ED properties for the environment relevant for BPAF apply to the salts as well.

Overall, BPAF has estrogen agonistic properties and induces adverse effects in zebra fish that are plausibly mediated by this endocrine activity. Furthermore, *in vivo* and *in vitro* evidence is provided that BPAF has androgen antagonistic properties. This endocrine activity could also plausibly contribute to the observed adverse effects on reproduction in zebra fish. The effects observed in fish are relevant for the environment as an effect on the reproductive function can have consequences at a population level.

Therefore, there is scientific evidence to conclude that BPAF fulfils the WHO/IPCS definition of an endocrine disruptor in the environment.

In accordance with Article 77(3)(c) of REACH Regulation, the MSC was requested to provide an opinion on the endocrine disrupting properties of BPAF and eight of its salts.**Error! Bookmark not defined.** The dossier submitter prepared a report containing the available information on the environmental ED properties to support the opinion-making of the MSC.[16]

1.1.5. **Manufacture and use**

According to the registration information BPA is manufactured and/or imported in the European Economic Area in a tonnage range of >1,000,000 tonnes per year.[17] This is in line with a BPA consumption in Europe reported by Merchant Research & Consulting ltd (2020).

[16] Article 77(3)(c) Request Supporting Information Report: Evaluation of endocrine disrupting properties for the environment for Bisphenol AF and its salts, April 2022: https://echa.europa.eu/documents/10162/2d940c3f-ada7-d8f1-226d-e1be2ee666a7
[17] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.133 (09/29/2022)

Both exports as well as imports of substances, mixtures and articles containing BPA occur. Large amounts of articles and products, containing bisphenols are imported into the EU. The quality and the quantity of the mixtures and articles imported are often unknown.

1.1.5.1. Manufacture, import and export

A steady growth of the tonnage of BPA consumed in the EU is expected during the next years (albeit the restriction of its use in thermal paper since January 2020) so that an annual BPA consumption growth of 3-6% is predicted for 2024 (see therefore research project on BPA in Annex H).

The following information on tonnage for the BoSC (BPB, BPS, BPF and BPAF) used annually in the EU was provided by the ECHA dissemination sites. The tonnage of other BosC is smaller than that of BPA.

Table 13: Registered tonnage band for BPA and the BPs with similar concern

Substance	CAS	Tonnage band (tpa)	Import[18] (substance)	Export[19] (substance)
BPA[20]	80-05-7	1,000,000 – 10,000,000	60,000	10,000
BPB[21]	77-40-7	1 - 10	-	-
BPS[22]	80-09-1	10,000 – 100,000	-	-
BPF[23]	620-92-8	1,000 – 10,000	-	-
BPAF[24]	1478-61-1	100 – 1,000	-	-

1.1.5.2. Uses

The main uses[25] for BPA are the manufacture of polycarbonate (PC) with about 70-80 % of the BPA production volume and manufacture of epoxy resin with around 15-30% of the BPA production volume. However, there is a remaining percentage with a share of less than 5% concerning the use of BPA as an additive with several technical functions and the manufacture of chemicals with about 0.3%).

The figures are in line with information from an earlier study commissioned by the Federal Environment Agency (UBA) (Fischer et. al., 2014) for Western Europe arriving at similar distributions with production of PC (75% of total BPA) being the main use, followed by the second largest use in the production of epoxy resins (17 % of total BPA use). All "other" uses accounted for about 2% of total BPA consumption. The remaining 6% were allocated to export. The exact tonnages that can be attributed to the respective uses for the bisphenols of similar concern are not available. What is clear is that - similar to BPA - they are attributed to one of three use groups:

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[18] EUROSTAT, query dated 3 March 2021.
[19] EUROSTAT, query dated 3 March 2021.
[20] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.133 (06/29/2021)
[21] https://echa.europa.eu/de/substance-information/-/substanceinfo/100,000.933 (06/29/2021)
[22] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.137 (06/29/2021)
[23] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.009.691 (06/29/2021)
[24] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.014.579 (06/29/2021)
[25] FKZ 3719654060, cf. Annex H.

- production of polymers (P),
- use as additives (A)
- and production of other chemicals (C).

Bisphenols and articles/mixtures derived from BPA and BoSC or containing it are used in a variety of sectors for many applications. For example, they are used in the transport industry (automotive industry, aviation), in the construction industry, for energy generation (wind turbines), the textile and paper industry, electronics and optics, in packaging, in toys and sports articles, and in a wide range of everyday consumer goods. In addition, they are found in coatings, paints and varnishes, adhesives and sealants, in flame retardants and material protection agents, lubricants, in medical technology and in the food industry.

Bisphenols, especially BPA, play an important role as a monomer in the production of polymers and as an additive in the production and processing of plastics being used wide dispersive. For other bisphenols of similar concern, this widespread distribution is not recorded or too little studied. However, since these substances are also used in the manufacture of other substances, including polymers, and since they can also be used as additives due to similar properties, a similar distribution into most of the sectors given above must be assumed at this point.

1.1.5.3. Uses of BPA

General information

BPA is used

- in the production of different polymers (P),
- as an additive (A),
- and it is feedstock to produce other chemicals (BPA derivates – C).

For some years now, many different sources have been available for the inventory of BPA uses. Companies have included some use descriptions both in the EU RAR (2008) and in the registration dossier under REACH. This content can also be found on ECHA's dissemination site. The German Environment Agency has carried out some research on emission pathways and thus also on uses. In 2012, the report on project no. (FKZ) 36001063 "Identification of relevant emission pathways to the environment and quantification of environmental exposure for bisphenol A" was published.[26] The uses were identified with project no. (FKZ) 3719654060 "Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials" (see also Annex H). Taking into account the source of the mentioned substance flow analysis by Fischer et al. (2014), a clear increase in the annual amount of BPA can be seen, which mainly flows into the production of polycarbonate and the production of epoxy resins. Total consumption of BPA increased by about 3%. With the help of the SPIN database (Substances in Preparations in Nordic Countries),[27] the sectors

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[26] Fischer et al. 2014: Identification of relevant emission pathways to the environment and quantification of environmental exposure for Bisphenol A (Umweltbundesamt – Texte). Avaliable online via https://www.umweltbundesamt.de/publikationen/identification-of-relevant-emission-pathways-to-the

[27] Substances in Preparations in Nordic Countries: Database via http://www.spin2000.net/spinmyphp/

in which BPA is relevant were identified by specifying the use categories and product categories.

Inventory of the main type of uses of BPA

With FKZ 3719 65 4060 (see also Annex H), the dossier submitter has aimed to cover the entirety of all possible and relevant uses, as they all contribute in their totality to the exposure of the environment to the endocrine disrupting substance BPA. BPA is used in the production of different polymers (P), as an additive (A), and it is feedstock to produce other chemicals (BPA derivates - C). In the following figure and table the different uses of BPA are shown and reproduced in a structured way:

Figure 2: Uses of BPA

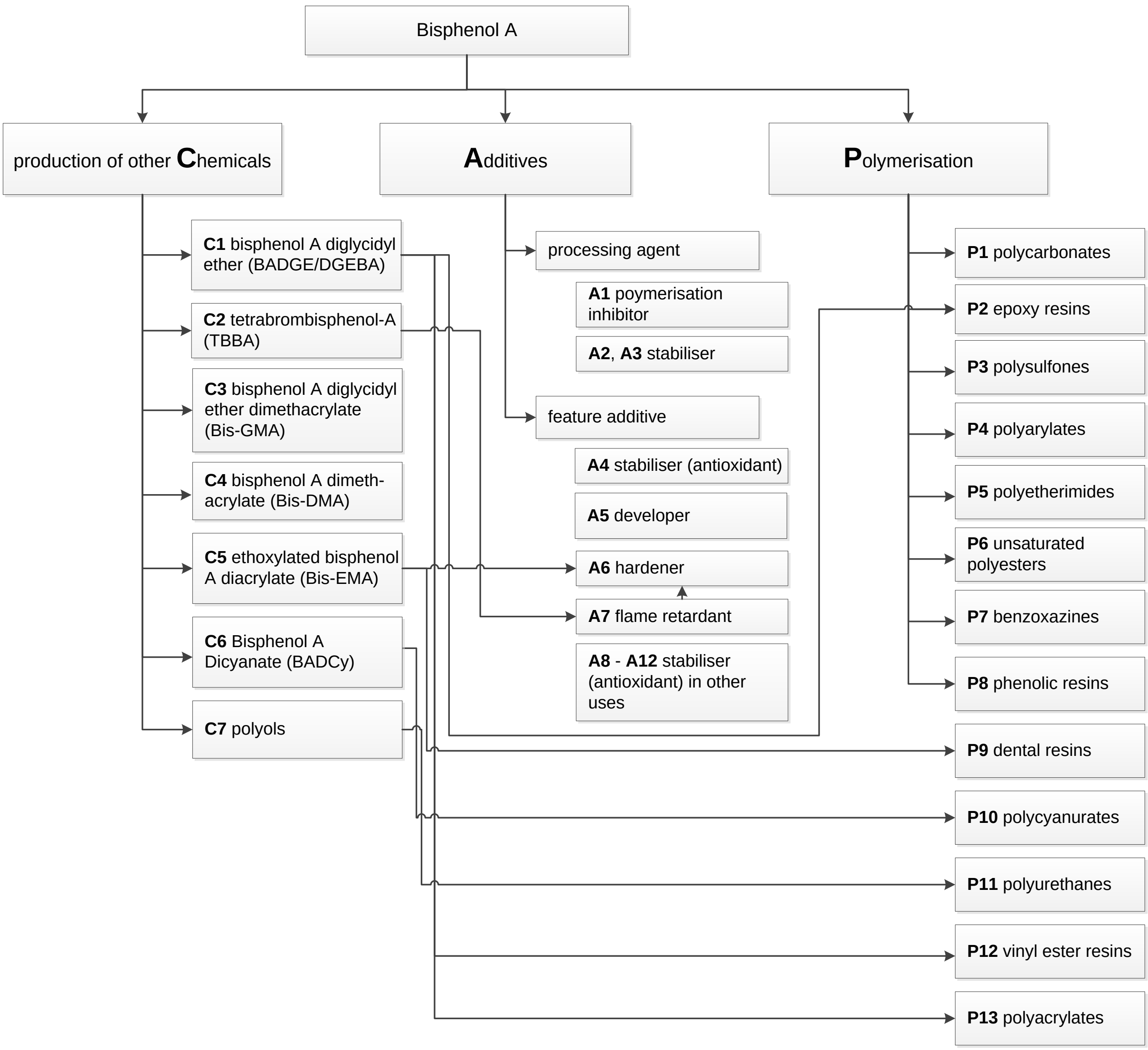

Table 14: Use and function of BPA

Objective	Use and function
Production of other **C**hemicals	**C1** production of bisphenol A diglycidyl ether (BADGE/DGEBA) to polymerise epoxy resins

Objective	Use and function
	C2 production of tetrabromo bisphenol A (TBBPA) to produce flame retardants
	C3 production of bisphenol A diglycidyl ether dimethacrylate (Bis-GMA) to polymerise dental resins and acrylic polymers
	C4 production of bisphenol A dimethacrylate (Bis-DMA) to polymerise dental resins and acrylic polymers
	C5 production of ethoxylated bisphenol A diacrylate (Bis-EMA) to polymerise dental resins and acrylic polymers **C6** production of bisphenol A dicyanate (BADCy) **C7** production of polyols
processing **A**gent	**A1** inhibitor for the polymerization of polycarbonates
	A2 stabilizer to prevent thermolysis and oxidation in PVC processing
	A3 stabilizer to prevent thermolysis and oxidation when producing plasticizers intended for use in PVC
feature **A**dditive	**A4** stabilizer (antioxidant) to prevent polymer oxidation (mainly PVC)
	A5 photo-developer in thermal paper
	A6 hardener in epoxy resins
	A7 flame retardant in polymers
	A8 stabilizer (antioxidant) to prevent oxidation in chain oil
	A9 stabilizer (antioxidant) to prevent oxidation in break fluids
	A10 stabilizer (antioxidant) to prevent oxidation in heat transfer fluids
	A11 stabilizer (antioxidant) to prevent oxidation in lubricant formulations **A12** stabiliser (antioxidant) to prevent oxidation when producing tyres
Polymerization	**P1** polymerization of polycarbonates
	P2 polymerization of epoxy resins
	P3 polymerization of polysulfones
	P4 polymerization of polyarylates
	P5 polymerization of polyetherimides
	P6 polymerization of unsaturated polyesters
	P7 polymerization of benzoxazines
	P8 polymerization of phenolic resins
	P9 polymerization of dental resins
	P10 polymerisation of polycyanurates
	P11 polymerisation of polyurethanes
	P12 polymerisation of vinyl ester resins

Objective	Use and function
	P13 polymerisation of acrylates

Sources: SKZ-KFE gGmbH, UBA (2010), Hahladakis et al. (2018), Schaefer Additivsysteme (2021), Dow (2014), GEM-Chem (2017), Ramboll Environ (2019), Aabøe et al. (2015), Dorobantu (2012), Dröge et al. (2018).

For a complete mapping of the uses of BoSC but also BPA, **A13** production of flourochemicals (FKM) (BPAF) is added to the main use A and under the main use P the uses **P14** syntans (BPS, BPF) and **P15** textile auxilliaries (BPS, BPF, BPA) are added.

Production of other chemicals (C)

As an example, BPA diglycidyl ether (EC No 216-823-5, CAS No 1675-54-3, DGEBA, BADGE) *(C1)* is an organic compound used as feedstock for epoxy resins *(P2)*. It is synthesized from BPA and epichlorhydrin as raw materials. It is used to polymerise epoxy resins. BADGE is also referred to as Liquid Epoxy Resin (LER). If BADGE is further reacted with BPA or if the stoichiometry of the reaction of epichlorohydrin and BPA is changed a polymer/oligomer is formed, which is called solid epoxy resin (SER).

Another important use of BPA is to produce tetrabromobisphenol A (EC No 201-236-9, CAS No 79-94-7, TBBPA) (C2) which is used as a flame retardant (additive and reactive) (A7). The primary use (ca. 90%) of TBBPA is as a reactive intermediate in the manufacture of flame-retarded epoxy and polycarbonate resins. It may also be used (ca. 10%) as an additive flame retardant, generally in conjunction with antimony oxide, for example in the manufacture of acrylonitrile-butadiene-styrene (ABS) resins. Last not least Cyanate esters, like BPA Dicyanate ester monomer (EC No 214-590-4, CAS No 1156-51-0, BADCy) (C6) is a specific chemical used in high-performance structural composites (P10). They are applied mainly in the aerospace industry, because of their outstanding mechanical properties and high operating temperature. Important products include filament windings, fiber-reinforced composites, pultrusion and syntactic foams. Cyanate ester resins also find some uses in the electronic industry including electronic chip adhesives, encapsulants, and thermal interface materials. These examples underline the importance of BPA as a starting material for the synthesis of other chemicals and its wide range of applications. Further and more detailed information on this can be found in Appendix A.

Use as an additive (A)

Less than 5%[28] BPA are used as additives per year. An additive may be present in the mixture unbound or embedded in the matrix. The way in which plastics are refined with additives such as stabilizers, polymerization inhibitors or flame retardants can vary depending on the type of polymer and additive and the individual machine capabilities of the manufacturers/processors of polymers and plastic products. Before or during the polymerization reactions of plastics as well as during stabilization of plasticizers or reactive polymerization monomers, the corresponding additives (e.g. polymerization inhibitors) and reaction partners (e.g. reactive flame retardants) are usually added to the reaction medium as pure substances in appropriate quantities.

[28] Cf. Annex H

After the synthesis of the raw polymers, further additives are added. This can be done in different ways. In the simplest case, the additives can be continuously added directly to a melted polymer in pure form with suitable metering units via a compounding process, before the polymer mixture is usually used to produce granules.

In other cases, the desired additives can be added to the plastic in the form of so-called masterbatches. Masterbatches are usually commercially available highly concentrated additive/polymer mixtures in granular form, which are then diluted to the desired concentration in a compounding process with the plastic to be refined. The advantage of such masterbatches is usually their easy dosing and the fact that they are already available as mixtures of several additives in one batch. Before being used for polymerisation reactions, granulate mixtures or, for example, mixtures of low-cross-linked polymer liquids or other bulk materials may be provided with BPA as an additive (e.g. 5%) for stabilization. Here, BPA is used in free radical polymer chain reactions as a polymerization inhibitor *(A1)* in order to stop the chain propagation.

Although BPA is mainly used as a radical scavenger in the production of PVC, it is also applied in the production of other plastics produced via radical polymerization, such as polymethylmethacrylate (PMMA) (Kadoma and Fujisawa, 2000). BPA is added in the synthesis, processing, and manufacturing of PVC *(A2, A3).* Altogether, there are four main uses of BPA in this field.

The polymerization of PVC takes place via a radical polymerization chain reaction. BPA is used as a polymerization inhibitor during the synthesis of PVC to stop the polymerization process and control the length of the polymer chain by deactivating free radicals (Groshart et al., 2001). In the same way, BPA as a radical scavenger prevents the undesired polymerization of vinyl monomers during their processing, storage, and transportation (Lartigue-Peyrou, 1996).

BPA is also part of an additive package for PVC processing and serves as a stabilizer *(A4)* in the production of plasticizers in PVC (Groshart et al., 2001). As a phenolic compound, BPA itself can be easily oxidized, which enables BPA to act as an antioxidant to prevent oxidative fragmentation of PVC plasticizers and degradation of the PVC polymer chain during the synthesis, processing, manufacture and final application (Darby et al., 1970). A more detailed view on other important application of BPA as an additive ((e.g. thermal paper *(A5)*, epoxy resins *(A6)*, Flame retardants *(A7)* etc.)) and in different industries, as well as responses from the stakeholder consultation on these, are provided in Annex A. The use of BPA in thermal paper has been restricted in the EU under REACH with a concentration limit of 0.02% in place sind January 2020.

Polymer/Plastics (P)

Polycarbonate (P1)

The production of polycarbonate *(P1)* is the largest use of BPA. Based on information from Plastics Europe, the different end uses of polycarbonate products are summarised in the following table (Fischer et al. 2014).

Polyester carbonates or polycarbonates (PC) contain carbonate and Polyester structures and are formed by condensation reaction between Bisphenol A, Phosgene and tetraphthaloyl chloride. Polycarbonates are particularly characterised by their high transparency, strength, impact resistance, rigidity and hardness and are therefore often, though not exclusively, used as an alternative to glass (CDs, headlights, spectacle lenses, etc.) (Kaiser 2011). Classic uses include microwave dishes, hair styling rods, and spotlight reflectors. For more detail see table below:

Table 15: Use of BPA in polycarbonate (Fischer et al. 2014)

Sector	**Application**
Optical Media	compact discs, CDs, DVDs, HD-DVDs, Blue-Ray Discs, Holography Discs, Innovative Data Storage Technology, forgery-proof holographic shadow pictures in ID cards
Electrical and Electronics	housing for cell phones, alarm devices, SLR cameras, electrical razors, hairdryers, steam irons, mixers, computers, monitors, TVs, copiers, printers, telephones, microwaves, coffee makers, front panels for electric cookers, electrical kettles, transparent front panels for vending machines, interior lighting panels for trains and airplanes, backlight units for TVs, housing for switch modules, distributor boxes, fuses, battery power stations, sockets, electrical meters, illuminated rotary switches, plug connectors, switches, sockets, plugs, lamp holders, fax machines, pagers, circuit breakers, cable sockets, displays, relays, LEDs, safety switches, fluorescent lightning diffusers, fridges
Construction	sheets for roofing, conservatory glazing, architectural glazing, greenhouse glazing, safety galzing, rooflights, cover for solar panels, noise reduction walls for roads and train tracks, carport covers, glazing for bus stop shelter, road signs, internal safety shields for stadiums, housing and fitting for halogen lightning systems, front panels for advertising posters, sign boards (e.g. at fuel stations), large advertising displays, dust & water-proof luminaries for streetlights and lamp globes, diffusing reflectors for traffic lights
Automotive	fixed side windows, transparent and retractable roof modules, windstops and convertibles, rear windows, transparent rear body parts, headlamp lenses, headlamp, tail light, indicator reflectors, foglamps, interior light covers, high-mount brake lights, housing for licence-plate lights, bumpers, radiator and ventilation grills, dashboards, rear light reflectors, coverings, moulded mirror housings, turn signals
Bottles and Packaging	reusable water bottles, unbreakable, reusable milk bottles, cutlery, food containers, drinking water generators, pitchers, water carboys, storage containers, tableware, water cooler bottles
Medical and Healthcare	blood oxygenators, cardiotomy reservoirs, dialysers, respirators, dentists´operating lamps, breast pumps, inhaler housings, prescription spectacles, i.v. connectors, scalpel cases, laparoscope handles, contact lens holders, syringe tops, medical packaging film, ampoules, three-way stopcocks and stopcocks manifolds, tweezers with integrated lighting, single-use operating instruments, eyeglass lenses
Leisure and Safety	Leisure: ski goggles, sun glasses, transparent building blocks in toys, mouthpieces for musical instruments, compass housings, binocular housings, transparent roof modules in caravans, instrumentation housings in boats, suitcase shells. Safety: safety goggles, protective visors for welding or handling of hazardous substances, protective visors for motorbikes or snowmobiles, motorbike and cycle helmets, fencing helmets, safety shields for policemen, guards to protect from moving machine parts, blends mainly used in automotive and electrical and electronics
Domestic Appliances	Blenders, cooking appliances
Others	

PC is purchased in the form of pellets or granules. Processing can happen via injection moulding, blow-molding (e.g. water bottles) or extrusion (e.g. sheets). PC can either be used in its existing state or be equipped with functional additives (stabilizers, colorants, UV-absorbers, fibers, mineral fillers), as well as blended with other polymers (e.g. PET, PBT, ABS, ASA) in a subsequent compounding step in order to achieve other specific performance properties.

The service life of PC articles varies largely depending on the application in which these articles are utilized. It can range from less than one day (disposable medical devices) to 25 years (electrical devices, sheets).

Epoxy resins (P2)

Epoxy resin production is the second largest use of BPA in the EU. There are a number of different epoxy resins which vary depending on the starting materials. However, diglycidyl ethers *(C1)* derived from BPA and epichlorohydrin are among the most widely used epoxy resins (European Commission, 2003). For their synthesis, BPA is first converted with epichlorohydrin to form the respective diglycidyl ether (BADGE/DGEBA in case of BPA). This is then polymerized with bisphenol A or other polyvalent amines as hardeners to form a cross-linked three-dimensional thermoset network. Other, less frequently used epoxy resins that are not based on BPA are, for example, novolaks or aliphatic epoxy resins (Pham and Marks, 2000; Hamerton, 1996)

Around 90% of the world production of epoxy resins (1.7 million tonnes in 2008) are produced based on BPA (BmVBS, 2012). In order to use the resin, it must be cross-linked with a curing agent or hardener *(A6)*. The choice of the curing agent is of highly significance in designing an epoxy resin for a given application. The major reactive groups in the resin can react with many other groups so that many types of chemical substances can be used as curing agents. The content of BPA in this reaction determines whether ER is liquid or solid. Liquid epoxy resin (LER) is produced by a reaction in which 45% of BPA and 55% of epichlorohydrin are mixed; in semi-solid epoxy resin (SsER) 61% of BPA is reacted with 39% epichlorohydrin. The bisphenol A derived epoxy resins are most frequently cured with acid anhydrides, aliphatic and aromatic amines and polyaminoamides, depending on the desired end properties. Some curing agents will cross-link the resin at ambient temperature while others require the application of heat. Some of the desired properties are superior electrical properties, chemical resistance, heat resistance, and adhesion. The following table gives a brief overview for the application of LER and SsER in various products.

Table 16: Examples for the use of LER and SsER[29]

Product	Type of ER
water pipes	LER
flooring	LER
wind rotor blades	LER and SsER

[29] Epoxy Resins Committee: Epoxy Resins – Assessment of potential BPA emissions – Summary Paper. July 2015. https://epoxy-europe.eu/wp-content/uploads/2015/07/Epoxy_ERC_BPA_WhitePapers_SummaryPaper.pdf (access 2022/05/04)

Product	Type of ER
marine coating	LER and SsER
automotive coating	SsER

Epoxy resins are a family of synthetic resins, including products which range from viscous liquids to high melting point solids. Epoxy resins are selected because of their corrosion protection, thermal stability and mechanical strength and are used primarily as coatings for consumer and industrial applications, such as food and drinks cans and protective coatings for automotive and marine uses, electrical and electronic laminates, adhesives and paving applications, protective coatings, structural composites, electrical laminates, electrical applications and adhesives (EU RAR, 2003, PE, 2006, Geens et al., 2011). Despite of the aromatic backbone and the resulting susceptibility to UV degradation, epoxy resins are frequently used as binding agent in top layers of anti-corrosion coating systems. An overview on the use of epoxy resins is given in the following table.

Table 17: Use of BPA in epoxy resins (Fischer et al. 2014)

Application Class	Application
Marine and Protective Coatings	water ballast tanks, underwater ship hulls, cargo tank linings, offshore oil drilling platforms, supporting steel structures, sea containers, steel bridges, storage tanks (metal and concrete), power plant scrubbers, electric motors, engines, machinery, drinking water distribution pipes (metal and concrete), gas pipes
Powder Coatings	construction panels (cladding, metal roofing, ceiling, garage doors), radiators, rebars (concrete reinforcement), gardening tools and equipment, engine blocks, automotive parts, steel furniture, steel racks, frames beds, office furniture (shelves, metal desks, filling cabinets), pipes, valves and fittings
Electrical and Electronics	potting / encapsulation electronic parts (transformers, inductors), printed circuit boards
Civil Engineering	flooring (industrial / public buildings), food / catering industry, chemical plants, pharmaceutical industry, hospitals), mortars grouting (tile and brick linings), fillers, crack repair, coatings concrete bridges (seal against water and de-icing chemicals), coatings secondary containment walls (ground water protection), anti-skid coatings for park desks
Can and Coil Coatings	Can: food and drink cans / can ends, menue trays, food trays, craps and closure, crown cork, drums, pails, general line cans (oil, hairspray), collapsible tubes (toothpaste, cream) Coil: construction panels (cladding, metal roofing, ceilings, garage doors), cookers, mobile homes, caravans, heat – ventilation- air conditioning equipment, office furniture (metal desks, shelves, filing cabinets, cupboards), fridges and freezers, dishwashers, washing machines, dryers, household appliances (e.g. vacuum cleaners)
Automotive Coatings	waterborne primers for cars, buses, railcars
Composites	rackets (tennis, badminton, squash), hockeysticks and golf clubs, ski, ski poles, snowboards, surfboards, boats, canoes, hang gliders, helmets, lightweight bicycles, pipes, valves and fittings, storage tanks, containers, gas bottles, windmill blades, scrubbers, pultruded structural parts (rods, bars, shafts, beams, grating), cars parts (body panels, cabin, spoiler, leaf springs,

Application Class	Application
	drive shafts), railcars, boats, yachts, aviation (aircraft), aerospace, military (helicopters)
Adhesives	DIY repair kits (adhesives, fillers), structural adhesives for buildings and constructions, adhesives for cars, boats, aircrafts
Photocure	printing inks, wood coatings, paper and board varnish incl. food packaging, coatings for plastics and primed metals

Information on the total amount of BPA used in epoxy resins as well as a breakdown into the main uses and areas of application can be found in a survey prepared by Wood Environment & Infrastructure Solutions UK Limited on behalf of the Epoxy Resins Committee (ERC) of Plastics Europe (2019). In total, 323,000 tonnes have been produced and sold into the five main sectors of application. More detailed information on synthesis, specific uses and service life of epoxy resins, also taking into account information from the stakeholder consultation, can be found in Annex A.

Other polymers (P3 – 13)

BPA is also used as monomer in the manufacturing of a number of other polymers: polysulfones *(P3)*, polyarylates *(P4)*, polyetherimides *(P5)*, unsaturated polyesters *(P6)*, polymerisation of benzoxazines *(P7)*, polymerisation of phenolic resins *(P8)*, polymerisation of dental resins *(P9)* and others.

Polysulfone resins *(P3)* are synthesized by condensation of the disodium salt of BPA with 4,4-dichlorodiphenyl sulfone (EC No 201-247-9, CAS No 80-07-9). They are used in electrical components, appliances, transport, medical equipment, pumps, valves and pipes, due to their good thermal stability, toughness, transparency and resistance to degradation by moisture (EFSA, 2015). Polyarylates *(P4)* are a group of polymers of which only a part contains BPA. These amorphous polymers are formed by copolymerizing BPA with aromatic dicarboxylic acids (mainly terephthalic acid and isophthalic acid). Polyarylates have good thermal resistance and toughness, in combination with clarity and stability to UV light, so that they find application in automotive, electronics, aircraft and packaging industries (EFSA, 2015).

High-temperature (HT) polymers of the polyarylsulfone family (Polyphenylsulfones - PPSU, Polysulfones - PSU, Polyethersulfones - PESU) are characterized by extraordinary, inherent flame retardancy and high transparency. Polyetherimides - PEI *(P5)* are also amorphous HT thermoplastics and therefore often compete with PESU or PPSU - especially in injection molding applications. Phenolic resins *(P8)* are synthesized from formaldehyde and phenolic compounds such as phenol, 3-cresol, 3,5-xylenol, resorcinol or BPA. In the first step of the reaction electrophilic substitution in *ortho*- or *para*-position of the phenolic compound intermediate products are formed which then react with an excess of formaldehyde to form a closely crosslinked polymer (Jakubke and Karcher 2001; Gehrke et al. 2010). They are thermosetting plastics which are characterized by their hardness and breaking strength. They are often used in cookware and E&E applications. A tabular overview and information on the application classes of the other polymers can be found in Appendix A.

Use as syntans (leather) (P14)

Synthetic tanning agents (aromatic syntans) are those that are artificially produced. Tanning makes the leather more stable and also preserves it against degradation by microorganisms. For the manufacture of syntans, BPS is the starting material for the condensation reaction with formaldehyde. The synthesis of the polycondensate takes place in a closed system. Formation of BPS and BPF is a by-product of partial sulfonation of phenol and condensation with formaldehyde. Syntans are used as leather tanning agents and textile colour fixers and may contain BPS and/ or BPF. Estimated production/use of worldwide syntans market in 2020 was about 115,000 t. Based on data from 2012 – 2014 stakeholders reported a yearly tonnage of 7,000 – 8,000 BPS for syntan production in the EU.

Use as textile auxilliary (P15)

Textile auxiliaries that contain BPS and BPF are used as colour fixers for polyamide textiles to provide longevity of colour. Globally, 80% of polyamide textiles undergo colour fixing with syntans. Stakeholders reported an annual production of BPS of 700 – 800 t for this textile auxiliary production for this purpose in the EU (Ramboll Deutschland GmbH, 2021). The textile auxiliaries are specifically post-treatment (anionic-after treatment – fixation of dyes) agents for polyamide (also spandex, elastane). When using recycled polyamide, effective post-treatment with these auxiliaries is required. Without this aftertreatment, recycled polyamide can no longer be used for the production of textiles, because standards for colour fastness are not adhered to. BPS/BPF is used in chemical production as raw material for synthesis of textile auxiliaries and is an unavoidable substance residue in products. The duration of service life is from 6 month (clothing) up to 10 years (carpets).

1.1.5.4. Uses of other bisphenols with similar concern[30,31]

BPA can be easily replaced by relevant (structurally-chemically similar) BoSC for use as an additive. The drop-in substitution solution has little technical impact on the process. It is more complex (as a complex chemical reaction is influenced here) when BPA is substituted during polymerisation, but still achievable if technical procedures and processes are optimised. For this reason, it can be assumed that bisphenols with similar concerns also have similar fields of application and can be classified with at least one, or even all, of the three categories of application into which BPA can be divided: use as additive (A), use as monomer for polymerization processes (P) and production of other chemicals (C).

Bisphenol B (BPB, 4,4'-(1-Methylpropyliden)bisphenol)[32]

The substance is not registered under REACH. There is no public information on tonnage and uses available. It is well known that BPB is used for the manufacturing of polycarbonate (P1), epoxy resins (P2) as well as phenolic resins (P8).[33]

[30] Cf. Annex H
[31] https://www.umweltbundesamt.de/publikationen/bewertung-des-endokrinen-potenzials-von-bisphenol
[32] https://echa.europa.eu/documents/10162/00872c55-2827-a6d7-273d-78ac4391906b
[33] Otto-Albrecht Neumüller (Herausgeber): Römpps Chemie Lexikon, 8. Auflage, Frank'sche Verlagshandlung, Stuttgart 1983, S. 454–455. ISBN 3-440-04513-7

In the US, according to HSDB[34], BPB may be used in the manufacture of phenolic and polycarbonate resins. BPB is in the 'List of Indirect Additives Used in Food Contact Substances' maintained by the U.S. Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN), in Section 175.300 'resinous and polymeric coating´. It is used in the food industry as an anti-corrosion agent for coating cans. The use categories describe above are consistent with those described for BPA. Since BPB differs from BPA by one additional methylene unit in one of the methyl substituents at the bridging quaternary carbon centre only, it can be assumed that the general use profile may the same as for BPA and that – from a technical point of view – BPB could substitute BPA in the full range of applications.

Bisphenol S (BPS, 4,4'-sulfonyldiphenol) and derivates[35]

The group BPS (EC 201-250-5) and BPS derivatives consists of Bisphenol S (BPS) and structurally similar substances that include as constituent(s) structures with exactly the same bridge as BPS between the two phenyl rings. The derivatives may have different substituents at the phenyl rings or may have the phenolic hydroxyls derivatized. The group includes 11 substances, 7 of these are registered substances (4 mono-constituent, 1 multi-constituent and 2 UVCBs). For detailed information refer to Annex A. Due to structural similarities with BPS, similar uses and therefore impacts may be hypothesized for the BPS derivatives in the group. In addition, as several members contain BPS in concentration of >0.1% they may show similar properties as BPS.

BPS itself is registered in a range of 10,000 – 100,000 tpa. On the ECHA website the following information on uses can be found: The substance is used in leather treatment products (P), for paper chemicals (A/P) and in polymers (P). The substance has an industrial use resulting in manufacture of another substance (C) (use of intermediates).[36] The substance is used for the formulation of mixtures and/or re-packaging, building and construction work and scientific research and development. The substance is used for the manufacture of paper products, chemicals, coatings, paints, varnishes and hygiene products (sector of use). The substance can be found in complex articles, with low release: leather, paper and construction materials. Furthermore, BPS and its derivatives is a direct alternative to BPA.

One important application of BPS has been thermal paper (A5). Regarding the use in thermal paper, widespread use and low indoor release is indicated for most substances. Thermal paper is used in point-of-sales (POS) applications like receipts, tickets, self-adhesive labels, tickets or fax paper. As of 2013, BPS seemed to be primarily used in higher quality thermal papers which last longer and are typically used for goods that have a longer warranty time. As of 2019, the overall market share of BPS-based thermal paper placed on the EU market stood at 39%, whereas those of BPA and other developers stood at 29% and 32% respectively. As mentioned above, the use of BPA in thermal paper has been restricted in the EU under REACH with a concentration limit of 0.02% in place sind January 2020.

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[34] (Hazardous Substances Data Bank [Internet]. Bethesda (MD): National Library of Medicine (US), Division of Specialized Information Services. 1986—[cited 2013 Jan 4]. Available from: http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB

[35] ECHA: Assessment of regulatory needs: https://echa.europa.eu/documents/10162/3448017/GMT_109_Bisphenols_Report_public_23502_en.pdf/1bd5525c-432c-495d-9dab-d7806bf34312?t=1647590013566 (access 2022/05/09)

[36] https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14986

A further use, mentioned for BPS, is as monomer or chromogenic agent in the manufacture of paper products. It is also common as the aromatic compound used in the synthesis of synthetic tannins (syntans) based on DDS (Di-hydroxy-Diphenyl-Sulphone) polymers. Syntans are indispensable for achieving the properties of the finished leather required by the industrial users as they fix collagen and stabilize the hide and skin in leather. Other applications of BPS include contact with food packaging (P2) (e.g. as coating in metal can linings or plastic container).[37] Based on its structural similarity to BPA and similarities in technical functionality (as monomer in epoxy-resins, developer in thermal paper) further substitution of BPA by BPS may be anticipated like BPS as resin and possibly also as surface modifier or solvent.

Bisphenol F (BPF, 4,4'-methylenediphenol) and derivatives

The group BPF (EC 210-658-2) and BPF derivatives consists of Bisphenol F and structurally similar substances that include as constituent(s) structures with exactly the same bridge as BPF between the two phenyl rings. The group includes 17 substances, 10 of these are registered substances (6 mono-constituent, 6 multi-constituent and 5 UVCBs). BPF bears also structural similarity to BPA and therefore, may be used as substitute for BPA or its derivatives. An extensive overview on BPF derivatives is found in Annex A.

BPF can be found in products with material based on: leather (e.g. gloves, shoes, purses, furniture), paper (e.g. tissues, feminine hygiene products, nappies, books, magazines, wallpaper), paper used for articles with intense direct dermal (skin) contact during normal use such as printed articles (e.g. newspapers, books, magazines, printed photographs) and paper used for articles with intense direct dermal (skin) contact during normal use such as personal hygiene articles (e.g. nappies, tissues, towels, toilet paper). BPF derivatives include coatings, polymers/plastic, board and paper, manufacture of other chemicals, finger paint and fillers, adhesives, lubricants and greases, washing and cleaning agents, perfumes and fragrances, plant protection products, photochemicals as well as leather and textile.[38]

Some of these uses are also registered for BPA (use in polymers/plastics) and in terms of technical functionality, the BPF derivatives share at least with BPA the technical functionality of being used as hardener in epoxy resins, as monomer, dye or binding agent. For example, BPF in epoxy resins is generally not used as a replacement of BPA in epoxy resins, but as a complementary building block. and is used as intermediate (to produce pre-polymeric glycidyl ethers of the starting material) and monomer. As mentioned above, the substances in this group are registered for a wide spectrum of uses. Many of the registered uses are indicated for professional and consumer use and hence, widespread exposure to workers, consumers and the environment can be expected. A detailed overview of the Reach registrations, tonnage band and typical uses of the BoSC can be found in Appendix A.

[37] BPS is listed in Regulation (EU) No 10/2011 for the use as monomer with an SML of 0.05 mg/kg. Specfic recommendations may exist in the different EU Member States e.g. in Germany as specified further in the BfR Recommendation XXXVI on paper and board for food contact as monomer for retention agents and in the BfR Recommendation LI on temperature resistant polymer coating systems for frying, cooking and baking utensils as monomer of polyethersulfone.
[38] (ECHA): https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.137

Bisphenol AF (BPAF, 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene] diphenol) and derivatives

The substances in this group include Bisphenol AF (BPAF, EC 216-036-7) and BPAF derivatives that were grouped on the basis of having constituents that have structural features common to BPAF. All BPAF derivatives in this group can be considered as a salt of BPAF; either a salt with inorganic counter ions (EC/List No 425-060-9 – sodium salt) or as organic salts (the other derivatives). Under environmental conditions the substances can be expected to dissociate to the anion (BPAF) and the respective cation.

Bisphenol AF is registered under REACH with an annual tonnage of 100 – 1000 t/a. BPAF and its derivatives are used as monomers in plastics (P) and polycarbonate (P others), which are used, for example, in textiles and packaging materials for food and personal care products, and as process auxiliaries or process regulators (A). The substance is used as a reactive process regulator in polymer materials and in rubber production and processing. Bisphenol AF is further used as a crosslinking agent for certain fluoroelastomers (FKM/FPM) and as a monomer for polyimides, polyamides, polyesters, polycarbonate copolymers and other specialty polymers[39]. The uses are described by US National Institutes of Health (NIH) as curing agent or crosslinker (vulcanizing agent) for fluoroelastomers and heat-resistant adhesives; precipitation agent for polymer-preparation emulsions; monomer for polyimides, polyamides, polyesters, polycarbonates, and other specialty polymers (e.g., epoxy resins and base-resistant primers).[40,41]

The other substances in this group are primarily used as vulcanising agents or cross-linkers in the production of fluoroelastomers (synthetic rubber), or as as monomers in plastics and polycarbonates, which end up in a wide array of products/articles ranging from plastic packaging and personal care products to textile and electronics and in automotive applications. Additionally, all substances are used as vulcanising agents or cross-linkers for fluorelastomers (FKM/FPM) in e.g. seals, polymer bearings, and high temperature composites. The substances are only used at industrial sites. For most of the substances, article service life is indicated in ECHA's dissemination database. Due to the similarities in substance composition, the great similarity of uses and the similar technical function, the interchangeability of substances within this group is to be expected. In addition, BPAF (and therefore possibly also its salts) may act as a substitute for BPA in the production of PC. An overview of the annual tonnage for Bisphenol AF and BPAF derivatives as well as further information on manufacture and application in the various sectors is given in Annex A.

1.1.5.5. Uses advised against by the registrants

For none of the registered bisphenols covered above (BPA, BPB, BPS, BPAF, BPF) uses have been advised against in the available registration dossiers.

1.1.6. **Emission assessment**

Despite the fact that there are various legal provisions on BPA in product-oriented, substance-oriented and media-related legislation, this substance can still be found in humans and the

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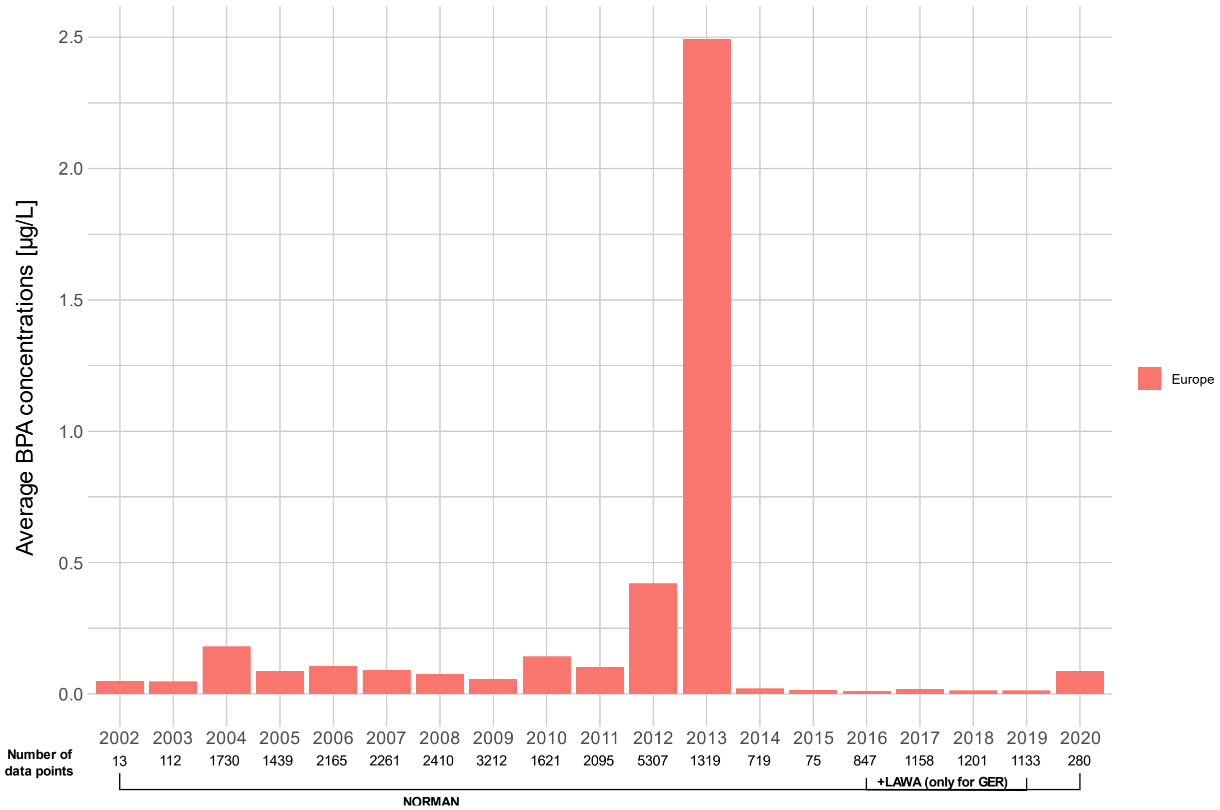
[39] (ECHA): https://echa.europa.eu/documents/10162/d4b588a0-d1e2-9978-a65b-3ebe209d16fa
[40] https://pubchem.ncbi.nlm.nih.gov/compound/73864#section=Use-and-Manufacturing
[41] https://ntp.niehs.nih.gov/ntp/htdocs/chem_background/exsumpdf/bisphenolaf_093008_508.pdf

environment. Especially due to the status of BPA as an SVHC for the environment, this finding resulted in the need to assess emissions in their entirety and to restrict their use. In the context of the grouping of bisphenols, the findings on regrettable substitution were revisited, which is why it is also necessary to address bisphenols with similar concern (BosC).

1.1.6.1. Monitoring

The following monitored BPA concentration trends in environmental media, especial surface water (most affected compartment) show regulatory measures may have an impact. However, the direct influence is not clear. An important factor of uncertainty is the frequency of testing in Europe and the changing locations for these measurement campaigns, which entail different parameters.

Figure 3: Average BPA concentrations [µg/L] per year in European surface waters.[42]



The graph shows the relevance of BPA in the environment. What makes the graph difficult to evaluate is that the values shown were collected both on an ad hoc basis and as part of monitoring programmes. However, it is easy to see that BPA was always measurable and that

[42] Cf. Annex B.4.2.5. for a list of contributing countries

clearly measurable concentrations were still present in 2020 (for more information, see Appendix B.4).

As a main result, the monitoring data show 0.3 µg/L (95th percentile) for BPA. This is inline with further findings from Staples et al. 2018.[43] However, there is no clear correlation between BPA consumption in the EU and BPA levels in surface waters.

The data for the BoSC is not as detailed. For this reason, a value of 0.4 µg/L was considered relevant for the European region. BPS has the second highest tonnage next to BPA (for details see Annex B.4). Here it is the same, that there is no clear correlation between BoSC consumption in the EU and concentration levels of the substances in European surface waters.

BPA is constantly and ubiquitously emitted. Even if it is a small input from each individual possible use, no main input pathway or use can be identified, but it is clear that the totality of all uses (wide dispersive) leads to this unacceptable situation. For the protection of the environment, no safe emission level can be derived due to the endocrine disrupting properties of BPA and BoSC. Since the emissions for BPS, BPB, BPF and BPAF are due to the same release mechanisms and pathways as for BPA, the assumption of BPA is adopted for the BoSC. Any exposure of environmental organisms must therefore be avoided.

A critical aspect for deriving trends is the issue of regrettable substitutes. Thermal paper (TP) serves as a prominent example where, following the restriction of BPA for this specific use, a substitution with BPS (a BoSC) has been observed. ECHA showed that while the quantities of BPA used in TP are decreasing, the quantities of BPS are increasing markedly.[44] One of the key findings was that 43% of TP manufactured by members of the European Thermal Paper Association (ETPA) contained BPS. A forecast scenario in consultation with ETPA covered a future increase of BPS between 60-70% in the period from 2020-2022, while BPA will be assumed with 0% due to the restriction of use of BPA in TP.

1.1.6.2. Emission Characterisation

BPA is an inherently degradable substance that does not remain stable for a long time (cf. Annex B, section B.4.1.2). The previous estimates do not compare emission and degradation rates. This was neglected because studies show that emissions of BPA into the environmental compartments do occur permanently. Additionally, PECs (Predicted environmental concentrations) do not need to be derived due to the availability of MECs (Measured environmental concentrations).

The following technical procedure was chosen by the dossier submitter to determine emissions. In the run-up to this restriction, a research project was commissioned which, among other things, was to determine all available data on release potentials and emissions of BPA as well as contents of BPA in materials from various sources or publications (Annex H). Much less information was available for the BoSC, so that more generic assumptions on emissions were made here, based on the registered tonnages. Emissions were specified by

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[43] Staples et al. (2018): Distributions of concentrations of bisphenol A in North American and European surface waters and sediments determined from 19 years of monitoring data. Chemosphere 2018, 201,, 448-458, available online via https://www.sciencedirect.com/science/article/pii/S0045653518303874

[44] https://echa.europa.eu/documents/10162/2564887/bpa_thermal_paper_report_2020_en.pdf/59eca269-c788-7942-5c17-3bd822d9cba0 (2021/24/08)

dossier submitter through two comprehensive stakeholder consultations (Calls for Evidence, CfE) and various exchanges with industrial sectors and associations.

Release

The highest release potential causing emission is associated with the step of application of ready-to-use mixtures both in the field of professional use and in the context of consumer use. Furthermore, the release for outdoor products is increased due to the stress of the materials (e.g. UV-radiation, precipitation, strong temperature fluctuations), as opposed to indoor use. In the case of indoor use, the main contributors are those that lead to emissions into wastewater through the actions of the user (e.g. washing clothes). This in no way implies that emissions from point sources such as manufacturing and processing are negligible. It is important to distinguish between a process in an industrial facility that is subject to IED requirements (Dircetive 2010/75/EU, Industrial Emissions Directive) and whose emissions to environmental compartments need to be monitored and mitigated, and a smaller facility that is used for processing or recycling, for example. For the latter, a higher emission potential applies in any case.

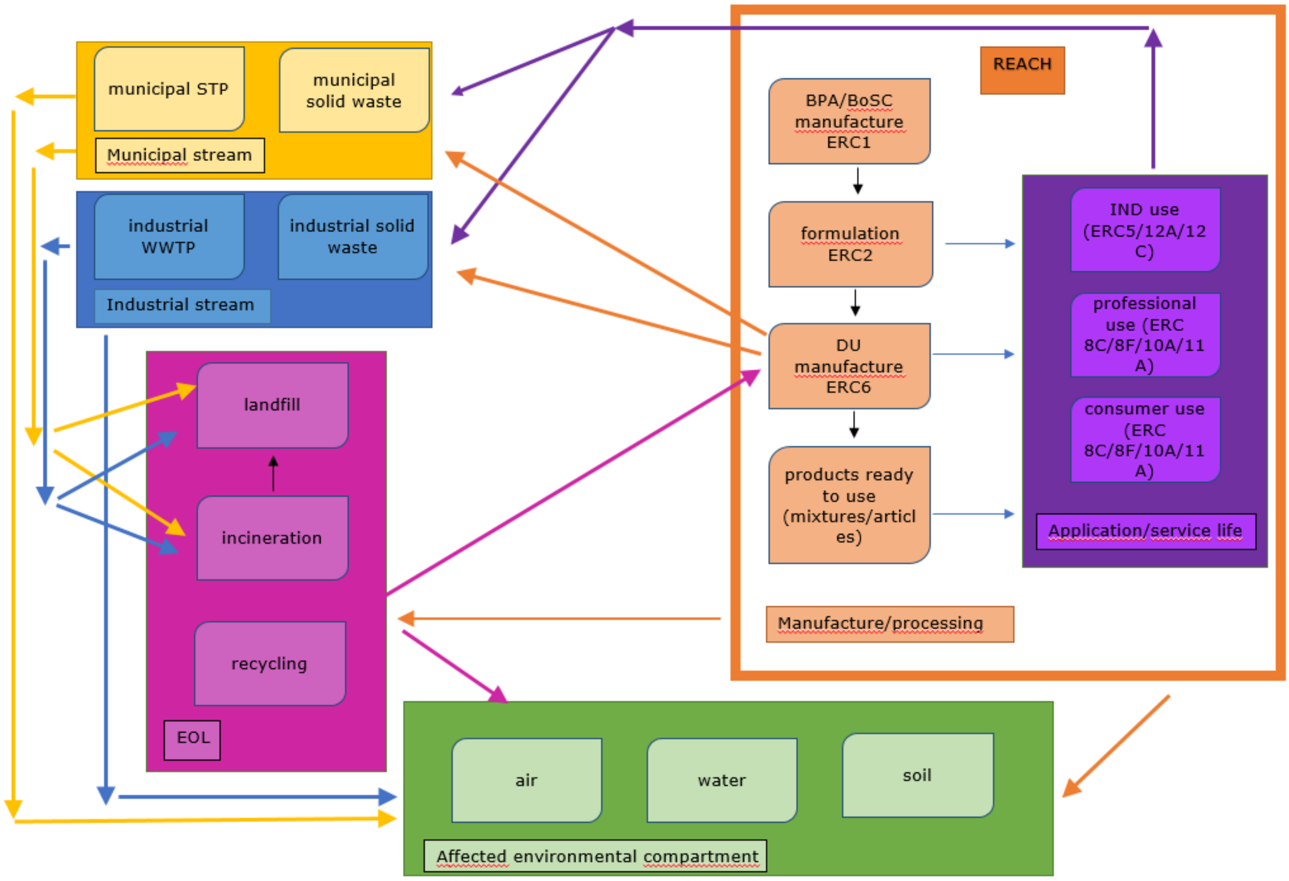
Pathways

BPA emissions are estimated and outlined according to the following structure:

a) emissions from the production of (raw) BPA itself,
b) results are presented per use,
c) per life cycle stage (i.e., processing, service life, end-of-life cycle) and
d) per environmental compartment (i.e. air, soil, surface water and WWTP).

In principle the same pathways fit for BoSC.

Figure 4: BPA/BoSC pathways or corridors of influence during lifecycle



This visualisation of emission paths and distribution pathways can help to show the purpose of the restriction at this point. In principle, the end of life (EOL) and waste streams in general are outside the scope of REACH. However, the substance flows via and from the EOL and waste streams are relevant for REACH or show the consequences of the (non-)regulation under REACH. The greatest benefit is the restriction under REACH itself in relation to the processes of processing and service life. Here, the possible emissions can be directly reduced through the restriction.

The EOL is relevant to understand the substance flow for BPA (Ramboll 2022).[45] Production sludges occur (e.g. paper recycling, leather production), which are treated differently in the individual EU countries depending on the legal requirements (e.g. landfilling or incineration). Basically, there are differences in the national guidelines on how to deal with waste, with some countries incinerating more waste and others providing for landfilling. The recycling process also contributes to emissions (e.g. the water-intensive process of paper recycling, which produces wastewater).

Considering the results from the research project on BPA from 2020 (Annex H), the distribution of total emissions is as follows.

[45] Ramboll Deutschland GmbH (2022): Substance Flow Analysis (SFA) and Regionalized Pathway Analysis (RPA) for emissions of Bisphenol A (BPA) into the environment - 2022 Update. Project number: 352000802

Table 18: Estimated total emissions per life cycle stage (evidence-based comprising publicly available data)

Life cycle stage	Portion of Total
Manufacture	~ 7%
Processing	~ 56%
Service life	~ 34%
End-of-life	~ 3%

Additional information suggests very high uncertainties especially in regard to a potential underestimation of the emissions from end-of-life. This allocation also applies to the BoSC, should they substitute BPA in the current uses, but also if they were used in one of the main categories in general.

Industrial Emissions vs Consumer Emissions (Ramboll 2022)

The relative contributions of industrial emission sources (e.g. manufacturing of BPA, manufacturing of BPA-derived substances and downstream manufacturing of products containing BPA and/or BPA-containing substances) versus consumer emission sources (e.g. per capita sources associated with the use and disposal of BPA-containing products) were assessed using the fugacity model (The purpose of the model is to predict BPA concentrations in different media, primarily in surface water). From this model it can be stated that consumer sources account for the majority of BPA found in surface waters in almost all coordination areas in the model. Industrial emissions enter the environment as major contributors in only three of the forty-six coordination areas studied. These results indicate that industrial emissions of BPA seem to be well controlled.

Emissions by Product Type**Error! Bookmark not defined.**

Emissions from consumer use arise from a whole range of different product types. Also, some products may originate from the EU and some from outside the EU. Products from these different sources are likely to have different levels of BPA. In addition, BPA/BoSC could be a component of plastics (as a monomer or additive) or coatings with which products are coated. An assessment of the relative importance of these specific source components was not possible based on the data collected. This is further complicated by the fact that the use of BPA/BoSC and the proceeding during EOL has changed over time. For example, the contribution of historical sources such as closed landfills are difficult to characterise. In this regard, it is assumed that significantly more products containing BPA/BoSC were landfilled even before recycling quotas were set for plastic waste or in the automotive sector.

1.1.6.3. Uncertainties impacting emission

Data on emissions is available on a use-specific or sector-specific basis. There are a variety of sources for these data, which have been adapted to meet clients/stakeholder requirements. There are large data gaps at the level of individual uses by sector and thus downstream users (for detailed discussion of uncertainties cf. Annex F). Bisphenol A and BoSC are used in a wide range of applications which have an impact on almost all areas of our lives.

The most frequently examined products (articles/mixtures) are made of polycarbonate or epoxy resin for end use. However, products made of e.g. plastic which contain this substance as an additive can also release BPA. In addition, there are a large number of different finishing options for materials or products covered by confidential business information (CBI), so it is impossible to compare all the mixtures/materials/plastics/products/articles made of and containing BPA or BoSC in their different functions.

In oder to meet uncertainties emission ranges from lower to upper boundaries were estimated. In the following, these ranges are derived for the bisphenols and their main uses.

1.1.6.4. Emission Assessment

Accordingly, the emission assessment for the bisphenols considered by this restriction proposal (BPA and BoSC) is structured as follows:

a) manufacturing of bisphenols,

b) processing of bisphenols

c) use of bisphenols divided in three main uses:

   - manufacturing and downstream use of polymers (P),
   - production and downstream use of other chemicals (C) and
   - additives use (A)

These are further divided in various polymers or chemicals produced and the type of additive used. For each of these main uses, the different steps of the life cycle are considered: production, formulation, application or processing/use of the polymer/chemical/mixture. For the uses P, A, C, specific substances or materials, mixtures made from BPA were investigated.

d) Finally, the end of lifecycle (EOL) step for each use is considered as data is also available for this purpose.

<u>Emission from the manufacture of BPA and BosC (M)</u>

Emission from production of (raw) BPA/BoSC are addressed in this preceding step before separating between the main BPA/BoSC uses (P, A, C).

This information originates from industry concerning environmental realease categories (ERCs) combined with monitored data. These data are published (see Annex H).

The absolute emission estimates for 2020 leading to a total of **5.96 tpa** of **BPA** emission during BPA production.

No detailed data are available for the manufacture of BoSC. Therefore, in a first step, the dossier submitter assumes a similar manufacturing standard as for BPA (in terms of risk mitigation measures (RMM). Accordingly, a similar relative release level is assumed for BoSC. Since the total tonnage is approximately 1% of the total tonnage of BPA, both of which concerning the EU consumption, the emission was derived as if the emission of BoSC was 1% of the emission of BPA: 6 tpa BPA * 0.01 = **0.06 tpa BoSC**.

Emission from the manufacture and use of other chemicals (C)

The emissions from C1-C7 (cf. **Error! Reference source not found.**) for the life and end-of-life cycles are assumed to be comprised in the emissions of the corresponding polymers or additives they are used for. Yet, the production of C1-C7 are separate processes which may potentially emit BPA.

It is possible that BPA is present as an impurity in these chemicals. It is also conceivable that these substances may release BPA/BoSC through transformation processes, for example. Furthermore, no structured data on the level of contamination is currently available. For these reasons, a more in-depth emissions assessment from this main use was not carried out. The dossier submitter is not aware of any use of BoSC for the production of other chemicals.

Emission from additives (A)

An additive may be present in the mixture unbound or embedded in the matrix. The way in which plastics are refined with additives such as stabilisers, polymerisation inhibitors or flame retardants can vary depending on the type of polymer and additive and, finally, the individual technical capabilities of the manufacturers/processors of polymers and plastic articles (see chapter 1.1.5.3).

In summary, BPA as an additive not chemically bound, can be more easily released and emitted into the environment. The research project on BPA from 2020 (Annex H) gathered information on emission potential for additive uses.

Emission from polymers (P)

With regards to polymers, one can differentiate between BPA that either is or is not bound in the polymer matrix. The latter is referred to as residual BPA and is generally expected to emit more readily, i.e. with less exposure to stress factors than the polymer-bound BPA (see Annex B8).

Starting point for the discussion on emissions from polymer uses are the findings from the research project on BPA from 2020 (Annex H) which are mainly based on data from Ramboll Environ (2015) Ramboll Environ (2017) and PlasticsEurope (2021). The dossier submitter evaluates this data in more detail, if deemed necessary, and discusses additional information from the two Calls for Evidence held prior to the dossier submission, in the respective Annexes.

1.1.6.5. Summary on Emissions

BPA

The monitoring data do not indicate that the current decrease in the environmental concentration is significant. The withdrawal of the registration of BPA for PVC and the restriction of BPA for thermal paper may have led to a decrease. As the environmental concentration (see Annex B.4.) is not decreasing in a stable way, it cannot be assumed that PVC will no longer be used to the extent it was at the time when this use was still supported by the registrant. Moreover, the tonnage used has increased from 2010 to 2020, which in any case also means greater emission potential. At this point, it remains speculative why the environmental concentrations of BPA have not dropped significantly as a result of the different regulatory measures. The representatives interviewed in the context of the CfE and the stakeholder dialogues were also unable to provide clarity here.

The most important findings on emissions (see Annex B.8 and Annex H) can be summarized as follows:

- Predominant sources are: processing and service life
- Significant releases occur at the consumer stage (= consumer uses (e.g. paper products like recycled toilet paper, ready-to-use mixtures, commodities during their service life) and professional uses (application))
- Main contributing pathway is municipal waste water
- Additional end-of-life (EOL) emissions are mainly caused by landfilling
- Identification of individual contribution of products (used in different sectors) from use phase is not possible due to lack of data
- Smaller sources are: Industrial manufacture
- Release is likely in all three main uses (P, A, C) with highest potential seen for Additives (not chemically bound in matrix) despite the lower tonnage share (A>P>C)

From the available data, it is clear that the restriction needs to be aimed at service life (use and processing) and has the greatest effect here. At the EOL point, recycling can remain possible without restrictions. Consideration of the requirements under REACH only becomes necessary again with the placing on the market (e.g. as a secondary raw material) or the service life of the recycled product/mixture. For the production of BPA or processing as an isolated intermediate, as a formulation step in industrial plants, the reduction potential seems to be exhausted by applying risk reduction measures and demonstrating the respective reduction potential of the individual measures. This area should be monitored under the umbrella of the IED. To this end, the review process of the respective BREF (here: Reference Document on Best Available Techniques, Production of Polymers (POL)), an adaptation or extension of the scope for the production/processing of BPA/BoSC would be necessary. A related obligation to monitor or control emissions of BPA/BoSC holds additional reduction potential outside REACH.

<u>BoSC</u>

With regard to BoSC, the reduction potential seems huge. Looking at tonnage alone and deriving the release potential only in terms of tonnage would suggest that the proportion is small as the share of BoSC in relation to the tonnage of BPA is most likely considerably less than 10%. However, if the most relevant uses for emissions, TP, syntans for leather and textile auxilliaries, are taken into account, the high release potential indicates a much higher emission estimate , in the three- to four-digit range. A value of ~**500 tpa** as a real case estimate (in a range from 200 – 1,700tpa) can be derived for the contribution to emissions by the assessed BoSCs. This total may be an overestimate, as for syntans and textile auxiliaries, either BPF or BPS account for 100% of the use or the ratio totals 100%. Since no general information is available on the ratio, the respective worst case was depicted here.

Emissions from the BoSC can be attributed on the one hand to the use phase, as it is assumed that washing processes (e.g. textiles) and leaching (e.g. leather in outdoor use) cause emissions. On the other hand, emissions are attributable to the processing phase (e.g. processing (recycled) paper) (Fischer et al. 2014).

Table 19: Summary of emissions for Bisphenols and outlook

Use	**Bisphenols used (tpa)**	**Bisphenol emissions (tpa)**	**Best estimate (tpa)**	**Bisphenol emissions 20 years (tonnes)**	**Best estimate (tonnes)**
A1-A4 (PVC manufacturing))	unknown	0 - 62	1 – 5	0 – 1,240	20 - 100
A1 - A4 (PVC recycling)	45.7	0.782 – 2.7	<2.700	15.64 - 54	<54
A5 (Thermal paper production)	4,026	5	5	100	100
A5 (Paper recycling containing TP)	Unknown	115	115	2,300	2,300
A6	Unknown				
A8 – A10 Stabilisers in closed loops)	unknown	0		0	
A11 (Lubricants)	unknown	(Up to 100 %)		(Up to 100 %)	
A12 (Tyres)	unknown	0.6	0.6	12	12
A13 (Fluoroelastomers/ FKM)	0.1-1	0.07-2.4	2.4	1.4 - 48	8
P1 Polycarbonate	1,242,000	<0.900 – 6.0	unknown	<18 - 120	unknown
P2 Epoxy Resins	315,000 275,000 (BPA based) + 40,000 (BPF based)	<0.526 - >10.551	unknown	<10.52 – >211.02	unknown
P3 - P13	<10,000	0.0259 (P8) 0.145 (P6)	unknown	0.518 (P8) 2.9 (P6)	unknown
P14 (syntans used for leather)	8,000	109 – 1,055	328	2,180 – 21,100	6,560
P15 (syntans used for polyamide treatment)	0,7-0,8	18.66 – 514	109	373 – 10,280	2,180
C1-C7	3,000	unknown		steady	
sum (best estimate)		251 – 1,773	**568**		

As a best estimate, the overall emissions are **568 tpa** (with variations from 251 – 1,773).

1.1.7. **Risk characterisation**

Environmental endocrine disruptors are considered as non-threshold substances since, as described under section 1.1.4, it is not possible to derive a safe level of exposure for such substances in environmental media that would be sufficiently protective for all species possibly affected. Therefore, any environmental emission of BPA and bisphenols of similar concern (BoSC) pose an unacceptable risk to all environmental compartments and organisms. Thus, the precautionary principle must be applied and emissions need to be minimised as much as possible.Environmental emissions for various uses are presented and discussed in Annex B.8.

As described in section 1.1.6 above emissions from additive uses of BPA and BoSC are estimated to represent the major share of the environmental burden. This is based on their technical application requiring ammounts of >>1,000 ppm of unbound BPA or BoSC in mixtures, articles and products. Residual ammounts of BPA and BoSC from uses where the bisphenols are covalentely bound to a polymeric matrix are estimated to be ≤ 100 ppm and hence representing a much smaller environmental emission potential. Thus, the risk arising from additive uses of BPA and further BoSC is much higher compared to the risk emenating from polymeric uses of these bisphenols. This is reflected in the proposed restriction scenarios described under section 2.3 aiming at a full substitution of additive uses of BPA and BoSC as well as lowering the emissions from polymeric uses as much as possible with respect to proportionality aspects.

1.2. Justification for an EU wide restriction measure

Due to their technical properties, BPA and other bisphenols of similar concern like BPS and BPB are imported, produced and used in a wide range of mixtures and articles in large quantities in the EU. BPA is registered with an aggregated tonnage of above 1,000,000 tpa and BPS with a tonnage of ≥10,000 tpa. Even if the remaining BoSC are used in smaller amounts (<1,000 tpa for BPAF and <100 tpa in case of BPF and its isomers) or are not yet fully registered (as in case of BPB), it is expected that their use as a substitute for BPA and BPS in the EU would significantly increase if only these two large scale bisphenols are restricted. The use pattern of BPA and the BoSC shows a lot of wide dispersive and wide spread uses and exposure of the environment cannot be excluded or is already demonstrated by monitoring data.

A large variety of emission sources contributes to the exposure of the environment and humans to BPA and other BoSC. Continuous and wide spreading via diffuse emissions into aqueous compartments potentially leads to spatial effects. Thus, adverse effects will not only occur at the point of release of BPA and BoSC but also far away from it. Additionally, BPA and BoSC may affect a very large number of species since the target endocrine pathways leading to adverse effects of these bisphenols which have been confirmed as ED for the environment are highly conserved among mammals, fish and amphibians. Furthermore, there are hints that also invertebrates might be affected by the ED effects caused by these bisphenols.

Monitoring data show that BPA and BPS are ubiquitously present in the aqueous environment (see Annex B.4.2.). Thus, co-exposure of BPA and other BoSC to other endocrine disrupting chemicals (e.g. alkylphenols and pharmaceuticals) in the environment acting via the same modes of endocrine action takes place potentially in all EU-Member States and synergistic effects cannot be excluded.

Thus, national regulatory actions will not adequately manage the risks of BPA and the BoSC. A broad scope EU-wide restriction ensuring that emissions to the environment are as low as possible is proposed. It is imperative that the full minimisation potential of releases to the environment has to be exploited and all sources where emissions may occur need to be addressed. An EU-wide restriction will prevent and reduce the releases of BPA and BoSC within the EU in a harmonised manner. Moreover, a restriction within the EU may be the first step for global action. In addition, Union-wide action is proposed to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to action undertaken by individual Member States.

Several regulatory steps have already been undertaken to mitigate the occurring risk of BPA to human health (HH) (and thereby also to indirectly reduce environmental exposure) on a substance- (e.g. restriction of BPA for the use in thermal paper) and product-oriented (e.g. food-contact material) level as well as on a media level (e.g. drinking water directive). **Error! Reference source not found.** shows a comprehensive overview of existing regulatory measures with regard to BPA.

Table 20 Substance-, product and media-oriented regulatory measures for BPA

Directive	**Regulation of**	**Requirement/ Concentration (medium)**	**Protection goal**[46]
Industrial Emissions Directive (2012/75/EC)	industrial emissions to ENV (air, water, soil), HH	Annex II - MS specific requirements according CMR property (permit by emission values)	HH, ENV
Water Framework Directive (2000/60/EC)	EQS (quality status concerning pollutants)	2.5 µg/L	ENV
Waste Framework Directive (2008/98/EC)	waste	Annex III – requirement and labeling as "hazardous waste" / SCIP notification >0.1% w/w	HH, ENV
Plastic Materials in Contact with Food Regulation (10/2011/EC) [does not apply to materials other than plastics]	food contact materials (FCM)	BPA may be used in FCM with specific migration limit of 0.05 mg/kg (food) (Note: BPA is not to be used for the manufacture of PC infant feeding bottles or PC drinking cups intended for infants and young children)	HH
Commission Regulation 2018/213 [amending Regulation 10/2011/EC]	Use of BPA in varnishes and coatings intended for plastic FCM	Amendment of entry No 151 for BPA in Annex I of Regulation 10/2011/EC, specifying its SML and	HH

[46] HH – human health; ENV - environment

Directive	**Regulation of**	**Requirement/ Concentration (medium)**	**Protection goal**[46]
		restriction on specific infant articles (see above)	
Toy Safety Directive (2009/48/EC) [does not apply e.g. to playgrounds, automatic machines, toy vehicles, slings, catapults]	toys	≤0.04 mg/L (leachate) (migration limit in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005)	HH
Medical Devices (93/42/EEC)	medical devices	Annex I - devices containing CMR must be labeled	HH
EU Drinking Water Directive (2020/2184)	drinking water	2.5 µg/L	HH
Cosmetics Regulation (1223/2009/EC)	cosmetics	CMR substances shall be prohibited, exemptions made for substances that comply with the food safety requirements	HH
REACH Regulation (EC) No 1907/2006 – Annex XVII entry 66	thermal paper	0.02%	HH

Despite these regulatory efforts to reduce BPA emissions, a wide range of available monitoring data shows that BPA is still released to different environmental compartments. Furthermore, co-exposure of BPA and other bisphenols (especially BoSC) have widely been reported in studies from China the U.S. but also in several European countries (see Annex B.4.2.). Hence an EU-wide and broad measure is needed to further reduce environmental exposure to BPA and other BoSC.

1.3. Baseline

The baseline scenario describes BPA and BoSC manufacture and use in the absence of any restriction measures. Thus, economic, environmental, distibutional and wider economic impacts are discussed assuming business-as-usual.

In the absence of further regulation measures use quantities in the EU are expected to grow over the next years. Exact numbers for the use of BPA in the EU are not available. Different stakeholders and sources cited slightly different numbers. Taken together the dossier submitter assumes a yearly production of BPA of 1.2 – 1.5 million tpa in 2020 and increasing use within the following 20 years due to expected growth in the polymeric uses.

Main uses are the manufacturing of polycarbonates and epoxy resins using approximately 70 -80% and 15-30% of the BPA. All other uses combined account for less than 3% of BPA use in the EU. Estimated quantities for all uses are summarised in Annex B.8.

For polycarbonate the stakeholders expect a yearly demand growth of 4% for the next years. For epoxy resin uses no information on future demand is available. The dossier submitter therefore assumes constant use quantities.

For other polymeric uses information on current or future use and emissions of BPA is incomplete. Industry expects a worldwide demand of more than 30,000 tons of polyetherimide by 2025 and a growth for HT polymers at an annual rate of 5% (Annex H). According to available information no emissions are to be expected from these uses.

According to stakeholder information it is possible that BPA is still used as an additive in the manufacturing in the EU but no further information is available. Stakeholders in 2021 also reported that the use in imported articles might be relevant. However, during the second call for evidence stakeholders stated that they expect those remaining uses to end within the next few years. No further information is available. The dossier submitter therefore assumes that the use will end within 5 years until 2026.
The use of PVC containing BPA additives in recycling processes will continue for a very long time into the future as materials with a long service life will continue to enter the recycling loop. However, quantities should decrease significantly within the next 20 years as additive uses decreased sharply within the last 10 to 20 years. No further information is available. Therefore, the dossier submitter assumes a yearly decrease of 10 percent in recycled PVC.

The intentional use of BPA in paper and board stopped after the transition period for the restriction on BPA in thermal paper ended in 2020. However, BPA is available in significant quantities in recycled paper and board. The dossier submitter expects the concentrations of BPA in paper and board to decrease by more than 90% until 2025 (see Annex B9).

Approximately 3,000 tpa BPA are used for the manufacturing of epoxy resin hardeners. No information on future demand is available. The dossier submitter therefore assumes constant use quantities.

For additive uses in lubricants and stabilisers in liquids no information was submitted or otherwise available. For the use in tyres no use of BPA in European manufacturing has been reported. It might be possible that imported tyres still contain BPA. Additional information is not available.

Approximately 3,000 tpa BPA are used in the production of other chemicals. No information on future demand is available. The dossier submitter therefore assumes constant use quantities.

BPF is used in the manufacturing of epoxy resins. As mentioned above no information on future demand for epoxy resins is available.

BPS is expected to remain the main substitute for BPA in the manufacturing of thermal paper after 2020. Stakeholders expect an annual growth rate of 2% in the thermal paper market in the EU. However, opposing trends have not been taken into account. Constant use numbers or even a decrease are possible.

BPAF is used to manufacture fluoroelastomers. The main uses are in harsh environments in automotive, aerospace and marine uses like seals, tubes and gaskets in combustion engines or fuel delivery and in electronics. The dossier submitter initially assumed that the future demand will decrease amidst the transition to electronic mobility. In a personal meeting stakeholders stated that they expect the demand for fluoroelastomers/FKM to be steady or even grow as FKM retains critical properties which are still needed for applications in e-motor that need to withstand friction and wear at higher speeds and extended use.

Emission estimates for 2020 are determined in detail in Annex B.8. Considering the trends as described the baseline for environmental emissions for the 20 years from 2025 to 2044 is presented in Table 21.

Table 21 Summary of Use and Emission estimates for 2025 – 2045

Use	Bisphenols used (tpa)	Bisphenol emissions (tpa)	Best estimate (tpa)	Bisphenol emissions 20 years (tonnes)	Best estimate (tonnes)
A1-A4 (PVC manufacturing))	unknown	0 - 62	1 – 5	0 – 1,240	20 - 100
A1 - A4 (PVC recycling)	45.7	0.782 – 2.7	<2.700	15.64 - 54	<54
A5 (Thermal paper production)	4,026	5	5	100	100
A5 (Paper recycling containing TP)	Unknown	115	115	2,300	2,300
A6 (hardener)	Unknown				
A8 – A10 (Stabilisers in closed loops)	unknown	0		0	
A11 (Lubricants)	unknown	(Up to 100 %)		(Up to 100 %)	
A12 (Tyres)	unknown	0.6	0.6	12	12
A13 (Fluoroelastomers/FKM)	0.1-1	0.07-2.4	2.4	1.4 - 48	8
P1 (Polycarbonate)	1,242,000	<0.900 – 6.0	unknown	<18 - 120	unknown
P2 (Epoxy Resins)	315,000 275,000 (BPA based) + 40,000 (BPF based)	<0.526 - >10.551	unknown	<10.52 – >211.02	unknown
P3 - P13 (polymers)	<10,000	0.0259 (P8) 0.145 (P6)	unknown	0.518 (P8) 2.9 (P6)	unknown
P14 (syntans used for leather)	8,000	109 – 1,055	328	2,180 – 21,100	6,560
P15 (syntans used for polyamide treatment)	0,7-0,8	18.66 – 514	109	373 – 10,280	2,180

Use	Bisphenols used (tpa)	Bisphenol emissions (tpa)	Best estimate (tpa)	Bisphenol emissions 20 years (tonnes)	Best estimate (tonnes)
C1-C7 (production of chemicals)	3,000	unknown		steady	

In the absence of further regulatory measures, the use of BoSC is going to increase as substitution of BPA is increasing for paper uses (ECHA 2020). BPS and BPF are the major emission sources with distinct industrial applications. Monitoring data shows the occurrence of BPA, BPAF, BPB, BPF and BPS in wastewater treatment plants' (WWTP) effluents, birds, fish and/or in human biomonitoring studies (Annex B 4.2.4.). With increased use of BosC, their concentration in environmental compartments and biota is almost certainly going to increase as well.

The use of BPA is likely to increase as well due to the increasing demand for e.g. PC. BPA emission, on the contrary, are likely to decrease even in a baseline scenario without further regulatory measures. A future scenario for Germany described by Ramboll Deutschland GmbH (2022) for the PC/BPA-Group of Plastics Europe predicts a reduction of BPA loadings to surface water between 83% and 89% compared to estimated current loadings. This reduction is mainly based on the assumption that there will be decreasing BPA emissions from paper and PVC recycling.

However, the model does not consider several important aspects: First, the global demand for BPA is expected to grow continuously during the next years. In Europe, raw BPA processing in the year 2020 was estimated to be >1.4 million tons. A steady growth is expected during the next years albeit the restriction of its use in thermal paper. Emission estimates for PC and ER are most likely underestimated by industry stakeholders (see Annex B9). Therefore, the dossier submitter expected that significant emissions from these uses will take place in the future.
BPA is already subject to regulatory measures at the EU level and also at national level (cf. Section 1.3). EU law regulates BPA in plastic materials, food contact material [Commission Regulation (EU) No 10/2011] and infant feeding bottles [Commission Directive 2011/8/EU]. A specific migration limit (SML) for BPA in varnishes and coating has been introduced and the SML for BPA in the Plastics Regulation has been revised [Commission Regulation (EU) 2018/213]. The ban of BPA in thermal paper became effective in January 2020 (see **Error! Reference source not found.** in section 1.2). Additional measures have been taken in several countries. For example, France implemented a general ban of BPA in all food contact materials [French Law No 2012-1442], whereas other countries like Denmark, Belgium and Sweden, banned it in those materials intended for children under 3 (Barouki, 2020). The European Food Safety Agency (EFSA) has re-assessed the risks of BPA in food and proposed to lower the tolerable daily intake (TDI) compared to its previous assessment in 2015.
Even though overall BPA concentrations in surface water have generally decreased in the past decade (cf. Section B.4.2.4), clear links between specific regulatory measures and the occurrence of BPA in the environment have not been identified. Thus, the measures in place cannot be considered a safe pathway towards minimization of emissions.

2. Impact assessment

2.1. Introduction

BPA and BoSC are substances with endocrine disrupting properties in the environment. Significant BPA concentrations have been measured in the environment in the past and even if emissions decrease it is expected that the occurrence of BoSC will increase resulting in a constant exposure of the environment causing adverse effects. Owing to lack of knowledge and data the risks of ED substances cannot be predicted and quantified by standard risk assessment methods and quantification and valuation of benefits via the assessment of the impacts on the environment is not possible. Instead, a cost-effectiveness analysis based on emissions reduction and the total costs of implementing is more appropriate for the proposed restriction. In this respect, total costs should include compliance costs, enforcement costs, and other additional social costs. Within this type of analysis, emissions reductions normally act as a proxy for benefits in terms of a reduced risk. The total costs of the measure are divided by the reduction in emissions to derive a cost per unit of reduction. In this respect, the level of emissions reduction acts as a proxy for the unquantified environmental benefits (in terms of reduced risk).

The stakeholder consultation and further research have resulted in a large amount of information on uses and emissions. However, information on emissions is very uncertain. For several uses substitution is not a feasible option as often alternatives are neither technically nor economically feasible. Considering societal importance of several uses, the dossier submitter decided to propose a restriction in which the use of BPA and BoSC is not completely banned. Instead emissions reductions will be achieved by concentration limits for BPA and BoSC in articles. Based on the difference in their emission potential, additive and polymeric uses of BPA and BoSC are addressed separately within the proposed restriction. As a result, emissions from the use of these articles and from the waste phase will decrease. The resulting costs to society arise from measures to comply with the concentration limit and if necessary with the migration limit proposed.
The restriction is necessary to avoid the possibility that BoSC are used as substitutes when other more sector specific regulatory measures are put in place for BPA, e.g. the restriction in thermal paper. Furthermore, the proposed restriction aims at reducing the environmental release of BPA and BoSC present in imported articles and mixtures.

2.2. Risk Management Options

On the basis of the conclusions of the risk assessment reported in section 1.1.7 and the issues discussed under section 1.2, the releases of BPA and the BoSC are considered to pose a risk to the environment that is not adequately controlled. As described under section 1.1.6 the main share of emissions of BPA and the BoSC into the environment, and hence the highest risk, can be attributet to the service life of products, the processing of mixtures and products as well as to the end of life and waste phase. Furthermore, the highest risk is estimated to come from wide spread and wide dispersive consumer uses of mixtures and articles. Thus, any risk management measure must address these relevant life stages either directly or indirectly (e.g. the waste pahse) to be efficient in further risk reduction with respect to BPA and the BoSC. It should be further noted that one major aim of this measure must also be, in addition to the already existing emissions of mainly BPA and other BoSC, to prevent a potential risk that arises from regrettable substitutions of e.g. BPA by another BoSC. This includes BoSC (e.g. BPB) that are not yet registered for uses in the EU market under REACH and hence difficult to address with certain risk management measures. Additionally, it is estimated that imported articles, products and mixtures significantly contribute to the identified risks and that the emission potential of additive uses of BPA and BoSC, i.e. uses where the substances are not covalently bound to any type of matrix, is generally much higher compared to polymeric uses.

Following the identification of these factors the dossier submitter has conducted an analysis of various risk management options (RMOs) to identify the most appropriate risk management measure to address these risks emenating from the group of BPA and the BoSC.

As a first step, the possibility to address the risks posed by this group of substances under other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs was examined. Whilst it was recognised, and taken into account when developing the scope of the proposed restriction, that some existing or proposed EU legislation or other measures could have an impact on the risk management of sepcific sectors and single substances, these were assessed as inappropriate to address all of the substances in the proposed scope (e.g. only identified SVHC substances can be regulated via authorisation), sectors and products with its specific life stages contributing to risk.

Another issue that was taken into account by the dossier submitter during RMO analysis is that additive uses represent a much higher emission and hence risk potential than the polymeric uses. Thus, it is proposed to minimise environmental emissions of BPA and the BoSC by fully restricting the additive uses and by introducing specific conditions for polymeric uses. This aims at reducing the environmental burden of BPA and BoSC as much as possible while maintaining socio-economic proportionality (see section 2.4 and 2.5 for further details on this aspect).

Therefore, the option to use a balanced and tailor-made restriction under REACH to address the identified risks was investigated further and assessed against the main criteria for restriction identified in Annex XV of REACH: effectiveness, practicality and monitorability.

As a result of this assessment, the restriction scenario presented in the summary is proposed and discussed further in section 2.3. This section also provides a presentation of two further possible restriction scenarios which are reflected in the following sections with regard to their economic and environmental impacts.

2.3. Restriction scenario(s)

To address the issues discussed under section 2.2, three major restriction options are described here. Beside this general overview provided here, the restriction scenarios for the sub-uses are described shortly in chapter 2.4 and in more detail in Annex E.

<u>Restriction Option 1 (RO1)</u>

This scenario is based on a concentration limit of 10 ppm in articles and mixtures for the sum of BPA and the BoSC. Applying this limit value will restrict all additive uses since for technical functionality here concentrations >1,000 ppm in articles and mixtures must be added. For residual ammounts of bisphenols in polymeric uses the dossier submitter got the information that 10 ppm is technically achievable for certain uses and hence this value is taken as the most restrictive limit value. However, from stakeholder consultations the dossier submitter is aware of the fact that the majority of polycarbonate uses in the EU contain residual ammounts of BPA ≤ 150 ppm and for epoxy resins residues of bisphenols are typically ≤65 ppm. This is reflected in the specific derogations of the proposed restriction as presented in section 2.2.

Based on the significant differences in the residual ammounts of BPA and BoSC in mixtures and articles, emissions and hence risk from polymeric uses during their service life and waste phase (e.g. landfilling is still in practice in Europe) are estimated to be generally smaller compared to additive uses, even when taking total production volumes into account (for details see section 1.1.5 and 1.1.6). Thus, polymeric uses that exceed 10 ppm can be continued if they fulfil the following conditions:

- Contact to water and hence emissions to the aquatic environment as the main entry path can be excluded during reasonable and foreseeable use throughout the service life.
- If contact to water cannot be excluded during reasonable and foreseeable use a migration limit in the respective mixtures and articles must not exceed 0.04 mg/L over the entire service life.

This structure shall ensure that additive uses of BPA and BoSC are fully restricted in the EU irrespective of whether they enter the EU market via imported articles and mixtures or they are applied in the EU (e.g. bisphenols in thermal paper). Secondly, this restriction option shall ensure that the main uses of BPA and its possible BoSC substitutes are not disproportionatedly regulated when taking socio economic aspects into account and it shall ensure a level playing field on the EU market for polymeric uses of the bisphenols in the scope of the proposed restriction.

Restriction Option 2 (RO2)

This restriction scenario is comparable to Option 1 except that the concentration limit here is set to 150 ppm for the polymeric uses by a specific derogation. Compared to Restriction Option 1, this scenario would allow residual amounts of the sum of BPA and the BoSC up to 150 ppm in mixtures and articles from polymeric uses while also fully restricting the additive uses.

Further specific derogations for polycarbonates and epoxy resins are not necessary here but the concentration limit can be applied to all polymeric uses. Based on the information regarding residual amounts of BPA and BoSC in polymeric uses gathered during the stakeholder concultations, the dossier submitter assumes that under Restriction Option 2 migration testing should only be needed for very few mixtures and articles, e.g. for imports. Thus, RO2 ensures that emissions from additive uses are avoided and emissions from the polymeric uses are lowered as much as possible with respect to proportionality by ensuring a level playing field for imported articles and mixtures as well as for products originating from the EU.

Restriction Option 3 (RO3)

The third restriction scenario is based on a concentration limit for the sum of BPA and BoSC of up to 1,000 ppm. Thus, this option will restrict the additive uses while, based on the knowledge gained during both stakeholder concultations, all polymeric uses can be continued without the need for migration testing.

The economic as well as the environmental impacts of each of the described restriction options are discussed in the following sections 2.4 and 2.5. Based on this analysis, Restriction Option 1, as described above, is proposed to be the most effective and proportionate option in case further use-specific derogations are considered.

2.4. Economic impacts

BPA and BoSC have various applications in consumer, professional and industrial products. These products have various modes of use, which lead to releases of bisphenols into the environment via various pathways. In many sectors the substitution potential with non BoSC substances is limited and/or information to assess the substitution potential is not sufficient.

The two largest and economically relevant uses, BPA used in the manufacturing of polycarbonates and epoxy resins, can be divided in several sub-uses, e.g. marine applications, construction, wind energy, etc. And within these broader sub-uses manifold specific applications can be differentiated, e.g. in the use of ER in marine and protective coatings: water ballast tanks, underwater ship hulls, cargo tank linings, offshore oil drilling platforms, supporting steel structures, sea containers, storage tanks, etc. (see Annex A for a more detailed listing of the numerous sub-uses). Due to informational limits it was not possible to assess the uses on a more granular level. It is most likely that for some uses alternatives are available, however stakeholder information suggests that for most uses a complete restriction would not be proportionate. Therefore, the dossier submitter evaluated restriction options based on the three concentration limits for the scenarios RO1 - RO3 as proposed in chapter 2.2.

Because of the variations in key factors, the socio-economic impacts and the proportionality of the proposed restriction are assessed in a use-specific manner, i.e. separately for additive and polymeric uses, as well as divided into sub-uses.

Recognizing the difficulties to obtain and consider all relevant information, the dossier submitter attempted to obtain data for quantitative analysis for all uses and especially those where the largest quantities of BPA and BoSC have been identified. However, for most uses it is necessary to rely on qualitative information as well to fully understand the projected impacts from the proposed restriction.

The geographical scope of the impact assessment is the European Economic Area (EEA), meaning the EU Member States plus Norway, Iceland and Liechtenstein, as the proposed restriction would take effect in the territory of the EEA. However, considering the withdrawal of the United Kingdom (UK) from the European Union (EU) on 31 January 2020, it is sometimes difficult to compare data. Whenever this dossier refers to the EU, it should be read to cover the three additional EEA countries, too. The temporal scope of the analysis is 2025 plus the 20 years until the end of 2044. It is expected that the scientific committees of ECHA finalize their opinions on the proposed restriction by the end of 2023. In case the committees and subsequently the Commission agree that a restriction with a concentration limit is the most appropriate measure to minimize the risks arising from the use of BPA and BoSC the restriction can enter into force in 2024. Considering a transition period of 18 months environmental and economic impacts will take place from 2025 onwards.

BPA and BoSC are environmental ED for which a safe concentration in the environment cannot be established with sufficient reliability. This is due to unpredictable and irreversible adverse effects on the environment. Therefore, BPA and BoSC must be analyzed in the same way as other non-threshold substances in the past, namely PBT/vPvB substances. Quantification of benefits is typically not possible for PBT/vPvB substances which makes it difficult to demonstrate quantitatively whether the benefits of a proposed restriction outweigh its costs. Accordingly, the same difficulties apply to the concerned ED substances. In line with previous restriction proposals the dossier submitter has therefore adopted a cost-effectiveness approach as recommended by SEAC for evaluating restriction proposals for PBT/vPvB(-like) substances.

The dossier submitter tried to obtain information to assess the economic and environmental impacts of the proposed restriction for all known uses and supply chains in two Calls for Evidence. It must be stressed that the dossier submitter could not obtain enough quantitative information to undertake reliable cost-effectiveness analyses for all uses.

Detailed information on available information as well as use-specific discussions on the restriction scenarios RO1 - RO3 are presented in Annex E4. Short summaries are given in the following:

C1 – C7: Production of other chemicals

No additional information was submitted in the two Calls for Evidence on impacts. It is expected that bisphenols are not present in other chemicals. No emissions are expected from the production processes.

A1-A4 (A1 inhibitor for polymerization, A2 stabilizer to prevent thermolysis and oxidation in PVC processing, A3 stabilizer to prevent thermolysis and oxidation when producing plasticizers intended for use in PVC, A4 stabilizer (antioxidant) to prevent polymer oxidation).

a) Virgin PVC

European PVC manufacturers representing approximately 70% of PVC manufacturing in Europe phased out the use of BPA completely before the year 2010. A stakeholder organization representing these manucturers stated that they are not aware of specific information on actual uses by other manufacturers. They assume that BPA might still be used in the EEA.

Two stakeholder organizations for the automotive industry mentioned the use of PVC in car wires and cables. No further information on use quantities and concentrations in articles is available. One stakeholder organization for manufacturers of medical devices reported on possible uses. Again, no further information is available. Stakeholders representing both industries stressed that the use of PVC is declining and expected to be phased out within the next few years. Substitution is already ongoing and expected to be completed soon. No information has been submitted regarding the required transition period.

Additional research did not lead to any robust information. It might be possible that PVC stretch films are still manufactured with BPA in some parts of the world.

Stakeholders agree that alternatives are commercially available and technically and economically feasible.

The limited information suggests that a restriction with a concentration limit of 10 ppm would restrict the further use of BPA and BoSC containing additives in PVC. A concentration limit of 150 ppm would most likely be effective to ban the use of BPA-containing plastizers for PVC in the EEA. However, imported articles might comply with a concentration limit of 150 ppm. A similar conclusion can be drawn regarding a concentration limit of 1000 ppm. While the use of plasticizers in the EEA might no longer be possible, a restriction with this concentration limit might have no or a very limited effect on imported articles.

Considering the largely completed and only partly still ongoing voluntary phaseout of the use of BPA for the manufacturing of PVC no or negligible costs are expected.

b) Recycled PVC

Stakeholder information suggests that recycled soft PVC (PVC-P) will not be able to comply with a 10 ppm concentration limit for BPA. Historically, PVC containing high concentrations of BPA has been used in several long-lasting applications (e.g. cables, construction materials, etc.) which only enter the recycling process now and will continue in the future.

A sharp decrease in BPA concentrations in recycled articles is expected in the next 5 to 10 years. A stakeholder argued that testing costs may be prohibitive for low value added applications and suggested that any BPA limit should be based on a yearly average content in recyclate and a certain number of batches should be allowed to exceed the BPA limit.

No additional information has been submitted in the two Calls for Evidence to assess the economic impact in case recycling is no longer possible. Therefore, the dossier submitter analyzed information provided in the background document from the restriction dossier on lead in PVC.[47] ECHA estimated that PVC waste that no longer can be recycled would be disposed of via landfill, incineration and export. The dossier submitter estimates approximately 111,000 tpa flexible PVC waste would need to be disposed of in a similar manner in case of a concentration limit of 10 ppm. Costs for landfilling and incineration would result in a total annual cost of €12.8 million.

Additionally, a restriction with a 10 ppm limit for BPA in recycled PVC is likely to increase prices of PVC articles. Considering information from the background document for lead in PVC an additional cost of €38.9 million.

The resulting total cost estimate is €51.7 million/year.

[47] ECHA documentation on the restriction dossier for lead and lead compounds in PVC: https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e180a40af7

Stakeholders reported that a concentration limit of 150 ppm will be achievable within the next few years. The Dossier Submitter evaluated the available information on current concentrations in recycled PVC and concludes that concentrations of less than 150 ppm can already be achieved now. Within the next few years concentrations will further decrease. Therefore no additional derogation is justified.

No stakeholder submitted information regarding the number of tests that are necessary to ensure compliance with the restriction. Stakeholders did not provide information to substantiate the claim that further testing of concentration limits leads to high and potentially disproportionate costs. Concentration limit testing is already required for lead contents in PVC and was deemed as negligible in the SEAC opinion.

A5 – Thermal Paper

a) Additive use in the manufacturing of thermal paper

The use of BPA in thermal paper is restricted since 2020 and has been replaced mainly by the use of BPS (see ECHA 2020). The dossier submitter expects that in case of a restriction BPS will be substituted with non-phenolic substances. In the two public consultations only very limited information was submitted. Regarding the economic impact of a restriction one atkeholder confirmed that overall substitution costs would range between 19 Mio € and 22 Mio € per year when considering D8 and PergafastTM 201. In addition, compliance costs of 150 000 and 250 000 € per year are expected.

Considering that no further information is available the dossier submitter estimates the costs of a restriction to be €19.15 – €22.25 Mio per year.

b) Paper Recycling

No stakeholder information was submitted on the economic impacts of a restriction on BPA and BoSC in regard to paper recycling. The dossier submitter therefore evaluated the available general information on the sector. Over 70% of paper waste is collected and recycled. The Confederation of European Paper Industries (CEPI) states that approximately 50 000 tonnes collected paper waste were utilised in the EU in 2021. Nearly 50 % of the 102 Mio tonnes raw material consumed for paper and board produced in Europe are recycled paper. Bisphenols that are in the scope of this restriction proposal have been detected in products with recycled content regularly in quantities ranging from <1 ppm to >10 ppm.

In case of a restriction of BPA and BoSC in articles with a limit value of 10 ppm for the sum of the bisphenols it is likely that recycling of paper waste will no longer be possible – at least for a number of years until impacts stemming from the restrictions on the use of BPA and BosC in thermal paper are large enough, i.e. no new quantities of bisphenols have been added to the recycling circle for a few years and bisphenols already in the recycling circle have been eliminated to a significant degree. A restriction with a concentration limit of 150 ppm would allow the recycling of paper waste to continue in the EEA without any significant impacts.

In Annex E.4. possible impacts stemming from a 10 ppm limit value are further discussed. In case of higher limit values ongoing emissions from paper recycling are expected to be significant for approximately 5-10 years following a ban of the use of BPS in thermal paper (see Annex B.8.6.4). However, the following main arguments are considered as substantial negative impacts in case of a 10 ppm limit value:

- Either industry ceases to manufacture recycling paper in the EEA for more than 5 years resulting in the closure of a large number of paper mills and job losses; or the paper industry finds a way to avoid this scenario, possibly by blending wood pulp with recycled materials to lower the concentration of bisphenols in the article. Bisphenols would remain in the recycling loop in unchanged quantities and with unchanged emissions potential resulting in no positive impacts for the environment.
- Although no further information is available to the dossier submitter, it is assumed that the increasing demand for wood in the paper industry (in case recycling would no longer be possible) would lead to a significant negative environmental impact, especially with regard to CO_2 emissions. Energy and water consumption would increase, too.
- Disposal of paper waste would partially happen via landfill, leading to direct emissions to the environment. Disposal via incineration would result in additional greenhouse gas emissions.
- Another possibility would be the export of paper waste to non-EU countries for recycling possibly resulting in large emissions there.

A6 – Epoxy Resins / Phenolic hardener

According to stakeholder information for some specific uses epoxy resins are polymerised with hardeners containing free bisphenols. Epoxy resins made of and containing bisphenols are usually needed to accelerate curing if fast curing is needed (no post-curing process). Uses were reported for automotive industry and powder coatings in general. No further information is available.

Phenolic hardeners contain up to 35% BPA/BoSC. The dossier submitter assumes that for all uses (i.e. during curing) contact to aqueous media in any form can be excluded. Subsequently the bisphenols included in the hardener are covalently bound to a matrix and accordingly the proposed general limit value will apply. No detailed information is available. However limited stakeholder information suggests that epoxy resins that are cured with phenolic hardeners comply with a 150 ppm limit but exceed the 10% concentration limit for BPA/BoSC. For further discussions see Annex B.8.6.5 (Use P2).

A7 – Flame retardant

No longer in scope of the restriction (see short discussion on the manufacturing of other chemicals with BPA).

A8 Chain oil, A9 brake fluids, A10 heat transfer fluids, A11 lubricant formulations

These uses are mentioned in the literature. No stakeholder information on current uses was submitted and additional research led to no further information.

A12 Production of tyres (A8-A12)

In tyre production, BPA has been employed as a part of the compounding formulation. Stakeholder information suggests that this use in the manufacturing of tyres has ceased.

Information from the stakeholder consultation suggests that no impacts on recycling processes must be expected. Granules from used tyres from four different European producers were tested for BPA contents. BPA concentrations ranged between 0.1 and 1 ppm. A literature search undertaken by the same stakeholder suggests average concentration of BPA in tyre shred might even be lower by an order of magnitude.

A13 – Fluoroelastomers / FKM

Mixtures containing BPAFs (fluoroelastomers/FKMs) are used in several sectors of the industry such as transport, oil & gas, aerospace and chemical processing and also end up in e.g. semiconductors, smart devices and communication devices.

Final articles manufactured from FKM include sealings, O-rings, stators for pumps and engines, gaskets, turbocharger hoses, particle filter hoses/Differential pressure hoses, fuel hoses/filler neck hoses.

The use of non-BPAF alternatives would lead to reduced crosslinking and processability, inferior scorch stability and lesser mould release characteristics. No equivalent BPAF alternative substances have been found to date.

Stakeholders argue the non-use of FKM would lead to the impediment of new generation electric cars and transport vehicles from being placed on the market (durability). Due to the specific applications of FKM, they are essential for safety and functioning of society.

Compliance with a 10 ppm (0.001% by weight) concentration limit is currently not possible. However, stakeholders stated explicitely that FKM based articles are generally not exposed to water. No further information is available to assess potential impacts related to potential minor uses with water contact. Those might already be derogated under RO2 when the 150 ppm limit value can be met. Under RO1 such uses must demonstrate that the proposed migration limit is met as all available stakeholder information stated that a 10 ppm limit for BPAF in fluroelastomers cannot be met.

P1 – Polycarbonates

Several alternatives are discussed in Annex E.2. The dossier submitter concludes that it is not possible to reach a reliable conclusion regarding the availability of alternatives. Information is lacking for which uses alternatives are available and economically feasible.

The dossier submitter assumes that economic impacts arising from RO1 comprise of the testing requirement, administrative costs, measures necessary to meet the migration limit and a possible shift to lower quality PVC. A more detailed discussion of this issue can be found in Annex E.4.

It is assumed that migration tests are necessary for 70% of the formulations but not for individual batches. Manufacturers of PC have to organize testing regimes and to develop suitable documentation a) to communicate test results through the supply chain and b) to describe if and how articles can be protected to meet the migration limit. The dossier submitter expects these costs to be most likely negligible.
Industry repeatedly expressed the opinion that PC employed for uses where heavy stressors are expected will already be protected, e.g. by suitable coatings. Limited information from the stakeholder consultation suggests that for some major uses, protective measures are in place to protect PC materials from stressors and thereby minimizing the migration potential of BPA.
The dossier submitter assumes that in case of a higher concentration limit of 150 ppm only a limited number of <10 % of formulations need to be tested to ensure that the 150 ppm limit is met for the article. Migration tests are not required then. Administrative costs will also be lower especially for the development of guidelines on how articles can be protected to meet the migration limit.
In absence of further information, the dossier submitter cannot quantify whether costs for protection of materials will arise however assumes them at least to be negligible. A shift to lower quality PC to meet the concentration limit seems unlikely under RO2.

The dossier submitter assumes that all PC formulations/articles already comply with a concentration limit of 1 000 ppm for BPA. Accordingly, only negligible administrative costs arise from RO3.

Possible costs resulting from the three restriction options are as follows:

Table 22: Cost estimates for P1 – Polycarbonates

	Costs 1 000 €/a	**Costs total over 20 years (1 000 €)**
RO1 (10 ppm)	C: 72 – 3 000 M: 2 520 – 175 000 (A: low one-time costs P: significant one-time costs possible S: unknown)	51 840 – 3 560 000 (+ A, P, S)
RO2 (150 ppm)	C: 24 – 1 000 M: 360 – 25 000 (A: low one-time costs P: no/low one time costs S: no costs)	7 680 – 520 000 (+ A, P, S) Less than 480 if all formulations comply with 150 ppm limit.
RO3 (1 000 ppm)	A: very low one-time cost	Unknown but very low

C: testing concentration limit; M: testing migration limit; A: administratve costs; P: Testing of recommended protective measures; S: substitution to inferior materials

Very high uncertainties and large ranges for the cost estimation result from the consideration of worst case scenarios for the testing requirements. However, the dossier submitter considers it to be likely that estimations for the lower testing costs are more realistic. Nevertheless, in order to come to more robust conclusions regarding the costs reliable input from stakeholders during the public consultation is needed.

P2 – Epoxy Resins

Approximately 70-80 % of epoxy resin uses is related to liquid epoxy resins which generally contain less than 10 ppm bisphenols. Those uses would be derogated under RO1, RO2 and RO3 resulting in negligible costs.

For the remaining 20-30% solid and semisolid epoxy resin (SER/sSER) uses stakeholders reported that bisphenol concentrations of < 65 ppm can be expected but > 10ppm residues. Consequently, for these uses impacts would arise from RO1 but not from RO2 and RO3.

A cost estimate for RO1 is not possible at the moment:

- No reliable information is available on the share of cured sSER/SER articles that come into contact with water and which share of those uses are already protected/coated so that no additional measures are required to meet the migration limit value.

- It is unclear whether migration testing would be done mainly by the manufacturers of the epoxy resins comparable to how it is suggested for the testing of polycarbonates. Stakeholders argue that the use of specific hardeners, their specific application for the curing process and the protection of materials against stressors vary according to specific user needs. Manufacturers of epoxy resins stress they cannot preset only a few specific hardeners with standardized curing processes and defined protection to which all downstream users adhere to meet the migration limit.

P3 – P13 Polysulfones (P3), Polyarylates (P4), Polyetherimides (P5), Unsaturated BPA Polyesters / Polyester resins (P6), Polybenzoxazin resin (P7), Phenolic resins (P8), Dental resins (P9), Polycyanurate (P10), Polyurethanes (P11), Vinyl ester resins (P12), Polyacrylate (P13)

Limited or no information is available for other uses in the manufacturing of polymers:

P3: Stakeholders reported the use of polysulfone (PSU) and polyphenylsulfone (PPSU) in medical devices. No information on use quantities is available, however, measured concentrations are reported to be below 1 ppm. Therefore, minor impact from RO1 – RO3 is expected.

P4: The use of polyarylates is reported from a stakeholder organization representing aerospace and defence industries. NO further information is available. One stakeholder reported the use of BPS for the manufacturing of polyarylene sulfones for membrane manufacturing. The stakeholder reported that residues are below the detection limit. Using this scarce information the dossier submitter expects no impacts from RO1 – RO3.

P5: Stakeholder organizations representing aerospace and defence industries and the medical sector reported the possible use. No further information was submitted.

P6: One stakeholder organization reported the use in Polyester binders used for the production of toners. Although the monomers are completely polymerized in the final product, residual amounts of free BPA may be present in toner. Residues are reported to be in the range 10 – 40 ppm. Therefore, RO2 and RO3 would not impact this use. No alternatives are available in case of a transition period of 3-4 years. The submitted information is of a very general nature. The dossier submitter does not understand for which specific purposes the BPA-based polyester binders are needed. Publicly available data suggests (see Annex E.4.)

that BPA-free alternatives exist and/or are in development. For example, alternatives are reported to be available for printing on food contact materials.

P7: No information was submitted in the two CfEs.

P8: One stakeholder reported the use of BPA in the manufacturing and downstream use of polymers, manufacturing of formaldehyde BPA resins for corrosion protection (mixtures/articles), composite board resins (wood based materials), coatings, impregnation resigns , electrodeposition coating, formaldehyde, halogen-free flame retardants, acrylic resins and urethane acrylates as well as phenolic resins. Formaldehyde resins do not enter the concentration limit. It is chemically not possible to comply with the 10 ppm Concentration limit. But articles/mixtures can comply with a 0.04 mg/L migration limit. BPA-Formaldehyde resin will be added to the basic resin (e.g. acrylates) as a corrosion inhibitor. This mixture will not comply with the proposed migration limit, but articles are enamel baked (Einbrennlackierung), wherein the BPA will chemically react into the matrix during the baking on metal. In this case the article will likely meet the requirements of the migration limit. No further information is available to assess the three restriction options. The dossier submitter does not fully understand whether the statement that the 10 ppm limit cannot be met only refers to the mixtures or also to the enamel baked final articles.

P9: No information was submitted in the two CfEs. Publicly available information suggests that up to 80 % of dental resins contain BPA residues. Exact concentrations in cured materials are not available to the dossier submitter.

P10: One stakeholder association mentioned this as a potential use. No stakeholder reported actual uses.

P11: : One stakeholder stated in the second Call for Evidence that no information is available that polyurethane foam was really made by BPA as a monomer.

P12: One stakeholder reported that vinyl ester resins are critical ingredients for making spar caps for long turbine blades. Vinyl ester resins in many cases are the only material system that can resist harsh chemical environments (chemical factories, food processing factories, desalination plants, mining operations, many others). In other areas they are highly cost-effective systems compared to expensive stainless steel and alloys. No information on BPA concentrations is available.

P13: No information on actual uses is available.

In sum, information is too limited or completely lacking to analyse the impact of RO1-RO3. The dossier submitter received no robust information that RO1 would impact P3-P13.

P14: Leather tanning

Syntans are used as leather tanning agents and textile colour fixers and may contain BPS and/or BPF. Based on data from 2012 to 2014 stakeholders reported a consumption of 7000 - 8000 t/a BPS for syntan production in the EU. Of these, 700 – 800 tpa BPS were used to produce syntans for textile colour fixing. The import of BPS for syntan production is considered < 500 t/a (Ramboll Deutschland GmbH, 2021).

50% of syntans are exported, equivalent to 3500 to 4000 t/a BPS (Ramboll Deutschland GmbH, 2021). Import of syntans was estimated as <20% by stakeholders (TEGEWA, 2022)

An often cited estimated value derived from the production and use of syntans globally in 2020 was 115,000 t/a (powder-based products). One stakeholder (CfE2#82) states the global market for syntans to be roughly 160,000 t/a, with roughly 30% (corresponding to 48,000 t/a) located in Europe.

According to the report provided by one stakeholder, the majority of syntan production within the EU happens in 3 to 4 large sites (2 of them in Germany). Approximately 1,500 EU tanneries. (With approx. 2/3 of them being situated in Italy) use the syntans to manufacture leather. The tanneries and the textile industry are also importing an unknown amount of syntans from outside the EU.

Many stakeholders state the value of BoSC (BPS and BPF) residues in the finished syntan within the range of 0,1-3%.

A German industry association representing the textile industry (TEGEWA, 2022) confirmed a 2,600 ppm mean concentration of BPS in leather articles for 75% of their members. Few articles with lower concentrations at 100 – 200 ppm BPS were reported in split or soft leather applications such as gloves. The stakeholder considered these applications so few, that they did not impact the mean concentrations of 2,600 ppm BPS. However, as discussed in Annex E.4 additional information is available suggesting considerably lower BoSC-concentrations in leather articles, with typical BoSC-concentrations of less than 800 ppm.

In case of entry into force of RO1 more than 80 percent of leather products could no longer be sold in the EU. RO2 would lead to a similar result as stakeholders reported that only a very limited number of soft leather products like gloves can meet such a concentration limit. It is not clear whether RO3 would also result in a situation where at least some leather articles can no longer be sold.

Stakeholders gave different estimates on possible economic impacts. In sum they expect that RO1 – RO3 would lead to the loss of 10 000 – 100 000 jobs in the EU and the loss of turnover of more than €100 bn.

Publicly available information suggests that syntan manufacturers are actively working on reducing the content of bisphenols in their products. No information is available how this impacts future costs for syntans.

P15: Polyamides

Syntans that contain BPS and BPF are used as colour fixers for polyamide textiles to provide longevity of colour. Globally, 80% of polyamide textiles undergo colour fixing with syntans. Stakeholders reported an annual consumption of BPS of 700-800 t for syntan production for this purpose in the EU (Ramboll Deutschland GmbH, 2021).

The concentration ranges between 200-1,000 ppm for BPS and BPF, although BPF is not used as often (TEGEWA, 2022). The lifespan of polyamide textiles was reported by stakeholders as few months to 20 years, the longer life spans can be observed in specific categories e.g. outdoor articles and technical textiles.

EU consumption of polyamide was reported by the Joint Research Centre (2014) as 621,368 tpa for clothing and 642,390 tpa for household textiles (calculated from Fig. 1 of the JRC report). Household textiles in this study included interior textiles. Technical textiles were not included in this study, although they make up 16% of EU textile production and often contain nylon (European Environment Agency, 2021).

Stakeholders confirmed that in case of a restriction no colourfast polyamide textiles can be manufactured or placed on the market. However, they also confirmed that it is possible to reduce the bisphenols in the final articles. Possible impacts would be reduction of colourfast properties and less durability.

Currently the dossier submitter cannot conclude on the most proportionate restriction option for this use. In general, alternatives to polyamide are available to manufacture textiles Also, information is available that BoSC-content in syntans can be reduced. In order to properly justify a specific derogation the dossier submitter and SEAC need additional information.

Only for a limited number of uses quantitative information on economic impacts is available. Table 23 sums up the information discussed in this chapter for RO1 – RO3:

Table 23: Economic Impacts resulting from the proposed restriction options

Use	RO1	RO2	RO3	Comments
C1 – C7	No impact	No impact	No impact	
A1 – A4 (PVC)	Negligible	No impact	No impact	
A1 – A4 (recycling)	€51.7 Mio/a	Negligible	Negligible	RO2 and RO3: Labelling costs
A5 (Thermal paper)	€19-€22 Mio/a	€19-€22 Mio/a	€19-€22 Mio/a	
A5 (recycling)	Unknown but very high costs	No impact	No impact	
A6 (ER hardener)	Unknown but significant costs	No impact	No impact	
A7 (Flame retardant)	No impact	No impact	No impact	
A8 – A11	No impact	No impact	No impact	
A12 (Tyres)	No impact	No impact	No impact	
A12 (recycling)	No impact	No impact	No impact	
A13 (Fluoroelastomers)	cost for unknown number of migration testing for small number of articles with water contact.	No impact	No impact	
P1 (Polycarbonates)	€52–€3 560 Mio. / 20 years	€7.7-€520 Mio. / 20 years	Negligible	
P2 (Epoxy resins)	Unknown but very high costs (SSER/SER uses)	Negligible	Negligible	
P3 – P5	No impact	No impact	No impact	
P6	Uncertain	No impact	No impact	Alternatives might be available for all uses. No information on substitution costs or

				transition period available
P7	No impact	No impact	No impact	
P8	Uncertain	No impact	No impact	Information on BPA concentration in articles is not sufficient
P9	No impact	No impact	No impact	
P10	No impact	No impact	No impact	
P11	No impact	No impact	No impact	
P12	No impact	No impact	No impact	No information on BPA concentrations
P13	No impact	No impact	No impact	
P14	Very high: loss of > 10 000 jobs, loss of > €100 bn turnover	Very high: loss of > 10 000 jobs, loss of > €100 bn turnover	Very high, but less than RO1 and RO2	
P15	Unknown, very high impact possible: Loss of > 80 business	Unknown, very high impact possible Loss of > 80 business	Unknown, most likely less durable articles	

2.5. Environmental impacts

For the purposes of this restriction proposal, BPA and the BoSC are considered as non-threshold substances owing to their endocrine disrupting properties in the environment. Hence, as described in section 1.1.7 their emissions to the environment are considered as a direct proxy for risk.

Therefore, the environmental impact of the proposed restriction can be described by the reduction in predicted future and actual estimated releases that are described as the baseline scenario in section 1.3. These baseline emissions are forecasted to occur without the proposed restriction and any further risk management measures in addition to the already enforced measures described in section 1.2.

Table 21 from section 1.3 provides an overview of the current emissions (estimated for the year 2020) from various sub-uses as well as the predicted emissions for the period from 2025 to 2045. It should be noted that owing to missing information from various use categories these estimates include high uncertainties. Especially for the best case estimates there is a significant risk for underestimating emissions since for use categories where no information is available the dossier submitter assumed negligible releases. Furthermore, it is expected that the volume of bisphenols used for certain use categrories would increase from 2025 to 2045. Thus, owing to missing growth estimates also here is an uncertaintiy that can lead to underestimation of the predicted uses. Hence, all environmental impacts, i.e. the amount of avoided emissions of BPA and BoSC, described for the proposed restriction should be taken as conservative estimates.

However, it can be derived that ≥ 80% of the total emissions originate from the additive uses (including waste water streams from leather tanning processes) listed in section 1.3. Since these uses are fully restricted, except larher tanning where a specific derogation is proposed, in all three described restriction scenarios it is expected that the proposed restriction leads to a cumulative reduction of at least 80% of the quantified emissions of BPA and the BoSC that would have occurred in the absence of the restriction entering into effect. For the period from 2025 to 2045 this reduction is estimated to be in the order of 2,500 t for the best case estimate to > 11,800 t for the worst case emission scenario.

Emissions from polymeric uses, even if of minor share compared to the overall emissions, were also be identified to bear an emission reduction potential. To address this consideration, three limit values and a migration limit are introduced in the restriction options discussed in section 2.3. This shall ensure that especially PC and ER, representing the economically most relevant uses, can be continued when manufactured according to high quality standards. The proposed limit values and the migration limit shall ensure that emissions from polymeric uses throughout their service life are minimised as much as possible and shall address the uncertainty in emission estimates originating from all polymeric uses, especially from imported articles and mixtures. In the following the environmental impacts of each restriction option are briefly discussed. Further details are presented in section 2.7 and 1.1.6.

Restriction Option 1: Limit value of the sum of BPA and BoSC: 10 ppm, no derogations for polymeric uses

This restriction option provides the highest potential to minimise environmental emissions. The additive uses are fully restricted since, owing to technical functionality, amounts orders of magnitude higher than 10 ppm in artciles and mixtures are needed. The 10 ppm limit value for polymeric uses ensures that residual amounts of BPA and BoSC do not exceed a technically achievable, according to stakeholder information, minimal concentration. Mixtures and articles form polymeric uses exceeding the 10 ppm limit are further regulated by the obligation to meet a migration limit of 0.04 mg/L over their entire servive life (as per paragraph 2(i)) or it must be demonstrated that they do not have any contact to water during their reasonable and forseebale service life (as per paragraph 2(ii)). By these provisions, emissions during service life are minimised as much as technically feasible. Based on stakeholder information it is estimated that around 30% of the polycarbonate and epoxy resin uses can meet the limit of 10 ppm. i.e. for 70% of these uses migration testing would be necessary and there is an emission reduction potential between 15 and 180 t for the period 2025 to 2044. It should be noted here that it is estimated that if the 10 ppm limit or the migration limit is met by all polymeric uses, the dossier submitter estimates that environmental concentrations will be around the limit of quantification for BPA and BoSC. Hence, compared to the described actual monitoring data no BPA and BoSC should be detectable in surface water bodies within the EU.

Restriction Option 2: Limit value of the sum of BPA and BoSC: 10 ppm, but derogation for polymeric uses: Limit value of the sum of BPA and BoSC of 150 ppm

Compared to RO1, in this scenario also all additive uses are fully restricted but it is estimated that now ≥80% of the polymeric uses can meet the proposed specific limit value of 150 ppm and only for some minor uses migration testing would be necessary. Hence, the potential for emission reduction from polymeric uses is much smaller compared to scenario 1 and mainly addresses the unkown emissions from imported mixtures and articles of lower quality.

Restriction Option 3: Limit value of the sum of BPA and BoSC: 1,000 ppm

Compared to both other scenarios in this restriction option the limit value will only restrict the additive uses. Hence, all known polymeric uses can be continued without further obligations like migration testing since it is estimated from a technical perspective that it is highly unlikely that residual amounts from polymeric uses of BPA and BoSC exceed 1,000 ppm.

2.6. Other impacts, practicability and monitorability

Social impacts affect workers, consumers and/or the general public. According to the SEAC guidance (i.e. ECHA, 2008), social impacts incorporate all impacts of a regulatory option that are not covered by the assessment of economic, health and environmental impacts, e.g. changes in employment, working conditions and social security. It is not possible to qualify or quantify these changes. However, it is obvious that several of the uses within the scope of this restriction directly affect some of the largest industries in the EEA. Some of these uses are critical for the functioning of society and others would at least endanger the competitiveness of articles on global markets, e.g.:

- The use of fluoroelastomers is necessary in the manufacturing of semi-conductors and critical for the manufacturing of safe and energy saving vehicles.
- Polycarbonates and epoxy resins are used in a multitude areas of modern life. It is not possible to assess the impacts in case ER and PC can no longer be used.
- Leather articles and polyamides, while not critical for the functioning of society, are nevertheless used in a very high number of different articles of clothes and technical textiles.

Therefore, significant wider economic impacts are expected in relation to a restriction on bisphenols without adequate derogations. As EU and non-EU suppliers of products to the EU market are equally affected by the restriction, no impact on competition is expected for the EU market. However, impacts on competition on the global market are expected to be severe.

Impacts on the recycling industry without a suitable concentration limit would be severe as discussed in chapter 2.4. Practicability cannot be fully judged due to the inherent uncertainties regarding identification of proper techniques to reduce the concentration limits in some articles (leather and polyamides, epoxy resins, toners, etc.) and in the recycling of paper and PVC waste. Generally, it can be concluded that in some cases a longer transition period will increase the practicability.

The proposed restriction is deemed to be enforceable. Enforcement actions, likely consisting of (i) documentation checks from the supply chain for mixtures and articles imported to as well as produced in the EU and (ii) testing to determine the concentration of BPA and BoSC are deemed to be feasible (see Annex E.2.3).

2.7. Proportionality (including comparison of options)

The quantification of adverse impacts of ED substances on the environment is not yet possible. This prohibits the use of a traditional cost-benefit analysis for assessing the proportionality of the proposed restriction. When cost estimates are available the cost-effectiveness of the assessed restriction options can be compared to a benchmark on the level of costs that are deemed worthwhile for reducing emissions. In all other cases the restriction options are discussed qualitatively.

Use	RO1	RO2	RO3
C1 – C7	no economic impacts/emissions expected → **proportionate**	no economic impacts/emissions expected → **proportionate**	no economic impacts/emissions expected → **proportionate**
A1 – A4 (PVC)	No significant economic impacts/emissions expected → **proportionate**	no economic impacts/emissions expected	no economic impacts/emissions expected
A1 – A4 (recycling)	Economic impact: 51.7 Mio./a Avoided emissions 2 700 kg CE: 19 150 €/kg → **likely to be proportionate**	Economic impact: labelling costs Ongoing emissions 2 700 kg per year,decrease over time → **proportionate**	Economic impact: labelling costs Ongoing emissions 2 700 kg per year,decrease over time → **proportionate**
A5 (Thermal paper)	Economic Impacts: €19-€22 Mio/a Avoided emissions: 86 t/a (central estimate) CE: 222 €/kg → **proportionate**	Economic Impacts: €19-€22 Mio/a Avoided emissions: 86 t/a (central estimate) CE: 222 €/kg → **proportionate**	Economic Impacts: €19-€22 Mio/a Avoided emissions: 86 t/a (central estimate) CE: 222 €/kg → **proportionate**
A5 (recycling)	Economic Impacts: very high (no recycling possible) Avoided emissions: initially high impact, then sharply decreasing Likely to be not proportionate	no economic impacts expected; initially high emissions, however decreasing → **proportionate**	no economic impacts expected; initially high emissions, however decreasing → **proportionate**
A6 (ER hardener)	Included in P2		
A8 – A11	no economic impacts/emissions expected	no economic impacts/emissions expected	no economic impacts/emissions expected
A12 (Tyres)	no economic impacts/emissions expected	no economic impacts/emissions expected	no economic impacts/emissions expected
A12 (recycling)	no economic impacts expected, ongoing emissions <1 t/a	no economic impacts expected, ongoing emissions <1 t/a	no economic impacts expected, ongoing emissions <1 t/a
A13 (Fluoroelastomers)	cost for unknown number of migration testing for small number of articles with water contact, avoided emissions unknown but most likely comparably small	no economic impacts expected, ongoing emissions <1 t/a	no economic impacts expected, ongoing emissions <1 t/a
P1 (Polycarbonates)	Economic impact: €52 – €3 560 Mio. / 20 years Avoided emissions: 18 – 120 t/20 years CE: 450 – 205 780 €/kg	Economic impact: €7.7 - €520 Mio. / 20 years Limited potential to reduce emissions	Economic impact: Negligible; No avoided emissions

P2 (Epoxy resins)	Unknown but potentially high costs (SSER/SER uses) Avoided emissions 10 - 149 t/20 years	Economic impact: Negligible; No avoided emissions	Economic impact: Negligible; No avoided emissions
P3 – P5	no economic impacts/emissions expected	no economic impacts/emissions expected	no economic impacts/emissions expected
P6	no economic impacts/emissions expected	no economic impacts/emissions expected	no economic impacts/emissions expected
P7	no economic impacts/emissions expected	no economic impacts/emissions expected	no economic impacts/emissions expected
P8	no economic impacts/emissions expected	no economic impacts/emissions expected	no economic impacts/emissions expected
P9	no economic impacts/emissions expected	no economic impacts/emissions expected	no economic impacts/emissions expected
P10	no economic impacts/emissions expected	no economic impacts/emissions expected	no economic impacts/emissions expected
P11	no economic impacts/emissions expected	no economic impacts/emissions expected	no economic impacts/emissions expected
P12	no economic impacts/emissions expected	no economic impacts/emissions expected	no economic impacts/emissions expected
P13	no economic impacts/emissions expected	no economic impacts/emissions expected	no economic impacts/emissions expected
P14	Economic Impact: Discontinuation of EEA leather industry Avoided emissions: 59 - 8 652 t/20 years	Economic Impact: Discontinuation of large parts of EEA leather industry Avoided emissions: unknown but very large	Economic Impact is uncertain but most likely: Discontinuation of parts of EEA leather industry Avoided emissions: unknown but most likely small
P15	Dye fixation no longer possible Avoided emissions: 8 – 1 560 t/20 years	Most likely high costs: Only limited possibility of dye fixation. Avoided emissions: unknown, but continuation of significant emissions possible	Negligible costs No avoided emissions

It is not possible to estimate the total costs associated with each restriction option quantitatively. However, it is safe to say that RO1 without any further derogations would lead to very high societal costs, mostly associated with the cost of no longer being able to manufacture and use fluoroelastomers as well as partly use polycarbonates, epoxy resins and leather textiles.

RO2 would lead to much lower but still very high societal costs asscociated with the cessation of the manufacture and use of leather and fluoroelastomers.

RO3 would only lead to significant but proportionate costs for the substitution of BoSC for the manufacturing of thermal paper as well as substitution costs for additive uses in the manufacturing of PVC (in case this use is still happening in the EEA).

RO3, on the other hand, is the least effective measure to minimize the emissions from BPA and BoSC uses. It is expected that under RO3 emissions will be reduced by less than 25%. Considering the major uncertainties associated with the emissions estimations from industry stakeholders and the dossier submitter the reduction might be even considerably lower.

For the restriction to be more effective it is necessary to reduce the emissions from those sources which are likely to be the largest. Further it is necessary to ensure that those uses that are suspected to be comparably minor emission sources are regulated in a way that they can still be placed on the market but that also uncertainties in regards to the future emissions from these uses are minimized. Considering the large variety of uses to manufacture polymeric materials with BPA and BoSC and considering the large range of concentrations in those materials the dossier submitter deems it necessary to propose concentration limits even for those uses where the socioeconomic value of a continued use is considered higher than the expected environmental impacts.

The dossier submitter therefore proposes a concentration limit for BPA and BoSC of 10 ppm for the placing on the market in mixtures and articles and proposes derogations were the socioeconomic impacts are likely to be not proportionate:

Table 24: Discussion on derogations

Use	Proposed Derogation	Reasons
C1 – C7	No derogation	10 ppm concentration limit is met in the chemicals
A1 – A4 (PVC)	No derogation	no economic impacts (additional information on ongoing uses could challenge this assessment)
A1 – A4 (recycling)	No derogation	Current concentrations in recycled PVC are estimated to be in the range 10ppm-150ppm. However, a sharp decrease of BPA-content in PVC waste is expected within the next few years.
A5 (Thermal paper)	No derogation	Socio-economic costs are considered to be proportionate considering previous restriction proposals for non-threshold substances.
A5 (recycling)	Concentration limit 150 ppm for 78 months	BoSC will be removed almost completely from the recycling loop within five years after a restriction on the use of BoSC in thermal paper becomes effective. However during that period no paper recycling would be possible in the EEA most likely leading to the demise of the paper recycling industry.
A6 (ER hardener)	No derogation	This use is already derogated by para. 2 of the restriction proposal
A8 – A11	No derogation	No information on current uses in EEA
A12 (Tyres)	No derogation	No information on current uses in EEA
A12 (recycling)	No derogation	According to staekeholder and literature information concentration limit can be met
A13 (Fluoroelastomers)	Concentration limit 50 ppm for 10 years	Stakeholder information suggests that BPAF concentrations in FKM are in the range 10 – 50 ppm. It might be possible to further reduce the content in the future.
P1 (Polycarbonates)	Concentration limit 150 ppm	10 ppm concentration limit can only be met by less than 30% of the currently manufactured PC. European manufacturers can meet 150 ppm concentration limit. Testing costs are deemed to be

		affordable and proportionate when considering that the concentration limit ensures a level playing field for EEA and non-EEA articles and mixtures.
P2 (Epoxy resins)	Concentration limit 65 ppm for the placing on the market of articles articles manufactured with solid and semisolid epoxy resins. Concentration limit of 1 ppm for epoxy resin mixtures intended for consumer uses	Stakeholders provided information that BPA and BPS residues in articles made of liquid epoxy resins amount to less than 10 ppm. Residues in articles made with solid epoxy resins contain less than 65 ppm residues. In order to minimize the emissions resulting from improper curing by consumers and from improper disposal by consumers products intended for use by consumers only epoxy resin mixtures with very limited emissions potential shall be used by non-professionals.
P3 – P13	No derogation	No information on current uses in EEA with BPA concentrations larger 10 ppm in articles or mixtures.
P14	Concentration limit 500 ppm for 5 years.	High uncertainty regarding current concentrations of BoSC in leather articles. Information available on R&D of syntans containing fewer quantities of BoSC. Limited costs expected when tanneries use new syntans. Information is lacking on whether even lower concentration limits can be met in the future.
P15	No derogation	Most likely disproportionate impacts resulting from not granting a derogation. However, in order to justify a specific derogation the Dossier Submitter and SEAC need additional information.

The dossier submitter received limited information on the uses of BPA and BoSC, available alternatives and on the time and costs associated with the substitution to alternatives from the majority of the stakeholders. As a result of this it is difficult to draw a robust conclusion on proportionality of the three assessed restriction options. Consequently, the dossier submitter proposes a differentiated proposal with several different concentration limits and accompanying obligations.

3. Assumptions, uncertainties and sensitivities

The application of quantitative methods, namely CEA (cost-efficiency analysis), was very limited due to missing data. Input variables that are considered highly uncertain and / or potentially impactful on the final conclusions can only be tested in a qualitative sensitivity analysis. The emissions are a key uncertainty, but these have not been tested in the sensitivity analysis as the uncertainty is already reflected in the broad range for the emission estimates.

Qualitative sensitivity analysis is presented together with the discussion on uncertainties for each use in Annex F. The dossier submitter considers the following uncertainties as most important:

A1-A4: Uncertainties about possible uses in the EEA; Uncertainties about the phase-out of uses in automotive and medical application.

Recycling (A1-A4, A5): Uncertainties about quantities of BPA and BPS in the recycling loop. Uncertainties regarding the time necessary to remove the substances from the recycling loop.

A5: Availability of alternatives in sufficient quantities within 18 months.

A 8- A12: Currently no information on actual uses in the EEA.

A13: Emissions potential during waste phase; share of articles with water contact and the resulting number of migration tests needed.

P1: Emissions potential especially during waste phase; average BPA concentration; possible uses with BPA residues above 150 ppm; total testing costs.

P2: Emissions during service life, especially during further processing and from curing by downstream users, possible uses with BPA residues above 100 ppm; possibility of upstream testing for all uses; impacts resulting from a restriction on consumer uses.

P6: Availability of alternatives.

P8, P12: BPA/BoSC concentrations in the articles.

Other polymeric uses: scarce information in general.

P14: Current emissions; possibilities to minimize emissions from leather tanneries; missing timeplane for the substitution of current generation of syntans with new ones containing less BoSC; Identification of a suitable general concentration limit; Identification of specific use-categories for which higher concentration limits than proposed are fully justified; Impact on article properties/quality of using less syntans.

Each of the mentioned uncertainties has the potential to challenge the current conclusions on derogations in case more reliable information will be provided in the public consultation.

4. Conclusion

BPA and the BoSC fulfil the WHO/IPCS criteria for endocrine disruptors in the environment. Environmental endocrine disruptors are considered as non-threshold substances, since information to derive a robust predicted no effect concentration (PNEC), that would be sufficiently protective for all possibly affected species, is currently insufficient. Therefore, it is not possible to conclude whether risks from emissions of BPA and the BoSC are adequately controlled, either now or in the future.

The dossier submitter therefore concludes that the bisphenols in the scope of this restriction proposal should be treated as a non-threshold substance for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation. Hence, any release to the environment and environmental monitoring data are regarded as a proxy for an unacceptable risk. In accordance with previous restriction proposals on non-threshold substances, the dossier submitter argues that every emission of BPA and the BoSC to the environment increases the likelihood of irreversible and adverse population relevant effects, i.e. effects on reproduction, growth and survival. Therefore, current and future emissions of these bisphenols have to be minimised as much as technically and economically feasible.To achieve an effective emission reduction the following aspects need to be addressed:

- BPA and BoSC are originating from a very broad spectrum of wide dispersive and wide spread uses.

- A group approach must be taken to cover all bisphenols having endocrine disrupting properties for the environment and fitting specific structural group boundaries, since owing to the high structural similarity of the bisphenols exhibiting the identified ED effects, there is a high risk that these substances are used among each other as drop-in substitutes for restricted uses (*e.g.* as it could be observed in thermal papers, where BPA has been largely replaced by BPS). This would render any restriction approach focusing on single ED bisphenols disproportionate.
- Regrettable substitution must be avoided to achieve an effective measure.
- Additive and polymeric uses differ significantly in their emission potentials.
- The service life of products, the processing of mixtures and products as well as to the end of life and waste phase have to be adressed either directly or indirectly.

With respect to this overall situation, national and/or sector specifc regulations (e.g. the restriction for BPA in thermal paper) are considered to be not adequate and an EU-wide and broad restriction is proposed to well balance the maximum that can be achieved for environmental emission reduction while keeping feasibility and proportionality into account. To address the specific differences of additive and polymeric uses of BPA and the BoSC three restriction options are described and analysed with respect to their economic and environmental impacts.

Restriction Option 1 including the proposed derogations is considered to be the most proportionate with respect to the identified risk and will lead to an unknown but significant emission reduction of up to ≥ 80% compared to the baseline scenario:

A concentration limit of 10 ppm in articles and mixtures for the sum of BPA and the BoSC is proposed. Applying this limit value will restrict all additive uses since for technical functionality here concentrations > 1000 ppm in articles and mixtures must be added. For polymeric uses partly higher limit values of up to 150 ppm are proposed based on proportionality considerations.Polymeric uses that exceed 150 ppm can be continued if they comply with the following conditions:

- Contact to water and hence emissions to the aquatic environment as the main entry path can be excluded during reasonable and foreseeable use throughout the service life.
- If contact to water cannot be excluded during reasonable and foreseeable use a migration limit in the respective mixtures and articles must not exceed 0.04 mg/L over the entire service life.

The cost-effectiveness of this proposed restriction option is expected to be similar to REACH restrictions that have been decided previously. Furthermore, the proposed restriction is considered affordable for the impacted supply chains. Additionally, an EU wide restriction would address imported articles and mixtures and the related uncertainties regarding their contribution to emissions and thus would create a level playing field amongst companies operating on the EU market. The costs for industry and enforcement agencies were assessed to be affordable. Analytical methods to enforce and/or to comply with the restriction and to monitor the effect are available. Finally, it should be noted that based on the described uncertainties the environmental impact of the proposed restriction is a conservative estimate, i.e. the avoided emissions in the period from 2025 to 2045 are likely to be higher than described for the best case estimate scenario.

References

Barouki R. (2020): HBM4EU AD5.4 Reporting first and second set substances v1.1-1-Bisphenols. INSERM - FR. https://www.hbm4eu.eu/wp-content/uploads/2021/02/HBM4EU_AD5.4_Reporting_first_and_second_set_substances_v1.1-1-Bisphenols.pdf

BAuA (2019): CLH report - Proposal for Harmonised Classification and Labelling - 4,4'-isopropylidenediphenol; Bisphenol A, date: April 2019. Bundesanstalt für Arbeitsschutz und Arbeitsmedizin. https://echa.europa.eu/documents/10162/72f2d169-a750-49ae-ea41-9200a2675b57

Bhandari R.K., vom Saal F.S., and Tillitt D.E. (2015): Transgenerational effects from early developmental exposures to bisphenol A or 17alpha-ethinylestradiol in medaka, Oryzias latipes. Sci. Rep. 5. DOI: 10.1038/srep09303

http://www.nature.com/srep/2015/150320/srep09303/abs/srep09303.html#supplementary-information

Blair R.M., Fang H., Branham W.S., Hass B.S., Dial S.L., Moland C.L., Tong W., Shi L., Perkins R., and Sheehan D.M. (2000): The estrogen receptor relative binding affinities of 188 natural and xenochemicals: structural diversity of ligands. Toxicol Sci 54 (1), 138-153. http://www.ncbi.nlm.nih.gov/pubmed/10746941; http://toxsci.oxfordjournals.org/content/54/1/138.full.pdf

Chen J., Xiao Y., Gai Z., Li R., Zhu Z., Bai C., Tanguay R.L., Xu X., Huang C., and Dong Q. (2015): Reproductive toxicity of low level bisphenol A exposures in a two-generation zebrafish assay: Evidence of male-specific effects. Aquat Toxicol 169, 204-214. DOI: 10.1016/j.aquatox.2015.10.020

Darby J.R., Touchette N.W., and Sears J.K. (1970): Antioxidant effects in PVC plasticized with DIDA. Journal of Applied Polymer Science 14 (1), 53-64. DOI: 10.1002/app.1970.070140106

ECHA, EFSA, Andersson N., Arena M., Auteri D., Barmaz S., Grignard E., Kienzler A., Lepper P., Lostia A.M., Munn S., Parra Morte J.M., Pellizzato F., Tarazona J., Terron A., and Van der Linden S. (2018): Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. 1831-4732. ECHA, EFSA with the technical support of the Joint Research Centre (JRC). DOI: 10.2903/j.efsa.2018.5311

Elsby R., Ashby J., Sumpter J.P., Brooks A.N., Pennie W.D., Maggs J.L., Lefevre P.A., Odum J., Beresford N., Paton D., and Park B.K. (2000): Obstacles to the prediction of estrogenicity from chemical structure: assay-mediated metabolic transformation and the apparent promiscuous nature of the estrogen receptor. Biochem Pharmacol 60 (10), 1519-1530. http://www.ncbi.nlm.nih.gov/pubmed/11020455; https://www.sciencedirect.com/science/article/pii/S0006295200004664?via%3Dihub

European Commission (2003): European Union Risk Assessment Report 4,4'-ISOPROPYLIDENEDIPHENOL (BISPHENOL-A), date: 1/1/2003. Communities O.f.O.P.o.t.E., Luxembourg

European Environment Agency M., S.; Smeets, A.; Arnold, M.; Mortensen, L. F. (2021): Plastic in Textiles: Potentials for Circularity and Reduced Environmental and Climate Impacts. ETC/WMGE 2021/1, date: 28/01/2021. European Topic Centre on Waste and Materials in a Green Economy. Eionet, Mol, Belgium. https://www.eionet.europa.eu/etcs/etc-wmge/products/etc-wmge-reports/plastic-in-textiles-potentials-for-circularity-and-reduced-environmental-and-climate-impacts

Fang H., Tong W., Perkins R., Soto A.M., Prechtl N.V., and Sheehan D.M. (2000): Quantitative comparisons of in vitro assays for estrogenic activities. Environ Health Perspect 108 (8), 723-729. http://www.ncbi.nlm.nih.gov/pubmed/10964792; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1638296/pdf/envhper00309-0079.pdf

FPS (2019): CLH report - Proposal for Harmonised Classification and Labelling - 4,4'-sulphonyldiphenol; bisphenol S, date: October 2019. FPS Public Health, Food Chain Safety and Environment. https://echa.europa.eu/documents/10162/21282a0f-29b9-712a-8004-b6f659248268

Frederiksen H., Nielsen O., Koch H.M., Skakkebaek N.E., Juul A., Jørgensen N., and Andersson A.-M. (2020): Changes in urinary excretion of phthalates, phthalate substitutes, bisphenols and other polychlorinated and phenolic substances in young Danish men; 2009–2017. International Journal of Hygiene and Environmental Health 223 (1), 93-105. DOI: https://doi.org/10.1016/j.ijheh.2019.10.002

Gil-Solsona R., Castaño-Ortiz J.M., Muñoz-Mas R., Insa S., Farré M., Ospina-Alvarez N., Santos L.H.M.L.M., García-Pimentel M., Barceló D., and Rodríguez-Mozaz S. (2022): A holistic assessment of the sources, prevalence, and distribution of bisphenol A and analogues in water, sediments, biota and plastic litter of the Ebro Delta (Spain). Environmental Pollution 314, 120310. DOI: https://doi.org/10.1016/j.envpol.2022.120310

Goto Y., Kitamura S., Kashiwaga K., Oofusa K., Tooi O., Yoshizato K., Sato J., Ohta S., and Kashiwagi A. (2006): Suppression of Amphibian Metamorphosis by Bisphenol A and Related Chemical Substances. Journal of Health Science 52 (2), 160-168

Groshart C.P., Okkerman P.C., and Pijnenburg A.M.C.M. (2001): Chemical study on Bisphenol A. RIKZ/2001.027, date: 01.07.2001. BKH Consulting Engineers

Rijkswaterstaat Institute for Coastal and Marine Management (RIKZ). Waterstaat M.v.V.e. and Rijkswaterstaat D.-G. https://edepot.wur.nl/174301

Hatef A., Alavi S.M., Abdulfatah A., Fontaine P., Rodina M., and Linhart O. (2012): Adverse effects of bisphenol A on reproductive physiology in male goldfish at environmentally relevant concentrations. Ecotoxicol Environ Saf 76 (2), 56-62. DOI: 10.1016/j.ecoenv.2011.09.021

Heimeier R.A., Das B., Buchholz D.R., and Shi Y.B. (2009): The xenoestrogen bisphenol A inhibits postembryonic vertebrate development by antagonizing gene regulation by thyroid hormone. Endocrinology 150 (6), 2964-2973. DOI: 10.1210/en.2008-1503

Hong H., Tong W., Fang H., Shi L., Xie Q., Wu J., Perkins R., Walker J.D., Branham W., and Sheehan D.M. (2002): Prediction of estrogen receptor binding for 58,000 chemicals using an integrated system of a tree-based model with structural alerts. Environ Health Perspect 110 (1), 29-36. http://www.ncbi.nlm.nih.gov/pubmed/11781162; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1240690/pdf/ehp0110-000029.pdf

Jobling S., Coey S., Whitmore J.G., Kime D.E., Van Look K.J.W., McAllister B.G., Beresford N., Henshaw A.C., Brighty G., Tyler C.R., and Sumpter J.P. (2002): Wild Intersex Roach (Rutilus rutilus) Have Reduced Fertility. Biology of Reproduction 67 (2), 515-524, 510. https://doi.org/10.1095/biolreprod67.2.515

Jobling S., Nolan M., Tyler C.R., Brighty G., and Sumpter J.P. (1998): Widespread Sexual Disruption in Wild Fish. Environmental Science & Technology 32 (17), 2498-2506. DOI: 10.1021/es9710870

Joint Research Centre I.f.P.T.S., ; Beton, A.; Perwueltz, A.; Desaxce, M.; Gibon, T.; Dias, D.; Boufateh, I.; Farrant, L.; Le Guern, Y. (2014): Environmental improvement potential of textiles (IMPRO Textiles). Publications Office. DOI: doi/10.2791/52624

JRC (2013): Key Scientific issues relevant to the identification and characterisation of endocrine disrupting substances – Report of the Endocrine Disruptors Expert Advisory Group (ED EAG). Comission E.

Kadoma Y. and Fujisawa S. (2000): Kinetic evaluation of reactivity of bisphenol A derivatives as radical scavengers for methacrylate polymerization. Biomaterials 21 (21), 2125-2130. DOI: https://doi.org/10.1016/S0142-9612(00)00088-0

Kitamura S., Suzuki T., Sanoh S., Kohta R., Jinno N., Sugihara K., Yoshihara S., Fujimoto N., Watanabe H., and Ohta S. (2005): Comparative study of the endocrine-disrupting activity of bisphenol A and 19 related compounds. Toxicol Sci 84 (2), 249-259. DOI: 10.1093/toxsci/kfi074

Klimisch H.J., Andreae M., and Tillmann U. (1997): A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data. Regul Toxicol Pharmacol 25 (1), 1-5. DOI: 10.1006/rtph.1996.1076

Lartigue-Peyrou F. (1996): The use of phenolic compounds as free-radical polymerization inhibitors, 489-505. DOI: 10.1016/S0926-9614(96)80036-0

Lucia M., Gabrielsen G.W., Herzke D., and Christensen G. (2016): Screening of UV chemicals, bisphenols and siloxanes in the Arctic

Miller H.D., Clark B.W., Hinton D.E., Whitehead A., Martin S., Kwok K.W., and Kullman S.W. (2012): Anchoring ethinylestradiol induced gene expression changes with testicular morphology and reproductive function in the medaka. PLoS ONE 7 (12), e52479. DOI: 10.1371/journal.pone.0052479

Molina-Molina J.M., Amaya E., Grimaldi M., Saenz J.M., Real M., Fernandez M.F., Balaguer P., and Olea N. (2013): In vitro study on the agonistic and antagonistic activities of bisphenol-S and other bisphenol-A congeners and derivatives via nuclear receptors. Toxicol Appl Pharmacol 272 (1), 127-136. DOI: 10.1016/j.taap.2013.05.015

Naderi M., Wong M.Y., and Gholami F. (2014): Developmental exposure of zebrafish (Danio rerio) to bisphenol-S impairs subsequent reproduction potential and hormonal balance in adults. Aquat Toxicol 148, 195-203. DOI: 10.1016/j.aquatox.2014.01.009

Nishihara T., Nishikawa J.I., Kanayama T., Dakeyama F., Saito K., Imagawa M., Takatori S., Kitagawa Y., Hori S., and Utsumi H. (2000): Estrogenic activities of 517 chemicals by yeast two-hybrid assay. Journal of Health Science 46 (4), 282-298. https://www.scopus.com/inward/record.uri?eid=2-s2.0-0033850463&partnerID=40&md5=a7b19bb0175c81b5c8e66806aa0171af

OECD (2018): Revised Guidance Document 150 on Standardised Test Guidelines for Evaluating Chemicals for Endocrine Disruption. DOI: doi:https://doi.org/10.1787/9789264304741-en

Oró-Nolla B., Lacorte S., Vike-Jonas K., Gonzalez S.V., Nygård T., Asimakopoulos A.G., and Jaspers V.L. (2021): Occurrence of Bisphenols and Benzophenone UV Filters in White-Tailed Eagles (Haliaeetus albicilla) from Smøla, Norway. Toxics 9 (2), 34. https://mdpi-res.com/d_attachment/toxics/toxics-09-00034/article_deploy/toxics-09-00034.pdf?version=1612867323

Qin J.Y., Ru S., Wang W., Hao L., Wei S., Zhang J., Xiong J.Q., Wang J., and Zhang X. (2021): Unraveling the mechanism of long-term bisphenol S exposure disrupted ovarian lipids metabolism, oocytes maturation, and offspring development of zebrafish. Chemosphere 277, 130304. DOI: 10.1016/j.chemosphere.2021.130304

Ramboll Deutschland GmbH (2021): Additional information on the leather tanning agent use of 4,4'-Dihydroxydiphenylsulfone (DHDPS) as described in the CSR. Project No. 352002177, date: 14.12.2021

Ramboll Deutschland GmbH (2022): Substance Flow Analysis (SFA) and Regionalized Pathway Analysis (RPA) for emissions of Bisphenol A (BPA) into the environment - 2022 Update. Project number: 352000802

Rosenmai A.K., Dybdahl M., Pedersen M., Alice van Vugt-Lussenburg B.M., Wedebye E.B., Taxvig C., and Vinggaard A.M. (2014): Are structural analogues to bisphenol a safe alternatives? Toxicol Sci 139 (1), 35-47. DOI: 10.1093/toxsci/kfu030

Ruus A. (2017): Environmental Contaminants in an Urban Fjord, 2016. http://hdl.handle.net/11250/2482314

Ruus A., Allan I.J., Beylich B., Bæk K., Schlabach M.L., and Helberg M. (2015): Environmental Contaminants in an Urban Fjord, 2014

SCA (2019): CLH report - Proposal for Harmonised Classification and Labelling - 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol; bisphenol AF, date: December 16, 2019. Swedish Chemicals Agency https://echa.europa.eu/documents/10162/b5cd80fe-60ad-e5e8-216c-e1d4691bcd4a

Shi M., Sekulovski N., MacLean J.A., Whorton A., and Hayashi K. (2019): Prenatal Exposure to Bisphenol A Analogues on Female Reproductive Functions in Mice. Toxicol Sci 168 (2), 561-571. DOI: 10.1093/toxsci/kfz014

Shioda T. and Wakabayashi M. (2000): Effect of certain chemicals on the reproduction of medaka (Oryzias latipes); 1. Chemosphere 40 (3), 239-243. http://www.ncbi.nlm.nih.gov/pubmed/10665413

Sohoni P., Tyler C.R., Hurd K., Caunter J., Hetheridge M., Williams T., Woods C., Evans M., Toy R., Gargas M., and Sumpter J.P. (2001): Reproductive effects of long-term exposure to Bisphenol A in the fathead minnow (Pimephales promelas). Environ Sci Technol 35 (14), 2917-2925. http://pubs.acs.org/doi/pdfplus/10.1021/es000198n

Tabata A., Kashiwada S., Ohnishi Y., Ishikawa H., Miyamoto N., Itoh M., and Magara Y. (2001): Estrogenic influences of estradiol-17 beta, p-nonylphenol and bis-phenol-A on Japanese medaka (Oryzias latipes) at detected environmental concentrations. Water Sci Technol 43 (2), 109-116

TEGEWA V.d.D.L.e.V. (2022): Fragensammlung TEGEWA, personal communication

Wagner R.L., Apriletti J.W., McGrath M.E., West B.L., Baxter J.D., and Fletterick R.J. (1995): A structural role for hormone in the thyroid hormone receptor. Nature 378 (6558), 690-697. DOI: 10.1038/378690a0

Wagner R.L., Huber B.R., Shiau A.K., Kelly A., Cunha Lima S.T., Scanlan T.S., Apriletti J.W., Baxter J.D., West B.L., and Fletterick R.J. (2001): Hormone selectivity in thyroid hormone receptors. Mol Endocrinol 15 (3), 398-410. DOI: 10.1210/mend.15.3.0608

Wang S., Rijk J.C., Besselink H.T., Houtman R., Peijnenburg A.A., Brouwer A., Rietjens I.M., and Bovee T.F. (2014): Extending an in vitro panel for estrogenicity testing: the added value of bioassays for measuring antiandrogenic activities and effects on steroidogenesis. Toxicol Sci 141 (1), 78-89. DOI: 10.1093/toxsci/kfu103

Yamaguchi A., Ishibashi H., Arizono K., and Tominaga N. (2015): In vivo and in silico analyses of estrogenic potential of bisphenol analogs in medaka (Oryzias latipes) and common carp (Cyprinus carpio). Ecotoxicol Environ Saf 120, 198-205. DOI: 10.1016/j.ecoenv.2015.06.014

Yamasaki K., Takeyoshi M., Sawaki M., Imatanaka N., Shinoda K., and Takatsuki M. (2003): Immature rat uterotrophic assay of 18 chemicals and Hershberger assay of 30 chemicals. Toxicology 183 (1), 93-115. DOI: https://doi.org/10.1016/S0300-483X(02)00445-6

Yang Q., Yang X., Liu J., Ren W., Chen Y., and Shen S. (2017): Exposure to Bisphenol B Disrupts Steroid Hormone Homeostasis and Gene Expression in the Hypothalamic–Pituitary–Gonadal Axis of Zebrafish. Water, Air, & Soil Pollution 228 (3), 112. DOI: 10.1007/s11270-017-3282-z

Yokota H., Tsuruda Y., Maeda M., Oshima Y., Tadokoro H., Nakazono A., Honjo T., and Kobayashi K. (2000): Effect of bisphenol A on the early life stage in Japanese medaka (Oryzias latipes). Environmental Toxicology and Chemistry 19 (7), 1925-1930. CCC:000087674600030 http://onlinelibrary.wiley.com/store/10.1002/etc.5620190730/asset/5620190730_ftp.pdf?v=1&t=hol80mne&s=5412ed3b555925e725d165df15a2595265fe998e