ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAME(S):

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

IUPAC NAME(S): 4-[2-(4-hydroxyphenyl)propan-2-yl]phenol

EC NUMBER(S): 201-245-8

CAS NUMBER(S): 80-05-7

CONTACT DETAILS OF THE DOSSIER SUBMITTER:

BAuA
Federal Institute for Occupational Safety and Health
Division 5 - Federal Office for Chemicals
Friedrich-Henkel-Weg 1-25
D-44149 Dortmund, Germany

VERSION NUMBER: 0.1

DATE: 7 October 2022

TABLE OF CONTENTS

TABLE OF TABLES

TABLE OF FIGURES

TABLE OF EQUATIONS

Annex A: Manufacture and uses

According to the registration information, BPA is manufactured and/or imported in the European Economic Area in a tonnage range of 1,000,000 to 10,000,000 tpa (tonnes per year).[1]

Both exports as well as imports of the 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 and bear high level of uncertainties.

A.1. Manufacture, import and export

The BPA consumption in Europe in 2019 was estimated to be 1,200,000 – 1,500,000 tpa (2020).[2] Moreover, a steady growth is expected during the next years (despite the restriction of its use in thermal paper (TP) since January 2020) so that an annual BPA consumption of more than 1,500,000 t is predicted for 2024. More specifically, the tonnage of BPA are allocated to polycarbonates (PC, 70 - 80%), epoxy resins (ER, 15 - 30%) and other applications (<3%).The percentage may vary in the dossier due to different sources of information.

The following information on used annual tonnage in the EU for the bisphenols of similar concern for the environment (BosC) covered in this dossier (BPB, BPS, BPF and BPAF) has been extracted from ECHA's dissemination sites. The tonnage of other bisphenols with similar concern (BosC) is smaller than that of BPA. In total, these bisphenols account for 1% of BPA.

Table 1: Registered tonnage band for BPA and the BPs with similar concern

Substance	CAS	Tonnage band (tpa)	Import[3] (substance)	Export[3] (substance)
BPA[4]	80-05-7	1,000,000 – 10,000,000	60,000	10,000
BPB[5]	77-40-7	1 -10	-	-
BPS[6]	80-09-1	10,000 – 100,000	-	-
BPF[7]	620-92-8	1,000 – 10,000	-	-
BPAF[8]	1478-61-1	100 – 1,000	-	-

---

[1] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.133 (06/29/2021)
[2] MC group (2020): Bisphenol A 2020 World Market Outlook and Forecast up to 2029.
[3] EUROSTAT, query dated 3 March 2021.
[4] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.133 (06/29/2021)
[5] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.000.933 (06/29/2021)
[6] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.137 (06/29/2021)
[7] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.009.691 (06/29/2021)
[8] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.014.579 (06/29/2021)

A.2. Uses

The uses for the bisphenols manufactured/imported in the EU are structured after manufacturing and downstream use of polymers (P), production and downstream use of other chemicals (C) and additives use (A).

The main uses[9] for BPA with high tonnage are the manufacture of polycarbonate (PC) with about 70 - 80% of the BPA production volume and manufacture of epoxy resin (ER) with around 15 - 30% of the BPA production volume. However, there is a remaining percentage with a share of <3% concerning the use of BPA as an additive with several technical functions.

The breakdown of use is rather abstract for the bisphenols of similar concern (BosC), as the exact tonnages that can be attributed to the respective uses cannot be found in such detail. What is clear is that they are attributed to one of three use groups: production of polymers (P), use as additives (A) and production of other chemicals (C).

Bisphenols and articles/mixtures derived from it or containing it are used in a variety of sectors for many applications. BPA for example can be found in the following sectors:[10,11,12,13,14,15,16,17, 17]

- construction
- medical devises
- traffic control
- automobile industry
- aircraft sector
- wind power plants
- textile Industry
- furniture sector
- toys
- food contact material/ Feed contact material
- commodities
- electronics sector

---

[9] Annex H

[10] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.133 (03/03/2021)

[11] http://spin2000.net/ (03/03/2021)

[12] Amaral, M. J. (2014): Non-toxic healthcare: alternatives to phthalates and bisphenol a in medical devices. In *Health Care Without Harm (HCWH) Europe*, pp. 1–25. Available online at https://noharm-europe.org/EDCs-report, checked on 3/3/2020.

[13] EFSA (2015): Scientific opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs: executive summary. In *EFSA J.* 13 (1), 3978/1.

[14] Eckardt, Martin; Kubicova, Marie; Tong, Duyen; Simat, Thomas J. (2020): Determination of color developers replacing bisphenol A in thermal paper receipts using diode array and Corona charged aerosol detection-A German market analysis 2018/2019. In *Journal of chromatography. A* 1609, p. 460437. DOI: 10.1016/j.chroma.2019.460437.

[15] Koehler Group: koehlerpaper.com. Available online at https://www.koehlerpaper.com/en/products/Thermal-paper/Thermal-technology.php, checked on 8/25/2020.

[16] Morgan, Alun (2015): Fire-Retardancy-What-Why-and-How. Isola Group. Available online at https://www.isola-group.com/wp-content/uploads/Fire-Retardancy-What-Why-and-How.pdf, checked on 8/31/2020.

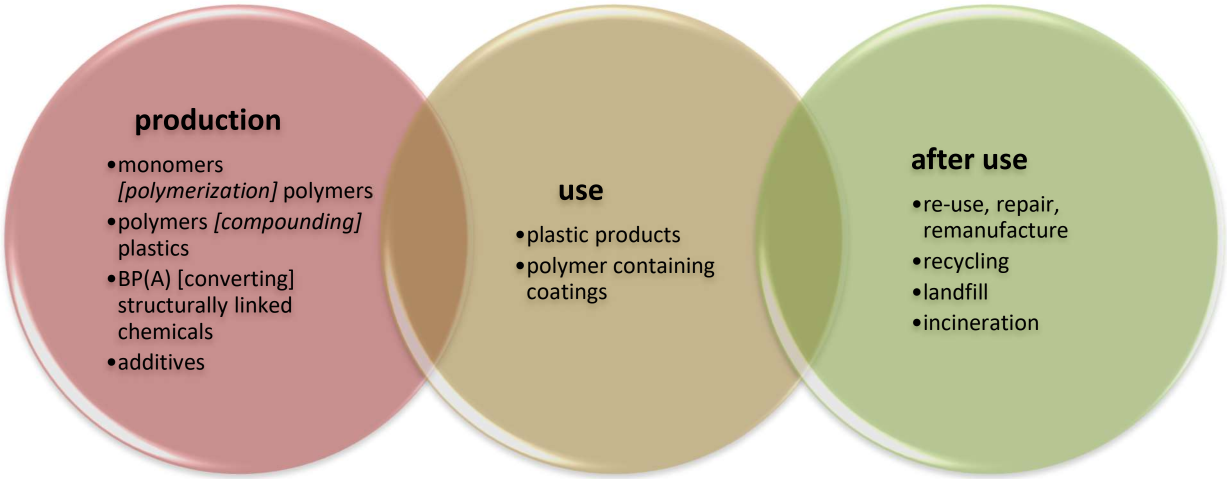
[17] Fischer B., Milunov M., Floredo Y., Hofbauer P., Joas A. (2014): Identification of relevant emission pathways to the environment and quantification of environmental exposure for bisphenol A: Research Project on behalf of the German environment agency - https://www.umweltbundesamt.de/publikationen/identification-of-relevant-emission-pathways-to-the

- optic sector
- paper industry
- packaging
- sectors producing mixtures: coatings, varnishes, lacquer, paints, adhesives, lubricants
- dye sector
- dentistry
- flame retardant
- cosmetics
- protection/safety

For other BosC, this widespread distribution is not known or studied too little. However, since these substances are also used in the manufacture of other substances, including polymers, and as 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.

Since the majority of BPA and other bisphenols are used in the production of polymers and plastics for most of the sectors given above, a brief look at the history of plastics is provided below. Global consumption of polymers and plastics has grown rapidly, from almost zero tonnes per year in the 1950s to 359 million tpa worldwide in 2018. In the EU, 61.58 million tpa were consumed in 2018. Bisphenols, especially BPA, play an important role as a monomer and as an additive in the production and processing of plastics. Since plastics have replaced other materials to a large extent, the importance of their use in all areas of application and life should be pointed out here. As a detailed insight, the life cycle of plastics will be briefly described on the basis of plastics made of or with BP(A). The following figure gives an overview of the lifecycle of plastics and thus allows an overview of the release possibilities, in this case for BP(A) ("release-cycle").

Figure 1: Schematic lifecycle (and "release-cycle") of plastics



A.2.1. Uses of BPA

A.2.1.1. 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 derivatives - 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 (Umweltbundesamt, UBA) has carried out 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.[18] 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" (interim report 06/2021) (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. With the help of the SPIN database (Substances in Preparations in Nordic Countries),[19] the sectors in which BPA is relevant were identified by specifying the use categories and product categories.

Information from the research project on BPA (Annex H) - Inventory of the main type of uses of BPA

With a research project on BPA (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:

---

[18] Available online via: https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_41_2014_identfifcation_of_relevant_emission_pathways_of_bisphenol_a_0.pdf

[19] http://www.spin2000.net/spinmyphp/

Figure 2: Uses of BPA

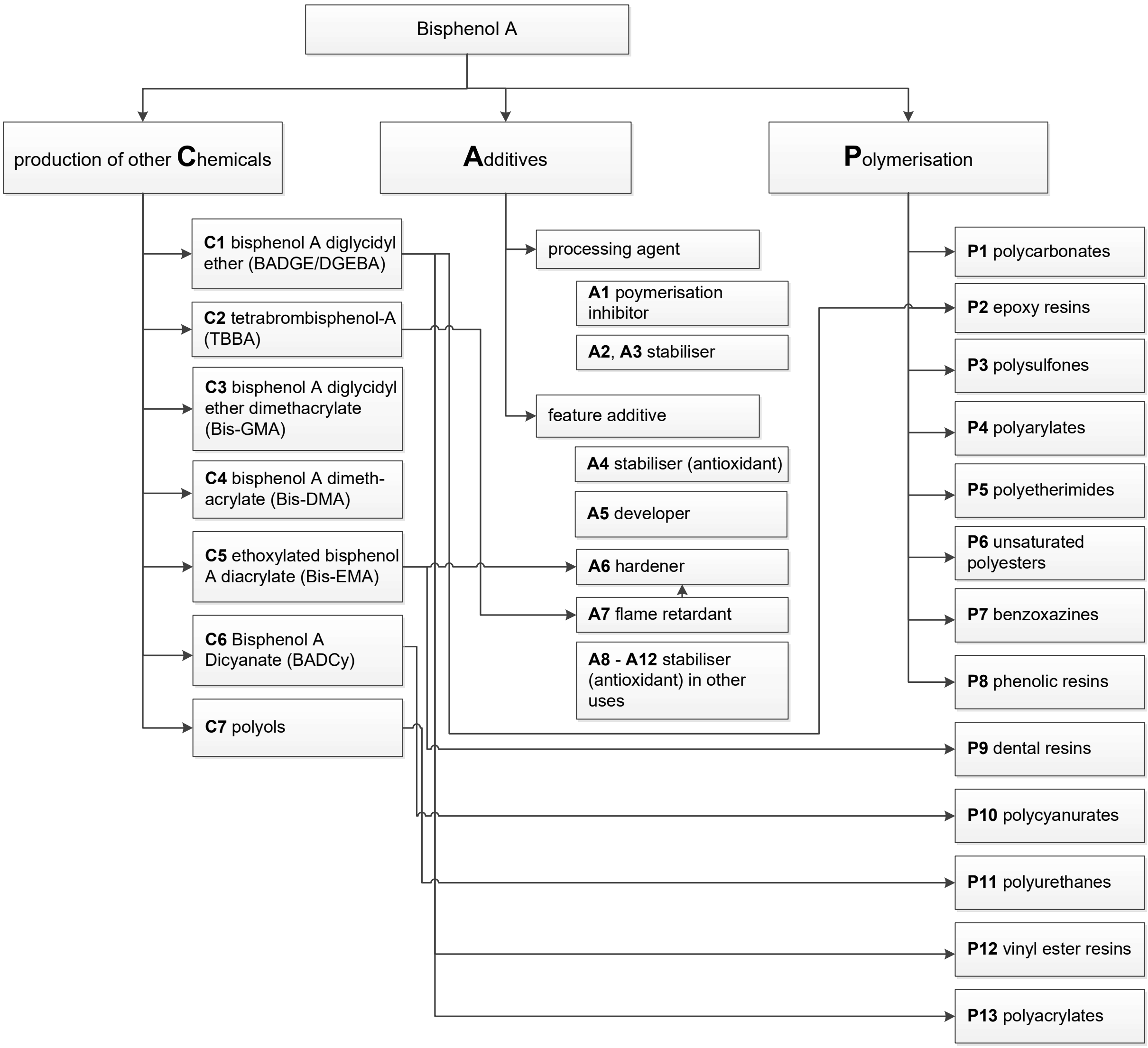


Table 2: Use and function of BPA

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

Objective	**Use and function**
	C6 production of bisphenol A dicyanate (BADCy) **C7** production of polyols
processing **A**gent	**A1** inhibitor for the polymerization of polycarbonates
processing **A**gent	**A2** stabilizer to prevent thermolysis and oxidation in PVC processing
processing **A**gent	**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)
feature **A**dditive	**A5** photo-developer in thermal paper
feature **A**dditive	**A6** hardener in epoxy resins
feature **A**dditive	**A7** flame retardant in polymers
feature **A**dditive	**A8** stabilizer (antioxidant) to prevent oxidation in chain oil
feature **A**dditive	**A9** stabilizer (antioxidant) to prevent oxidation in break fluids
feature **A**dditive	**A10** stabilizer (antioxidant) to prevent oxidation in heat transfer fluids
feature **A**dditive	**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

Objective	Use and function
	P11 polymerisation of polyurethanes
	P12 polymerisation of vinyl ester resins
	P13 polymerisation of acrylates

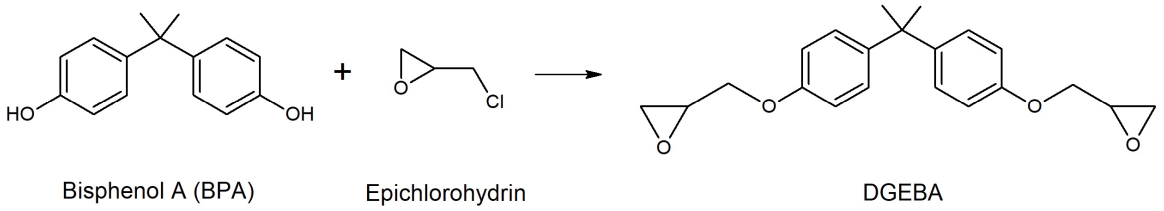
Sources: SKZ-KFE gGmbH, UBA (2010), Hahladakis et al. (2018), Schaefer Additivsysteme (2021), Dow (2014), GEM-Chem (2017), Ramboll Environ (2019), Aabøe et al. (2015), Dorobantu (2012), Dröge et al. (2018).

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)

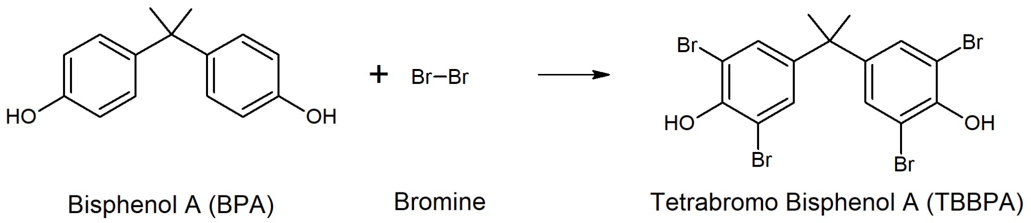
Bisphenol A diglycidyl ether (DGEBA, BADGE) (C1)

Bisphenol A diglycidyl ether 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).



Tetrabromobisphenol A (C2)

BPA is used to produce tetrabromobisphenol A (TBBPA, EC No. 201-236-9, CAS No. 79-94-7) 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.

TBBPA is also used in the manufacture of derivatives, such as TBBPA bis(methyl ether), bis(bromopropyl ether), bis(allyl ether), bis(2-hydroxyethyl ether), brominated epoxy oligomer, and carbonate oligomers. The main use of these derivatives is as flame retardants. This substance is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing and at industrial sites. Based on the results of biodegradation tests, TBBPA is not readily biodegradable but can undergo primary biodegradation to form several products, including BPA.[20]

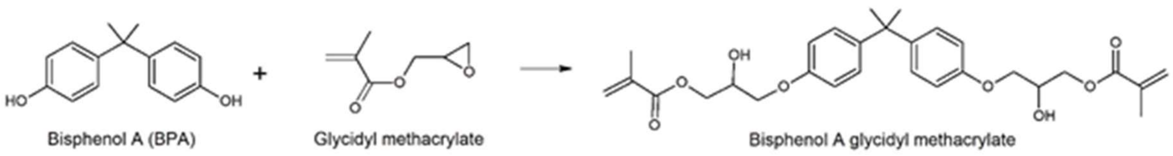
It is used in the following activities or processes at workplace: the low energy manipulation of substances bound in materials or articles, production of mixtures or articles by tabletting, compression, extrusion or pelletisation and high energy work-up of substances bound in materials or articles (e.g. hot rolling/forming, grinding, mechanical cutting, drilling or sanding).

Release to the environment of this substance can occur during industrial use: industrial abrasion processing with low release rate (e.g. cutting of textile, cutting, machining or grinding of metal) and in the production of articles. Other release to the environment of this substance is likely to occur from: outdoor use in long-life materials with low release rate (e.g. metal, wooden and plastic construction and building materials) and indoor use in long-life materials with low release rate (e.g. flooring, furniture, toys, construction materials, curtains, foot-wear, leather products, paper and cardboard products, electronic equipment).

This substance can be found in complex articles with no intended release, e.g. machinery, mechanical appliances and electrical/electronic products (e.g. computers, cameras, lamps, refrigerators, washing machines – important is the usage in printed circuit board laminates). This substance can be found in products with material based on: plastic (e.g. food packaging and storage, toys, mobile phones).[21]

Bis-GMA/Bis-DMA (C3, C4)

Dental composites bisphenol A glycidyl methacrylate (Bis-GMA) and bisphenol A dimethacrylate (Bis-DMA) are produced with BPA.

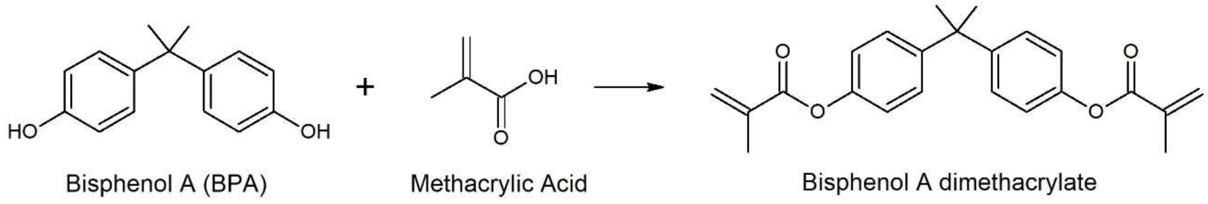


Bisphenol A glycidylmethacrylate can be synthesized in two different ways. The first route (shown above) starts with BPA and glycidyl methacrylate as educts, which then react via a ring opening reaction. On the second pathway, methacrylic acid is reacted with bisphenol A diglycidyl ether (BADGE/DGEBA) to form Bis-GMA.

---

[20] Scientific Committee on Health and Environmental Risks (SCHER): 2,2′,6,6′-Tetrabromo-4,4′-isopropylidene diphenol (Tetrabromobisphenol-A) Opinion adopted on1 15 January 2008: https://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_071.pdf

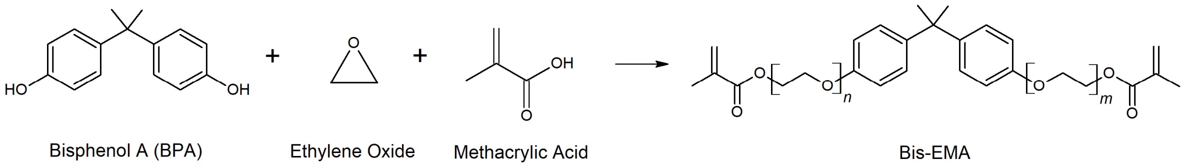
[21] https://echa.europa.eu/de/brief-profile/-/briefprofile/100.001.125



A condensation reaction between BPA and methacrylic acid leads to the formation of Bis-DMA.

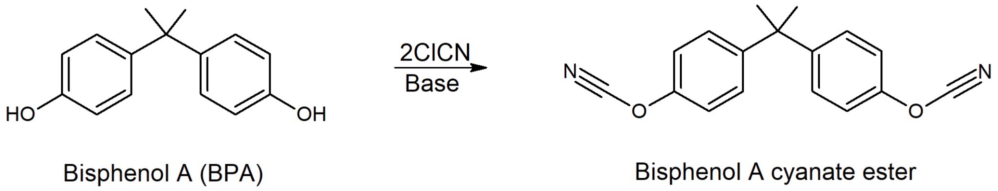
Ethoxylated Bisphenol A Diacrylate (Bis-EMA) (C5)

Ethoxylated bisphenol A diacrylates are very common monomer compounds that are used for the synthesis of dental resins *(P9)* and other acrylic polymers. Bis-EMA is mainly synthesized from BPA, ethylene oxide and methacrylic acid.



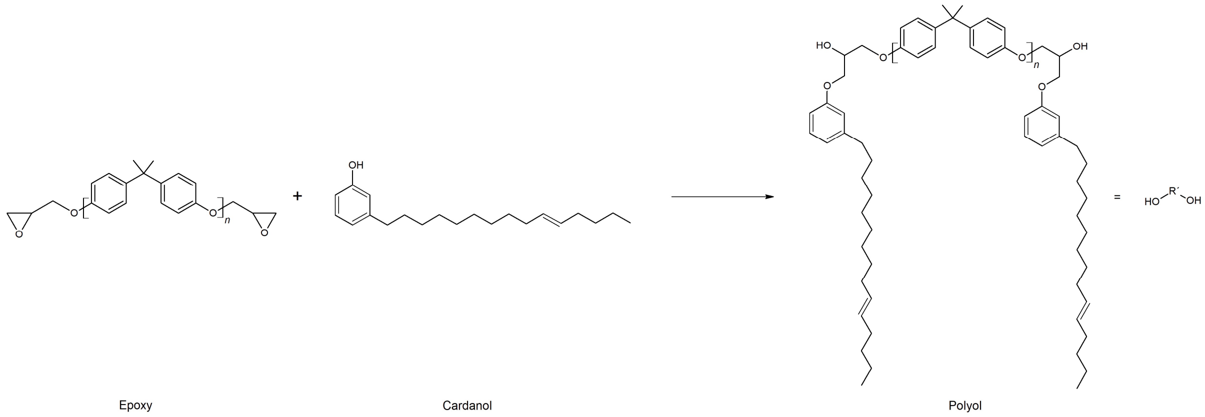
Bisphenol A Dicyanate (BADCy) (C6)

Cyanate esters are used in high-performance structural composites *(P10)*, 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.



Polyols (C7)

Bisphenol A based Polyols can be used in both water-based and solvent-based coatings. They are furthermore used to produce certain Polyurethanes *(P11)*. An example for the synthesis of a cardanol based polyol is given in the scheme below.



A bisphenol A epoxy (bisphenol a diglycidylether) is reacted with cardanol to form the polyol product. This product can then further react with an isocyanate species to form the corresponding polyurethane.[22]

A.2.1.2. Use as an additive (A)

About 2%[23] of BPA are used as an additive 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.

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.

Pre-formulation/mixtures (masterbatches)

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.

In polymers as a polymerization inhibitor (A1)

BPA is used in free radical polymer chain reactions as a polymerization inhibitor. The function of BPA is to deactivate the free radicals that are necessary for the polymerization

---

[22] https://patents.google.com/patent/KR20160091924A/en

[23] FKZ 37196540, cf. Annex H

of the monomers 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 radical polymerization of other plastics, 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 as 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 unwanted polymerization of vinyl monomers during their processing, storage, and transportation (Lartigue-Peyrou, 1996).

BPA also serves as a stabilizer (A4) and as part of an additive package for PVC processing and as a stabilizer 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).

Information from Stakeholder consultations

As part of the second CfE, various stakeholders also submitted information on the use of BPA in PVC. BPA is still applied in products made of PVC in the automotive industry as well as medical technology. At the end of service life, BPA from PVC products plays a role in the recycling of plastics.

In the automotive industry, BPA is used as an additive in lubricants, brake fluids, greases, in thermoplastics and also in PVC. BPA is mainly used as an epoxy hardener and in PVC cables. Both uses of BPA in the automotive industry are declining in their quantities. Alternatives already exist, so that the use of BPA both as an epoxy hardener and in PVC is no longer necessary. Alternatives are therefore technically feasible and are already used in many cases, say the stakeholder. There are also reports of compounding use, where the PVC cable sheathing is mixed with non-hazardous plasticisers to produce a recycled compound

In the medical field, there are thousands of uses for BPA-based polymers in medical devices and in vitro diagnostic equipment. The information from Medtech Europe shows that PVC-based products are also used in medical technology (e.g. printed circuit boards and thermistors). According to the Medical Devices Regulation (MDR) the presence of ED substances above 0,1% w/w require a risk-benefit assessment and alternative assessment as adequate justification of presents in an article. Articles that go in or on humans or (re)administer or store medicine/fluids/gas will be labeled as containing the hazardous substances if > 0,1% w/w is met and it will be mandatory for the manufacturer to provide the labelled information (Unique Device Identifiers (UDI) data elements) to the UDI database. This information on the devices will be accessible to the public via the European Database on Medical Devices.

It is worth noting that European PVC manufacturers have reported to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) that they no longer use BPA in PVC production. This would indicate that this ingredient was used in the medical sector to a certain extent before this transition was undertaken. Alternatively, it could be from outside the EU, where a similar declaration has not been made.

However, no information on the quantities of BPA as an additive in PVC used in the respective sectors (automotive industry, medicinal sector etc.) has been obtained. Therefore, a quantitative assessment of the use of BPA in these sectors is not possible here. In this respect, the use of BPA in PVC in the medical sector is expected to decline in the same way, as described above for the automotive sector.

Especially in PVC-P recyclates BPA can be present via old stabilizer formulations. BPA is present as an undesirable contaminant in plastic/rubber cable sheathing waste generated after stripping cables for copper/metal recovery and the sorted PVC fraction, which is further recycled. The PVC fraction from cable sheathing is mainly processed for the direct production of articles in traffic management (e.g. road cones, pedestals, cable bridges) by compression moulding. Other uses include riding tracks, stable equipment and industrial mats.

Stakeholders estimate that between 110,000 t and 140,000 t of PVC from post-consumer cables are recycled in the EU, including the UK, Norway and Switzerland. Of this, 100,000 t of the products are then used in the EU.

Thermal paper (A5)

In thermal paper (TP), BPA is used as a photo developer that, during heating and/or change in pH, reacts with the leuco dye (usually spirolactones, fluoranes, spiropyranes, etc.) which in turn changes into its colored form. In this case, BPA acts as a weak proton donor. Protonating the leuco dye leads to a ring opening reaction of the lactone moiety and the formation of the cationic blue carboxylic acid form of the dye (van Es, 2014). TP can be used for cash register receipts, paper for certain printers, labels, tickets, lottery tickets, stickers, fax paper, bank notes, etc. (Fischer et al., 2014). The use of BPA in TP has been restricted in the EU under REACH with a concentration limit of 0.02% in place since January 2020.[24]

Epoxy resins/phenolic hardener (A6)

In some epoxy resins, BPA is used as a phenolic hardener. During the curing process, BPA reacts with the epoxy components of the resin, leading to crosslinking of the polymer chains and the formation of a very stable three-dimensional polymer network. Upon reaction with the epoxy resin BPA is transformed and becomes an integral part of a highly crosslinked, three-dimensional polymer matrix (ECHA 2019).

Flame retardants (A7)

BPA serves as a flame retardant in the form of its brominated derivative tetrabromobisphenol A (TBBPA). TBBPA is directly synthesized from BPA and is employed either as an additive (admixture without chemical reaction) or reactive flame retardant in polymers such as epoxy resins, polycarbonate or acrylonitrile butadiene styrene (ABS). In contrast to its use as an additive, TBBPA as a reactive flame retardant is chemically incorporated into the polymer backbone and is thus an integral part of the matrix. During combustion, TBBPA undergoes thermal degradation to release active hydrogen and bromide atoms into the gas phase which quench the highly reactive H or OH radicals in the

---

[24] Commission Regulation (EU) 2016/2235 of 12 December 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bisphenol A (Text with EEA relevance): https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.337.01.0003.01.ENG&toc=OJ:L:2016:337:TOC

flame, decreasing the probagation of the radical oxidation reaction of combustion (Dagani et al. 2000; Morgan 2015; Salmeia et al. 2015).

Information from Stakeholder consultations

[1] This confidential information is contained in a separate annex which is not available in the published version of the dossier.

Chain oil, brake fluids, heat transfer fluids, lubricant formulations, production of tyres (A8-A12)

Similar to its use as an antioxidant in the stabilisation of plasticisers for PVC production, BPA is also used in the stabilisation of chain oil, brake fluids, heat transfer fluids as well as lubricant formulations, preventing oxidative degradation of those systems. In tyre production, BPA is employed as a part of the compounding formulation. In the presence of the other ingredients and during the curing process, the bisphenol A becomes incorporated into the polymer matrix. It is used as an antioxidant which appears to be specifically for the compounding phases, and it is intended to protect the materials at this stage. There is no indication that it is intended to be the major antioxidant in the actual tyres, and it is not expected to be present at significant levels in the finished product (Groshart et al. 2001).

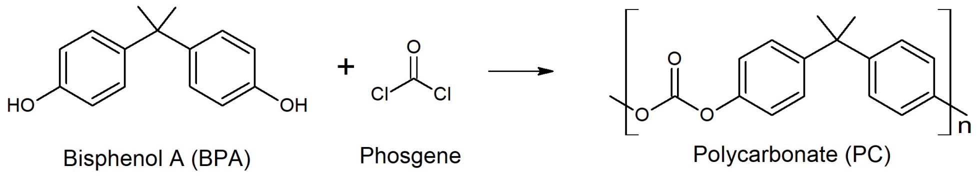
Information from Stakeholder consultations

Other applications of BPA as an additive are adhesive products (cured, bonded and coated, or small exposable surface). Most of these products contain 0.1% BPA. BPA is further used as an additive in powder coatings for crosslinking during curing.

A.2.1.3. Polymer/Plastics (P)

Polycarbonate (P1)

The production of polycarbonate 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 (Plastics Europe, 2012 and PE, 2012b).



Polycarbonates are polyesters of carbonic acid. Although other synthesis routes are possible, the most commonly used polycarbonates are synthesised from BPA and phosgene (see figure above). 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).

Polyester carbonates contain carbonate and polyester structures and are formed by condensation reaction between BPA, phosgene (EC no. 200-870-3, CAS no. 75-44-5) and terephthaloyl chloride (EC no. 202-829-5, CAS no. 100-20-9). Classic uses include microwave dishes, hair styling rods, and spotlight reflectors. For more uses in detail see the table below:

Table 3: Use of BPA in polycarbonate (FKZ 36001063)

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

Sector	**Application**
	for policemen, guards to protect from moving machine parts, blends mainly used in automotive and electrical and electronics
Domestic Appliances	Blenders, cooking appliances
Others	

Information from Stakeholder consultations

A large amount of feedback and additional information has been provided by stakeholders regarding the manufacture and use of polycarbonate.

PC is synthesized either via polycondensation of BPA and phosgene in the liquid phase process, or from BPA and diphenylcarbonate (DPC) in the melt process. Residual BPA content in polycarbonate is reasonably controllable in virgin PC.

It 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 < 1 day (disposable medical device) to 25 years (electrical devices, sheets).

The majority of PC applications (> 80%) is not regularly exposed to intense contact to water. Outdoor applications which are exposed to regular contact to water, are usually protected to prevent by coatings or by protective coextruded layers.

[2] This confidential information is contained in a separate annex which is not available in the published version of the dossier.

The difference between demand and production capacity is mainly due to export (SEA 2021). Another stakeholder (CfE2 # 164) states that the use of BPA for the manufacture of PC in the EU approximately 840,000 tons in 2015 and Consumption of PC in the EU of approximately 640,000 tons in 2015 (growth rate 3% 2015-2020; 5% 2020-2025).

60,000-80,000tpa PC films are produced globally with EU 50% share.

Another automobile application not mentioned yet are batteries & powertrains in electric cars, as well as car OEM wall boxes for electric home charging. Other uses of PC include plastic hoods of lamps, plastic manholes, cable distribution cabinets (especially telecommunications), pedestrian signal request devices, radio ripple control receiver, fuse boxes, and applications in aerospace & defense. One stakeholder (CfE2 # 186) mentions the additive use of PC after leather tanning.

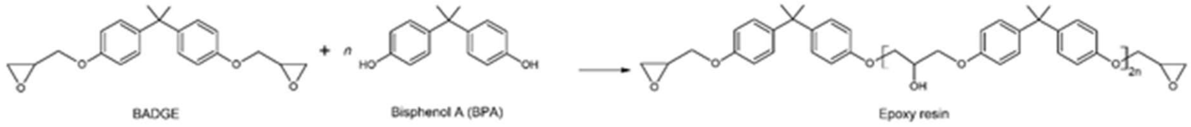
Epoxy resins (P2)

Epoxy resin production is the second largest use of BPA in the EU (see also Chapter C1). 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). 90% of the world production of epoxy resins (1.7 million tonnes in 2008) are 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.

Table 4: Examples for the use of LER and SsER[25]

Product	**Type of ER**
water pipes	LER
flooring	LER
wind rotor blades	LER and SsER
marine coating	LER and SsER
automotive coating	SsER

Epoxy Resins (BPA diglycidyl ether epoxy resins (BADGE resins)) (P2)



---

[25] 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)

The majority of epoxy resins used worldwide are based on BPA. For their synthesis, BPA or BPF is first converted with epichlorohydrin (1-chloro-2,3-epoxypropane, EC no. 203-439-8, CAS no. 106-89-8) to form the respective diglycidyl ether (BADGE/DGEBA in case of BPA, EC no. 216-823-5, CAS no. 1675-54-3). This is then polymerized with bisphenol A or other polyvalent amines as hardeners to form a cross-linked three-dimensional thermoset network. Epoxy resins are characterized by good temperature and chemical resistance and are used in a wide range of different applications. 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).

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). Epoxy resin-based coatings are widely used for corrosion protection. 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 5: Use of BPA in epoxy resins (FKZ 36001063)

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,

Application Class	**Application**
	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, 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 from Stakeholder consultations

Epoxy resins can be used together with phenolic resins or polyesters acrylic resins to form 1 K systems, which are thermally dried or radiation cured and react via a polycondensation. These coatings have a very high chemical resistance and are thus used for coil coating, metal packing and primer as well as corrosion protection of bulk material (for example fasteners) and technical surfaces. Epoxy resins are also used with hardeners, such as amines, amides or polyamines and polyamides to form two- component 2-K-systems. These systems are highly important for heavy corrosion protection, i. e. used for large objects such as bridges, marine applications or off-shore wind parks, but also applications such as floor coverings and epoxy resin primers.

Life for uncured LER and SER is typically 2 years at maximum. Service life of cured Epoxy Products (coatings, adhesives, composites) are usually in a range of several years for home and leisure or electronics, up to 20 and more years in the case of wind rotor blades and composites for cars, or even up to 30 or 40 years in the case of use in aircrafts or building and constructions. During service life coated articles are mainly exposed to wear and tear. app. 50% of the epoxy coating systems are overcoated with UV-resistant topcoats like acrylics or polyurethanes. Epoxy resins degrade in the very top layer (2-7 microns) upon exposure to UV light, a process called chalking.

BPA uses in the Epoxy manufacturing are taking place in industrial settings only. Users of uncured Epoxy Resins and hardeners are industrial users, professionals and selected consumer users.

In individual cases, information of a confidential nature was also submitted, which cannot be reproduced here. Overall, concrete information on the quantities of BPA used in the overall area of epoxy resins was only provided in individual cases. In some cases, no distinction was made between the use of BPA for the production of epoxy resins or polycarbonate. It was also not always clear whether the quantities indicated referred to the BPA itself or to the products made from it. Also, a breakdown of the classified amount of BPA (t/a) by use (e.g. adhesive, sealant, coating, additive, hardener) was not possible. In this respect, no up-to-date information on the use of the quantity of BPA (t/a) by sector (e.g. motor vehicles, aviation, electricity distribution networks) could be derived from the isolated data.

The main areas of application for epoxy resins are as follows:

- Building and construction (e.g. panels, corrugated/flat sheets, flooring, wood coatings, profiles, infrastructure, bridges, sanitary ware, swimming pools, subsea construction etc.)
- Automotive and transportation (e.g. components for cars, trucks and trains, container panels, pipes, brake fluids, lubricants, greases)
- Electric and electronic equipment, EEE (e.g. electric insulation, printed circuit boards, components/modules, semiconductor devices)
- Industrial application and food industries (e.g. machinery, metal primer, food package, can coatings)
- Wind energy industry (e.g. blades and spar caps for wind turbine blades)
- Aerospace and defence products (materials for the manufacture, maintenance and repair)
- Medicine and medical instruments: (e.g. MRI machines, cardiac catheters, medical probes and ultrasound; Bonding various parts of breathing apparatus, from tubing to masks and bags; Bonding cannulae to hubs in needle assemblies; Prosthetics and implantable devices)
- sports and leisure: (e.g. rackets (tennis, badminton, squash), golf clubs, boats, ski and snowboards)

From the dossier submitter's point of view, the information in **Error! Reference source not found.** on the various application classes and uses of epoxy resins is therefore comprehensive.

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)[26].

In total 323,000 tonnes have been produced and sold into the five main sectors of application. EU manufactures representing >80% of the EU Epoxy Resin market. The quantities are distributed as follows:

-	1. Construction:	93,000t (29%)
-	2. Energy:	81,000t (25%)
-	3. Transport	44,000t (14%)

---

[26] PlasticsEurope (2019): Epoxy Resins updated Socio-Economic Report. https://epoxy-europe.eu/wp-content/uploads/2020/07/Epoxy_socioeconomic_report_2019_main-findings.pdf

- 4. Home, leisure, ICT and medical	36,000t (11%)
- 5. Food & water	19,000t (6%)
- Other	48,000t (15%)

The report describes the main sectors of the use of ER.

In construction, epoxy resins are used extensively as extra strong adhesives, sealants and fillers. Epoxy resins are often marketed as replacements for mechanical fasteners and bridge deck repair and are suitable for indoor and outdoor use due to their strength, durability and chemical resistance. Epoxy resins are also widely used for flooring as they protect against wear, prevent slipping and have high chemical and abrasion resistance. This is the largest end-use sector surveyed, accounting for 22% of epoxy resin manufacturers' sale.

Epoxy resins are used in the „Energy Sector” for manufacturing of wind turbine blades as structural elements, (reinforced fiber composites), as coatings of generators and other components and as adhesives. They are further used in electrical and energy distribution systems as sealants, coatings and adhesives, as well as in the manufacturing of primary components such as transformers, insulators and bushings. They are used also as protective coatings in large generators and on printed circuit board. (Windenergy 39,000tpa; electrical and energy distribution systems 42,000tpa).

In the transportation sector, epoxy resins are used in cars, trucks, motorcycles, trains, boats and aircraft. In internal parts, advantages include weight reduction which also leads to lower greenhouse gas emissions. Further reasons are increased durability, mechanical strength and heat resistance as well as to reduce the need for repair and replacement. In aviation and aerospace, epoxy resins have supported the increased use of lightweight composite components with improved strength and durability of aircraft components. Last not least their use increases the safety and reliability of components, prevents corrosion, helping to extend operational life. (aircraft 7,000tpa; other 37,000tpa).

In the fourth sector, epoxy resins are used in various sporting equipment, in composites with glass or carbon fibre. Another field of application is in DIY Home improvement, some of the most common uses of epoxy resins are in sealants, adhesives, mortars and for the repair of woods and plastics. In ICT applications, like internal circuits, transistors and smartphones epoxy resins protect vital components from light, humidity, dust and electrical and physical shocks. In the medical field, the uses are surgical instruments, diagnostic equipment and prosthetics.

The use of LER (liquid epoxy resin) and SER (solid epoxy resin) in the different areas can be differentiated as follows:

- Energy Sector (>95% LER, <5% SER)

- Construction (>90% LER, <10% SER)

- Transport (LER/SER 50:50%)

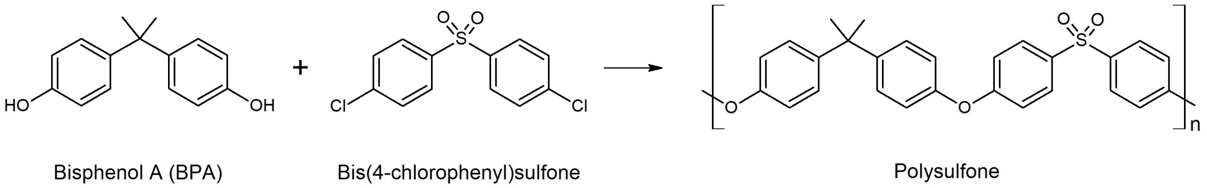
- Home & Leisure incl. Information & Home & Medical, Communication Technology and Medical (<50% LER/>50% SER)

- Food and Water (>70% SER)

A comparison of this information with the results according to Annex H on the use of BPA for epoxy resins and the quantities used gives a somewhat different picture. In contrast to the volume of 323,000tpa for the processing of epoxy resins (representing 19% of the total tonnage of BPA used for the production of polymers in Europe), a total quantity of 275,000tpa was calculated in Annex H. The latter is considered to be the best estimate based on data from all identified sources. In this respect, there is a difference of > 40,000tpa to the total amount of BPA for epoxy resins compared to the PlasticsEurope survey. However, in the second CfE PlasticEurope points out that the different categories quantified should not be confused with pure products, as Novolacs or BPF-based resins often react with BPA-based resins.

Polysulfones (P3)

BPA is also used as monomer in the manufacturing of other polymers: polysulfones, polyacrylates, polyetherimides, unsaturated polyesters, polymerisation of benzoxazines, polymerisation of phenolic resins, polymerisation of dental resins, polymerisation of dental resins. High-temperature (HT) polymers of the polyarylsulfone family (Polyphenylsulfone - PPSU, Polysulfone - PSU, Polyethersulfone - PESU) are characterized by extraordinary, inherent flame retardancy and high transparency. Polyetherimides (PEI) are also amorphous HT thermoplastics and therefore often compete with PESU or PPSU - especially in injection molding applications.



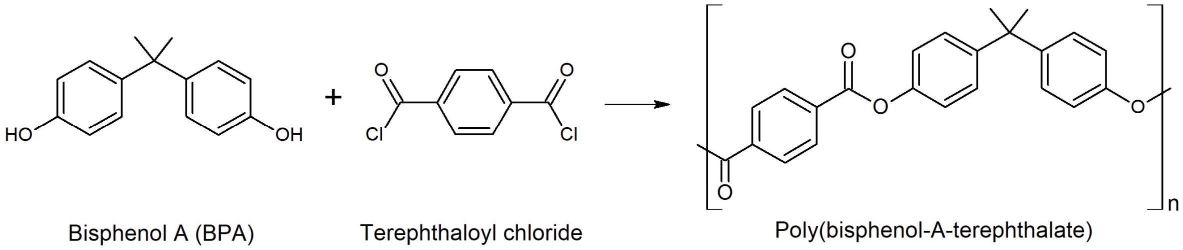
Polysulfone resins are made by condensation of the disodium salt of BPA with 4,4-dichlorodiphenyl sulfone. They are used in electrical components, appliances, transport, medical equipment, pumps, valves and pipes, due to their good thermal stability, toughness, transparency and resistance to degradation by moisture (EFSA, 2015).

Information from Stakeholder consultations

Medical applications of PSU include the transparent portion of anaesthesia masks, pharmaceutical filter housings, heart valve sizers, used to estimate the size of the heart valve when it is replaced, dialysis filtration cartridges used for continuous renal replacement therapy (also used for filter housings and caps), the outer shell of implantable catheter ports used for venous access in oncology, and transparent covers e.g. for surgical instrument trays. Medical applications of PPSU include Dental instruments and Surgical instrument cases.

PPSU has medical applications too, such as devices for supplying dialysis fluid in dialysis therapy, but is also used as a polymeric pipe fitting for sanitary and drinking water systems.

Polyarylates (P4)



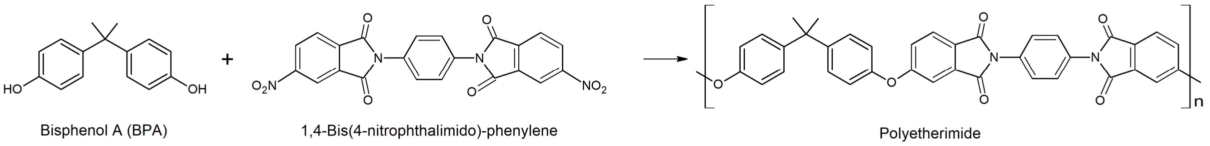
Polyarylates are a group of polymers of which only a part contains BPA. These amorphous polymers are formed by copolymerizing BPA with aromatic dicarboxylic acids (mainly terephthalic acid and isophthalic acid). Polyarylates have good thermal resistance and toughness, in combination with clarity and stability to UV light, so that they find application in automotive, electronics, aircraft and packaging industries (EFSA, 2015).

Information from Stakeholder consultations

Polyarylate (and polyethersulfone) are used as raw materials to produce the PEPA® hollow fiber membrane. Various filters used for dialysis therapy (for purifying dialysate or blood, and thus with the membranes directly in contact with each) contain about 10,000 PEPA® hollow fiber membranes.

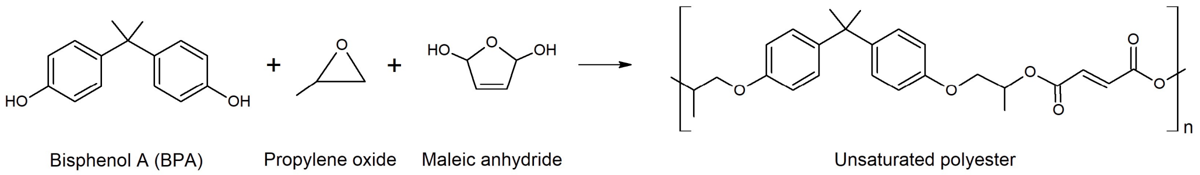
Polyarylate is also used for the manufacture, maintenance and repair of aerospace and defence products.

Polyetherimides (P5)



Polyetherimides (PIs) are synthesized by reaction of BPA with 1,4-Bis(4-nitrophthalimido)-phenylene or the melt condensation of BPA bis(phthalic anhydride) with a diamine, usually m-phenylenediamine. PIs are used in medical applications, in electronic components and in aircraft interiors, also in food contact applications, in blends with polycarbonates. Their properties of good thermal and hydrolytic stability is a consequence of the ether linkage, so that migration of BPA, if there is any, would be attributed to unreacted BPA in the dianhydride starting substance (EFSA 2015).

Unsaturated BPA Polyesters / Polyester resins (P6)



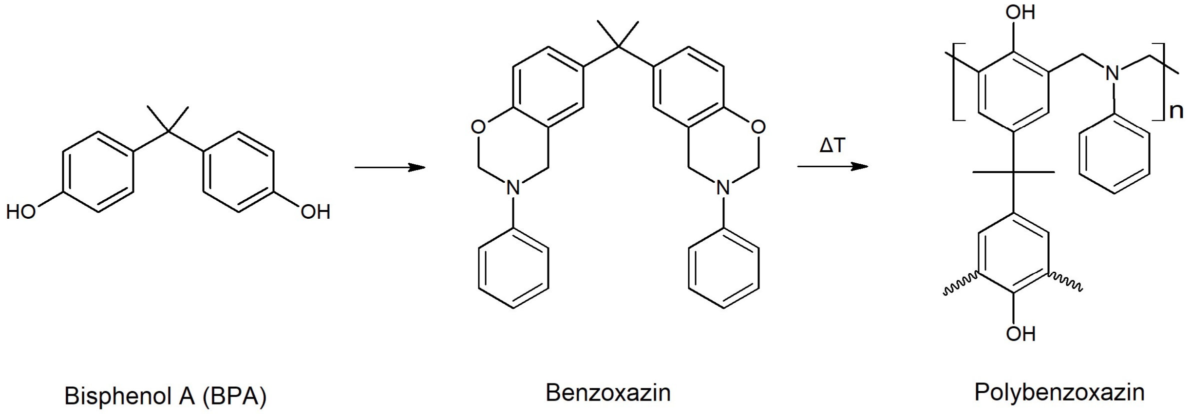
Unsaturated polyester resins are generally synthesized by reacting diols with dicarboxylic acids or their anhydrides. Although the majority of commercial unsaturated polyester resins are derived from phthalic and maleic anhydride as the saturated and unsaturated component and 1,2-propylene glycol as the diol in the polymer, there are unsaturated polyesters that contain bisphenol A as building blocks. The linear non-crosslinked polyesters are formed for example via a polycondensation reaction between bisphenol A, propylene oxide and maleic acid anhydride. If necessary, the resulting polyesters can further be crosslinked by a radical chain reaction with styrene or other vinyl monomers as hardeners (Polymer Properties Database 2020).

Information from Stakeholder consultations

Unsaturated polyester (UP) resins and epoxy vinyl ester (VE) resins are liquid products containing linear unsaturated polyester polymers respectively epoxy vinyl ester polymers (50-70%) and mainly styrene (30-50%). Uses include the fields Building (panels, corrugated/flat sheets, profiles, infrastructure, bridges, sanitary ware, swimming pools, subsea construction etc.); Tanks, Containers, Pipes (incl. relining of pipes); Electrical (wind turbines, appliance, circuitry boxes); Marine (pleasure boats, utility vessels); Automotive (cars, trucks, trains, container panels); Castings (artificial stone, cultured marble etc.); and Formulated products (gelcoats, adhesives, putties).

Polybenzoxazine resin (P7)

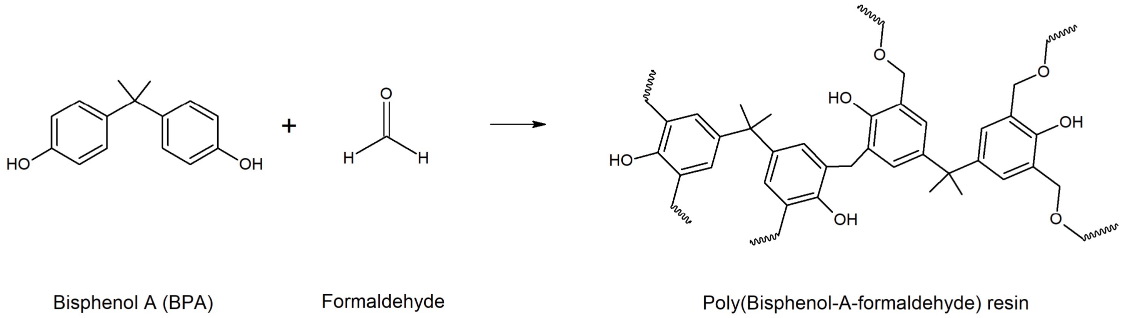
Polybenzoxazines are a relatively new class of thermosets. In the first reaction step, phenolic compounds such as bisphenol A are reacted with formaldehyde and an aromatic amine to form a benzoxyzine. The benzoxazine then undergoes thermal ring opening polymerization to form the fully cured thermoset resin.



Polybenzoxazines have a high decomposition temperature and are therefore mainly used in high temperature applications. In addition to that they show little cure shrinkage, high flame retardance and good thermal mechanical properties (Polymer Properties Database 2020). One field of application is the manufacture, maintenance and repair of aerospace and defense products.

Phenolic resins (P8)

Phenolic resins are thermosetting plastics which are characterized by their hardness and breaking strength. They are often used in cookware and electrical and electronic (E&E) applications. Phenolic resins 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).

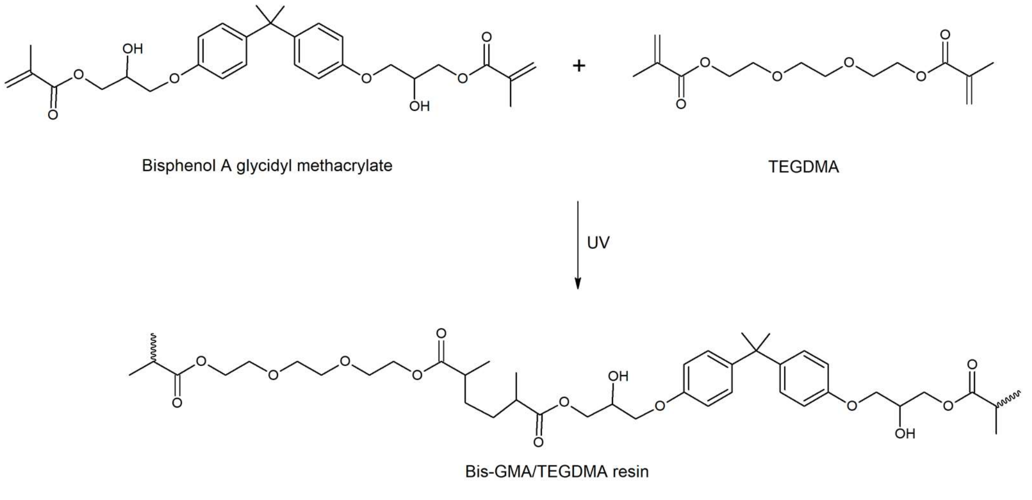


Information from Stakeholder consultations

Another application of phenolic resins is the production of special prepregs for ballistic protection. Epoxy resins can also be used together with phenolic resins or polyesters acrylic resins to form 1 K systems, which are thermally dried or radiation cured and react via a polycondensation. These coatings are thus used for coil coating, metal packing and primer as well as corrosion protection of bulk material (for example fasteners) and technical surfaces.

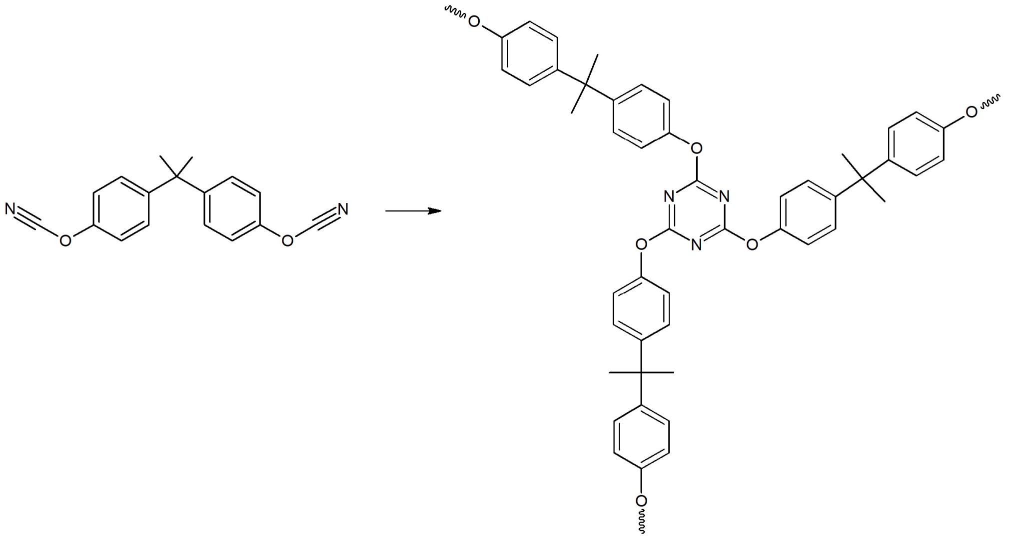
Dental resins (P9)

BPA containing methacrylic compounds such as Bis-GMA, Bis-DMA and Bis-EMA are widely used as monomers in dental composites, dental sealants and dental cements. Hardening of those compounds typically take place by a photopolymerization reaction (UV irradiation) between the BPA-containing component and a low-viscosity diluent monomer such as triethylene glycol dimethacrylate (TEGDMA, EC no. 203-652-6, CAS no. 109-16-0). The general reaction mechanism is shown below. Dental sealants and coatings have both direct and indirect contact with patients.



Polycyanurate (P10)

Polycyanurates are a class of polymer compounds with distinct stability. The uncured monomers and prepolymers, the cyanate esters and triazine resins, contain reactive cyanate functional groups that undergo a cyclotrimerization reaction in the presence of a suitable catalyst and/or when heated to form highly crosslinked network polymers the so called polycyanurates (Polymer Properties Database 2020). One field of application is the manufacture, maintenance and repair of aerospace and defense products.

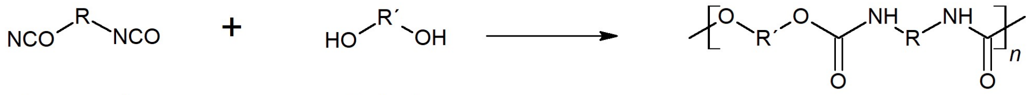


Bisphenol A cyanate ester

Polycyanurate

Polyurethanes (P11)

Polyurethanes are synthesized by reacting a polyol (e.g. a bisphenol species) with an isocyanate. They can be used in a variety of different applications. Those applications range from foams used in automotive and truck seating, upholstering and bedding over footware, structural parts in electronic instruments, flexible straps and bands to cast and injection molded components for various materials in agriculture, military and automotive industry.



Isocyanate

Polyol

Polyurethane

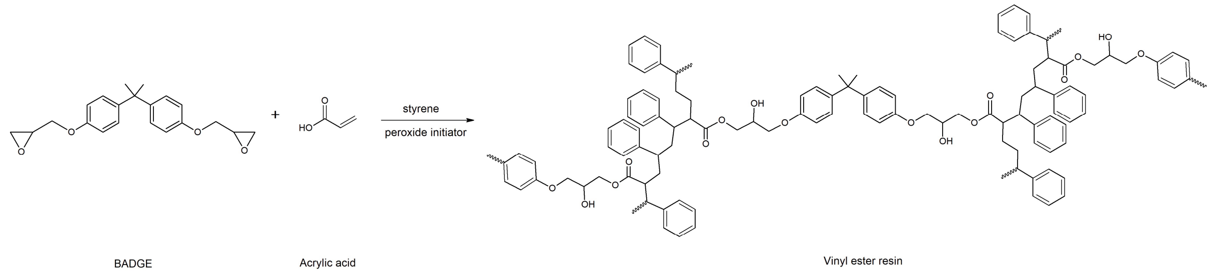
Information from Stakeholder consultations

Approximately 50% of the epoxy coating systems are overcoated with UV-resistant topcoats like e.g. polyurethanes. In low corrosivity environments direct-to-metal polyurethanes are to some extent alternatives to epoxy resins. However, aside from the health concerns related to the isocyanates, the resistance of polyurethane coatings is much lower and adhesion properties are usually not as high as for epoxy coatings. Together with epoxy resins, the polyurethanes are an important substance class for polyaddition resins, which are used for two component (2K) coatings.

Polyurethanes are also mentioned as one of the alternatives for phthalates in medical devices.

Vinyl ester resins (P12)

For their synthesis, BPA is first converted with epichlorohydrin to form bisphenol A diglycidyl ether (BADGE/DGEBA) which is then converted via an addition reaction with acrylic acid to form an ester with an acrylic moiety. This vinyl monomer can then be dissolved for example in styrene and a peroxide initiator is added to the reaction mixture to start the radical copolymerization. The vinyl ester forms a crosslink between the polystyrene segments.



Information from Stakeholder consultations

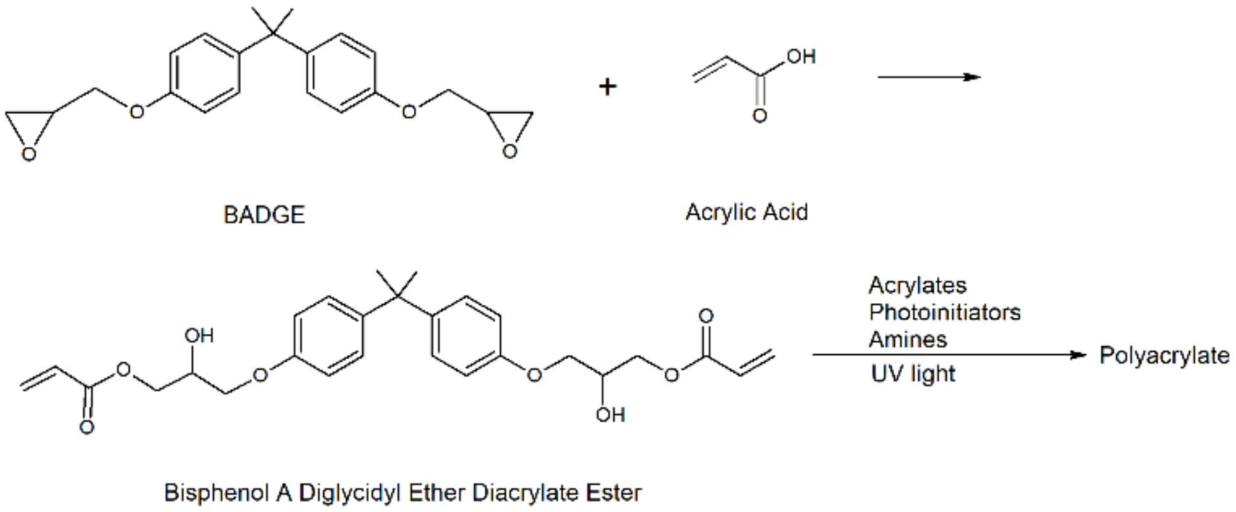
Vinyl ester resins, once cured, are highly resistant to hydrolysis and to chemicals. Vinyl ester resins are critically important for many chemicals and gasoline containment vessels, chemical processing operations, seawater desalination operations, marine applications, renewable energy applications (e.g., blade used in wind turbines), and the manufacture, maintenance and repair of aerospace and defense products. Other uses include the fields of building (panels, corrugated/flat sheets, profiles, infrastructure, bridges, sanitary ware, swimming pools, subsea construction etc.), pipes (incl. relining of pipes), electrical (appliance, circuitry boxes), automotive (cars, trucks, trains, container panels), castings (artificial stone, cultured marble etc.) and formulated products (gelcoats, adhesives, putties).

Polyacrylate (P13)

In addition to polyacrylates for dental resins (P9) BPA is also used in polyacrylate polymers for overprint varnishes (OPVs), inks or for the coating of textiles. Due to their high curing speed and relatively low price, OPVs are almost always based on BPA-containing epoxy acrylates such as bisphenol A diglycidyl ether diacrylate ester (Arceneaux et al. 2018)[27]. The relatively high viscosity of the BPA epoxy acrylate allows a high quantitative use in order to reach the desired viscosity range for the OPV. OPVs are used for example for multi wall bags, wax based substrates, or for wet trapping oil based litho inks. Furthermore, many flexo, litho and screen inks use BPA epoxy acrylates in their base formulations to enhance adhesion, resistance properties, cure speed or tack adjustment.

---

[27] Arceneaux, J. A.; Wang, T. (2018): Bisphenol A free resin options for inks and overprint varnishes. https://radtech.org/proceedings/2018/Printing%20+%20Packaging%20I/Arceneaux_JoAnn-Bisphenol-A-Free-Resin-Options-for-Inks-and-Overprint-Varnishes.pdf, accessed 02.06.2021.



The content of BPA and other compounds is highly variable and depends on the overall desired product properties as well as the application.

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. 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.

For polycondensate reaction BPS is starting material, condensing BPS with formaldehyde. The poly-condensate is synthesized in a closed system (unreacted BPS will remain). A second kind of reaction is the sulfonation of phenol and condensation with formaldehyde (formation from BPS and BPF is side product from partial reaction).
The Syntans can be liquid products or sprayed powders, which get added to the leathers in an aqueous float in a tanning drum. Ca. 90% is taken up by the leather, ca. 10% remain in the float. The float is submitted to a waste water treatment process.

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 a yearly 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).

Table 6: Use of BPA in other polymers

Code	Polymer	Application Class	Application
P3	Polysulfone	Membranes	hemodialysis, drinking and ultra-pure waters, gas separation, food & beverage concentration, dairy
		Medical and Healthcare	surgical trays, nebulizers, humidifiers
		Food service	microwave cookware, beverage and food dispensers, milking machine parts
		Plumbing	hot water fittings, manifolds, mixer tape cartridges
P4	Polyarylates	Medical and Healthcare	Dental composite resins (BPA as impurity)
P5	Polyetherimide		Electronic and Electrical, Automotive, aircraft industries, microwave applications
P6	Unsaturated polyesters	Bottles and Packaging	BPA fumarates: storage tanks, process vessels
		Adhesives, Medical and Healthcare	BPA dimethylarcylates: adhesives, dental compounds
P7	Benzoxazines	Composites, Coatings, Adhesives, Encapsulant´s Manufacturing	Variety of uses, capability to exhibit the thermal and flame retardant properties of phenolics along with mechanical performance and molecular design flexibility
P8	Phenolic resins	Electrical & Electronics	commutators in electric motors, water pumps/housing, vacuum pumps
		Food service	cookware (handles for pans etc.)
P9	Dental resins	Medical & Healthcare	dental composites, dental sealants and dental cements

Code	Polymer	Application Class	Application
P10	Polycyanurates	Aerospace	fibre enforced composites
		Electrical & Electronics	chip adhesives, thermal interfaces
P11	Polyurethanes	Clothing	textiles (spandex), footwear
		Automotive	foams, truck seating, upholstering and bedding
		Diverse	electronic instruments, flexible straps and bands, injection moulded components
P12	Vinyl ester resins	Diverse	corrosion-resistant components and coatings for tanks, pipes and chimney linings
P13	Polyacrylate	Diverse	Over print varnishes, inks, coating textiles
P14	syntans	leather – e.g. automotive, clothing, shoes, furniture	leather tanning and functioning (fur, hide)
P15	textile auxilliaries (colour fing)	textiles – e.g. clothes, functional textiles	colour fixing agent for polyamide (e.g. spandex, elastane)

Information from UBA research project (Fischer et al., 2014)[28]

In Western Europe, the main use is the production of PC (75% of total BPA), followed by the second largest use in epoxy resin production (17% of total BPA use). Besides that, BPA has been used in a range of other applications and articles, such as TP. All these 'other' applications represented around 2% of the total BPA use whereas the use of BPA in TP only accounts for 0.16% of the total BPA consumption in 2005/2006.

Information from the SPIN data base[29]

In the SPIN database (database on the use of substances in preparations in the Nordic countries) BPA is listed in the following use categories: the highest reported tonnages are found in lubricants and additives, construction material, adhesives and binding agents, paints, lacquers and varnishes as well as process regulators. Minor tonnages are reported for surface treatments, softeners, hydraulic fluids and additives, fillers, stabilizers, anti-

---

[28] https://www.umweltbundesamt.de/publikationen/identification-of-relevant-emission-pathways-to-the

[29] Source: Spin database, http://spin2000.net/ (accessed 03/15/2020)

static agents, insulating materials, intermediates, viscosity adjustors, non-agricultural pesticides and preservatives, reprographic agents.

According to the SPIN database, BPA or products containing BPA are used in the following sectors: construction activities, vehicles, manufacturing of chemicals and chemical products, rubber and plastic products, metals and metal products, electrical equipment, wood and wood products, furniture, machinery, transport equipment, computer, electronic and optical products, paper and paper products, non-metallic mineral products, civil engineering, extraction of crude petroleum and natural gas and air transport.

Information from registrations on ECHA website[30]

ECHA publishes the following information on uses of BPA in the Brief Profile: The substance is used in polymers (product category) and used industrially in the manufacturing of other substances (use of intermediates). In addition, BPA is used for the formulation of mixtures and/or re-packaging, building and construction work as well as for scientific research and development. It is used to manufacture plastic products, chemicals, machinery and vehicles (sector of use). It can be found in complex articles, with no release intended: machinery, vehicles, mechanical appliances and electrical/electronic products (e.g. computers, cameras, lamps, refrigerators, washing machines). Furthermore, the substance occurs in material based on plastic (e.g. in food packaging and storage, toys, mobile phones).

Registered uses

Table 7: Registered uses for BPA currently disseminated on ECHA website

	Use(s)
Manufacture	Industrial Manufacturing of Bisphenol A Industrial Use of Bisphenol A as Laboratory Reagent Manufacture of Bisphenol A
Formulation	Formulation of epoxy resin hardeners Formulation of preparations Formulation, Transfer and Packing Industrial repacking of Bisphenol A Industrial Use of Bisphenol A as Anti-Oxidant for Processing PVC Industrial Use of Bisphenol A for Manufacturing Epoxy Resin Hardeners Industrial Use of Bisphenol A in Epoxy Resin Hardeners Manufacture of thermal paper - formulation into materials Professional Repackaging of Bisphenol A

---

[30] https://echa.europa.eu/de/brief-profile/-/briefprofile/100.001.133 (accessed 06/03/2020)

	Use(s)
	Professional repacking of Bisphenol A
Uses at industrial sites and uses as intermediate	Blending of polycarbonate
	Industrial manufacture of articles made of polycarbonate
	Industrial use
	Industrial Use in Epoxy Adhesives and Encapsulants
	Industrial Use in Polymer Preparations
	Industrial Use of Bisphenol A for Manufacturing Polymers
	Industrial Use of Bisphenol A as Anti-Oxidant for Processing Polyvinylchloride (PVC)
	Industrial Use of Bisphenol A as Anti-Oxidant for Processing PVC
	Industrial Use of Bisphenol A for Manufacturing Chemicals
	Industrial Use of Bisphenol A for Manufacturing Coating Materials
	Industrial Use of Bisphenol A for Manufacturing Epoxy Resin Hardeners
	Industrial Use of Bisphenol A for Manufacturing Epoxy Resins
	Industrial Use of Bisphenol A for Manufacturing Polycarbonate
	Industrial Use of Bisphenol A for Manufacturing Polymers
	Industrial Use of Bisphenol A for Manufacturing Thermal Paper
	Industrial Use of Bisphenol A for Manufacturing Thermal Paper (including paper recycling)
	Industrial Use of Bisphenol A in Epoxy Resin Hardeners
	Industrial use of epoxy resin hardeners
	Manufacture of coating materials
	Manufacture of epoxy resin hardeners
	Manufacture of epoxy resins
	Manufacture of epoxy resins hardener
	Manufacture of other substances
	Manufacture of polycarbonate
	Recycling of thermal paper

	Use(s)
	Use of Bisphenol A as laboratory reagent Use of epoxy resin hardeners
Uses by professional workers	Professional Repackaging of Bisphenol A Professional Use of Bisphenol A as Anti-Oxidant for Processing Polyvinylchloride (PVC) Professional Use of Bisphenol A as Anti-Oxidant for Processing PVC Professional Use of Bisphenol A in Epoxy Resin Hardeners Professional use of Epoxy Resin Hardeners Use of epoxy resin hardeners Use of epoxy resin hardeners, indoor flooring
Consumer Uses	Consumer use of Bisphenol A in articles made of PVC Consumer use of Bisphenol A in articles of epoxy resins
Article service life	Consumer indoor use of articles made of polycarbonate Consumer outdoor use of articles made of polycarbonate Consumer Use of Articles made of Epoxy Resins Consumer Use of Articles made of Polycarbonate Consumer Use of Articles made of Polyvinylchloride (PVC) Consumer Use of Bisphenol A in Articles made of PVC Consumer Use of Bisphenol A in Thermal Paper Consumer Use of Thermal Paper Professional indoor use of articles made of polycarbonate Professional outdoor use of articles made of polycarbonate Professional Use of Articles made of Polyvinylchloride (PVC) Professional Use of Thermal Paper Service life of thermal paper (consumers) Service life of thermal paper (professional worker) Use of recycled paper

A streamlined range of supported and described uses was implemented in a comprehensive update of the joint chemical safety report during the substance evaluation process on BPA in which the dossier submitter acted as the evaluating member state competent authority. As a result, some of the registrants stopped supporting and describing and supporting "additive" uses of BPA, e.g. in PVC or thermal paper (see table below). However, these uses continue to be considered in this dossier as not all registrants have withdrawn from these uses. In the run-up to this dossier, discussions were held with industry representatives, including representatives of the ZVEI (German Electrical and Electronic Manufacturers' Association (Zentralverband Elektrotechnik- und Elektronikindustrie e. V.)). It was also confirmed that soft PVC is still used and BPA is still widely applied for this purpose.

It is quite likely that uses for which BPA is registered in the EU differ from those outside the EU. The research shows that the range of uses is more diverse (as shown with SEv for BPA in 2016). Products are also imported into the EU in which BPA is present in free or bound form. The products are partly re-exported as waste, but also recycled or re-used within the EU. Also missing from the registration dossier are uses such as additives to stabilise mixtures before transport or during processing as revealed from CfE.

A.2.2. Uses of other bisphenols with similar concern[31] [32]

BPA is easy to substitute for additive uses, due to the drop-in substitution solution, as this has little impact on the process. It is more complex 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).

BosC are also used in aerospace, defense and automotive types of applications, such as Bisphenol S which is a monomer in polymers that are used.

A.2.2.1. Bisphenol B (BPB)[33]

The substance is not registered. There is no public information on uses available.

It is well known, that BPB is used for the manufacturing of polycarbonate (P1), epoxy resins (P2) and phenolic resins (P8).[34]

In the US, according to HSDB[35], BPB may be used in the manufacture of phenolic and polycarbonate resins that may be released into the environment through various waste streams. In addition, BPB can be released from resin linings used as corrosion inhibitors to coat cans in the food industry. 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´.

The use categories describe above are consistent with those described for BPA. Since BPB differs from BPA by an ethylgroup 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.

A.2.2.2. BPS and derivates[36]

The group BPS and BPS derivatives consists of bisphenol S (BPS) (EC 201-250-5) 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) (see table below).

---

[31] Annex H

[32] https://www.umweltbundesamt.de/publikationen/bewertung-des-endokrinen-potenzials-von-bisphenol

[33] https://echa.europa.eu/documents/10162/00872c55-2827-a6d7-273d-78ac4391906b

[34] Otto-Albrecht Neumüller (Herausgeber): *Römpps Chemie Lexikon*, 8. Auflage, Frank'sche Verlagshandlung, Stuttgart 1983, ISBN 3-440-04513-7, S. 454–455.

[35] (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)

[36] ECHA, 2021: Assessment of regulatory needs: Bisphenols, 16 December 2021, available via https://echa.europa.eu/de/assessment-regulatory-needs/-/dislist/details/0b0236e184441d47

Table 8: Substances in the group of BPS and derivates

EC/List number	CAS number	Substance name	Substance name acronyms (*)
201-250-5	80-09-1	4,4'-sulphonyldiphenol	BPS
235-986-3	13080-89-2	4,4'-[sulphonylbis(4,1-phenyleneoxy)]dianiline	
263-920-3	63134-33-8	p-[[p-benzyloxyphenyl]sulphonyl]phenol	BPS-MPE
277-962-5	74665-14-8	Phenol, sulfonated	
405-520-5	95235-30-6	4-(4-isopropoxyphenylsulfonyl)phenol	D8 (D88)
411-570-9	41481-66-7	2,2'-diallyl-4,4'-sulfonyldiphenol	TG-SB, TG-SH, TG-SH(H)
427-620-8	-	D-90	
479-880-7	97042-18-7	4-(4-Allyloxy-benzenesulfonyl)-phenol	BPS-MAE
680-791-2	9017-72-5	Naphthalenesulfonic acid polymer with formaldehyde and 4,4'-sulfonylbis[phenol]	
700-375-7	568572-17-8	4-({4-[4-(4-{[4-(Propan-2-yloxy)phenyl]sulfonyl}phenoxy)butoxy]phenyl}sulfonyl)phenol	Tomilac 214
941-992-3	-	Reaction product of Phenol, Sulphuric acid and Sodium hydroxide	

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.

Table 9: BPS derivates that have been reported to contain BPS

[3] Information on substance composition is considered as confidential and as such is contained in a separate annex which is not available in the published version of the dossier.

Overview of uses

Main uses described in the registration dossiers for this group of substances are as color developer in thermal paper (A5), as surface modifier in the tanning of leather (P other) or precursor for the production of tanning agents (P other). Most handling of the substances is indicated to take place in closed systems in dedicated facilities and transfer or formulation typically takes place under controlled conditions, though there still are some reported instances of use in 'open systems' and/or 'non-dedicated facilities' (e.g. EC 405-520-5, EC 479-880-7, EC 411-570-9 and EC 277-962-5).

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).[37] 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.

Use in 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. A more general exposure of the public to thermal paper and hence to these substances may be expected during the thermal paper service life (as is indicated for EC 201-250-5, EC 405-520-5, EC 479-880-7, EC 411-570-9 and 700-375-7) similar to what is found for BPA used in thermal paper. EC 405-520-5, EC 479-880-7 and EC 411-570-9 note that use in thermal paper is *envisaged*, suggesting that this may not yet be a ‘common practice’, which stands in contrast to other information suggesting that these substances may in fact already be in use. EC 405-520-5 thereby indicates a foreseen typical concentration of 0.5 g/m^2 in thermal paper. EC 411-570-9 describes the envisaged use in thermal paper not only as developer, but also as binder/filler in the formation of a coating for thermally sensitive recording paper. To what extent such coating formation may lead to reduced exposure potential to the substance during its article service life may warrant further investigation. Service life of thermal paper applications can vary between a few minutes (cash receipts) and several days (labels on packages). In general, thermal paper can be stored for many years. EC 201-250-5 is particularly mentioned in recycled paper as a source of possible high or intended release indoors.

Of these substances, EC 201-250-5, EC 405-520-5, EC 411-570-9 and EC 427-620-8 are reported in the Annex XV proposal for Restriction for BPA in TP[38] as possible direct alternatives for substitution. Furthermore, BPS is a direct alternative to BPA. 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.

- EC 405-520-5 (D8): D8 is typically used for thermal paper applications requiring highly sensitive paper (e.g. mobile printers needing less energy when the paper is more sensitive, queuing ticket printers...). This is confirmed by the ETPA (European Thermal Paper Association).

- EC 411-570-9 (TG-SA): No information is available in the Annex XV dossier regarding the use of TG-SA as alternative to BPA in thermal paper. It notes that stakeholders name it as an alternative to BPA but there is no indication of the actual use. However, some recent studies show clearly that TG-SA is frequently used in thermal paper.

EC 427-620-8 /D-90: D-90 is known to be used in thermal paper, and confirmed to be in use by thermal paper manufacturers. The Annex XV dossier describes that D-90 may (also)

---

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

[38] ECHA website: Annex XV restriction dossier on the use of BPA in TP: https://echa.europa.eu/de/registry-of-restriction-intentions/-/dislist/details/0b0236e18051ba62

be used to improve the stabilization of the image and enhances the efficiency of other photo developers present in the thermal paper.

Use in paper products (P)

A further use, mentioned for BPS is as monomer or chromogenic agent in the manufacture of paper. Use in formulations, industrial use and article service life are indicated in the registration dossier. This use is put separately from the use of thermal paper and may therefore involve either the production of other types of photo-active paper (e.g. tickets, mailing envelopes, airplane boarding passes, and airplane luggage tags), or the production of (epoxy) coated paper products. Consumer exposure may be possible during its service life. In the table below, this use in paper is merged with the use in thermal paper.

Use in leather tanning (P other)

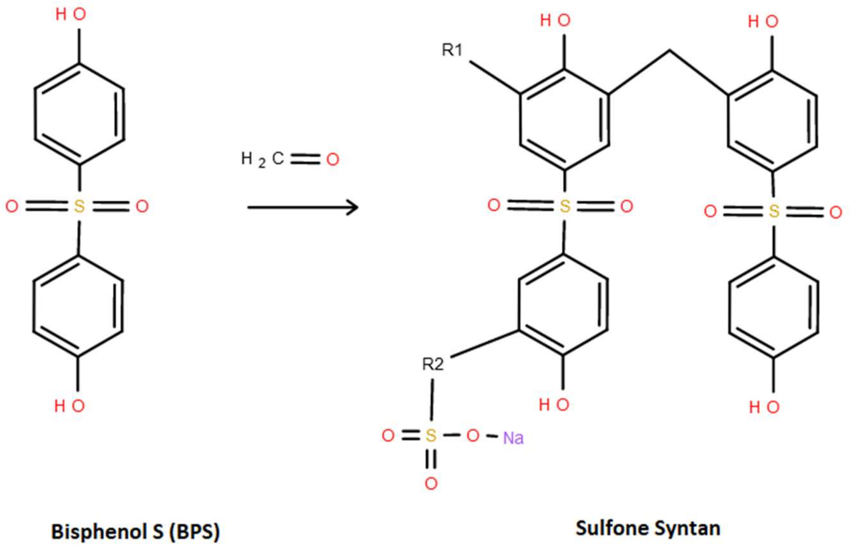
Tanning of leather and the indoor and outdoor use of leather articles may result in exposure of consumers and workers. Widespread uses by professional workers has been reported for both EC 201-250-5 and EC 277-962-5. For EC 277-962-5 registrants have reported spraying, rolling and calendering activities used to treat leather. For BPS, wide spread use was reported with intended indoor release for leather articles, where it was indicated that the substance is used as a monomer in the production of tanning agents and may be released as a consequence of its remaining presence as unintentional impurity.

Information from Stakeholder consultations

In the 2nd Call for Evidence, a large amount of feedback has been provided by stakeholders in the leather manufacturing industry.

BPS (often referred to as "sulfone" within the leather industry) is produced via the reaction of phenol with sulphuric acid or sulphur trioxide. It is common as the aromatic compound used in the synthesis of synthetic tannins (syntans) based on DDS (Di-hydroxy-Diphenyl-Sulphone) polymers. Due to the phenol group being important for the tanning effect, it is claimed to be indispensable for achieving the properties of the finished leather required by the industrial users of syntans, like fullness, dye distribution, lightfastness, softness, light/pastel colour shades, and to prevent iron staining and heat yellowing. The syntans fix collagen and stabilize the hide and skin in leather.

In syntan production, BPS reacts with formaldehyde, forming a poly-condensate. However, since formaldehyde is always employed in sub-equimolar ratio to ensure that no free formaldehyde remains in the final product, traces of the other reactants (like BPS) can remain as a residue instead. Depending on the desired performance properties, the amount of syntan produced with 1 kg BPS can vary between 2 – 5 kg.



Reaction of BPS to sulfone syntan. 25% sulfonation degree = 1 out of 4 phenolic moieties are sulfonated with a SO_3Na group. R2= i) CH_2, deriving from formaldehyde + $NaHSO_3$ + BPS; ii) direct bond, deriving from treatment of BPS with H_2SO_4. (Ramboll Deutschland GmbH, 2021)

BPF is an unwanted reaction by-product of syntan production with BPS, and many stakeholders refer to BosC in syntans without differentiating between BPS and BPF. Stakeholder data referring specifically to BPF will be discussed later.

The quantity of BosC used by the leather industry at global level is difficult to assess, since there are no official statistics of leather production and where these exist at national level they are expressed in m^2.

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

According to the report provided by one stakeholder (CfE2#82), the majority of syntan production within EU happens in 3 to 4 large sites (2 of them in Germany), with a usage of 7,000 – 8,000tpa BPS (annual average of the years 2012, 2013 and 2014). Of these, approximately 500tpa are imported from outside EU. Approx. 3,500 – 4,000tpa are exported again, with 700 – 800tpa being delivered to the textile industry, the rest to approx. 1,500 EU tanneries. (With approx. 2/3rd of them being in Italy.) The tanneries and the textile industry are also importing an unknown amount of syntans from outside EU.

Another stakeholder (CfE#2 124) cites the total use of 4,000 tpa BPS for syntans, and attests the claim of 8,000tpa syntan production in EU, with an export of 50%.

Many stakeholders state the value of BosC (BPS and BPF) residues in the finished syntan within the range of 0.1–3%.

While the production of BPS, syntans and the tanning takes place within EU, 90% of the production of the final product does so outside of EU.

Syntan production happens as slurry in completely closed systems (drums). Operators are protected by wearing safety equipment, and dosing systems are fully automated. The product reaches the clients either as liquid (stored in tanks and transported in tank trucks) or solid, as granulate or spray-dryed as powder (stored in silos and transported in bags).

Within leather production, syntans represent a major role during tanning (chrome-free "wet white" tanning in combination with a reactive tannin like glutaraldehyde) and a key role during retanning. (According to a notation by the BfR, ca. 80% of EU produced leather are retanned.) BPS is transferred to the hide or skin matrix in aqueous industrial processes. The pretanned leather is treated in rotating drums, where syntans, dyes and fatliquors are added. These anionic products then bound to the leather by reducing the pH. Syntans end up being tightly fixed into the leather matrix. In the wet-end process, synthetic tanning agent are fixed to the leather via acidification of the leather, while in the tanning processes, the fixation can be done via basification. After the treatment (several) washing and rinsing steps as well as squeezing and/or drying processes are following. Residues from cleaning are transferred to wastewater treatment plants.

Nevertheless, there are BPS residual to be found in the collagen matrix of the finished leather. One stakeholder (CfE2#82) points out that according to an OECD emission scenario document[39], 80% of syntans become fixated in the leather matrix, thus 20% remaining in the waste water. The same stakeholder also points out to a labory study (2015) which gives for retanning the values of 65% of syntans in leather and 35% in waste water. Another stakeholder (CfE2#95) states that a BosC concentration in syntans of 3,000 mg/kg results in 200 mg/kg in leather. A BfR notation gives the BPS amount in finished leather as 200 – 5000ppm, with 0,00 – 0,50% (18–2958 mg/kg) migrating.

Roughly 20% of global leather production are for are for upholstery (automotbiles, public transports, aircrafts, furniture) and fashion (shoes, bags, clothes). Only low quality leather (e.g. for working gloves) can be produced without syntans. Other products named are saddles, belts and work shoes.

The processing of hides and skins also generates other by-products, which find outlets in several industry sectors such as pet and animal food production, fine chemicals (including photography and cosmetics), and fertilisers.

The potential lifespan of the products has been described as several months to "generations".

Stakeholders claim no outdoor use for many applications. Regarding leather clothes, stakeholders point out that those are supposed to be dry-cleaned.

Syntans are also used in textiles as post-treatment agents for polyamide dyeing (possibly also wool) resulting in sufficient color fastness. BPS content in polyamide textiles ranges from 200 to 1,000ppm, in one study[40] even 2,190ppm. A perspiration fastness test showed that when polyamide fibers are treated with acid and alkalic medium and washed, BPS content was reduced by 25 – 30%, suggesting migration potential. Polyamide fibres are used for outdoor textiles, sports- and swimwear, underwear, corsetry, hosiery, socks, medical products (e.g. compression stockings), home textiles (e.g. carpets) and the automotive sector.

---

[39] (OECD, 2004)

[40] (Li and Kannan, 2018)

Other uses – not registered

A review of available online information reveals possible other uses for BPS (EC 201-250-5) which are not (explicitly) included in its registration dossier. Among these, it is used as food contact material[41] (P2) (e.g. as coating in metal can linings, or plastic containers made of e.g. PES or PSU (P5)) and epoxy based adhesives (P2). 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 than is currently reflected in the BPS registration dossier. Similarly, based on structural similarity to BPS, one may anticipate that EC 405-520-5, EC 411-570-9 and EC 479-880-7 might also be used like BPS as resin and possibly also as surface modifier or solvent. There is currently no information in their registration dossiers that substantiates this, but market shifts may be expected once further regulatory measures are developed for BPS.

Information from Stakeholder consultations

Both BPS and BPAF are used as curatives or vulcanizing agents and are designed to become the cross-link itself. BPS can serve as curative for epichlorohydrin elastomers. The BPS masterbatch is sold to industrial customers who manufacture cross-linked epichlorohydrin elastomer parts for the automotive and heavy-duty industry. Common application are multilayer fuel hoses, fuel vent lines or turbo charger hoses. The masterbatch as manufactured contains about 75% BPS. The dust collected from the spot ventilation is handled with the appropriate waste designation. The pelletized product is used by industrial customers typically in the 0.5 – 3% range. The service life of automotive parts is generally high and commonly designed to exceed the life of the end-use article (engine or vehicle).

Polymers broadly used in medical devices include specialised polymers/plastics like Polyethersulfone (BPS-based). In most cases, polymerisation (and handling of unreacted bisphenols) takes place upstream at plastics manufacturers' sites. The majority of uses by the medical technology companies would be limited to the handling of finished materials (polymer granulates) and articles (components, subassemblies. etc.). These might contain unintended trace amounts of residual monomer. For highly specialised applications such as dialysis hollow-fibre membranes, state-of-the-art technology is limited to bisphenol (BPA/BPS) based polymers.

BPS is also used as (co-)monomer in epoxy resins.

To produce polyarylene sulfones for membrane manufacturing, BPS based polymers and its derivatives are dissolved in an (aprotic) solvent. This solution is processed to filtration membranes, filters are used for (industrial) water treatment purposes. The tonnage is 10 -100 tpy (BPS). The majority of membrane filters are based on BPS/BPA type polymers. The NF market is estimated to be 10% of the total membrane market on BPS/BPA type polymers.

---

[41] 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.

Table 10: overview main uses BPS

Main types of applications structured by product or article types	201-250-5	235-986-3	263-920-3	277-962-5	405-520-5	411-570-9	427-620-8	479-880-7	680-791-2	700-375-7	941-992-3
Use in thermal paper	F, I, A				I, A	I, A		I, P, A		I, A	
Use as monomer in polymers	I										
Use as intermediate				F, I							I
Use in leather	I, P, A			I, P, A							
Non-specified		x					I		x		
Alternatives to BPA-thermal developer (Assessed as realistic -Annex XV Restriction)	x				x	x	x				
Technical function.											
Monomer	x										
Resin	x										
Developer (thermal)	x				x	x	x	x		x	
Surface modifier	x			x							
Solvent	x										
Not specified		x							x		

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life, X: means yes for the case

A.2.2.3. Uses of BPF (and derivatives)

The group BPF and BPF derivatives consists of Bisphenol F (BPF) (EC No. 210-658-2) 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.

The group is built around BPF (EC 210-658-2) based on structural similarity. Uses registered for the 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, leather and textile. 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.

Table 11: Overview and registration status of BPF derivates

EC/List number	CAS number	Substance name	Substance name acronyms (*)	Registration status (tonnage band; full / intermediate registrations)
204-279-1	118-82-1	2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol	TBMD; IONOL 220	Full registration 100-1000T
210-658-2	620-92-8	4,4'-methylenediphenol	BPF	C&L notification
218-257-4	2095-03-6	2,2'-[methylenebis(p-phenyleneoxymethylene)]bisoxirane	Bisphenol F diglycidyl ether	C&L notification
226-378-9	5384-21-4	4,4'-methylenedi-2,6-xylenol	Tetramethyl Bisphenol F	Full registration 100-1000T
405-790-4	101657-77-6	4,4'-methylenebis(2,6-dimethylphenyl cyanate)		Claimed NONS 1-10 T
432-740-9	-	BIS26X-MBOC		Claimed NONS 1-10 T
439-910-1	93705-66-9	2,2'-(methylenebis((2,6-dimethyl-4,1-phenylene)oxymethylene))bis oxirane	YSLV-80XY	Claimed NONS 1-10 T
500-770-2	64448-68-6	4,4'-methylenediphenololigomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with acrylic acid		C&L notification

EC/List number	CAS number	Substance name	Substance name acronyms (*)	Registration status (tonnage band; full / intermediate registrations)
608-164-0	28064-14-4	2-(chloromethyl)oxirane; Formaldehyde; Phenol		C&L notification
632-557-6	93705-66-9	[No public or meaningful name is available]		C&L notification
680-136-0				
700-487-6	-	reaction products of diglycidyl ether bisphenol F (DGEBF) and oligomeric phenol diglycidyl ethers with acrylic acid	Epoxy half acrylate; Epoxidhalbacrylat 6	Full registration 100-1000T
701-263-0	-	Reaction mass of 2,2'-[methylenebis(2,1-phenyleneoxymethylene)]bis(oxirane) and 2,2'-[methylenebis(4,1-phenyleneoxymethylene)]bis(oxirane) and 2-({2-[4-(oxiran-2-ylmethoxy)benzyl]phenoxy}methyl)oxirane		Full registration >1000T
908-912-9	1333-16-0	Reaction mass of 4,4'-methylenediphenol and 2,2'-methylenediphenol and o-[(4-hydroxyphenyl)methyl]phenol		Full registration 1-10T
941-357-0	-	Reaction mass of 2,2'-{methylenebis[(2,6-dimethyl-4,1-phenylene)oxymethylene]}dioxirane and 1,3-bis{4-[3,5-dimethyl-4-(oxiran-2-ylmethoxy)benzyl]-2,6-dimethylphenoxy}propan-2-ol and 3,3'-{methylenebis[(2,6-dimethyl-4,1-phenylene)oxy]}bis(1-{4-[3,5-dimethyl-4-(oxiran-2-ylmethoxy)benzyl]-2,6-dimethylphenoxy}propan-2-ol)		Full registration >1000T
941-435-4	-	Reaction products of Bisphenol F and phenol with aniline and formaldehyd		C&L notification
946-144-6	-	Reaction mass of 3-phenyl-6-[(3-phenyl-3,4-dihydro-2H-1,3-benzoxazin-8-yl)methyl]-3,4-dihydro-2H-1,3-benzoxazine and 6,6'-methanediylbis(3-phenyl-3,4-dihydro-2H-1,3-benzoxazine)		Full registration >1000T

Overview of uses

As mentioned above, the substances in this group are registered for a wide spectrum of uses. Only one substance is indicated to be used as a photochemical. 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 short reflection on some of the more typical uses is provided below. Some special attention is given to possible uses of BPF, which is not yet registered and hence has no registration dossier available to extract a specific use profile from.

BPF (EC 210-658-2)

BPF is commonly mentioned as one of the substitutes for BPA. While BPF itself is not registered, a reaction mass containing a mixture of isomers of BPF – 4,4′-BPF, 2,4′-BPF and 2,2′-BPF – is registered under the identifier "2-[(2-hydroxyphenyl)methyl]phenol; 2-[(4-hydroxyphenyl)methyl]phenol; 4-[(4-hydroxyphenyl)methyl]phenol" (List 908-912-9, CAS 1333-16-0) in the tonnage band of 1,000 – 10,000 tpa. ECHA publishes in the Brief Profile the following information on uses: The substance is used in polymers (product category). The substance has an industrial use resulting in manufacture of another substance (use of intermediates). 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 plastic products and chemicals (sector of use). The substance can be found in complex articles.

The hazardous substances Data bank (HSDB)[42] indicates that BPF is used in the manufacturing of plastics and epoxy resins. It is used in the industry as a way of increasing the thickness and durability of materials.[43] Its use in this way is important in the production of tank and water pipe linings, industrial floors, road and bridge deck toppings, structural adhesives, grouts, coatings and electrical varnishes.[44] BPF is also utilized in liners, lacquers, adhesives, plastics, and the coating of drinks and food cans. Another use for BPF is in dental materials, where it can be found in restorative materials, liners, adhesives, oral prosthetic devices and tissue substitutes. [45] A US study revealed BPF to be widely used in feminine hygiene products and personal care products in the US.[46] Furthermore, some sources indicate the presence of BPF in thermal paper receipts.[47,48] However, the extent of this use is unknown and it is expected to be relatively insignificant. Despite its low current use in thermal paper, it is possible that BPF becomes more widely used in the future in the event that regulatory risk management measures are applied to other bisphenols.

---

[42] (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)

[43] Rochester, Johanna Ruth; Bolden, Ashley Louise (2015). "Bisphenol S and F: A Systematic Review and Comparison of the Hormonal Activity of Bisphenol A Substitutes". Environmental Health Perspectives. 123 (7): 643–50. doi:10.1289/ehp.1408989

[44] Cabaton, Nicolas; Chagnon, Marie-Christine; Lhuguenot, Jean-Claude; Cravedi, Jean-Pierre; Zalko, Daniel (2006). "Disposition and metabolic profiling of bisphenol F in pregnant and nonpregnant rats". Journal of Agricultural and Food Chemistry. 54 (26): 10307–10314. doi:10.1021/jf062250q. ISSN 0021-8561. PMID 17177575

[45] Rochester, Johanna Ruth; Bolden, Ashley Louise (2015). "Bisphenol S and F: A Systematic Review and Comparison of the Hormonal Activity of Bisphenol A Substitutes". Environmental Health Perspectives. **123** (7): 643–50. doi:10.1289/ehp.1408989. PMC 4492270. PMID 25775505

[46] Gao et al., 2020 and Liao and Kannan 2014.

[47] Ullah et al. (2019). Effect of bisphenol F, an analogue of bisphenol A, on the reproductive functions of male rats

[48] U.S. Environmental Protection Agency (EPA) (2014), BISPHENOL A ALTERNATIVES IN THERMAL PAPER, Final Report.

Polymers and plastics (A6/P8)

EC 226-378-9, EC 701-263-0 and EC 908-912-9 are indicated for use in polymers and plastics as resin (EC 226-378-9 and EC 701-263-0) and/or hardener (EC 701-263-0 and EC 908-912-9). EC 226-378-9 is used in formulations with only industrial use. EC 701-263-0 and EC 908-912-9 are also used by professional. EC 701-263-0 is furthermore used by consumers in Do-It-Yourself (DIY) products.

Information from Stakeholder consultations

Epoxy Resins

BPF is one of the building blocks for Epoxy Resins and is used as intermediate (to produce pre-polymeric Glycidyl Ethers of the starting material) and monomer. Stakeholder CfE2 # 43 provides a none-exhaustive list of uses:

Wind Turbine Blades: As composite materials, adhesives and protective coatings in the construction of wind turbine blades, epoxy resins provide blade strength, durability and low weight, enabling longer blades and hence greater energy production. Wind turbine blades are manufactured in industrial setting.

Solar Panels: As head and chemical resistant adhesive

Electrical and Energy Distribution systems: as circuit boards, transformers, insulators and bushings and sealants, coatings and adhesives, to provide durability and performance in high-voltage systems and increase component lifetimes.

Flooring: Indoor to prevent slipperage and providing high chemical and abrasion resistance in hospitals, food and phama industry, general industry storage and production areas. Outdoor, parking structure to prevent corrosion, protect against oil leaks and prevent slipperage

Strong bond engineering adhesives, e.g. replacements for mechanical fixings (e.g. repair bridge decks)

Sealants and Fillers

Rebars (composites): to replace steel structures (light weight) less energy intensive)

Cars, trucks, motorcycles, trains, boats: Coatings for corrosion protection, adhesives, Composites for E- cars enabling lighter and more durable internal parts

Aerospace: increased use of composite materials with improved strength, durability, weight reductions, improving fuel and CO2 efficiency, reduction of repair, maintenance, and replacement costs

Home & Medical: Powder coatings (corrosion protection) for appliances, such as washing machines, toaster, microwave etc. as well as on medical devices and apparatus, coatings for lab or medical tables and benches, surgical instruments, diagnostic equipment (e.g., x-ray and magnetic resonance machines) and prosthetics. DIY as sealants, adhesives, mortars for repair of woods and plastics

Leisure: Various sporting equipment, in composites with glass or carbon fibre such as tennis or other rackets. Corrosion protection on bike, leisure boats or other.

Information communications technology: in ICT applications, such as internal circuits, transistors and smartphones, to protect vital components from light, humidity, dust and electrical and physical shocks

Production machinery (food): as protective coatings to prevent corrosion

Cans: Prevention of trace metals to migrate into food, corrosion protection, prolonging food shelf-life without affecting flavour.

Water infrastructure: Corrosion protection, leaks prevention extending operational lifetimes of pipes, in-situ repair to underground pipes use of a 'sock', preventing additional road work and construction work.

The stakeholder furthermore provides data on EU epoxy resin production by raw material component for the year 2017:

Resins based on BPF/BPFDGE*: 40,000 t, with 26,000 t covalently bound BPF

Resins based on Novolacs [made from formaldehyde and Phenol. Contain BPF backbone] *: 8,000 t, with 5,200 t covalently bound BPF

*The categories should not be mistaken for pure products, often novolacs or BPF based resins are co-reacted with BPA based resins

Further information provided by stakeholder CfE2 # 43 regarding BPF: The vast majority of Bisphenol F epoxy resins are actually not made using BPF. They are produced by reacting formaldehyde, phenol and epichlorohydrin. While BPF might be generated in the reactor as an intermediate stage and may be present in residual quantities, it usually is not used as a starting substance in the same way as for instance BPA is. BPF-based epoxy resins are used in mixtures or mixed oligomers with BPA-based epoxy resins as they confer better temperature stability at lower temperature, i.e., they reduce the propensity of the epoxy resin to crystallize and solidify. BPF in epoxy resins is generally not used as a replacement of BPA in epoxy resins, but as a complementary building block.

Washing and cleaning agents (A4)

EC 204-279-1 is used as stabilizer and anti-oxidant in washing and cleaning agents with a high exposure potential for industrial and professional workers, consumers and the environment.

Coatings and inks, adhesives (A4)

EC 204-279-1 is used as stabilizer and anti-oxidant in coatings and inks. Wide spread indoor and outdoor consumer use is indicated. For its professional use in coatings and inks where rolling, brushing and dipping, and close contact with only personal protective equipment are indicated.

List No 700-487-6, List No 701-263-0 and List No 908-912 are used as resin or binder or hardener in coatings, inks or adhesives. List No 700-487-6 is an epoxy half acrylate used to form adhesives that is formulated and used at industrial sites. Furthermore, the substance is reported to be used for treatment of fibres. However, for this specific use it is reported that the transferring of the preparation to fibre cloth takes place in a closed spraying facility without a release of liquid waste to wastewater.

Exposure of workers and the environment may take place for List No 701-263-0 during professional use. Consumer uses for List No 701-263-0 can be found in the form of DIY coatings and adhesives with the possibility of exposure, and the emission to the environment. The substance serves the primary functions of adhesion promoter, surface modifier, resin and hardener.

List No 908-912-9 is only used in an industrial setting under controlled conditions and exposure of workers and the environment is expected to be limited.

Lubricants and greases, and functional fluids (A8-A11)

EC 204-279-1 is used as stabilizer and anti-oxidant in lubricants and greases, and metal working, heat transfer and hydraulic fluids. Industrial and professional uses predominantly take place under controlled conditions in dedicated facilities with low exposure potential for workers and the environment. However, the registration dossier indicates the lubricant/grease as a release agent, which raises a suspicion that environmental emissions may still take place. For lubricants and greases, wide spread indoor and outdoor consumer use is indicated with a high exposure potential for consumers. There are some general consumer uses reported for this substance in the registration dossier, including filling and draining of containers and enclosed machinery.

Textile (P2/P8)

List No 946-144-6 is used as resin to treat reinforced fabric. The industrial use indicated in their registration dossiers takes place under controlled conditions. Exposure of workers at industrial sites may occur during dipping and pouring activities with the articles to be treated. Exposure of consumers during use of treated textile and leather is suspected to be low due to typical low monomer residue in cured resins. Similarly, the environmental exposure is expected to be low.

Information from Stakeholder consultations

Polyamide

BPF is an unavoidable reaction by-product in chemical production of textile auxiliaries. In the textile industry the proposed restriction could affect the recycling of Polyamide. Phenol-based products (containing Bisphenol F) are available as aqueous solution. Polyamide fibres are used for outdoor textiles, sports- and swimwear, underwear, corsetry, hosiery, socks, medical products (e.g. compression stockings), home textiles (e.g. carpets) and automotive sector. The service life ranges from a few years to 20 years for e.g. outdoor articles. Typical conditions which could lead to fatigue are e.g. washing, water (e.g. sweat, rain, etc) and sun light. Free BosC in the articles are expected to be released during the initial period of use, e.g. by washing. Degradation of the polymer will probably only occur under harsh conditions. Phenol-based after-treatment agents available as alternative to BPS contain a certain level of Bisphenol F. Although the concentration is somewhat lower than for Bisphenol S, they will also not be able to meet the proposed limits on textile.

Paper and board (P2/P8)

EC 701-263-0 is used as resin. The industrial use indicated in the registration dossiers takes place under controlled conditions. Exposure of consumers during use of treated textile and leather is suspected to be low due to typical low monomer residue in cured resins. Similarly, exposure of the environment is expected to be low.

Table 12: Overview of main uses

Main types of applications structured by product or article types	Lubricants and greases	Functional fluids (metal working,	Coating products, adhesives and inks	Washing and cleaning agents	Perfumes, fragrances	Plant protection products	Water treatment chemical	Polymers/plastics	Finger paint	Fillers, putties, plasters	Textile	Paper and board	Electrical products	Photo-chemical	Manufacture of (bulk) chemicals	Technical function
201-245-8 (BPA)[49,50]			F, I, P, A					F, I, P, A				F,P,A				Intermediate Monomer Hardener in epoxy resins Binder, dye
210-658-2 (BPF)			F,I,P,C, A					I,P,C,A				F,P,C,A				Hardener in epoxy resins Monomer Binder
204-279-1[51]	F, I, P, C, A	F, I, P	F, I, P, C	F, I, P, C	F	F, I			F	F						resin, stabilizer, anti-oxidant, lubricating agent, dye
226-378-9								F, I							I	Monomer, resin, anti-oxidant, intermediate
405-790-4																

---

[49] Despite the fact that BPA (EC 201-245-8) does not belong to this group, it is suspected that some of the substances in the group can serve as drop-in substitutes to BPA for various uses.

[50] The uses reported for BPA are largely derived from registration dossiers. However, there have been a wide range of other (more specific) uses reported in the literature, including but not confined to, textile{1,2}, lubricants, greases and adhesives {1,2,3,4,5}, orthodontic adhesives (1), and surface coatings {1,2,3}, Therefore, inter-substitutability between BPA and other substances included in this substance group should be viewed in the context of a wider range of uses, than what can be directly inferred from registration dossiers.

[51] The sole use in Formulation for finger paints, and fillers, putties and plasters, without any professional or consumer use or article service life stands to question. It is suspected that these two uses indicated double with the more 'complete' use indicated for coating products.

Main types of applications structured by product or article types	**Lubricants and greases**	**Functional fluids (metal working,**	**Coating products, adhesives and inks**	**Washing and cleaning agents**	**Perfumes, fragrances**	**Plant protection products**	**Water treatment chemical**	**Polymers/plastics**	**Finger paint**	**Fillers, putties, plasters**	**Textile**	**Paper and board**	**Electrical products**	**Photo-chemical**	**Manufacture of (bulk) chemicals**	**Technical function**
432-740-9													I			Photochemical
439-910-1													I, A			Semi-conductor, Photo-voltaic agent
500-770-2																
608-164-0																
632-557-6																
680-136-0																
700-487-6			F, I													Resin (epoxy)
701-263-0			F, I, P, C, A				I	F, I, P, C, A		F, I, P, C			I, P	F, I	F, I, P	Resin, binder Intermediate
908-912-9			I					F, I, P,		I					F, I, P	Resin (epoxy-hardener), Intermediate
941-357-0 (TMBPF-DGE)															I	Intermediate
941-435-4																
946-144-6										I	F, I					Resin

F: formulation, I: industrial use, P: professional use, C: consumer use, A: article service life

Additional significant uses of BPF

During the second CfE (22 October 2021 until 22 December 2021), the use of BPF during leather tanning processes was highlighted by stakeholders. According to the information provided in the call the substance is not used directly in leather tanning but in syntans. These syntans are produced with BPF.

Information from Stakeholder consultations

In the 2nd Call for Evidence, a large amount of feedback has been provided by stakeholders in the leather manufacturing industry.

Two stakeholders (CfE2#13 & CfE2#73) state that BPF is used less frequently than BPS for syntan production, and another stakeholder (CfE2#160) states that it is used in the synthesis of phenolic-type syntans. However, most stakeholders know BPF merely as an unwanted reaction by-product of syntan production (synthesis of phenol formaldehyde condensates) via BPS. Many stakeholders therefore refer to BosC in syntans without differentiating between BPS and BPF.

The quantity of BosC used by the leather industry at global level is difficult to assess, since there are no official statistics of leather production and where these exist at national level they are expressed in m^2.

A frequently quoted estimate for the production and use of syntans in 2020 is 115,000 tpa worldwide (powdered products). One stakeholder (CfE2#82) puts the global market for syntans at about 160,000 tpa, with about 30% (i.e. 48,000tpa) being used in Europe.

According to the report provided by one stakeholder (CfE2#82), the majority of syntan production within EU happens in 3 to 4 large sites (2 of them in Germany). Approx. 3,500 – 4,000 tpa of syntans are exported, with 700 – 800 tpa being delivered to the textile industry, the rest to approx. 1,500 EU tanneries. (With approx. 2/3rd of them being in Italy.) The tanneries and the textile industry are also importing an unknown amount of syntans from outside EU.

Another stakeholder (CfE#2 124) provides the value of 8,000tpa syntan production in EU, with an export of 50%.

Many stakeholders state the value of BosC (BPS and BPF) residues in the finished syntan within the range of 0,1 – 3%. In cases in which BPF is mentioned separately, the concentration in syntans is usually stated to be 0.1 - 1% by weight.

Syntan production happens as slurry in completely closed systems (drums). Operators are protected by wearing safety equipment, and dosing systems are fully automated. The product reaches the clients either as liquid (stored in tanks and transported in tank trucks) or solid, as granulate or spray-dryed as powder (stored in silos and transported in bags).

Within leather production, syntans represent a major role during tanning (chrome-free “wet white” tanning in combination with a reactive tannin like glutaraldehyde) and a key role during retanning. BPS is transferred to the hide or skin matrix in aqueous industrial processes. The pretanned leather is treated in rotating drums, where syntans, dyes and fatliquors are added. These anionic products then bound to the leather by reducing the pH. Syntans end up being tightly fixed into the leather matrix. In the wet-end process, synthetic tanning agent are fixed to the leather via acidification of the leather, while in the tanning processes, the fixation can be done via basification. After the treatment (several) washing and rinsing steps as well as squeezing and/or drying processes are following. Residues from cleaning are transferred to wastewater treatment plants.

Nevertheless, there are residuals of BosC to be found in the collagen matrix of the finished leather. One stakeholder (CfE2#82) points out that according to an OECD emission scenario document[52], 80% of syntans become fixated in the leather matrix, thus 20% remaining in the waste water. The same stakeholder also points out to a labory study (2015) which gives for retanning the values of 65% of syntans in leather and 35% in waste water. Another stakeholder (CfE2#95) states that a BosC concentration in syntans of 3,000 mg/kg results in 200 mg/kg in leather. In cases in which BPF is mentioned separately, stated ranges for residues in finished leather are 200 – 300ppm (CfE2#22), 200 – 100ppm (BfR notation) 400 – 600ppm (CfE2#67) and 0 – 10,000ppm (CfE#79), with the latter stakeholder adding that the limit value of 200ppm is impossible to comply.

Roughly 20% of global leather production are for are for upholstery (automobiles, public transports, aircrafts, furniture) and fashion (shoes, bags, clothes). Only low quality leather (e.g. for working gloves) can be produced without syntans. Other products named are saddles, belts and work shoes.

The processing of hides and skins also generates other by-products, which find outlets in several industry sectors such as pet and animal food production, fine chemicals (including photography and cosmetics), and fertilisers.

The potential lifespan of the products has been described as several months to "generations".

Stakeholders claim no outdoor use for many applications. Regarding leather clothes, stakeholders point out that those are supposed to be dry-cleaned.

Syntans are also used in textiles as post-treatment agents for polyamide dyeing (possibly also wool) resulting in sufficient color fastness. I one study[53] BPF contents up to 1,280ppm could be measured. Affected consumer goods are outdoor, sports and swimwear, underwear, corsetry, fine stockings, socks, medical products (e.g. compression stockings), home textiles, automotive, etc.

---

[52] (OECD, 2004)

[53] (Li and Kannan, 2018)

A.2.2.4. Uses of BPAF (and derivatives)

The substances in this group include Bisphenol AF (BPAF) 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 (425-060-9 – sodium salt) or as organic salts (the other derivatives). Under environmental conditions the substances can be expected to dissociate to the cation and the anion (BPAF). Internet search suggests the existence of two more potassium salts of BPAF (not yet registered nor C&L notified) that may already be on the worldwide market and could easily become available in Europe.

Bisphenol AF is registered under REACH with an annual tonnage of 100 – 1,000tpa. 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.

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).[54,55]

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 like BPAF (EC 278-305-5), 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 in e.g. seals and gaskets and high temperature composites (for e.g. food and pharma processing equipment). The substances are only used at industrial sites. For most of the substances article service life is indicated in the ECHA brief profile suggesting the possibility for exposure of consumers and the environment in addition to exposure of industrial workers. The high similarity in technical function and chemical composition of the substances suggest that BPAF and its derivatives may be used interchangeably.[56,57,58,59,60]

Table 13: Overview of annual tonnage (ECHA dissemination database)

EC /List number	CAS-No.	Tonnage/a
216-036-7	1478-61-1	100-1,000
278-305-5	75768-65-9	10-100
425-060-9	74938-83-3	0-1
443-330-4	475569-04-1	1-10

---

[54] https://pubchem.ncbi.nlm.nih.gov/compound/73864#section=Uses
[55] https://ntp.niehs.nih.gov/ntp/htdocs/chem_background/exsumpdf/bisphenolaf_093008_508.pdf
[56] https://echa.europa.eu/de/brief-profile/-/briefprofile/100.071.165
[57] https://echa.europa.eu/de/registration-dossier/-/registered-dossier/3140/9
[58] https://echa.europa.eu/de/brief-profile/-/briefprofile/100.104.882
[59] https://echa.europa.eu/de/brief-profile/-/briefprofile/100.105.216
[60] https://echa.europa.eu/de/brief-profile/-/briefprofile/100.242.962

468-740-0		1-10
469-080-6		1-10
479-100-5	577705-90-9	1-10
943-265-6		Full registration 10-100
947-368-7		Full registration; 10-100

BPAF and its derivatives are used as monomers in plastic (P) and polycarbonate (P other) for use in e.g. textiles and packaging material for food and personal care products, and as process aids or process regulators (A).

In scientific literature the presence of low concentrations of BPAF in personal hygiene products in USA and China is described, and modelling suggests worldwide use/exposure (Wang et al. 2020).[61]

Based on the similarities in substance composition, high similarity in uses and similar technical function, interchangeability of substances within this group is expected. In addition, BPAF (and therefore possibly also its salts) may act as a substitute for BPA in the production of polycarbonate.

At present, there is no information in the registration dossiers of the substances in this group that would suggest use as colour developer in thermal paper. Despite the current lack of indication that any of the substances in this subgroup are used to replace BPA in thermal paper, it is still considered a viable option to use it instead of BPA in thermal paper due to structural and functional similarities of BPF and its derivatives to BPA.

Information from Stakeholder consultations

During the second Call for Evidence, stakeholders provided comprehensive information on the functioning, use and applications of BPAF as a fluoroelastomer (FKM). It was pointed out several times that BPAF is used exclusively as a crosslinker for fluoroelastomers and BPAF is not a monomer or additive, but rather a reactant to form the crosslink and build the network. These are necessary steps in the industrial supply chain to manufacture large quantities of fluorelastomer seals.

FKM as material offers a much higher maximum service temperature and chemical resistance than comparable sealing materials. They are designed to achieve the highest requirements in extreme environments. This includes high temperatures in a combination of contact with fuel, diesel and manufactured substances. Due to its high price level, it is only used when it's main advantage (service temp or media compatibilty) is required in the application. FKM is primarily used for the production of seals and polymer bearings.

Machinery and equipment for all conceivable industrial/professional segments of society as a whole to be mentioned here, e.g.: Mechanical Engineering, Automobiles, Ships, Trains, Chemical Manufacturing, Pharmaceutical Manufacturing, Aerospace, Construction,

---

[61] Worldwide average human daily intakes are determined based on biomonitoring data from human urine. Daily intakes found in order of decreasing importance: BPA, BPF, BPS, BPP, BPAP, BPB, BPZ, BPAF. BPAF is shown to be at least present in human urine in Saudi Arabia and India. Wang, H., Liu, Zh., Zhang, J. et al. Human exposure of bisphenol A and its analogues: understandings from human urinary excretion data and wastewater-based epidemiology. Environ Sci Pollut Res 27, 3247–3256 (2020). https://doi.org/10.1007/s11356-019-07111-9

Petroleum and Mining, Electronics, Energy, Transportation, Agricultural Equipment, Processing Equipment, Defence, Fluid Power, Machine Tools, Presses, Robotics, Plumbing and more. Other markets for FVC-based general rubber goods (GRG) include household appliances, leisure articles and food contact materials.

The manufactured components are made of spoken diverse depending on the industrial sector. In the automotive industry, o-rings and seals for fuel connections, tank seals, fuel injection nozzles, cylinder head gaskets, air intake, turbochargers, engine seals and sensors play an important role. In the field of industrial plants and mechanical engineering, these are mainly valvesand seals for oil and gas lines, hose lines, pneumatic cylinders, pumps, sealing plates and hydraulic systems. O-rings and gaskets made of FKM are widely usedalso in semiconductor manufacturing and related equipment (SMRE), and in water distribution and waste chemical systems.

The production of finished articles using BPAF is a multi-stage process. BPAF is used in concentrations of 1-3 parts per hundred in fully formulated recipes, as typically described in elastomer recipes. 100% BPAF is used to manufacture cure complexes. The curative complexes contain 30-90% Bisphenol AF and are manufactured, shipped, imported, exported, and sold as intermediate products for the manufacture of cure incorporated elastomers and BPAF masterbatches. Cure incorporated elastomers are generally in the 1-8% range. One stakeholder reported that a typical concentration of BPAF in masterbatches (preparations in the form of granulates with contents of colourants or additives) might be up to 50% w/w. The final product is sold as FKM cure incorporated pre-compound while the concentration (e.g. raw fluoro rubber mixtures) ranges between 1% and 4% w/w. Lower values in the range of 0.3 - 3.0% as well as higher values (5%) are also reported. One company is selling cure incorporated FKM pre-compounds on the market that could contain up to 2% of BPAF.

The raw rubber compound contains the fluoropolymer, reinforcing fillers and bisphenol AF (vulcanising agent) as essential components. The resulting products are in the shape of solid slabs. By means of shaping processes like injection moulding, compression moulding, extruding/calendering and autoclave curing or coating/jacketing this is then processed into the desired products. Normally, BPAF is also used together with accelerators such as quaternary phosphonium salts.

In the course of the manufacturing process, starting with the uncrosslinked FPM polymer via the crosslinking agent (blend) to the rubber mixture and the individual finished article from the full mixture, the concentration of BPAF decreases continuously from the double-digitpercentage range to theppm range. There is not a significant amount of data about cured articles, but it is estimated they may be in the range of 50 – 300ppm extractable BPAF. Most of the stakeholders concluded that during vulcanization of the rubber mixture, Bisphenol AF reacts and it is no longer present in the final rubber matrix, nor in the articles to significant levels. As the crosslinked elastomer article or product is a three-dimensional structure there is no evidence for the release of BPAF during the use or end of life cycle. Nevertheless, most companies concluded that a residual BPAF content of below 10ppm in FKM-based products cannot be met.

In certain semiconductor devices, BPA may also be present as an impurity or by-product in the substrate laminate in the range of 0.1 to 1%. The concentration in the product varies but is most likely above 10ppm. In lithographic applications, the components are usually encapsulated and migration to the environment is likely to be very slow. Unreacted BosC monomers may be present in PCB prepregs up to 4000ppm.

One of the stakeholders estimated that the amount of FKM rubber used in rubber articles is in the range of 3,600-14,000 tonnes per year and BPAF is present in FKM uncured rubber mixtures in the range of 4-16 tonnes per year. Another stakeholder estimate that 14-50 kilotons of rubber goods require the use of fluoropolymers, accounting for 0,5 to 2% of the overall production of rubber goods in Europe – among those FKM rubber containing BPAF.

One company calculates the production of BPAF-based FKM at 8,000 tonnes/year. According to another industry estimate the market volume of BPAF used in the EU is ca.120 tons of BPAF.

It can be concluded that a large number of components made of FKM are used in closed systems over a very long period of time. Furthermore, applications are also conceivable where the components are exposed to the weather outdoors in addition to their usual stress due to heat, aggressive chemicals and high pressure and are subject to faster ageing. For the automotive sector one stakeholder concluded that typical requirements include sealing performance under broad conditions for long periods of time, e.g., 10 years. At the end-of-use, seals and hoses are likely to end up in automotive shredder residue or comparable waste streams. For many other components based on FKM, e.g. in the area of machinery and equipment, the service life should be longer than 10 years before they have to be replaced and disposed of.

A.3. 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.

Annex B: Information on hazard and risk

B.1. Identity of the substance(s) and physical and chemical properties

B.1.1. Name and other identifiers of the substance(s) [1]

This proposal for restriction covers the substances Bisphenol A and other Bisphenols of similar concern (BosC). The term 'BosC' covers the following additional substances:

- Bisphenol S
- Bisphenol F
- Bisphenol B
- Bisphenol AF.

Table 14: Substance identity of BPA Table 14 summarizes chemical and regulatory identifiers for BPA. Table 15 to Table 20 summarize chemical and regulatory identifiers of the other BosC included in this proposal for restriction.

Table 14: Substance identity of BPA

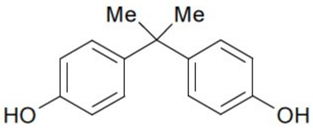
EC number:	201-245-8
EC name:	4,4'-isopropylidenediphenol
CAS number (EC inventory):	80-05-7
CAS number:	80-05-7
CAS name:	Phenol, 4,4'-(1-methylethylidene)bis-
IUPAC name:	2,2-bis(4-hydroxyphenyl)propane
Index number in Annex VI of the CLP Regulation	604-030-00-0
Molecular formula:	$C_{15}H_{16}O_2$
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; B 0494; BPA; BPA 154; BPA 157; BPA-M; Bis(4-hydroxyphenyl)dimethylmethane; Bis(p-hydroxyphenyl)propane; Dian; Diano; Diphenylolpropane; HT 3082; Hidorin F 285; Hidorin F 568; Ipognox 88; Isopropylidenebis(4-hydroxybenzene); NSC 1767; NSC 17959; Parabis; Parabis A; Pluracol 245; Rikabanol; p,p'-Bisphenol A; p,p'-Dihydroxydiphenylpropane; p,p'-Isopropylidenebisphenol; p,p'-Isopropylidenediphenol; β,β'-Bis(p-hydroxyphenyl)propane*
Structural formula:	

Table 15: Substance identity of BPS

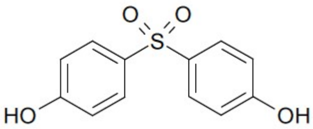
EC number:	201-250-5
EC name:	4,4’-sulphonyldiphenol
CAS number (EC inventory):	80-09-1
CAS number:	80-09-1
IUPAC name:	4-(4-hydroxybenzenesulfonyl)phenol
Index number in Annex VI of the CLP Regulation	N/A
Molecular formula:	$C_{12}H_{10}O_4S$
Molecular weight range:	250.27 g/mol
Synonyms:	*Bisphenol 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(HYDROXYPHENYL)SULPHONE; Bis(p-hydroxyphenyl) sulfone; BPS 1; Dihydroxydiphenyl sulfone; DIHYDROXYDIPHENYLSULPHONE; Diphone C; p,p'-Dihydroxydiphenyl sulfone; Phenol, 4,4'-sulfonylbis- (9CI); Phenol, 4,4'-sulfonyldi- (6CI, 8CI); Phenol, sulfonylbis-; Phenol, sulfonyldi-; PHENOL, SULPHONYLBIS; PHENOL, SULPHONYLDI; Sulfonyldiphenol-; SULPHONYLDIPHENOL*
Structural formula:	

Table 16: Substance identity of BPB

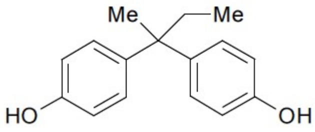
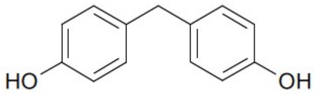
EC number:	201-025-1
EC name:	4,4'-(1-methylpropylidene)bisphenol
CAS number (EC inventory):	77-40-7
CAS number:	77-40-7
CAS name:	Phenol, 4,4'-(1-methylpropylidene)bis
IUPAC name:	4,4'-(1-Methylpropylidene)bisphenol 4-[2-(4-hydroxyphenyl)butan-2-yl]phenol
Index number in Annex VI of the CLP Regulation	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 17: Substance identitiy 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; 4,4'-methylenediphenol
Structural formula:	

Instead of disseminated data from a registration dossier on BPF itself, the following data is reported from the ECHA dissemination database on List No 908-921-9, a multi-constituent substance comprising BPF and its two stereoisomers, section “Physical & chemical properties”.[62]

Table 18: Structurally related substance(s) of BPF identity

List No number:	908-912-9
EC name:	2-[(2-hydroxyphenyl)methyl]phenol; 2-[(4-hydroxyphenyl)methyl]phenol; 4-[(4-hydroxyphenyl)methyl]phenol
SMILES:	See below
CAS number (in the EC inventory):	1333-16-0
CAS number:	1333-16-0

---

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

IUPAC 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
Synonyms (trade names):	GX-460; KD-9005; KD-9007; KD-9009; KDF-214M; KDF-438; KDN-253; SP-2000; SP-2000P; YDPN-638A80; YDPN-638N

Substance type: multi-constituent

The registered substance is an isomeric mixture of (from left to right) 4,4'-BPF, 2,4'-BPF and 2,2'-BPF (see below).

Table 19: Constituents of structurally related substance List No 908-912-9

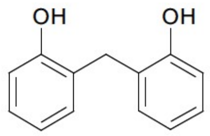
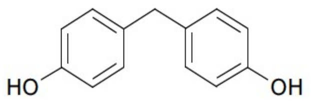
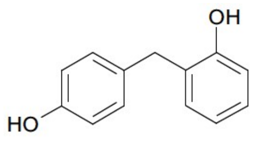
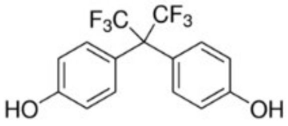
Constituents	**EC Number**	**CAS number**	**SMILES / structural formula**
2,2'-methylenediphenol	219-578-2	2467-02-9	Oc1ccccc1Cc2ccccc2O 
4,4'-methylenediphenol	210-658-2	620-92-8	Oc2ccc(Cc1ccc(O)cc1)cc2 
o-[(4-hydroxyphenyl)methyl]phenol	219-579-8	2467-03-0	Oc2ccc(Cc1ccccc1O)cc2 

Table 20: 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, 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 21: List of 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.

B.1.2. Physicochemical properties

Table 22: Physicochemical properties of BPA (as per lead registration dossier)

Property	**Value**	**Comment (e.g. measured or estimated)**
Physical state at 20°C and 101.3 kPa	Bisphenol A is a white solid at environmentally relevant temperatures	
Melting/freezing point	155 °C	Experimental result Method 10294, ASTM D4493, Method 58255B
Boiling point	Boiling Point at 17 hPa: 250 - 252 °C (with potential decomposition), Boiling Point at 1013 hPa: 360 °C (with decomposition)	
Relative density	1.2 g/cm^3 at 25 °C	
Vapour pressure	4.12E-09 hPa at 25 °C	Experimental result OECD Guideline 104 (Vapour Pressure balance)

Property	**Value**	**Comment (e.g. measured or estimated)**
Surface tension	Waiver	In accordance with column 2 of REACH Annex VII a study does not need to be conducted as, based on structure, surface activity is neither expected or predicted nor a desired property of the substance.
Water solubility	300 mg/L at 25 °C	Experimental result OECD Guideline 105 (flask method)
Partition coefficient n-octanol/water	3.4 at 21.5 °C and pH 6.4	
Granulometry	Waiver	In accordance with column 2 of REACH Annex VII, a study does not need to be conducted as the substance is marketed or used in a non-granular form.
Stability in organic solvents and identity of relevant degradation products	Waiver	In accordance with column 1 of REACH Annex IX, a study does not need to be conducted as the stability of the substance is not considered to be critical.
Dissociation constant	11.3 at 20 °C	
Viscosity	Waiver	In accordance with section 1 of REACH Annex XI, a study does not need to be conducted as the substance is a solid at ambient temperatures.

Table 23: Physicochemical properties of BPS (as per lead registration dossier)

Property	**Value**	**Comment (e.g. measured or estimated)**
Physical state at 20°C and 101.3 kPa	A fine white odourless powder, solid at 20°C and 101.3 kPa	
Melting/freezing point	245-248°C	Beilstein (2007) covers a melting point of 245 - 248 °C as a range of 8 independent entries. GESTIS (2008) gives 242 -247 °C as value for the melting point. The range of values cited in Beilstein was taken as key value.

Property	**Value**	**Comment (e.g. measured or estimated)**
Boiling point	not applicable	decomposition at 315°C The boiling point of the test item could not be determined, because at a temperature of 315°C a continuously increasing pressure was observed. This is presumably caused by a limited stability and a thermal change of the test item.
Vapour pressure	negligible	The melting point of the substance is between 200 °C and 300°C. The calculated value of vapour pressure at 25°C is quite low as expected (6.29E-10 hPa at 25°C).
Surface tension	not applicable	Based on chemical structure, no surface activity is predicted.
Water solubility	1.1g/l at 20°C	
Partition coefficient n-octanol/water	1.2 at 23°C (pH 6.2)	
Granulometry	particles <100µm approximate 55%, particles <10µm approximate 1.8%, particles <4µm approximate 0.4%	
Stability in organic solvents and identity of relevant degradation products	not applicable	The stability of the substance is not considered as critical.
Dissociation constant	pKa (at 20°C) = 8	
Viscosity	not applicable	Substance is a solid at 20° C and atm. pressure.

Table 24: Physicochemical properties of BPF[63]

Property	**Value**	**Comment (e.g. measured or estimated)**
Melting/freezing point	162.5 °C	
Boiling point	Sublimation	
Vapour pressure	3.7X10-7 mm Hg at 25 °C (est)	
Partition coefficient n-octanol/water	2.91	
Stability in organic solvents and identity of relevant degradation products		Soluble in ethanol, ether, chloroform, alkali; slightly soluble in DMSO; insoluble in carbon disulfide

Table 25: Physicochemical properties of BPB

Property	**Value**	**Comment (e.g. measured or estimated)**
Physical state at 20°C and 101,3 kPa	white to low brown powder	
Melting/freezing point	120.5° - 139.43 °C	
Boiling point	375.14 °C (pressure not specified)	
Relative density	1.2 g/cm³ at 25°C	
Vapour pressure	3.3E-05 Pa at 25 °C	
Water solubility	29.23 mg/L at 25 °C (pH not specified)	
Partition coefficient n-octanol/water	3.4 at 21.5°C and pH6.4	OECD 107
Dissociation constant	11.3 at 20 °C	

---

[63] National Center for Biotechnology Information (2021): PubChem Compound Summary for CID 12111, 4,4'-Methylenediphenol, Bisphenol F. National Center for Biotechnology Information. https://pubchem.ncbi.nlm.nih.gov/compound/4_4_-Methylenediphenol.

Table 26: Physicochemical properties of BPAF (as per lead registration dossier)

Property	**Value**	**Comment (e.g. measured or estimated)**
Physical state at 20°C and 101,3 kPa	solid: particulate/powder	
Melting/freezing point	161.7 °C at 101.325 kPa	
Boiling point		Not determined (decomposition at ≥ 350 °C); EU Method A.2.; C Bär (2017)
Relative density	1.573 g/cm³ at 20°C	EU Method A.3
Vapour pressure	0 Pa at 20°C	EU Method A.4
Water solubility	222.4 mg/L at 20°C	EU Method A.6.; C Bär (2017)
Partition coefficient n-octanol/water	2.79 at 20°C	EU Method A.8. ; C Bär (2017)
Granulometry	L10D (v, 0.1) = 4.40 µm, L50D (v, 0.5) = 13.96 µm, L90D (v, 0.9) = 36.33 µm;	CIPAC MT 187; C Bär (2017

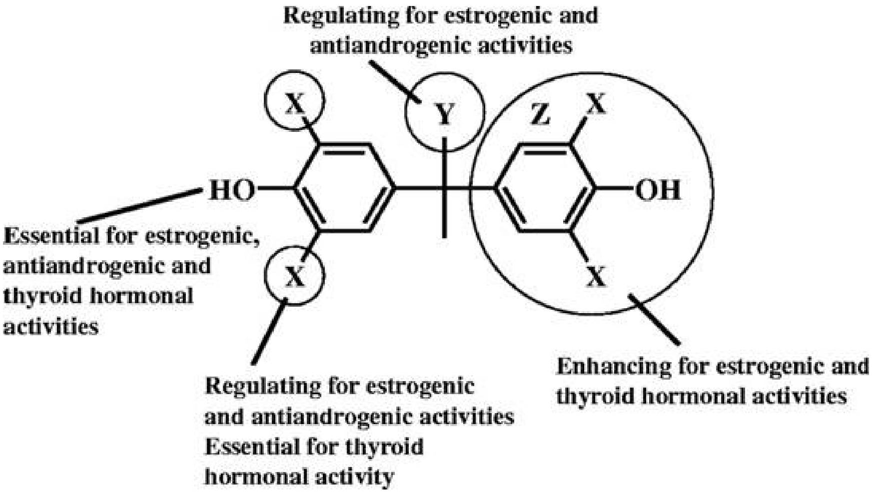
B.1.3. Justification for grouping

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 3: 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.

Bisphenol A and Bisphenol B were identified as substances of very high concern according to Art 57(f) of the REACH regulation because they showed endocrine disrupting effects in the environment. For BPS, BPF and BPAF, the available data from in vitro as well as from in vivo mammalian and fish studies show that they also fulfill the WHO/IPCS criteria for an ED in the environment. For more details please refer to chapter B.7.

B.2. Manufacture and uses (summary)

B.2.1. Tonnage – consumption BPA and BosC

According to the registration information BPA is manufactured and/or imported in the European Economic Area in a tonnage range of 1,000,000 to 10,000,000 tons per year.[64] As stated above, MC group (2020)[65] estimates the BPA consumption in Europe in 2019 to be 1,242,000 t. Moreover, a steady growth is expected during the next years (despite the restriction of its use in thermal paper since January 2020) so that an annual BPA consumption of 1,718,000 t is predicted for 2024. More specifically, they allocate the 1,242,000 t of BPA to polycarbonates (80%), epoxy resins (18%) and others (2%). Both, exports as well as imports of the substance, mixtures containing BPA and articles occur.Percentage may vary in the dossier. These values depend on the date of the research and the source.

The following information on tonnage for the BosC (BPB, BPS, BPF and BPAF) used annually in the EU is provided on the ECHA dissemination sites. The tonnage of other bisphenols with similar concern is smaller than that of BPA. In total, the tonnage of these bisphenols corresponds to 1% of the tonnage of BPA.

Table 27: Registered tonnage band for BPA and BosC

Substance	CAS number	Tonnageband (tpa)	Import [66](substance)	Export [67](substance)
BPA[68]	80-05-7	1,000,000 – 10,000,000	60,000	10,000
BPB[69]	77-40-7	1 - 10	-	-
BPS[70]	80-09-1	10,000 – 100,000	-	-
BPF[71]	620-92-8	1,000 – 10,000	-	-
BPAF[72]	1478-61-1	100 – 1,000	-	-

---

[64] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.133 (06/29/2021)
[65] MC group (2020): Bisphenol A 2020 World Market Outlook and Forecast up to 2029.
[66] EUROSTAT 03.03.2021
[67] EUROSTAT 03.03.2021
[68] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.133 (06/29/2021)
[69] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.000.933 (06/29/2021)
[70] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.137 (06/29/2021)
[71] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.009.691 (06/29/2021)
[72] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.014.579 (06/29/2021)

B.2.2. Sectors in which BPA and BosC are used

Bisphenols and the articles/mixtures derived from it or containing it are used in a variety of sectors for many applications. BPA for example can be found in the following sectors:[73,74,75,76,77,78,79,80]

- construction
- medical devises
- traffic control
- automobile industry
- aircraft sector
- wind power plants
- textile Industry
- furniture sector
- toys
- food contact material/ Feed contact material
- commodities
- electronics sector
- optic sector
- paper industry
- packaging
- sectors producing mixtures: coatings, varnishes, lacquer, paints, adhesives, lubricants
- dye sector
- dentistry
- flame retardant
- cosmetics
- protection/safety

For other bisphenols of similar concern (BosC), this widespread distribution is not known or too little studied. However, these substances are also used in the manufacture of other

---

[73] https://echa.europa.eu/de/substance-information/-/substanceinfo/100.001.133 (03/03/2021)

[74] http://spin2000.net/ (03/03/2021)

[75] Amaral, M. J. (2014): Non-toxic healthcare: alternatives to phthalates and bisphenol a in medical devices. In *Health Care Without Harm (HCWH) Europe*, pp. 1–25. Available online at https://noharm-europe.org/EDCs-report, checked on 3/3/2020.

[76] EFSA (2015): Scientific opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs: executive summary. In *EFSA J.* 13 (1), 3978/1.

[77] Eckardt, Martin; Kubicova, Marie; Tong, Duyen; Simat, Thomas J. (2020): Determination of color developers replacing bisphenol A in thermal paper receipts using diode array and Corona charged aerosol detection-A German market analysis 2018/2019. In *Journal of chromatography. A* 1609, p. 460437. DOI: 10.1016/j.chroma.2019.460437.

[78] Koehler Group: koehlerpaper.com. Available online at https://www.koehlerpaper.com/en/products/Thermal-paper/Thermal-technology.php, checked on 8/25/2020.

[79] Morgan, Alun (2015): Fire-Retardancy-What-Why-and-How. Isola Group. Available online at https://www.isola-group.com/wp-content/uploads/Fire-Retardancy-What-Why-and-How.pdf, checked on 8/31/2020.

[80] Fischer B., Milunov M., Floredo Y., Hofbauer P., Joas A. (2014): Identification of relevant emission pathways to the environment and quantification of environmental exposure for bisphenol A: Research Project on behalf of the German environment agency - https://www.umweltbundesamt.de/publikationen/identification-of-relevant-emission-pathways-to-the

substances, including polymers, and they can theoretically also be used as additives, a similar distribution into most of the sectors given above must be assumed at this point.

B.2.3. Bisphenol A

B.2.3.1. Uses - function

The uses for the bisphenols manufactured/imported in the EU are structured after manufacturing and downstream use of polymers (P), production and downstream use of other chemicals (C) and additives use (A).

The main uses[81] for BPA with high tonnage are the manufacture of polycarbonate (PC) with about 80% of the BPA production volume and manufacture of epoxy resin with around 18% of the BPA production volume. However, there is a remaining percentage with a share of 0.02% concerning the use of BPA as an additive with several technical functions.

Table 28: Registered uses for BPA currently disseminated on ECHA website

	Use(s)
Manufacture	Industrial Manufacturing of Bisphenol A Industrial Use of Bisphenol A as Laboratory Reagent Manufacture of Bisphenol A
Formulation	Formulation of epoxy resin hardeners formulation of preparations Formulation, Transfer and Packing Industrial repackaging of Bisphenol A Industrial repackaging of Bisphenol A Industrial repacking of Bisphenol A Industrial Use of Bisphenol A as Anti-Oxidant for Processing PVC Industrial Use of Bisphenol A for Manufacturing Epoxy Resin Hardeners Industrial Use of Bisphenol A in Epoxy Resin Hardeners Manufacture of thermal paper - formulation into materials Professional Repackaging of Bisphenol A Professional repacking of Bisphenol A
Uses at industrial sites and uses as intermediate	Blending of polycarbonate Industrial manufacture of articles made of polycarbonate Industrial use Industrial Use in Epoxy Adhesives and Encapsulants Industrial Use in Polymer Preparations Industrial Use of Bisphenol A for Manufacturing Polymers Industrial Use of Bisphenol A as Anti-Oxidant for Processing Polyvinylchloride (PVC) Industrial Use of Bisphenol A as Anti-Oxidant for Processing PVC Industrial Use of Bisphenol A for Manufacturing Chemicals Industrial Use of Bisphenol A for Manufacturing Coating Materials

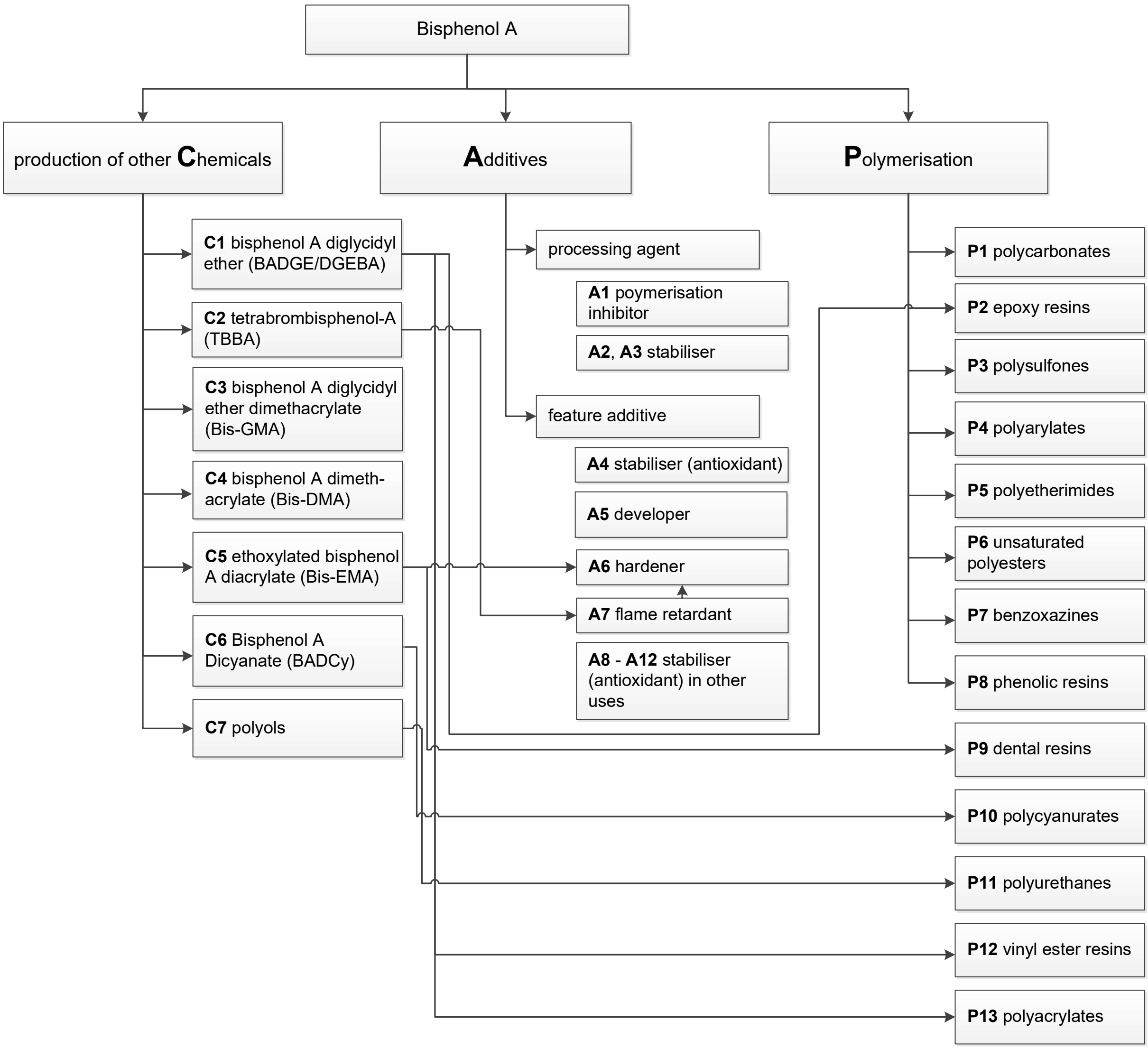
---

[81] Annex H

	Industrial Use of Bisphenol A for Manufacturing Epoxy Resin Hardeners Industrial Use of Bisphenol A for Manufacturing Epoxy Resins Industrial Use of Bisphenol A for Manufacturing Polycarbonate Industrial Use of Bisphenol A for Manufacturing Polymers Industrial Use of Bisphenol A for Manufacturing Thermal Paper Industrial Use of Bisphenol A for Manufacturing Thermal Paper (including paper recycling) Industrial Use of Bisphenol A in Epoxy Resin Hardeners Industrial use of epoxy resin hardeners Manufacture of coating materials Manufacture of epoxy resin hardeners Manufacture of epoxy resins Manufacture of epoxy resins hardener Manufacture of other substances Manufacture of polycarbonate Recycling of thermal paper Use of Bisphenol A as laboratory reagent Use of epoxy resin hardeners
Uses by professional workers	Professional Repackaging of Bisphenol A Professional Use of Bisphenol A as Anti-Oxidant for Processing Polyvinylchloride (PVC) Professional Use of Bisphenol A as Anti-Oxidant for Processing PVC Professional Use of Bisphenol A in Epoxy Resin Hardeners Professional use of Epoxy Resin Hardeners Use of epoxy resin hardeners Use of epoxy resin hardeners, indoor flooring
Consumer Uses	Consumer use of Bisphenol A in articles made of PVC Consumer use of Bisphenol A in articles of epoxy resins
Article service life	Consumer indoor use of articles made of polycarbonate Consumer outdoor use of articles made of polycarbonate Consumer Use of Articles made of Epoxy Resins Consumer Use of Articles made of Polycarbonate Consumer Use of Articles made of Polyvinylchloride (PVC) Consumer Use of Bisphenol A in Articles made of PVC Consumer Use of Bisphenol A in Thermal Paper Consumer Use of Thermal Paper Professional indoor use of articles made of polycarbonate Professional outdoor use of articles made of polycarbonate Professional Use of Articles made of Polyvinylchloride (PVC) Professional Use of Thermal Paper Service life of thermal paper (consumers) Service life of thermal paper (professional worker) Use of recycled paper

With the UBA report from 2020 (Annex H), the dossier submitter has endeavored to cover the totality 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 structed way:

Figure 4: Uses of BPA



B.2.3.2. Products[82]

Polymers (P)

BPA use for the manufacturing polycarbonates (PC) (P1)

In polymers, BPA is used as a monomer and covalently bound into a polymer matrix. The main use of BPA is to produce polycarbonate (PC). The annual production of PC in Europe takes up 1,2 million tons BPA [83]. PC is a well-known and widely distributed thermoplastic.

---

[82] http://www.spin2000.net/spinmyphp/

[83] Cf. Annex H

Since the potential applications are so manifold and the different uses need different material properties and thus material formulations, a wide variety of PC formulations and PC blends are commercially obtainable.

Table 29: EU consumption of PC by sector

Sector	Application/ Products	Consumption
Building & Construction	glazing, walls, covers, signs, cabins	25%
Electrical & Electronics	housings, panels	20%
Automotive	windows, lamps, parts, grills, housings	15%
Optical Media	compact Discs, CD-ROMs, Discs, DVDs, ID cards, lenses, goggles	12%
Domestic Appliance	Blenders, cooking appliances	10%
Safety & Leisure	goggles, helmets, shields, glasses, toys, sport equipment	5%
Bottles & Packaging	reusable bottles, food containers	4%
Medical & Healthcare	medical devices	4%
Others		5%

Sources: BioMath GmbH, SKZ-KFE gGmbH, Ramboll Deutschland GmbH (2017)

BPA for the manufacture/use of epoxy resins (ER) (P2)

Products of epoxy resins (ER) are used in a wide field of application e.g. for composite materials, adhesives, paints and varnishes and epoxy resins as potting compounds for most of the electrical components on printed circuit boards.

Epoxy resins are mainly used in the production of paints and coatings (40%) and electrical and electronics applications (33%). In other applications such as adhesives, composites, building materials, epoxy resins are used extensively and new uses of epoxy resins in various applications are foreseen. The annual consumption of BPA for this application is estimated to be around 275,000 tons.

Table 30: EU consumption of ER by sector

Table: EU consumption of Epoxy ResinsSector	Application/ Products	Consumption
Civil Engineering	paint and coatings, flooring	20%
Marine and protective coatings	windmill rotor blades, smart grids, turbine insulators	15%
Automotive coatings	cars, trains, airplanes, ships	8%
Building and construction	pipelines	20%
Electrical and electronics	internal circuits, transistors and printed circuit boards, LED's, solar panels	16%
Leisure	boats, skateboards	11%
Household and furniture	can coatings	10%

Sources: BioMath GmbH, SKZ-KFE gGmbH, Ramboll Deutschland GmbH (2017)

BPA use for the manufacturing/use of other polymers (P3-P13)

BPA is also used as the monomer in the manufacturing of other polymers: polysulfones, polyacrylates, polyetherimides, unsaturated polyesters and furthermore used in the polymerisation of benzoxazines, phenolic resinspolymerization and of dental resins. High-temperature (HT) polymers of the polyarylsulfone family (Polyphenylsulfone - PPSU, Polysulfone - PSU, Polyethersulfon - PESU) are characterized by extraordinary, inherent flame retardancy and high transparency. Polyetherimide - PEI are also amorphous HT thermoplastics and therefore often compete with PESU or PPSU - especially in injection molding applications.

Table 31: EU consumption of other polymers

Code	Polymer	Sector	Application/ Products	Consumption
P3	Polysulfones	Medical & Healthcare	surgical trays, nebulisers, humidifiers, membranes for haemodialysis	24%
		Automotive	cooling water circuit, headlights	18%
		Food service	microwave cookware, dispensers, milking machines, membranes for dairy	13%

Code	Polymer	Sector	Application/ Products	Consumption
		mechanical engineering	water treatment, gas, solar technology	15%
		Electric/ Electronics	housings, plugs	12%
		Others (Aircraft, Military, Sanitary)	hot water fittings, manifolds, mixer tape, trolleys, seats	18%
P4	Polyarylates	Automobile	exterior glazing	n.a.
		Electrical & Electronics	solar energy panels, electrical connectors, lighting fixtures, appliance housing	n.a.
P5	Polyetherimide	Electrical & Electronics	electrical switches and controls, electrical motor parts, printed circuit boards, and connectors, electronic chips, and capacitors	n.a.
		Automotive	electrical and lighting systems, transmission components, throttle bodies, ignition components, thermostat housings, bezels, reflectors, lamp sockets	n.a.
		Aircraft	interiors	n.a.
		Medical & Healthcare	reusable medical devices, membrane applications, handles and housings for surgical instruments, non-implanted prostheses	n.a.
		Domestic	institutional kitchenware, steam and curling irons, microwave cookware	n.a.
P6	Unsaturated BPA Polyesters	Bottles & Packaging	storage tanks, process vessels	n.a.
		Medical & Healthcare	sanitary ware, adhesives, dental compounds	n.a.
		Clothing	textiles (swimwear, underwear)	n.a.
P7	Benzoxazines	Encapsulant’s Manufacturing	composites, coatings, adhesives, encapsulants	100%

Code	Polymer	Sector	Application/ Products	Consumption
P8	Phenolic resins	Electrical & Electronics	commutators in electric motors, water pumps/housing, vacuum pumps	n.a.
		Food service	cookware (handles for pans etc.)	n.a.
P9	Dental resins	Medical & Healthcare	dental composites, dental sealants and dental cements	100%
P10	Polycyanurates	Aerospace	fibre enforced composites	n.a.
		Electrical & Electronics	chip adhesives, thermal interfaces	n.a.
P11	Polyurethanes	Clothing	textiles (spandex), footwear	n.a.
		Automotive	foams, truck seating, upholstering and bedding	n.a.
		Diverse	electronic instruments, flexible straps and bands, injection moulded components	n.a.
P12	Vinyl ester resins	Diverse	corrosion-resistant components and coatings for tanks, pipes and chimney linings	n.a.
P13	Polyacrylate	Diverse	Over print varnishes, inks, coting textiles	n.a.

Source: BioMath GmbH, SKZ - KFE gGmbH, UBA (2014)

Other Chemicals (C)

Bisphenol A diglycidyl ether (DGEBA, BADGE) (C1)

The substance 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxymethylene)]bisoxirane or Bisphenol A diglycidyl ether (BADGE, EC no. 216-823-5, CAS no. 1675-54-3) is an organic compound used as feedstock for epoxy resins. It is synthesized from the starting materials BPA and epichlorhydrin.

Tetrabromobisphenol A (TBBPA) (C2)

BPA is used to produce tetrabromobisphenol A (TBBPA, EC no. 201-236-9, CAS no. 79-94-7) which is used as a flame retardant (additive and reactive). 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.

TBBPA is also used in the manufacture of derivatives, such as TBBPA bis(methyl ether), bis(bromopropyl ether), bis(allyl ether), bis(2-hydroxyethyl ether), brominated epoxy oligomer, and carbonate oligomers. The main use of these derivatives is as flame retardants. This substance is used by consumers, in articles, by professional workers (widespread uses), in formulation or re-packing and at industrial sites.[84]

It is used in the following activities or processes at workplace: the low energy manipulation of substances bound in materials or articles, production of mixtures or articles by tabletting, compression, extrusion or pelletisation and high energy work-up of substances bound in materials or articles (e.g. hot rolling/forming, grinding, mechanical cutting, drilling or sanding).

Bis-GMA/Bis-DMA/Bis-EMA (C3, C4, C5)

BPA is used in the manufacture of dental composites, e.g. BPA glycidyl methacrylate (Bis-GMA) and BPA dimethacrylate (Bis-DMA).

Ethoxylated bisphenol A Diacrylates (Bis-EMA) are widely used monomer compounds used for the synthesis of dental resins and other acrylic polymers.

Bisphenol A Dicyanate (BADCy) (C6)

Cyanate esters are used in high-performance structural composites, 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.

Polyols/Polyurethanes (C7)

Bisphenol A based polyols are furthermore used to produce certain polyurethanes. An example for the synthesis of a cardanol based polyol is given in the scheme below.

Additives use (A)

About 2%[85] of BPA are used as an additive 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 stabilisers, polymerisation 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 polymerisation reactions of plastics as well as during stabilisation of plasticisers or reactive polymerisation monomers, the corresponding additives (e.g. polymerisation inhibitors) and reaction partners (e.g. reactive flame retardants) are usually added to the reaction medium as pure substances in appropriate quantities.

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

---

[84] Scientific Committee on Health and Environmental Risks (SCHER), 2008: Tetrabromobisphenol A, Environmental Part: https://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_071.pdf

[85] FKZ 3719654060, cf. Annex H

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.

Pre-formulation/mixtures (masterbatches)

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.

Polymerisation inhibitor (A1)

In polymer production BPA is also used as a polymerisation inhibitor. The function of the BPA is to deactivate the free radicals that are necessary for the polymerisation of the monomers in order to stop the chain propagation.

Stabiliser/Antioxidant for PVC (A2, A3, A4, A8, A9, A10, A11, A12)

BPA is also used as a stabiliser and as part of additive packages for PVC processing and as a stabiliser in the production of plasticisers used 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 plasticisers and degradation of the PVC polymer chain during synthesis, processing, manufacture and final application (value depends on base formulation by area of application, e.g. compact sewer pipes, foam core pipes, drainage pipes, electrical pipes, gutters, fittings, window profiles, roller shutters, foam boards, PVC wood composites, cables, floor coverings, paints, foils, hoses, shoe soles). In fact, 69% of all PVC produced is used in building and construction.[86]

Similar to its use as an antioxidant in the stabilisation of plasticisers for PVC production, BPA is also used in the stabilisation of chain oil, brake fluids, heat transfer fluids as well as lubricant formulations, preventing oxidative degradation of those systems. In tyre production, BPA is employed as a part of the compounding formulation. In the presence of the other ingredients and during the curing process, it becomes incorporated into the polymer matrix. It is used as an antioxidant which appears to be specifically for the compounding phases, and it is intended to protect the materials at this stage. There is no indication that it is intended to be the major antioxidant in the actual tyres, and it is not expected to be present at significant levels in the finished product (Groshart et al. 2001).

For the last 20 years, synthetic fibres have become the most common type of fibre for textiles. The production amounts arose EU wide to around 65 million tons per year. Synthetic fibres are dominated by polyester. This plastic is almost always the same as the plastic which is known as polyethylene terephthalate (PET) when used for water bottles or packaging.[87,88] For polyester, BPA is used as a chemical intermediate in the production of dyes and antioxidants in finishes. The antioxidants are used to obtain properties of the finished fabrics, like UV resistance, fade protection, waterproofness, softness and microbiological and antistatic protection [89]. Studies summarized the available concentration

---

[86] Häkkinen et al., 2019, Plastics in Buildings – A study of finnish blocks of flats and daycare centers. Available online: https://www.ymparisto.fi/download/noname/%7b76B1ED3C-6D8D-4108-80D1-487F69957E45%7d/152008

[87] EEA, 2019c, Textiles in Europe's circular economy, EEA Briefing No 10/2019, European Environment Agency (https://www.eea.europa.eu/publications/ textiles-in-europes-circular-economy).

[88] ETC/WMGE, 2019, Textiles and the environment in a circular economy, European Topic Centre on Waste and Materials in a Green Economy, Mol, Belgium (https://www.eionet.europa.eu/etcs/etc-wmge/ products/etc-reports/textiles-and-the-environment-ina-circular-economy).

[89]https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_240.pdf

in clothes from 72-210 ng/g (average 26.9 ng/g). The BPA occurrence is about 90%. Detected BPA concentrations from clothing samples outside the EU show up to 252 ng/g.

Photo developer (A5)

In thermal paper, BPA is used as a photo developer that, during heating and/or pH change, reacts with the leuco dye (usually spirolactones, fluoranes, spiropyranes, etc.) which in turn changes into its colored form (van Es 2014a). Frankowski et al. 2020[90] analysed the level of BPA presence in receipts. Receipts from 39 countries showed that BPA remains the most common compound used for receipt paper with 69% of samples containing the color developer. Analysed receipts were mostly from Europe given its recent change in regulations to restrict BPA use in thermal paper to <0.02% by weight (EU 2016/2235; January 2020). Samples collected from Japan and the United States were found to contain only BPS. None or only trace levels of other bisphenols (F, AF, E, and B) considered as possible alternatives for BPA were detected. ECHA (2020) reports that BPA use for thermal paper decreased by 45% (1,810 up to 3,304 tons) from 2018 to 2019. During the same period, BPS use increased by 66% (1,476 up to 2,454 tons).[91] For this A-ES 4 Scenario it was assumed that 100% phaseout of BPA was substituted by 100% BPS.

Hardener in epoxy resins (A6)

In some epoxy resins, BPA is used as a phenolic hardener. During the curing process, BPA reacts with the epoxy components of the resin, leading to crosslinking of the polymer chains and the formation of a very stable three-dimensional polymer network. Upon reaction with the epoxy resin BPA is transformed and becomes an integral part of a highly crosslinked, three-dimensional polymer matrix (ECHA 2019).

Flame retardant (A7)

BPA is used as a flame retardant in the form of its brominated derivative TBBPA. TBBPA is directly synthesized from BPA and is employed either as an additive (admixture without chemical reaction) or reactive flame retardant in polymers such as epoxy resins, polycarbonate or acrylonitrile butadiene styrene (ABS). In contrast to its use as an additive, TBBPA as a reactive flame retardant is chemically incorporated into the polymer backbone and is thus an integral part of the matrix.

Table 32: Additive uses of BPA

Additive function	Examples for Application/ Products
Stabiliser of Mixtures	masterbatches
Polymerisation inhibitor (A1)	radical scavenger in the production of polymers
Antioxidant/Stabiliser (A2, A3, A4, A8, A9, A10, A11, A12)	To prevent thermolysis or oxidation in PVC processing; tire, textile manufacturing; to prevent oxidation in lubricants, brake fluids
Photo developer (A5)	Thermal paper
Hardener[92] (A6)	Phenolic hardener in epoxy resins

---

[90] Frankowski, Robert, et al. The presence of bisphenol A in the thermal paper in the face of changing European regulations–A comparative global research. Environmental Pollution (2020): 114879.

[91] ECHA. 2020. The use of bisphenol A and its alternatives in thermal paper in the EU during 2014 -2022. ECHA-20-R-07-EN.

[92] Data taken from the registration

Additive function	Examples for Application/ Products
Flame retardant (TBBPA) (A7)	Reactive substance incorporated in polymer

B.2.4. BosC

The breakdown of uses is rather abstract for the BosC, as the information on the exact quantities that can be attributed to the respective uses cannot be found in such detail. However, it is clear that they can be assigned to one of three use groups: production of polymers (P), use as additives (A) and production of other chemicals (C).

Table 33: BosC uses

BosC	use	P/A/C
BPB	to manufacture PC, ER and phenolic resins	P
BPS	photo developer, surface modifier in the tanning of leather or precurser for the production of tanning agents, monomer or chromophoric agent in the manufacture of paper, monomer manufacturing food contact material	P/A/C
BPF	to manufacture coatings, plastics, other chemicals, paints, coatings, inks, adhesives, lubricants, greases, cleaning agents, fragrances, photo-chemicals, plant protection products, textiles, paper	P/A/C
BPAF	to manufacture polymers, vulcanising agent or cross-linker in the production of fluoroelastomers	P/A

BPA is often easy to substitute for additive uses by BosC, due to the drop-in substitution solution, as this has little impact on the process. It is more complex when BPA is substituted during polymerisation, but still achievable if technical procedures and processes are optimised.[93] Therefore, it can be assumed that bisphenols with similar concern 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 BP(A) can be divided. These are: use as additive (A), use as monomer for polymerization processes (P) and production of other chemicals (C).

---

[93] Annex H

B.3. Classification and labelling

B.3.1. Classification and labelling in Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

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 34: 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). It proposes to add the following hazard classes and hazard statements to the existing entry for BPA:

Table 35: CLH proposal for BPA adding environmental hazard classes to Annex VI entry

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 confirmed the CLH proposal in its opinion.

Bisphenol S is currently 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). It proposes to add an entry with the following hazard classes and hazard statements for BPS:

Table 36: 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 confirmed the CLH proposal 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 the regulatory group strategy[94]. It proposes to add the following hazard classes and hazard statements to the existing entry for BPAF:

Table 37: CLH proposal for BPAF for a reprotoxic hazard class for Annex VI 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)		
	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 was published on the 18th of March 2021. RAC confirmed the CLH proposal in its opinion.

---

[94] The substances covered by the CLH proposals are EC/List No 216-036-7 (BPAF); (https://echa.europa.eu/fi/registry-of-clh-intentions-until-outcome/-/dislist/details/0b0236e1830f8b24); 278-305-5; 479-100-5; 943-265-6; and 947-368-7

B.3.2. Classification and labelling in classification and labelling inventory/ Industry’s self-classification(s) and labelling

The following hazard classes are notified in the C&L inventory for Bisphenol A:

Table 38: Industry's self-classification and labelling for BPA (ECHA C&L inventory)

Substance	CAS No. or EC No.	Hazard Class and Category Code (s)	Hazard statement Code (s)	Number of Notifiers
Bisphenol A	80-05-7	Acute Tox. 4	H302	2
		Skin Irrit. 2	H315	1
		Skin Sens. 1	H317*	2663
		Eye Dam. 1	H318*	2663
		Eye Irrit. 2	H319	1
		STOT SE 3	H335*	2663
		Repr. 1B	H360F*	544
		Repr. 2	H361	2114
		Aquatic Chronic 2	H411*	530
		Aquatic Chronic 3	H412	25

*joint entry

For the other BosC, the following hazard classes are notified in the C&L inventory:

Table 39: Industry's self-classification and labelling for the BosC (ECHA C&L inventory)

Substance	CAS No. or EC No.	Hazard Class and Category Code (s)	Hazard statement Code (s)	Number of Notifiers
BPS	80-09-1	Skin Irrit. 2	H315	7
		Eye Irrit. 2	H319	18
		STOT SE 3	H335	7
		Repr. 1B	H360FD*	11
		Repr. 2	H361	87
		Aquatic Chronic 3	H412	1
		Not classified		289
BPF	620-92-8	Skin Irrit. 2	H315	88
		Skin Sens. 1	H317	15
		Eye Dam. 1	H318	14
		Eye Irrit. 2	H319	88
		STOT SE 3	H335	87
		Aquatic Chronic 2	H411	14
		Aquatic Chronic 3	H412	52
		Not classified		5
BPF in reaction	1333-16-0	Skin Sens. 1	H317*	7
		Eye Dam. 1	H318*	15

mass of 4,4'-methylenediphenol and 2,2'-methylenediphenol and o-[(4-hydroxyphenyl)methyl]phenol		Eye Irrit. 2	H319	1
		STOT SE 3	H335	8
		STOT RE 2	H373	1
		Aquatic Chronic 3	H412	7
		Not classified		55
BPB	77-40-7	Acute Tox. 4	H302	39
		Acute Tox. 4	H312	1
		Skin Irrit. 2	H315	3
		Skin Sens. 1	H317	2
		Eye Irrit. 2	H319	41
		Acute Tox. 4	H332	1
		STOT SE 3	H335	1
		Aquatic Chronic 4	H413	38
BPAF	1478-61-1	Skin Irrit. 2	H315	137
		Eye Dam. 1	H318*	76
		Eye Irrit. 2	H319	139
		STOT SE 3	H335	62
		Repr. 1B	H360*	76
		STOT RE 2	H373*	75
		Aquatic Acute 1	H400	86
		Aquatic Chronic 1	H410*	160

*joint entry

B.4. Environmental fate properties

B.4.1. Degradation

B.4.1.1. Abiotic degradation

B.4.1.1.1. Hydrolysis

Bisphenol A

The physical and chemical properties of BPA suggest that hydrolysis and photolysis under environmental conditions is negligible (European Commission, 2003; European Commission, 2008). An atmospheric half-life of 0.2 days was calculated (EUSES) based on the reaction kinetics of BPA with hydroxyl radicals (European Commission, 2003; European Commission, 2008).

Bisphenol S

Data waiving is applied in the registration dossier. The substance is considered as hydrolytically stable, based on phenols data. Phenols are generally regarded as stable towards hydrolysis (Lyman et al., 1990).

Bisphenol F

Hydrolysis is not expected to be an important environmental fate process since this compound lacks functional groups that hydrolyze under environmental conditions (pH 5 to 9) (Lyman et al., 1990).

Bisphenol B

In the Annex XV support document for BPB, the abiotic degradation is assessed and described: *The physical and chemical properties of BPB suggest that hydrolysis and photolysis under environmental conditions are negligible. Kovačič et al. (2019), investigated the hydrolysis, adsorption, biological treatment and UV photolysis of 18 BPs including BPB and BPA under laboratory conditions. BPB, just like BPA, was shown to be stable in the hydrolysis experiment (>90% at the end of exposure time of 48 h). Adsorption to biomass seems one primary mechanism for BPB removal from wastewater, as was the case for BPA. The photolysis assay showed that BPB removal follows pseudo-first-order kinetics, with a rate constant of 0.028 min*$^{-1}$ *and a half-life of 24.76 min (51% BPB remaining after 240 min UV irradiation), whereas BPA shows a rate constant of 0.002 min*$^{-1}$ *and a half-life of 346.57 min. The removing efficiency of BPB is higher than BPA.*

Bisphenol AF

BPAF is not expected to undergo hydrolysis in the environment due to the lack of functional groups that hydrolyze under environmental conditions (Lyman et al., 1990). In the registration dossier a test according to OECD TG 111 was reported resulting in negligible (<10%) hydrolysis at pH 4, pH 7 and pH 9. The half-life of BPAF was estimated to be longer than one year (at 25 °C).

B.4.1.1.2. Phototransformation/photolysis

Bisphenol A

Air

After exposure to air, BPA will be rapidly degraded by photochemical processes. The rate constant for indirect photolysis in air (OH-mediated photodegradation) is $80.6 \cdot 10^{-12}$ cm^3/(molecule·sec) and the half-life is 0.13 days, assuming 12 hours daylight and a hydroxyl radical concentration of $1.5 \cdot 10^6$ molecules/cm^3 (EPISuite v3.12, AOPWIN v1.91, model (US EPA, 2000)).

Water

BPA has a half-life of 0.5 to 10 days for direct photolysis and 0.7 to 1.3 days for indirect photolysis reported from laboratory experiments (Chin et al., 2004; Eriksson et al., 2004; Zhan et al., 2006).

Bisphenol S

Air

Photodegradation was estimated by QSAR using EPIWIN calculation (SRC AOP v1.92). For calculation, a degradation rate constant of $14.5 \cdot 10^{-12}$ cm^3/molecule·sec, a 24-hour day and a mean OH radicals' concentration of $0.5 \cdot 10^6$ OH/cm^3 were assumed.

A dissipation half-life (DT_{50}) of 26.5 h was calculated in the registration dossier, therefore photochemical degradation is swift.

Bisphenol F

Air

BPF in the vapor phase will be degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals. The half-life of this reaction in air is estimated to be 5 hours. BPF in the particulate phase will be removed from the atmosphere by wet or dry deposition.[95]

Bisphenol B

In the Annex XV support document for BPB the abiotic degradation is assessed and described. For the photodegradation two studies were described in the report:

Vela et al. (2018b), investigated the photodegradation of BPs at pilot plant scale by photolysis (with and without oxidant) or photocatalysis with different forms of TiO_2*. The degradation rates obtained were significantly lower after 240 min in photolysis (remaining BPB was 48 ± 5% (45% for BPA)) compared to photocatalysis (remaining BPB was 0.002 to 0.004 ± 0.001% for BPB and BPA depending on the form of TiO2 used). Mineralisation was not complete at the end of exposure. Toxicity was then assessed with V. fischeri bioluminescence inhibition assay (UNE-EN-ISO 11348-3). Toxicity to V. fisheri decreased from 67 ± 7% to 48 ± 8% (photolysis) or to 19 ± 5% (*TiO_2 *P25) at the end of the treatments. All compounds followed an apparent first-order degradation curve and the degradation rate was in the order: BPB > BPA. The BPB* DT_{90} *was 501 min with* TiO_2 *P25 and 1001 min with* TiO_2 *vlp 7000.*

In a second study (Vela et al., 2018a), they investigated the photodegradation of substances including BPA and BPB in laboratory and at pilot plant scale under natural sunlight in June 2016. The efficiency of the process was significantly slower at the pilot scale with natural light than those observed under laboratory conditions mainly due to the presence of interfering substances like some anions and cations and dissolved organic matter. Toxicity was then assessed with V. fischeri bioluminescence inhibition assay (UNE-EN-ISO 11348-3). Toxicity to V. fischeri decreased from 70% to 45 ± 8% (photolysis) and to 11 ± 5% (photocatalysis) at the end of the experiment. The kinetics of disappearance followed an apparent first-order degradation curve. The DT_{50} *of BPB was 5 min and the* DT_{90} *was 18 min (7 and 24 min for BPA, respectively) (Vela et al., 2018a).*

Bisphenol AF

Using EPI Suite as structure estimation method,[96] the rate constant for the vapour-phase reaction of BPAF with photochemically-produced hydroxyl radicals has been estimated as $8.0 \cdot 10^{-11}$ cm^3/molecule-sec at 25 °C. This corresponds to an atmospheric half-life of about 1.6 hours at an atmospheric concentration of $5 \cdot 10^5$ OH/cm^3.

Phenols can undergo sensitized photo-oxidation in surface waters exposed to sunlight via reaction with hydroxyl and peroxy (RO_2) radicals with half-lives in the order of days to weeks at the water surface (Theodore Mill, 1991).

---

[95] [Hazardous Substances Data Bank (HSDB): (Bidleman, 1988)
(2) US EPA; Estimation Program Interface (EPI) Suite.
Ver. 4.1. Nov, 2012. Available from, as of Nov 21, 2017: https://www2.epa.gov/tsca-screening-tools]

[96] (US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.10. Jan, 2011. Available from, as of Nov 5, 2012: https://www.epa.gov/oppt/exposure/pubs/episuitedl.htm)

B.4.1.2. Biodegradation

B.4.1.2.1. Biodegradation in water

Bisphenol A

In three **screening tests** on ready biodegradation according to test guideline OECD 301F, mineralisation levels for BPA were above the trigger value of 60%. Three screening tests show negligible degradation rates at the end of the test period. BPA therefore meets the criteria for rapid degradation.

Table 40: Summary of biodegradation screening tests

Method	Test concentration	Results	Reference
OECD 301 F	7 mg/l and 25 mg/l	78.2-81.0% O_2 consumption after 28 days 10 day window fulfilled	(West et al., 2001)
OECD 301 F	unknown	87.8±6.9% O_2 consumption after 28 days; 10 day window fulfilled	(Stasinakis et al., 2008)
OECD 301 F	100 mg/l	85-93% O_2 consumption after 28 days 10 day window fulfilled	Registration Dossier (Katagiri, 2004)
OECD 301 C	unknown	0% after 14 days	(MITI, 1992)
OECD 301 D	8.9 mg/l	0% O_2 consumption after 28 days	(European Commission, 2010); (Stone and Watkinson, 1983)
OECD 301 B	8.9 mg/l	1-2% CO_2 evolution after 28 days	(European Commission, 2010); (Stone and Watkinson, 1983)

The results from the **tests in freshwater** demonstrate a rapid degradation of BPA under aerobic conditions with a half-life of 4 days (lag period 2-8 days) (Kang and Kondo, 2002; Kang and Kondo, 2005; Klečka et al., 2001; Suzuki et al., 2004). Under anaerobic conditions in river water, 10% of the initial BPA concentration dissipated until day 10 (Kang and Kondo, 2002).

In **seawater**, the concentration of BPA did not change until day 30 or 40 (lag-phase), independent of temperature (4 °C, 25 °C or 35 °C). After 60 days 30% primary degradation was observed at 4 °C and 80% primary degradation at 25°C and 35°C, respectively (Kang and Kondo, 2005). In another study (Ying and Kookana, 2003), only 17% BPA dissipated after 35 days, but was almost completely degraded (>90%) after 56 days. Under anaerobic conditions no primary degradation was observed until day 60 in seawater (Kang and Kondo, 2005).

Table 41: Summary of tests in fresh- and seawater

Conditions	**Test concentrations**	**Results**	**Reference**
Freshwater, aerobic (EPA OPPTS 835.3170; shake flask die-away)		DT_{50} = 0.5-1.4 days Lag period 2-8 days 65-80% $^{14}CO_2$ after 18 days Respirometry test: DT_{50}= 0.5-2.6 days Lag period = 2.3-4.4 days 59-96% CO_2 after 18 days	(Klečka et al., 2001)
Freshwater aerobic anaerobic (other method: shake flask die-away)	0.2 mg/L	Primary degradation: DT_{50} = 2-3 days DT_{50} > 10 days	(Kang and Kondo, 2002)
Freshwater, aerobic (each endpoint other method: shake flask die-away) Seawater, aerobic Seawater, anaerobic	1 mg/L	Primary degradation: DT_{50} = 4 and 3 days (25 and 35 °C) Lag period = 30 days (25 °C and 35 °C), 40 days (4 °C) → no DT_{50} After 60 days: 80% primary degradation at 25 and 35 °C 30% primary degradation at 4 °C No degradation until day 60	(Kang and Kondo, 2005)
Freshwater, aerobic (other method: shake flask die-away)	1 and 10 mg/L	Primary degradation > 90% in 6 days DT_{50} = 0.4-1.1 days Lag period 2-3 days	(Suzuki et al., 2004)
Freshwater aerobic (other method: shake flask die-away)		Lag period = 2-5 days In 14 days: 34 of 44 river water microcosms: 40 - 90% removal 6 of 44 river water microcosms: 100% removal 4 of 44 river water microcosms: 0% removal	(Ike et al., 2000)
Seawater, aerobic (other method: shake flask die-away)	5 µg/L	Dissipation: ~17% after 35 days > 70% after 42 days > 90% after 56 days	(Ying and Kookana, 2003)

The available die-away studies indicate that BPA can be removed rapidly from freshwater environments.

Due to the limited information available it is difficult to conclude whether the measured rate of removal of BPA is the result of primary degradation or dissipation from the test system.

In conclusion, BPA can be rapidly removed from surface waters.

Bisphenol S

For screening, a modified MITI test was conducted according to OECD 301C test guideline (Anonymous, 1998) over a period of 28 days with the use of 30 mg/l non-adapted activated sludge taken from 10 different sites (municipal STPs, industrial STPs, lakes and rivers) in Japan. 0% degradation was observed after 28d (TOC).

The substance is therefore considered to be not readily biodegradable.

In simulation tests, biodegradation of a variety of bisphenols, including BPS, was examined under aerobic and anaerobic conditions (Ike et al., 2006). In this study, the biodegradability of BPS was examined in an aerobic simulation test according to the TOC-Handai method. Natural river water from three sites of four streams running over Osaka and sediment from one pond (Inukai Pond) in Japan were used. The test results supported the non-ready biodegradability results. Under aerobic conditions the biodegradability of BPS is 0% after 22 days incubation. Under anaerobic conditions, after a lag phase of 60 days, biodegradation reached about 60% at ca. day 80.

Another study examined the degradation of three bisphenols (BPA, BPF and BPS) in seawater using the TOC-Handai (TOC, potential test) and river (sea) die-away (SDA, simulation test) method (Danzl et al., 2009). The TOC method uses seawater microorganisms collected through filtration from natural seawater. The retained organisms are then dispersed into artificial seawater at original levels of cell density. The SDA method uses samples of indigenous seawater microorganisms in their natural seawater. Degradation of BPS was not observed using any of these methods. The BPS concentration remained unchanged over the test period of 60 days in the TOC and SDA samples; a biodegradability of 0% resulted after 60 days.

BPS might thus remain in the aquatic environment for a long time.

Frankowski et al. (2020) evaluated the biodegradation of bisphenols including BPB and BPA as well as BPF, BPS and BPAF using river water and activated sludge from two wastewater treatment plants (WWTPs). In the biodegradation test with BPS, a removal in the range from 40 to 50% was found, which was similar in all three tests (city sample, rural sample, sample with river water).

Zhou et al. (2020) examined the degradation of different bisphenols (BPA, BPAF, BPS, BPB, BPB, BPE, BPZ, BPM) in Taihu Lake. Under aerobic conditions, BPS was recalcitrant to biodegradation in the lake water. The concentrations of BPS remained almost unchanged during the whole incubation period.

In conclusion, BPS is not readily biodegradable and is not rapidly removed from surface waters.

Bisphenol F

There are various modified river and seawater die-away tests indicating ready biodegradability.

In a Japanese MITI test, BPF, present at 100 mg/L, reached 1% of its theoretical BOD in 4 weeks using an activated sludge inoculum at 30 mg/L.[97]

In 22-day aerobic river die-away tests using several river water samples in 24 microcosms, BPF showed complete degradation (mineralization) in 21 microcosms and complete primary degradation in another microcosm. When assessing the anaerobic biodegradation using pond sediment, BPF showed >80% degradation over 84 days of incuabation with no lag period (Ike et al., 2006).

Frankowski et al. (2020) evaluated the biodegradation of BPs including BPB and BPA as well as BPF, BPS and BPAF with river water and activated sludge from two WWTPs. The study found that only BPA and BPF undergo complete primary biodegradation. Other bisphenols were pooly biodegraded. It was assumed that bacteria species degrading one bisphenol do not degrade all the other bisphenols. For the two inoculum from WWTPs, the biodegradation was 100% after 52 days (100% already reached after 15 days). Biodegradation in river water reached 100% after 37 days.

In conclusion, BPF is likely to be rapidly removed from surface waters.

Bisphenol B

In the Annex XV support document on BPB, its biodegradation was assessed:

The BIOWIN degradation models were run to estimate BPB biodegradation. According to Biowin 2 (non-linear model) and Biowin 6 (MITI non-linear model), BPB does not biodegrade fast (p=0.41). Ultimate biodegradation could range between weeks to months (Biowin3). In addition, aerobic biodegradation pathways were not identified by in silico prediction using the pathway prediction system of EAWAG-BBD tool. Nevertheless, a possible biodegradation of BPB by specific microorganisms was suggested in the literature (Lobos et al., 1992; Sakai et al., 2007).

Frankowski et al. (2020), evaluated the biodegradation of BPs including BPB and BPA with river water and activated sludge from two wastewater treatment plants (WWTPs). Primary biodegradation of BPB was found to be minimal in all tests. It was below 10% after 52 days in river water (<20% for BPA), without significant biodegradation, and 40% for the two inoculum from WWTPs (100% for BPA). Biodegradation started immediately for the city sample, increased linearly to 40% until day 20 and remained stable then until the end of the assay. This highlights the fact that WWTPs dealing with urban wastewater are adapted to this type of chemical and have the ability to degrade them to some extent.

Ike et al. (2006), investigated the biodegradation of BPs including BPB and BPA in water under aerobic conditions. At the end of the assays (23 days), BPB was not degraded in 50% of the microcosms and incomplete primary degradation occurred for the other 50% under aerobic conditions. The aerobic degradability of BPB with river water microbes was lower than that of BPA (complete primary degradation in 19/24 microcosms with complete mineralisation in 2 microcosms). Under anaerobic conditions, all the tested BPs were biodegraded to a certain extent, although the degradation proceeded very slowly compared with the aerobic degradation. BPA and BPB showed a long lag period of 50–60 days, before

---

[97] NITE; Chemical Risk Information Platform (CHRIP). Biodegradation and Bioconcentration. Tokyo, Japan: Natl Inst Tech Eval. Available from, as of Nov 21, 2017]: https://www.safe.nite.go.jp/english/db.html

the anaerobic degradation started, and the degradation was about 40–60% (80 days). BPB was found to be the most recalcitrant.

In conclusion, BPB is may not rapidly removed from surface waters.

Bisphenol AF

For BPAF a ready biodegradation test according to OECD Guideline 301B is available in the registration dossier. In this test no degradation could be observed within the test duration of 28 days.

Frankowski et al. (2020) evaluated the biodegradation of BPs including BPB and BPA as well as BPF, BPS and BPAF with river water and activated sludge from two WWTPs. In the study it was found that primary biodegradation of BPAF was minimal in all testsmaking BPAF the least degradable substance tested. The tests with municipal WWTP activated sludge revealed that the metabolic acitivity of microorganisms was reduced strongest by BPAF.

Zhou et al. (2020) examined the degradation of different bisphenols (BPA, BPAF, BPS, BPB, BPB, BPE, BPZ, BPM) in Taihu Lake. Under aerobic conditions, BPAF was recalcitrant to biodegradation in the lake water. The concentrations of BPAF remained almost unchanged in lake water collected in October 2018 and in the one collected in May 2019 during the whole incubation period of 49 days.

In conclusion, BPAF is not rapidly removed from surface waters.

B.4.1.2.2. Biodegradation in sediments

Bisphenol A

For the assessment of removal of BPA in sediment three reliable studies are available. A study with marine sediment determined a disappearance half-life time $DisT_{50}$ of 14.5 days (Ying and Kookana, 2003). A test using aquifer material (sediment and groundwater) showed no degradation within 70 days under aerobic conditions (Ying et al., 2003). Under anaerobic conditions (monitored with resazurin as a redox indicator in Ying and Kookana, 2003) both studies showed no changes in the BPA concentration until day 70. In a study with estuarine sediment the half-life time DT_{50} was > 162 days (Voordeckers et al., 2002). Sarmah and Northcott (2008) observed a biphasic pattern with rapid initial dissipation (>90% in the first 4 days) of BPA and a smaller rate until the end of the test with trace amounts still remaining after 70 days.

Table 42: Summary of biodegradation tests in sediment

Conditions	Test concentrations	Results	Reference
Marine sediment (other method: shake flask die-away) aerobic anaerobic	1 µg/g	$DisT_{50}$ = 14.5 days $DisT_{50}$ > 70 days	(Ying and Kookana, 2003)

Aquifer material (sediment and groundwater; other method: batch equilibrium) aerobic anaerobic	1 µg/g	Primary degradation DT_{50} > 70 days DT_{50} > 70 days	(Ying et al., 2003)
Estuarine sediment (other method: shake flask die-away) anaerobic	200 µM (45.6 mg/L)	Primary degradation DT_{50} > 162 days	(Voordeckers et al., 2002)
River-water sediment (other method: shake flask die-away) Dissipation (whole system) Aerobic | anaerobic Groundwater-aquifer material (other method: shake flask die-away) Aerobic | anaerobic	100 µg/L	Dissipation > 90% after 4 days $DisT_{50}$ = 1.212 d | 1.38 d $DisT_{90}$ = 2.75 d | 4.901 d $DisT_{50}$ = 0.57 | 2.315 days $DisT_{90}$ = 2.26 | 306.9 days	(Sarmah and Northcott, 2008)

In conclusion, on the basis of this information, currently no definite conclusion on degradation of BPA in sediments is possible. However, some studies indicate persistence of BPA in sediment.

Bisphenol S

Ike et al. (2006) conducted an anaerobic biodegradation test using pond sediment. BPS showed in the test about 60% degradation over the approximately 80 days of incubation.

Bisphenol F

Chang et al. (2014) investigated the aerobic degradation of BPF, as well as BPB, BPA, TBBPA and TCBPA in river sediment. The degradation rates of BPA and BPF were enhanced by adding brij 30, brij 35, rhamnolipid, surfactin, or crude enzyme. BPF showed the highest degradation rate from the tested bisphenols in the sediment (degradation half-live was 3.5 d for BPF and 5.0 d for BPA).

(Ike et al., 2006) conducted an anaerobic biodegradation test using pond sediment. Different bisphenols (BPA, BPF, BPE, BPB, BPS, …) were tested. BPF was degredad most rapidly compared to BPE, BPA and BPB. It was degraded without an apparent lag period and the removal reached more than 80% during the about 80-day experimental period.

Bisphenol B

In the Annex XV support document, the biodegradation in sediment was assessed:

Chang et al. (2014) investigated the aerobic degradation of BPA, BPB and other BPs in river sediment collected from heavily contaminated streams of the Erren River in Taiwan. The degradation rates in the sediment were BPA > BPB, with a DT50 of 6.3 days for BPB and 5 days for BPA.

Ike et al. (2006) investigated the biodegradation of BPs including BPB and BPA in sediment under anaerobic conditions. Sediment sampled originates from Inukai Pond in the Suita Campus of Osaka University (Osaka, Japan). They were centrifuged, washed three times with phosphate buffer, and resuspended to obtain 2-times condensed inoculum. Final concentration of BPs were 10mg/L in a 25 ml sealed bottle where headspace was totally replace by N2 gas and performed at 28°C. Analyses of degradation product were performed by HPLC. Under these anaerobic conditions, all the tested BPs were biodegraded to a certain extent, although the degradation proceeded very slowly compared with the aerobic degradation in water previously described. BPA and BPB showed a long lag period of 50–60 days, before the anaerobic degradation started, and the degradation was about 40–60% (80 days). BPB was found to be the most recalcitrant bisphenol in this study.

Bisphenol AF

No data available.

B.4.1.2.3. Biodegradation in soil

Bisphenol A

In soil radio-labelled Bisphenol A showed a rapid dissipation (DT_{50} < 3 days) (Fent et al., 2003). The major route of dissipation was the formation of non-extractable residues (NER). After 120 days 76.0 - 81.6% non-extractable residues (NER) were formed in the four tested soils. Less than 20% of the applied radioactivity could be recovered as $^{14}CO_2$. A further study confirmed the rapid dissipation (DT_{50} = 7 days) of Bisphenol A in soil under aerobic conditions (Ying and Kookana, 2005), whereas under anaerobic conditions no degradation was observed within 70 days.

Table 43: Summary of biodegradation tests is soil

Conditions	Test concentrations	Results	Reference
Four different agricultural soils (two sandy loam and two loamy silt) (Laboratory simulation of soil die-away test, SETAC internal guideline)	6 µg/100 g soil	after 120 days: $^{14}CO_2$ = 13.1-19.3% of the applied radioactivity Non-extractable = 76.0-81.6% of the applied radioactivity Extractable = 1.5-2% of the applied radioactivity Dissipation: $DisT_{50}$ < 3 days	(Fent et al., 2003)

One soil (sandy loam) (Batch equilibrium method, no further specification of guideline)	1 µg/g	Aerobic: DT_{50} = 7 days Anaerobic: DT_{50} > 70 days	(Ying and Kookana, 2005)

In conclusion, BPA is removed rapidly from soil under aerobic conditions. On the basis of the available conflicting data, currently no definite conclusion on removal of BPA in soil under anaerobic conditions is possible.

Bisphenol S

Choi and Lee (2017a) studied the aerobic biodegradation of BPS as well as BPAF and BPA at 100 µg/kg soil and 22 ± 2 °C up to 180 days in a forest soil and an organic farm soil. BPS had short half-lives of < 1 day in both soils similar to BPA.

Cao et al. (2020) evaluated the fate of BPS in an oxic soil (46.7% clay, 37.9% silt, and 15.4% sand; pH 7.03; cation exchange capacity of 23.4 cmol/kg; soil organic carbon of 36.5 g/kg; total nitrogen of 2.75 g/kg) for 28 days. BPS disappeared quickly, with a half-life of 2.8 days. Most of the BPS was mineralized (53.6 ± 0.2% of initial amount by day 28) or transformed into NERs (45.1 ± 0.3%). When mixed with fresh soil, BPS-derived NERs became unstable and bioavailable.

Bisphenol F

Biodegradation of BPF was 8-58% after 30 days using an aerobic degradation test and seawater microcosms following a 6-12 day lag period. Biodegradation of BPF was >92% after 60 days (Danzl et al., 2009).

Bisphenol B

No data available.

Bisphenol AF

Based on an estimated[98] K_{oc} value of $7.6 \cdot 10^5$, BPAF is expected to be immobile in soil.

The estimated pKa of 9.2[99] indicates that this substance will exist partially in the anionic form in the environment; anions generally do not adsorb more strongly to soils containing organic carbon and clay than their neutral counterpats (Doucette, 2000).

Choi and Lee (2017a) studied the aerobic biodegradation of BPAF as well as BPS at 100 µg/kg soil and 22 ± 2 °C up to 180 days in a forest soil and an organic farm soil. BPAF was much more persistent than BPS and BPA with half-lives of 32.6 and 24.5 days in forest and farm soils, respectively.

---

[98] US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.10. Jan, 2011. Available from, as of Nov 5, 2012: https://www.epa.gov/oppt/exposure/pubs/episuitedl.htm

[99] PARC; pKa/property server. Ver 4.6., Oct, 2011. Available from, as of Nov 5, 2012: https://archemcalc.com/sparc/

B.4.1.2.4. Summary and discussion of abiotic and biotic degradation

Bisphenol A

The physical and chemical properties of BPA suggest that abiotic degradation via hydrolysis and photolysis is negligible. The screening tests show that BPA can be rapidly removed from surface waters by biotic degradation processes and therefore is rapidly degradable.

In surface waters, on the basis of the information available, BPA is rapidly removed.

In sediments under aerobic and anaerobic conditions, on the basis of the available conflicting data, currently no definite conclusion on degradation of BPA is possible. Some studies however indicate persistence of BPA in sediment.

In soil, under aerobic conditions, BPA is removed rapidly. On the basis of the available conflicting data, currently no definite conclusion on removal of BPA in soil under anaerobic conditions is possible.

No information is available on the environmental half-life of BPA in sediments or soils under standard test guideline conditions.

Bisphenol S

After exposure to the air, BPS will be degraded relatively fast by photochemical processes (DT_{50} of 26.5 hours). However, as BPS shows low potential of volatilisation, photodegradation in air should not be considered as an important degradation pathway.

No data on hydrolysis are available. However, phenols are generally regarded as stable towards hydrolysis (Lyman et al., 1990).

BPS is considered not readily degradable according to OECD 301C.

Two simulation tests (water/sediment) confirmed that BPS is not biodegradable (and meets the criteria for being "persistent" according to Annex XIII).

Bisphenol F

The physical and chemical properties of BPF suggest that abiotic degradation via hydrolysis and photolysis is negligible.

For biodegradation, there are inconsistent test results with indication of ready biodegradability in modified river and seawater die-away tests as well as anaerobic biodegradation using pond sediment and no biodegradation in a MITI test.

Tests with river water and activated sludge from two WWTPs suggest a biodegradation similar to BPA.

Bisphenol B

In the Annex XV support document for BPB, the summary of degradation properties is described as follows:

The physical and chemical properties of BPB suggest that abiotic degradation via hydrolysis and photolysis is negligible. The available data show that BPB, just like BPA, is stable in hydrolysis experiment. BPB can be rapidly removed from waters by abiotic degradation *when using enhanced physico-chemical degradation technique such as UV-assisted and natural light photocatalysis and is therefore rapidly degradable under these conditions.*

According to level III fugacity model (EPIsuite), the estimated half-life of BPB is 37.5 days in water, 75 days in soil and 337.5 days in sediment. Considering the fragmented experimental and predicted information, there is an alert on P/vP properties of BPB in sediment based on P criteria under REACh regulation (vP > 180 days).

The few information available in the literature suggest a possible biodegradation of BPB in water, in sediment (Chang et al., 2014; Ike et al., 2006) or by specific microorganisms (Lobos et al., 1992; Sakai et al., 2007). Besides biodegradation, adsorption onto sludge is one of the most crucial parameters affecting removal efficiency, given that BPB tends to adsorb onto sludge. The data highlight that BPB may be difficult to biodegrade in natural water and sediment under environmental conditions.

No information is available on environmental half-life in waters, sediments or soils under standard test guideline conditions and no conclusion is possible on the persistence of BPB.

Bisphenol AF

The physical and chemical properties of BPAF suggest that abiotic degradation via hydrolysis and photolysis is negligible. The available data show that BPAF is stable in a hydrolysis experiment. In a ready biodegradability test no degradation of BPAF could be observed.

Comparision of results for the bisphenols considered

The differences in biodegradation may be related to their structure. The structure of BPB, BPA and BPF are similar with the bridge between the phenol rings only containing a hydrocarbon unit (BPF: methylene; BPA: 2,2-isopropylidene; BPB: 1-methylpropylidene). In contrast, the bridging units in BPS (sulfonyl) and BPAF (hexafluoro-2,2-isopropylidene) contain other heteroatoms, i.e. sulphur and fluorine, respectively. According to previous studies, BPA-degrading bacteria ubiquitously exist in environments (Ike et al., 2000; Kang and Kondo, 2002; Lobos et al., 1992). Therefore, results from some studies suggest that exclusively hydrocarbon-containing BPs are easily biodegraded in lake water, but BP which contain non-hydrocarbon elements such as BPS (containing sulfur) and BPAF (containing fluorinated methyl groups) may continue to accumulate in the aquatic environment.

B.4.2. Environmental distribution

B.4.2.1. Adsorption/desorption

Bisphenol A

Adsorption/Desorption studies where conducted according to OECD Guideline 106 (Adsorption - Desorption Using a Batch Equilibrium Method) and one on a field-scale lysimeter. The organic carbon-water partition coefficient K_{oc} ranges from 251 to 1507 L/kg. The average normalised partition coefficient value of 750 L/kg shows that BPA is likely to be strongly adsorbed to solids upon release to the environment (assuming that K_{oc} values from 150 to 500 L/kg correspond to moderate adsorption and K_{oc} values 500 to 5000 l/kg point towards strong absorption).

Bisphenol S

The K_{oc} value was calculated using EPIWIN (KOCWIN v2.00). Although the substance is not fully within the applicability domain of the model, the result of calculation is regarded as plausible.

Applicability domain (OECD principle 3)	Domains:	
	1) Molecular weight (range of test data set: 32.04 to 665.02 g/mol; On-Line KOCWIN User's Guide, Ch. 6.2.4 Domain)	Substance within range (250.27 g/mol)
	2) log K_{ow} (range of test data set: -2.11 to 8.12; On-Line KOCWIN User's Guide, Appendices E & F)	Substance within range (1.20)
	3) Correction factors: Number of instances of the identified correction factor does not exceed the maximum number as listed in Appendix D (On-Line KOCWIN User's Guide)	Not fulfilled.

The K_{oc} of BPS is estimated to be 88.4 L/kg (log K_{oc} = 1.94).

The calculated K_{oc} is supported by the K_{oc} values estimated with the method of Franco and Trapp, applicable for ionisable substances (corrected log K_{oc}=1.70, corrected K_{oc}=50). With a pK_a of 7.93, BPS is a weak acid and it is present in unionized form under normal environmental conditions (5.00 < pH < 8.00).

In view of the calculated log K_{oc} of 1.94, the substance is expected to be slightly mobile in soil.

Based on this value, we assume that BPS has a potential to adsorb to organic particulate matter, at least in soil, as suggested by the EPIsuite model (see the results of the Distribution modelling in section 3.2.3)

No additional information suggesting absorption to soil and sediment is available.

Bisphenol F

Based on the log K_{oc} of 4.18 (derived from an estimated K_{oc} of 15,000; using EPI KOCWIN model), BPF is expected to be immobile in soil.

Bisphenol B

The calculated log K_{oc} of 3.543 (KOCWIN v2.00) suggest that BPB is expected to be immobile in soil.

Kovačič et al. (2019) investigated the hydrolysis, adsorption, biological treatment (see section 3.1.2.3) and UV photolysis of 18 BPs including BPB and BPA under laboratory conditions. Adsorption to biomass was suggested as one primary mechanism for BPB removal from wastewater, as was the case for BPA.

Bisphenol AF

Based on the log K_{oc} value of 3.36 derived from an OECD Guideline 121 study documented in the registration dossier, BPAF is expected to be immobile in soil.

B.4.2.2. Volatilisation

Bisphenol A

Volatilisation is not considered to be a significant removal mechanism for BPA from water. At ambient temperature and atmospheric pressure, BPA is not volatile, with a Henry's law constant calculated to be $3.12 \cdot 10^{-7}$ $Pa \cdot m^3/mol$ from aqueous solubility and vapour pressure.

Bisphenol S

Henry´s law constant was estimated to be $4.48 \cdot 10^{-9}$ $Pa \cdot m^3/mole$ at 25°C by EPIWIN (SRC HENRYWIN v3.10 via vapour pressure and aqueous solubility).

BPS will slowly evaporate from surface water into the atmosphere. However, this is strongly dependent on water depth and also on the concentration of particulate organic matter in the water.

Bisphenol F

The Henry's Law constant for BPF is estimated as $1.83 \cdot 10^{-5}$ $Pa \cdot m^3/mole$ (EPI HENRYWIN via vaour pressure and aqueous solubility). This Henry's Law constant indicates that BPF is expected to be non-volatile from water and moist soil surfaces.[100] It is not expected to volatilize from dry soil surfaces (SRC) based upon an estimated vapor pressure of $3.7 \cdot 10^{-7}$ mm Hg (SRC), determined from a fragment constant method.[101]

Bisphenol B

According to HENRYWIN model of EPIsuite,[102] BPB exhibits a Henry’s law constant value of $2.73\ 10^{-4}$ Pa m^3/mol suggesting a low probability of partitioning from the aqueous system to the atmosphere. In the atmospheric compartment, BPB is predicted to undergo reactions with hydroxyl radicals with an estimated half-life of 1.57 hours.

---

[100] Lyman WJ et al; Handbook of Chemical Property Estimation Methods. Washington, DC: Amer Chem Soc pp. 15-1 to 15-29 (1990)

[101] US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.1. Nov, 2012. Available from, as of Nov 21, 2017: https://www2.epa.gov/tsca-screening-tools

[102] US EPA. 2020. Estimation Programs Interface Suite™ for Microsoft® Windows, v 4.1. United States Environmental Protection Agency, Washington, DC, USA.

Bisphenol AF

According to HENRYWIN model of EPIsuite v.3.20, BPAF exhibits a Henry's law constant value of 5.76x 10^{-5} Pa m^3/mol, suggesting a low probability of partitioning from the aqueous system to the atmosphere.

B.4.2.3. Distribution modelling

Bisphenol A

Level III Mackay-type modelling shows that nearly all BPA goes into the water and soil compartments. The exact proportion in each depends on where emissions enter the environment.

Bisphenol S

Following Mackay, Level I (LEVEL 1, V3.00), which is the model used by the registrant(s), the substance will primarily distribute to water (99.3%) with minor distribution predicted to soil and sediment (0.35% each):

Applying the Level III Fugacity Model (Episuite 4.1), the following results are obtained:

Equal emission to all compartments

	Mass Amount (percent)	**Half-Life (hr)**	**Emissions (kg/hr)**
Air	$3.36 \cdot 10^{-5}$	17.7	1000
Water	16	360	1000
Soil	83	720	1000
Sediment	0.966	$3.24 \cdot 10^{3}$	0

To air

	Mass Amount (percent)	**Half-Life (hr)**	**Emissions (kg/hr)**
Air	$8.2 \cdot 10^{-5}$	17.7	1000
Water	3.7	360	0
Soil	96.1	720	0
Sediment	0.224	$3.24 \cdot 10^{3}$	0

To water

	Mass Amount (percent)	**Half-Life (hr)**	**Emissions (kg/hr)**
Air	$1.07 \cdot 10^{-13}$	17.7	0
Water	94.3	360	1000
Soil	$1.26 \cdot 10^{-7}$	720	0
Sediment	5.69	$3.24 \cdot 10^{3}$	0

To soil

	Mass Amount (percent)	**Half-Life (hr)**	**Emissions (kg/hr)**
Air	$2.58\cdot10^{-13}$	17.7	0
Water	0.195	360	0
Soil	99.8	720	1000
Sediment	0.0118	$3.24\cdot10^{3}$	0

To air and water

	Mass Amount (percent)	**Half-Life (hr)**	**Emissions (kg/hr)**
Air	$5.97e\cdot10^{-5}$	17.7	1000
Water	28.3	360	1000
Soil	70	720	0
Sediment	1.71	$3.24\cdot10^{3}$	0

To air and soil

	Mass Amount (percent)	**Half-Life (hr)**	**Emissions (kg/hr)**
Air	$3.96\cdot10^{-5}$	17.7	1000
Water	1.89	360	0
Soil	98	720	1000
Sediment	0.114	$3.24\cdot10^{3}$	0

To water and soil

	Mass Amount (percent)	**Half-Life (hr)**	**Emissions (kg/hr)**
Air	$2.19\cdot10^{-13}$	17.7	0
Water	24.5	360	1000
Soil	74	720	1000
Sediment	1.48	$3.24\cdot10^{3}$	0

BPS partitions mainly to soil (83%) and to a lesser extent to water (16%) when the substance is equally emitted to air, surface water and soil. However, when there are only emissions to water, BPS partitions mainly to water (94.3%). This seems to indicate that BPS emissions to water remain in the aquatic compartment and only small amounts of the substance will migrate to the sediment compartment (5.69%). When only emissions to soil are considered, BPS remains in this compartment (99.8%).

Little information about the releases of BPS are available now. However, based on the calculation above, we can assume that water (and sediment to a lesser extent) and soil could be affected by the substance.

Bisphenol F

Applying the Level III Fugacity Model (Episuite 4.1.25), the following results are obtained:

	Mass Amount (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	$2.58 \cdot 10^{-5}$	3.12	1000
Water	14.5	360	1000
Soil	78.8	720	1000
Sediment	6.7	$3.24 \cdot 10^{3}$	0

BPF partitions mainly to soil (78.8%) and to lesser extend to water (14.5%) and sediment (6.7%), when it is equally emitted to air, surface water and soil.

Bisphenol B

Applying the Level III Fugacity Model (Episuite 4.1.25), the following results are obtained:

	Mass Amount (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	$8.52 \cdot 10^{-5}$	3.14	1000
Water	6.78	900	1000
Soil	66.4	$1.8 \cdot 10^{3}$	1000
Sediment	26.8	$8.1 \cdot 10^{3}$	0

BPB partitions mainly to soil (66.4%) and to lesser extend to sediment (26.8%) and water (6.78%), when it is equally emitted to air, surface water and soil.

Bisphenol AF

Applying the Level III Fugacity Model (Episuite 4.1.25), following results are obtained:

	Mass Amount (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.000629	3.2	1000
Water	0.929	4.32e+003	1000
Soil	56.4	8.64e+003	1000
Sediment	42.6	3.89e+003	0

BPAF partitions mainly to soil (56.4%), to a little lesser extend to sediment (42.6%) and much lesser to water (0.929%), when it is equally emitted to air, surface water and soil.

B.4.2.4. Summary and discussion of environmental distribution

Bisphenol A

BPA is likely to be strongly adsorbed to solids upon release to the environment and it is not volatile. Consequently, data suggest that BPA goes into the water and soil compartments.

Bisphenol S

BPS has the potential to adsorb to organic particulate matter, at least in soil, and is expected to slowly evaporate from surface water. Modelling suggest that BPS partitions mainly to soil and to a lesser extent to water when it is equally emitted to air, surface water and soil. When there are only emissions to water, BPS partitions mainly to water.

Bisphenol F

BPF is expected to be immobile in soil and to be non-volatile from water and moist soil surfaces. Modelling suggests that BPF partitions mainly to soil and to a lesser extent to water and sediment when it is equally emitted to air, surface water and soil.

Bisphenol B

BPB is expected to be immobile in soil. Adsorption to biomass seems one primary mechanism for BPB removal from wastewater similar to BPA. Volatilisation is not expected for BPB. The substance partitions mainly to soil and to a lesser extend to sediment and water.

Bisphenol AF

BPAF is expected to be immobile in soil. Volatilisation is not expected for BPAF. Modelling suggest that BPAF partitions mainly to soil and to a little lesser extend to sediment.

B.4.2.5. Occurrence in environmental and human matrices - monitoring/field data

The aim of the present monitoring section is to provide an overview of available monitoring data in European environmental and human matrices. For archiving this goal, we selected key studies and results from monitoring programmes exemplifying and substantiating the concerns associated with the exposure to BPA and BosC. Searches for primary research studies and monitoring programmes reporting on the occurrence, levels and accumulation in different environmental samples and food webs from different compartments were applied. We aim to give a comprehensive overview of BPA and BosC contamination in various environmental compartments and biota from Europe. Data for the occurrence of BosC is more available from studies outside of Europe whereas data for BPA is more available in Europe. In most cases the data is taken from sources after the year 2010.

B.4.2.5.1. Monitoring Data for Bisphenol A

B.4.2.5.1.1. Surface Water

The majority of monitoring studies focussed on BPA in surface waters. This becomes evident in the NORMAN database system, which develops and maintains various online databases on the environmental occurrence of emerging contaminants including BPA. A review by Staples et al. (2018) compiled data on the occurrence of BPA in European freshwater (1996-2014) based on the NORMAN EMPODAT database (accessed 2016) and published literature/governmental reports. The results for Europe showed overall median concentrations of 0.029 µg/L (n = 3,675; 95th percentile: 0.3 µg/L), whereas concentrations in North America (n = 805; median: 0.005 µg/L; 95th percentile: 0.3 µg/L) were lower. Based on qualitative analysis, freshwater BPA concentrations in both regions appear to have remained relatively stable over the 19-year period during which BPA production and use in polycarbonate plastic manufacturing increased significantly. However, the number of datapoints varied greatly among the years, which limits the assessments of temporal trends (Staples et al., 2018). Further environmental data from the European Commission on BPA in European surface waters showed, compared to Staples et al. (2018), lower median concentrations (0.01 µg/L), whereas the 95th percentile was broadly similar (n = 848; 95th%ile: 0.35 µg/L; European Commission (2008).

For marine compartments, concentrations in surface waters were considerably lower, which might be a result of higher admixture and greater distances to emission sources. For example, median concentrations of marine surface water were one order of magnitude lower in the report by the European Commission (2008) (median 0.002 µg/L; 95th percentile: 0.09 µg/L; n=115) and in Staples et al. (2018) (median: 0.007 µg/L; 95th percentile: 0.15 µg/L; n=456). Furthermore, concentrations in marine water were lower in North America (median: 0.001 µg/l; 95th percentile: 0.024 µg/L) compared to Europe according to the data compiled by Staples et al. (2018).

The NORMAN database was accessed (NORMAN, 2022) and data on BPA in surface waters extracted, which resulted in 26,069 data entries (2002-2020) vs 3,775 entries reported in Staples et al. (2018). Furthermore, 3,028 data points were added from federal monitoring programs in Germany (2016-2019, LAWA (2020)) resulting in a total of 29,097 data points. The complete data set for 14 EU countries showed a median concentration of 0.013 µg/L (mean: 0.279 µg/L) with a 95th percentile of 0.26 µg/L. The average values are lower compared to Staples et al. (2018) but similar to those reported by the European Commission (2008), whereas the 95th percentile were broadly similar in both cases. In total, 14 countries contributed data on BPA in surface waters. However, the reported time frames, as well as number of datapoints, varied considerably among the countries and years (**Error! Reference source not found.**). These variations complicate a spatial/temporal assessment of BPA concentrations in Europe which was also observed in Staples et al. (2018). The majority of data points came from Germany (n=18,009) and only three more countries contributed more than 1,000 data points to the NORMAN database (France, Netherlands, Slovakia). As shown in **Error! Reference source not found.**, mean concentrations in most countries were between 0.004 (Italy) and 0.504 µg/L (Sweden), whereas concentrations in the Netherlands, particularly those in 2013, were considerably higher (mean: 2.05 µg/L, max: 3142 µg/L). The results in the Netherlands during 2013 (mean: 19.28 µg/L, 95th percentile: 0.023 µg/L) were largely driven by a single data point (3,124 µg/L, river Meuse), which demonstrates that specific sampling locations (as well as sampling times) constitute crucial factors when assessing BPA concentrations in surface waters.

Table 44: Range of BPA mean concentrations in surface waters of European countries

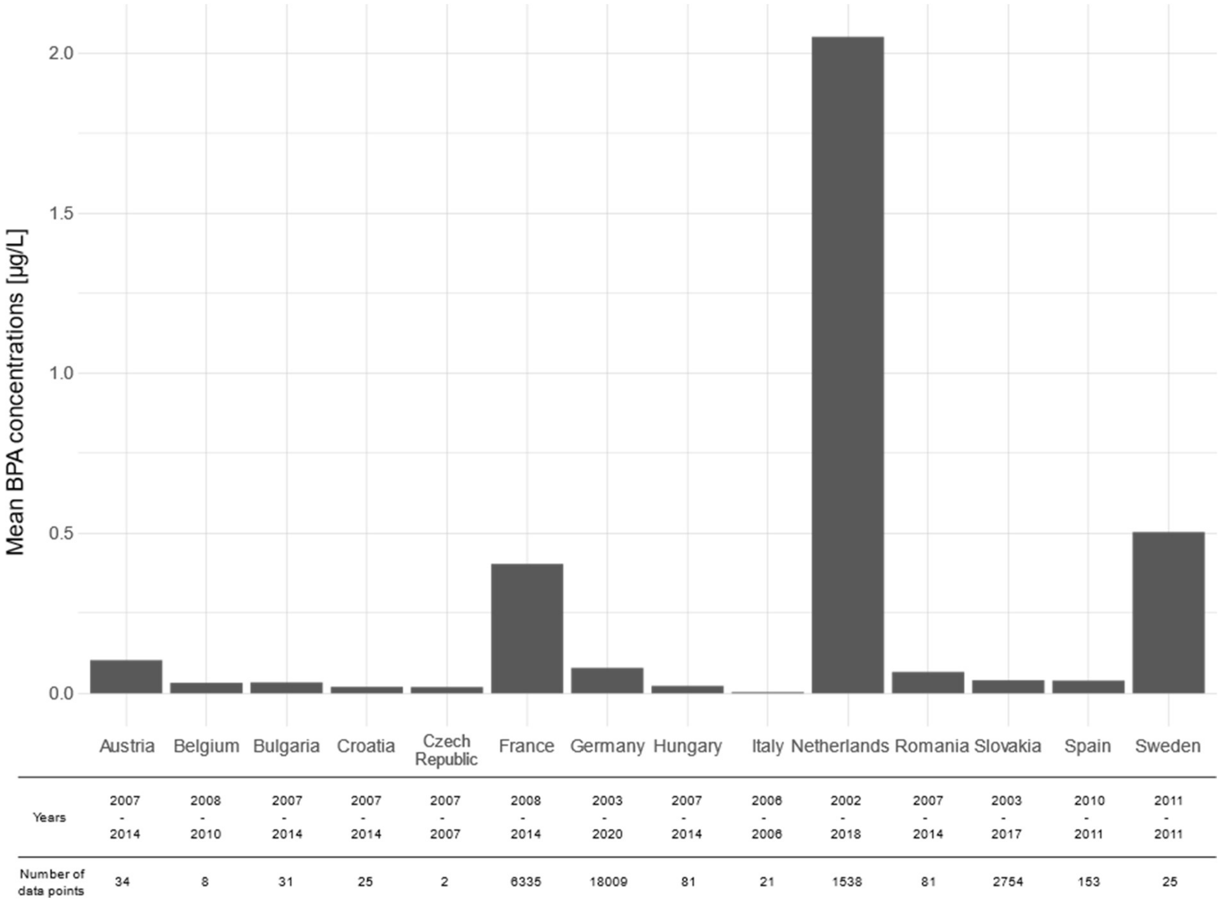
	Concentration (µg/L)	**Sample size**	**Year**	**Country/Region**
Germany (2003-2020)				
Lowest value	<MDL	18,009		
Mean value	0.079			
Highest value	40		2007	Lausitzer Neiße
France (2008-2014)				
Lowest value	<MDL	6,335		

Mean value	0.404			
Highest value	725		2012	Adour Garonne river basin
Netherlands (2002-2018)				
Lowest value	<MDL	1,538		
Mean value	2.051			
Highest value	3142		2013	Meuse river
Slovakia (2003-2017)				
Lowest value	<MDL	2,754		
Mean value	0.041			
Highest value	15.7		2004	Modranka, Trnava

At least 1000 data entries when combining NORMAN (2022) and LAWA (2020); see **Error! Reference source not found.**. Abbreviations: MDL=method detection limit.

With respect to reported maximum concentrations (Table 44), data gathered via NORMAN (2022) showed concentrations up to 725 µg/L in France (Adour Garonne river basin, 2012), 40 µg/L in Germany (Hartau, Lausitzer Neiße, 2007), and 15.67 µg/L in Slovakia (Modranka, Trnava 2004). This is further emphasized in monitoring campaigns reporting concentrations up to 6.01 µg/L for river water in Italy (downstream wastewater treatment plant (WWTP)) (Bicchi et al., 2009). For a representative spatial assessment among European countries, a larger data set would be needed due to the low numbers for 10 of the 14 participating countries and missing data in additional 13 countries of the EU. Furthermore, information about potential point pollution sources such as e.g., paper industry would be required to evaluate and compare the observed data among European countries.

Figure 5: Mean BPA concentrations [µg/L] in European surface waters per country



	Austria	Belgium	Bulgaria	Croatia	Czech Republic	France	Germany	Hungary	Italy	Netherlands	Romania	Slovakia	Spain	Sweden
Years	2007 - 2014	2008 - 2010	2007 - 2014	2007 - 2014	2007 - 2007	2008 - 2014	2003 - 2020	2007 - 2014	2006 - 2006	2002 - 2018	2007 - 2014	2003 - 2017	2010 - 2011	2011 - 2011
Number of data points	34	8	31	25	2	6335	18009	81	21	1538	81	2754	153	25

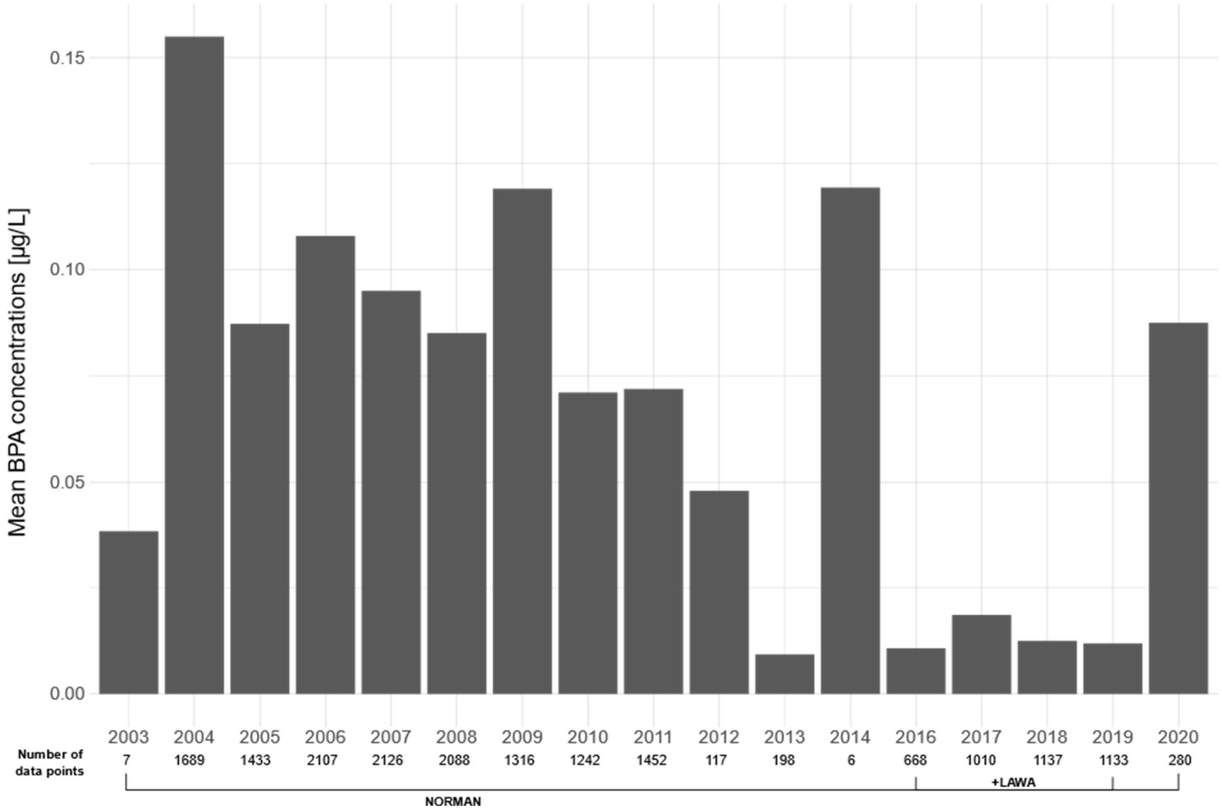
Note: Range of years and number of data points included. The data was extracted from NORMAN (2022) (n = 26,069, access 02/2022). For Germany, additional data points were added from federal monitoring programs (n=3,028, 2016-2019) (LAWA, 2020). Concentrations below the limit of detection (LOD) were replaced with zero. The mean concentration in the Netherlands is strongly influences by a single data point (3,124 µg/L, river Meuse, Table 44).

Temporal trends in German surface waters

A study by Ramboll Deutschland GmbH (2022) investigated BPA in German surface waters during a six-year period starting in 2015. The study reported an average BPA concentration of 0.05 µg/L before 2015 (95th percentile : 0.17 µg/L) and lower concentrations between 2015-2018 (average: 0.025 µg/L, 95th percentile: 0.07 µg/L) and 2019-2020 (0.016 µg/L, 95th percentile: 0.05 µg/L) (Table 2). The study predicted that BPA concentrations will drop to <0.005 µg/L in the future based on the restriction of BPA in thermal paper and associated lower use from 2019 onwards. The use of BPA in thermal paper remained relatively stable between 2014-2018 in the European Union (European Chemicals Agency, 2020), which is why reduced concentrations in surface water before 2019 were suggested to be related to a decreased use of BPA as additive in manufacturing as well as potential improvements in WWTPs processes and landfill handling (Ramboll Deutschland GmbH, 2022). The contribution of thermal paper as a source for BPA in German surface water is described in more detail by the Ramboll Deutschland GmbH (2022) study below. We further analysed the data from the NORMAN network (NORMAN, 2022) for a temporal assessment of BPA concentrations in German surface waters. It is important to mention that non-detects were replaced by LOD/2 in Ramboll Deutschland GmbH (2022) whereas they were set to zero in NORMAN (2022), which lowers the values of the reported summary statistics (Table 45).

As stated in B.4.2.5.1.1, a Europe-wide temporal trend assessment is not possible as the majority of extracted data points from NORMAN (2022) is not evenly distributed among member states and samples years. Most data points in NORMAN (2022) came from Germany (~62%) and to a lesser extent from France (~22%), Slovakia (~9%), the Netherlands (~5%), whereas others contributed less than 2% (see **Error! Reference source not found.**). A temporal assessment of BPA in Germany is therefore the most robust assessment even though variations in data points per year still existed (**Error! Reference source not found.**). When analysing data from NORMAN (2022) for Germany surface water (2003-2020, n=14,981) and data provided by federal monitoring programs from Germany (2016-2019, n=3,028, LAWA (2020)), the results show that BPA concentrations before 2015 were almost double as high (mean: 0.098 µg/L, 95th%ile: 0.29 µg/L between 2003 to 2014) compared to the ones reported in Ramboll Deutschland GmbH (2022) (0.05 µg/L, see Table 2) . When analysing the data after 2015, concentrations from NORMAN (2022) and LAWA (2020) showed similar to Ramboll Deutschland GmbH (2022) a considerable decline compared to values before 2015 (**Error! Reference source not found.**, Table 45). However, NORMAN (2022) reports comparably high values for 2020 (0.09 µg/L), which are in the range of the concentrations observed before 2015. However, the samples size in 2020 was comparably low and interpretation therefore warrants caution.

Figure 6: Mean BPA concentrations [µg/L] in German surface waters



Note: Data for the period 2003-2020 based on extracted data from NORMAN (2022) (n=14,981). Additional data points for 2016-2019 were received from federal monitoring programmes (LAWA, 2020) in Germany and added to the analysis (n=3,028). Concentrations below the limit of detection were replaced with zero.

Besides the restriction of BPA in thermal paper, BPA was also banned in baby bottles in 2011 and the tolerable daily intake for human health was also lowered during recent years. These regulatory changes might have caused declines in surface water emissions of BPA in Germany. A more detailed discussion on BPA sources in German surface waters will follow in the next chapter. Whether or not the decline of BPA was accompanied by an increased use of non-regulated bisphenols (i.e. BosC) during the recent past, requires further investigations as those data is largely missing (NORMAN, 2022).

B.4.2.5.1.2. Sources of BPA in the environment

A relevant emission sources of BPA in surface waters represent, among others, WWTP effluents. In general, concentrations in influents to WWTPs (mean value 0.775 µg/L, max: 2.96 µg/L) seems to be higher than those in effluents (mean value 0.112 µg/L, max 0.48 µg/L) as reported in the NHC-Report HS Baltic Municipalities 2018 (Gercken J., 2018). This is an indication that considerable elimination of BPA can occur during wastewater treatment. Nevertheless, the WWTP represent an important source for BPA in the environment due to continuous releases from retained BPA. Further emission sources to freshwater represent e.g. stormwater as BPA can be transferred through rainfall events due to its presence in the road and transport environment (road construction materials, lubricants, vehicle components, etc.) (Markiewicz et al., 2017) as well as in indoor and outdoor dust (Liv Bruås Henninge, 2020; Vasiljevic and Harner, 2021).

In 2018, Ramboll investigated the main input pathways and sources of BPA in German surface waters, which represents the basis for the following text in this chapter (Ramboll Deutschland GmbH, 2019). In the study, aqueous samples, sewage sludge, and suspended matter were investigated from 23 WWTPs from Germany.

In agreement to the results above, BPA levels in all effluents were lower (mean: 0.16 µg/L, <0.01 (LOQ)-0.65 µg/L) compared with those in influents (mean: 40.7 µg/L, 0.33-905 µg/L). In general, concentrations were higher in influents of WWTP that were fed by paper processing industries. Removal rates in the respective WWTPs ranged from 13.3% to 99.9% with 16/23 WWTPs exceeding 90% removal efficiency. When extrapolating results for Germany based on annual average flow volume, the total BPA load entering the environment was estimated to range between <100 kg/a to ~6,500 kg/a (average ~1,600 kg/a). However, during a previous study by Ramboll, total estimated BPA loadings ranged between 4,083-14,653 kg/a, which was suggested to be related to the broader variety of investigated wastewater cleaning types and the fact that overflow events were considered. This example demonstrates the limitation of the extrapolation approach by Ramboll Deutschland GmbH (2019). Due to the large variety of WWTPs and applied clean-up technologies, emission of BPA from WWTPs into surface waters might considerably vary across Europe. The presented data of Ramboll Deutschland GmbH (2019) therefore only serves as a first estimate for BPA emissions in one European member state.

For sewage sludge, samples were taken from 15 WWTPs and concentration varied between 0.068-200 mg/kg with an average of 9.2 mg/kg dw, which represented considerably higher values (>1 order of magnitude) compared to those in literature. Sewage sludge is used by most federal states in Germany for agriculture and when extrapolating the results of Ramboll Deutschland GmbH (2019), approximately 6,758 kg/a were expected to enter the environment via sewage sludge. Water samples from 21 legacy and active landfills (e.g. from groundwater, collection tanks, open pools etc) were analysed during 2018 as well. In general, BPA emissions by landfill leachates were considered to be highly variable based on waste characteristics and landfill type. Concentrations of untreated landfill leachates ranged from <0.03 µg/L (LOQ)–11,000 µg/L, whereas concentrations in leachates that are directly entering surface waters ranged between 0.03–5.15 µg/L. When extrapolating these results for Germany, total BPA emissions of 3,769 kg/a were estimated for active and legacy landfills. However, the extrapolation warrants caution as the total number of landfills in Germany is unknown and the fact that only a few sampling locations were included in the study. As a consequence, BPA emissions from landfills might be higher as precise information on the number and types of active and legacy landfills as well information on illegal landfills are missing.

Ramboll Deutschland GmbH (2019) also considered products as a potential source for BPA in surface waters. During a previous study by Ramboll, BPA released from products containing polycarbonates or epoxy resins have shown to be responsible for only a minor part of BPA emissions in surface waters, which is why they were excluded in Ramboll Deutschland GmbH (2019). Ramboll Deutschland GmbH (2019) focussed on product categories that are likely to contain BPA based on literature (e.g. the EU-Risk Assessment report on BPA) and are likely to release BPA into surface waters. The selection resulted in 133 products such as textiles, paper, PVC, recycling PVC, rubbers, inks and others. For sample extraction, 5 mL of methanol were added to 1g of crushed sample and rested for 1h at room temperature before being analysed. In general, the observed concentrations of the selected products (see above) were low (<1,000 µg/kg) compared to e.g. printed newspaper (12,564 µg/kg), toilet paper (48,409 µg/kg) or PVC granules (204,810 µg/kg). For the selected product categories mentioned above, extrapolated emissions in German surface water ranged from 13.2 kg/a for clothes to 28,601 kg/a for recycled PVC. However, thermal paper was expected to be the major source for releasing BPA in Germany based on marketed amounts in the EU taken from European Chemicals Agency (2019) and assuming proportional thermal paper use to population size in the EU (resulting in 534tpa for Germany). Due to the high BPA residues in PVC granules and the high production volumes of recycled PVC, Ramboll Deutschland GmbH (2019) investigated additional products that are made from recycled PVC. These products contained up to 615,800 µg/kg for riding area mats, 29,340 µg/kg for roofing and flooring mats and 1,691,700 µg/kg for traffic management systems. In summary, results of Ramboll Deutschland GmbH (2019) indicate that BPA releases into German surface waters were mainly driven by emissions from thermal paper (recycling) whereas emission from WWTP effluents, sewage sludge, landfill leachates and the majority of products were considerably lowe. However, the presented extrapolations are subject to uncertainties and potential inaccuracies that arise from estimating BPA emissions under specific circumstances. Extrapolating BPA emissions on European level requires considerably more data across different member states in order to reflect local conditions. The extrapolations from Ramboll Deutschland GmbH (2019) represent a first estimate for emission in Germany under certain conditions and should be interpreted with caution.

Recently, Ramboll Deutschland GmbH updated its substance flow analysis and performed a regionalised pathway analysis for emission of BPA into German surface waters, which represents the basis for the next section (Ramboll Deutschland GmbH, 2022). In this analysis, the model now considers individual usage and discharge patterns rather than generalised consumer use pathways used in previous models. Potential BPA sources were classified into primary manufacturing, downstream manufacturing, and consumer use while considering that BPA is no longer used for thermal paper production. However, BPA is still part of the paper recycling process and is therefore also present in paper articles that contain recycled paper content. These emission sources represent the basis for modelling emissions for two current scenarios (Current A and B). Furthermore, one future scenario was estimated by the model:

- In the scenario A (Current A), article usage, residual BPA content, and proportion of recycled newspaper and thermal paper from Ramboll Deutschland GmbH (2019) were used to estimate BPA emission during the recycling process. Removal efficiencies of WWTP were set to 85.7% and loadings were estimated based on the number of member companies in the German Pulp and Paper association multiplied by loadings per recycler.

- For scenario B (Current B), average WWTP effluent loadings serving paper recyclers in Ramboll Deutschland GmbH (2019) were extrapolated based on the number of recyclers present in a respective coordination area. BPA loadings were based on measured effluent loadings after treatment and did not directly consider treatment efficiencies
- Furthermore, a future scenario in Ramboll Deutschland GmbH (2022) is assuming zero BPA emissions from paper recycling and articles made from recycled paper as a consequence of the implemented restrictions.

The updated study used a FlowEQ model for assessing the fugacity-based fate and transport of BPA into environmental media. The model assumes a uniform concentration and considers the impacts of surface water flow across model units, while local hotspots are not considered. In general, fugacity-based models estimate the partitioning of a substance into various environmental media by assuming steady-state conditions, meaning the input of a chemical equals the removal rate. For more details see Ramboll Deutschland GmbH (2022).

The updated study by Ramboll Deutschland GmbH (2022) estimated the total loading coming from the paper recycling process to be 18,511 kg/a and 11,928 kg/a, while emissions from thermal paper manufacturing were set to zero (Current A and B). In the models, emissions coming from paper recycling and the use of articles that contain recycled paper were the dominant sources of BPA in surface waters. In total, these emission pathways accounted for 77% to 85% of the BPA that is currently detected in surface waters. In the future scenario (complete removal of BPA from paper articles and recycling processes), BPA loadings were assumed to drop to 2,046 kg/a, which is almost one order of magnitude lower than scenario A (Current A). Whereas landfills represent only a minor source for BPA in the current scenarios (~6-9%), they were estimated to be the dominant source for BPA in surface water in future (~53%) (followed by consumer uses (33%; in particular epoxy resin containing articles)). Taken together, the models predict that landfills and consumer uses will be responsible for the majority of BPA emissions in surface waters in future, while in current scenarios the use and recycling of paper articles are most dominant. Based on the outcomes of the models, the restriction of BPA in thermal paper and associated reduced manufacturing and recycling would result in considerably reduced emission to surface water. It is important to mention that information on BPA loadings from landfills were based on Ramboll Deutschland GmbH (2019), which investigated only a small number of landfills (n=22) to extrapolate loadings, while precise information on the total number and types of landfills in Germany are unknown. Despite these uncertainties, Ramboll Deutschland GmbH (2022) assumed emissions from landfills to decline as a result of restrictions on landfilling in Germany and associated low new loadings. However, sample sizes were comparably low and information on the decay and leaching of BPA from landfills are missing, which represents a shortcoming for extrapolating BPA emissions on a national scale.

The models from Ramboll Deutschland GmbH (2022) also predicted surface water concentrations for the respective scenarios and compared them with monitoring data from federal monitoring programmes (Table 45). However, it is important to mention that the modelling results are based on specific assumptions (e.g. not considering point pollution), which may result in inaccuracies for BPA predictions. For example, concentrations in 2020 from NORMAN (2022) were considerably higher compared to the modell prediction (see B.4.2.5.1.1.1). The modelling approach for Current A predicts surface water concentrations of 0.05 µg/L, which assemblies with compiled data from Ramboll Deutschland GmbH (2022) for the pre-2015 period. For Current B concentrations of 0.025 µg/L were predicted, which assembles with data from 2015-2018 (Table 45). Compared to NORMAN (2022) and (LAWA, 2020), the predicted concentrations for Current A represent, except for 2020, higher concentrations to those observed after 2015, while predicted concentrations for Current B are within the same range of the post-2015 period (Table 45).

Table 45: Comparison of measured and modeled BPA concentrations (µg/L)

Data for German surface waters from Ramboll Deutschland GmbH (2022) with data from NORMAN (2022) and LAWA (2020).		
µg/L	**NORMAN (2022) and LAWA (2020)**	**Ramboll Deutschland GmbH (2022)**
Pre-2015 (measured)		
Mean	0.098	0.051
95th %ile	0.290	0.17
2015-2018 (measured)		
Mean	0.014	0.025
95th %ile	0.057	0.070
Post-2018 (measured)		
Mean	0.027	0.016
95th %ile	0.081	0.052
Current A (modelled)		
Mean		0.053
95th %ile		0.13
Current B (modelled)		
Mean		0.025
95th%ile		0.11
Future (modelled)		
Mean		0.0037
95th%ile		0.014

In summary, Ramboll Deutschland GmbH (2022) concluded that already implemented restrictions lead to a considerable decreases of BPA in German surface waters, which together with improvements of landfill management and stormwater infrastructure in WWTP were regarded as key features for reducing the environmental impact of BPA. In contrast, implementing additional restrictions on consumer articles were regarded of as minor importance due to their modest BPA emissions to surface waters in the models. However, the temporal decline of BPA in the paper cycle could not be modelled by Ramboll Deutschland GmbH (2022), which together with the longevity of BPA applications may result several years until declining BPA concentrations can be observed in surface waters. Furthermore, the global demand for BPA is expected to grow in future (see Annex D: Baseline) and zero emissions from paper procession seems unlikelyand might result in additional BPA emissions and higher concentrations in surface water compared to the Future model in Ramboll Deutschland GmbH (2022).

B.4.2.5.1.3. Sediment

In aquatic compartments, BPA can (partly) adsorb to suspended matter, sediments and fine particles, whereas the majority of BPA is present in the aqueous phase (Ramboll Deutschland GmbH, 2019). In general, BPA concentrations in sediments are in the same order of magnitude as concentrations in the marine aqueous phase. Freshwater sediments show similar to surface waters higher concentrations (median: 0.007 µg/g dw; n = 705; 95th%ile: 0.117 µg/g dw) compared to marine sediments (0.003 µg/g dw, n = 221; 95th%ile: 0.063 µg/g dw) in the EU RAR (2008). These results are in agreement with a study of Klečka et al. (2009), which reported higher median BPA concentrations in freshwater sediments (0.016 µg /g dw; n > 347; 95th%ile: 0.256 µg /g dw) compared to marine sediments (0.0085 µg/g dw; n > 74; 95th%ile: 0.566 µg g/g dw) as well. Further studies reported mean concentrations of BPA in freshwater and marine sediments of 0.57 – 1.97 µg/g (Hansen and Lassen, 2008; Puy-Azurmendi et al., 2010). In the Gulf of Gdansk, mean concentrations between 0.006 µg/g dw (n=4; coast close to urbanized areas) and 0.011 µg/g dw (n=3; river estuaries) were reported in sediments (Staniszewska et al., 2016).

Table 46: Range of BPA mean concentrations in sediments

Representation based on monitoring data found in literature (post-2010; Europe)					
	Mean concentration	**Sample size**	**Year**	**Place**	**Reference**
River sediments (No. of considered studies: 3)					
Lowest found value	11 ng/g dw	3	2011/2012	Poland (Gulf of Gdansk)	Staniszewska et al. (2016)
Highest found value	29 ng/g dw	262 data points	2012	France (Seine river basin)	(NORMAN, 2022)
Marine sediments (No. of considered studies: 2)					
Lowest found value	3 ng/g dw	1	2010	Sediment (brackish water)	Casatta et al. (2015)
Highest found value	6 ng/g dw	3	2011/ 2012	Poland (Gulf of Gdansk)	Staniszewska et al. (2016)
Suspended matter (No. of considered studies: 2)					
Lowest found value	480 µg/kg dw	3	2004	Danube river, Austria	(NORMAN, 2022)
Highest found value	2000 µg/kg dw	1	2010	WWTP, Greece	(NORMAN, 2022)

B.4.2.5.1.4. Soil

Only few studies have investigated BPA levels in soils. In Canada, BPA is not manufactured and various risk management actions, such as measures by the paper recycling industry, were established to reduce BPA emissions since 2012. However, between 2014 and 2015 BPA was frequently detected in agricultural soils from Canada with median concentrations ranging from <0.05 to 8.6 ng/g dw (Gewurtz et al., 2021). Even though the application of biosolids generally represents a likely BPA contamination source, no clear link between biosolid application and BPA concentrations was found in Gewurtz et al. (2021). In Spain, BPA was detected in agricultural soils at concentrations from 0.7 to 4.6 ng/g dw and in industrial soils from 1.1 to 44.5 ng/g dw (Sánchez-Brunete et al., 2009).

A screening program by the Norwegian Environment Agency even detected BPA in sand and sediments from sand traps at a waste handling area in Oslo at a median concentration of 135000 ng/kg dw (n = 8; 95th%ile: 2865000 ng/kg dw) (Liv Bruås Henninge, 2020).

Table 47: Range of BPA mean concentrations in agricultural soil

Monitoring data found in literature (also pre-2010; Global) on agricultural soil (No. of considered studies: 2)					
	Mean concentration	Sample size	Year	Place	Reference
Lowest found value	0.7 ng/g dw	1	n.a.	Different Spanish regions	Sánchez-Brunete et al. (2009)
Highest found value	8.6 ng/g dw	1 pooled sample	2015	Field 2 yrs. post biosolids application; Ontario, Canada	Gewurtz et al. (2021)

B.4.2.5.1.5. Atmosphere

There is a limited number of studies that reported BPA levels in the atmosphere, especially for Europe (Guerranti et al., 2019). Even though, BPA has a low volatility and a rapid photo-oxidization half-life (0.2 days, EU RAR, 2008), BPA can be found globally in the atmosphere. For example, the open burning of plastic in urban areas around the world has shown to be positively correlated to higher concentrations of BPA in outdoor air. BPA levels range from 0.004 to 17 ng/m^3 with much lower concentrations in rural areas (0.005 to 0.2 ng/m^3 in China and Germany). Furthermore, BPA was detected in Ocean areas (0.001 and 0.03 ng/m^3) as well as in polar regions (0.001 to 0.017 ng/m^3) (Fu and Kawamura, 2010), which emphasizes the wide-spread presence of BPA in atmosphere. High concentrations as those observed in Thessaloniki, Greece (Salapasidou et al. 2011) were suspected to be related to uncontrolled fired of household waste and electronic equipment in the area (Guerranti et al., 2019; Salapasidou et al., 2011).

Table 48: BPA concentrations in the atmosphere in Europe

Reference	**Place**	**Matrix**	**Sample size**	**Min [ng/m^3]**	**Max [ng/m^3]**	**Mean [ng/m^3]**
Berkner et al. (2004)	Waldstein Mountain Range, Bavaria, Germany – forest clearing	Outdoor air	3	0.012	0.015	0.0135

Berkner et al. (2004)	Waldstein Mountain Range, Bavaria, Germany - forest	Outdoor air	3	0.01	0.01	0.01
Berkner et al. (2004)	Bayreuth, Bavaria, Germany	Outdoor air	8	<DL	<DL	<DL
Teil et al. (2016)	Paris, France	Outdoor air	6	0.01	0.1	0.05
Salapasidou et al. (2011)	Thessaloniki, Greece (urban-industrial site)	PM10	10	<DL	47.3	13.2
Salapasidou et al. (2011)	Thessaloniki, Greece (urban-traffic site)	PM10	10	0.06	18.6	6.78

DL: Detection limit

B.4.2.5.1.6. Indoor dust

Several studies investigated the content of BPA in indoor dust in private houses as well as public places. The majority of studies detected BPA in 100% of samples (Caban and Stepnowski, 2020; Dueñas-Mas et al., 2019; Liv Bruås Henninge, 2020; Velázquez-Gómez et al., 2019; Wang et al., 2015). Median concentration values range from 0.6 µg/g in private homes (n=23) (Wang et al., 2015) to 43.3 µg/g in a museum (n=6) (Velázquez-Gómez et al., 2019) and tend to be higher in samples from public vs private spaces (Velázquez-Gómez et al., 2019). Within the studies that are based on a relatively high sample size, similar median concentrations between 1.2 and 1.5 µg/g dw were found (Larsson et al., 2017; Liv Bruås Henninge, 2020; Velázquez-Gómez et al., 2019; Wang et al., 2015) :

Table 49: Range of BPA median concentrations in indoor dust

Monitoring data found in literature (post-2010, Europe) on indoor dust (No. of considered studies: 7)					
	Median concentration	Sample size	Year	Place	Reference
Lowest found value	0.6 µg/g	23	2012-2014	House dust, Romania	Wang et al. (2015)
Highest found value	48,65 µg/g	6	n.a.	High schools, Spain	Velázquez-Gómez et al. (2019)

Indoor floor mopping and laundry transfer some of the indoor BPA contamination to wastewater. In addition, human intake of dust leads to BPA transport via men to WWTP.

B.4.2.5.1.7. Human

A trend analysis of BPA in urine for Germany is expected to be published in 2022.

Exposure

In the monitoring program HBM4EU, infants from 1 day up to 6 months have shown to have an average internal BPA exposure ranging from 0.042 µg/kg bw per day to 0.226 µg/kg bw per day (estimated by forward modelling). The average internal exposure for infants aged 6 to 12 months and children aged 3 to 10 years ranged from 0.301 µg/kg bwto 0.387 µg/kg bw per day. The internal exposure of the adolescents, the elderly and very elderly population groups was 0.124 µg/kg bw to 0.172 µg/kg bw per day. The average external exposure to BPA from non-dietary sources such as toys and cosmetics was estimated by EFSA to be less than 0.001 µg/kg bw per day and 0.005 µg/kg bw per day, in all population groups, respectively (EFSA Panel on Food Contact Materials, 2015).

Findings in human urine and tissue

BPA is detectable in almost all urine and blood samples studied, as populations in industrialised countries are ubiquitously exposed to low-dose BPA via consumer products (Michałowicz, 2014).

Between 1995 and 2009, 24-h urine samples from a total of 600 students were analysed in Germany. These samples from the German Environmental Specimen Bank showed a median concentration of 1.49 µg total BPA/L in stored urine samples (95th percentile: 7.37 µg/L) (Koch et al., 2012).

In France, urine samples from 500 children and 900 adults were analysed for bisphenols between 2014 and 2016. Bisphenols A, S and F were detected in almost all samples; the geometric mean in BPA was 2.25 and 2.69 µg/g creatinine, respectively, in children and adults; equivalent to 0.44 and 0.53 µg/g creatinine for BPS, and 0.26 and 0.31 µg/g creatinine for BPF. Impregnation with bisphenols was higher in children than in adults. The results obtained were close to those observed in North American countries (Balicco et al., 2019).

During 2020, the Austrian Environment Agency analysed six bisphenols in urine of 6-10-year-old children (n=85) and detected BPA, BPAF, BPF and BPS with BPA showing highest median concentration 0.73 µg/L (95th%ile = 4.6 µg/l). BPA was detected in urine of 94% of all children (Hartmann, 2021).

All over Europe, the results of the HBM4EU monitoring study in 2020 shows measured exposure values for children and mothers (Barouki, 2020):

- In children, the weighted geometric mean (95% CI) for urinary BPA was 1.97 µg/L (1.81-2.15) in the total European study group.
- In mothers, it equalled 1.78 µg/L (1.62-1.94 µg/L).

Among young Danish men, a significant decrease in urinary concentrations over time was observed. Median concentrations of BPA were more than halved between 2009 to 2017 and the detection rate slightly decreased (n=300) (Frederiksen et al., 2020). On the other hand, the detection rate of both urinary BPS and BPF increased over the study period to 86% and 87%.

For children, the HELIX study found concentrations in samples that were collected in six different EU countries (UK, France, Spain, Lithuania, Norway, Greece) in 2014 and 2015 that were at least twice as high as reported in the Danish young men study (Casas et al., 2018; Haug et al., 2018). Also the French Esteban cross-sectional study found higher concentrations of BPA in urine of children than in adults (Balicco et al., 2019).

Due to the occupational exposure of cashiers to BPA via thermal paper, urinary biomonitoring studies detected even higher median concentrations of free BPA in urine of cashiers, e.g in France: 8,92 µg/L (n=90, 95th percentile: 44 µg/L, max: 1915 µg/L) (Ndaw et al., 2016).

Mid and long-term exposure to BPA might be assessed more adequately in adipose tissue than in urine or blood serum (Artacho-Cordón et al., 2017). Table 50 shows median concentrations of BPA in various human tissues and blood serum that were identified by Corrales et al. (2015) in peer-reviewed studies after 2010. The table does not reflect all available human monitoring data on BPA since a comprehensive literature research was not conducted.

Table 50: Median concentrations of BPA in various human tissues and blood serum

n ≥ 10; Adaptation of Corrales et al. (2015) (post-2010, Europe).				
Description	**Median concentration**	**Sampe size**	**Country**	**Reference**
Human adipose tissue				
Unconjugated BPA; Eight males & three females (9-62 years old, autopsy samples)	2.09 ng/g	11	Belgium	Geens et al. (2012)
Women undergoing surgical treatment of malignant and benign diseases	4.79 ng/g	20	Spain	Fernandez et al. (2007)[103]
Human blood serum				
Adults (70 years old)	2.08 ng/mL (female) & 3.89 ng/mL(male)	1016	Sweden	Olsén et al. (2012)
Women a few days after giving birth	<LOD	15	Sweden	Gyllenhammar et al. (2012)
Human brain				
Unconjugated BPA; 8 males & 3 females (9-62 years old, autopsy samples)	0.57 ng/g	11	Belgium	Geens et al. (2012)
Human cord blood				
Unconjugated BPA; Boys born after 34 weeks gestation with cryptorchid or descended testes	0.86 ng/mL	106	France	Fenichel et al. (2012)
Human colostrum				
Healthy women within three days after delivery	1.47 ng/mL	21	France	Migeot et al. (2013)
Human liver				
Eight males & three females (9-62 years old, autopsy samples)	1.03 ng/g	11	Belgium	Geens et al. (2012)

Human placental tissue				
Pregnant women at the moment of delivery	8.7 ng/g	10	Spain	Vela-Soria et al. (2015)
Human urine				
24h urine samples from of 600 students	1.49 µg/L	600	Germany	Koch et al. (2012)
6-10-year-old children	0.73 49 µg/L	85	Austria	Hartmann (2021)
Children (Geometric mean), HBM4EU	1.97 µg/L		Europe	Barouki (2020)
Mothers (Geometric mean), HBM4EU	1.78 µg/L		Europe	Barouki (2020)
Cashiers	8,92 µg/L	90	France	Ndaw et al. (2016)

B.4.2.5.1.8. Biota

Despite the frequent detection of BPA in surface waters, BPA was, with exception of freshwater fish from Sweden (n=3, median 135.9 ng/g, 95th%ile: 156.6 ng/g) and Poland (n=6, mean: 430.4 ng/g and n=6 mean: 236.3 ng/g), not detected in muscles of freshwater and marine fish from central and northern Europe according to data from NORMAN (2022) and Corrales et al. (2015).

However, BPA has shown to be more frequently detected in bile at considerably higher concentrations, e.g. in fish from France, Spain and United Kingdom (Bizarro et al., 2014; Couderc et al., 2015; Fenlon et al., 2010; Geens et al., 2012). This was also observed in the study of Pettersson et al. (2007), where the detected BPA concentration in fish bile was up to 7.7 µg/g.

A study investigating the occurrence of eight bisphenols in Norwegian raptor tissues (n=44) demonstrated that the preen gland showed highest concentrations followed by liver and kidney with BPA being the overall dominant bisphenol (González-Rubio et al., 2020; Oró-Nolla et al., 2021). Interestingly, concentrations tended to increase with the expected trophic position of the investigated species, indicating that BPA might be transferred in food webs (González-Rubio et al., 2020).

BPA was furthermore detected in plasma of passerine birds from Canada and exposures were suggested to be related by human activity as BPA was detected in all tree swallows sampled next to waste water treatment plants and showed the highest concentrations in starlings next to a landfill (Gewurtz et al., 2021).

When considering filtrating organisms such as mussels, BPA has shown to reach comparably high bioconcentration factors, indicating that assimilation rates might exceed excretion rates (Staniszewska et al., 2017). In Staniszewska et al., 2017, concentrations of up to 0.27 µg/g dw were reported (mean 0.04 g/g dw), whereas in Gatidou et al. (2010) concentrations of up to 0.63 µg/g dw were reported for mussels.

Table 51: Range of BPA median or mean concentrations in biota (Europe & Canada)

	Concentration	Sample size	Year	Place	Reference
Bird plasma No. of considered studies: 1					
Lowest found median value	0.54 ng/mL	1	2009	Tree swallow, WWTP site, Canada	Gewurtz et al. (2021)
Highest found median value	6.2 ng/mL	9	2015	Europ. Starling, field 2 yrs post biosolid application	Gewurtz et al. (2021)
Bird preen gland No. of considered studies: 1					
Lowest found median value	6.2 ng/g ww	2	2009,2011	Long-eared owls, Normandy, France	González-Rubio et al. (2020)
Highest found median value	94.6 ng/g ww[104]	8	1997-2009	White-tailed sea eagle, Greenland	González-Rubio et al. (2020)
Fish bile No. of considered studies: 3					
Lowest found mean value	31.9 ng/mL	12-20	2012	Thicklip grey mullet, fishing port	Bizarro et al. (2014)
Highest found mean value	3109.1 ng/mL	6	2011,2012	Yellow eel, Loire estuary, France	Couderc et al. (2015)
Fish liver No. of considered studies: 1					
Lowest found mean value	164 ng/ g dw	6	2008-2011	Cod, Gulf of Gdansk	Staniszewska et al. (2014)
Highest found mean value	250.5 ng/g dw	6	2008-2011	Flounder, Gulf of Gdansk	Staniszewska et al. (2014)
Fish muscle No. of considered studies: 3					
Lowest found median value	25 ng/g dw	5	2008,2009	Common bream, Rhone river, France	Miege et al. (2012)

---

[104] Median concentration in animals where BPA was detected; Detection rate: 37.5%

Highest found mean value	430.4 ng/g dw	6	2008-2011	Flounder, Gulf of Gdansk	Staniszewska et al. (2014)

The results for biota demonstrate that BPA exposure prevails and that sampling location (e.g. landfills) sampling matrix (e.g. glands, liver), trophic position as well as feeding ecology (e.g. filtration) might be crucial factors for detecting bisphenols in biota samples.

B.4.2.5.2. Monitoring Data of BosC

Monitoring Data for Bisphenol B

In the Annex XV support document for the identification of BPB as an SVHC (France, 2021), the following data was assessed:[105]

BPB was measured in Indian municipal WWTPs (Karthikraj and Kannan, 2017) as well as in Slovenian and Croatian municipal and industrial WWTPs (Česen et al., 2019; Česen et al., 2018) with a detection rate of 60 to 100% in India, 8.3% to 67% in Slovenia and Croatia and with a mean concentration of 2.5 ng/L, 8.46 ng/L and 27.1 ng/L in India, Slovenia and Croatia, respectively.

BPB was also measured in 46 samples of fresh sludge from WWTPs of six geographical regions in China (North China, Northeast China, Eastern China, Central South China, Southwest China and Northwest China) and from 15 cities in the Henan province(Pang et al., 2019; Zhu et al., 2019b). The mean concentration of BPB was of 1.38 ng/g dw and the maximum concentration was 3.55 ng/g dw with a detection rate of 6.52% in sludge from WWTPs. It ranged from not detected (nd) to 5.23 ng/g dw (mean value of 0.38 ng/g dw) with a detection rate of 33% in sewage sludge from WWTPs of cities. The average contribution of BPB to total BP concentrations was 0.688% (BPA = 85.8%) for fresh sludge sampled in the 46 WWTPs and 0.2% for WWTPs samples of the Henan province, respectively. Significant correlations were found between BPB and WWTP characteristics, namely BPB is positively correlated with the ratio of treatment capacity to populations served (Pang et al., 2019).

BPB in sewage sludge was exceptionally detected in one sample during a USA nationwide study at 1.1 ng/g dw (Yu et al., 2015).

BPB was not detected in the influent, primary effluent, final effluent and sludge from two WWTPs in Albany, New York State (Xue and Kannan, 2019) and in sewage sludge of Indian, Slovenian and Chinese WWTPs (Karthikraj and Kannan, 2017; Song et al., 2014b; Sun et al., 2017; Sun et al., 2018). BPs considered in the studies had different behaviour in WWTPs, some being preferentially biodegraded, others removed by adsorption on sludge or being both biodegraded and adsorbed (Česen et al., 2018; Sun et al., 2017).

Moreover, BPB was recently detected in source water and drinking water from 20 drinking water treatment plants (DWTPs) across China (March-November 2017). BPB was detected in 10% of the 20 source water samples with mean concentration of 1.0 ng/L (nd–14.3 ng/L) (BPA = 80% detection frequency and mean concentration of 12.8 ng/L (nd–34.9 ng/L)). In finished drinking water, BPB was also detected in 10% of the 20 samples with

---

[105] https://echa.europa.eu/documents/10162/5083c47f-a2dd-e54b-2bcc-c5c9d0e634a7

mean concentration of 0.2 ng/L (nd–3.2 ng/L) (BPA = 40% detection frequency and mean concentration of 1.6 ng/L (nd-6.5 ng/L) (Zhang et al., 2019).

In aquatic ecosystem, BPB was the least frequently detected bisphenol, as reviewed in Chen et al. (2016) and Noszczyńska and Piotrowska-Seget (2018). BPB was not detected in sediment or surface water in China (Jin and Zhu, 2016; Wang et al., 2017b; Yang et al., 2014b; Zheng et al., 2015), Japan, Korea, USA and India (Liao et al., 2012d; Yamazaki et al., 2015) except in one sediment sample (10.6 ng/g dw) (Liao et al., 2012d).

Contrasting with previous results, recent studies investigating BPs occurrence in Taihu freshwater lake in China report its detection in almost all water and sediment samples (Liu et al., 2017; Yan et al., 2017). The mean concentration of BPB ranged between 7.3 ng/L (Yan et al., 2017) and 19.8 ng/L (Liu et al., 2017) in water and between 1.2 ng/g dw (Yan et al., 2017) and 2.12 ng/g dw (Liu et al., 2017) in sediment. During previous sampling campaigns done in the same lake in 2013 (Jin and Zhu, 2016) and in 2015 (Wang et al., 2017b), no BPB was detected in water or sediments, suggesting a recent local increase in BPB release into the environment.

BPB was also detected in seawater from 25 sites in the Pearl River Estuary in south China collected in December 2017. BPB median concentrations were 1.51 ng/L in seawater (0.17-13.1 ng/L min-max, with 100% detection), 73.3 ng/L in suspended particulate matter (SPM) (ND- 97.1 ng/L min-max, with 44% detection) and 3.94 ng/L in the total system (0.36-18.1 min-max, with 100% detection) (Zhao et al., 2019). BPB was found in 0% of surface sediment samples and BPA in 97.9% of surface sediment (GM: 1.87, range: nd-116 ng/g) collected from the Bohai Sea and Yellow Sea in northern Chinese coastal areas. BPB was not frequently detected in sediment cores (detection rate (DR) comprised between 0-16% for surface sediment and three sediment cores extracted from the inner shelf of Yellow Sea, the central and inner shelves of northern part of East China Sea using a gravity corer, nd-20.9 ng/g) (Liao et al., 2019).

In the Elbro Delta (Spain), BPB was detected in all sea water samples taken from Gil-Solsona et al. (2022) in a range of 2.1 to 8.7 ng/L (median: 4 ng/L) in march 2019.

Jurek and Leitner (2018), determined the occurrence of BPs in paper products (various cellulose, paper and board samples (virgin fibre and recycled fibre)) from different European paper and board manufacturers collected in 2015. BPB was always below the LOQ (0.40 to 1.32 µg kg−1, depending on paper type).

Regarding dissemination in the environment, BPB has shown to adsorb on PVC (Polyvinyl chloride) microplastics with pseudo-second order kinetics, increasing with increasing concentration of PVC, with a maximum adsorption efficiency of 0.22 ± 0.01 mg/g and a 68% efficiency adsorption alone and 41% when in mixture with other BPs (Wu et al., 2019).

BPB occurrence in the environment has been poorly investigated in Europe. Albeit not frequently detected, recent studies suggest an increased occurrence in WWTPs and freshwater ecosystems, with detection even in remote areas.

BPB has been detected in human food samples in several studies mainly conducted in Europe and Asia. It is reported in canned food in particular, but also in non-canned food, e.g. egg and oils (Liao and Kannan, 2014) and milk (Grumetto et al., 2013), baby food (García-Córcoles et al., 2018) as well as chicken and oil (Gonzalez et al., 2020). Indoor dust data are very limited and indicate a low BPB detection rate. BPB was also detected in dental sealant and in pacifiers. However, only few data are available and relate mainly to non-European countries.

The available human biomonitoring studies suggest that BPB can be detected in both urine and serum in the same order of magnitude as BPA although detected less often than BPA. BPB was also detected in maternal plasma and in human cord blood. However, those data are too limited to be considered representative of the general population and thus not sufficient to draw solid conclusions on the frequency and the concentrations of BPB in these matrices.

Furthermore, it is worth noting that BPB is included in the list of HBM4EU priority substance group "bisphenols"[106]*. HBM4EU is a joint effort of 28 countries, the European Environment Agency and the European Commission, co-funded under Horizon 2020. Running from 2017 to 2021, HBM4EU aims to generate knowledge to provide better evidence of the actual exposure of citizens to chemicals. More information on human exposure to BPB in Europe is expected in the upcoming years.*

Additional monitoring data is also needed to assess the environmental contamination and occurrence of BPB, especially in Europe. BPB detection and occurrence are low, in particular compared to BPA that is used at a larger scale, but they are increasing and may reflect an increase in use.

Table 52: Monitoring data for Bisphenol B

Environmental samples				
Reference	Country	Sample type	Frequency of detection	Concentration
(Česen et al., 2019)	Slovenia	River (23rd May and 12th July 2017)		< LOD
(Gil-Solsona et al., 2022)	Spain, Ebro River	Sea water (March 2019 – two weeks)	100%	2.1 – 8.7 ng/L; Median: 4 ng/L (LOD: 0.01 – 0.07 ng/L)
(Wang et al., 2018)	China	River		< LOD
(Liu et al., 2017)	China	Surface water (November 2016)	100%	18 - 46 ng/L Mean: 19.8 ng/L
(Yan et al., 2017)	China - Taihu freshwater lake	Surface water (April 2016)		Mean: 7.3 ng/L
(Zhao et al., 2019)	China - Pearl River Estuary	Seawater (December 2017)	100%	0.17-13.1 ng/L (median: 1.51 ng/L)
(Zhang et al., 2019)	China	Source water drinking water treatment plants (DWTPs)	10% (2/20)	n.d. - 14.3 ng/L (mean: 1.0 ng/L)

---

[106] https://www.hbm4eu.eu/the-substances/bisphenols/

		(March to November 2017)		
(Zhang et al., 2019)	China	drinking water of DWTPs (March to November 2017)	10% (2/20)	n.d. - 3.2 ng/L (mean: 0.2 ng/L)
(Tang et al., 2020)	Australia, South East Queensland	Wastewater (2012 – 2017; all n=108)	0%	Median: <0.44 µg/L
(Jin and Zhu, 2016; Wang et al., 2017b; Yang et al., 2014c)	China	Sediment or surface water		Not detected
(Liao et al., 2019); (Yamazaki et al., 2015)	Japan, Korea, USA and India	Sediment or surface water		Not detected
(Liao et al., 2012d)		Sediment	One sample	10.6 ng/g dw
(Yan et al., 2017)	China - Taihu lake	sediment		Mean: 1.2 ng/g
(Liu et al., 2017)	China - Taihu lake	Sediment (November 2016)		1.8 – 4.0 ng/g dw Mean: 2.12 ng/g
(Pang et al., 2019);(Zhu et al., 2019b)	China	fresh sludge from WWTPs from six regions	6.52%	Mean: 1.38 ng/g dw; max.: 3.55 ng/g dw
(Pang et al., 2019);(Zhu et al., 2019b)	China	sewage sludge from WWTPs from 15 cities of Henan province	33%	Mean: 0.38 ng/g dw; max.: 5.23 ng/g dw
(Yu et al., 2015)	USA	Sewage sludge	1 sample in national wide study	1.1 ng/g dw
(Karthikraj and Kannan, 2017)	India	municipal WWTPs	60 – 100%	Mean: 2.5 ng/L
(Česen et al., 2019; Česen et al., 2018)	Slovenia (23rd May and 12th July 2017) and Croatia	municipal WWTPs	8.3 – 67%	Mean: 8.46 ng/L and 27.1 ng/L
(Xue and Kannan, 2019)	Albany, New York State	influent, primary effluent, final effluent and sludge from two WWTPs		Not detected
(Ruus et al., 2020)	Norway, Inner Oslofjord	Cod (liver/bile)	Liver: 0 Bile: 0	Liver: < 2.5 - <2.5 ng/g w/w; mean: n.d. Bile: < 2.5 - <2.5 ng/g w/w; mean: n.d.

Paper, foodstuff, and hygiene products				
Reference	Country	Sample type	Frequency of detection	Concentration
(Jurek and Leitner, 2018)	European paper and board manufacturers collected in 2015	paper products (various cellulose, paper and board samples (virgin fibre and recycled fibre)		< LOQ (0.40 to 1.32 µg/kg, depending on paper type).
(Liao and Kannan, 2014)	Europe and Asia	non-canned food, e.g. egg and oils	detected	
(Grumetto et al., 2013)	Europe and Asia	Milk	detected	
(García-Córcoles et al., 2018)	Europe and Asia	Babyfood	detected	
(Gonzalez et al., 2020)	Europe and Asia	Chicken and oil	detected	

Abbreviations: LOD=limit of detection, n.d. = non-detect

Monitoring Data for Bisphenol S

Surface Water

The NORMAN database was accessed (NORMAN, 2022) and data on BPS in surface waters was extracted which resulted in 145 data entries (2002-2020).

The majority of the measured concentrations were below the limit of quantification. Only three measurements resulted in individual values (270 ng/L Hungary, 140 ng/L Romania and 210 ng/L Austria, all in the year 2013 in the Danube).

In addition to the data extracted from NORMAN database, also publications were evaluated documenting measurements in river water in France, Slovenia, Austria, and China. The concentrations ranged from 0.07 to 65,600 ng/L. The highest measured concentration of bisphenols was reported for BPS, at 65.6 µg/L (Huang et al., 2018).

In samples taken in the Ebro river in Spain in 2019 by Gil-Solsona et al. (2022) showed that BPS was ubiquitous in alle the environmental compartmens with a detection frequency of 100% of water samples (similar to BPA). The concentrations ranged from 7.0 to 20.4 ng/L for BPS (except for one sample that contained > 500 ng/L). The concentrations found in Spain were approximately one order of magnitude lower than those found in different studies in China. Similar to the concentrations found in river water, in sea water BPS (and BPA) was detected in all samples with concentrations ranging from 0.8 to 25.3 ng/L.

Sediment

Choi and Lee reported in 2017 BPS concentrations up to 1,970 ng/g in sediment samples taken from 2000 to 2012 (Choi and Lee, 2017b). (Huang et al., 2018) recordered lower concentrations in Chinese river sediment in samples collected between 2016 and 2017 (mean: 7.25 ng/g; max.: 45.4 ng/g).

In sediments collected in Ebro River in Spain by Gil-Solsona et al. (2022), BPS was not found but in marine sediment from the Ebro Delta 25% of the samples contained BPS in low concentrations (up to 1.1 ng/g).

Biota

(González-Rubio et al., 2021) determined the occurrence of eight bisphenols in six raptor tissues, including muscle, kidney, liver, brain, preen gland and adipose. The samples (n=44) (Eurasian sparrowhawks, long-eared owls, and white-tailed eagles) were taken from 1997 to 2011 from France and Greenland. BPB (7/44) was detected more often than BPS (6/44) and BPA (4/44). The median concentrations for BPA was 67.5 ng/g w/w, for BPF was 3.01 ng/g w/w, for BPB was 1.60 ng/g w/w, and for BPS was 0.65 ng/g w/w. BPAF was not detected.

BPS was also detected in eggs from the black-legged kittiwake and glaucous gull by (Lucia et al., 2016). The expamined 10 eggs of seabirds and 10 fishes (muscle). The samples were collected in 2013 and 2014 in Kongsfjorden (island of the Svalbard Archiplago). The measured concentrations in Artic scar were below the limit of quatification (0.3 ng/g), while concentrations in seabird eggs were between <0.3 and 1.1 ng/g w/w.

(Zhao et al., 2021) evaluated the occurrence of bisphenols in marine organisms (13 species; n = 74), as well as seawater (n = 15), from East China Sea. In seawater BPA concentration was highest (mean: 18 ± 9.7 ng/L) followed by BPS (mean: 3.7 ± 2.8 ng/L). Bisphenol F was found in concentrations of 0.31 ± 0.17 ng/L (mean) and BPAF with 0.24 ± 0.15 ng/L (mean). In marine organisms (without hydrolysis), BPA and BPS were as well the predominant bisphenols with concentrations of BPA of 3.8 ng/g mean (range 1.2−7.7 ng/g) and BPS of 1.5 ng/g mean (range: 0.19−6.1 ng/g). After enzymatic hydrolysis treatment, mean concentrations of the bisphenols increased 1.8 (BPS) to 3.7 (BPA) times in marine organisms.

In 2019, Zhao reported BPS concentrations between not detected and 328 ng/ (median: 1.28 ng/g) from wild-cought shellfisch (n=11) and fish (n=10) cought in the Pearl River Estuary in South China (Zhao et al., 2019).

(Ruus et al., 2015) examined BPS in samples of plankton (0.24 – 4.83 ng/g), bird eggs (not detected-44.2 ng/g), polychetes (0.06-2.35 ng/g), fish (<0.5-20.5 ng/g), prawns (1.34-2.87 ng/g) and mussels (<0.3-1.89 ng/g) from an urban fjord (Inner Osloford) in Norway in 2014. The monitoring program "Environmental Contaminants in an Urban Fjord" repeated the measurements in the following years. In 2016 and 2018, BPS was not detected in cod (liver neither in blood) nor in eggs from the herring gull (Ruus, 2017) (Ruus et al., 2019). In 2019 BPS was again detected in cod liver and bile (<1 – 1.52 ng/g w/w; <1 – 1.58 ng/g w/w) (Ruus et al., 2020).

(Liao and Kannan, 2019) collected samples from eleven mollusc species from five cities along the Bohai Sea (China) between 2006 and 2015. BPS was detected in less than 5% of the samples (186) and the concentrations ranged between not detected and 4.68 ng/g dw (geometric mean: 0.146 and mean: 0.141 ng/g dw).

Human

<u>Findings in human urine and tissue</u>

There a several biomonitoring studies available, reporting BPS findings in human urine from general populations outside of Europe [China, India, Japan, Korea, Kuweit, Malaysia, United States and Saoudi Arabia ((Asimakopoulos et al., 2016); (Duan et al., 2018); (Liao et al., 2012b); (Liu et al., 2019a); (Yang et al., 2014a); (Yao et al., 2018); (Zhou et al., 2014)), from cashiers and non-cashiers in U.S.-North Carolina (Thayer et al., 2016) and in pregnant women in Australia (Heffernan et al., 2016), China (Wan et al., 2018a), (Zhang et al., 2020a), USA (Ihde et al., 2018) and Israel (Machtinger et al., 2018)].

For Europe less information is available. There were 11 studies examining urine samples in Europe in pregnant women (Gyllenhammar et al., 2017); (Philips et al., 2018b), in children and dolescents (Tkalec et al., 2021), in cashiers and non-cashiers (Ndaw et al., 2018) and in general population ((Balicco et al., 2019); Danish Young Men Study, 2009, 2013, 2017 (Jørgensen); (Husøy et al., 2019); Norwegian biomonitoring study, 2012; (Sakhi et al., 2018)).

Within Europe:

Geometric mean concentrations found in the urine of mothers ranged from below the LOQ (0.03 ng/mL) and 0.36 ng/mL.

In children the mean concentrations ranged from 0.021 ng/mL and 0.36 ng/mL. For cachiers and non-cachiers the geometric mean concentrations of total BPS were 2.48 ng/mL and 0.72 ng/mL.

Outside Europe:

The concentrations measured ranged not detected to 13.3 ng/mL (geometric mean, general populations). In school children the range of measured concentrations was 0.25 to 50 ng/mL.

Indoor dust

Some studies investigated the content of BPS in indoor dust in private houses as well as public places:

Indoor dust samples were collected in China, Korea, Japan and the US. In all samples (100%) BPS was detected ranging from 0.8 to 26600 ng/g (geometric mean: 340 ng/g) (Liao et al., 2012b).

(Wang et al., 2015) found BPS in indoor dust samples collected in 12 countries (China, Colombia, Greece, India, Japan, Kuweit, Pakistan, Romania, Saudi Arabia, South Korea, U.S., and Vietnam) in homes (n=284) and other microenvironments (n=104: laboratories, offices, cars, air conditioner, and e-waste workshop). BPS was detected in all samples from Ronania (n=23) and 85% of the samples from Greece (n=28). The mean concentrations found in in house dust in Greece and Romania were 1500 and 380 ng/g, respectively.

(Dueñas-Mas et al., 2019) detected BPS in Spain from public environments (n=10) using SUPRASs (simultaneous extraction/clean-up method based on the use of supramolecular solvents) in a concentrations range detection limit (DL) to 736 ng/g, which is up to four times more than BPF. The mean concentration was 290 ng/g and the median was 193 ng/g. BPS was detected in 70% of the samples (n=10).

(Liu et al., 2019a) detected BPS in indoor dust samples from Singapore as well as urine from 33 participants. BPS was detected in all dust samples using a vacuum cleaner in a range of 153 to 6491 ng/g, with an average concentration of 714 ng/g.

In the study by (Larsson et al., 2017) very high concentrations of BPA and BPS (2300 and 800 ng/g, respectively) were found in dust in Swedish preschools.

(Liao et al., 2012b) measured the BPS concentrations of BPS in indoor dust in U.S., Japan, China, and Korea. BPS was detected in all samples in concentrations from 0.83 to 26,600 ng/g.

Likewise, (Xue et al., 2016) reported BPS detections in indoor air samples (parking garages, auto repair shops, cars, barber shops, public places, homes, labs and offices) in the U.S. (Albany). The concentrations in bulk air (sum of particulate and vapor phase concentrations) ranged from <LOQ to 0.94 ng/m³, with a mean of 0.07 ng/m³. The detection rate was 26.5% and therefore the most frequently detected of the eight bisphenols.

Table 53: Monitoring data for Bisphenol S

Environmental samples				
Reference	**Country**	**Sample type**	**Frequency of detection**	**Concentration**
Norwegian Environment Agency (2014)	Norway	Landfill leachate		<LOD – 3.1 µg/L
(Ruus et al., 2015)	Norway, Inner Oslofjord (urban fjord)	Plankton Bird eggs Polychaetes Fish Prawns Mussels (2014-2015)		0.24-4.83 ng/g n.d. – 44.2 ng/g 0.06 – 2.35 ng/g <0.5 – 20.5 ng/g 1.34 – 2.87 ng/g <0.3 – 1.89 ng/g
(Ruus, 2017)	Norway, Inner Oslofjord	Cod liver Blood and eggs from herring gull (2016)		n.d.
(Ruus et al., 2019)	Norway, Inner Oslofjord	Cod liver Blood and eggs from herring gull (2018)		n.d.
(Ruus et al., 2020)	Norway, Inner Oslofjord	Cod (liver/bile) (2019)	Liver: 1 Bile: 3	Liver: <1 – 1.52 ng/g w/w; Mean: 0.8 ng/g w/w Bile: <1 – 1.58 ng/g w/w; Mean: 0.3 ng/g w/w
(González-Rubio et al., 2021)	France and Greenland	six raptor tissues, including muscle, kidney, liver, brain, preen gland and adipose	14% (6/44)	Median: 0.65 ng/g w/w
(Lucia et al., 2016)	Kongsfjorden (Island of the Svalbard Archipelago)	Artic seabird eggs of black-legged kittiwake and glaucous gull (2013-2014)	10 eggs of seabird 10 muscle of fishes	< 0.3 – 1.1 ng/g w/w <LOQ (0.3 ng/g)

(Liao and Kannan, 2019)	Cities at coastal areas along Bohai Sea, China	Mollusc species (11) (2006 – 2015)	< 5%	n.d. – 4.68 mg/g dw (geomean: 0.146 ng/g dw, Median: 0.141 ng/g dw)
(Zhao et al., 2019)	South Cina, Pearl River Estuary	Shellfish (n=11) Fish (n=10)		n.d. – 328 ng/g (median: 1.28 ng/g)
(Zhao et al., 2021)	East China Sea	Marine organisms (May 2019)		0.19−6.1 ng/g Mean: 1.5 ng/g
(Gil-Solsona et al., 2022)	Spain, Elbro River	Fish plasma	90%	<LOD – 30.1 ng/mL; Median: 13.05 ng/mL)
(Gil-Solsona et al., 2022)	Spain, Elbro River	Fish liver	100%	0.21 – 1.6 ng/g; Median: 0.55 ng/g
(Gil-Solsona et al., 2022)	Spain, Elbro River	Fish muscle	80%	<LOD – 4.2 ng/g; Median: 0.03 ng/g
(Gil-Solsona et al., 2022)	Spain, Ebro River	River water (March 2019 – two weeks)	100%	7.0 – 20.4 ng/L; Median: 16.1 ng/L; one sample: > 500 ng/L (LOD: 0.01 – 0.07 ng/L)
(Gil-Solsona et al., 2022)	Spain, Ebro River	River sediment	0%	< LOD (0.02 – 1.09 ng/g)
(Gil-Solsona et al., 2022)	Spain, Ebro River	Sea water (March 2019 – two weeks)	100%	0.8 - 25.3 ng/L; Median: 5.1 ng/L (LOD: 0.01 – 0.07 ng/L)
(Gil-Solsona et al., 2022)	Spain, Ebro River	Sea sediment (March 2019 – two weeks)	25%	<LOD – 1.1ng/L; Median: 0.62 ng/L; (LOD: 0.02 – 1.09 ng/g)
(Schmidt et al., 2020)	France	Urban river (May 2017 to April 2018)		3.7 – 20.5 ng/L
(Česen et al., 2019)	Slovenia	River (23rd May and 12th July 2017)		1.68 – 35.2 ng/L
(Brueller et al., 2018)	Austria	River (August 2017 until February 2018)		< LOD
(Huang et al., 2020)	China	Rivers (March and July 2015)		0.07 – 133 ng/L
(Zheng et al., 2019)	China	River (15 July, 2018)		2.24 – 73.3 ng/L
(Wang et al., 2018)	China	River		40 – 70 ng/L
(Huang et al., 2018)	China	River		19.9-65600 ng/L

		(December 2016 and January 2017)		
(Wan et al., 2018b)	China	River (March to July, and September 2015)		0.18-14.9 ng/L
(Liu et al., 2017)	China	Surface water (November 2016)		4.1-160 ng/L
(Yan et al., 2017)	China - Taihu lake	Surface water (April 2016)		Mean: 140 ng/L
(Yan et al., 2017)	China - Luoma lake	Surface water (April 2016)		Mean: 6.8 ng/L
(Zhao et al., 2021)	East China Sea	Surface water (May 2019)		mean: 3.7 ± 2.8 ng/L
(Choi and Lee, 2017a)	China	Sediment (2000 – 2012)		Increase of BPS
(Tang et al., 2020)	Australia, South East Queensland	Wastewater (2012 – 2017; all n=108)	100%	Median: 1.1 µg/L
(Choi and Lee, 2017b)	China	Sediment		Up to 1940 ng/g
(Huang et al., 2018)	China	River sediment (2016 – 2017)	100%	Up to 45.4 ng/g Mean: 7.25 ng/g
Human biological samples				
Reference	**Country**	**Sample type**	**Frequency of detection free BPS**	**Concentration free BPS**
(Liu et al., 2019a)	Singapore	Urine	(33 participants)	<0.012 to 1.97 ng/mL (mean: 0.070 ng/mL)
(Liao et al., 2012b)	U.S.	Urine		Mean: 0.299 ng/mL
(Zhou et al., 2014)	U.S., Atlanta	Urine	87% 2009 to 2012	< LOD (0.03) to 12.3 ng/mL Median: 0.13 ng/mL)
Ye et al. (2015)	U.S. residents	Urine (2000 – 2014)	19 – 74% upward trend (25% in 2000; 74% in 2014)	< LOD (0.1) to 3.06 µg/L
(Shang et al., 2019)	Canada, Montreal (Jewish General Hospital	Urine		0.17 to 1.8 µg/gm creatinie
(Tang et al., 2020)	Australia, South East Queensland	Urine (2012 – 2017)		Median: 0.64 µg/L

(Liao et al., 2012b)	China	Urine		Mean: 0.226 ng/mL
(Yang et al., 2014a)	China	Urine	9.4% (free) 40.4% (total)	Mean: 0.022 µg/mL (free) Mean: 0.028 ng/mL (total)
(Duan et al., 2018)	China	Urine	58% 5/2016 to 6/2017	n.d. to 0563 µg/g creatinie
(Yao et al., 2018)	China	Urine school children	40 children (8-11 years old)	0.25 to 50 ng/mL
(Liao et al., 2012b)	Japan	Urine		Mean: 1.180 ng/mL
(Liao et al., 2012b)	Kuweit	Urine		Mean: 0.172 ng/mL
(Liao et al., 2012b)	Vietnam	Urine		Mean: 0.160 ng/mL
(Liao et al., 2012b)	India	Urine		Mean: 0.072 ng/mL
(Liao et al., 2012b)	Korea	Urine		Mean: 0.030 ng/mL
(Asimakopoulos et al., 2016)	Saoudi Arabia	Urine		Mean: 13.3 ng/mL
(Jørgensen)	Denmark	Urine (Adults 20 - 39y , N = 23 ; Teenagers 12 - 19y , N = 76)	100% 2017	0.021 ng/mL
(Jørgensen)	Denmark	Urine (Adults 20 - 39y , N = 30 ; Teenagers 12 - 19y , N = 70)	100% 2013	0.021 ng/mL
(Jørgensen)	Denmark	Urine (Adults 20 - 39y , N = 30 ; Teenagers 12 - 19y , N = 69)	100% 2009	0.021 ng/mL
Human Exposure to Toxicants Through the Indoor Environment 2012	Norway	Urine (Children 6 - 11y , N = 48 ; Teenagers 12 - 19y , N = 2)	52%	0.100 ng/mL
Human Exposure to Toxicants Through the Indoor Environment 2012	Norway	Urine (Adults 20 - 39y , N = 17 ; Adults 40 - 59y , N = 39)	56%	100 ng/L
(Husøy et al., 2019)	Norway	Urine (Adults, N=144)	29% 9/2016 – 11/2017	Geometric mean: 0.19 ng/mL (0.04 – 12.74 ng/mL)
(Balicco et al., 2019)	France Esteban corss-sectional study	Urine (Adults, N =900; Children, N=500)	In almost all samples 4/2014-3/2016	Geometric mean: 0.53 µg/g creatinine

(Tkalec et al., 2021)	Slowenia	First morning void of Children, N= 246 (6-9 years), Adolescents (11-15 years)	27% of children 35% of adolescents	Geometric mean: 0.30 µg/L Geometric mean: 0.36 µg/L Highest measured conc: 23 µg/L in adolescents BPA: in 99% and 100% of kids and adolescent samples with meao means 2.1 and 1.9 µg/L
(Ndaw et al., 2018)	France	Urine 17 cashiers and 15 controls		Geometric mean (cashiers): 2.48 µg/L (2.12 µg/g creatinine) Geomean (controls): 0.72 µg/L (0.52 µg/g creatinine)
(Thayer et al., 2016)	U.S., North Carolina	Urine 77 cashiers and 36 controls (2011 – 2013)		Geometric mean (cashiers, pre-shift): 0.23 µg/g creatinine; (cashiers, post-shift): 0.54 µg/g creatinine; (non-cashiers): 0.41 µg/g creatinine
(González et al., 2019)	Spain	Adults working in hazardous waste incinerator (N = 29)	0% (only BPA, traces of BPB were found)	
(Sakhi et al., 2018)	Norway	Urine Mothers and their children	42% mothers 48% Children Spring 2012	Geometric mean: 0.11 ng/mL Geometric mean: 0.16 ng/mL
(Gyllenhammar et al., 2017)	Sweden	Urine first time mothers	N = 178 2009 to 2014	Mean: 0.11 ng/L
(Philips et al., 2018b)	Netherlands	Urine (frist trimester spot) of pregnant women	2/2004 – 7/2005	Median: 0.35 ng/mL 29.5% of the values below LOD (0.05 ng/mL)
(Heffernan et al., 2016)	Australia	Urine pregnant women	10%	< LOR to 8.1 ng/mL
(Wan et al., 2018a)	China	Urine pregnant women	93.7% (N = 985)	Mean: 0.17 µg/L
(Ihde et al., 2018)	U.S., New Jersey	Urine mothers	60% (N = 30)	Median: 0.04 ng/mL Mean: 0.19 ng/mL (0.04 to 8.883 ng/mL)
(Zhang et al., 2020a)	South China e-waste dismantling area	Urine, Serum, amniotic fluid pregnant women	100%	Geom. mean: 0.05 ng/mL
(Machtinger et al., 2018)	Israel	Urine pregnant women	27% (N = 50)	0.4 µg/L
Indoor dust, Paper, foodstuff, and hygiene products				

Reference	Country	Sample type	Frequency of detection	Concentration
(Dueñas-Mas et al., 2019)	Spain	indoor dust in private houses as well as public places	70% (7/10)	n.d. – 736 ng/g (mean: 290 ng/g)
(Liu et al., 2019a)	Singapore	Indoor dust		153 – 6491 ng/g (mean: 714 ng/g)
(Larsson et al., 2017)	Sweden	Dust in preschools		800 ng/g
(Liao et al., 2012b)	U.S.	Indoor dust	100%	5.6 – 25500 ng/g (mean: 620 ng/g)
(Liao et al., 2012b)	China	Indoor dust	100%	0.83 – 12600 ng/g (mean: 130 ng/g
(Liao et al., 2012b)	Japan	Indoor dust	100%	250 – 2550 ng/g (mean: 820 ng/g)
(Liao et al., 2012b)	Korea	Indoor dust	100%	900 – 26600 ng/g (mean: 430 ng/g)
(Wang et al., 2015)	Romania	Indoor dust (homes and other microenvironments)	100% (23)	Mean: 380 ng/g
(Wang et al., 2015)	Greece	Indoor dust (homes and other microenvironments)	85% (28)	Mean: 1500 ng/g
(Xue et al., 2016)	Albany, U.S.	Indoor air samples (parking garages, auto repair shops, cars, barber shops, buplic ples, homes, labs, offices)	26.5%	<LOQ – 0.94 ng/m^3 (bulk air (mean: 0.07 ng/m^3)
(Goldinger et al., 2015)	Switzerland 2013 – 2014	Thermal paper receips	In 4 out of 124 receips	8.3 – 12.6 mg/g Mean: 10.2 mg/g
(Russo et al., 2017)	Italy 2015 – 2016	Thermal paper receipts	In 31 out of 50 samples	<LOQ – 3579.89 mg/g Mean: 419.7 mg/g
(Molina-Molina et al., 2019)	Brazil, Spain, France	Thermal paper reciepts (N=22, 43, 47)	9.1%, 4.6%, 21%	<0.03 – 13.29 mg/g

Abbreviations: LOD=limit of detection, LOQ= limit of quantification, n.d. = non-detect.

Monitoring Data for Bisphenol F

The levels of BPF in human and environmental samples, as well as in papers and foodstuff have been analysed in several biomonitoring studies in Europe and globally. A compilation of biomonitoring data is presented in the table below.

The use of BPF is widespread and potentially increasing as indicated by the type and number of patents. Many studies detect BPF in human samples (urine, breast milk and serum) at varying levels. The substance is detected in humans from various geographical locations, age groups and in both sexes. Compared to BPA, BPF is generally found in lower concentrations when measured in urine. However, because most samples were collected before 2016, even in the newest studies, it is uncertain what the ratio of BPA-BPF is today considering the possible substitutions of BPA to BPF that might have occurred since then. A recent study (Lucarini et al., 2020) reports higher mean concentrations of BPF than BPA in urine from diapers of infants and toddlers. One study in Sweden observed an increase of BPF in the urine of first-time mothers between 2009-2014, but a decrease between 2014-2018 (Bjermo, 2019). BPF is also occurring naturally in mustard, which may be an additional source of exposure (Zoller et al., 2016).

Surface water

In surface/river water measurements in China as well as Slovenia were reported with mean concentrations from n.d. up to 117 ng/L (Slovenia) (Česen et al., 2019; Yan et al., 2017; Zhang et al., 2019; Zhao et al., 2021).

In sewage sludge, most publications measuring outside Europe (Korea, China, U.S.) reported detection frequencies for BPF as high as 75% and as low as 5% with concentrations between not determinded to 1780 ng/g (Lee et al., 2015).

Sediment

In sediment concentrations ranging from not determined to 9650 ng/g (median: 2.76 ng/g) were found between 1998 and 2012 in China, U.S., Japan and Korea (Liao et al., 2012d; Yan et al., 2017).

Biota

Some publications reported measurements of BPF in marine organisms (Ruus et al., 2020; Zhao et al., 2021), and raptor tissues (González-Rubio et al., 2020; Oró-Nolla et al., 2021). The concentrations ranged from below quantification limit (0.13 ng/g) to 286 ng/g (bile of cod from the Inner Oslofjord).

Human

Some measuring programmes are reported e.g. from Danish young men or Norwegians. Additionally, measurements in pregnant women urine from Puerto Rico, Spain, Valencia, China, Netherlands, as well as Sweden, and Swizerland are available. The mean measured concentrations range from 42 to 350 ng/L ((Philips et al., 2018a);(Sanchis et al., 2020r)). The detection frequency ranged from 20% to 92%.

Infants, teenagers, and adults were also examined. The mean measured concentrations of BPF in urine ranged from not detected to 540 ng/L (Ashrap et al., 2018; Husøy et al., 2019; Jacobson et al., 2019; Jørgensen; Lehmler et al., 2018; Lucarini et al., 2020; Martínez Steele et al., 2020; Tanner et al., 2020; Yang et al., 2014a; Ye et al., 2015). The detection frequency ranged from 2% to 100%.

Table 54: Monitoring data of BPF

Environmental samples				
Reference	Country	Sample type	Frequency of detection	Concentration

Norwegian Environment Agency (2014)	Norway	Landfill leachate		<LOD – 17 µg/L
Lee et al. (2015)	Korea	Sewage sludge (July–October 2011)	75% (30/40)	n.d.-1780 ng/g (median=249 ng/g)
Ruan et al. (2015)	China	Sewage sludge	66% (10/15)	n/a
Yu et al. (2015)	U.S.	Sewage sludge (August 2006 and March 2007)	68% (52/76)	<1.79-242 ng/g
Song et al. (2014b)	China	Sewage sludge (October 2010 to May 2011)	63% (33/52)	3.84 ng/g
(Šauer et al., 2021)	Norway	Municipal sewage sludge	< LOQ (N = 16)	n.d.
(Šauer et al., 2021)	The Czech Republic	Polar organic chemical integrative samplers in surface waters	33% (N = 21)	<LOQ – 205 ng/L Mean of positive detection: 91 ng/L
Liao et al. (2012d)	U.S., Japan, Korea	Sediment (1998 to 2012)	62% (27-59%)	n.d.-9650 ng/g (median=2.76 ng/g)
(Yan et al., 2017)	China - Taihu freshwater lake	Sediment (April 2016)		Mean: 4.7 ng/g dw
(Grung et al., 2021)	Norway	Sludge from WWTP		Mean: 4.2 ng/g dw
(Česen et al., 2019)	Slovenia	River (23rd May and 12th July 2017)		2.54 – 117 ng/L Mean: 44.3 ng/L
(Gil-Solsona et al., 2022)	Spain, Ebro River	River water (March 2019 – two weeks)	0%	<LOD (0.01 – 0.07 ng/L)
(Gil-Solsona et al., 2022)	Spain, Ebro River	Sea water (March 2019 – two weeks)	0%	<LOD (0.01 – 0.07 ng/L)
(Tang et al., 2020)	Australia, South East Queensland	Wastewater (2012 – 2017; all n=108)	29%	Median: <0.013 µg/L
(Zhang et al., 2019)	China	Source water (March to November 2017)	35% (7/20)	n.d. – 12.6 ng/L (mean: 2.2 ng/L)
(Yan et al., 2017)	China - Taihu lake	Surface water (April 2016)		Mean: 120 ng/L
(Yan et al., 2017)	China - Luoma lake	Surface water (April 2016)		Mean: 21 ng/L

(Zhang et al., 2019)	China	Drinking water (March to November 2017)	5%	n.d. – 0.9 ng/L (mean: 0.4 ng/L)
(Zhao et al., 2021)	China (Hangzhou Bay)	Seawater (May 2019)	60% (9/15)	<0.19 – 0.65 ng/L (mean: 0.31 ng/L)
(Zhao et al., 2021)	China (Hangzhou Bay)	Marine organisms (May 2019)	46%	<0.13 – 0.63 ng/g (Mean: 0.36 ng/g)
(Ruus et al., 2020)	Norway, Inner Oslofjord	Cod (liver/bile) (4,4-bis-F)	Liver: 2/2 Bile: 5/13	Liver: 11.3 – 13.7 ng/g w/w; mean: 12.5 ng/g w/w Bile: <7 – 286 ng/g w/w; mean: 38.8 ng/g w/w
(Oró-Nolla et al., 2021)	Norway	Raptor tissues	0/38	n.d.
(González-Rubio et al., 2020)	France and Greenland	Raptor tissues (1997 – 2011)	4/20 (white-tailed eagles) 3/12 /long-eared owls) 1/12 (Eurasian sparrowhawks)	Median: 3.01 ng/g w.w. (BPA: 67.5 ng/g w.w.)
Human biological samples				
Reference	**Study**	**Sample type**	**Frequency of detection free BPF**	**Concentration free BPF**
Ye et al. (2015)	U.S. residents	Urine (2000 – 2014)	42-88% (616 samples)	150-540 ng/L
Yang et al. (2014a)	Residents living near a BPAF manufacturing plant in China	Urine	2.1% (2/94)	mean 205 ng/L
Niu et al. (2017)	Healthy voluntary donors living in Hunan Province, China	Breast milk	60% (12/20)	10-166 ng/L
Lucarini et al. (2020)	Used diapers of infants and toddlers 6-36 months of age, from Swiss daycares.	Urine (2019)	2% (2/109)	60-80 ng/g creatinine
Tanner et al. (2020)	First-trimester pregnant women from Värmland county, Sweden.	Urine (2007-2010)	92% (718 samples)	mean 160 ng/L

Wang et al. (2019)	Healthy male volunteers aged 21-28.	Urine (2012-2013)	85% (520 samples)	mean 160 ng/L
Jacobson et al. (2019)	Children aged 6-19.	Urine (2013-2014 and 2015-2016)	52% (948/1831)	median 200 ng/L
Lehmler et al. (2018)	U.S adults.	Urine (2013-2014)	67% (1808 samples)	median 350 ng/L
Ashrap et al. (2018)	Pregnant women from Puerto Rico	Urine (2010-2016)	41% (1005 samples)	mean 300 ng/L
Sanchis et al. (2020)	Spanish breastfeeding mothers aged 20-45.	Urine (2015)	20% (103 samples)	mean 42 ng/L
Husøy et al. (2019)	Norwegian population aged 24-72	Urine	4% (140 samples)	-
Dualde et al. (2019)	Breastfeeding women from Valencia.	Breast milk (2015)	22% (91 samples)	<LOQ–460 ng/L
Li et al. (2020)	Pregnant women from eight different provinces in China	Serum	20% (37/181)	<LOD-446 ng/L
Martínez Steele et al. (2020)	U.S population aged 6 and above	Urine (2013-2016)	55% (2562/4655)	mean 2.3 nmol/g creatinine
Philips et al. (2018a)	First-trimester pregnant women from Netherlands	Urine (2004-2005)	40% (1396 samples)	median 570 ng/L
(Jørgensen) HBM4EU	Danish Young Men – cross sectional study: Adults 20 - 39y , N = 30 ; Teenagers 12 - 19y , N = 69	Urine (2009)	100%	Mean: 54 ng/L
(Jørgensen) HBM4EU	Danish Young Men – cross sectional study: Adults 20 - 39y , N = 30 ; Teenagers 12 - 19y , N = 70	Urine (2013)	100%	Mean: 54 ng/L
(Jørgensen) HBM4EU	Danish Young Men – cross sectional study: Adults 20 - 39y , N = 23 ; Teenagers 12 - 19y , N = 76	Urine (2017)	100%	Mean: 54 ng/L

(Jørgensen) HBM4EU	Norwegian Human Exposure to Toxicants Through the Indoor Environment: Children 6 - 11y , N = 48 ; Teenagers 12 - 19y , N = 2	Urine (2012)	52%	70 ng/L
(Jørgensen) HBM4EU	Norwegian Human Exposure to Toxicants Through the Indoor Environment: Adults 20 - 39y , N = 17 ; Adults 40 - 59y , N = 39	Urine (2012)	56%	70 ng/L
Indoor dust, Paper, foodstuff, and hygiene products				
Reference	**Country**	**Sample type**	**Frequency of detection**	**Concentration**
Liao et al. (2012b)	U.S., Japan, Korea, China	Indoor dust (1998 to 2012)	74% (56-98%)	nd-107 000 ng/g (median= 96 ng/g)
Pivnenko et al. (2015)	Denmark	Household wastepaper	33% (5/15)	<LOQ - 240 ng/g (median=0.04 ng/g)
(Zhang et al., 2020b)	South China University students	Indoor dust (n= 40)	57%	< LOQ (10) – 770 ng/g Geometric mean: 80 ng/g
Cao and Popovic (2015)	Canada	Canned fish	7.6% (4/52)	1.8-5.7 ng/g
Liao and Kannan (2014)	China	Various foodstuffs	19.4%	<LOQ-623 ng/g (mean = 2.50 ng/g, median=0.025 ng/g)
Liao and Kannan (2013)	U.S	Various foodstuffs	10.1%	Up to 1130 ng/g, mean=0.929 ng/g
Gao and Kannan (2020)	U.S	Feminine hygiene products	Up to 92% (Tampons, n=12)	Up to mean 14.2 ng/g (Tampons, n=12)
Grumetto et al. (2013)	Italy	Commercial milk samples	52.9% (36/68)	n.d.–26.2 ng/mL

* Abbreviations: n.d.=non-detect, LOQ=limit of quantification, n/a=not analysed.

Monitoring Data for Bisphenol AF

Surface water

Some publications reported measured concentrations of BPAF in samples from surface water of France, Slovenia, or China. The measured concentrations ranged from not detected to 0.14 µg/L.

Biota

González-Rubio et al. (2021) determined the occurrence of amongst others eight bisphenols in six raptor tissues, including muscle, kidney, liver, brain, preen gland and adipose. The samples (n=44) (Eurasian sparrowhawks, long-eared owls, and white-tailed eagles) were taken from 1997 to 2011 from France and Greenland. In contrast to the other bisphenols as BPA or BPS, BPAF was not detected.

Zhao et al. (2021) evaluated the occurrence of Bisphenols in marine organisms (13 species; n = 74), as well as seawater (n = 15), from East China Sea. In seawater BPA concentration was highest (mean: 18 ± 9.7 ng/L). Bisphenol AF was found in concentrations of 0.24 ± 0.15 ng/L (mean) in 80% of the seawater samples. In marine organisms (without hydrolysis), BPA and BPS were as well the predominant bisphenols. BPAF was found in concentrations of 0.29 ng/g (mean). After enzymatic hydrolysis treatment, mean concentration of BPAF increased 1.9 times in marine organisms.

Gil-Solsona et al. (2022) found BPAF in fish plasma (up to 6.7 ng/mL, detection frequency: 25%), fish muscle (up to 11.6 ng/g, DF: 10%) and fish liver (up to 0.17 ng/g, DF: 21%) from the Ebro River delta (Spain).

Oró-Nolla et al. (2021) investigated the occurrence of eight bisphenols in Norwegian raptor tissues (n=38). BPAF was the most ubiquitous contaminant, detected in 32 liver samples at concentrations ranging from 1.08 to 6.68 ng/g w/w, followed by BPA.

Table 55: Monitoring data for Bisphenol AF

Environmental samples				
Reference	Country	Sample type	Frequency of detection	Concentration
(Huang et al., 2020)	China (March and July 2015)	Rivers		<LOD-6.59 ng/L
(Schmidt et al., 2020)	France (May 2017 to April 2018)	Urban river		<LOD
(Gil-Solsona et al., 2022)	Spain, Ebro River	River water (March 2019 – two weeks)	0%	<LOD (0.01 – 0.07 ng/L)
(Gil-Solsona et al., 2022)	Spain, Ebro River	Sea water (March 2019 – two weeks)	0%	<LOD (0.01 – 0.07 ng/L)
(Gil-Solsona et al., 2022)	Spain, Ebro River	River sediment	100%	Median: 0.4 ng/g
(Gil-Solsona et al., 2022)	Spain, Ebro River	Sea sediment	75%	<LOD – 0.6 ng/g; Median: 0.45 ng/g

(Česen et al., 2019)	Slovenia	River (23rd May and 12th July 2017)		<LOD
(Zheng et al., 2019)	China (15 July, 2018)	River		1.50-16.2 ng/L
(Wang et al., 2018)	China	River		10-40 ng/L
(Liu et al., 2017)	China (November 2016)	Surface water		110-140 ng/L
(Zhang et al., 2019)	China	Source water	50%	n.d. – 10.8 ng/L (mean: 3.0 ng/L)
(Zhang et al., 2019)	China	Drinking water	30%	n.d. – 4.7 ng/L (mean: 0.4 ng/L)
(Zhao et al., 2021)	China (East China Sea) (May 2019)	Surface water	80%	<0.13 – 0.57 ng(/L Mean: 0.24 ng/L
(Zhao et al., 2021)	East China Sea (May 2019)	Marine organisms		Mean: 0.29 ng/g
(Tang et al., 2020)	Australia, South East Queensland	Wastewater (2012 – 2017; all n=108)	1%	Median: <0.0021 µg/L
(González-Rubio et al., 2021)		Raptor tissues (n=44)		n.d.
(Oró-Nolla et al., 2021)	Norway	Raptor tissues	84% (32/38)	1.08 – 6.68 ng/g w/w (mean 2006: 1.88; 2009: 4.71)
(Ruus et al., 2020)	Norway, Inner Oslofjord	Cod (liver/bile)	Liver: 0 Bile: 6	Liver: < 0.5 - <0.5 ng/g w/w; mean: n.d. Bile: < 0.5 – 2.72 ng/g w/w; mean: 0.6 ng/g w/w
(Gil-Solsona et al., 2022)	Spain, Elbro River	Fish plasma	25%	<LOD – 6.7 ng/mL; Median: 5.1 ng/mL)
(Gil-Solsona et al., 2022)	Spain, Elbro River	Fish liver	21%	<LOD – 0.17 ng/g; Median: 0.67 ng/g
(Gil-Solsona et al., 2022)	Spain, Elbro River	Fish muscle	10%	<LOD – 11.6 ng/g; Median: 5.9 ng/g
Human biological samples				
Reference	Study	Sample type	Frequency of detection	Concentration
Ye et al. (2015)	U.S. residents	Urine	0 - 2%	< LOD (0.1 µg/L)

		(2000 – 2014)		
Yang et al. (2014a)	Residents living near a BPAF manufacturing plant in China	Urine		
(Zhang et al., 2020b)	South China University students	Urine (n= 160)	85%	< LOQ (0.005) – 2.04 µg/L Geometric mean: 0.04 µg/L
Indoor dust				
Reference	Study	Sample type	Frequency of detection	Concentration
(Zhang et al., 2020b)	South China University students	Indoor dust (n= 40)	70%	<LOQ (0.005) – 0.03 µg/L Geometric mean: 0.01 µg/g
(Wang et al., 2015)	China	Indoor dust (house)	100% (n = 34)	Mean: 4.4 ng/g
(Wang et al., 2015)	Colombia	Indoor dust (house)	98% (n = 42)	Mean: 4.3 ng/g
(Wang et al., 2015)	Greece	Indoor dust (house)	79% (n = 28)	Mean: 4.6 ng/g
(Wang et al., 2015)	India	Indoor dust (house)	83% (n = 35)	Mean: 1.7 ng/g
(Wang et al., 2015)	U.S.	Indoor dust (house)	100% (n = 22)	Mean: 4.7 ng/g

Abbreviations: LOD=limit of detection, n.d.=non-detect.

B.4.2.6. Summary and discussion of environmental distribution

Bisphenol A (BPA)

Abiotic degradation is assumed to be negligible. Available data show that BPA is rapidly biodegradable and rapidly removed from surface waters. For sediments, there is no definite conclusion possible. Under aerobic conditions, BPA is removed rapidly in soil. For anaerobic conditions no conclusion is possible. It is assumed that Bisphenol A adsorbs to sewage sludge due to its potential to moderately adsorb to solids (EU RAR Bisphenol A (2003), 2008, chapter 3.1.3.3, page 26) (BUA substance report no. 203, Bisphenol A, chapter 6.3, page 40). The application of sewage sludge can lead to an entry of BPA into soil. Modelling based on physico-chemical properties of BPA shows that nearly all BPA goes into the water and soil compartments with exact proportion depending on where emission enter the environment.

Despite the rapid biodegradation of BPA, when emissions into an environmental compartment exceed removal/degradation rates, a substance still accumulates in the respective medium, which may result in so-called "pseudo-persistence". In monitoring studies, BPA has shown widespread environmental contamination, especially in surface waters. In general, concentrations in freshwaters are higher compared to those in marine waters, which is considered to be a result of higher admixture and greater distances to emission sources in marine compartments.

Data from NORMAN database (NORMAN, 2022) was accessed to perform a European temporal assessment of BPA trends in surface waters but focussed on data from Germany (18,009 data points (2003-2020) as only limited data was available for other European countries.The temporal assessment revealed that mean BPA concentrations were generally higher before 2015 and declined afterwards. However, one exception represents 2020, which shows concentrations in the same range as values before 2015. When comparing these values with those from Ramboll Deutschland GmbH (2022), the data before 2015 from NORMAN (2022) and LAWA (2020) were almost double as high. Both data sources report a decline of measured BPA concentrations in German surface waters after 2015.

Sources of BPA in the aquatic environment are mainly related to WWTP effluents despite the fact that BPA generally shows high removal rates (>70%). Extrapolations for Germany from 23 WWTP effluents from Ramboll Deutschland GmbH (2019) modelled BPA emissions ranging from 1,600-14,653 kg/a depending on the type of WWTP and stormwater protection. The second biggest source of BPA in German surface water in Ramboll Deutschland GmbH (2019) was sewage sludge (extrapolated: 6,758 kg/a), followed by landfills (extrapolated: 3,769 kg/a). For products, extrapolated emissions ranged from 13.2 kg/a in clothes to 28,601 kg/a in recycled PVC. However, thermal paper was expected to represent the most important BPA source for German surface waters (~ 534tpa for Germany based on European market amounts). However, the extrapolations by Ramboll Deutschland GmbH (2019) are based on a small sample number of the respective matrices and e.g. the total number of landfills in Germany is unknown. Interpretation, especially for European emissions, therefore warrants caution. Currently, Ramboll Deutschland GmbH (2022) assumed that emissions from paper recycling and the use of articles that contain recycled paper are the most important source for BPA in surface water, while emissions from thermal paper are neglectable. In future, the model of Ramboll Deutschland GmbH (2022) predicts that landfills will be responsible for the majority of emissions (53%) followed by consumer uses while assuming that BPA will disappear from the paper recycling chain. However, it is important to mention that the modelling results are based on specific assumptions (e.g. not considering point pollution) and does not consider that the global demand for BPA is expected to grow in future (see Annex D: Baseline). Furthermore, zero emissions from paper procession seem unlikely. Therefore, Ramboll Deutschland GmbH (2022) may underestimate future BPA emissions in surface waters.

BPA emissions not only result in environmental contamination of surface waters but also of sediments and suspended matter as BPA can adsorb to solid matrices in aquatic compartments. For sediments, the pattern of BPA is similar to surface water with freshwater sediments showing higher concentrations than marine sediments. Only a few studies investigated BPA contamination in soil. BPA has shown to be frequently detected in agricultural soils but a clear link to biosolid application could not be established by Gewurtz et al. (2021). Similar to soil, there is limited information available on BPA in the atmosphere, where BPA can be detected despite its low volatility as a result of e.g. open burning of plastics in household or electronic waste. A matrix that shows a particular high BPA concentration represents indoor dust, which is expected to result in human exposures and WWTP exposures. For humans, BPA is frequently detected (up to 100%) in urine and blood samples in humans from industrialised countries. Furthermore, infants are already exposed to BPA, which demonstrates a widespread BPA contamination in humans. In a study on Danish young men, urinary BPA concentrations decreased between 2009-2017, while detection rate of BPS and BPF increased (Frederiksen et al., 2020). This example underlines the necessity of considering BPA together with its replacement substances in order to assess environmental emissions. In biota (wildlife), BPA is less frequently detected compared to human, which may be related to the large variety of analysed species and matrices. For example, BPA is only occasionally detected in muscles of fish (25 to 430 ng/g dw), whereas BPA shows higher detections rates in more polar matrices such as bile and blood. However, BPA was also found in liver (164 to 251 ng/g dw), which may be related to the fact the liver is the metabolic most competent organ.

Taken together, BPA has shown to be frequently detected in various environmental matrices. The aquatic environment seems to be contaminated primarily via wastewater effluents whereas indoor dust is expected to represent an important exposure sources for humans.

Bisphenol B

Similar to BPA and BPS abiotic degradation is negligible. Modelling data suggest that BPB may be persistent in sediment. Some data suggest a possible biodegradation of BPB in water, in sediment or by specific microorganisms. BPB tends to adsorb to sludge and may be difficulat to biodegrade in natural water and sediment under environmental conditions.

Recent monitoring data demonstrates the presence of BPB in biota of remote areas. BPB has been detected in eggs of Arctic char (Salvelinus alpinus), kittiwakes (Rissa tridactyla) and glaucous gull (Larvus hyperborus) from a Svalbard island in a monitoring report of the Norwegian Polar Institute (Lucia et al., 2016). BPB has been detected in cod, and blood samples and eggs of herring gull in a series of monitoring reports of an Urban Fjord in Norway (Ruus et al., 2016 and 2017). Here, BPB, just like BPA, was among the most quantitatively abundant compounds found in seabird eggs (Lucia et al. 2016). Hence, BPB can reach habitats from various sources, and can be present in surface waters and other compartments. Many organisms may therefore be exposed more or less continuously to BPB and potentially cannot avoid exposure.

Bisphenol S

For BPS abiotic degradation is assumend to be negligible as for BPA. BPS has some potential to adsorb to organic particulate matter in soil, suspended matter and sediment. Only calculated data are available for the environmental distribution. Based on the calculation, we can assume that water (and sediment to a lesser extent) and soil could be affected by the substance.

Simulation and screening tests suggest that BPS is not (readily) biodegradable.

Monitoring data show that BPS is found in river water as well as biota. BPS was detected more often than BPA (González-Rubio et al., 2021). There were also findings of BPS in indoor dust (in 70% of the samples) (Dueñas-Mas et al., 2019) as well as human urine (Liao et al., 2012b; Liu et al., 2019a) and (Danish Young Men Study; Norwegian study).

Bisphenol F

Similar to BPA and BPS, hydrolysis for BPF is expected to be negligible but the vapor pressure indicates that BPF will exist in both, vapor and particulate phases in the atmosphere. In contrast to BPS but similar to BPA, data for BPF suggest that the substance is likely to biodegrade and be rapidly removed from surface waters. In sediment and soil, degradation under aerobic conditions is likely.

Modelling data suggest that BPF is immobile in soil and non-volatile from water and moist soil surfaces. It may partition mainly to soil and to a lesser extend to water and sediment when equally emitted.

Monitoring data show that BPF is often detected in the samples. The concentrations were lower than BPA before 2016 but higher in newer studies. The concentrations in indoor dust were lower than for BPA and BPS.

Bisphenol AF

Similar to BPA and BPS, abiotic degradation such as hydrolysis or partitioning in the atmosphere from aqueous system is assumend to be negligible for BPAF. Screening data suggest no rapid biodegradation. Based on modelling data BPAF is expected to be immobile in soil. BPAF seems to be more persistent than BPS and BPA in soil.

Modelling data suggest that BPAF partitions mainly to soil and to a little lesser extend to sediment.

Monitoring data show that it is fould in biota but less often than BPA or BPS. In case of BPAF detection in the samples, the concentrations were in similar range.

B.4.3. Bioaccumulation[1]

B.4.3.1. Bioaccumulation in aquatic organisms

B.4.3.1.1. Bisphenol A

The MSC's (ECHA, 2017b) support document for identification of bisphenol A as a substance of very high concern because of its endocrine disrupting properties draws following conclusion for bioaccumulation:

Bioaccumulation was evaluated in the EU Risk Assessment Report of Bisphenol A (European Commission, 2010). The log Kow of 3.4 indicates a moderate bioaccumulation potential. However, the available measured data indicated a low bioaccumulation potential (BCF ≤ 73.4 for fish and up to 144 for freshwater clams).

B.4.3.1.2. Bisphenol B

Calculations with EPIWEB 4.1 for BPB resulted in a predicted log kow of 4.13 and a BCF of 170.2 (Chen et al., 2016).

BPB concentrations in Taihu Lake were examined by Wang et al. (2017b) as described in previous paragraphs. BPB was not detected in water samples but in biota at a frequency of 64.7%, concentrations were below 2 ng/g ww.

Higher concentrations of BPB were found in three fish species of the Persian Gulf, Iran (Akhbarizadeh et al., 2020). For *Epinephelus coioides* (n=20) the mean concentration ± SD of BPB was 2.38 ± 1.84 µg/kg wet weight. The concentrations in this species ranged from non-detecteded to 5.51 µg/kg wet weight. The range for *Platycephalus indicus* (n=20) was non-detecteded to 2.52 with a mean of 1.97 ± 0.50 µg/kg wet weight. Lastly, BPB concentration in *Liza klunzingeri* (n=10) ranged from 1.13 to 2.52 µg/kg wet weight, the mean concentration was 1.90 ± 0.70 µg/kg wet weight. Trophic transfer in this three fish food chain was determined as trophic magnification factor (TMF) at 1.32, which indicates magnification of BPB. This value carries some uncertainty as the calculation of trophic levels from stable N isotope data was not reported.

In the Annex XV dossier for BPB (France, 2021), the following studies on bioaccumulative properties was provided:

Wang et al. (2020), evaluated the toxicokinetics and bioconcentration of eight BPs in mixture, including BPA and BPB (each BP at 50 nM) in the common carp (Cyprinus carpio) according to OECD TG 305. The eight BPs were not detected or close to the LODs in the carp tissues of the control group and they were all detected at significant levels in the various tissues of the carp on the second day upon exposure. The BPtotal concentrations in the whole body of carp and various tissues increased continuously but did not reach equilibrium within 28 days exposure. The BPtotal concentrations decreased gradually during the 40 days depuration period. The contribution of conjugated BPA in the whole body of carp was 72.7%, comparable to data available in literature, and 62% for BPB. Based on the BPtotal, the t1/2 was 10.76 ± 1.75 days for BPB and 5.98 ± 0.32 days for BPA. For BPB, kinetic BCF in free form range from 2.5 in the blood to 309.3 L/kg in the kidney and 29.1 L/kg in the whole body. The estimated kinetic BCF of BPB based on the total concentrations at the end of exposure was 80.2 L/kg for BPB, lower than the value estimated in this study by the author by using EPIWEB 4.111 (245.47) possibly because accumulation did not reach a steady state.

Additionally, field data available for BPB was assessed (France, 2021):

Tian et al. (2019), investigated the presence of BPs in northern pike (Esox lucius) collected in late May to early June 2014 and 2015 from the St. Lawrence River, Canada, 4 km upstream (n = 12) and 4 km downstream (n = 14) of the point of discharge of a major primary WWTP. None of the ten BPs were detected in the muscle tissues of the 26 northern pike collected.

Zhao et al. (2019), determined the occurrence, distribution, bioaccumulation, and ecological risk of 19 substances including BPB and BPA in organism samples (marine organisms (n=21), including shellfish species (n=11) and fish species (n=10)) from 25 sites in the Pearl River Estuary in south China collected in December 2017 (see 3.2.1 for occurrence data). In marine organisms, BPB measured median concentration was 12.3 ng/g (nd - 161 ng/g min-max, 36.4% detection). Highest concentrations of BPB were found in Moerella iridescens (161 ng/g) and Flower screw (66.6 ng/g) (shellfish). For BPB, the calculated logarithm of bioaccumulation factors (log BAF) was between 1.42 and 4.49 with a median value of 3. More especially, the values for Flower screw, Moerella iridescens and Sea crab were determined to be 12700 (log BAF = 4.11), 30800 (log BAF = 4.49) and 5200 (log BAF = 3.72), respectively, with a median value for all biota of 2360 (log BAF = 3.25) and a mean value of 6700 (log BAF = 2.92). Based on the observed logBAF, BPB has the potential to bioaccumulate. For BPA, median and mean values were respectively 23 (log BAF = 1.36) and 715 (log BAF = 1.42).

Liao and Kannan (2019), investigated the species-specific accumulation and temporal trends of BPs and benzophenones in mollusc samples collected from coastal areas of five cities along the Bohai Sea from 2006 to 2015 (except for 2008). BPB was detected in <5% of the samples ranging from nd-65.3 ng/g dw. BPA and Bisphenol F (BPF, EC no 219-578-2, EC name 2,2'-methylenediphenol) collectively accounted for >90% of all BPs in molluscs.

B.4.3.1.3. Bisphenol S

The Annex XV dossier for BPS[107] prepared by Belgium in 2022 gives following information for aquatic bioaccumulation for BPS:

The log Kow is determined by HPLC method according to OECD guideline 117: log Kow = 1.2, at 23°C and pH 6.2.

The bioaccumulation of the test substance was determined in Cyprinus carpio under flow through conditions following a method similar or equal to OECD guideline 305 C (CITI, 1998). The study was run with a concentration of 50 µg/l and 500 µg/l over a period of 6 weeks. The BCF for the test substance was measured to be very low: respectively < 2.2 and < 0.2.

Chen et al. (2016) calculated a similar log kow of 1.65 and a BCF of 3.53 with EPIWEB 4.1.

A similarly low BCF (bioconcentration factor) value of 0.3 was derived by Wang et al. (2020) for *Cyprinus carpio*, although steady state was not reached. The experimental set up is described in detail for BPB.

Wang et al. (2017b) evaluated the bioaccumulation and biomagnification of bisphenol analogues in the Taihu Lake. Water and biota samples were taken in May 2015 at 31 different locations, including plankton, fish and invertebrates. The detection frequency of BPS in water samples was 100%. It was the third most common bisphenol found in water

---

[107] Annex XV dossier on BPS: https://echa.europa.eu/documents/10162/0d8d148e-bc4f-abc4-eb6a-f9337c210faf

samples after BPA and BPAF. The mean concentration of BPS was 27.6 ng/L. In biota the detection frequency pf BPS was 70.6%. Concentrations of BPS in biota samples were below 2 ng/g ww for all species and the resulting BAF (bioaccumulation factor) were below five throughout. BPS was detected in organisms at different trophic levels, but the concentrations did not correlate with trophic level. BAF were lower than for BPA and log BAF showed a linear relationship with log kow for BPS, BPF, BPA, BPE, BPAF, BPZ and BPC.

Zhao et al. (2019) measured different bisphenol analogues in the Pearl River estuary of South China. BPS was detected in 100% of water and suspended particle matter samples. Concentrations ranged from 1.6 to 59.8 ng/L in water and 3.3 to 343 ng/L in suspended particle samples. Ten marine fish and eleven shellfish species were sampled. Detection frequency in biota samples was 92.9% with concentrations ranging from non-detected to 328 ng/g. BAF were calculated for all species where possible. Lower values occurred for fish of which nine species presented BAF below 300 although a high BAF of 14000 was determined for the species *Epinephelus awoara*. In shellfish a similar pattern was observed with most BAF values below 300 and three species exceeding BAF of 1000, with 1380 for the flower screw, 1690 in the Osmathus clam and 12900 for the razor clam. The mean BAF for all marine species tested was 1690, the median BAF was 54.2.

B.4.3.1.4. Bisphenol F

Carp (*Cyprinus carpio*) was exposed to 25 and 2.5 ug/L BPF for 4 weeks. The BCF was 3.8-7.7 and <7.7-18, respectively (National Center for Biotechnology Information, 2021).

Chen et al. (2016) calculated a BCF of 28.02 and a log kow of 3.06 for BPF with EPIWEB 4.1. These values are very similar to those presented by the US EPA including a calculated BCF of 53.5 using the QSAR data suite OPERA and a experimental log kow of 2.91 (U.S. EPA, 2021).

BPF concentrations in lake Taihu were examined as described above for bisphenol S (Wang et al., 2017b). The detection frequency in water samples was 87.1%, the mean concentration was 4.12 ng/L. The detection frequency in biota was 82.4% with concentrations below 2 ng/g ww. BPF was detected in organisms at different trophic levels, but the concentrations did not correlate with trophic level. BAF values were below 30 for all aquatic organisms sampled.

BPF was also sampled by Zhao et al. (2019) as described above for BPS. The detection frequency in water and suspended particle samples were 100%. In biota samples the detection frequency was 78.6%. The concentrations in water samples ranged from 2.37 to 282 ng/L, in particle samples from 61.6 to 9910 ng/L and in biota from non-detected to 247 ng/g. For shellfish, higher BAF were found in the sea snail (3480) and flower screw (980) otherwise BAF were below 100. In fish the BAF were below 400 except for Turbot (1080) and *Epinephelus awoara* (1030). The mean BAF for all marine species was 388, the median BAF was 18.4.

Liao and Kannan (2019), investigated the species-specific accumulation and temporal trends of BPs and benzophenones in mollusc samples collected from coastal areas of five cities along the Bohai Sea, China from 2006 to 2015 (except for 2008). The detection frequency of BPF in molluscs was 26,9%, with a geometric mean of 0.747, median of 0.141 and range from non-detecteded to 457 ng/g dry weight. BPF and BPA contributed to > 90% of all bisphenols found in samples, amounting to 38.5% and 53.0% of the sum of all bisphenol burden, respectively.

B.4.3.1.5. Bisphenol AF

Following the OECD 305 guideline Shi et al. (2016) exposed six-month-old zebra fish

(*Danio rerio*) to 20 µg/L BPAF for 168 h under semi static conditions (changing the water every 12 h) followed by a 24 h depuration phase. Steady state was reached. The BCF was 9.8 ± 1.0 for males and 5.3 ± 0.8 for females.

Wang et al. (2017b) measured BPAF in the Taihu Lake. BPAF was found in all water samples and was the dominant bisphenol after BPA. The mean concentration in water was 140 ng/L. BPAF was also detected in all biota samples at concentrations ranging between 0.179 and 23.8 ng/g ww. Resulting BAF values ranged from 5.1 for plankton to 676 in Anchovy. BPAF was analysed in species of different trophic levels for which ln concentrations displayed a strong positive linear relationship with trophic levels. A TMF of 2.52 was determined for BPFA indicating a potential trophic magnification for BPFA in the food chain of the Taihu Lake.

BPAF was also measured by Zhao et al. (2019) as described above for BPS. Detection frequency in sea water and suspended particle samples was 100%. Concentrations in water ranged from 0.4 to 3.59 ng/L and 51.7 to 392 ng/L in suspended particle samples. The detection frequency in biota was 92.1% with concentrations ranging from non-detected to 1.27 ng/L. The highest BAF was 121 for *Moerella iridescens* all other BAF were below 60. The median was 20.7 and the mean was 27.6.

B.4.3.2. Bioaccumulation in terrestrial organisms

B.4.3.2.1. Bisphenol A

MSC's support document for identification of bisphenol A as a substance of very high concern because of its endocrine disrupting properties (ECHA, 2017b) references the EU RAR:

The EU Risk Assessment Report of Bisphenol A (European Commission, 2010) calculated a bioconcentration factor for earthworms of 7.9 kg/kg based on QSARs (as implemented in EUSES).

B.4.3.2.2. Bisphenol B

The Annex XV support document for BPB (France, 2021) contains the following study:

According to EPIsuite, BPB has a log Koc derived from LogKow of 4.13 and estimated from molecular connectivity index of 4.86. The estimated log Koa was 13.43, indicating that BPB could potentially bioaccumulate in air-breathing organisms. These results suggest that BPB has a tendency to adsorb to suspended solids, to accumulate and to be less mobile in sediment and soils.

Zhu et al. (2019a), determined the occurrence of 45 substances in bovine urine samples collected from three countries: China (Tianjin; n = 100), India (Mettupalayam, Tamil Nadu; n = 45), and the United States (Murray, Kentucky; n = 38) between March and November 2018. The selected sites were rural and agricultural areas with no point sources in the vicinity. The bovines from China were zero-grazed (housed permanently in shelters) and fed with commercial feed, in contrast to India and the United States where bovines were allowed to graze in open pastures/ grasslands and fed with a combination of grain and grass. BPB was found sporadically and at low concentrations whereas BPA was found in >70% of the urine samples analysed. The bovine urinary distribution of BPs among the three countries was similar.

B.4.3.2.3. Bisphenol S

BPS was measured in bovine urine samples from China, India and the US (Zhu et al., 2019a) as described for BPB above. BPS was found in more than 70% of samples at concentrations ranging from non-detected to 4 ng/mL, which was lower than concentrations for BPA or BPB.

B.4.3.2.4. Bisphenol F

Bovine urine samples were analysed as described above (Zhu et al., 2019a). Detection frequency of BPS was above 90% in China, India and the United States. Concentrations of BPS ranged from non-detected to 242 ng/mL. Mean and median concentrations were higher for BPF than other bisphenols sampled. The authors suggest an increasing trend of BPF use in agriculture.

B.4.3.3. Summary and discussion of bioaccumulation

B.4.3.3.1. Bisphenol A

MSC's document (ECHA, 2017b) support document for identification of bisphenol A as a substance of very high concern because of its endocrine disrupting properties draws following conclusion for bioaccumulation:

As discussed in the RAR of Bisphenol A (European Commission, 2010), the bioconcentration factor for fish is estimated to be ≤ 73.4 and using QSAR methods a bioconcentration factor for earthworms was calculated to be 7.9 kg/kg.

Hence, Bisphenol A has a low potential for bioaccumulation in aquatic and terrestrial organisms (fish, earthworms).

B.4.3.3.2. Bisphenol B

In the Annex XV support document for BPB (France, 2021), the following conclusion for bioaccumulative properties was provided:

Regarding bioconcentration, BPB has an estimated logKow of 4.13, a higher value than measured logKow 3.4 for BPA, and it indicates a potential for BPB to bioaccumulate. BPB has an estimated BCF in fish of 248.1 (EPIsuite), higher than the BCF determined for BPA with a BCF for fish estimated to be ≤ 73.4 (ECHA, 2017b). Considering the worst-case scenario of no biotransformation, a BCF of 1391 was estimated which is under the limit of 2000 set for the B criterion under REACh. The rare available experimental data provide BCF values ranging from 2.5 to 309 L/kg depending on organ consideration. The estimated kinetic BCF for BPB based on the total concentrations at the end of exposure was 80.2 L/kg for BPB. Based on this data, BPB is not likely to fulfil the B criteria under REACh. However, the few biomonitoring data available suggest that BPB might bioconcentrate in aquatic organisms. The calculated logBAF for BPB is between 1.8 and 3.7, and the observed log BAF can reach 4.49 for Moerella iridescens, in accordance with the log BAF of 2.23 estimated by EPISuite, indicating that BPB can bioaccumulate, even to a high amount in some organisms. Moreover, BPB has an estimated log Kow of 4.13 and an estimated logKoa of 13.43, indicating that BPB has the potential to biomagnify in terrestrial food chains and air-breathing marine wildlife as well as in humans. Overall, environmental data suggest a slightly higher bioaccumulation potential compared to BPA, although more experimental data are required to fully characterise the bioaccumulation potential of BPB.

B.4.3.3.3. Bisphenol S

BPS has an experimentally derived log K_{ow} of 1.2.[108] Modelled and experimentally derived BCF values were below 4 (Chen et al., 2016; CITI, 1998; Wang et al., 2020). Based on this information BPS does not accumulate in aquatic organisms. Monitoring data however has shown a high detection frequency for BPS in freshwater organisms (Wang et al., 2017b; Zhao et al., 2019). Additionally, BAF derived from monitoring studies indicate moderate to high bioaccumulation, ranging from below 100 to 14,000 for fish and shell fish species (Zhao et al., 2019). As BAF values exceed BCF values, dietary uptake seems to be of greater importance in comparison to other exposure pathways. Based on monitoring data,

---

[108] Annex XV dossier on BPS: https://echa.europa.eu/documents/10162/0d8d148e-bc4f-abc4-eb6a-f9337c210faf

BPS has bioaccumulation potential in some aquatic species. However more experimental data is needed to fully characterize the bioaccumulation potential of BPS.

B.4.3.3.4. Bisphenol F

BPF has an experimentally derived log Kow of 2.91 (U.S. EPA, 2021). The experimental BCF for Carp (*Cyprinus carpio*) was 18 (U.S. EPA, 2021). Similarly to BPS, BPF does not meet the criteria for bioaccumulation in standard testing but has been found at high detection frequency in biota in monitoring studies (Liao and Kannan, 2019; Wang et al., 2017b; Zhao et al., 2019). BAF values in these studies range from below 30 to 3480 for molluscs and 1030 in fish. They indicate a high bioaccumulation potential of BPF in some aquatic species. More data is needed to conclude on the bioaccumulation potential of BPF.

B.4.3.3.5. Bisphenol AF

Laboratory testing of BPAF has determined a BCF below 10 for fish (Shi et al., 2016). In monitoring studies BPAF showed detection frequencies above 90% in aquatic organisms (Wang et al., 2017b; Zhao et al., 2019). BAF values in these studies were below 700 indicate moderate bioaccumulation potential. Wang et al. (2017b) however calculated a TMF of 2.52 for BPFA suggesting for BPFA to magnify in the food chain of the Taihu Lake. Data suggests low bioaccumulation in aquatic organisms but more studies are needed to determine the tropic magnification potential of BPAF.

B.5. Human health hazard assessment

Not considered in the scope of this dossier.

B.6. Human health hazard assessment of physicochemical properties

Not considered in the scope of this dossier.

B.7. Environmental hazard assessment regarding endocrine disrupting properties

B.7.1. General remarks

The aim of the presented restriction proposal is to minimise environmental exposure of Bisphenol A and further bisphenols that have endocrine disrupting properties in the environment as much as possible. Environmental endocrine disruptors are considered as non-threshold substances since, as described under section 1.3, it is not possible to derive a safe level of exposure for such substances in environmental media that would be protective for all possibly affected species.

To avoid regrettable substitution of BPA and BPB which are already identified as SVHC based on their endocrine disrupting properties in the environment, with further bisphenols sharing the same hazard profile and to protect the aqueous environment against endocrine disrupting bisphenols, the scope of the present restriction shall cover all bisphenols where the available scientific data demonstrate a similar environmental concern compared to BPA and BPB. Hence, 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 intrinsic hazardous properties in this case is stated 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:

- Show an adverse and population relevant effect in organisms. With regard to this all effects that impact the survival, the growth or the reproduction of an organism are considered to be adverse and of population relevance.

- 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. The data were grouped into three categories following the conceptual framework of 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. Based on the adverse effects identified, results were further integrated into lines of evidence, defined as a "set of relevant information grouped to assess a hypothesis," using a weight-of-evidence approach (ECHA et al., 2018).

The relevance of a given study is assumed if the study design allows to answer 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).

B.7.2. Bisphenol A

The entry of BPA in the candidate list has been amended in January 2018 as BPA has been identified as a substance meeting the criteria of Article 57 (f) of Regulation (EC) 1907/2006 (REACH) as, according to the support document prepared for the MSC,

> *[…] 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 for other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.*
>
> *The analysis of results for fish and amphibians according to the OECD Guidance Document for Endocrine Disrupters reveals that BPA needs to be considered as an endocrine disruptor. It fulfils the WHO/IPCS definition of an endocrine disruptor as interpreted by the European Commission's Endocrine Disruptor Expert Advisory Group in their recommendations for a substance to be identified as an endocrine disruptor.*
>
> *For BPA there is scientific evidence from good quality studies that the substance causes endocrine mediated adverse effects in several fish and amphibian species.*
>
> ***BPA clearly acts as an oestrogen agonist in fish.***
>
> *In several* ***fish*** *species clear evidence that BPA acts as oestrogen agonist is provided:*
>
> *- In vitro data unambiguously show that BPA binds to vertebrate (human and fish) oestrogen receptors in the µM range and modulates gene expression. BPA also competitively inhibits androgenic activity of a known AR agonist.*
>
> *- The oestrogen agonist mode of action is unambiguously substantiated by in vivo data in several species. Diagnostic for the oestrogenic mode of action are the observed Vitellogenin (VTG) induction, changes in gonadal staging, testis ova, altered sex ratio, and reduced male secondary sex characteristics.*
>
> *The effects observed are clearly adverse, such as the skewed sex ratio towards females. A direct link between the oestrogenic mode of action in vivo (e.g. VTG induction, testis, ova) and the adverse effects (sex ratio, reduced egg production) is provided for* O. latipes, D. rerio *and is very likely for* P. promelas. *Additionally, for six other fish species adverse effects which are known to be sensitive towards an oestrogenic mode of action were demonstrated, such as affected growth, behaviour and fertilisation success.*
>
> *In addition, there is evidence that BPA potentially acts as oestrogen agonist in amphibians:*
>
> *- An agonistic VTG induction was demonstrated in hepatocytes of* X. laevis *at 22.8 µg/L in vitro. Further evidence is provided by the in vitro studies demonstrating binding to the oestrogen receptor in other vertebrates.*
>
> *- The oestrogenic mode of action is substantiated in* X. laevis *by a skewed sex ratio (23 µg/L), a delay of development, altered testicular structure (2.28 µg/) and the ability to induce Vitellogenin in vivo (22.8 µg/L) as well as similar results for E2.*
>
> *- A direct link is provided between VTG induction in vitro and in vivo through a plausible binding to the oestrogen receptor and changes of the sex ratio and reproduction observed in vivo for* X. laevis *as well as three other species. These effects are considered adverse.*

BPA clearly acts as a thyroid antagonist in <u>amphibians</u>:

- In vitro studies with amphibian, fish and mammal cells demonstrate that BPA is interfering with the HPT (Hypothalamic-Pituitary-Thyroid) axis (e.g. thyroid receptor, transport proteins).

- The endocrine mode of action is substantiated by in vivo data. Diagnostic for a thyroid mode of action in amphibians is the accelerated/asynchronous development or an abnormal histopathology, which could be demonstrated in 3 species. BPA inhibited the (TH induced and spontaneous) metamorphosis in vivo, leading to a delayed development and disturbed life-cycle in R. rugosa, X. laevis *and* X. tropicalis*.*

- Hence, a direct link between the in vitro and in vivo evidence can be shown. The observed in vivo effects (delayed development and disturbed life-cycle) are considered adverse.

*In addition, there is some evidence that BPA also may act via a thyroidal mode of action in **<u>fish</u>**, although data is scarce. This is substantiated by in vitro studies, demonstrating an interference with the HPT axis and thyroid-related hormones in fish cells together with accelerated embryonic development in* O. latipes *which was blocked by the thyroid-antagonist Amiadorone in vivo. The thyroid-mediated effects (accelerated development, earlier hatching and smaller individuals) are considered adverse.*

Further support for endocrine-related effects of BPA

*The analysis of **<u>invertebrate taxa</u>** revealed indications that adverse effects of BPA are possibly endocrine-mediated. It has to be kept in mind that there is still lack of an agreed guidance document which is clearly defining biological plausible links between endocrine modes of action and adverse effects for invertebrate taxa and that knowledge is still scarce in light of the large number and variety of invertebrates and their endocrine systems.*

- *In <u>molluscs</u>, characteristic adverse effects on reproduction and development were an increased egg production, mitigated by anti-oestrogens in two species in vivo, as well as the induction of superfemales, malformations of genital tissues (known for E2 and OP) in four species as well as embryo malformations in two species. BPA acts similar to known vertebrate-type (xeno-)oestrogens. A possible oestrogen receptor binding (in vitro, in vivo), mRNA expression and increased VTG or VTG-like protein levels were shown in three species.*

- *For arthropods such as insects and crustaceans ecdysteroids are known to regulate reproduction- and development-related processes. For <u>insects</u>, adverse effects of BPA were similar as for (xeno-)oestrogens (OP, NP, EE2), comprising a delayed development, reduced fecundity and emergence rates as well as increased weight/growth. In vitro evidence for antagonistic ecdysteroid receptor binding and changes in mRNA expression is provided for Drosophila and Chironomus. For <u>crustaceans</u>, adverse in vivo effects are associated with embryo malformation, developmental delay, moulting disturbances and altered reproductive outcome (enhanced or reduced). Effects were similar to (xeno-)oestrogens and could be mitigated by ecdysteroids. Due to the close relationship to insects, a binding or interference with the ecdysteroid related processes is possible.*

For <u>further invertebrate species</u>, such as echinoderms, poriferans or cnidarians, data for BPA and knowledge of the endocrine systems is very fragmentary. However, developmental disturbances including embryo malformations are typical after BPA *exposure and similar to the effects observed for other (xeno-)oestrogens in these groups.*

***Overall**, Bisphenol A is clearly shown to disrupt steroid- (oestrgen) and thyroid mediated processes in fish and amphibians respectively, leading to adverse effects on the organisms which can affect population stability and recruitment. Endocrine-mediated effects occurred and at lower concentrations than acute, systemic or narcotic toxicity.*

BPA is also identified as an SVHC according to article 57(f) for probable serous effects on human health due to its endocrine disrupting properties on the basis of data on mammals. There is a large degree of conservation of the primary amino acid sequences in proteins, which implies large commonalities between non-mammalian and mammalian vertebrate species in regard to hormones, enzymes and receptors involved in the EATS (Estrogen/ Androgen/ Thyroidal/ Steroidogenesis) modalities (OECD 2017: Draft revised OECD Guidance No. 150). Evidence of endocrine disruptive properties of BPA on mammalian vertebrate species therefore provides further support for similar properties in non-mammalian vertebrates, in particular with regard to disruption of oestrogenic pathways.

Bisphenol A is considered as a substance giving rise to an equivalent level of concern due to its endocrine modes of action and the type of effects caused by these modes of action in wildlife species (fish, amphibians).

The assessment followed the same line of arguments as for previous SVHC-identifications according to 57(f) ED for the environment. Due to the amount of data available for BPA a large number of arguments for an equivalent level of concern can be provided. All arguments are used in a weight of evidence and as such, none of the arguments alone are decisive for the decision and not all of them are needed to conclude on the equivalent level of concern. We decided to present the available evidence to get a view on the overall picture on the data analysed.

- BPA causes severe effects on reproduction- and development-related processes (including sexual development) in fish and amphibians, clearly linked to the endocrine mode of action. Results for fish demonstrate that BPA may cause a complete sex reversal resulting in all-female phenotype populations. In amphibians, thyroidal pathways, metamorphosis and development are disturbed, and additionally sex ratio skewed via a suspected additional oestrogen mode of action. Supporting evidence is provided by effects observed in invertebrates.

- BPA in particular causes severe effects on organisms when exposure took place during sensitive time windows or early life stages, also after short-term exposures when exposure later ceases. Many of these effects have to be regarded as irreversible, such as sex reversal or embryo or adult malformations which may have long-term consequences for the population. Moreover, some effects may only occur after exposure during particular seasons as shown for amphibians.

- BPA elicits long-term effects across generations and affects populations and communities. Transgenerational effects were observed for several fish species, where the following generations became much more sensitive to BPA exposure (after continuous as well as short-term exposures of the parental generation). Long-term effects were shown in one mesocosm study, where low BPA concentrations affected the fish population and changes in gonad morphology are likely endocrine-mediated.

- BPA affects a large variety of ecologically important species in different ecosystems, covering lentic, lotic, marine and terrestrial environments. BPA exposure is not restricted to certain environments but shown to be ubiquitously present. Certain fish (and also

mollusc) species were shown to be particularly sensitive, but as data is only available for a small proportion of existing species, it is not possible to exclude that further species are equally or even more sensitive. Also, endangered species such as amphibians may be affected. It has to be kept in mind, that effects first become prominent in later life stages or in the next generation, even when organisms have migrated to uncontaminated regions.

- BPA has already, based on available data including a large number of results from studies on mammalian mainly rodent species, been concluded to be an endocrine disrupter of concern for human health according to Article 57 (f) of REACH. Whereas the available mammalian studies are relevant for human health, it is plausible, that they are also of relevance for other mammalian species including mammalian wildlife species. In relation to the environment, 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. The effects observed in rats are of particular concern for mammalian wildlife species with a natural low reproductive output (including endangered species) as negative effects on reproduction have an even higher potential for causing long term negative effect at the population level for such taxa. However, it is unclear whether the effects observed for mammals in the human health assessment will lead to population level effects in mammalian wildlife species.

- Based on the current data and knowledge it appears difficult to derive and quantify a safe level of exposure for BPA, although it might exist. Effects on non-traditional endpoints and in specific species occurred at lower concentrations than those considered by standard OECD test guidelines. Moreover, as effects often occur in certain species, or after exposure during specific time windows and early life stages, some effects might be overlooked. Effects of BPA are presumably provoked via different modes of action and a greater variety of species could be affected.

In conclusion, there is scientific evidence that Bisphenol A causes probable serious effects in the environment which give rise to an equivalent level of concern to thoseof other substances listed in points (a) to (e) of Article 57 of REACH Regulation.

***Therefore**, it is concluded that the substance 4,4'-isopropylidenediphenol (bisphenol A) meets the criteria of Article 57(f) of REACH, due to its 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 for other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.*

Cited from ECHA (2017a) 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

B.7.3. Bisphenol B

BPB has been added to the candidate list in July 2021 as it is 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 for other substances listed in paragraphs (a) to (e) of Article 57 of REACH.

Summary of how BPB meets the criteria set out in Article 57(f) of the REACH Regulation

Adverse effects

*Consistent adverse effects are observed in rodents and fish exposed to bisphenol B (**BPB**). The observed adverse effects in mammalian vertebrates are reduced sperm count and quality consistently observed in several reliable studies in two species (rats and mice). In fish, adverse effects include an altered hepato-somatic index and gonado-somatic index in male and female zebrafish. Qualitative observations of altered testis tubules and a decreased amount of mature spermatids in males also provide supportive evidence. BPB was demonstrated to significantly reduce fecundity of adult fish exposed for 21 days and to decrease embryo hatching and survival of F1 generation in a reliable study. Supportive evidence is provided by the induction of malformations (no detailed information) in zebrafish in one study.* ***BPB therefore induces adverse effects on the male reproductive system in rodents and fish.***

Estrogenic activity

*BPB exposure leads to higher estrogen and lower androgen levels in both in vitro and in vivo studies in rodents and fish. Additionally, in vitro data unambiguously show the estrogenic activity of BPB: competitively binding to ER of several vertebrate species (e.g. human, bovine, rat, mouse and medaka in the µM range), activation of ER signalling pathway (e.g. ER transactivation in reporter cell lines, increased promoter occupancy and induction of ER-regulated gene expression) and physiological cell response (e.g. proliferation) with similar or higher potency than 4,4'-isopropylidenediphenol (bisphenol A; **BPA**). This estrogeno-mimetic activity of BPB is also supported by the results of immature rat uterotrophic assays with increase in watery uterine content and blotted uterine weight. This effect was similar to BPA, but with a slightly higher magnitude for BPB. In fish, the increase in levels of vitellogenin (**VTG**) gene expression in the liver of male medaka and male zebrafish, and the increase in ER-regulated cyp19a1b expression in the brain of male zebrafish also strongly support the estrogenic activity of BPB.*

BPB was therefore shown to have clear estrogenic effects in rats and fish.

Other potential modes of action

*BPB was shown to bind the androgen receptor (**AR**) and to induce an anti-androgenic response in most vertebrate cell lines including in human cells but this effect was not confirmed in the Hershberger assay.* ***Therefore, BPB possibly has anti-androgenic effects.***

*The in vivo data also showed a decrease in luteinising hormone (**LH**) - and follicle stimulating hormone (**FSH**) -related gene expression in brain and gonads of male zebrafish and a decrease in plasma LH and FSH levels in rats, suggesting an action of BPB via the hypothalamic-pituitary axis. It is however not known whether it may be a cause, a consequence or a specific mode of action in addition to estrogenic and possible anti-androgenic effects.*

Oxidative stress was reported in several rodent studies and may also have an impact on the testis. It is however not known whether it may be a consequence or a specific mode of action in addition to estrogenic and possible anti-androgenic effects.

Plausibility of the link between effects and endocrine activity

BPB may have multiple modes of action that interact or superimpose and are difficult to distinguish from each other. The estrogenic effects of BPB are established in fish and rats and anti-androgenic effects are suggested. Estrogenic and anti-androgenic modes of action are known to be involved in the regulation of spermatogenesis and are closely *inter-related. Considering the concomitant decrease in plasma testosterone levels and the increase in plasma oestradiol levels, the link between these endocrine activities and the adverse effects on the male reproductive system in rodents and fish is highly plausible.*

Relevance of effects and endocrine modes of action

In the present assessment, the in vivo available evidence on rodents shows that BPB can affect the male reproductive system. These observed adverse effects in mammalian vertebrates are considered relevant for effects on human health and on mammalian wildlife species in the environment (such as mice, rats) and supportive for non-mammalian vertebrate species (fish, amphibians) with respect to the underlying mode of action and adverse effects.

Supportive evidence from BPA

The link between the observed effects and the specific endocrine activity is supported by the data on BPA, as BPB and BPA share very similar structures, adverse effects and modes of action. BPA has been identified already as SVHC due to its endocrine disrupting properties relevant for human health and the environment. It should be noted that considering the extremely large database available for BPA, it was decided to focus the SVHC identification for BPA due to its endocrine properties for human health on the endpoints having the strongest plausible link at the time of the identification. Male reproduction was not included. However, the effects of BPA on male reproduction are acknowledged, in addition to female reproduction, in the justification to classify BPA as Repro 1B for reproduction. In contrast, the endpoints included in the BPA SVHC identification for human health are largely not investigated for BPB. However, when data are available, they provide indications of a similar effect of BPB to BPA for female reproduction and metabolic effects. This support the consistency of effects between BPB and BPA.

Conclusion on endocrine disrupting properties

Overall, BPB has estrogen agonist properties and induces adverse effects on the male reproductive system in rodents and fish that are plausibly mediated by this endocrine activity. 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 rodents and fish. The effects on rodents are relevant for human health and the effects in fish and rodents are relevant for the environment as an effect on the reproductive function can have consequences at a population level. Therefore, there is scientific evidence that BPB fulfils the definition of an endocrine disruptor relevant for the environment and human health.

The effects of BPB due to its endocrine disrupting properties are considered to be of equivalent level of concern to substances listed in Article 57 points (a) to (e). The concern is substantiated by the severity and irreversibility of the effects on organisms and populations that may have long term consequences, the large variety of species that may be adversely affected and the difficulties to quantify a safe level of exposure with regard to the endocrine mediated effects. An equivalent level of concern is also supported by the potential for combined exposure with other bisphenols that share similar modes of action. The assessment shares similar lines of argumentation as for 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, the main arguments justifying the equivalent level of concern of BPA are also relevant to BPB.*

***Therefore**, it is concluded that the substance 4,4'-(1-methylpropylidene)bisphenol (Bisphenol B) meets the criteria of Article 57(f) of REACH, due to its endocrine disrupting properties for which there is scientific evidence of probable serious effects to the environment and human health which give rise to an equivalent level of concern to those for other substances listed in paragraphs (a) to (e) of Article 57 of REACH Regulation.*

Cited from ECHA (2021) 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

B.7.4. Bisphenol S

The Belgian CA has submitted an Annex XV dossier to identify BPS as an SVHC according to Art. 57f) REACH.[109] Additionally, with this Annex XV dossier the substance is proposed to be identified as a substance meeting the criteria of Article 57(c) of Regulation (EC) No 1907/2006 (REACH) owing to its classification in the hazard class toxic for reproduction category 1B, H360FD. Therein, also the endocrine disrupting properties of BPS for human health and environment were depicted. The part describing the endocrine disrupting properties in the environment is section 5.7.2ff of the dossier. In the following the summary from the Annex XV dossier is cited:

Summary of how the substance meets the criteria set out in Article 57 of the REACH Regulation

Adverse effects

Human health:

BPS consistently affects the estrous cyclicity in female rodents, at different windows of exposure. All the available studies show irregular cycles, linked in most of them to a prolongation of the diestrus phase. The disturbance of estrous cycle is considered as EATS (estrogenic, androgenic, thyroidal, and steroidogenic)-mediated.

In addition, effects that are sensitive to, but not diagnostic of, EATS (as potentially linked also to other Modes of Action) were also reported regarding rodent female reproduction. A statistically significant decrease of the number of embryo implantation sites was observed in reproductive toxicity studies, resulting in decreased fertility and number of pups.

Other developmental and male reproductive adverse effects were observed in the available rodent studies supporting the endocrine disrupting properties of BPS. These include EATSmediated effects such as reduced sperm count and motility at low doses and a high incidence of male rodent mammary gland multifocal atrophy. Additionally, adverse effects sensitive to, but not diagnostic of, EATS were observed including dose-dependent increased post-implantation loss in reproductive toxicity studies and higher adrenal glands weight, in particular in males, in several independent studies.

---

[109] Annex XV dossier on BPS: https://echa.europa.eu/documents/10162/0d8d148e-bc4f-abc4-eb6a-f9337c210faf

These adverse effects have been observed at doses showing neither maternal toxicity nor severe general toxicity. Moreover, since estrogen signalling is critical to reproductive success in all vertebrates including mammals, it is assumed that the observed adverse effects on fertility through disruption of estrogen signalling in rodents are relevant to humans.

The complexity of the effects sensitive to, but not diagnostic of, EATS observed following exposure to BPS suggests the interaction of multiple MoAs to produce the observed effects, increasing the concern for human health. For example, the consistent effects on the mammary gland in males in two rodent species provides an indication of hormonal disturbance and may have influence on e.g. human breast tumor development.

Environment:

There is evidence in literature that BPS affects sperm count and sex ratio in zebrafish (Danio rerio) after exposure in the µg/L range. In a ZEOGRT (OECD TG 240 adapted for zebrafish), the findings on sex ratio were not significant. However a similar trend towards feminisation was observed with the number of males close to or even below natural variation at low concentrations. These EATS-mediated effects were observed at concentrations below general toxicity.

In addition, effects that are sensitive to, but not diagnostic of, EATS (as potentially linked also to other Modes of Action) were also reported regarding reproductive effects: reduced fecundity, reduced hatching rate and altered oocyte maturation in fish.

Other important adverse effects on brain neurogenesis and behaviour were identified in fish. Experimental data on zebrafish demonstrated that these effects depend on BPS-induced changes in aromatase activity.

Effects on apical endpoints such as fecundity and altered sex ratio are considered to impair population stability and recruitment. Therefore, these effects are to be considered population relevant for the environment.

BPS induces adverse effects on development and reproduction in rodents and fish.

Endocrine activity

Bisphenols are known to target many endocrine pathways. Consistent in vivo and in vitro evidence is available on steroidogenesis and in particular on estrogenic activity.

- *Estrogenic activity*

In vitro ER binding assays demonstrate that BPS is capable of binding to the estrogen receptor, with IC_{50} ranging from 5.8 to 105 µM depending on the cell line used (rat and human). Several in vitro literature studies using different cell cultures showed a weak increase in the estrogenic activity (ER reporter gene assays, proliferative assays and ER-regulated gene expression assays). In vivo, the increase in uterine weight, observed in all rodent uterotrophic assays, is a parameter diagnostic of estrogenicity.

Vitellogenin, a biomarker of estrogenic activity in fish, was induced in embryonic and adult male zebrafish. Literature data also reported a change in steroidal hormone *balance with decreased testosterone and increased estradiol levels and an increased E2/T ratio in zebrafish.*

BPS exhibits estrogenic activity.

- *Steroidogenesis*

In a range of in vitro assays investigating steroidogenesis following exposure with BPS, a clear trend towards decreased testosterone was observed. Furthermore, an increase in testis aromatase expression was observed in several studies following exposure to BPS. Several, but not all, in vivo studies, showed decrease in serum testosterone level in rodents.

Moreover, the impact on the synthesis of steroid hormones (decrease of testosterone and increase of estrogen) was clearly shown in in vivo studies with zebrafish. These findings were accompanied by an increased expression of genes involved in steroidogenesis and specifically in aromatase (CYP19a, CYP19b in testis and brain resp.).

BPS is shown to affect steroidogenesis.

Plausible link between adverse effects and endocrine activity

Human health:

Considering the results of all available experimental studies, there is strong evidence that the adverse effects on fertility in female rodents are due to the estrogenic activity of BPS. The increase in uterus weight (as seen in the available uterotrophic assays) is a strong diagnostic parameter for estrogenicity. Furthermore, the prolongation of the estrous cycle was consistently observed in the majority of the studies. In addition, the number of implantation sites was decreased in three reproductive studies, resulting in a decrease of both fertility and number of pups. All of these parameters are considered as either EATS-mediated or sensitive to, but not diagnostic of, EATS modalities. The different effects of BPS, in particular on the female reproductive system, can be plausibly linked to the estrogenic activity of the substance and could therefore explain the adverse impacts seen on fertility endpoints.

Other modes of action than those involving estrogenic activity and/or signalling pathways are likely. For example, altered testosterone production is probably linked to adverse effects on the male reproductive system (reduced sperm count and motility) or the male mammary gland. Despite the fact that these data give further indications of the endocrine activity of BPS, they are considered as supportive adverse human health effects.

In conclusion, the effects on the female reproductive organs and functional parameters are consistent with an estrogenic mode of action of BPS. The adverse effects on the estrous cycle are EATS-mediated, therefore, in the absence of information proving the contrary, the biologically plausible link is already pre-established based on existing scientific knowledge. There is strong evidence that the ***adverse effects on fertility and sexual function are plausibly linked to the estrogenic activity of the substance. BPS is therefore an endocrine disruptor according to the WHO/IPCS definition with regard to human health.***

Environment:

Based on the weight of evidence approach and considering the results of all available studies there is evidence that the adverse effects of BPS on sperm count and sex ratio in zebrafish are due to the estrogenic activity and to disrupted steroidogenesis.

Skewed sex ratio is recognised as an EATS-mediated effect. Altered gametogenesis as reduced sperm counts has been also observed. Based on the existing knowledge in mammals and the similarities with fish gametogenesis, reduced sperm count is considered as EATS-mediated also in fish. The estrogenic activity of BPS is demonstrated in mammals and is further evidenced by vitellogenin induction in fish. Altered steroidogenesis may lead to the observed decreased sperm counts and altered oocyte maturation which, in turn, may lead to impaired hatchability of the eggs. Increased aromatase activity is consistently observed and is clearly responsible for effects on fish brain and behaviour. Impaired social behaviour may also result in reduced reproduction.

All mammalian data were considered in a weight of evidence approach for the assessment of the ED properties in the environment, knowing that there is a large degree of conservation of the endocrine system. This implies large commonalities between non-mammalian and mammalian vertebrate species in regard to hormones, enzymes and receptors involved in the EATS modalities. Evidence of endocrine disruptive properties of BPS on mammalian vertebrate species therefore provides further support for similar properties in non-mammalian vertebrates, in particular with regard to disruption of estrogenic pathways.

Considering all relevant and reliable information in a weight of evidence approach, it is concluded that BPS is an endocrine disruptor according to the WHO/IPCS definition with regard to environment.

Equivalent level of concern:

The effects of BPS due to its endocrine disrupting properties are considered to be of equivalent level of concern to CMR Cat. 1, PBT or vPvB substances as listed in Article 57 points (a) to (e) of the REACH Regulation.

Based on the scientific evidence, the effects on organisms and populations are considered to be severe and irreversible as effects on estrous cycle, sex ratio, etc. are observed following developmental exposure. Such effects are considered to impair population stability and recruitment. Moreover, a wide range of taxa in different ecosystems may be adversely affected due to conservation of the endocrine system. However, the difference between taxa concerning specific hormones affected, binding affinities and modes of action makes it difficult to determine the most sensitive species and thus to quantify a safe level of exposure with regard to the endocrine mediated effects.

Bisphenols are widely used and can be found together in the environment. It has been already recognised that bisphenols can act jointly in the environment by sharing the same mode of action resulting in additive effects. Bisphenols can also act together with chemicals other than bisphenols (sharing the same and/or a different MoA) occurring in the environment, at comparatively low concentrations, displaying the same and/or additional effects. This supports equivalent level of concern as endocrine *disruptors with similar MoA but also chemicals with different MoA can act additively or even synergistically.*

In conclusion:

Based on all available scientific evidence, it can be concluded that BPS fulfils the WHO/IPCS (2002)3 definition of an endocrine disruptor[110]:

- *It shows clear reproductive adverse effect in rodents and fish. The reproductive endocrine system is highly conserved not only between mammals, but also between mammals and other vertebrates like fish.*
- *It has endocrine modes of action: clear estrogenic mode of action and alteration of steroidogenesis.*
- *The adverse effects, including the recognised EAS-mediated effects (e.g. on estrous cycle and sex ratio) and effects sensitive, but not diagnostic of EAS (e.g. fecundity, fertility, implantation sites and number of pups), are a consequence of the endocrine modes of action.*

The assessment performed demonstrates that there is scientific evidence of ***probable serious effects of BPS to the environment and human health due to its endocrine disrupting properties, which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57 of the REACH Regulation.***

Cited from the Annex XV dossier for the identification of BPS as a substance of very high concern, Belgian Federal Public Service Health, Food Chain Safety and Environment Risk Management service, Date: 9 September 2022

B.7.5. Bisphenol F

B.7.5.1. Previous assessments of the endocrine properties of BPF

In March 2021 the SE CA provided an RMOA for BPF also discussing the ED concern with a focus on ED properties for human health. The SE 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 main focus of the SE CA's RMOA. [111]

B.7.5.2. Assessment of information on ED properties of BPF

The Member State Committee was requested for an opinion in accordance with Article 77(3)c of REACH Regulation. The updated Supporting Information Report presenting the evaluation of the endocrine disrupting properties of BPF for the environment is cited in the following.

---

[110] *An endocrine disruptor is an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, its progeny or (sub)populations.*

[111] 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

A literature search was performed to identify all studies available in open literature relevant for the assessment of endocrine disrupting properties of Bisphenol F in relation to the environment. As the substance is not registered, an assessment of the results presented in study reports from the registration dossier could not be included in the assessment here.

Search strings and number of hits are presented in the table below.

Date of search	*Database*	*Search string*	*Number of articles*	*Comment*
Again on 10.09.2021	*PubMed*	*(Bisphenol F) OR (4,4'-methylenediphenyl) OR (620-92-8 OR (210-658-2) AND ((fish OR human OR toxicity) OR (endocrine* OR hormone* OR androgen* OR estrogen* OR thyroid* OR steroid*))*	*498 publications* *Manual screening narrowed the result to 36 potentially relevant publications*	*The title and abstracts of the identified articles were screened manually. Expert judgement was also used to determine whether a study was likely to provide information of relevance for the ED assessment.*

The last PubMed search was performed on September 10th 2021. This resulted in 498 hits.

The quality and reliability of all in vitro and in vivo studies were assessed, and each study was assigned a reliability score based on the Klimisch categories 1, 2, 3 or 4 (Klimisch et al., 1997) combined with an expert judgement statement. • 1: reliable without restriction • 2: reliable with restriction • 3: not reliable or • 4: not assignable

The following sections report and discuss the relevant and reliable data to conclude on the environmental ED properties of BPF according to the approach described above.

B.7.5.2.1 In vitro information indicative of endocrine activity

There are eleven studies available investigating estrogenic, anti-estrogenic, androgenic, anti-androgenic, thyroidal and steroidal activity of BPF. Additionally, growth hormone production, metabolism and cytotoxicity were investigated in some studies. All studies are rated as Klimisch 2, except the study performed by Park et al. (2020), which is rated Klimisch 1 as it follows OECD TG 455.

The following table provides an overview of the available in vitro data which are further discussed in the respective subsections.

Table lvi: Available in vitro data on BPF

Method	***Results***	***Reference***
Culture system (foetal testis assay) tested with BPS, BPF *Tested substances: BPA; BPS; BPF*	*BPA: 10 nM reduces basal testosterone secretion of human foetal testis explants* *Addition of LH in FeTA system enhances BPA min effective conc in mouse and human but not in rat foetal testis*	*Eladak et al. (2015)* *(Klimisch 2)*

	BPS / BPF: 10 nM decreased basal testosterone secretion by human foetal testis *BPA and BPF: 1000 nM min effective concentration in foetal mouse testes* *BPA / BPS / BPF: 10000 nM reduced Insl3 expression in cultured mouse foetal testes*	
Luciferase reporter gene assay with HepG2 cells transiently transfected with ERα or Erβ *Tested substances: BPS; 4,4′-BPF; BPAP; BPAF; BPB; BPP; BPZ; D-8; BPE; TMBPA; BDP*	*ERα-agonism: 63.1% max efficacy, rel.* $EC_{50} = 1.6 \cdot 10^{-6}$*M (BPA: 110.3%,* $1.2 \cdot 10^{-6}$*M)* *ERβ-agonism: 97.9%max Efficacy, rel.* $EC_{50} = 1.3 \cdot 10^{-6}$*M (BPA: 97.4%,* $3.5 \cdot 10^{-7}$*M)* *ERα-antagonism: 37.6% max. inhibition, rel.* EC_{50} *= - (BPA: 11.9%, -)* *ERβ-antagonism: 12.5% max. inhibition, rel.* EC_{50} *= - (BPA: 35.2%, -)* *AR antagonism: 66.2% max. inhibition, rel.* $IC_{50} = 5.9 \cdot 10^{-6}$*M (BPA: 98.8%,* $5.1 \cdot 10^{-7}$*M)*	*Pelch et al. (2019a)* *(Klimisch 2)*
Mixture effects: *Stably transfected transcriptional activation (STTA) assay according to OECD TG 455:* *Human ERα-expressing HeLa9903 cells + MCF-7 cells* *Tested substances: BPA; BPS; E2; hydroxyflutamide (HF); DHT; dioxin (TCDD); 4,4′-BPF*	***ER transactivation activity in Hela9903 cells****. HeLa9903 cells treated with E2 (1 nM) or:* *BPA: 1.0 x* 10^{-10} *to 1.0 x* 10^{-4}*M → 1.51 µM compared to 100% activity induced by E2* *BPF: 1.0 x* 10^{-10} *to 1.0 x* 10^{-4}*M → 3.96 µM* ***ERα protein expression in MCF-7 cells*** *MCF-7 cells were treated with E2 (10 nM) or:* *BPA: 1 µM decreased the Erα-expression 0.69-fold* *BPF: 1 µM no change observed, 10 µM 0.53-fold reduced ERα protein levels (for BPA, BPF, BPS)* ***androgenic activities in AR-EcoScreen cells*** *AR-Ecoscreen cells were treated with DHT (10 nM) and: BPA:* $1.0 \cdot 10^{-10}$ *to* $1.0 \cdot 10^{-5}$ *M; BPF:* $1.0 \cdot 10^{-9}$ *to* $1.0 \cdot 10^{-5}$ *M → no AR agonist activity;* ***anti-androgenic activities in AR-EcoScreen cells*** *AR-Ecoscreen cells were treated with DHT (500 pM) or/and HF (100 nM) and* *BPA* $1.0 \cdot 10^{-10}$ *to* $1.0 \cdot 10^{-5}$ *M, BPF* $1.0 \cdot 10^{-9}$ *to* $1.0 \cdot 10^{-4}$ *M* *BPA and BPF had antagonistic activity at 10 µM* *Compared with the 100% activity induced by 500 pM DHT (positive control), AR activity was decreased 50% by 8.93 µM BPA, 10.8 µM BPF.* ***AhR activities in DR-EcoScreen cells****. DR-Ecoscreen cells were treated with TCDD (100pM) and* *BPA* $1.0 \cdot 10^{-10}$ *to* $1.0 \cdot 10^{-5}$*M, BPF* $1.0 \cdot 10^{-9}$ *to* $1.0 \cdot 10^{-4}$ *M → 10 µM BPA, 100 µM BPF, and 100 µM BPS had very low, but significant, AhR-mediated activity*	*Park et al. (2020) (Klimisch 1)*

Comparative study in vitro (and in vivo) sperms and testicular tissue of rats (BPA, BPB, BPF, BPS) *doses (0, 1, 10, and 100 ng/ml)* *stock solutions with ethanol* *tissue from 7 Sprague–Dawley male adult rats*	*Antioxidant enzyme activities and oxidative stress markers were induced in the testes, whereas testosterone production was reduced*	*Ullah et al. (2018a) (Klimisch 2)*
In vitro (and in vivo) zebrafish *Tested substances: BPA; BPS; BPF CAS 620-92-8; E2; EE2*	*Efficient transactivation of all zebrafish estrogen receptor (zfER) subtypes in zebrafish hepatic reporter cell lines (ZELH-zfERs). BPA was selective for zfERα while BPS and BPF were slightly more potent on zfERβ subtypes*	*Le Fol et al. (2017)* *(Klimisch 2)*
HPLC-APCI/APPI-HRMS was coupled with CALUX in vitro reporter gene bioassays *Tested substances: BPA;: BPAF; BPAP; BPB; BPBP; BPE; 2,2'-BPF; BPF; BPG; BPM; BPP; BPS; BPTMC; TBBPA; TBBPS*	*TTR binding potency: BPAF = BPF > BPA = BPE* *anti-androgenic activities: BPAF > BPE > BPA > BPTMC > BPF > BPS*	*Šauer et al. (2021)* *(Klimisch 2)*
Hepatocytes isolated from liver of O.mykiss *24 h expo to BPF* *0, 15.63, 31.25, 62.50, 125, 250, and 500 µM* *LDH (lactate dehydrogenase assay) and antioxidant defence system indicators* *Tested substances: BPF (Sigma-Aldrich, MO, USA;* $CH_2(C_6H_4OH)_2$*, MW: 200.23*	*LDH assay: increasing cytotoxicity in cells (dose-dependent)* *Increased malondialdehyde content (indicative of lipid peroxidation) sign between 15.63 and 250 µM.* *Toxic mechanism mainly based on cell membrane damage and oxidative stress*	*Aykut and Kaptaner (2021)* *(Klimisch 2)*
1) Caco-2 cells: in vitro intestinal transport study *2) HepaRG: in vitro liver metabolism study* *3) QIVIVE for* EC_{50}/IC_{50} *extrapolation*	*2) 4,4'-BPF slightly slower metabolization than BPA and 2,2'-BPF* *Yeast estrogen bioassay* EC_{50} *(4,4'-BPF) = 20 µM* EC_{50} *(2,2'-BPF) = NA but anti-ER* IC_{50}*= 70 µM* EC_{50} *(BPA) = 20 µM*	*Punt et al. (2019) (Klimisch 2)*

Tested substances: 2,2’-BPF (CAS 2467-02-9); 4,4’-BPF (CAS 620-92-8)	*Yeast anti-androgen bioassay:* *IC_{50} (4,4’-BPF) = 20 µM* *IC_{50} (2,2’-BPF) = NA* *IC_{50} (BPA) = 30 µM*	
fluorescence competitive binding assay *Coactivator recruitment assay* *TR-mediated luciferase reporter gene system using GH3 cells* *T-screen assay* *Tested substances: T3; BPA; BPF; BPS*	*Fluorescence competitive binding assay: BPS and BPF bound to TH receptors (TRα and TRβ) (binding potencies an order of magnitude lower than BPA)* *Coactivator recruitment assay: BPS and BPF recruited coactivator to TRβ but not TRα, with weaker potencies than BPA* *TR-mediated reporter gene transcription assay: agonistic actions in the absence or presence of T3* *BPA, BPF, BPS induced TH-dependent GH3 cell proliferation* *BPA and BPF inhibited T3 induction in presence of T3*	*Zhang et al. (2018)* *(Klimisch 2)*
In vitro *ERE-luciferase reporter assay using MCF-7 cells + ARE-luciferase reporter assay + induction of growth hormone production in GH3 cells* *Tested substances: TBBPA, TCBPA, BPA, BPAD, BPB, BPF, BPAF, BPS,…*	*MCF-7 estrogen luciferase reporter assay:* *BPF-EC_{50} = 1.0 µM* *BPA-EC_{50} = 0.63 µM* *BPS-EC_{50} = 1.1 µM* *Luciferase Reporter Assay (anti-androgenic act. against DHT):* *BPF-IC_{50} = 12 µM* *BPA-IC_{50} = 4.3 µM* *BPS-IC_{50} = 17 µM* *Growth hormone production assay of GH3 cells:* *BPA, BPF showed no activity*	*Kitamura et al. (2005)* *(Klimisch 2)*

B.7.5.2.1.1 Estrogen pathway

Several in vitro reporter gene and transactivation assays show a clear agonistic activity of BPF on both ERα and ERβ subtypes of the receptor proteins (Kitamura et al., 2005; Le Fol et al., 2017; Park et al., 2020; Pelch et al., 2019b). In these studies, BPF (i.e. 4,4´-BPF) showed similar EC_{50} values in the low µM range as BPA. Additionally, there is a yeast estrogen bioassay performed by van Leeuwen et al. (2019) which also shows estrogen agonistic activity of BPF and BPA, both at EC_{50} values of 20 µM.

Anti-estrogenic activities of BPF were observed in the studies by Pelch et al. (2019b) and Park et al. (2020) in the transactivation assay set up and in an MCF-7 cell-based ERα protein expression level.

B.7.5.2.1.2 Androgen pathway

No androgen agonistic activity is reported in the available studies. Anti-androgenic activity was observed in several assays (Kitamura et al., 2005, Punt et al., 2019, Pelch *et al., 2019b, Park et al., 2020, Šauer et al., 2021). Reported IC_{50} values and effect concentrations of BPF and BPA were similar or at least in the same order of magnitude.*

B.7.5.2.1.3 Thyroid pathway

BPF showed binding to both subtypes of the thyroid receptor protein in a competitive binding assay (Zhang et al., 2018). The same study found that BPS and BPF recruited coactivator to TRβ but not to TRα in a coactivator recruitment assay but with weaker potencies compared to BPA. Additionally Zhang et al. (2018) performed a TR-mediated reporter gene transcription assay and found agonistic actions of BPF in the absence or presence of T3. The study further showed that BPA, BPF, BPS induced TH-dependent GH3 cell proliferation and that BPA and BPF inhibited T3 induction in the cells in presence of T3. Šauer et al. (2021) showed that BPF can bind to the TTR transport protein. TTR binding potency of BPF was comparable to that of BPAF and higher compared to BPA in this assay.

B.7.5.2.1.4 Steroid pathway

Eladak et al. (2015) found that BPF and BPA comparably decreased basal testosterone secretion by human and mouse foetal testis in a culture assay set up. Growth hormone production was analysed in GH3 cells by Kitamura et al. (2005) without any effects of BPF and BPA.

Cytotoxicity of BPF in hepatocytes isolated from liver of Oncorhynchus mykiss was investigated by Aykut and Kaptaner (2021) using a LDH assay. This study observed significant cytotoxic effects based on oxidative stress (lipid peroxidation and membrane damage) between 15.63 and 250 µM.

B.7.5.2.1.5 Conclusion

BPF shows significant endocrine activity in the available in vitro studies. Most prominent are estrogen agonistic effects and anti-androgenic effects with effect concentrations (in the low µM range) in the same order of magnitude as or even equal to the concentrations observed for BPA, which is already identified as an ED in the environment based on estrogenic and or anti-androgenic effects in fish. These results are consistent across different cell lines and studies. BPF also shows thyroidal activity based on binding to the thyroid receptor protein as well as to the transport protein TTR. One study demonstrated an inhibitory effect of BPF on testosterone production in a testis cell culture assay.

Significant cytotoxicity of BPF was observed in one study using isolated hepatocytes from rainbow trout, however severe effects were seen at higher concentrations compared to effect concentrations triggering ED specific endpoints in the other available in vitro studies.

B.7.5.2.2 In vivo information indicative of endocrine activity

In the following table the available in vivo fish and amphibian data is summarised. All studies are rated as Klimisch 2 since they represent high quality exploratory studies.

Table lvii: Available in vivo data with fish on BPF

Method	***Results***	***Reference***
Danio rerio (AB strain) *28 ± 0.5 °C* *6 male and 6 female fish in 10-L glass aquaria*	*Geometric mean conc.:* *0.00071, 0.0072, 0.079, 0.75 mg/L* *No mortalities in any treatment*	*Yang et al. (2017)* *(Klimisch 2)*

control, 0.001, 0.01, 0.1, and 1 mg/L BPF for 21 days following OECD guidelines 229 and 230 *0.01% DMSO* *Two replicates* *Semi-static* *Histological analysis under microscope* *Hormone measurements using ELISA* *RNA extraction and gene expression analysis*	*HSI at 1 mg/L sign higher in males + GSI sign decreased in females and males at 1 mg/L* *Egg production, hatching rate, survival rate sign reduced at 1 mg/L* *Exposing parental fish resulted in malformed embryos and larvae (sign at 0.1 and 1 mg/L)* *Histological examination: decrease in number of early sperm stages, enlargement of interstitial space in male fish, females: lower proportion of later follicular stages; no intersex individuals* *Sign differences in concentrations of steroid hormones: decrease in T conc. In homogenate of 0.001, 0.1 and 1 mg/L + sign increase of E2 conc. In 0.1 and 1 mg/L* *Liver: sign increased vtg1 expression in males (dose-dependent), but not in females.*	
Zebrafish (Danio rerio, AB strain) *<u>Acute tox test</u>: 20 eggs (2 hpf) in 6-well cell culture plates with 10 mL test solution in triplicate (0, 1, 10, 100, 1000, 2000, 4000, 6000, or 8000 µg/L, 0.01% DMSO)* *expo: 2 hpf to 120 hpf* *16 h light per day* *28 ± 0.5 °C* *<u>Long-term expo</u>: 500 eggs in 500 mL glass beakers in triplicate (0, 1, 10, 100, or 1000 µg/L)* *Semi-static* *At 10 dpf larvae transferred to 10 L glass aquaria* *Expo: 1 to 60 dpf* *Gonadal histology (microscope)* *ELISA* *Rea-time PCR* *<u>Analytical verification</u>: LC-MS* *<u>Statistics</u>: Levene’s test on homogeneity of variances + Kolmogorov-Smirnov test on normality; one-way analysis of variance Tukey’s post -hoc test ($p < 0.05$)*	*Mean measured conc:* *0.93, 11.51, 98.56, and 1047.93 µg/L* *96h-LC_{50} = 10,030 µg/L* *120h-LC_{50} = 9391 µg/L* *100 and 1000 µg/L BPF:* - *led to trend for a female sex ratio bias* - *Gonad histology: 10 and 22% intersex fish + all male fish developed ovo-testes* - *Abnormal testicular development* *Steroid hormone conc.:* - *Conc. T decreased sign in ≥ 10 µg/L* - *E2 increased sign in ≥ 10 µg/L* *VTG expression increased sign from 20 dpf in ≥ 10 µg/L expo groups*	*Yang et al. (2018)* *(Klimisch 2)*
Zebrafish embryos (wild-type WIK strain)	*96h-LC_{50}:* *BPA 12 mg/L*	*(Moreman et al., 2017)*

	BPA, BPF, BPS, BPAF *Ethanol 0.01%* *LC-MS analysis* *Co-exposure with ICI 182780 (CAS 129453-61-8) (ER antagonist)* *20 embryos per group in 100 mL water in triplicate* *28 ± 1 °C* *Semi-static* *Toxic effects + morphological abnormalities: OECD TG 236 (96h)* *Estrogenic response by GFP induction 0 to 120 hpf*	*BPF 32 mg/L* *BPS 199 mg/L* *Hatching success 72hpf EC50:* *BPA 5.7 mg/L* *BPF 14 mg/L* *BPS 155 mg/L* *Similar morphological abnormalities, including acriac edema, spinal malformation and craniofacial abnormalities (96 hpf) + lack of pigmentation at 10 mg BPF/L and above*	*(Klimisch 2)*	
	Zebrafish (wild-type AB) *Control – solvent control - 0.0005 – 0.5 – 5.0 mg/L* *triplicates* *2 hpf in 24-well plates (RNA-Seq Test)* *OR QPCR 2 hpf in 1 L beaker (150 mL exposure solution) with 120 embryos; at 48 hpe 85 embryos from each replicate OR Chip-seq test*	*All treatments with BPF:* *Reduction of swimming distance and locomotive activity at 6 dpf;* *Activity range and swim speed of BPF-treated larvae generally lower than control* *0.5 and 5.0 mg BPF/L: sign affect motor neuron development at 72 hpf with an inhibition of axon growth → comparative analysis: BPF stronger influence on zebrafish motor neuron development than BPA* *No transcriptional changes observed for estrogenic genes in BPF treatment*	*(Yuan et al., 2019)* *(Klimisch 2)*	
	Danio rerio (AB strain) *28 ± 0.5 °C* *14 h light per day* *7.08 – 72.43 – 700.43 µg/L (mean measured conc.)* *TUNEL staining*	*OECD TG 212: 96h-LC_{50} = 7.40 mg/L* *Free-swimming total distance: tended to decline in a dose-dependent manner (sign at 70 and 700 µg/L)* *300 µg/L CPF (positive control): same effect* *Oxidative stress in 3 dpf and 6 dpf larvae: decrease of activities of SOD, increase of activity of MDA (dose-dependent)* *Apoptosis in larvae brain: increased number of death cell in larvae brain with increasing BPF conc. (sign at 70 and 700 µg/L)*	*(Gu et al., 2020)* *(Klimisch 2)*	

	Decreased expressions of genes regulating neurodevelopment (dose-dependent) *Histopathological abnormalities in brain (sign at 700 µg/L)*	
Danio rerio Embryo (< 4 hpf) *Until 120 hpf* *DMSO < 0.1%* *Carbon-filtered tap water* *25 ± 1 °C* *14 h light/day* *96-well plates* *Observation of survival, hatching, malformation: 1 larva per well, 6 wells per replicate, 4 replicates per treatment at 0.4, 2, and 10 mg/L for both BPA and BPF;* *Measurement of THs in larval fish: 160 larvae per replicate, three replicates per treatment in a glass beaker (200 mL volume) at 0.08, 0.4, and 2 mg/L for both BPA and BPF at 0.4 and* *2.0 mg/L for both BPA and BPF;* *Transcriptional analysis: mass chamber (50 mL of media/batch) with 25 per replicates and three replicates per treatment at 0.08, 0.4, and 2 mg/L for both BPA and BPF*	*Survival:* *NOEC = 2.0 (BPA) or 10 (BPF) mg/L* *Time-to-hatch:* *LOEC = 2.0 (BPA) or 0.08 (BPF) mg/L* *Hatchability:* *No sign. effect for BPF; NOEC = 2.0 mg/L for BPA* *Sign. increase of T3:* *At 0.4 mg/L BPA* *Sign increase of T4:* *At 2.0 mg/L for BPF* *Transcriptional changes in TH regulating genes:* *Up-regulated hematopoietically expressed homeobox (hhex), transthyretin (ttr) and ridine diphosphate glucuronosyltransferase 1 ab (ugt1ab) genes by BPA, BPF, and BPS.*	*(Lee et al., 2019)* *(Klimisch 2)*
Danio rerio (wild-type AB strain and transgenic lines Tg(cyp19a1b:GFP)) eggs collected 2hpf *28.5 °C* *80 embryos per treatment* *Glass flask (100 mL medium)* *28.5°C ± 0.5°C* *14 hour light per day* *DMSO, EE2 (1nM = positive control)* *BPA, BPS, BPF, BPAF, BPAP: 1 and 0.1 µM*	*Hatching success (measured at 55 hpf):* *BPA sign. at both conc.* *BPF no sign. effect* *BPAF sign. at 1 µM* *BPS sign. at both conc.* *Locomotor activity (using ZEBRALAB):* *No sign effect on swimming distance, but reduction of swimming speed over time for all substances tested. BPAF showed as ignificantly reduced locomotor activity following 6 days of exposure.*	*(Coumailleau et al., 2020)* *(Klimisch 2)*

Danio rerio (AB strain) *40 fish (20 males + 20 females) for one group* *2 replicates per conc.* *14 days exposure* *1, 10, 100, 1000 µg/L* *≤ 0.01% DMSO* *Semi-static (24h renewal)* *ELISA analysis* *RNA-seq analysis* *qRT-PCR analysis* *DNA extraction*	*Sign increased 1L-1ß and TNF-α levels (indicating intestinal inflammation)* *ELISA analysis showed induced oxidative damage and inflammatory response* *Different changes in microbial community of zebrafish intestine*	*(Wang et al., 2021)* *(Klimisch 2)*
(In vitro and) in vivo zebrafish *quantifying the expression of brain aromatase using a transgenic cyp19a1b-GFP zebrafish embryo assay*	*BPA, BPF, BPS: induced GFP in a concentration-dependent manner.* *BPS only partially induced brain aromatase at the highest tested concentrations (>30 µM) while BPA and BPF strongly induced GFP, in an ER-dependent manner, at 1–10 µM. Additionally, BPF strongly induced vitellogenin synthesis in adult male zebrafish.*	*(Le Fol et al., 2017)* *(Klimisch 2)*
Danio rerio *21 d exposure to BPA, BPF, or BPS* *30 µg/L – 0.005% v/Vv ethanol* *Acclimatisation or acute test (18°C and 28 °C)* *14 h light per day* *9-15 fish per treatment*	*BPF, BPS, not BPA: reduced swimming performance – no interactions between bisphenol exposure and acclimatisation*	*(Wu and Seebacher, 2021)* *(Klimisch 2)*
Acute toxicity testing to algae, daphnia, fish + chronic	*Daphnia 48h-EC50= 7.3 mg BPA/L or 8.7 mg BPF/L* *Zebrafish 72h-EC50 (hatching inh)= 4.0 mg BPA/L or 6.8 mg BPF/L* *Zebrafish 48h LC50= 15.9 mg BPA/L or BPF not determined as not as toxic*	*(Tisler et al., 2016)* *(Klimisch 2)*
Zebrafish embryos and larvae	*reduced amount of eggs and hatching rate*	*(Ren et al., 2017)* *(Klimisch 2)*
Danio rerio *96h- acute toxicity + gene expression* *1, 2, 4, 6, 8, 10, 12, 14* $mg \cdot L^{-1}$	*96h-*$LC_{50} = 1.6 \cdot 10^{6} \mu M$	*(Han et al., 2021)* *(Klimisch 2)*
Cyprinus carpio *Juvenile* *10 – 15 g*	*60d: no sign difference in fish body weight, survival rates, body length compared to control*	*(Qiu et al., 2018b)* *(Klimisch 2)*

5 L glass tanks *5 fish per tank, 4 replicates* *0.005% DMSO, blank, 0.1, 1, 10, 100, and 1000 µg/L* *Analytical monitoring* *Semi-static* *100 µg/L BPA or BPF for 60 d – survival rate, body weight, body length, HSI,…*	*HSI sign increased at 1000 µg/L BPF* *Oxidative stress at 100 and 1000 µg/L BPF* *BPF similar effects as BPA on immune modulation*	
Zebrafish (wild-type AB) embryos (2 hpf) *Developmental tox test:* *24-well plates* *Blank -solvent control (Acetone) – 0.005 – 0.5 – 5 mg/L; 3 replicates; 96h expo* *Transcriptomic test: 1-L beakers; 3 replicates; Blank -solvent control (Acetone) – 0.005 – 0.5 mg/L; 50 embryos per beaker; at 48 hpf: 25 hatched larvae per replicate evaluated* *qPCR validation: 0.0005, 0.5 and 5.0 mg/L in 1L-beakers; 100 embryos; 3 replicates; at 48 hpf: 25 hatched larvae per replicate evaluated* *analytical verification of conc. (measured less than 20% different from nominal)*	*Pigmentation reduction (sign less melanin in eyes, yolk sac, notochord)* *Size and number of melanocytes sign reduced in embryos of 5 mg/L BPF treatment* *Developmental defects: abnormal spontaneous movements at 0.5 and 5.0 mg/L; decreased heart rate hatch inhibition sign at 5.0 mg/L* *Sign. effect on motor neuron development at 0.5 or 5.0 mg/L*	*(Mu et al., 2019)* *(Klimisch 2)*
Zebrafish (Danio rerio, AB strain) *<u>Acute tox test:</u> embryos 1.55-1.7 hpf in 24-well plates with 2 mL exposure solution in triplicate* *Expo: 4 days* *Semi-static (renewal every 24h)* *14 hours light per day* *26°C* *<u>Developmental Toxicity Test:</u>* *embryos 1.55-1.7 hpf in 24-well plates with 2 mL exposure solution in triplicate (control, 0.1, 0.5, 1.0 mg/L)* *<u>Estrogenic Activity Test:</u> about 100 embryos in 1-L-beakers with 500 mL exposure solution in triplicate (0.2, 2, 10 mg/L)* *Expo: 2 hpf to 96 hpf* *60 embryos per replicate collected* *<u>ELISA tests:</u> 30 embryos per sample homogenized with saline on ice*	*No solvent effect* *96h-LC50 = 19.59 mg/L* *Sign inhibition of embryo hatching ratio: 15% at 5 mg/L and 65% at 10 mg/L at 72 hpf* *Pigmentation of eyes, yolk sac, notochord of embryos sign reduced (35% at 1 mg/L; 57% at 5 mg/L; 82% at 10 mg/L)*	*(Mu et al., 2018)*

Gene Expression Analysis: *Total RNA extracted from 30 embryos per sample + qPCR validation* *Chemical confirmation of substances:* *UPLC-MS*		
Danio rerio (Zebrafish, AB strain) larvae *0.01% DMSO, 0.2, 2, 20, and 200 µg/L* *2 hpf to 144 hpf* *500 embryos; 6 replicates* *LC-MS/MS*	*Increase of T3 and decrease of T4 contents, increased ratios of T3/T4* *TSH content sign induced in concentration-dependent manner* *Increased gene transcription of dio2, crh and nis and tg*	*(Huang et al., 2016)* *(Klimisch 2)*

Table lviii: Available in vivo data with amphibia on BPF

Method	***Results***	***Reference***
Xenopus laevis *T3-induced metamorphosis assay* *Tadpoles stage 52 in glass tanks (9 per tank); 3 replicates* *0.001% DMSO* *10, 100, 1000, 10000 nM in absence or presence of 1 nM T3* *22 ± 1 °C* *24h expo* *In vitro tail assay* *Spontaneous metamorphosis assay* *Histological examination*	*In the presence of T3, higher concentrations of BPF (100–10000 nM) antagonized T3-induced TH-response gene transcription and morphological changes in a concentration-dependent manner, whereas 10 nM BPF exerted stimulatory effects on T3-induced integral metamorphosis, displaying TH signaling disrupting effects with complicated concentration–response relationships* *In the absence of T3, BPF inhibited development at metamorphic climax, but promoted pre- and pro-metamorphic development, displaying a developmental stage-dependent manner* *agonistic actions of BPF on Notch signaling in the intestine*	*(Zhu et al., 2018)* *(Klimisch 2)*
Pelophylax nigromaculatus tadpoles (Gosner stage 27) *TH-response gene transcription assay* *0.01–10 µM BPA, BPS, or BPF in the presence or absence of 0.2 nM T3 for 48 h* *Three replicate test beakers*	*BPA, BPF, BPS induced TH-response gene transcription in the tadpoles* *In presence of T3 altered T3-induced gene transcription in biphasic concentration-response manner*	*(Zhang et al., 2018)* *(Klimisch 2)*
Xenopus laevis *NF 52 stage tadpoles* *Semi-static test system* *T3-induced (1nM) Xenopus metamorphosis assay*	*TH-response gene expression*: *BPA increases like st3, dio3 and thibz expression in brain – BPF upregulated dio3 but not the other; co-exposure: BPA antagonised T2-induced upregulation of tgm2, thibz, st3, and dio3 expression - In the presence of T3, BPF exhibited more*	*(Niu et al., 2021)* *(Klimisch 2)*

10, 100, and 1000 nM BPA or BPF in absence or presence of 1 nM T3 *Glass tanks (4L water)* *9 tadpoles per tank with three replicates* *0.001% 8v/v) DMSO* *96h test duration*	*remarkable biphasic effects on T3-induced expression of all the test TH-response genes except for tgm2.* *Brain morphology:* *BPA and BPF antagonised T3-induced brain remodelling*	

B.7.5.2.2.1 Fish data

There is a clear indication of an estrogenic endocrine MoA in the zebrafish studies. One study observed a significant dose-dependent increase in VTG levels in male zebrafish after 7 days of exposure to 0.1 µM BPF in the water (Le Fol et al., 2017). Another study also observed a significant increase in VTG in both male and female zebrafish, after 60 days exposure to 0.0001 mg/L water (Yang et al., 2018). In addition, the endocrine MoA is supported by an observation of increased estradiol levels in both juvenile and adult male and female zebrafish, at doses of 0.01 mg/L water (juvenile) and 0.1 mg/L water (adult) (Yang et al., 2017 and 2018).

B.7.5.2.2.2 Amphibian data

In vivo mechanistic data from Xenopus laevis and Pelophylax nigromaculatus tadpoles show that BPF exerts some activity on the HPT axis. Zhou et al. (2018) found that in the absence of T3, BPF inhibited development of the tadpoles at metamorphic climax, but promoted pre- and pro-metamorphic development, displaying a developmental stage-dependence. The study performed by Zhang et al. (2018) on Pelophylax nigromaculatus tadpoles showed that BPA, BPF, BPS induced TH-response gene transcription in the tadpoles. In presence of T3 altered T3-induced gene transcription was observed in a biphasic concentration-response manner. Niu et al. (2021) found effects of BPF on thyroid specific gene expression as well as antagonised T3-induced brain remodelling in X. laevis.

B.7.5.2.2.3 Conclusion

The available fish data clearly and consistently show an estrogenic and/or anti-androgenic mode of action of BPF. The effect concentrations are in the low mg/L range (0.01-1 mg/L) and hence comparable to those observed for BPA and 4-nonylphenol[112] *which are already identified ED substances based on their estrogenic activity.*

This observed in vivo endocrine activity fits to the observed endocrine effects of BPF in the available in vitro data.

Furthermore, BPF shows activity on the HPT axis, which also fits to the effects observed in the available in vitro data and effects reported for BPA.

---

[112] Annex XV dossier containing the proposal for identification of 4-nonylphenol, branched and linear […] as a Substance of Very High Concern based on its environmental ED properties: https://echa.europa.eu/de/registry-of-svhc-intentions/-/dislist/details/0b0236e180e4ba35

B.7.5.2.3 In vivo adverse effect data

B.7.5.2.3.1 Fish data

Adverse and population relevant effects in fish were observed in the study of Yang et al. (2017). In this study Danio rerio (AB strain, 6 males and 6 females in two replicates) was exposed in a semi static set up to 0.001, 0.01, 0.1, and 1 mg/L BPF for 21 days following OECD guidelines 229 and 230. Histological analysis was performed via microscopy, hormone measurements (testosterone and E2) via ELISA were included and a gene expression analysis (vtg1) was done. Egg production in F0, hatching rate and survival rate of F1 were significantly reduced at 1 mg/L of BPF. Hence, clear adverse effects on reproduction could be shown.

HSI at 1 mg/L was significantly higher in males and GSI was found to be significantly decreased in females and males at 1 mg/L. The histological examination revealed a decrease in the number of early sperm stages and an enlargement of interstitial space in male fish. In female fish a lower proportion of later follicular stages was observed and no intersex individuals could be detected. Significant differences in concentrations of steroid hormones were observed with a decrease in testosterone concentration in the full body homogenate of the 0.001, 0.1 and 1 mg/L treatment. A significant increase of E2 was observed at concentrations of 0.1 and 1 mg/L BPF. The gene expression analysis performed in liver homogenate revealed a significant increased vtg1 expression in males (dose-dependent), but not in females.

Furthermore, the long-term fish study performed by Yang et al. (2018) on zebrafish showed adverse and population relevant effects. In this study, 500 eggs were exposed in triplicate to 0, 1, 10, 100, or 1000 µg/L of BPF under semi-static conditions. At 10 dpf the larvae were transferred to 10 L glass aquaria, and exposure to BPF was continued to 60 dpf. Histology of the gonads was performed at the end of the test, and E2 and testosterone concentrations in full body homogenate were measured via ELISA. Real-time PCR was performed for gene expression analysis (vtg1 in liver). Adverse effects were seen at 100 and 1000 µg/L BPF since histology of the gonads revealed that there is a significant increase in intersex fish of 10 and 22%, respectively. Simultaneously, all males developed ovo-testes and showed an abnormal development. Additionally, there was a trend towards a female-biased sex ratio with a statistically significant shift of the sex ratio towards females at 100 µg/L.

Hormone measurements showed a decrease in testosterone concentration significant from 10 µg/L onwards and an increase of E2 also significant from ≥ 10 µg/L. Liver VTG expression increased significantly from 20 dpf in the ≥ 10 µg/L exposure groups.

B.7.5.2.3.2 Conclusion

Two fish studies performed with Danio rerio clearly show consistent adverse effects on the reproductive capacity of the animals after exposure to BPF. The study performed by Yang et al. followed an OECD TG 229 (fish short-term reproduction assay) and demonstrated adverse effects on egg production in F0 females as well as on hatching and survival of the larvae of the F1 generation. The same study shows effects for an estrogenic and/or anti-androgenic mode of action in absence of indications for unspecific systemic toxicity. Hence, according to OECD GD 150 this study can be used to conclude on ED mediated adversity.

The long-term fish study of Yang et al. (2018) investigated the sexual development of zebrafish. Here, clear adverse effects could be shown on gonadal development and on the sex ratio. The further endpoints investigated in this study clearly point to an underlying estrogenic and/or anti-androgenic mode of action of these adverse effects. Indications for systemic toxicity that could have triggered the observed effects on sexual development were not seen in this study. According to OECD GD 150, the effects observed in this study are also conclusive for ED mediated adverse and population relevant effects

B.7.5.2.4 Conclusion regarding ED properties relevant for environment

B.7.5.2.4.1 Adverse effects relevant for ED identification

As described above, the 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.

B.7.5.2.4.2 Endocrine activity

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.

B.7.5.2.4.3 Plausible link between adverse effects and endocrine activity

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[113], 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).

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.

Other supporting evidence

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

---

[113] https://aopwiki.org/aops

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 BPA. The data available for 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. Based on these data BPA and BPB have been identified already as SVHC due to its endocrine disrupting properties in the environment.

B.7.5.2.5 Conclusion on ED properties

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.***

Reference: Article 77(3)(c) Request Supporting Information Report: Evaluation of endocrine disrupting properties for the environment submitted by Germany, Date: April 2022 (updated 04 July 2022)

B.7.6. Bisphenol AF (BPAF, EC No 216-036-7)

B.7.6.1. Previous assessments of the endocrine properties of BPAF

BPAF is registered under REACH and is manufactured in and / or imported to the EU at ≥ 100 to < 1 000 tonnes per year. BPAF was proposed to be classified as a reprotoxicant 1B according to the CLP regulation. In March 2021 ECHA´s Risk Assessment Committee (RAC) adopted its opinion on this proposal, which is based on the available mammalian data for BPAF. In their opinion on the CLH proposal on BPAF, RAC concluded that the available data provide clear evidence of adverse effects of BPAF on sexual function and fertility in mammals. Changes in male reproductive organ weight, size and histopathology are indicative of an (anti-androgenic) endocrine mechanism. Based on the available data, estrogenic or anti-androgenic mechanism are thought to play a dominant role *in vivo*. RAC further states that the observed effects on male and female sexual function and fertility are not considered to be a secondary non-specific consequence of parental systemic toxicity.

B.7.6.2. Assessment of information on ED properties of BPAF

The Member State Committee was requested for an opinion in accordance with Article 77(3)c of REACH Regulation. The updated Supporting Information Report presenting the evaluation of the endocrine disrupting properties of BPF for the environment is cited in the following.

A literature search was performed to identify all studies available in open literature relevant for the assessment of endocrine disrupting properties of

Bisphenol F in relation to the environment. As the substance is not registered, an assessment of the results presented in study reports from the registration dossier was not possible.

Search strings and number of hits are presented in the table below.

Date of search	*Database*	*Search string*	*Number of articles*	*Comment*
Again on 15.09.2021	*PubMed*	*(Bisphenol AF) OR (4,4'-methylenediphenyl) OR (1478-61-1) AND ((fish OR human OR toxicity) OR (endocrine* OR hormone* OR androgen* OR estrogen* OR thyroid* OR steroid*))*	*259 publications* *Manual screening narrowed the result to potentially relevant publications*	*The title and abstracts of the identified articles were screened manually. Expert judgement was also used to determine whether a study was likely to provide information of relevance for the ED assessment.*

The last PubMed search was performed on September 15th 2021. This resulted in 256 hits.

The quality and reliability of all in vitro and in vivo studies were assessed, and each study was assigned a reliability score based on the Klimisch categories 1, 2, 3 or 4 (Klimisch et al., 1997) *combined with an expert judgement statement. • 1: reliable without restriction • 2: reliable with restriction • 3: not reliable or • 4: not assignable*

B.7.6.2.1 In vitro information indicative of endocrine activity

There are three studies available investigating estrogenic and anti-estrogenic activity of BPAF. The studies are all rated as Klimisch 2.

The following table provides an overview of the available in vitro data, which are further discussed below.

Table lix: Available in vitro data on BPAF

Method	*Results*	*Reference*
In vitro models for evaluation of effects on ER α and β using three human cell lines (Ishikawa, HeLa, and HepG2) *10 – 100 – 1000 nM*	*Estrogenic activity as agonist for ERα in a dose-dependent manner* *At lower concentrations BPAF acted as antagonist for ERβ in HeLa cells* *ERE-mediated activation was via AF-2 function of ERα* *Endogenous ERα target genes and rapid signaling vie the p44/42 MAPK pathway were activated by BPAF*	*Li et al. (2012)* *(Klimisch 2)*

HepG2 and HeLa cells used to determine the agonistic activity of BPAF on ERα and ERβ via the luciferase reporter assay. Ishikawa cells stably expressing ERα used to determine changes in endogenous ER target gene expression by bisphenol-AF.	*Activation of ERα3xERE-mediated responses in HepG2 cells.* *Significantly induction of 3xERE and pS2ERE mediated activity.* *Activation of ERβ3xERE and pS2ERE mediated activity.* *effects on ERα target genes (PR, pS2, GREB1, SPUVE, WISP2, and SDF-1) using real-time PCR in Ishikawa/ERα stable cells: significant induction of endogenous ERα target genes PR,pS2, GREB1, SPUVE, WISP2 and SDF-1. In contrast, expression of target genes in the Ishikawa/vector stable cells did not change with bisphenol-AF treatments.*	*(Li et al., 2013)* *(Klimisch 2)*
Receptor binding activity to ER α and β + competitive binding (BPA, 17β-estradiol, 4-OHT)	*Binding to ERs over ERRgamma* *Receptor binding activity 3-times stronger for ERβ (IC_{50} = 18.9 nM) than for ERα* *Almost completely inactive in stimulating the basal constitutive activity of ERβ* *Antagonist against activity of 17β-estradiol*	*(Matsushima et al., 2010)* *(Klimisch 2)*
H295R cell assay *Real-time RT-PCR* *10, 30, and 50 µM*	*Supports in the amphibian model the conclusion that BPAF is an oestrogen/anti-androgen ED* *Dose-dependent elevated progesterone secretion (similar to BPF)* *Decreased testosterone levels* *Inhibited production of cortisol* *Inhibition of aldosterone secretion (similar to BPA and BPS)*	*(Feng et al., 2016)* *(Klimisch 2)*
H295R cell assay and MVLN luciferase gene reporter assay	*H295R cell assay: BPAF does not increase the E2/T ratio significantly* *MVLN: BPAF is most active in nuclear ERα binding compared to BPB, BPA, BPF, or BPS*	*(Lin et al., 2021)* *(Klimisch 2)*

Estrogen pathway

Two cellular assays (Li et al., 2012 and Li et al., 2013) analysed the ability of BPAF to interact with the ERα and ERβ proteins using luciferase reporter gene assays. The study performed by Li et al. (2012) found estrogen agonistic activity of BPAF for ERα in a dose-dependent manner. At lower concentrations BPAF acted as antagonist for ERβ in the HeLa cell assay. Gene expression analysis showed that endogenous ERα target genes and rapid signaling vie the p44/42 MAPK pathway were activated by BPAF exposure of the cells.

Li et al. (2013) observed activation of ERα3xERE-mediated responses in HepG2 cells as well as a significant induction of 3xERE and pS2ERE mediated activity after BPAF exposure. Gene expression studies using real-time PCR revealed

effects on ERα target genes (PR, pS2, GREB1, SPUVE, WISP2, and SDF-1) in BPAF treated Ishikawa/ERα stable cells.

The third study performed by Matsushima et al. (2010) investigated the receptor binding activity of BPAF to ERα and ERβ proteins in a competitive binding assay. The authors found that receptor binding activity of BPAF was three times stronger for ERβ (IC_{50} = 18.9 nM) compared to ERα. Furthermore, BPAF almost completely inactivated the basal constitutive activity of ERβ and acted as an antagonist against the activity of 17β-estradiol. Hence, the authors concluded that BPAF is a full agonist for the ERα but a highly specific antagonist for ERβ.

Conclusion

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 and the receptor binding assay.*

B.7.6.2.2 In vivo information indicative of endocrine activity

In the following table, the available in vivo fish data for BPAF is summarised. The studies performed by Shi et al. (2015) and Yang et al. (2016) are rated as Klimisch 1 since they represent high quality studies that were performed according to OECD TG 234 and 215, respectively. The study by Song et al. (2014) is rated as Klimisch 2 since it is an exploratory study of high quality.

Table lx: Available in vivo data on BPAF

Method	***Results***	***Remarks***	***Reference***
Fish Sexual Development Test equivalent to OECD TG 234 *Danio rerio AB strain* *No analytical monitoring* *Vehicle: ethanol 100 µL/L* *Semi-static* *3 replicates with 120 embryos – 50 larvae – 4 males and 2 females* *SC – 5 – 25 – 125 µg/L (nominal)*	*120d-$NOEC_{F0-mortality}$ > 125 µg/ (nominal)* *120d-$NOEC_{F1-time\_to\_hatch}$ < 5 µg/L (nominal)* *F0: Fecundity of female decreased but not statistically significant in 125 µg/L-group;* *F0: significant reduction in fertilisation success of spawn eggs in 125 µg/L-group;* *F1: malformation rates in 125 µg/L-group significantly higher than SC after 3 dpf (most malformed larvae died in first few days); survival rates sign lower after 6 dpf in 125 µg/L-group* *F0 males: sign increased plasma E2 in 25 and 125 µg/L-groups; plasma T sign reduced in 25 and 125 µg/L-groups*	*VTG concentrations not determined;* *VTG gene expression via measurements of mRNA as indicator for ER stimulation*	*(Shi et al., 2015)* *(Klimisch 1)*

	F0 females: sign increased E2 levels in 125 µg/L-group; T levels unchanged *F0 gene expression: liver of male fish vtg1 sign increased in 25 and 125 µg/L-groups; vtg1 unchanged in female fish; brain expression of gnrh2, fshb, lhb, cyp19b in male sign increased in 125 µg/L-group; no changes in female brain; gonads expression of fshr, cyp19a, cyp11a1 sign increased; testis star with cyp17 sign decreased in 125 µg/L-group; ovaries increase of fshr + decrease of star in 125 µg/L-group*		
Danio rerio *Analytical monitoring (LC/MS)* *Vehicle: DMSO* *Embryo test: n.a. + reproduction test: semi-static, 2 mo old fish* *Embryo test: 144 dpf; reproduction test: 21d* *3 replicates with 30 embryos OR with 10 males randomly selected* *Control - SC - 0.5 – 1.0 – 1.5 – 2.0 mg/L (nominal)*	*144h-$LC_{50,embryos}$ = 1.75 mg/L* *144h-$NOEC_{larval\_development}$ = 1 mg/L* *144h-$NOEC_{embryo\_mortality}$ = 1.5 mg/L* *21d-$NOEC_{adult\_mortality}$ ≥ 1.5 mg/L* *Male adults: VTG induction in all concentrations of BPAF (21d)* *Embryo test: 100% mortality at 2.0 mg/L after 144 hpf; statistically sign increase of pericardial oedema at 1.5 mg/L slightly delayed hatching in 1.0 and 1.5 mg/L-group (not sign)* *Not reported: body length, number fish in swim-up stage at one or more time periods, behavioural abnormalities*	*Combination of embryo development test (144 hpf) with reproduction test (21 d)*	*(Song et al., 2014a)* *(Klimisch 2)*
Fish juvenile growth test equivalent to OECD TG 215 *Danio rerio (2 mo old)* *No analytical monitoring* *Vehicle: DMSO* *Semi-static* *3 replicates with 9 fish* *SC - 0.05 – 0.25 – 1 mg/L (nominal)*	*28d-$NOEC_{mortality}$ ≥ 1 mg/L (n)* *28d-$NOEC_{length\_increased}$ = 0.05 mg/L (n); 28d-$NOEC_{weight\_increased}$ = 0.05 mg/L (n)* *Male fish hepatocytes swollen and irregularly shaped in 1 mg/L-group* *Vacuolization in liver in 1 mg/L-group but no hepatic damage in any female fish* *No obvious alterations in the gills and intestines of both sexes* *Males: germ cells in all stages of spermatogenesis* *females: significantly higher proportion of stage I cells in 0.25 and 1 mg/L-groups* *Male fish: T-levels in whole-body homogenates reduced in dose-dependent manner + E2 levels increased with increase of BPAF concentration*	*Dissolved O_2-concentration not reported*	*(Yang et al., 2016)* *(Klimisch 1)*

	Female fish: T levels increased in 0.05 and 0.25 mg/L-groups + decreased in 1 mg/L group; increase in E2 levels in 0.05 and 1 mg/L-groups but slightly decrease in 0.25 mg/L-group *VTG gene in liver sign upregulated in males of 1 mg/L-group*		
Danio rerio *6 hpf to 7 d exposure* *28 ± 0.5 °C, 7.8 ± 0.2* *0.5% DMSO* *96-well plates* *Three replicates* *60 embryos per replicate* *ELISA kit used* *Histological examinations* *TUNEL and DAPI staining (for detection of apoptosis)*	*12.5 and 125 µg/L: decreased levels of thyroid hormones (TT4, FT3, TT3, FT3) and deiodinases (dio1, dio2) but increased expressions of transthyretin* *≥ 12.5 µg/L: decreased thyroid hormone receptor levels → TR antagonist* *125 µg/L: liver impairment (mainly cell necrosis of hepatocytes)* *≥ 12.5 µg/L: apoptosis*	*Thyroidal MoA*	*(Chen et al., 2022)* *(Klimisch 1)*
Danio rerio *26 ± 2°C* *16 h light per day* *Four male fish per replicate., three replicates per conc.:* *Control, 24.7 µg BPAF/L, 5.6 µg SMX/L, mixture* *(SMX = CAS 723-46-6)* *21 d expo* *ELISA (T4)* *cDNA microarray* *qPCR assay*	*No mortality observed* *Plasma total T4 conc. slightly decreased in BPAF group (not statistically sign.)* *BPAF expo: trh, trhr1 and tshß mRNAs in brain sign up-regulated + sign up-regulation of dio2 and down-regulation of tpo in thyroid tissue*	*Thyroidal MoA*	*(Kwon et al., 2016)* *(Klimisch 2)*
Fish Embryo Toxicity Test acc. To OECD TG 236 *Danio rerio* *168h expo* *Semi-static* *Beakers (0.5 L)*	*No sign effects on survival, length, weight* *72 hpf-LOEC (hatchability) = 0.05 mg/L (reduced) - No sign differences at 96 hpf* *LOEC (TT4 + TT3 sign decreased) = 0.05 mg/L*	*Thyroidal MoA*	*(Tang et al., 2015)* *(Klimisch 1)*

0, 0.005, 0.05, 0.5 mg/L (HPLC analysis) *0.1% DMSO* *300 eggs per replicate* *3 replicates* *28.5°C, 14 h light per day*	*LOEC (sign reduced whole body content Free T4) = 0.05 mg/L* *Sign reduced basal Free T3 in all treatments* *LOEC (decreased tr-α mRNA levels) = 0.05 mg/L*		
Xenopus laevis *In vitro fertilization* *2-cell embryo stage exposed up to 96h* *0.003 – 25 µM* *0.03% Ethanol or DMSO* *14 h light/d* *Semi-static* *Duplicate or triplicate* *300 – 1000 embryos*	*Within 1-6 h: Disrupted cleavage divisions, slowed cytokinesis, cellular dissociations* *2-96 h: Dose-dependent increase of embryo abnormality and mortality* *Dose-dependent reduction of survival rates → LC_{50} = 0.013 µM (BPA: 10.7 µM)* *Shorter tails and curved body axes with tail flexures in the dorsal-ventral directions, malformed mouths and eyes (similar to BPA)*	*Effects not directly ED related*	*(Arancio et al., 2019)* *(Klimisch 2)*
Xenopus laevis tadpoles (stages 45/46) *Exposure to stage 53 and 66* *1, 10, 100 nM* *Semi-static* *Prolonged treatment at 100 nM*	*Stage 53: decreases in both size and number of gonadal metameres (gonomeres) in testes, looking like ovaries* *Stage 53 and 66: ovarian cavity and poorly developed seminiferous tubules on WPM8 (eighth week post-metamorphosis)* *Stage 53: inhibited expression of male highly expressed genes in testes* *Stage 50: inhibited cell proliferation in testes (like E2)*		*(Cai et al., 2020)* *(Klimisch 2)*

Fish data

The OECD 234 study performed by Shi et al. (2015) showed that after 120 d of exposure of zebrafish to BPAF, E2 and E2/testosterone ratio was significantly increased in both males and females in a dose-dependent manner. In male fish, several HPG axis related genes were either significantly suppressed or induced in all tissues. In the liver of male fish vtg1 expression significantly increased in the highest two concentrations tested, whereas no changes were observed in female fish. Genes involved in the regulation of gonadotropin releasing hormone, LH and FSH were also affected, and thus the regulation of testosterone and estrogen may be affected.

Song et al. (2014) observed VTG induction in male fish in all concentrations of BPAF tested in a 21-d fish study using zebrafish. Additionally, the authors

reported a slight but not statistically significant delayed hatching rate in the 1.0 and 1.5 mg/L treatment group.

The fish juvenile growth test performed by Yang et al. (2014) according to OECD TG 215 showed germ cells in all stages of spermatogenesis in male fish and significantly higher proportion of stage I cells in 0.25 and 1 mg/L treatment groups of female fish. Furthermore, testosterone levels in whole-body homogenates of male fish were reduced in a dose-dependent manner, and E2 levels significantly increased with increase of BPAF concentration. In female fish, testosterone levels increased in 0.05 and 0.25 mg/L groups and decreased in 1 mg/L group. Additionally, an increase in E2 levels in the 0.05 and 1 mg/L groups but a slight decrease in the 0.25 mg/L treatment group was observed in females. VTG gene expression in the liver was significantly upregulated in males of the 1 mg/L treatment group.

Conclusion

The available fish data clearly and consistently show an estrogenic and/or anti-androgenic MoA of BPAF. The effect concentrations are in the low mg/L range (0.05-1 mg/L) and hence comparable to those observed for BPA and 4-nonylphenol,[114] which are already identified ED substances based on their estrogenic activity.

This observed in vivo endocrine activity fits to the observed endocrine effects of BPAF in the available in vitro data.

B.7.6.2.3 In vivo adverse effect data

Fish data

Adverse and population relevant effects in fish were observed in the study of Shi et al. (2015). In this study, Danio rerio was exposed in a semi static set up to 0.5, 1.0, 1.5 and 2.0 mg/L BPAF according to the test design and parameters described in OECD guideline 234. For the F0 generation there was a significant reduction in fertilisation success of spawned eggs in the 125 µg/L treatment group. Additionally, the malformation rate of offspring was also significantly increased at the highest concentration. Fecundity of female fish decreased but not statistically significant in the 125 µg/L treatment group. Signs of systemic toxicity were not reported in this study up to the highest concentration of BPAF tested. Thus, there are no indications for other toxic modes of action that could explain the observed adverse effects on fertility in the fish.

Conclusion

The long-term fish studies performed by Shi et al. (2015) with Danio rerio clearly show an adverse effect on the reproductive capacity of zebra fish after exposure to BPAF. The study performed according to an OECD TG 234 set up demonstrated significant adverse effects on the fertilization rate of spawned eggs at 125 µg/L. The same study shows effects for an estrogenic and/or anti-

---

[114] Annex XV dossier containing the proposal for identification of 4-nonylphenol, branched and linear […] as a Substance of Very High Concern based on its environmental ED properties: https://echa.europa.eu/de/registry-of-svhc-intentions/-/dislist/details/0b0236e180e4ba35

androgenic MoA in absence of indications for unspecific systemic toxicity. Hence, according to OECD GD 150 this study can be used to conclude on ED mediated adversity. BPAF shows adverse effects on reproduction (decrease in fertility) that fit to the observed estrogenic and anti-androgenic activity of the substance in further in vivo and in vitro studies.

Read-across to the salts of BPAF

The conclusion on the ED properties for BPAF is read across to the eight salts of BPAF due to the occurrence of BPAF as the counter anion in these substances.

Under environmental conditions the substances can be expected to dissociate to the cation and the anion (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.

B.7.6.3 Conclusion regarding ED properties relevant for environment

B.7.6.3.1 Adverse effects relevant for ED identification

The available data for BPAF show a clear adverse and population relevant effects on reproduction in zebrafish. The observed effects fit to an estrogenic and/or anti-androgenic MoA and no indications of further non-ED mediated pathways were found in the key long-term fish study.

B.7.6.3.2 Endocrine activity

The available in vitro as well as in vivo mechanistic data clearly and consistently demonstrate an estrogenic and/or anti-androgenic activity of BAPF in fish.

B.7.6.3.3 Plausible link between adverse effects and endocrine activity

The estrogenic and/or anti-androgenic effects of BPAF are established in zebra fish by the available data showing significant adverse effects on the fertilization rate of spawned eggs. Estrogenic and anti-androgenic modes of action are well known to be involved in the regulation of sexual development and reproduction. 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 demonstrate an estrogenic and/or anti-androgenic MoA. Thus, the link between these endocrine activities and the observed adverse effects on egg fertilization is highly plausible.

B.7.6.3.4 Other supporting evidence

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

data BPA and BPB have been identified already as SVHC due to its endocrine disrupting properties in the environment.

B.7.6.3.5 Conclusion on ED properties

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 definition of an endocrine disruptor in the environment.

The conclusion on the ED properties for BPAF is read across to the eight salts of BPAF due to the high ratio of BPAF counter ion and the fact that under environmental conditions the substances can be expected to dissociate to BPAF.

Reference: Article 77(3)(c) Request Supporting Information Report: Evaluation of endocrine disrupting properties for the environment submitted by Germany, Date: April 2022 (updated 28 September 2022)

B.8. Emission Characterisation and assessment

No exposure assessment is carried out either, as a risk already arises at the point of emission of BPA and BosC. Any emission to the environment is considered as proxy for risk to the environment, so further distribution in the environment once released is not considered relevant.

B.8.1. Introduction

The aim of this restriction is to minimise the environmental exposure of BPA and bisphenols of similar concern as much as possible. The following exposure sections address all relevant use areas and, where information is available, specific uses that contribute to environmental exposure. Based on these exposure estimates and the related discussion, three restriction options will be presented and discussed with respect to their risk reduction efficiency and appropriateness in terms of socio-economic considerations.

Owing to the broad variety of uses and products containing BPA and the BosC, the exposure assessment and the development of the restriction scenarios follow some strategic decisions to structure the discussion within this dossier:

- The identification of environmentally relevant uses and emission estimates are principally based on the data and knowledge available for BPA. For the BosC here it is assumed that they will be used as BPA drop-in substitutes and hence will follow the same use pattern and emission parameters that can be derived for BPA. Exceptions from this approach are made and discussed where specific uses of BosC are known, e.g. in leather tanning, textiles or in fluorelastomers.

- The uses of BPA and the BosC are roughly divided into "additive" uses, i.e. uses where the bisphenols are not covalentely bound to any type of matrix, and polymeric uses (please refer to section A / B.8.6 for further specifications). Both of these use categories are covered differently in this dossier with respect to risk management considerations.

- For the additive uses it is assumed that in the products a high concentration (>1000ppm) of free bisphenol is required to achieve the desired technical function (e.g. antioxidant or colour developer). Thus, there is principally a high release potential of these uses at least at the waste or end-of-life stage. Since this waste stage cannot properly be controlled, in contrast to the service life where emissions might be minimised via e.g. coatings, and the data discussed in the sections below point to landfills as a significant source for bisphenol emissions into the environment, for additive uses a complete restriction is proposed. This is expected to cover the largest share of environmental emissions and will also ensure a level playing field for the European industry since additive uses are not registered at least for BPA within the EU and hence only relevant for imported products and articles.

- For the polymeric uses the assumption is that emissions here occur via unreacted residual bisphenol in the polymers and/or via aging of the polymer matrix in the use phase. Hence, the emission potential here is substantially lower even in the waste stage of the polymer containing products compared to the additive uses of bisphenols. However, the polymeric uses of BPA and BosC cover the vast majority of registered uses in the EU and even small emissions can lead to significant amounts of bisphenols in the environment. Thus, for the polymeric uses the approach is to further allow bisphenols but with limit values for either residual contents or migration limits throughout the service life of the products. This approach is developed into three restriction options for polymeric uses varying in their risk reduction capacity and appropriateness (e.g. efficency vs. testing efforts).

- This approach allows to focus the analysis of alternatives and possibly related derogations to the few additive uses identified as relevant.

Beside this it should be noted that the available database, e.g. regarding migration data, refers mostly to few specific applications of BPA and the BosC. Hence, the estimation of release potentials for the various use sectors described below is often related to high uncertainties. To deal with this situation pragmatic and where possible evidence-based assumptions are made to pave a corridor of best and worst case estimates for certain use sectors.

As described previously (Chapter 1.5.1), most BPA production in the EU is processed into polycarbonate (70 - 80%) and epoxy resins (about 15 -30%), with a smaller portion (< 2%) processed into specialty chemicals and other polymers. Due to the great economic importance of BPA, its wide application in diverse sectors, its large quantities and widespread distribution, it is ubiquitous in the environment. Although, there are no natural sources of Bisphenol A (Corrales et al., 2015; Cousins, 2002; Fischer et al., 2014; Flint et al., 2012; Fromme, 2002). Other bisphenols of similar concern (BosC) which can either replace BPA or are still found in applications beyond the use of BPA are also addressed in the following consideration of release and emission.

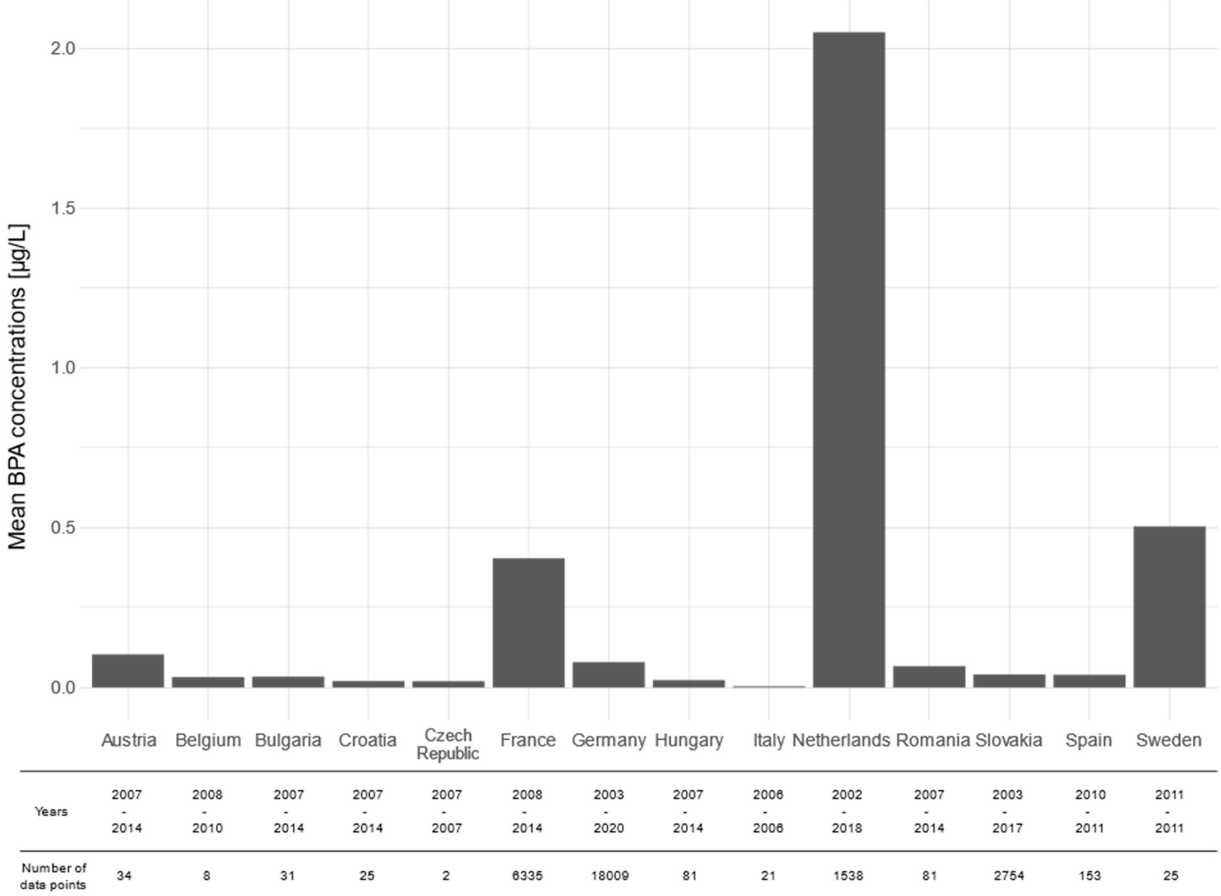
B.8.1.1. Sources of emission known from monitoring data

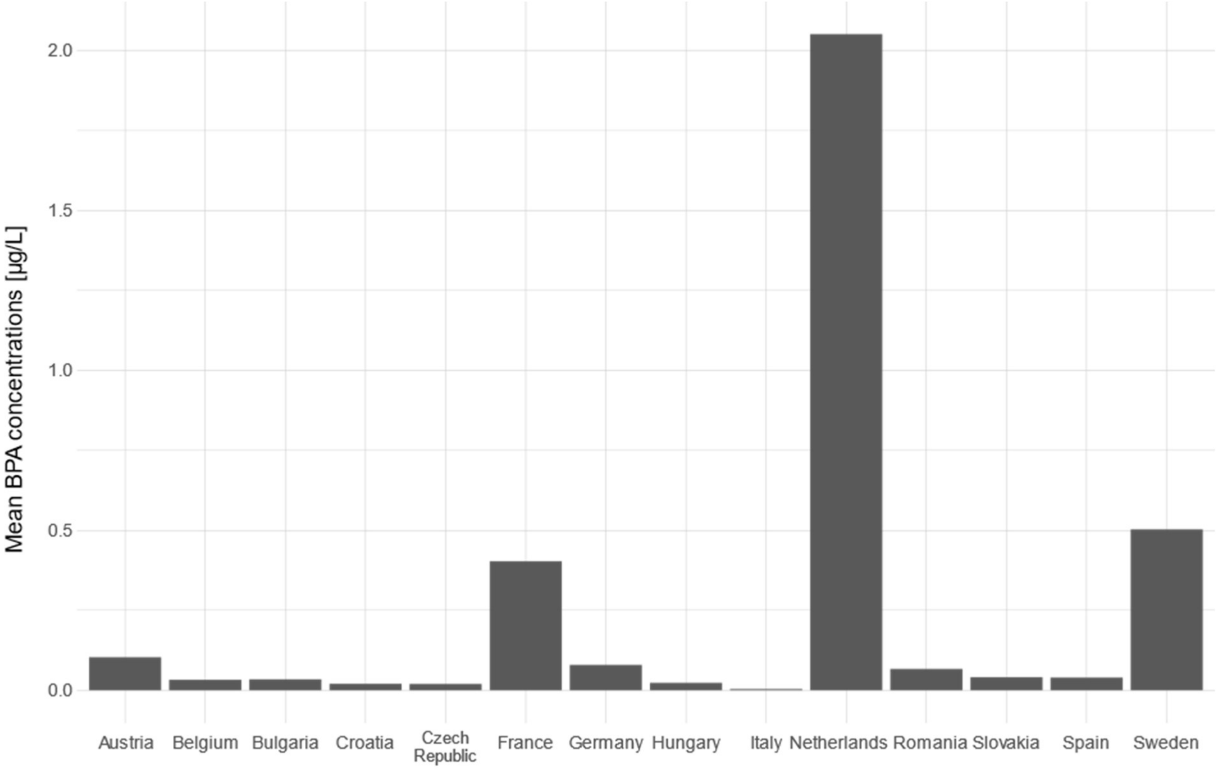
Monitoring data from environmental compartments

Monitoring of BPA and bisphenols in the human body and in environmental compartments and organisms shows that releases and exposures of these substances occur continuously.

BPA is widely used and therefore ubiquitous to be found in all environmental compartments (freshwater, marine water, soil, biota, sediment, sewage sludge, air/dust). Variations occur, for example, according to season, location and the sample examined (water, tissue, soil, sediment, air). This leads to the reasonable assumption that releases of BPA from articles or mixtures happen during their application and service life.

A review by Staples et al. (2018) compiled data on the occurrence of BPA in European freshwater (1996-2014) based on the NORMAN EMPODAT database (accessed 2016) and published literature/governmental reports. The results for Europe showed overall median concentrations of 0.029 µg/L (n = 3,675; 95th percentile: 0.3 µg/L), whereas concentrations in North America (n = 805; median: 0.005 µg/L; 95th percentile: 0.3 µg/L) were lower. Further environmental data on the occurrence of BPA in European surface waters showed compared to Staples et al. (2018) lower median concentrations (0.01 µg/L), whereas the 95th percentile was broadly similar (n = 848; 95th percentile: 0.35 µg/L; European Commission (2008). The dossier submitter accessed data from NORMAN database (NORMAN, 2022) for making a European temporal assessment of BPA trends in surface waters but focused on data from Germany (18,009 data points (2003-2020) as only limited data was available for other European countries. The presentation in Figure **7** below includes the range of years and number of data points. The data was extracted from NORMAN (2022) (n = 26,069, access 02/2022). For Germany, additional data points were added from federal monitoring programs (n=3,028, 2016-2019) (LAWA, 2020). Concentrations below the limit of detection were replaced with zero. The mean concentration in the Netherlands is strongly influences by a single data point (3,124 µg/L, river Meuse). The complete data set for 14 EU countries showed a median concentration of 0.013 µg/L (mean: 0.279 µg/L) with a 95th percentile of 0.26 µg/L (26,069 data points).

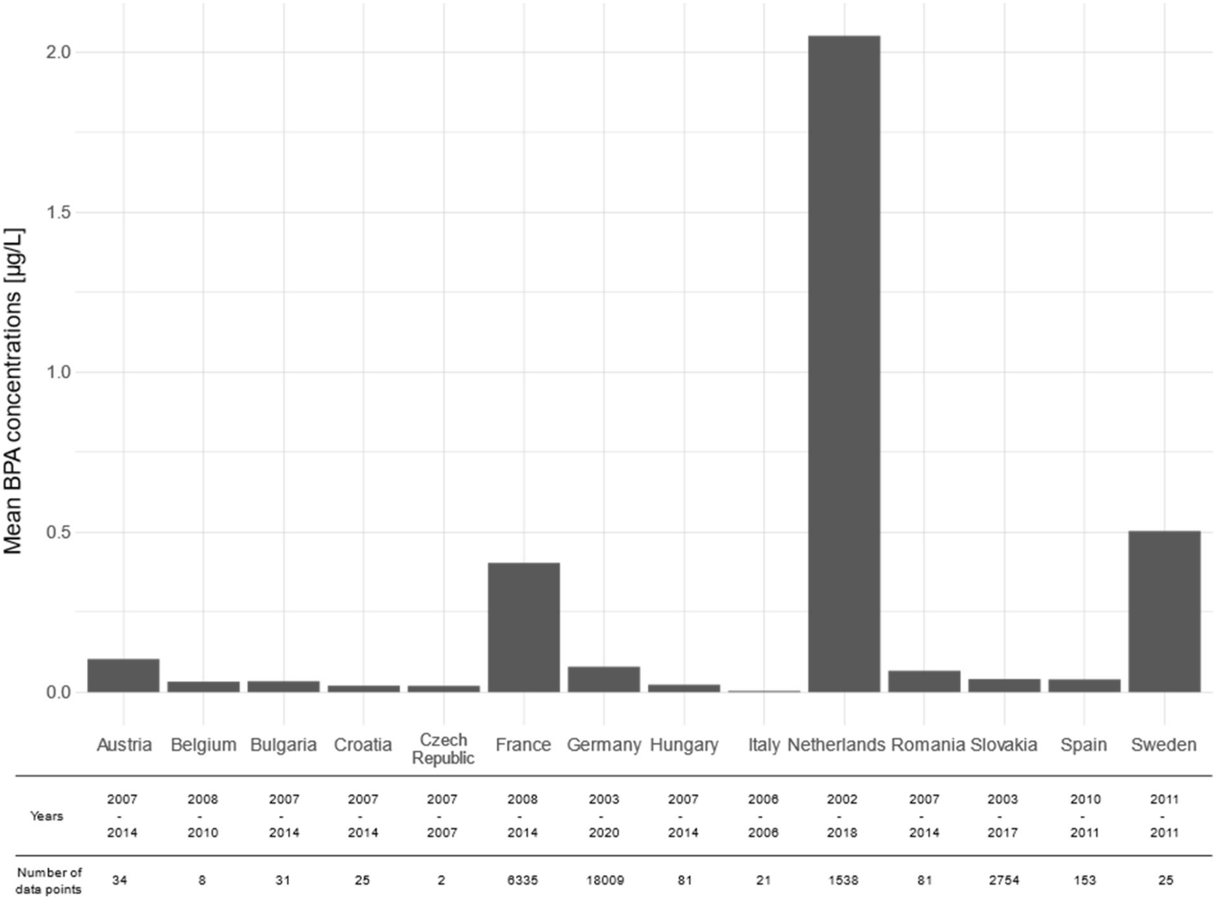




	Austria	Belgium	Bulgaria	Croatia	Czech Republic	France	Germany	Hungary	Italy	Netherlands	Romania	Slovakia	Spain	Sweden
Years	2007 - 2014	2008 - 2010	2007 - 2014	2007 - 2014	2007 - 2007	2008 - 2014	2003 - 2020	2007 - 2014	2006 - 2006	2002 - 2018	2007 - 2014	2003 - 2017	2010 - 2011	2011 - 2011
Number of data points	34	8	31	25	2	6335	18009	81	21	1538	81	2754	153	25

Figure 7: Mean BPA concentrations [µg/L] in European surface waters per country

A temporal assessment revealed that mean BPA concentrations were generally higher before 2015 and declined afterwards. However, one exception represents 2020, which shows concentrations in the same range as values before 2015. When comparing these values with those from Ramboll Deutschland GmbH (2022), the data before 2015 from NORMAN (2022) and LAWA (2020) were almost double as high. Both data sources report a decline of measured BPA concentrations in German surface waters after 2015. The table below lists concentration rances in surface waters of European countries after 2010 with at least 1000 data entries (for BPA) when combining NORMAN (2022) and LAWA (2020) (cf.



	Austria	Belgium	Bulgaria	Croatia	Czech Republic	France	Germany	Hungary	Italy	Netherlands	Romania	Slovakia	Spain	Sweden
Years	2007 - 2014	2008 - 2010	2007 - 2014	2007 - 2014	2007 - 2007	2008 - 2014	2003 - 2020	2007 - 2014	2006 - 2006	2002 - 2018	2007 - 2014	2003 - 2017	2010 - 2011	2011 - 2011
Number of data points	34	8	31	25	2	6335	18009	81	21	1538	81	2754	153	25

Figure **7**).

Table 61: Range of BPA and BosC concentrations (µg/L)

µg/L	**Germany (2010-2020)**	**France (2010-2014)**	**Netherlands (2010-2018)**		**Slovakia (2010-2017)**
NORMAN (+LAWA) - BPA					
Min	<MDL	<MDL	<MDL		<MDL
Max	9	725	3,141		9.91
Mean	0.06	0.42	3.15		0.05
n	4,215	6,104	1,001		1,036
NORMAN (+LAWA)- BosC – BPS					
µg/L	**Germany (2013)**	**Austria (2013)**	**Hungary (2013)**	**Romania (2013)**	**Slovakia (2013)**
Min	<MDL	<MDL	<MDL	<MDL	<MDL
Max	<MDL	0.21 (n=1)	0.27 (n=1)	0.14 (n=1)	<MDL
Mean	<MDL	<MDL	<MDL	<MDL	<MDL
n	16	17	25	49	14

International - BosC – BPS (only detects)									
µg/L	**France (2017)**	**Slovenia (2017)**	**Austria (2018)**	**China (2015)**	**China (2018)**	**China**	**China (2016/17)**	**China (2015)**	**China (2016)**
Min	0.037	0.168	<MDL	0.007	0.224	0.04	0.199	0.018	0.041
Max	0.205	0.352	<MDL	0.133	0.733	0.07	65.6	0.149	0.16
Mean									
n									
Source	Schmidt et al. (2020)	Česen et al. (2019)	Brueller et al. (2018)	Huang et al. (2020)	Zheng et al. (2019)	Wang et al. (2018)	Huang et al. (2018)	Wan et al. (2018b)	Liu et al. (2017)

International - BosC – BPF					
µg/L	**China (seawater) (2019)**				
Min	<MDL				
Max	0.00065				
Mean	0.00031				
n					
Source	Zhao et al. (2021)				

International - BosC – BPB (only detects)				
µg/L	**China (2016)**	**China (2016)**	**China (2016)**	**China (seawater) (2017)**
Min	0.018			0.00017
Max	0.046			0.0131
Mean		0.0073	0.0198	0.0015 (median)
n				
Source	Liu et al. (2017)	Yan et al. (2017)	Liu et al. (2017)	Zhao et al. (2019)

International - BosC – BPAF (only detects)					
µg/L	**China (2016)**	**China (seawater) (2019)**			
Min	0.11				
Max	0.14				
Mean		0.00024			
n					
Source	Liu et al. (2017)	Zhao et al. (2021)			

Abbreviation: MDL=method detection limit.

Sources of BPA in the aquatic environment are mainly related to wastewater treatment plant (WWTP) effluents despite the fact that BPA generally shows high removal rates (>70%). Extrapolations for Germany from 23 WWTP effluents from Ramboll Deutschland GmbH (2019) modelled BPA emissions ranging from 1,600-14,653 kg/a depending on the type of WWTP and stormwater protection. The second biggest source of BPA in German surface water in Ramboll Deutschland GmbH (2019) was sewage sludge (extrapolated: 6,758 kg/a), followed by landfills (extrapolated: 3,769 kg/a). For products, extrapolated emissions ranged from 13.2 kg/a in clothes to 28,601 kg/a in recycled PVC. However, thermal paper was expected to represent the most important BPA source for German surface waters (~534 tpa for Germany based on European market amounts). However, the extrapolations by Ramboll Deutschland GmbH (2019) are based on a small sample number of the respective matrices and e.g. the total number of landfills in Germany is unknown. Interpretation, especially for European emissions, therefore warrants caution. Recently, Ramboll Deutschland GmbH (2022) assumed that emissions from paper recycling and the use of articles that contain recycled paper are the most important source for BPA in surface water, while emissions from thermal paper are neglectable. In future, the model of Ramboll Deutschland GmbH (2022) predicts that landfills will be responsible for the majority of emissions (53%) followed by consumer uses while assuming that BPA will disappear from the paper recycling chain. However, it is important to mention that the modelling results are based on specific assumptions (e.g. not considering point pollution) and does not consider that the global demand for BPA is expected to grow in future (see Annex D: Baseline). Furthermore, zero emissions from paper procession seem unlikely. Therefore, Ramboll Deutschland GmbH (2022) may underestimate future BPA emissions in surface waters.

BPA emissions not only result in environmental contamination of surface waters but also of sediments and suspended matter as BPA can adsorb to sold matrices in aquatic compartments. For sediments, the pattern of BPA is similar to surface water with freshwater sediments showing higher concentrations than marine sediments. Only a few studies investigated BPA contamination in soil. BPA has shown to be frequently detected in agricultural soils but a clear link to biosolid application could not be established by Gewurtz et al. (2021). Similar to soil, there is limited information available on BPA in the atmosphere, where BPA can be detected despite its low volatility as a result of e.g. open burning of plastics in household or electronic waste. A matrix that shows a particular high BPA concentration represents indoor dust, which is expected to result in human exposures and WWTP exposures. For humans, BPA is frequently detected (up to 100%) in urine and blood samples in humans from industrialised countries. Furthermore, infants are already exposed to BPA, which demonstrates a widespread BPA contamination in humans. In a study on Danish young men, urinary BPA concentrations decreased between 2009-2017, while detection rate of BPS and BPF increased (Frederiksen et al., 2020). This example underlines the necessity of considering BPA together with its replacement substances in order to assess environmental emissions.

In biota (wildlife), BPA is less frequently detected compared to human, which may be related to the large variety of analyzed species and matrices. In general, sample numbers are lower compared to e.g. surface water, which in combination with analytical differences complicates the assessment of BPA in biota. For example, BPA is only occasionally detected in muscles of fish, whereas BPA shows higher detections rates in more polar matrices such as bile and blood. However, BPA was also found in liver, which may be related to the fact that the liver is the metabolic most competent organ. In the LIFE Apex project, BPA was only occasionally detected in muscles of fish (NORMAN, 2022), whereas other studies detected BPA in up to 90 and 100% of caught fish (Mita et al., 2011; Staniszewska et al., 2014).

Monitoring data from human – Emission to environment via man

The global average use of plastics is 45 kg per person per year. Western Europe (Europe excluding central Europe and the Commonwealth of Independent States) uses three times as much — around 136 kg per person.[115] For this reason, it seems not surprising that components of plastics are found in the human body and excreted. The mass of consumption in western countries also suggests that BPA is being released from humans into the environment. Human exposure to BPA is mostly caused by diet (about 90%). The exposure through dust is considered to be a minor exposure source [116]. As described by the EFSA scientific opinion[117], BPA is used as a monomer for the production of plastic food contact materials, in accordance with Commission Regulation (EU) No 10/2011/EU on plastic materials and articles intended to come into contact with foodstuffs[118]. Environmental sources can include surface water (during swimming) and outdoor air (inhalation of aerosols). In addition, BPA from epoxy-based floorings, adhesives, paints, electronic equipment and printed circuit boards may be released into indoor air (including airborne dust) and dust. Environmental sources can potentially contribute to oral and dermal exposure, as well as inhalation to BPA.

Several studies investigated the content of BPA in indoor dust in private houses as well as public places. The majority of studies detected BPA in 100% of samples (Caban and Stepnowski, 2020; Dueñas-Mas et al., 2019; Liv Bruås Henninge, 2020; Velázquez-Gómez et al., 2019; Wang et al., 2015). Median concentration values range from 0.6 [µg/g] in private homes (n=23) (Wang et al., 2015) to 43.3 [µg/g] in a museum (n=6) (Velázquez-Gómez et al., 2019) and tend to be higher in samples from public vs private spaces (Velázquez-Gómez et al., 2019). Within the studies that are based on a relatively high sample size, similar median concentrations were found:

- 1.2 [µg/g dw] in dust at private homes in Norway (n=57; 95th%ile: 5.1 [µg/g dw]) (Liv Bruås Henninge, 2020)
- 1.3 [µg/g dw] in dust at preschools in Sweden (n=100; 95th%ile: 11 [µg/g dw]) (Larsson et al., 2017)
- 1.5 [µg/g dw] in house dust in Greece (n=28) (Wang et al., 2015)
- 1.5 [µg/g dw] in house dust in Barcelona, Spain (n=11) (Velázquez-Gómez et al., 2019)

Indoor floor mopping and laundry transfer some of the indoor BPA contamination to wastewater. In addition, human intake of dust leads to BPA transport via men to WWTP.

In its risk assessment (EU 2010, p. 246), the European Commission calculates the following "worst case" intake levels for bisphenol A:

- Infants (6 - 12 months old): 40 micrograms of BPA per day.
- Infants (1.5 - 4.5 years old): 200 micrograms of BPA per day

---

[115] Plastics Insight, 2016, 'Global consumption of plastic materials by region (1980-2015)', Market statistics (https://www.plasticsinsight.com/globalconsumption-plastic-materials-region-1980-2015/) accessed 17 January 2020.

[116] K. Larsson, C.H. Lindh, B.A. Jönsson, G. Giovanoulis, M. Bibi, M. Bottai, A. Bergström, M. Berglund Phthalates, non-phthalate plasticizers and bisphenols in Swedish preschool dust in relation to children's exposure
Environ. Int., 102 (2017), pp. 114-124, 10.1016/j.envint.2017.02.006

[117] EFSA scientific opinion: DOI: https://doi.org/10.2903/j.efsa.2015.3978

[118] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. OJ L 12, 15.1.2011, p. 1 – 89

- Adults: 100 micrograms BPA per day (excluding wine consumption)
- Adults: 600 micrograms BPA per day (including wine consumption)

EFSA reassessed consumer exposure to BPA in 2013. (Packaged) food is - in agreement with the EU and UBA - the most important source of BPA, followed by thermal paper (for all population groups aged over three years, thermal paper was the second most important source of BPA after diet-potentially accounting for up to 15% of total exposure in some population groups). It was found that BPA consumer exposure is lower than previously estimated. In the reassessment from 2015 the following exposure values were detected:

For infants from 1 day up to 6 months, the average internal exposure to total BPA, as estimated by forward modelling, ranged from 0.042 µg/kg bw per day to 0.226 µg/kg bw per day. The average internal exposure for the population older than six months ranged from 0.301 to 0.387 µg/kg bw per day in children aged 3 to 10 years and infants aged 6 to 12 months. The adolescent and elderly/very elderly show an internal exposure concentration from 0.124 to 0.172 µg/kg bw per day. The average external exposure to BPA from non-dietary sources such as toys and cosmetics was estimated by EFSA to be less than 0.001 µg/kg bw per day and 0.005 µg/kg bw per day, respectively, in all population groups[119].

The results of the HBM4EU[120] monitoring study in 2020 show following measured values in urine:

- in children, the weighted geometric mean (95% CI) for urinary BPA was 1.97 µg/L (1.81-2.15) in the total European study group
- in mothers, it was 1.78 µg/L (1.62-1.94)

With respect to the excretory potential, the geometric means of BPA result in 1.97 µg/day (1000 mL urine/day) for children and 2.67 µg/day for adults (1500 mL urine/day). 448 Mio. inhabitants in the EU[121] 19% children[122] and 81% adults results in a release of 0.168 kg BPA/day from children and 0.969 kg BPA/day from adults. This is in total are release of BPA from humans of 1.137 kg BPA/day and 0.415 t BPA/year.

Due to the occupational exposure of cashiers to BPA via thermal paper, urinary biomonitoring studies detected even higher median concentrations of free BPA in urine of cashiers, e.g in France: 8.92 µg/L (n=90, 95th percentile: 44 µg/L, max: 1915 µg/L) (Ndaw et al., 2016).

B.8.1.2. BPA contents

During the literature search for emission rates that could be extracted, standardized and used for the mass flow model of BPA, several publications were identified which were not suitable, but still provided information on residual BPA contents in polycarbonate (P1) and epoxy resins (P2). While their information could not be used to obtain standardized emission rates, it still provides a rough but useful insight. The results of the literature search are summarized in this section.

---

[119] EFSA scientific opinion 2015: https://www.efsa.europa.eu/de/efsajournal/pub/3978

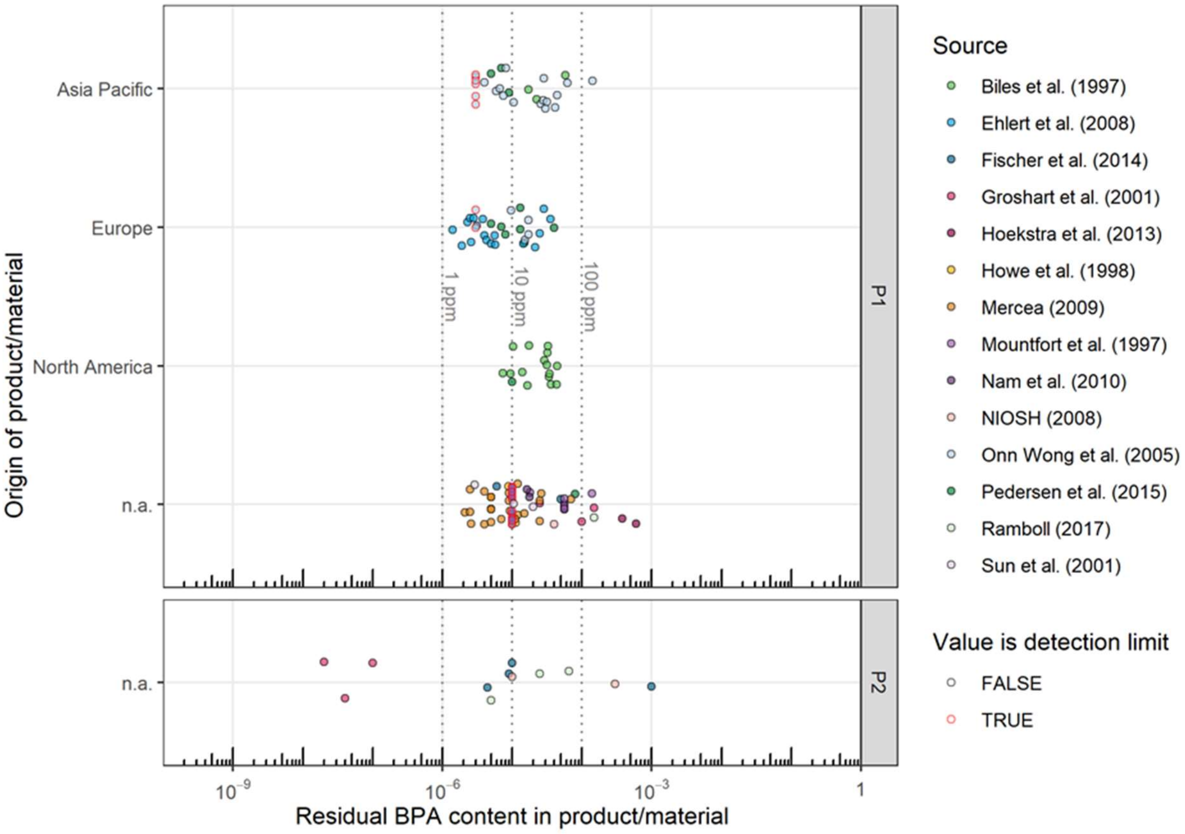
[120] HBM4EU deliverables: https://www.hbm4eu.eu/wp-content/uploads/2021/02/HBM4EU_AD5.4_Reporting_first_and_second_set_substances_v1.1-1-Bisphenols.pdf

[121] https://de.statista.com/statistik/daten/studie/164004/umfrage/prognostizierte-bevoelkerungsentwicklung-in-den-laendern-der-eu/

[122] https://de.statista.com/statistik/daten/studie/1023033/umfrage/anteil-der-kinder-und-jugendlichen-weltweit-nach-kontinenten-und-altersgruppen/

It is not clear-cut how to precisely separate and measure amounts of BPA that were or were not bound/fixed in the polymer matrix. Accordingly, the measurement methods differ between studies. Furthermore, some of the extracted data are not measurements from studies at all, but rather statements from the industry. What all these values have in common, however, is that the authors state that they represent estimates of the residual BPA content in the respective polymer. Notice that some publications even differentiated between different countries/regions regarding the articles' origin, which allows for an even more informative result**Error! Reference source not found.**. Figure 8 shows that most measurements/estimates for residual BPA in P1 and P2 lie below 100ppm. These findings are in accordance with Fischer et al. (2014) who stated that the residual content in P1 is typically < 10 mg/kg (i.e. < 10ppm). In addition, industry reported that P1 contains a maximum of 100ppm residual BPA (EC JRC 2010). It can be argued that there is no obvious difference between the origins of the products regarding the residual BPA content.

Figure 8: Extracted data on residual BPA content in BPA-based polymers



In Figure 8 above, for every BPA content reported as non-detectable, the detection limit of the respective detection method was assumed instead - these values are shown as circles with a red outline and may thus in reality be lower than displayed (Source: BioMath based on data from : Biles et al. 1997; Ehlert et al. 2008; Fischer et al. 2014; Groshart et al. 2001; Hoekstra et al. 2013; Howe et al. 1998; Mercea 2009; Mountfort et al. 1997; Nam et al. 2010; NIOSH 2008; Onn Wong et al. 2005; Pedersen et al. 2015; Ramboll Environ 2017; Sun et al. 2001).

There are further sources that providede information on this matter, but were not directly transferrable to be used. Ali et al. (2019) found 0.04 ± 0.07 ng residual BPA/mL 50% ethanol in water after shaking the solution inside 15 P1 baby bottles for one minute. Kosaka et al. (2012) report concentrations in ng BPA / l tap water from 24-month continuous leach tests with P2 pipes. Finally, two good overviews in all identified sources on any measurements of BPA contents can be found in the section "Release and exposure of BPA" in Geens et al. (2012) and Table 1-3 in Hoekstra et al. (2013).

Groshart et al. (2001) points out that given a residual BPA content, there may only be a migration rate of 10% and that "according to polycarbonate producers a migration level of < 10 ppb is more realistic".

<u>Examples for BPA concentrations in products</u>

The following mixtures and articles, which have been marketed and tested for BPA content, are intended to show that there is evidence of the potential for the release of BPA from products.

Table 62: BPA concentrations in selected products (Ramboll Deutschland GmbH, 2022)

article/mixture	concentration [µg/kg]	concentration [ppm]	notes on environmental release potential
socks	41	0.041	surface water via WWTP due to washing
banners	298	0.298	every environmental compartment due to weathering
rigid pipes/fittings	1.73	0.002	every environmental compartment depending on location used (e.g. under ground, in water)
tyre shred	431.7	0.432	soil, water (e.g. use on soccer pitch)
recycled PVC granules from a hose	<0.5	0.001	use dependent
protective varnishes	2.8	0.003	use dependent (soil, water)
synthetic oil-based inks	839	0.839	soil, surface water
newspaper printing ink	<0,5	0.001	surface water due to recycling of paper
garden hoses	1,148	1.148	soil and surface waters due to weathering outdoor
vegetable oil-based inks	2,881	2.881	soil, surface water
posters	5,743	5.743	soil, surface waters due to weathering outdoor and recycling
cables	6,701	6.701	soil, surface waters if installed outdoor
shower curtains	10,914	10.914	surface water via drain and WWTP
compost bags	11,473	11.473	soil
newspaper printed	12,564	12.564	surface water due to recycling of paper
newspaper blank	13,989	13.989	surface water due to recycling of paper
inks UV-colour	20,230	20.230	surface water due to recycling of paper

toners	22,110	22.110	no direct contact with water (environment affected via man du to inhalation, dermal contact and excretion)
toilet paper	48,409	48.409	surface water via drain and WWTP
toilet paper tube	47,561	47.561	surface water due to recycling of paper
PVC granules	204,810	204.810	soil, surface water as second raw material depending on foreseen use (e.g. cable)
thermochromic inks	4,605,000	4,605	soil, surface water depending on foreseen use (e.g. textile, poster)

In the following table, higher-level uses or groups are derived on the basis of BPA and these are shown together with the BPA amount applied therein.

Table 63: Information on main use and function with the typical amount of BPA applied

Objective	**Use and function**	**BPA amount applied**
Production of other chemicals (C)	**C1** production of bisphenol A diglycidyl ether (BADGE/DGEBA) to polymerise epoxy resins	67%
	C2 production of tetrabromobisphenol A (TBBPA) to produce flame retardants	42%
	C3 production of bisphenol A diglycidyl ether dimethacrylate (Bis-GMA)	45%
	C4 production of bisphenol A dimethacrylate (Bis-DMA)	63%
	C5 production of ethoxylated bisphenol A diacrylate (Bis-EMA)	42%
	C6 production of bisphenol A dicyanate (BADCy)	82%
	C7 production of polyols	35%-65%
Additive (A)	**A1** inhibitor for the polymerisation of PVC	< 0.1%
	A2 antioxidant to prevent thermolysis and oxidation in PVC processing	< 0.1%
	A3 antioxidant to prevent thermolysis and oxidation when producing plasticizers intended for use in PVC	0.5%
	A4 stabilizer to prevent oxidation (mainly for PVC)	< 0.1%
	A5 developer in thermal paper	1%
	A6 hardener in epoxy resins	n.a.
	A7 flame retardant in polymers	25%
	A8 stabiliser to prevent oxidation in chain oil	0.1 - 1%
	A9 stabiliser to prevent oxidation in break fluids	0.2%
	A10 stabiliser to prevent oxidation in heat transfer fluids	< 1%
	A11 stabiliser to prevent oxidation in lubricant formulations	0.1 - 1%
	A12 stabiliser to prevent oxidation when producing tyres	0.037%

Polymerisation	**P1** polymerisation of polycarbonates	89%
	P2 polymerisation of epoxy resins	50%
	P3 polymerisation of polysulfones	52%
	P4 polymerisation of polyarylates	according P9
	P5 polymerisation of polyetherimides	39%
	P6 polymerisation of unsaturated polyesters	54%
	P7 polymerisation of benzoxazines	66%
	P8 polymerisation of phenolic resins	61%
	P9 polymerization of dental resins	Bis-GMA 29% Bis-DMA 41% Bis-EMA 27%
	P10 polymerisation of polycyanurates	n.a.
	P11 polymerisation of polyurethanes	17,5%-32,5%
	P12 polymerisation of vinyl ester resins	15 – 22%
	P13 polymerization of polyacrylates	5 – 30%

Source: Annex H

The content does not allow a direct statement regarding the extent to which BPA can be released. As soon as a matrix inclusion passes through covalent bonding (hardener e.g. crosslinker/inhibitor), the release is low in the resulting product. The release potential is higher in any case for pure additive use, since there is no reaction with the matrix here, but only inclusion in the matrix. The retention is then only limited by physical forces (e.g. stability of the matrix, pore size).

BosC may be used as a substitute for BPA in the uses listed above, or they may be used as an additive, monomer/reactant or in the manufacture of chemicals without substituting for BPA, or in a different function from that specified (P other/A other/C other). The functions of BosC are less specifiable because there is less data to specify them. As a generic approach, it is assumed that the total tonnage of BosC is 1% in relation to that of BPA (see Dossier Annex A). For this reason, BosC, as far as known, are treated very generally here. In addition, stakeholder information is used.

The content of bisphenols (BPA and/or BosC) in the final product and the amount which can be released, depend on the type of use, the concentration originally used and to which extend the material consisting of the bisphenolic monomer/reactant and/or containing bisphenols as an additive is protected. The likelihood of a release depends on whether it is a direct, environmentally open outdoor application or an indirect emission due to indoor use or the release of BPs from articles during service life regardless of whether embedded in a matrix or applied as an additive. The content alone does not provide an indication of the release potential. The content of BPA/BosC in article, combined with the quantitative distribution of the use (e.g. everyday articles) gives an indication of an increased potential for distribution and release if it permeates all areas of life. For additive uses, for example, it is the case that concentrations are basically low, but since they are not matrix-bound manner but, e.g. applied in a mixture, their release is more likely. From a chemical point of view, release is possible from all areas of application of BPA and/or the BosC.

B.8.1.3. General discussion on releases

Information sources

Mainly, evidence-based data (what is meant here with evidence based data are data from publicly available sources, compiled in the context of the research project on BPA (see Annex H) were used to determine the environmental emission after the study of BPA. With worst-case assumptions according to the use descriptor system (ECHA guidances on information requirements R.12/R.16) led to overestimated data. The generalistic release assessment cannot be related to the current average environmental concentration. Furthermore, there are hardly any data available for BosC, so that ultimately a pragmatic exposure assumption was chosen, which is based on the quantitative proportion of BosC in relation to the total registered tonnage of BPA. In addition, this data was supplemented by information from stakeholders from the call for evidence. This also applies to the evidence-based data for BPA. The following data sources were used mainly.

Table 64: Sources for information and evidence

Source	Bisphenols	Date	Main information on
registration dossiers **(IUCLID)**	BPA/BosC	latest updates 2022	ERC, worst case scenarios indoor, outdoor – consumer, professional, total EU wide emissions
Substance flow analysis (SFA) **(Fischer et al. 2014)**	BPA	2014	emission pathways, monitoring
Substance flow analysis (SFA) and regionalized pathway analysis (RPA) for emissions of bisphenol A (BPA) into the environment **(Ramboll Deutschland GmbH, 2022)**	BPA	2022	Article concentrations, sewer pathway, emission from EOL
FKZ 3719654060 (Annex H)	BPA	2018-2020	evaluation of any release data from literature, evaluation of any release data detection of all relevant uses
CfE 2x **(Annex G)**	BPA & BosC	2020-2022	confidential information from sites, sectors, single uses
Stakeholder information (e.g. NGO, association information)	BPA & BosC	2018-2022	confidential information from sites, sectors, single uses

The different data sources have different data focuses, as well as different levels of detail, for example in relation to specific uses by company. The focus of the registration dossier is on the presentation of safe use. The 2014 material flow analysis aimed to complete the general sources of release and emission of BPA. SFA and RPA from Ramboll show evidence for individual contributions from products and life cycle contributions. Annex H summarises all publicly available evidence for BPA and the resulting release and emissions. The CfE was used to obtain information from sectors or specific to sites or product types. Other stakeholder information shows additional data on, for example, release.

BPA

BPA has been regularly monitored in environmental compartments for well over a decade. Since then, the question has arisen as to the source of the emissions, the plausibility of emission pathways and which application(s) are responsible. Even in the 2014 substance flow analysis (Fischer et al., 2014), the emission sources could not be limited to only a few uses. This study showed that there are a large number of possible emitters. Also, with information from this substance flow analysis it was possible to provide a first overview of individual sites where the release can apparently be well explained. The German Environment Agency (UBA) also commissioned evidence-based research to compare actual release potentials and emissions with environmental concentrations. The substance flow analysis studies show that potential emitters of BPA are also landfills and the paper processing industry, as well as the environmentally friendly use of recycled materials in the form of, for example, traffic safety equipment for which recycled PVC is used beneath polymeric articles/plastics releasing BPA. However, the data are limited to individual sites in Germany and should not be generalised to the whole EU. Through various studies it has become clear that the individual release potentials e.g. from articles made of polymers or that are coated are small, but in their totality, they fit very well with the data found in monitoring studies (see therefore summary at the section 9.3 of this Annex). The previous chapters have shown the high market volume of bisphenol A, its ubiquitous use, and the multiple areas of life simultaneously permeated by materials made of/with BPA.

In the following, an allocation of release potentials with regard to the manufacturing and processing step and applications by sector and material for BPA is presented. A more detailed analysis with regard to individual uses is not possible, as a certain use may occur in several sectors or different uses in one sector. This would be a complex way to generate data that has many uncertainties and differs from downstream user to downstream user. In addition, there are many companies in various industries (see Appendix A) which process BPA or BPA-containing products or mixtures. As an example, an interior design company may work with BPA-containing mixtures to make epoxy floors or apply coatings by brushing, cut BPA-containing products such as polycarbonate sheets or epoxy coated products with BPA-containing adhesives and also paint with BPA containing/releasing paints.

The aim is to primarily describe the release potentials by application and the type of material in the three main uses:

- polymers (P),
- additives (A),
- other chemicals (C).

With this assessment it is the aim to identify the level of emissions through the release rates in order to be able to derive the reduction potential of the restriction. Various data and approaches are available for emission/exposure assessment. The evaluation of all available evidence-based data was considered useful. Here, the monitoring data were intersected with the available information on uses and contents, as well as on the release potential.

BosC

For BPA, a broad and structured database is available. For BosC, it is different. The exposure assessment for the other BosC, which are also addressed by this restriction besides BPA, is mainly based on the information from the registration dossiers and the quite new information from the two "Call for Evidence"-processes (see Annex G, as well as the description of uses in Annex A). According to what is known from research, science and application, other bisphenols are sometimes also used in the same function as BPA: in the production of other chemicals (C), in the production of polymers (P) or also plastics or as additives (A) in mixtures and articles. In many cases, they are used as drop-in substitutes to replace BPA in processes and products because of their structural similarity.[123,124,125] For bisphenols of similar concern, it is thus possible to assign information on the amounts used to the main uses for

- polymers (P),
- additives (A) and
- use in the manufacture of other chemicals (C).

However, BosC are also used without being a substitute. A specification of the function is partly done by means of examples. More precise information for the uses is not always possible, as less data is available for BosC than for the use of BPA.

B.8.2. Summary of the existing legal requirements

Due to its status as an SVHC (based on its properties as a reproductive toxicant and ED for the environment and human health) and with the harmonised classification H400 and H410 for the environment, BPA is regulated in different legislations. This substance is thus regulated on a media, substance and product basis (for further details see Annex C).

Under REACH, BPA was already proposed for restriction by the FR CA in 2016 based on risks identified for human health. The restriction concerns the use in thermal paper (TP), where BPA is used in the ink developer layer. Entry 66 in Annex XVII to Regulation (EC) No 1907/2006 became legally effective in January 2020 and states: [BPA] "Shall not be placed on the market in thermal paper in a concentration equal to or greater than 0.02% by weight after 2 January 2020."

According to article 7 of the REACH legislation and the, there exists a notification obligation for articles with a higher content of SVHC than 0.1% w/w. With the "Guidance on requirements for substances in articles" it is shown how SVHC in articles (SiA) need to be addressed in the article supply chain. This requirement has no clear regulatory impact, but as is known from discussions with stakeholders, this leads to an internal industry "blacklist". Therefore, this may also contribute to substitution pressure.

For structurally analogous bisphenols with a similar concern no legislation due regulate them at the moment, except BPS. BPS is currently authorised under Regulation (EU) No 10/2011 to be used as a monomer in plastic food contact materials (FCM) with a Specific Migration Limit (SML) of 0.05 mg/kg food.The European Commission (EC) asked EFSA to assess the impact on the current authorisation of BPS in plastic FCM of the newly generated studies submitted by the registrant(s) of BPS in response to ECHA's decision on the substance evaluation under the REACH Regulation (EC) No 1907/2006.[126]

---

[123] Cf. Annex H

[124] https://echa.europa.eu/de/-/bisphenol-s-has-replaced-bisphenol-a-in-thermal-paper

[125] https://www.umweltbundesamt.de/publikationen/bewertung-des-endokrinen-potenzials-von-bisphenol

[126] https://www.efsa.europa.eu/en/supporting/pub/en-1844 (accessed 2022/20/09)

For the environment, it is not reasonable or possible to derive safe conditions of use for BPA and BosC. As substances that show endocrine effects on environmental organisms does not have a safe threshold level. The only way to safely handle BPA, or to avoid the ban on handling of BPA and BosC, is to show that the emissions to the environment are negligible or lead to undetectable values in the environmental compartments.

B.8.3. Summary of the effectiveness of the implemented operational conditions and risk management measures

The number of regulatory areas already show that bisphenol A needs regulation in general. The following monitored BPA concentration trends in environmental media, especial surface water (most affected compartment) show that BPA is still present in the European surface waters (see also B.8.1).

Monitoring-Data

With regard to the environment, there have been few concrete specifications of migration values so far, despite the fact that BPA is found in all environmental compartments and biota. In principle, all regulations may have an effect on the amounts of BPA that enter the environment. The less BPA is released from manufacturing and use, the lower the environmental impact. For the environment, deriving safe use conditions for bisphenol A is impossible. A substance that shows endocrine effects on environmental organisms does not have a safe threshold level. The only way to safely handle BPA, or to avoid the ban on handling BPA, is to show that the emissions to the environment are negligible or undetectable in the environmental compartments. Therefore, if regular monitoring can show that there are no more BPA findings in the environment, the proposed restriction can be considered a success.

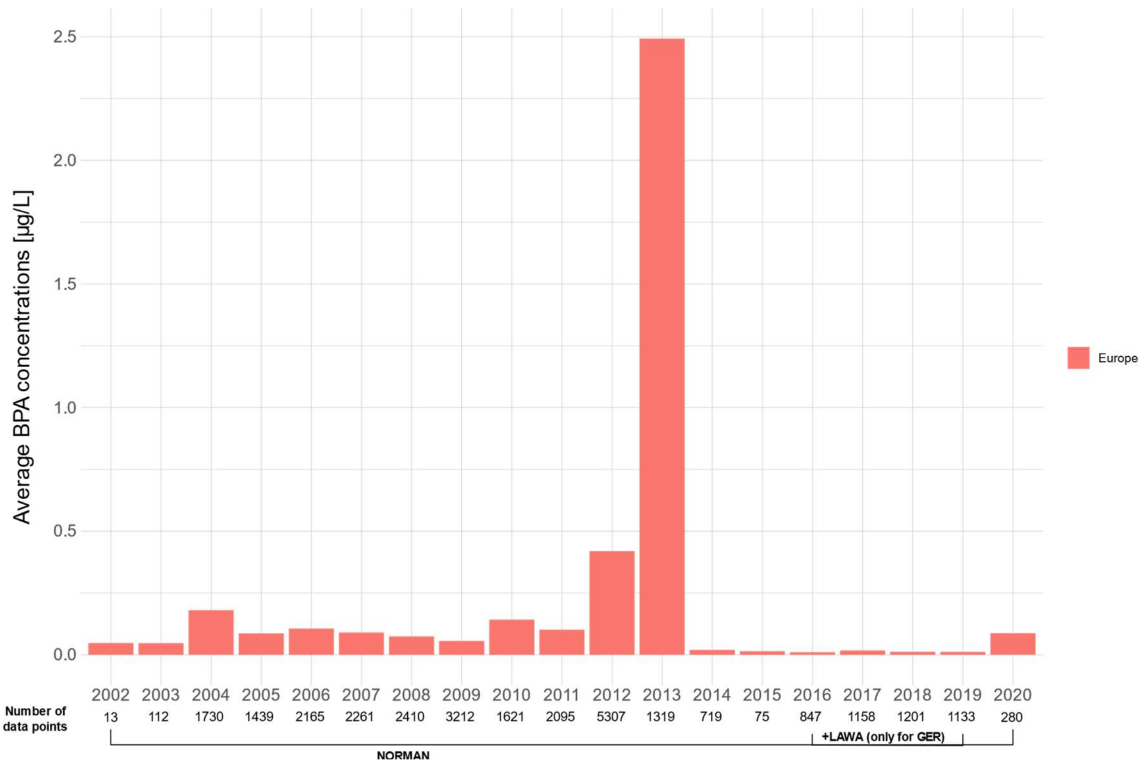


Figure 9: Average BPA concentrations [µg/L] per year in European surface waters.[127]

Figure 9 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 clearly measurable concentrations were still present in 2020 (for more information, see Appendix B.4).

The aim of this restriction is to reduce the release and emission of BPA and the BosC. First, the release potentials during the lifecycle of BPA/BosC (and the resulting mixtures/articles) have to be determined. In the next step the resulting emissions have to be compared with the reduction potentials by limiting the content of free BPA (e.g. as residual or through reversion) together with migration limits in a tired approach.

<u>Restriction on thermal paper (since 2020)</u>

For the sake of this dossier, it is assumed that the restriction of BPA in thermal paper (TP) is tantamount to a ban on its use and that BPA is substituted for this use. Emissions into the environment may be reduced accordingly. Uncertainty exists with regard to a lack of information on the decrease of BPA concentration in recycling paper still containing TP with residual BPA and the respective time frame. What is the time frame for the decline of the BPA content in the paper recycling cycle? Are only waste paper and cardboard from the EU processed or are there material flows that bring BPA into the EU paper recycling process? Detailed monitoring can provide information on this. BPA also plays a role in printer inks and paper/cardboard coatings, which is why the the TP restriction on the BPA content in recycling paper has a huge influence on environmental concentrations, but there are still other sources leading to release of BPA from the paper circle. Ramboll (Ramboll

---

[127] Summary statistics are given in Table 2. Countries that contributed data to the NORMAN Empodat database are listed in Figure 4 (see chapter 9.3)

Deutschland GmbH, 2022) has shown that the BPA concentration in wastewater is indeed decreasing during study, but that the substance can still be found. Another critical aspect for thermal paper is the substitution of BPA with BPS (and/or BosC). ECHA showed that while the quantities of BPA used in TP are decreasing, the quantities of BPS are increasing markedly.[128] 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.

Table 65: Developer used in thermal paper placed on the EU market (in tpa)[129]

developer	2014	2015	2016	2017	2018	2019	% growth from 2018 to 2019
Bisphenol A	2799	2784	2606	2776	2516	956	-62%
Bisphenol S	150	125	200	397	678	1626	+140%

Note on paper articles:

Even if a significant decrease of BPA release from TP can be expected, it has to be taken into account that it takes some time until BPA is actually removed from the material cycle (experience shows 4-5 years), and that other paper products also contain BPA, for example through paper finishing and printing action, and this gets into the environment during the recycling process. However, a precise quantification of the contribution of BPA or BosC from printing inks and paper finishing in general is impossible due to a lack of data.

B.8.4. General assumptions on releases and the emission characterization

Detailed information on release and emission with regard to BPA and BosC is contained in the registration dossiers. For BPA, the environmental release data from the registration were contrasted with evidence-based data from the review research initiated by UBA (2018-2020) (Annex H). Despite the fact that the evidence-based data show gaps in the representation of lifecycle emissions, these total emissions data show the best fit with the monitored data. In this exposure/emission assessment, the presentation of evidence-based data shows that emissions can affect all compartments in the environment and occur in all types of applications.

The general standard release factors and thus the release probabilities differ for the applications (industrial, commercial, residential) and contribute to the differentiation into the respective environmental release categories (ERCs). The description of release rates by ERCs is correct at this point, however the generic release default values overestimate the release probability of polymers. Therefore, the assumption of release potentials by various studies is considered acceptable and meaningful, as these values can be used to conclusively confirm the emission in the EU in comparison with monitoring data. In the

---

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

[129] by ETPA members in 2014-2019 (source: https://echa.europa.eu/documents/10162/2564887/bpa_thermal_paper_report_2020_en.pdf/59eca269-c788-7942-5c17-3bd822d9cba0 (2021/24/08))

following, the ERCs are nevertheless discussed in order to overlap them with the sectors and to discuss them together with the information from industry on release probability.

The focus of this chapter is on processing and service life. In the use phase, the articles (BPA used as monomer or additive) in their application are addressed as well as the ready-to-use mixtures (BPA used as monomer or additive). The reduction potential in the manufacture and formulation of BPA lies more with the Industrial Emissions Directive (IED, Directive 2010/75/EU). With the registration dossier measures are presented that effectively prevent emissions into the environmental compartments. The end-of-life (EOL) step is also, in terms of the process, outside REACH. Nevertheless, the restriction on release (and emission) and thus also on content has an effect on the EOL. Products made from recycled material (manufactured with BPA/BosC) should also be able to release less BPA/BosC). When the recycled materials re-enter the service life are they subject to the specifications of this restriction. However, the restriction does not have an effect on the current release from landfills. For more information on risk reduction capacity see Annex E.5.

Release potential from mixtures

The release potential of BPA and BosC from mixtures results from the application of the mixtures. The first focus is on the actor processing or using the mixtures. Professional users, on the one hand, exhibit trained and practised handling of hazardous mixtures. Consumers tend to be untrained or inexperienced and are usually unaware of general protective measures. The second focus is on the place where the mixture is processed. When mixtures are used indoors (e.g. industrial use at a site), the potential for release is lower than when they are applied outdoors.

Release potential from articles

In general, releases from articles may occur independently from the type of application. The emergence of BPA as well as the release potential depends on e.g. additives used to protect the article or physical barriers like coatings used to protect the articles from migration of BP(A) and/or degradation (as long the coating is fully functional and ideally applied – the duration is depending of the application, but may no longer last more than 5 years). Also, the kind of condition or stressor (e.g. indoor; indoor with stressors like changing pH and/or; outdoor use with stressors like global radiation) influences material (degradation) behaviour. The releases shown in the current study on BPA levels in materials (Annex H) were assumed for emission potential.

Findings on sources and pathways of BPA from lifecycle

As there are still knowledge gaps about which specific sources and pathways are responsible for the release of BPA into the environment, a first modelling study (on behalf of the German Environment Agency (Fischer et al. 2014) was done. Here, investigations were carried out on the sources and pathways of BPA into the environment. In a second study (by Ramboll), research was conducted on the release of BPA from articles in the environment on behalf of the BPA-REACH consortium. In a third study (Ramboll Deutschland GmbH (2022)), the Plastics Europe PC/BPA Group commissioned Ramboll to conduct a follow-up project to further investigate the sources of BPA emissions to the environment and to fill data gaps.

This third study comprised three measurement campaigns:

1) Sampling of suitable wastewater treatment plants in Germany and sampling of influent, effluent and sewage sludge for BPA.

2) Sampling of suitable landfills in Germany and landfill leachate for BPA.

3) Sampling of suitable products for BPA.

The studies by Ramboll (1-3) have shown that the

1) the main receiving compartment is the water body (due to waste water)
2) BPA release due to paper processing and recycling plays an important role
3) the contribution to environmental release of BPA from polycarbonate (PC) and epoxy resins (ER) are negligible compared to other uses

These findings were considered to conclude on the scope and effectiveness of the restriction.

<u>End of life cycle (EOL)</u>[130,131,132]

BPA /BosC release during this life stage is relevant, because monitoring data show their occurrence e.g. from disposal, uncaptured or untreated landfill leachates (see chapter B.9.4.). The occurrence of hazardous substances in articles made from recycled materials need to be qualitatively assessed.

Plastics made from BP(A) or containing BP(A) as an additive are treated differently at the end of their life cycle. Products are fed into a second life cycle, but they can also be recycled and consumed as secondary raw material or used for energy recovery. This depends, for example, on the sector in which the products are used, whether they are composite materials or whether they can be recycled by type.

Coated materials that contain or release BPA, such as wood, paper, steel, plastics, inorganic fibres, are also treated very differently at the end of their life cycle. They can also be reused, recycled or incinerated. The waste treatment, whether and to which extent it is landfilled, sorted or incinerated, also depends on the region in Europe.

Recycled materials, including paper, plastics, rubbers, and textiles may contribute to the increasing contents of hazardous substances, substances of concern and/or substances of very high concern in the newly produced articles from this second raw material.

Even though recycling is a sustainable and desirable method of preserving valuable materials from the point of view of resource conservation, recycling involves the risk of release and potentiating hazardous substances such as BPA. Waste generated during production/processing is excluded here.

---

[130] Arp, H. P. H.; Morin, N. A. O.; Hale, S. E.; Okkenhaug, G.; Breivik, K.; Sparrevik, M. The mass flow and proposed management of bisphenol A in selected Norwegian waste streams. Waste Management 2017, 60, 775–785

[131] Jiang, D.; Chen, W. Q.; Zeng, X.; Tang, L. Dynamic Stocks and Flows Analysis of Bisphenol A (BPA) in China: 2000-2014. Environ Sci Technol 2018, 52 (6), 3706–3715

[132] Pivnenko, K.; Laner, D.; Astrup, T. F. Dynamics of bisphenol A (BPA) and bisphenol S (BPS) in the European paper cycle: Need for concern? Resources, Conservation & Recyclings 2018, 133, 278–287

B.8.5. Uncertainties impacting emission

Data on emissions are available on a use-specific or sector-specific basis. There are large data gaps at the individual use level by sector and thus downstream user. Bisphenol A and BosC are used in a variety of applications, which have an impact on almost all areas of life.

The data shown either correspond to the evidence or are estimated. In addition to the timeliness of the data, which influences its relevance, many more factors are responsible for the representation of the current situation.

There are isolated studies on release rates of selected products of sectors, which, cannot be taken as a proxy for other products (e.g. information from stakeholder during CfE – see Annex G). 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. There is also a large number of different finishing options for materials or products, which are considered to fall under business confidentiality, so that it is impossible to compare all the mixtures/materials/plastics/products/articles made of and with bisphenol A and BosC in its different functions.

The uncertainties open up emission ranges from lower to upper boundaries. In the following, these ranges are derived for the individual uses and bisphenols. All the uncertainties listed differ in their weighting or impact on the level of emissions. It is also possible that different weightings for uncertainties arise for individual uses.

The following uncertainties question the emission data and their application to the respective uses and lifecycle steps for some applications and uses.

Table 66: General uncertainties of exposure assessment

Lifecycle stage	description	impact
Information on tonnage	Source and access dependend	Varying tonnage has linear impact on emission
service life	indoor vs. outdoor	The information from the registration dossier refers to 80% indoor use and 20% outdoor use, depending on the use. This distribution is derived for polycarbonate. Other uses may be subject to different distributions. Overall, this leads to lower emission potential for indoor applications, except for washing (e.g. of textiles).
Application stage	especially P2 and other mixtures prior to end use (professional use, consumer use)	This life cycle step was not considered in detail due to lack of evidence, but theoretically the application has a high emission potential (taking into account the requirements of R.16[133] for ERC5, ERC8F).

---

[133] https://echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf/b9f0f406-ff5f-4315-908e-e5f83115d6af

		It is likely that this stage of the life cycle is underestimated in some places. No evidence was available to support this lifecycle step.
EOL	- Different share in EU concerning incineration, landfilling and recycling rates - plastic used in many sectors, but the respective shares unclear - EOL more generic due to limited data - Export of waste	Affecting environmental concentration e.g. due to lowering emission potential in products and consequently from landfills.
Free BPA/BosC content	- Release from materials is not investigated in great detail, or the equipment of the plastics is largely unclear (confidential business information - CBI), so few conclusions can be drawn between the same types of polymer/plastic. - The same release was nevertheless assumed for one type of material (polymer) (only a distinction was made between indoor and outdoor application). - Emission has been related to the proportion of residues, although it is clear that the degradation of the polymer takes place at surface layer (hydrolysis, photolysis, etc.).	In consequence the different assumptions lead to ranges of emissions for the uses.
STP	- Data for access to STP/WWTP and cleaning performance are available on a rudimentary basis for individual countries; it is known that the availability of an STP varies in the EU states. - Similar for bypass events	This directly affects the surface water concentration. For the evidence-based data a removal efficiency due to wastewater treatment of 88% was assumed by the research project on BPA (Annex H). This value is not valid for the EU. Therefore, an adjustment to 61% (Fischer et al. 2014, p. 41) was deemed more realistic, considering bypass events and the fact that not all households in the EU are connected to municipal wastewater treatment plants.
Compartments considered	Surface water was the only environmental compartment considered as monitoring data was available. There are however studies indicating that other environmental compartments are also relevant (Vermeirssen, 2017)	This may lead to a generic underestimation of the emissions.

	Examples include the transport sector (e.g. vehicles), but also the construction sector (e.g. sealed surfaces). The leaching of BPA/BosC from coated surfaces, e.g. made of cured epoxy resin, does not necessarily take place via sewer.	
Emission scenarios	- Evidence-based emissions from the research project on BPA (Annex H) - stakeholder data	In consequence the different assumptions from the different sources lead to ranges of emissions for the uses.
Material flow	- incomplete material flows e.g. due to imports	This may lead to a generic underestimation of the emissions.
Distribution	Especially outdoor use and application lead to a relevant environmental impact. However, any use with water contact must be taken into account; this can also take place indoors (e.g. wiping/washing). However, there is a lack of evidence for a more concrete estimate of the actual contribution.	This may lead to a generic underestimation of the emissions.
Withdrawel of registered uses	The withdrawal of the registration of BPA for PVC and the restriction of BPA for thermal paper have led to this trend. Since the environmental concentration (see Annex B.4.) is not decreasing, it cannot be assumed that PVC will no longer be used to the extent it was when this use was still supported by the registrant.	This may lead to a generic underestimation of the emissions.
thermal paper	BPA is no longer registered for this use. Recycling and paper refinement still emit BPA BPS substitutes the use of BPA. For this reason, uncertainty arises at this point on the subject of emissions from paper in general. This is because paper recycling still releases BPA as a photo-developer from older thermal paper. Moreover, the paper cycle is not free of BPA even then, as it is used for chromophoric printing inks for paper printing, in toners and also for paper finishing.	For lack of data, the BPA emission contribution is massively underestimated at this point.

Data on emissions are mostly available on a use-specific or sector-specific basis. There are large data gaps at the individual use level by sectors and thus downstream users. BPA and BosC are used in a variety of applications, which have an impact on almost all areas of life. In addition to these overarching uncertainties, there are also scenario-specific uncertainties. These result from the fact that the data available to derive a scenario are so specific that they may not apply equally to all actors applying this substance. Such uncertainties are discussed under the relevant sub-chapters and according scenarios.

Due to the uncertainties, the varying stakeholder information, and then the associated emissions estimates will be provided within a lower, and higher band.

In the following, the upper and lower bounds for the emission scenarios by use and substance (BPA and BosC) are derived. These limits are derived with respect to the most influential use-specific uncertainty. This can be derived quite differently due to the different data situations.

B.8.6 Emission Estimation

The discussion on emissions is structured as follows:

- emissions are discussed use-specific
- each use is assigned to one of the main categories A, P, C
- for each use it is pointed out which BosC is related to this use
- if more than one BosC is related to a use separate discussions are presented in B.8.7
- The starting point of each discussion for the uses of BPA is the presentation of the data from the research project on BPA commissioned by UBA 2018-2020 (Annex H) which is mostly based on data from industry stakeholders from before 2020. If necessary, additional information from the most recent CSR is discussed. Finally, if available, additional and/or alternative information from the two stakeholder consultations, stakeholder meetings and additional publicly available information will be discussed.
- Considering all available information as well as missing information and uncertainties the dossier submitter presents upper and lower estimates for emissions of the individual uses. If possible, a central estimate is indicated.

Emissions of BPA and BosC occur during

(i) the manufacture of BPA,

(ii) the subsequent production and processing of the respective BPA use,

(iii) usage / life cycle of articles and mixtures and

(iv) end of lifecycle (EOL).

Emissions may depend on article and mixture material characteristics, process technologies and use and application. BPA can be emitted to surface water, soil, air and WWTP, with the latter not necessarily being a final emission sink but rather reducing the BPA content in the wastewater that may afterwards flow into surface water.

In general, the release of considerable amounts free BPA to air from products that are used at ambient temperature is unlikely due to the relatively high boiling temperature of BPA of 360 °C. The half-life here is only 1-10 days, therefore atmospheric deposition is considered to be very low. Emissions to the water component mainly occur on-site via wastewater.

Release into the environment may also occur from disposal of waste via landfill (Huang et al. 2012).

In Table 67 below,

- the manufacturing and processing steps (M/F)
- and the main uses of BPA:
  - use of polymers (P),
  - use as additive (A)
  - and manufacture of chemicals (C),

are shown with available information on the tonnage used yearly (tpa). For the description of the release categories by use, the **environmental release categories** determined in the registration according to the "Guidance on information requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment" were adopted. This presentation here applies to the description of the release probability. The ERCs are used to illustrate the release probability. This generic list is discussed together with the data and information provided by industry. This should result in the evidence-based information on the release of uses according to the life cycle also being linked to the actual "polluters" of the emissions.

Table 67: Overview of the lifecycle of BPA and BosC*

Identifier	**Title (ERC)**	**Tonnage BPA and BosC (production tonnes per year tpa)[134,135]**
M**	Manufacture (ERC1)	1,200,000 - 1,500,000 + 0.01*1,200,000 - 1,500,000[136]
F	Formulation – repacking (ERC2)	30,000 - 50,000[137] + ?
P1 **Polycarbonate**	Formulation ERC2 Application/use (ERC5, ERC6C) Article service life (ERC10A, ERC11A, ERC12A; ERC12C)	1,242,000
P2 **Epoxy Resin**	Formulation (ERC2, ERC3, ERC5) Application/use (ERC6C, ERC8C, ERC8F) article service life (ERC10A, ERC11A)	BPA + BPF: 275,000 + 40,000Sum: 315,000⁺

---

[134] Source: Annex H

[135] consumption values may differ

[136] tonnage bands for BosC are in sum maximal 1% oft he tonnage of BPA

[137] Registration dossier

P3-P13 **other Polymers**	Formulation ERC2 Application/use (ERC5, ERC6C) Article service life (ERC10A, ERC11A, ERC12A; ERC12C)	18,184: 3,094 POS; 1,740 PEI; 3,600 unsaturated Polyesters; 8,800 phenolic resins + 950 polyurethanes + others n.a.)
P14 **Leather tanning agents** **P15** **textile auxiliaries (polyamide)**	Formulation ERC2 Application/use (ERC5, ERC6C) Article service life (ERC10A, ERC11A, ERC12A; ERC12C)	BPS/BPF (syntans and textile auxiliaries) syntans: 8,000tpa – 10,000 tpa (4,000tpa export)
C1*** **manufacture BADGE**	intermediate use (ERC6A)	n.a.
C2*** **manufacture TBBPA**	Formulation (ERC2) Application/use (ERC6A)	Production outside EU (40,000)
C3*** **manufacture Bis-GMA**	Application/use (ERC6A)	n.a.
C4*** **manufacture Bis-DMA**	Application/use (ERC6A)	n.a.
C5*** **manufacture Bis-EMA**	Application/use (ERC6A)	n.a.
C6*** **manufacture BADCy**	Application/use (ERC6A)	n.a.
C7*** **manufacture polyols**	Application/use (ERC6A)	n.a.
A1 **manufacture PVC**	application/use (ERC8C, ERC8F) article service life (ERC10A, ERC11A, ERC12A)	250++
A2/3/4/8/9/10/11/12 **stabilizer**	application/use (ERC6D, 8C) article service life (ERC10A, ERC11A)	1,955tpa
A5 **photo developer (thermal paper)**	article service life (ERC10A, ERC11A, ERC12A)	4,026 tpa BPS (due to BPA restriction for thermal paper from 01.01.2020)
A6	application/use	n.a.

hardener	(ERC8C, ERC8F) article service life (ERC10A, ERC11A, ERC12A)	
A7 **flame retardants**	article service life (ERC10A, ERC11A, ERC12A)	40,000 TBBPA (it was conservatively assumed that 17,000 tons of BPA in the form of ca. 40,000 tons TBBPA (used as flame-retardant within products) was imported)
A13 **flourelastomeres (FKM)**	Formulation ERC2 Application/use (ERC5, ERC6C) Article service life (ERC10A, ERC11A, ERC12A; ERC12C)	fluorelastomere (FKM): 100 - 1,000 tpa BPAF

* production /processing step (M, F) and main use (P, C, A) with resprective environmental release category (ERC)

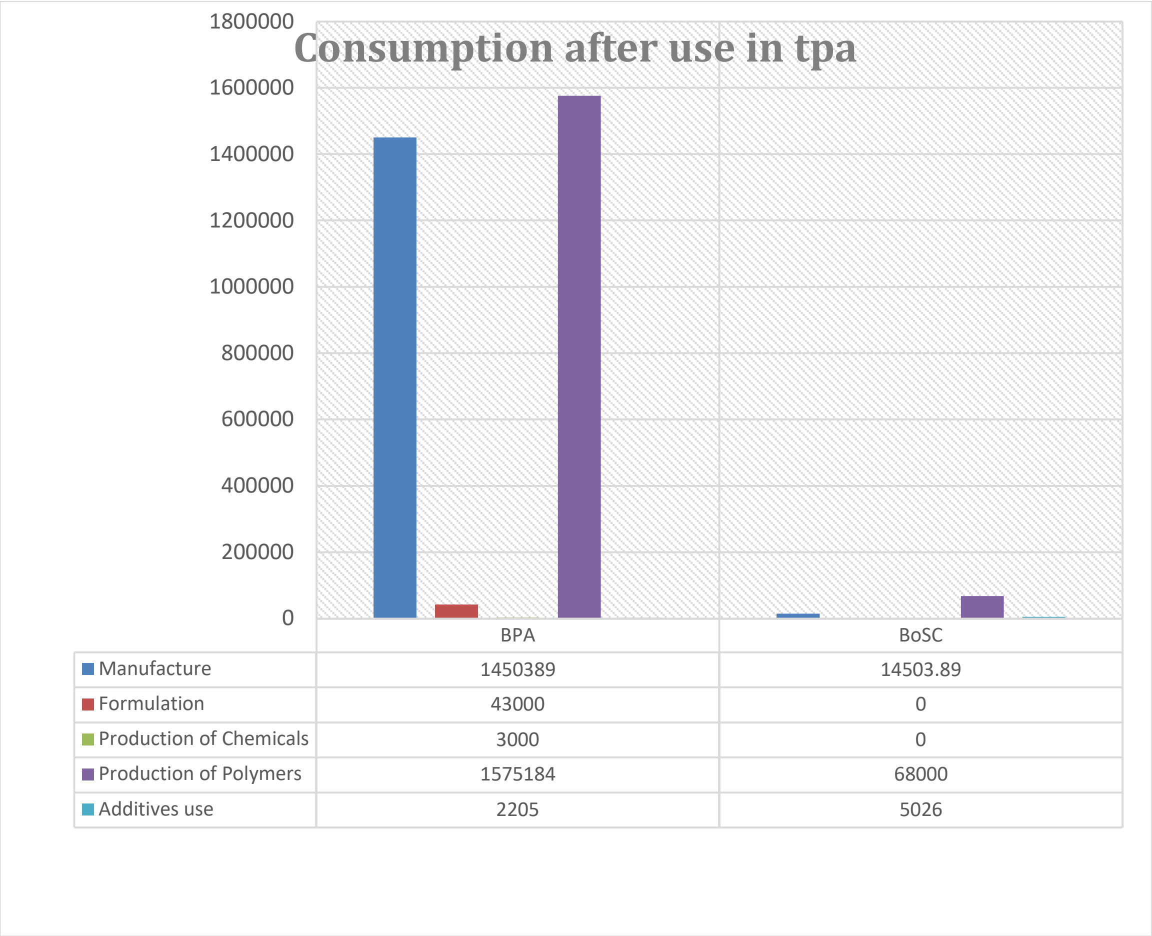
[+] the data set used here is one of many that differ depending on the source of the information.

[**] The tonnage of BPA/BosC produced is not identical to the tonnage consumed in the EU, as material flows such as imports and exports have to be taken into account for these substances.

[++] this tonnage corresponds to the source Annex H. It is known that the use has been withdrawn. The tonnage is nevertheless mentioned, as it has also become known through the process of consultation that the refinement still plays a role and that emissions from this refinement cannot be ruled out.

[***] No relevant literatures are known for these uses. However, it is known from the registration that 1,000 - 5,000tpa BPA go into this use.

Error! Reference source not found.



	BPA	BoSC
🟦 Manufacture	1450389	14503.89
🟥 Formulation	43000	0
🟩 Production of Chemicals	3000	0
🟪 Production of Polymers	1575184	68000
🟦 Additives use	2205	5026

The figure above visualizes that the majority of both BPA and BosC go into the production of polymers. The share of additives is considerably smaller by comparison.

Using the environmental release categories results in different releases and emissions depending on the main use, i.e. which technical function the BPA and also the material made from it have, the sector and the circumstances of the use and the user. Using the ERCs already indicates that the release potential of a material such as polycarbonate differs significantly between sectors, but also within a sector. Polycarbonate can be used indoors as well as outdoors.

Due to the generic release rates, the **highest release potential** 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 (ERC8C/ERC8F). Furthermore, the release for outdoor products is increased due to the stress of the materials (ERC10A), as opposed to indoor use (ERC11A). Based on the registration data, an average of 14% for PC and 21% for ER was derived for the most important uses in terms of tonnage. 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 (e.g. ERC1, ERC5) and processing (e.g. ERC6A) are negligible. It is important to distinguish between a process in a facility that is subject to IED requirements and where emissions to environmental compartments need to be monitored and mitigated, and a smaller facility that is, for example, processing or recycling. For the latter, a higher emission potential applies in any case.

As already mentioned, the EOL is relevant to understand the substance flow for BPA (Ramboll Deutschland GmbH, 2022). Production sludges occur (e.g. paper recycling, leather production), which are treated differently in the individual EEA countries depending on the specifications (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).

However, using standard ERCs does not explain the observed concentrations of bisphenols in the environment which are much lower than what could be expected if emission behavior would be as suggested by only using ERCs. In order to account for this the dossier submitter decided to use ERCs where plausible but to adjust the emission estimations for the individual uses when it seemed plausible to considering additional information from all the available sources.

The following graph visualises the material flow of BPA into the individual uses:

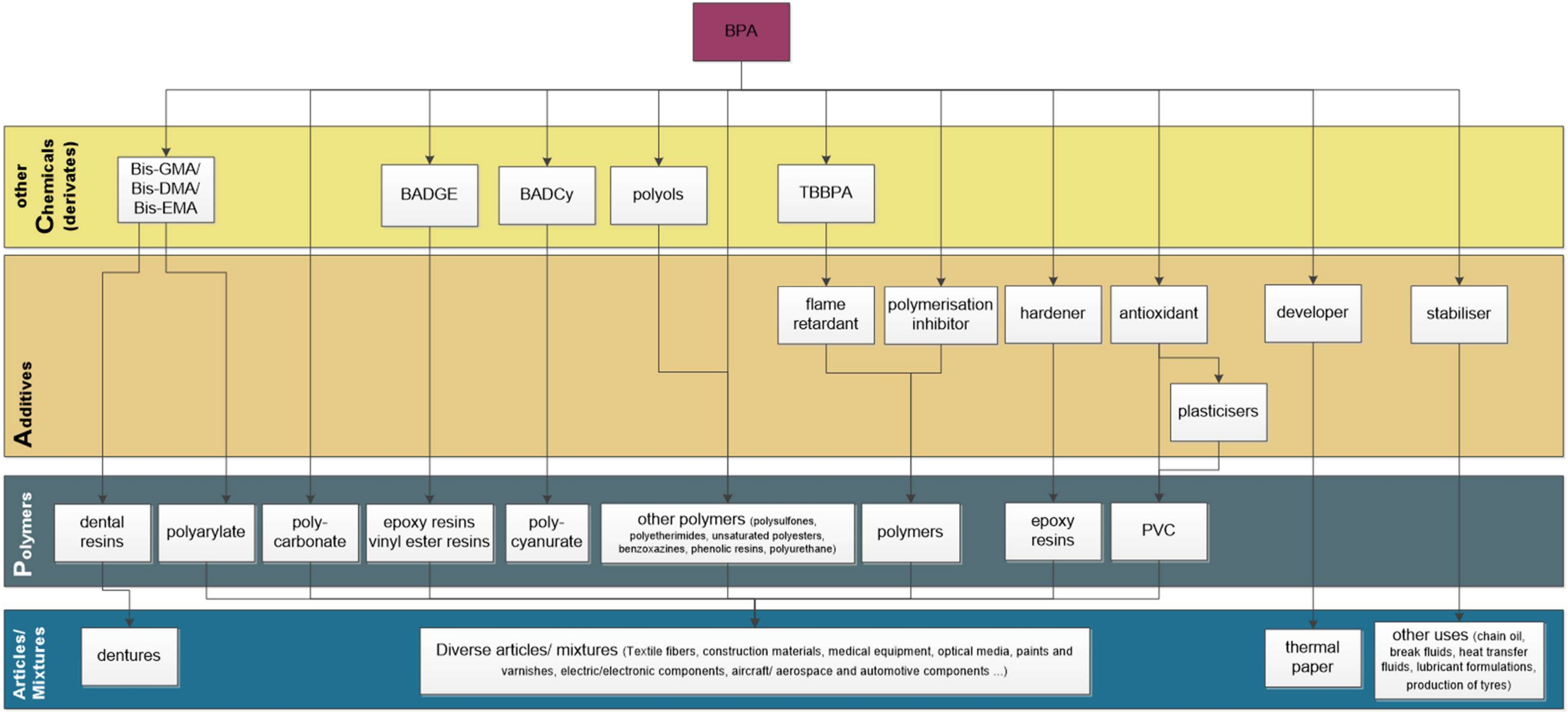


Figure 10: Inventory of main uses of BPA (Source: Annex H)

B.8.6.1. Emission during Lifecycle

Potentially, any article/material/mixture which contains BPA may emit (part of) the contained BPA to the environment. Naturally, the amount of emitted BPA depends on several things, such as the type of application, sector of use, article category and quality and the environmental/chemical/physical stressors. Within the framework of this report's mass flow model, several assumptions are made to allow for a systematic estimation of BPA emissions.

In the following sections, BPA emission pathways are outlined, and emissions are estimated. After

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 are assumed for BosC.

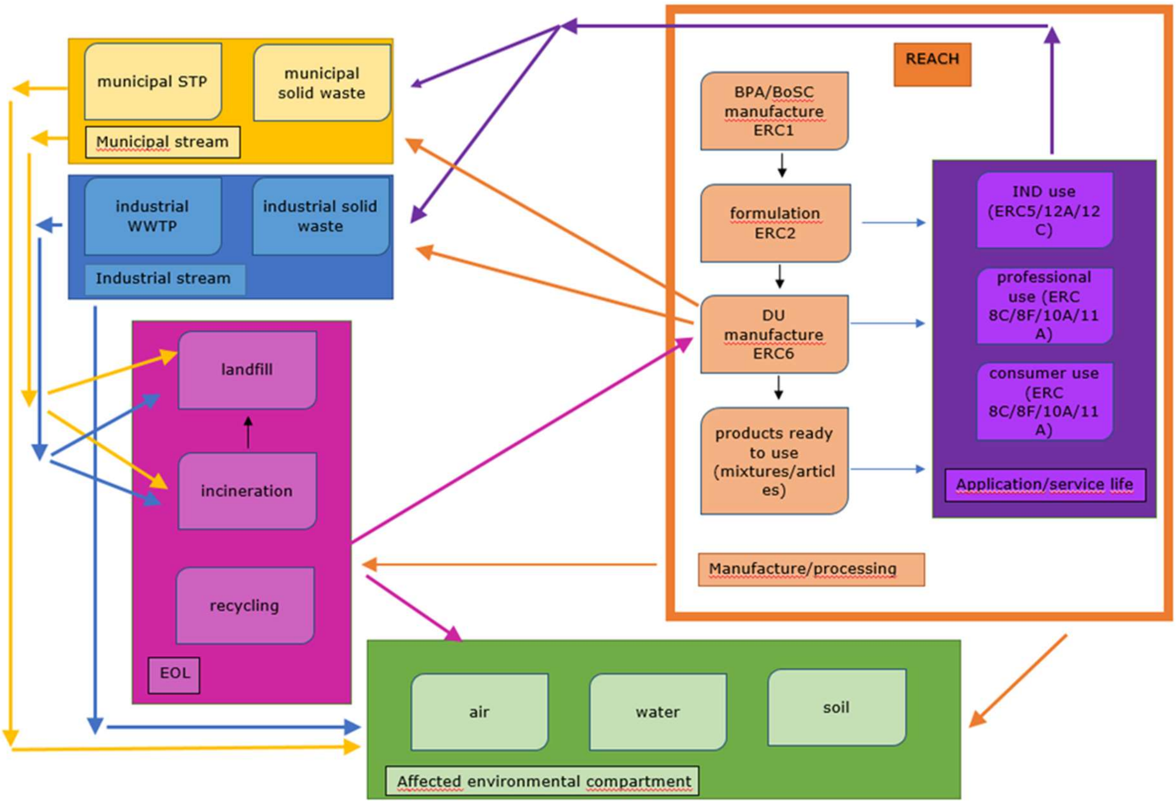


Figure 11: BPA/BosC pathways or corridors of influence during lifecycle

This visualisation of emission paths and distribution pathways can help to show the purpose of the restriction at this point. In principle, the 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 the alignment of the restriction under REACH or show the consequences of the (non-)regulation under REACH. The processes that are directly regulated under reach, however, have a direct and thus greater effect on environmental emissions and thus also on environmental concentrations with the design of the restriction.

Methodology:

In order to assess contents in materials and to obtain an overview of the release potentials of BPA, the dossier submitter initiated a the research project on BPA (Annex H) in the run-up to the dossier preparation. Initially, the dossier submitter intended to use only the data from this research project for the exposure assessment. However, in the later stages of the dossier preparation it became clear from additional stakeholder information and from updated industry stakeholder information which was also used for the updated Chemical Safety Report, that a more thorough discussion of the emissions needs to be undertaken. In a pragmatic approach the dossier submitter decided to use the geerated data from the research project on BPA (Annex H) as a starting point adding additional information and discussion to arrive at more nuanced estimates for the individual uses.

Using the additional data and stakeholder information and taking the uncertainties into account, the dossier submitter derives lower and upper emission scenarios for most individual uses.

Methodological note A)

Emissions are estimated as

- standardized emission rates, i.e., proportions of emitted BPA per BPA present in the emitter and
- absolute emission totals, i.e., tonnages ultimately resulting from the tonnage of raw BPA produced in the reference year 2020

for each environmental compartment as well as for all life cycle stages and all uses.

Methodological note B)

Tonnages are given for the main stages of the BPA life cycle:

(1)	(2)	(3)	(4)
production of →	processing of	→ consumption of	→disposal
of raw BPA/BosC containing	raw PBA/BosC into	BPA/BosC containing	BPA/BosC
	P/A/C P/A/C	P/A/C	
production	**processing**	**service life**	**end-of-life**
	= consumption of raw BPA = production of P/A/C		

To avoid confusion, the term ‘processing’ herein explicitly refers to the production of BPA/BosC-containing P, A, C, and consumption explicitly refers to the consumption of BPA/BosC-containing P, A, C and not to the consumption of raw BPA/BosC (as done by many of the identified data sources). The application stage was not considered separately in this approach.

Methodological note C

Emissions are estimated as

- standardized emission rates, i.e., proportions of emitted BPA per BPA present in the emitter and
- absolute emission totals, i.e., tonnages ultimately resulting from the tonnage of raw BPA produced in the reference year 2020 for each environmental compartment as well as for all life cycle stages and all uses.

Methodological note on application (IND ERC 5/prof ERC8F/consumer ERC8F)

This life cycle step was not considered in detail due to lack of evidence, but theoretically the application has a high emission potential (taking into account the requirements of R.16[138] for ERC5, ERC8F). One use is considered based on a contributing activity where a safe use is described. No conditions for safe use for the application of e.g. resins (polycarbonate resins, epoxy resins) for the environment were derived from the registration dossier, despite knowledge of industrial use and use by professionals and consumers.

An example that demonstrates the relevance of this life cycle step is marine coating (cf. B.9.2.2.2.4 - stakeholder information on P2). Additional information is also available from stakeholders, e.g. use of epoxy resin for marine coating, among others. The probability of release is determined by the user. For example, if ready-to-use mixtures (products) exceed the specified concentration limit (derived in the context of the restriction), it must be ensured that conditions are prescribed to ensure safe use from an environmental point of view.

It is likely that this stage of the life cycle is not considered adequately in the exposure assessment and results in an underestimation of emissions in some places. However, evidence is lacking to assess this lifecycle step quantitatively.

B.8.6.2. Emission from the manufacture of BPA and BosC (M)

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

Information discussed in the research project on BPA (Annex H):

Essentially, all previously identified sources with transferrable rates for the emission of BPA during (raw) BPA production base their conclusions on the emissions of six production sites in Europe in 1999 (EC JRC 2003, 2008a; Fischer et al. 2014; Groshart et al. 2001). Additionally, Ramboll Environ Fig. 3 (2015) assumes that there should be no emissions to soil. Solid waste from BPA production is incinerated (Leisewitz et al. 1997).

Ultimately, the identified emission rates are standardized so that for each ton of raw BPA being produced, about 2.9 g and 1.4 g of BPA are emitted to surface water and air, respectively, while no emissions occur to WWTP and soil. The tonnage for raw BPA production in Europe was estimated to be between 1,200,000 – 1,500,000 tpa.[139]

---

[138] ECHA (2016): Guidance on information requirements and Chemical Safety Assessment Chapter R.16: Environmental exposure assessment: https://www.echa.europa.eu/documents/10162/13632/information_requirements_r16_en.pdf (access 2022/27/09)

[139] Annex H

Accordingly, in the research project for BPA (Annex H) the absolute emission estimates for 2020 are 1.97 tons to air and 3.98 tons to surface water, leading to a total of **5.98 tons** of BPA emission during raw BPA production.

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

B.8.6.3. Emission from the manufacture and use of other chemicals (C1-C7)

Bisphenol is a starting material for the production of other chemicals. In this case, the release is to be expected in the manufacturing process itself, and possible residues are also to be expected as contamination of the substance. A release through physico-chemical effects on polymers made from the other chemicals produced is not considered due to missing data. However, the possibility of release still exists.

The emissions from C1-C7 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.

No BPA emission occur during C2 production in Europe, since 100% of C2 consumed in Europe is imported. For all other chemicals, no information on tonnages produced and on emission during production could be found in the identified sources.

It is possible that BPA is present as an impurity in these chemicals. It is also chemically possible that these substances can release BPA/BosC, for example through transformation processes. For TBBPA[140], for example, photolytic-destructive processes are conceivable, albeit under laboratory conditions. However, there is a lack of comprehensive methodological studies here that would indicate a defined release. Furthermore, no structured data on the level of contamination is available at the present time. 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.

B.8.6.4. Emission from additives (A1-A12)

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 machine capabilities of the manufacturers/processors of polymers and plastic articles. Before or during the polymerisation reactions of plastics as well as during stabilisation of plasticisers or reactive polymerisation monomers, the corresponding additives (e.g. polymerisation inhibitors) and reaction partners (e.g. reactive flame retardants) are usually added to the reaction medium as pure substances in defined quantities. Furthermore, it can be used in the production of antioxidants for textile finishing.

---

[140] https://www.researchgate.net/publication/280830909_Scientific_Opinion_on_Tetrabromobisphenol_A_TBBPA_and_its_derivatives_in_food_EFSA_Panel_on_Contaminants_in_the_Food_Chain_CONTAM

After the synthesis of the raw polymers, further additives can be added for stabilisation of the mixture/raw polymer-material (e.g. as granules or liquid). This can be done in different ways. In the simplest case, the additives can be added in pure form directly to a polymer melt using suitable dosing equipment via a compounding process on a continuous basis before a granulate is produced from the polymer mixture.[141]

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. 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. There are some applications where BPA/BosC is/are directly used as additive (e.g. as stabilizer of mixtures) and can therefore easily be released to the environment during processing and service life. Compared to the use in polymers, in these applications BPA is not chemically bound or held back in a matrix and may therefore be much more accessible for leaching for example by water (Fischer et al., 2014). The direct type of application (by user: industrial, professional or consumer) and the likelihood of release is higher for mixtures containing BPs as an additive. As a proxy, it can be assumed that when used by professionals and consumers, controlled conditions/operational conditions/risk mitigation measures may not be applied to the same extend as at industrial site. Therefore, the release of BPA/BosC into the environment can occur at a higher rate than industrial use..

In summary, BPA as an additive can be more easily released. The research project on BPA (Annex H) gathered information on emission potential for additive uses. The following graphs summarise standardized emission rates of A1 – A12 during processing, service life, and end-of-life cycle. Deviating from this, the use of the additive as crosslinker (curing agents A6 and A13) leads to a more stable incorporation into the matrix than would otherwise be expected for the additives. Whereby the release behaviour is more in line with that of the polymers.

PVC Uses (A1-A4)

Results from the research project on BPA (Annex H):

Regarding the processing of BPA to BPA-based additives, emission rates greater than zero could be extracted only for A1-A4 and to surface water and/or WWTP. Thus, emissions may occur during the production process of PVC where BPA serves as a processing agent and during the use of PVC products containing BPA as an antioxidant.

The highest emission ratio is that of A1 reported in EC JRC (2003), where it is stated that "For the use of bisphenol-A in the production of PVC as an inhibitor during or at the end of the polymerisation process it is reported that approximately 2/3 bisphenol-A is incorporated into the polymer, the remaining 1/3 is lost to wastewater. […] For the continental and regional scenarios, the release figure will be applied to the total tonnage (250 tonnes), this gives a release to wastewater of 83 tonnes/year."

Finally, in Table 3.3 of the EC JRC report this wastewater emission is split 70:30 between WWTP and Surface Water, leaving emission ratios of ca. 0.7*83 tons and 0.3*83 tons for WWTP and surface water, respectively. Accordingly, the rates of emitted BPA per BPA processed are high, resulting in strikingly high absolute emissions of BPA during A1 production even after wastewater treatment (0).

---

[141] Information given in CfE (Annex G)

The use of PVC products containing BPA (A1-A4) may lead to emissions to WWTP (mostly for indoor uses; leaching) and to surface water (outdoor uses; weathering effects). Yet, EC JRC (2003, p.37) assume for A2 "annual losses […] to be 0.05% to air and 0.15% through leaching - the latter is assumed to go to soil and surface water in the ratio 50:50" and a lifetime of 30 years, resulting in service life emissions of 1.5% to air, 2.25% to soil and 2.25% to surface water.

During the end-of-life-stage, only emissions from landfills and to WWTP are assumed. Thus, there should be no direct emissions from landfills[142] to surface water or soil. Furthermore, Ramboll Environ (2015, Fig. 3) assume that the only emissions from municipal landfills are to water and not to air or soil.

PVC will be recycled for the most part, only small amounts are estimated to be incinerated and to go to landfills. Emission rates of BPA-based products during the end-of-life stage are especially scarce, but Xu et al. (2011) reported a 34.7% leachability of BPA from PVC shopping bags, which was therefore assumed for A1-A4 to WWTP. From the latter, BPA contained in this plastic waste might be released to surface water (A1-A4).

Table 68: Overview on PVC uses

Use	Life cycle stage	Air (tons)	Soil (tons)	Surface Water¹ (tons)	Total (tons)	Total / Consumption²
A1	Processing	0	0	31.9	31.9	32 t = 13% of 250 tons
	Service life	0	0	n.a.	0	
	End-of life	n.a.	n.a.	0.174	0.174	
A2	Processing	0	0	0.361	0.361	28 t = 6.2% of 450 tons
	Service life	6.74	10.1	10.1	26.9	
	End-of life	n.a.	n.a.	0.468	0.468	
A3	Processing	0	0	0.108	0.108	1 t = 0.12% of 900 tons
	Service life	0	0	n.a.	0	
	End-of life	n.a.	n.a.	0.936	0.936	
A4	Processing	0	0	0.366	0.366	1 t = 0.19% of 450 tons
	Service life	0	0	n.a.	0	
	End-of life	n.a.	n.a.	0.467	0.467	

Additional stakeholder information:

---

[142] https://www.sciencedirect.com/science/article/pii/S0045653500000795

One stakeholder representing the voluntary sustainable development programme of the European PVC industry informed the dossier submitter that the PVC industry in Western Europe has made the decision to substitute the use of BPA as a polymerization inhibitor by the end of 2001.

Regarding the other uses the stakeholder stated that in the past BPA was used as antioxidant in PVC formulations, to protect the plasticizer against thermal oxidation during the processing as well during the manufacturing and service life of the PVC article.

The stakeholder stressed that BPA may still be used directly as an additive especially in PVC cable formulations. Their understanding is that this use is however today very limited. BPA has almost completely been replaced by alternative antioxidants. The stakeholder is not aware of other niche uses in Europe and therefore concludes that those uses, if any, would be limited.

Additional information suggests that the use of BPA was also mostly discontinued 10 years ago at a global level. The only exception known to this stakeholder were some wire and cable formulations in Japan. Based on the fact that typical applications would be found in building and industrial applications, the risk for introduction of BPA in the European Union through import seems rather limited.

Additional information was submitted by stakeholders from the automotive industry who stated that BPA still is in use in PVC cables. However, one stakeholder stated that this use is decreasing its volume and will be phased out in the future.

In the medical field, there are thousands of uses for BPA-based polymers in medical devices and in vitro diagnostic equipment. A sectorial organisation stated during the stakeholder consultation that PVC-based products are also used in medical technology. (e.g. printed circuit boards and thermistors). European PVC manufacturers have reported to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) that they no longer use BPA in PVC production. This would indicate that the substance was used in the medical sector to a certain extent before the switch. Alternatively, it could be from outside the EU, where a similar declaration has not been made.

According to market data from industry association Plastics Europe the demand for PVC in the EU amounts to 5 milliontpa. The share of soft-PVC is 30%.

In a study commissioned by European plastics industry stakeholders PVC products with a relevant market share and contact with water during their usual use were tested. 29 samples were taken and results for BPA-content range between LOQ and just under 11ppm. 21 samples contained <0.1 ppm, three samples 0.1-0.8 ppm and five samples between 1-11 ppm BPA. Four of the five articles with content >1 ppm were manufactured outside the EEA. For the fifth the origin is unclear.

Discussion

The research project on BPA (Annex H) estimation of emissions for A1-A4 is high. In absence of additional information, the contractor used available data from before 2010. However, new information suggests that the use for A1 has ceased completely or almost completely in the EEA. And considering that emissions from this use are almost completely created during the manufacturing of PVC and not during service life and end of life it is reasonable to assume that the emission potential from A1 from imported PVC is very low, too, even if BPA is still used as polymerization inhibitor outside the EEA.

Regarding the uses A2-A4 as stabilizer to prevent oxidization the additional stakeholder information is not equally unambiguous. Stakeholders mentioned uses in the automotive industry and for medical devices or otherwise characterized the use vaguely as almost completely phased out.

Most importantly, the second call for evidence answers and additional stakeholder information do not contain any information on the quantities of BPA as an additive in polyvinyl chloride used in the respective sectors (automotive industry, medicinal sector etc.). Therefore, a quantitative assessment of the use of BPA in these sectors is not possible. Considering the available qualitative information, the use of BPA in PVC in the medical sector is expected to decline in the same way, as described above for the automotive sector.

Notably, the dossier submitter found no information on the use of BPA for (non-recycled) PVC in the CSRs submitted for BPA.

The dossier submitter did not receive any certain information on EEA-import and EEA-export quantities of PVC, neither in regard to PVC resins nor in regard to PVC imported/exported as part of articles. Plastic Europe estimates that a maximum of 640 000 tonnes of PVC per year could have been imported into Germany and this PVC could contain BPA (Ramboll Deutschland GmbH, 2022). No information on the share of flexible PVC, on a central estimate or on the BPA contents is available.

In summary, considering that

- no information on a continued wide use of BPA for A1-A4 within the EEA was submitted in the two CfEs or is available publicly,
- that alternatives are available in general,
- that substitution also takes place in the rest of the world although not in all regions

the dossier submitter considers that the initially assumed 62tpa emissions from the use of BPA for A1-A4 is not plausible. First of all, it is based on industry data from 2006 which only considers 'Western Europe' (JRC 2008) and therefore would be an underestimation for EU27 assuming all other conditions being equal in 2020. Secondly, manufacturers representing more than 70% of European PVC manufacture phased out the use of BPA at least 10 years ago. It seems unlikely that all of the remaining <30% is manufactured using BPA for A1-A4. The above-mentioned sampling of PVC articles suggests (albeit in a very limited and non-representative study) a small share of articles produced in the EEA with A1-A4. The same study demonstrates that especially imported articles might still be a significant source for BPA emissions.

In absence of further scientific data the dossier submitter considers that, based on expert judgement, it seems unlikely that more than 10% of flexible PVC used in the EEA contains significant amounts of PVC. Further considering the results from the sample testing it seems very likely, even for imports, that considerably less BPA is used for PVC when A1-A4 are relevant (only a maximum of 11 ppm BPA and only for one article was measured). Therefore, for the emissions estimate it is assumed that BPA emissions to the environment of 1-5 tpa are created by additive PVC uses.

Recycled PVC (A1-A4 residues)

BPA is present as an undesired impurity in PVC waste which is recycled. In this regard recycling is defined as processing PVC waste for the original or other purposes, excluding energy recovery and fuel production. Around 800 000 tonnes of PVC waste have been recycled in 2021 in the EU. PVC industry estimates that by 2025, 900 000 and by 2030 1 000 000 tonnes will be recycled per year. Around 300 000 tonnes were post-consumer waste, i.e. material returned from distribution or generated by the end-users of products that has fulfilled its intended purpose or can no longer be used and which the holder discards, intends to, or is required to discard. Around 500 000 tonnes were pre-consumer waste, i.e. material diverted during a manufacturing process that the holder discards, intends to, or is required to discard (VinylPlus 2022).

Information from industry stakeholders (Ramboll Deutschland GmbH, 2022) suggests that only (or at least mostly) flexible PVC that enters the recycling process contains BPA. According to one estimate the quantity of BPA placed on the market in Germany in recycled PVC amounted to 28.6tpa in 2013. In order to derive a quantity of BPA for 2021 for the EEA one can assume that:

- Germany recycled 69 500 t flexible PVC from post-consumer waste and 192 500 t post-consumer waste PVC in total, i.e. approximately 37% of total post-consumer waste PVC is flexible PVC.

- In the EEA in 2021 approximately 300 000 t post-consumer waste PVC has been recycled. 37% amount to roughly 111 000 t flexible PVC waste.

- If 69 500 t amounts to 28.6 t BPA placed on the market, then 111 000 t flexible PVC waste amounts to 45.7 t BPA placed on the market in recycled PVC (rPVC) (with a concentration of 0.041% w/w in the material rPVC).

Above the dossier submitter considered that EC JRC (2003, p.37) assume for A2 "annual losses […] to be 0.05% to air and 0.15% through leaching - the latter is assumed to go to soil and surface water in the ratio 50:50" and a lifetime of 30 years, resulting in service life emissions of 1.5% to air, 2.25% to soil and 2.25% to surface water. Using these values for recycled PVC the following emission estimate for recycled PVC during service life can be derived:

Table 69: emission estimate for recycled PVC during service life

Use	**Life cycle stage**	**Air (tons)**	**Soil (tons)**	**Surface Water[1] (tons)**	**Total (tons)**	**Total / Consumption**
A1-A4 recycled	Processing	Unknown				
	Service life	0.7	1	1	2.7	2.7 t = 6% of 45.7 tons
	End-of life	Unknown				

Stakeholders (Ramboll Deutschland GmbH, 2022) presented their own calculations to the dossier submitter. They estimate emissions of 782 kg/a from recycled PVC in Germany. However, the dossier submitter could not comply with the calculations and also does not agree with the stakeholders' view that migration from BPA only occurs from surface areas in case of additive uses. Due to technical diffusion processes between the layers in the polymer/article, substances can diffuse from the polymer interior to the surface and thus also be accessible to leaching. Regarding processing the dossier submitter notes that it seems likely that already during the recycling process significant quantities of BPA will be emitted. Plastic waste will be cleaned and sorted with water and in several production steps shredded to powder. No additional information is available in regard to the emissions potential. Additionally, in regard to the subsequent processing by downstream users no information is available.

Stakeholders submitted that the BPA content of recycled PVC articles in the marketplace has already dropped and is expected to drop further as a result of the phaseout of the use of BPA in PVC in Europe after 2000. While the dossier submitter agrees in general that it is a plausible assumption that the amount of BPA will decrease in the future, it is noted, firstly, that most PVC articles have a long service life of 30-50 years. Accordingly, it can be expected that for at least the next 10-30 years large quantities of BPA-containing PVC will be recycled. Secondly, it is noted that the average content of BPA in recycled articles would decrease automatically in case the share of pre-consumer waste in relation to post-consumer waste increases. The dossier submitter has no detailed information with regard to this but notes that at least for the years 2020 to 2021 an increase of more than 20% in pre-consumer waste has been reported while post-consumer waste decreased by approximately 5%. This might already explain, at least partly, the current drop of the BPA content in recycled PVC.

A5 Thermal Paper

Use of BPA:

BPA was used in the production of thermal paper (TP). As of January 2, 2020, BPA cannot be legally placed on the market in the EU in thermal paper in a concentration greater than or equal to 0.02% by weight (Commission Regulation (EU) 2016/2235). As a result, BPA is no longer used to manufacture thermal paper.

Use of BPS:

The quantity of BPA used in TP has been decreasing for years reaching 0 t in 2021 while the use of BPS in TP increased strongly since.[143,144] One of the key findings of data provided by ECHA is that 43% of thermal paper 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.

Table 70: Developer used in thermal paper placed on the EU market*

Developer	2014	2015	2016	2017	2018	2019	% growth from 2018 to 2019
Bisphenol A	2799	2784	2606	2776	2516	956	-62%
Bisphenol S	150	125	200	397	678	1626	+140%

* by ETPA members in 2014-2019 [tonnes], Source: ETPA

Thermal paper was not evaluated for environmental emissions by the lead registrant of BPA but discussed to contribute to emissions from landfill and to be easily leachable due there is no covalent bonding or binding into matrix. Fischer et al. (2014) present data for BPA-emissions to receiving waters from thermal paper production which can be considered to be comparably minor (<0,2tpa in EU) and the dossier submitter argues that this conclusion can be transferred to the manufacture of thermal paper with BPS.

Since during service life articles made of thermal paper do not come into contact with water, BPS does not enter the wastewater stream during service life. Thermal paper is a

---

[143] All news - ECHA (europa.eu) (access 2022/06/04)

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

compact matrix into which colour developers are firmly embedded. Therefore, emissions into air during service life are expected to be not relevant.

However, as it is assumed also for BPS that 100% of the substance is leachable, emissions to the environment are expected during recycling and other end-of-live fates of thermal paper. Paper recycling has been estimated by ETPA in consultation with the Institute for Paper Science and Technology at the Technical University of Darmstadt in 2008. Estimations for the (then) four major uses are presented in the following table.

Table 71: Use and recycling pattern for thermal paper

Use area	Usepercentage [%]	Fraction recycled	Percentage of total recycled [%]
Point-of-sale receipts	50	0.3	15
Self-adhesive labels	30	0.1	3
Lottery	10	0.2	2
Fax	10	1	10

Source: Fischer et al., 2014 – Table 24

As the use of fax paper has virtually ceased the dossier submitter recalculates by transferring the usepercentage for fax proportionately to the other uses:

Table 72: Use and recycling pattern for thermal paper (recalculated)

Use area	Usepercentage [%]	Fraction recycled	Percentage of total recycled [%]
Point-of-sale receipts	55.6	0.3	16,7
Self-adhesive labels	33.3	0.1	3,3
Lottery	11.1	0.2	2,2
Fax	0	0	0

Studies confirm that different paper products made from recycled papers may contain BPA due to contamination arising from the recycling process and that BPA may again circulate through use, disposal and recycling. Concentrations of BPA in paper products made from recycled paper (e.g. napkins, toilet paper) have been reported in a dimension of µg/g (Fischer et al., 2014). Gehring (2004) found BPA in toilet paper made from recycled paper in concentrations between 3.2 and 46.1 µg/g dry matter and in waste paper in concentrations between 0.09 and 4.23 µg/g dry matter. Lopez-Espinosa et al. (2007) found BPA levels in paper and cardboard containers used for take-away food to range from 0.05 to 1817 ng/g at a detection frequency of 45%. BPA could also be detected in kitchen roll from recycled paper (0.6–24 µg/g), while kitchen roll from virgin paper contained no or negligible BPA concentrations (Geens et al., 2011; Vinggaard et al., 2000). Since BPS acts as a drop-in substitute for BPA, but BPS has not yet been analysed to the extent as BPA in articles, it is assumed that these values for BPS are already or will very soon be in the same range (Pivnenko et al., 2018; Pivnenko et al., 2015).

Following ETPA's consultation with ECHA, ECHA developed a scenario in which 75% of the quantities of BPA used are substituted with BPS. ETPA agreed with this scenario. Into the estimate, a thermal paper consumption growth of 2% was integrated. The following estimations[145] resulted:

Table 73: Thermal paper placed on the EU market

Developer	2019	2020	2021	2022	Share in 2020-2022
BPA	136,125tpa	0	0	0	0%
BPS	**187,064tpa**	**294,941tpa**	**300,840tpa**	**306,857tpa**	**61%**
Other developer	153,648tpa	191,433tpa	195,261tpa	199,167tpa	39%
total	476,837tpa	483,374tpa	496,101tpa	506,023tpa	100%

Source: ECHA 2020

Table 74: Past and projected consumption of thermal paper on the EU market

Developer	2014	2019	2022 estimated	Growth 2014-2022	Share in 2020-2022
BPA	247,198tpa	136,125tpa	0	-100%	0%
BPS	**64,499tpa**	**187,064tpa**	**306,857tpa**	**376%**	**61%**
Other developer	115,211tpa	153,648tpa	199,167tpa	42%	39%
total	426,908tpa	476,837tpa	506,023tpa	19%	100%

Source: ECHA 2020

From this data the tonnage of BPS used as photo-developer for thermal paper (A5) can be derived for 2022:

- 2019: 2,454 tpa BPS used to manufacture 187,064 tpa TP
- 2022: 4,026 tpa BPS will be used to manufacture 306,857 tpa TP with BPS

The starting point for the estimation of the BPS-emissions from recycling is the update in 2022 of the "Substance flow analysis (SFA) and regionalized pathway analysis (RPA) for emissions of bisphenol A (BPA) into the environment" from Plastics Europe PC/BPA Group (Ramboll Deutschland GmbH, 2022). In this report it was estimated for BPA that approximately 15,800kg BPA per year will be released to surface waters due to thermal paper manufacturing and recycling in Germany. Extrapolated to the territory of the EU, this would correspond to a derived surface water emission of 85tpa (15.8tpa*448mio inhabitants EU[146]/83mio inhabitants Germany[147]=85.3tpa) with the data.

---

[145] ECHA (2020): The use of bisphenol A and its alternatives in thermal paper in the EU during 2014 – 2022. https://echa.europa.eu/documents/10162/23294236/bpa_thermal_paper_report_2020_en.pdf

[146] https://ec.europa.eu/eurostat/documents/2995521/11081093/3-10072020-AP-EN.pdf/d2f799bf-4412-05cc-a357-7b49b93615f1 (access 2022/19/04)

[147] https://www.destatis.de/EN/Themes/Society-Environment/Population/Current-Population/_node.html (access 2022/19/04)

Table 75: Defaults for emission estimation of BPS for A5

life cycle stage	Environmental release category	Default Release rate to surface water prior WWTP	Tonnage used yearly for scenario	Cleaning performance WWTP[148]	Total yearly tonnage	Emission*
manufacture thermal paper	ERC 3	0.2 %	4,026tpa	61%	5,234tpa	5tpa

* calculated in

Equation 1: Emission BPS from **A5**

Equation 1: Emission BPS from A5 from TP manufacture

$$Emission = (4{,}026\text{tpa} * 0.2\% * 61\%)$$

$$Emission = 5tpa$$

The BPA emissions that enter the environmental compartment surface water during the production of thermal paper amount to 5 tpa.

The material flow of BPA from the publication by Fischer et al. 2014 in Thermal Paper ((Fischer et al., 2014), Figure 3-3) shows that in the course of processing (recycling) recovered paper (pulp) from the "non- deinking route" leads to an emission of 369 tpa of BPA into the pulp and from the "de-inking route" 22 tpa, with most of the BPA remaining in paper products. Furthermore, in emissions of a similar magnitude from paper sludge that is incinerated or landfilled (12%). Direct emissions of BPA to surface waters were in the same magnitude as the calculation showed for BPS.

To derive a first estimate for BPS emission from recycling it is assumed that if in 2019 the use of 1,810 tpa BPA[149] lead to 85 tpa BPA emissions from recycling, 2,454 tpa BPS lead to **115 tpa** in the environment.

Equation 2: derivation tonnage BPS in relation to BPA (A5 – base scenario)

$$tonnage\ Emission\ BPS = 85tpa\ Emission\ BPA * \frac{2{,}454tpa\ BPS}{1{,}810tpa\ BPA}$$

$$tonnage\ Emission\ BPS\ = 115.2tpa$$

However, the estimations from the SFA updated in 2022 are very uncertain and the actual emissions might be considerable higher or lower:

- SFA 2022 assumes that an estimated 50% of TP, or 267,000 kg/a BPA, ends up in the recycling loop. The dossier submitter could not find any explanation for this

---

[148] Annex H Figure 36

[149] ECHA (2020): The use of bisphenol A and its alternatives in thermal paper in the EU during 2014 – 2022; https://echa.europa.eu/documents/10162/23294236/bpa_thermal_paper_report_2020_en.pdf, table 6

assumption. Fischer et al. (2014) estimated that only 30% of TP is recycled and the dossier submitter argues above that this number needs to be adjusted to 22.5% considering that the use of fax paper has virtually ceased. In that case the actual amount of thermal paper entering the recycling loop would be less than half of what is assumed in SFA 2022.

- SFA 2022 assumes a 15% bypass event frequency for Germany. The dossier submitter is not aware of any data to check whether this number can be applied for the entire EEA.

- SFA considers the total amount of paper collected for recycling for the emissions. However, imports and exports need to be considered. Germany is a net importer for waste paper while the EU is a net exporter. In 2020 the EU exported approximately 12% of collected waste paper outside the EU.[150] Therefore, it is possible that more than 10% of BPA in collected paper waste will be emitted outside the EEA.

- The dossier submitter does not comply with the assumption from SFA 2022 that 20% of BPA is extracted to wastewater during recycling. In his view the cited sources in table 5.8 of the SFA do not justify this assumption, e.g. the cited BMLEV 2012 explicitely states that uncertainties in their data are too high to derive any estimations from them. Additionally, the dossier submitter notes that the SFA does not discuss the impact of the de-inking process, BPA emitted to paper sludge and the ensuing uses of the sludge (e.g. agriculture, incineration, landfilling). According to Fischer et al. (2014), mostly in case of the 'non-de-inking' route significant amounts of BPA may remain in paper products from recovered paper which may again circulate through use, disposal, and recycling and may release BPA to the environment. The substance flow analysis in Fischer et al. (2014) indicates emissions related to thermal paper only of about 0.1 tpa from TP production and recycling, plus a potential for emissions from 257tpa paper sludge that may be landfilled. In the recovered paper from the recycling process, about 30% thermal paper remain. Stakeholders from the European paper industry estimate that 12% of sludge from paper recycling is landfilled151. One recycler in the UK reports that 90% of the residue produced is put to agricultural use (composting and spreading) or used as a raw material to produce cement and bricks.[152]

- Fischer et al. (2014) report that sludges are generally incinerated at 96% in Germany. However, there are major differences in this regard in the EU. There is also no reliable information on the other possible uses, e.g. for cement and fertiliser. As a worst-case assumption for the EU, it might be assumed that 12% of recycled paper sludge and broke paper sludge originate from thermal paper processing but with an unknown share of release and emission. In addition, 20% other uses with emission potential (e.g. fertilisers and compost products) might be assumed. Consequently, other uses continue to have emission potential as well, such as fertilisers (produced from sewage sludge) and compost products (e.g. through the use of compostable paper bags).

- Considering the discussions in Fischer et al. 2014 the extracted 20% might be an over- or understimate and having no detailed information on the other mentioned variables might be a source of severe over-/underestimation, too.

---

[150] https://www.euric-aisbl.eu/position-papers/item/614-press-release-global-free-fair-sustainable-recovered-paper-trade-is-crucial-for-recycling-industry

[151] https://sustainability.cepi.org/circular-economy/

[152] https://recycled-papers.co.uk/green-matters/why-use-recycled-papers/reduce-landfill

In sum, the dossier submitter concludes that the emission estimate of 115tpa for BPS is very uncertain. Considering other information on recycling shares for thermal paper, net exports of waste paper and the other uncertainties emissions could be more than 60% lower. On the other hand, SFA 2022 considered only two product categories for emissions from recycled articles (toilet paper and newspaper). For example, board was completely excluded from the analysis. There is also a chance that the assumptions for bypass event frequency and extraction to wastewater are not overestimates but might be too low.

Considering all uncertainties, the dossier submitter proposes an uncertainty range of ±%60%%. As there is more evidence available that SFA 2022 might overestimate the emissions the dossier submitter proposes a central estimate of only 75% of 115tpa corresponding to 86tpa – which could already be explained by 50% less thermal paper (i.e. 25% in total) going into the recycling process than the 50% assumed by the SFA.

Disregarding the uncertainties, an important finding is that regarding the relevance for environmental emissions BPS as a drop-in substitute for BPA in thermal paper accounts for a significant share of the presence of BosC in the environment already today.

BPA-emissions from paper recycling

Thermal paper production was one of the smallest industrial uses of BPA. However, due to intensive water use and the lack of covalent bonding of additive BPA in paper coatings, recycling of thermal paper generated a large industrial source of BPA entering wastewater treatment plants (WWTPs). BPA can be removed relatively well in modern WWTPS (best cases show over 90% removal rates), but given the large entering volumes, recycling was and still is a significant source of surface water emissions.[153]

The use of BPA in thermal paper (A5) was restricted to 0.02% w/w in EU starting from 2 January 2020.

According to expert estimates the elimination of most BPA from the recycling loop takes 5 years(Pivnenko et al., 2018). Considering the assumptions from the SFA (and leaving aside the uncertainties discussed above) this seems plausible. According to SFA 2022, one can assumes that from each quantity recycled 20% of BPA content leaves the recycling loop via waste water and that an additional 25% of the remaining 80% will not enter the next recycling loop If one then assumes that at a given time no BPA-emissions are added to the recycling loop via thermal paper then the remaining stock will inevitably decline over time. If one further assumes that each quantity (i.e. fibre) is recycled on average 3 times a year the reduction of BPA content for an exemplary quantity of 100 would look like illustrated in Table 76.

Table 76: BPA concentrations in paper after restriction on BPA in TP

	Recycling	**Ingoing qty**	**20% extracted to waste water**	**next service life**	**25% not going into next recycling**
Year 1	1	100	20	80	20
	2	60	12	48	12

---

[153] European Preferable Purchasing Rapid Research, PPRC (2010): Thermal Paper & BPA–Trash or Recycle, August 2010 (Updated November 2010), available at http://pprc.org/research/rapidresDocs/PPRC_Thermal_Paper_Recycle_or_Trash.pdf

	3	36	7,2	28,8	7,2
Year 2	1	21,6	4,32	17,28	4,32
	2	12,96	2,59	10,37	2,59
	3	7,78	1,56	6,22	1,56
Year 3	1	4,66	0,93	3,73	0,93
	2	2,8	0,56	2,24	0,56
	3	1,68	0,34	1,34	0,34
Beginning year	4	1			

In this calculation, BPA quantities are reduced by 99% within 3 years. Above it was estimated for 2019, based on the data from SFA 2022, that surface water emissions of 85 tpa occurred. It seems likely that in 2020 and maybe 2021 still significant amounts of thermal paper used prior to 2020 entered the recycling loop. However, going further into the future those amounts will be minimized. Considering the model calculation BPA-emissions from paper recycling could amount to <1 tpa from 2025 onward.

Some uncertainties remain, e.g.:

- Approximately 2-3 t imported recycling waste from outside the EU might contain thermal paper

- Some fibres are recycled more often than 3 times a year and others might only be recycled after several years.

No further details are available but it might be possible that for a longer period of time BPA contained in waste paper enters the recycling loop. Therefore, the best estimate of the dossier submitter is that <1–5 tpa BPA will be emitted to the environment for an unknown period of time.

Landfilling:

In principle, thermal paper should not be disposed of with paper waste, but with household waste. The landfilling of household waste, which is still partly the practice in European countries, can release BPA into surface water.

For these reasons, uncertainty arises at this point on the subject of emissions from paper in general. Moreover, the paper cycle is not free of BPA even then, as it is used for chromophoric printing inks for paper printing, in toners and also for paper finishing. For lack of data, the BPA emission contribution might be underestimated at this point.

A6 - Hardener in epoxy resins

Phenolic hardener (A6) (unreacted) contain up to 35% BPA. The derived solids contain <0.1% or 70ppm. For this application, no information is available on thepercentage of hardener for ER cured with BPA. For the estimation of environmentally relevant emissions, information on the share of environmentally relevant uses, i.e. rather outdoor, is necessary, which is not available. The step of application (by professional user and consumer) is also assumed to be emission-relevant. Here, too, no information is available. Since A6 and P2 are inseparable and more information is available for the derived resins, the emission discussions were also moved here.

Emissions from the use as hardener in epoxy resins (A6) cannot be separated from emissions from epoxy resins themselves and therefore considered in the next chapter. For hardeners in epoxy resins (A6) the ultimate allocation to a compartment naturally depends on the sector and/or use of the respective polymer.

Table 77 Information from stakeholders for the use A6

use	sector	source	description	emission
A6	CfE	formulator	Phenolic hardeners contain up to 35% free BPA while solid epoxy resins typically contain < 1000ppm (0,1%)	Concentration hardener 35% BPA (unreacted) Derived solid resins < 0.1%
A6	CfE	formulator	Non-cured powder coatings containing phenolic hardeners may contain up to 5,6% free BPA initial free BPA concentration of about 6 wt% have been analyzed for residual free bisphenol A after curing	5.6% free BPA (uncured) 6wt% free BPA (cured)
A6	CfE	Applicant ER	low BPA containing phenolic hardeners for existing products fulfill a limit of max 400ppm in the hardener itself and of	400ppm (hardener) 70ppm (product)

A7 TBBPA

Nearly all applications of TBBPA flame retardants (A7/C2) are indoor applications without contact to water and therefore, release of unbound TBBPA is not very likely (Fischer et al. 2014). As TBBPA only contains trace amounts of BPA (typically less than 3 ppm) the amount of BPA present in TBBPA containing products seem negligible (Fischer et al. 2014).

At the end of life the ultimate allocation to a compartment depends on the sector and/or use of the respective polymer. Either way, no data on BPA emissions are available.

For the use of BPA in A7 no information on tonnage is available. But note 100% loss as worst case assumption.

A8 – A10 - Stabiliser in liquids used in closed loops

For all applications of BPA as stabiliser in liquids used in closed loops (i.e., with no foreseeable water contact; A8 – A10) no emission to the environment is to be expected. Groshart al. (2001, Tab. 1) state that no emissions to air and to water for A9 and A12 are expected.

All applications of BPA as stabiliser in liquids used in closed loops (A8 – A10) are incinerated, no emission to the environment is to be expected.

For the use of BPA in A8, A10 no information on tonnage is available. But note 100% loss due to leakage or improper disposal as worst case assumption.

A11 - Lubricants

For BPA-based additives in lubricant formulations (A11), only emissions to WWTP or surface water are expected, but no emission rates are available.

For the use of BPA in A11 no information on tonnage is available. But note 100% loss as worst case assumption.

A12 Tyres

For BPA-based additives in tyres it can be argued that emission to surface water would be expected, but Groshart et al. (2001, ch. 4.1.10) and EC JRC (2003, ch. 3.1.1.12) state that during the lifetime use of car tyres, there should be "no significant environmental release of bisphenol A." SFA2022 reports: BPA has been used as a compounding agent in car tyres and in brake fluids, however, the consortium reports that these processes no longer use BPA in the EU, though imports from non-EU could contain BPA.

Table 78 Information from stakeholders for the use A12

A12	CfE	Tyre	tyre shred content	60ppm
A12	(Ramboll Deutschland GmbH, 2022)	Tyre	tyre shred content/abrasion information	370ppm (content) 0.045tpa (from abrasion) in one country results in 0.2 tpa in the EU tyre shred for outdoor application 0.4tpa

A13 - Additional stakeholder information: Emission from rubber/fluorelastomers (FKM) (BP-AF)

The bisphenol BPAF is mainly used as a cross-linking agent (A13) for the production of rubber/flourelastomers.

The raw rubber compound contains the fluoropolymer, reinforcing fillers and bisphenol AF (vulcanising agent) as essential components. The resulting products are in the shape of solid slabs. By means of shaping processes like injection moulding, compression moulding, extruding/calendering and autoclave curing or coating/jacketing this is then processed into the desired products. Normally, BPAF is also used together with accelerators such as quaternary phosphonium salts.

In the course of the manufacturing process, starting with the non-crosslinked polymer via the crosslinking agent (blend) to the rubber mixture and the individual finished article from the full mixture, the concentration of BPAF decreases continuously from the double-digitpercentage range to theppm range. The content of bisphenol AF in the raw rubber compound is b 1-3% (w/w). There is not a significant amount of data about cured articles, but it is estimated they may be in the range of 50 – 300ppm extractable BPAF. Most of the stakeholders concluded that during vulcanization of the rubber mixture, Bisphenol AF reacts and it is no longer present in the final rubber matrix, nor in the articles to significant levels. As the crosslinked elastomer article or product is a three-dimensional structure there is no evidence for the release of BPAF during the use or end of life cycle. Nevertheless, most companies concluded that a residual BPAF content of below 10ppm in FKM-based products cannot be met.

BPAF is registered in an aggregated tonnage of 100-1,000tpa. The main use found was the production of fluorelastomers (FKM). In this manufacturing process, BPAF acts as a crosslinker (additive use). As no further or different information is available, the upper limit of 1,000 tpa of the tonnage band was used for this application.

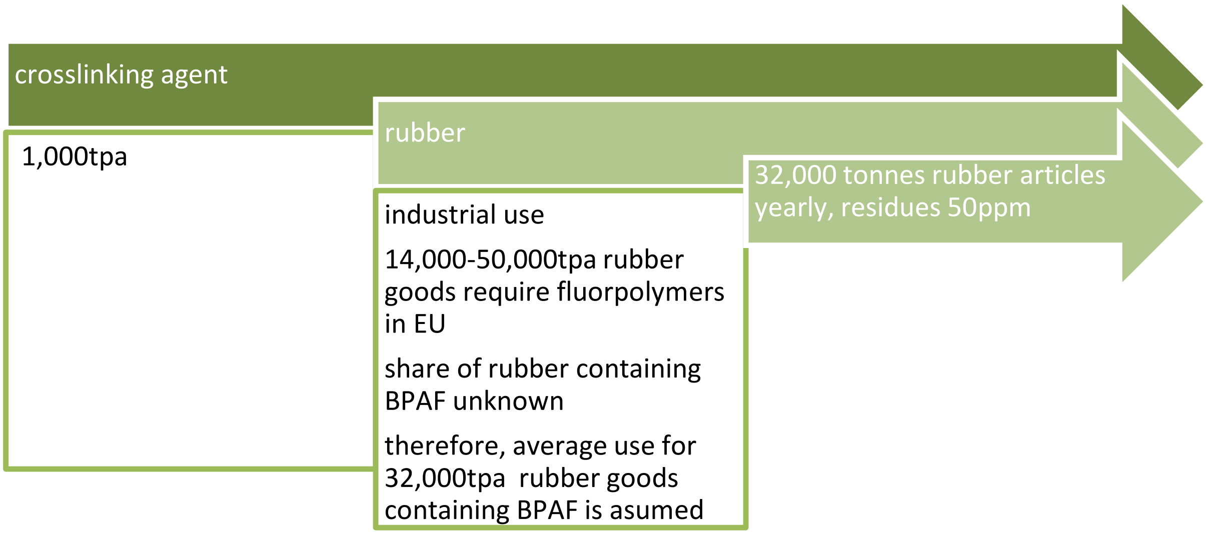


Figure 12: Processing of FKM

For this scenario, stakeholder information was used, which is based on a possible use quantity for rubber goods (FKM) 32,000 tpa containing BPAF. However, this would not correspond to the assumption that 1,000 tpa of BPAF would be used for this application if the pre-compounds contain a maximum of 5% BPAF. For this reason, the tonnage shown by the stakeholders is considered as a refinement for this scenario. Based on the 32,000 tpa FKM and a residual level of 50 ppm, the release potential is 1.6tpa BPAF (32,000 tpa FKM*50ppm = 1.6 tpa). This assumption assumes that 100% of the FKM is used outdoors. To refine this assumption, it was deduced on the basis of the product portfolio that a large number of components made of FKM are used in closed systems (e.g. sealings, O-rings) and are not relevant to environmental emissions. However, due to the lack of precise information on proportions, it is estimated that this is 75% of the product portfolio. For this reason, the estimated tonnage is multiplied by 0.25. This results in 0.4tpa BPAF that may emit to the environment. As the manufacturing and processing processes are water-free, no emissions are expected from these life cycle steps. Experts have revealed that in the recycling process, small products such as O-rings are separated into the light shredder fraction, which is then sent to landfill. In addition, it became known that despite strict recycling requirements in the context of car recycling, these small parts are not recycled but landfilled.

Table 79: Information from stakeholders for uses of BPAF

use	sector	source	description	emission
A6	semiconductor manufacturer	CfE	content in PCB prepregs*	laminate 0.1-1% final product 4,000ppm
A13	Rubber manufacturer	CfE	pre-compound content of FKM	0.3-5%
A13	Rubber manufacturer	CfE	most BPAF-cured FKMs will not be able to comply with 10ppm – best knowledge without analysis	>10ppm

A13	Rubber manufacturer	CfE	cured rubber contains less than 8ppm - analysed	<8ppm
A13	Rubber manufacturer	CfE	content	50-300ppm

* A **PCB prepreg** is a (glass) fibre fabric ((glass) fibre epoxy material) impregnated with a resin binder. The prepreg acts as an insulating layer in a PCB and is also a dielectric material. For insulation, the prepreg is located, for example, between a core and a copper foil. Prepregs can contain different amounts of resin (they are divided into standard resin (SR), medium resin (MR) and high resin (HR) according to the resin content they contain). The resin content determines the thickness of a laminate when pressed. In addition, the resin content also has a significant impact on such properties as dielectric constant, coefficient of thermal expansion (CTE) and drilling and etching quality. For prepreg PCBs, resin flow is another important principle in the lamination process.

The upper and the lower boundary are derived concerning the highest impacting uncertainty use specific.

Table 80: Stakeholder information and uncertainties impacting estimated total emissions of BPAF (upper - lower emission band)

Use	**base scenario**	**Lower emission scenario**	**Upper emission scenario**
A13	0.4 tpa	0.07 tpa (32,000tpa*8ppm*0.25)	2.4 tpa (32,000tpa*300ppm*0.25)
total	1.6 tpa	0.07 tpa	2.4 tpa

For all other additives, emissions appear to be either negligible or unknown.

Overall absolute emissions for processing and downstream use as an additive (A)

Table 81: Stakeholder information and uncertainties impacting estimated total emissions for A1-A13 (upper – lower emission band)

Use	base scenario	Lower emission scenario	Upper emission scenario
A1		0	32 tpa
A2		0	28 tpa
A3		0	1 tpa
A4		0	1 tpa
A1 – A4 recycling	46tpa	46 tpa (decreasing trend)	46 tpa
A5 BPA	106tpa (data generated for Germany with deviating technical standards, e.g. for waste water treatment and more incineration than landfill practice) additionally, 12% sludge in landfill from 257tpa paper sludge = 31tpa with unpredictable share of release and emission	Decrease of BPA in recycling loop of estimated 20% per year from 2020 2020 85tpa 2021 64tpa 2022 42tpa 2023 21tpa 2024 0tpa additionally, 12% sludge in landfill from 257tpa paper sludge = 31tpa with unpredictable share of release and emission	106tpa Additionally, 12% landfill from recycling paper sludge and from broke paper sludge from processing thermal paper → 12% of 257+240 t = 60tpa with unpredictable share of release and emission Additionally, 20% other uses with emission potential (e.g. fertilizer and compost products (Ramboll Deutschland GmbH, 2022)) Additionally, considering a smaller decrease in the recycling loop
A5 BPS	manufacture 5tpa recycling 115.2 tpa	manufacture 5tpa recycling 115.2 tpa	manufacture 5tpa recycling 115.2 tpa
A6[154]	-		loss is thinkable/curing mistakes leads to higher residues

---

[154] Since the hardeners are essential for the resin production, this discussion was classified under the estimation of P2 - epoxy resins.

Use	base scenario	Lower emission scenario	Upper emission scenario
		70ppm	60,000ppm
A7			
A8			100% loss
A9	0 tpa		
A10			100% loss
A11			100% loss
A12	0 tpa		0.6 tpa
A13	1.6 tpa	0.07 tpa	2.4 tpa
total	331 tpa	161.27tpa	332 tpa (but may qualitatively be significant higher)

BPA consumption is expected to grow by 6%. According to information from stakeholders, the annual growth rate is assumed to be 3 %. However, it remains unclear whether the increased demand for BPA is evenly distributed across all sectors. Furthermore, it is clear that the figures for BPA in TP are declining due to the restriction of BPA in TP.[155] For this reason, this information is not taken into account for the time being.

Since the hardeners also contribute to residues in the finished product, but the proportion cannot be determined precisely, the residues are related to epoxy resins (P2) for which typical residues have been investigated and quantified. At this point, however, it should be mentioned that the curing process and the conscientious execution of the process are decisive in defining the residues of unreacted BPA.

For other uses, there was simply no data to quantify the contribution of BPA/BosC to environmental emissions. However, it can be assumed that not every lubricant is used in a closed system. Hydraulic systems are also limited to the proper functioning of the shoring and seals. With the base scenario, 331 tpa were estimated that could be released through the life cycle of BPA/BosC used as an additive. Due to the aforementioned technical uncertainties, it is assumed that this quantity of emissions represents an underestimate.

B.8.6.5. Emission from polymers (P1-P15)

When BPA and/or BosC are used as a monomer in polymers, it is incorporated into the polymer matrix and covalently bound on it. Releases from polymers can occur through leaching of residual monomers in the polymer matrix or through the breakdown of chemical bonds and thus the destruction of the polymer structure, for example through weathering

---

[155] https://echa.europa.eu/documents/10162/2564887/bpa_thermal_paper_report_2020_en.pdf/59eca269-c788-7942-5c17-3bd822d9cba0 (access 2022/19/04)

during outdoor use (e.g. hydrothermal stress). If BPA/BosC are used as an additive for the production of plastics, it can as an exemption be incorporated into the matrix (e.g. crosslinker) but as a rule diffuse freely in the 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.

Starting point for the discussion on emissions from polymer uses are the findings from the registration dossier, the research project on BPA (Annex H), data from Ramboll Environ (2015), Ramboll Environ (2017) and PlasticsEurope (2021) and data from other projects like migration (and degradation) experiments.[156] The dossier submitter evaluates this data in more detail, if deemed necessary, and discusses additional information from the two calls for evidence.

P1 Polycarbonate

For polycarbonate (P1) production, emissions to soil or wastewater are not expected by Fischer et al. (2014, ch. 3.3.2). While emissions to air are not expected by EC JRC (2003), emission rates larger than zero are provided by Groshart et al. (2001, ch. 4.1.1) and Fischer et al. (2014, ch. 3.3.2). Analogously, emissions to surface water are not expected by Fischer et al. (2014, ch. 3.3.2), but an emission of 202.3 BPA kg/year surface water emission (in a year where 486,880 tons of BPA were assumed for P1 production) is given in Groshart et al. (2001, ch. 4.1.1 & Tab. 1).

Ramboll Environ (2017) and PlasticsEurope (2021) provided most of the extractable emission rates. In their emission estimation, the authors of these sources explicitly incorporated information on the portion of total product in use which realistically experiences water contact. As expected, the highest number of emission rates could be extracted for P1 sector ‘Bottles & Packaging’, as the field of plastic baby bottles receives an above average amount of attention in the scientific field. Here, the highest emission rates was transferred from findings by Biedermann-Brem et al. (2009): They detected a BPA concentration of 137 µg/L after 10 min of sterilizing a 118 g P1 baby bottle with 200 mL water. Assuming a lifetime of 2 years and 25 sterilizations per year, a standardized emission rate of ca. 0.000013 kg BPA / kg BPA in emitter per lifetime can be obtained.

According to stakeholders not every release potential leads to an emission. Therefore, some stakeholders attempted to derive the share of outdoor applications, especially for the two main uses P1 and P2. Due to the stressors acting on the products in the outdoor area, the majority of emissions are expected here.

In conclusion and regarding the service life of BPA-based polymers, emission rates greater zero could be extracted for all P1 sectors except optical media all going surface water and/or WWTP.

During the end-of-life-stage, only emissions from landfills and to WWTP are assumed. Thus, there should be no direct emissions from landfills to surface water or soil. Furthermore, Ramboll Environ (2015, Fig. 3) assume that the only emissions from municipal landfills are to water and not to air or soil.

Emission rates of BPA-based products during the end-of-life stage are especially scarce, but Xu et al. (2011) reported a 0.83% leachability of 6.1 ppm residual BPA in P1 bottle waste. Moreover, Ramboll Environ (2017) assume (i) “that 3.2% of residual BPA in [P1]

---

[156] G.A. Petersen et al.: Migration of bisphenol A from polycarbonate plastic of different qualities Environmental project No. 1710, 2015 – Danish Ministry of the Environment. Available online via https://backend.orbit.dtu.dk/ws/portalfiles/portal/110762088/BPA_MST_project_No_1710_2015.pdf

disposed of in landfills is leached from municipal solid waste as landfill leachate” and (ii) that “[P1] plastics are estimated to contain a maximum of 0.015% residual BPA” so that an emission rate of 0.048% is assumed.

Finally, absolute emissions per and across life cycle stages and environmental compartments were estimated where possible.

Note that for the final absolute emission estimation, the BPA that was originally emitted to WWTP is treated and its remaining fraction is ultimately added to surface water emissions, so that WWTP does not appear as one of the three final compartments air, soil and surface water.

According to the data presented in Annex H for P1, the absolute emissions would sum up to 1 t.

Table 82: total emissions for P1 per life cycle stage and sector (initial estimate)

Code	Sector	Life cycle stage	Air (tons)	Soil (tons)	Surface Water[1] (tons)	Total (tons)
P1	Production	Manufacture	0.422	0	0.48	0.902
	Building & Construction	Service life	0	0	0.152	0.152
	Electrical & Electronics	Service life	0	0	0.00706	0.00706
	Optical Media	Service life	0	0	0	0
	Automotive	Service life	0	0	0.0911	0.0911
	Domestic Appliance	Service life	0	0	0.000343	0.000343
	Other	Service life	0	0	0.000393	0.000393
	Safety & Leisure	Service life	0	0	0.000863	0.000863
	Bottles & Packaging	Service life	0	0	0.0625	0.0625
	Medical & Healthcare	Service life	0	0	0.026	0.026
	Building & Construction	End-of-life	0	0	0.00618	0.00618
	Electrical & Electronics	End-of-life	0	0	0.00309	0.00309
	Optical Media	End-of-life	0	0	0.00089	0.00089
	Automotive	End-of-life	0	0	0.0000556	0.0000556
	Domestic Appliance	End-of-life	0	0	0.000742	0.000742
	Other	End-of-life	0	0	0.000371	0.000371
	Safety & Leisure	End-of-life	0	0	0.000371	0.000371
	Bottles & Packaging	End-of-life	0	0	0.000124	0.000124
	Medical & Healthcare	End-of-life	0	0	0.000297	0.000297 t

[1] Surface Water also includes emissions to WWTP after WWTP treatment. BPA removal efficiency of WWTP treatment assumed as 88%.

[2] The total emission across life cycle stages and compartments divided by the corresponding total consumption.

Source: BioMath (Annex H)

The dossier submitter argues that the data provided by industry stakeholders more recently and the previous data used by the researcher of the project on BPA is highly uncertain and both might underestimate emissions significantly:

- Both analyses use an annual release rate of 0.15 mg/m^2 for (non-coated) outdoor polycarbonate applications as derived in the European Risk Assessment Report on BPA (EU-RAR 2003), page 23 for all relevant outdoor applications. However, for EU-RAR 2003, samples of polycarbonate sheet were analysed with a residual bisphenol-A content of 6 mg/kg. Considering recent stakeholder information from the two CfEs (see below) the dossier submitter estimates that more than 70% of PC have a residual bisphenol-A content of 10-200 mg/kg, i.e. using the release rate from RAR 2003 will underestimate emissions. Assuming a worst-case average BPA content of 150 mg/kg and linear emission potential the annual release rate could be minimum 25 times higher (6 mg/kg = 0.15 mg/m^2; 150 mg/kg = 3.75 mg/m^2).

- Samples of circulating water within the system were taken for analysis. For SFA 2022 the authors assume that release of BPA from landfilled Polycarbonate (PC) has been estimated conservatively by using experimental laboratory data determined at parameters similar to the typical conditions in a landfill. The following release value has been determined: 24.9 mg BPA/kg PC per year, which can be transferred to an annual release of 0.0025% (BPA release per landfilled PC). The value used in the previous Chemical Safety Report (2015) of 0.0088% was no longer used, as it had been assumed to be determined at unrealistic conditions not representative for typical landfill situations.

- The dossier submitter points out that the release value determined for the updated SFA (Ramboll Deutschland GmbH, 2022) is based on data from Sajiki et al. (Sajiki J. , 2003). The authors do not further specify the properties of the test samples used (they are characterized as PC-tubes). No information is given on BPA-residues. Therefore, it is unknown how generalizable the results are. Further, the emissions for the SFA 2022 are estimated on an annual basis. PC-articles have a very diverse service-life. [4] Further confidential information is contained in a separate annex which is not available in the published version of the dossier.

- Considering a restriction scenario over 20 years, in absence of more detailed information, the dossier submitter assumes that landfilled waste has a service life of 10 years on average. Therefore, for a 20-year emissions scenario, yearly emissions from landfilling need to be multiplied by 10. Further, in the SFA 2022 the authors assume an average degradation rate in subsequent waste water treatment of ~88% to calculate the surface water loadings from annually landfilled PC to 0.34 t BPA. The dossier submitter understands that the 88% does not consider bypass events, thereby underestimating emissions.

- Lastly, the updated SFA tries to empirically check the plausibility of the assumptions: "Surface water loadings from German landfills have been calculated based on measured landfill effluent data (Ramboll Deutschland GmbH, 2019) and a respective modelling via a "Substance Flow Analysis (SFA) and Regionalized Pathway Analysis (RPA) for Emissions of Bisphenol A (BPA) into the Environment" (Ramboll Deutschland GmbH, 2022). These measurements and respective calculated loadings intrinsically comprise BPA releases from various landfilled materials, which may contain BPA, such as paper, PVC, Polycarbonate, epoxy resins and other materials. For the modelled domain, which comprises Germany and adjacent areas, annual surface water loadings from landfills have been calculated at ~ 1100 kg. For a rough estimation this figure is extrapolated to EU by adjusting via the respective population number (model domain: 137,204,98850; EU: 447,710,00051). The respective approximation for the annual surface water loadings in EU results in: ~3590 kg." The dossier submitter points out that the share of landfilling in Germany – and especially that of municipal waste with less than 0.2%– is far lower than the EU-average.[157,158] Therefore, even if the calculations for Germany are valid, the extrapolation to the EU is most likely a large underestimation of the annual surface water loadings. Therefore, the dossier submitter disagrees with the claim of the authors that this empirical data checks the plausibility of their theoretical calculations.

Further information from the two calls for evidence and literature:

Several stakeholders reported that they cannot meet a concentration limit of 10 ppm for their PC-uses. Taking all information into account it seems likely that between 60 – 80% of PC manufactured does not meet a 10ppm concentration but most likely 150ppm (some stakeholders referred to being able to meet a 200ppm limit and did not explicitely discuss whether they could meet 150ppm).

Lamprea et al. (2018) investigated a representative selection of building materials and car accessories, and identified painted car bodies as an important source of BPA contamination in urban runoff with a tested water emission of up to 360 ng/cm2 (24 times larger than the used emission factor of 0,15 mg/kg). According to this finding it cannot be excluded that the emission of BPA from weathered coatings play a significant role in the overall exposure.

Conclusion: The researcher of the project on BPA (Annex H) estimated annual emissions of approximately 1 t from the use of BPA for the manufacture of PC. In the current registration for BPA, a comparably low overall emission comprising of releases to European surface water from all PC articles in use of 87.8 kg is estimated. The manufacture of BPA and polycarbonate approximately 0.4 t (the dossier submitter does not fully understand the given value of 92tpa emissions from industrial uses in Germany and how it translates to a value for the EU for manufacture of PC and the used BPA); end of life emissions via landfilling 0.34 t. The dossier submitter pointed out shortcomings in both estimates which lead to the conclusion that emissions might be underestimated. While the data for manufacturing of PC could not be further checked and therefore seems plausible, the dossier submitter argues that emissions from service life could be up to 25 times higher than the estimations from the 2022 SFA or the registration (mainly because the chosen annual release rate might be too low) and that releases from landfilling could be more than 10 times higher (over twenty years) or even more (because of uncertainties in regard to the waste water treatment.

Considering the large uncertainties, the dossier submitter estimates a possible range of emissions from <0,9tpa - >6tpa. Details are summarized in Table 83.

Table 83: Emissions from PC uses (only to surface water)

Use	SFA 2022 tpa	Annex H tpa	Upper emission scenario tpa
P1 total	<0.9	approx. 1.0	>6.0
- Manufacture	<0.4	0.480	<0.4
- Service life	0.088	0.317	2.195
- End of Life	0.340	0.012	>3.4

---

[157] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=File:Waste_treatment_by_type_of_recovery_and_disposal,_2018_(%25_of_total_treatment)_30-04-2021.png

[158] https://www.umweltbundesamt.de/daten/ressourcen-abfall/ablagerungsquoten-der-hauptabfallstroeme#ablagerungsquoten-

P2 – Epoxy Resins

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

Annex H estimated that for epoxy resin (P2) production, only emissions to surface water are expected. The highest emission rate was given in Epoxy Resin Committee (2015, p. 2) as “between 5 and 19 g of BPA per produced ton of epoxy resin was released after on-site and municipal waste water treatment in the past ten years”.

Epoxy resin-based products, usually coatings, adhesives, sealants, or composites are based on cured epoxy resins. The original resins before curing have BPA contents in the lowerppm range. Curing further reduces the residual levels. There is no validated method for a robust quantification of BPA in cured epoxy resins. Validated methods are only available for epoxy resins before curing. Therefore, a comparison of release of BPA versus residual of BPA in cured resins was not feasible.

Regarding emissions from landfills, Annex H considered information from Ramboll Environ (2017) that 3.2% of the 0.0025% residual BPA in P2 may emit from products disposed of in landfills.

Emission estimates from the research project on BPA (Annex H) are summarized in Table 84.

Table 84: estimate for total emissions for P2 (only BPA) per life cycle stage and sector

Code	Sector	Life cycle stage	Air (tons)	Soil (tons)	Surface Water[1] (tons)	Total (tons)	Total / Consumption[2]
P2	Production	manufacture	0	0	10.5	10.5	
	Marine & Protective Coatings	Service life	0	0	0.00015	0.00015	
	Automotive Coatings	Service life	0	0	0	0	
	Electrical & Electronics	Service life	0	0	0	0	
	Leisure	Service life	0	0	0.022	0.022	
	Building & Construction	Service life	0	0	0.00598	0.00598	
	Civil Engineering	Service life	0	0	0.00598	0.00598	
	Household & Furniture	Service life	0	0	0.0024	0.0024	
	Marine & Protective Coatings	End-of-life	n.a.	n.a.	0	0	
	Automotive Coatings	End-of-life	n.a.	n.a.	0	0	

	Electrical & Electronics	End-of-life	n.a.	n.a.	0.000192	0.000192
	Leisure	End-of-life	n.a.	n.a.	0.0000634	0.0000634
	Building & Construction	End-of-life	n.a.	n.a.	0.000384	0.000384
	Civil Engineering	End-of-life	n.a.	n.a.	0.00000576	0.00000576
	Household & Furniture	End-of-life	n.a.	n.a.	0.0000576	0.0000576

Source: BioMath (Annex H)
[1] Surface Water also includes emissions to WWTP after WWTP treatment. BPA removal efficiency of WWTP treatment assumed as 88.
[2] The total emission across life cycle stages and compartments divided by the corresponding total consumption.

Updated confidential stakeholder information from 2022 concludes that emissions of BPA from the manufacture and use of epoxy resins are lower even during service life. While the dossier submitter does not fully understand the calculation for manufacturing, it is very likely that according to this estimation the expected emissions from the manufacturing of epoxy resins are <500 kg/a. The expected emissions from service life are reported to be extremely low at <5kg/a BPA emissions from all uses. For end-of-life 21 kg/a emissions are stated.

Discussion:

Both studies (by design and explicitly) do not consider emissions from BosC, namely BPF, which is used to manufacture approximately 40 000 tpa epoxy resins (stakeholder information, 2nd CfE). This will be considered separately by the dossier submitter.

Additionally, the dossier submitter points out that both project research on BPA (Annex H) and the current registration data most likely contain fundamentally flawed emission estimates and are likely to severely underestimate the emissions of bisphenols from uses in epoxy resins during service life and waste phase.

Manufacturing: The dossier submitter does not fully understand the estimations by project research on BPA (Annex H) and the registration and therefore recalculates the information given by the epoxy resin committee: "Additional BPA may be released when leftovers and excessive quantities of BADGE are washed during manufacturing of the Liquid Epoxy Resins. BPA dissolved in water is assumed to be disposed of via the waste water treatment plants and sewages. ERC Members indicated that between 5 and 19 g of BPA per produced ton of epoxy resin were released after on-site waste water treatment in the past ten years (Epoxy Resin Committee 2015[159])". According to this information emissions from manufacturing amount to:

Equation 3: BPA emission from manufacture ER

BPA: 275,000tpa x 0.000005-0.000019 = 1.37 – 5.21 tpa

The dossier submitter assumes that the same emissions estimate can be used for BPF:

---

[159] https://epoxy-europe.eu/safety/assessment-of-potential-bpa-emissions-from-epoxy-applications/ (access 2022/30/09) [Epoxy Resin Committee 2015: EPOXY RESINS IN WATER PIPES. ASSESSMENT OF POTENTIAL BPA EMISSIONS, https://epoxy-europe.eu/resources/factsheets/]

Equation 4: BPF emission from manufacture ER

BPF: 40,000 tpa x 0.000005-0.000019 = 0.2 – 0.76 tpa

Service-life:

Both the project research on BPA (Annex H) and current registration data do not consider the *application stage* when epoxy-coatings are applied to articles and the manufacturing stage when articles are manufactured from epoxy resins. It is difficult to conclude on emission potential from this lifecycle step but factsheets provided by the epoxy resin committee point out the potentially significant emissions.[160] A scenario for marine uses estimates 96 kg BPA release to the environment, for wind energy applications up to 70 kg of BPA residues might be landfilled (approximately one third of use quantities become waste during the manufacturing of the blades). Other factsheets (e.g. automotive, water pipes) report lesser quantities.

Use quantities for marine coating and wind energy applications amount to approximately 16 and 8% respectively of total epoxy resins use in the EU. The emissions estimation for the application stage is the largest. However, using this as a worst-case assumption for all uses would most likely overestimate the real emissions (multiply by 4.2=697 kg/a). Marine applications have a comparably high share of solid epoxy resins (SER) use. Stakeholders report a 70% share for SER-uses. Additionally, several other uses are industrial with presumably better emissions control during the application stage (e.g. automotive industry, electronics, medical devices). On the other hand, no information is available for large parts of direct consumer uses and uses by SME and in craft workshops. In sum, the dossier submitter needs to come to an expert judgement and assumes that the emission potential for the remaining 76% is one third lower than that of marine and wind energy related uses. Emissions from the application stage are than estimated to be less than 0.515 tpa for BPA and BPF.

Both the project research on BPA (Annex H) and the registration data consider the actual service life to be of very minor importance for the emissions. Annex H estimates <50 kg/a and the registration even <5 kg/a. For the CSR estimate the dossier submitter points out:

- All emissions estimations are based on preliminary results from a study Epoxy Europe launched in 2021 with the Institute for Materials Research and Testing (BAM). The dossier submitter is not aware of a proper documentation of the test setup at the moment of writing this dossier. Especially, no specifics are available in regard to the tested materials. If those are SERs it is not possible to use them to predict emissions from LER uses as long as no more detailed information is available. The dossier submitter's understanding is that BPA residues in LER are between <0.5ppm and LoQ. BPA residues in SER are <65ppm. Consequently, emissions for some uses could be underestimated by a factor of far over 130. Some stakeholders estimated approximately 30% use of SER.

- Emission estimates are based on best practice. However: "The potential for release of BPA seems to be high in case epoxy resins are not used in the right way, which means that for example the ratio between curing agent and resin was incorrect or the temperature and dry time have not been sufficient to allow complete polymerisation and thus hardening of the resin. Also, in case sealed surfaces like surfaces in cans show scratches, increased leaching has been observed (Fischer et al. 2014).

---

[160] https://epoxy-europe.eu/resources/factsheets/

- For some uses with a long service life damage to the coating can be severe. For example, it is the dossier submitters understanding that for marine ballast water tanks between 3 and 20% of the coating are lost within 8 years of service life (see Eliasson et al. 2008, especially P.9[161]).

- Lamprea et al. (2018) investigated a representative selection of building materials and car accessories, and identified painted car bodies as an important source of BPA contamination in urban runoff with a tested water emission of up to 360 ng/cm^2 (24 times larger than the used emission factor of 0.15 mg/kg). According to this finding it cannot be excluded that the emission of BPA from weathered coatings play a significant role in the overall exposure.

In sum, the dossier submitter notes that the emissions from approximately 70% LER-use might be comparably low (from LOQ to <10ppm), but there is the distinct possibility of significant wide dispersive emissions from SER-uses, considering the total amount of BPA residues which amount to a maximum of

Equation 5: emissions from SER use

65 ppm x 107,000 tpa = 6.955 tpa

No further information is available. Therefore, the dossier submitter assumes significant BPA emissions.

End of life:

Assumptions from the project research on BPA (Annex H) and the BPA registration about the share of articles that end up in landfilling are very uncertain. Both analyses end up with very small quantities: findings from the research project on BPA (Annex H) with<1kg/total and CSR ([5] further confidential information is contained in a separate annex which is not available in the published version of the dossier).

- For wind rotor blades the CSR contains an for the amount of epoxy resins annually is used in wind turbines production ([6] further confidential information is contained in a separate annex which is not available in the published version of the dossier). Usually not landfilled but used in cement kiln. Thermal degradation of Epoxy Resin during this process is assumed. Only 10% is assumed to end up in landfills. Then the amount of residual BPA is calculated with an assumption that 65% are manufactured using LER and 35% using SER: 799 kg/a. Although 10% is assumed to end up in landfilling only 1% of residual BPA, 0.07 tpa is calculated for the emissions estimate. The dossier submitter notes that besides this inconsistency the assumption that most rotor blades are incinerated in cement kilns is wrong. There is already a ban on landfills in Austria, Germany, Finland and the Netherlands (the Netherlands have potentially large exemptions). According to Wind Europe (2020)[162] landfilling is still the cheapest way to dispose of the rotor blades. They give an example from the Netherlands: 'Under the 3rd edition of the National Waste Management Plan landfilling of composite waste is banned 'in principle'. However, wind farm operators can benefit from an "exemption" if the cost of alternative

---

[161] The Future of Ballast Tank Coatings By Johnny Eliasson, Stolt-Nielsen Transportation Group, and Rodney Towers, 2007. https://www.paintsquare.com/library/articles/The_Future_of_Ballast_Tank_Coatings_fullreport.pdf

[162] WindEurope/Cefic/EuCIA: Accelerating Wind Turbine Blade Circularity, 2020, https://windeurope.org/wp-content/uploads/files/about-wind/reports/WindEurope-Accelerating-wind-turbine-blade-circularity.pdf

treatment is higher than 200 EUR/t. According to a survey conducted by WindEurope, the cost of mechanically recycling wind turbine blades in the Netherlands ranges between 500-1,000 EUR/t including onsite pre-cut, transport and processing. Mechanical recycling itself costs between 150-300 EUR/t. This means landfilling is still practised.’ In the same report it is mentioned that only one pilot project cement kiln for co-processing exists in Germany. Part of the industry is trying to increase the recycling rate for turbine blades (WindEurope et al. 2020). Therefore, the dossier submitter’s worst-case assumption is that at the moment 90% of turbine blades are landfilled. However, it is also noted that most likely more recycling will take place in the near future.

- The current registration data states 1.940 t of residual BPA for automotive uses considering the use of 50% SER. It s argued that the waste will be completely recycled or incinerated. However, according to one recent study a ‘serious problem in the EU are 'lost vehicles' that are never delivered to the recycling network. The scale of this phenomenon is approx. 35% of all deregistered vehicles in the EU. There is a high probability that a large portion of these vehicles is not disposed of according to the requirements of the Directive and other European regulations (Merkisz-Guranowska et al. (A., 2022)). Further, it is possible that a significant share of epoxy resin uses end up in automotive shredder residue. Automotive recycling is focused above all on metallic fraction recovery constituting about 75% in weight of the vehicle The remaining 25%, after most of the metal content has been removed, is called “car-fluff” or ASR (Automotive Shredder Residue), and it is mainly intended for landfill disposal. It consists of a heterogeneous mix of glass, plastic, rubber, oil, petrol, coolant additives, brake fluid, some metals, stones, mud, felt and other natural fibers, wood, water, and general road dirt. In 2019, the total recycling and reuse rate of end-of-life vehicles in EU-27 was 89.6%.[163] Morin et al. report that car fluff was one of the waste categories with the largest concentrations of BPA (6490 ± 3350 µg/kg) in their research in Norway (Morin N., 2015).

The dossier submitter proposes to recalculate emissions from end of life as follows for an upper limit estimation:

Table 85: Bisphenol A content in waste from cured epoxy resins and calculated leachable fraction of BPA from the waste over 20 years

Waste stage	**Epoxy used annually in sector**	**Residual BPA in used tonnage annually (kg/year)**	**Bisphenol A in cured epoxy resin landfilled waste** 9 **(kg/year)**	**Leachable Bisphenol A in cured epoxy coating waste (kg/20 years)**10
Marine coating	61,000 mt	2.800	Unknown but small	>0
Water pipes	2,846 mt	1.4	1.4	0.5
Wind rotor blades	27,300 mt	799	720	230.4
Automotive	29,862 mt	1.940	<1.940	<620,8
Flooring	102,000 mt	51	10	3,2
Other uses	98,000 mt	1,313.2	1,313.2	420,2
Total	**321,000 mt**		**<1 275,1**	

---

[163] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=End-of-life_vehicle_statistics

Leaching was calculated with the yearly leaching rate proposed by CSR 2022 of 1.6%.

With a removal rate of 61% in waste water treatment of the landfill leachate **<497 t** emission over 20 years from one year use quantities are possible.

Table 86: Emissions from ER uses (only to surface water)*

Use	**SFA 2022 kg/a**	**Annex H kg/a**	**Dossier submitter scenario kg/a**
P2 total			>7 467
BPA			+ unknown emissions from use phase
BPF			
Total	<10 551	<526	
- Manufacture			
BPA			*1 370 – 5 210*
BPF			*200 – 760*
Total	10 500	<500	1 570 – 5 970
- Service life (processing)			
BPA			87.5 – 450.6
BPF			12.5 – 64.4
Total	-	-	< 0,515 (likely to be lower, but >100 kg)
- Service life (use phase)			Unknown: wide dispersive use with the possibility of several hundred kg emissions.
BPA			
BPF			
Total	<50	<5	
- End of Life			
BPA			<435
BPF			<62
Total	<1	21 (one year)	<497 (20 years)

* without consideration of epoxy hardeners

The dossier submitter notes the high uncertainties which are mainly due to the complex uses and missing information. Additionally, some general assumptions underly high uncertainties. Leachate from landfills is assumed to undergo treatment onsite and/or in WWTP. However, SFA 2022 estimates that in Germany 8% of landfills emit leachate without treatment and for 21% it is unclear if and what kind of leachate treatment is done.

In Ramboll 2019, a number of 37,500 wild landfills was assumed. Wild landfill loadings were calculated based on population fractions in each coordination area. For these wild landfills, direct discharge to surface water was assumed (0% removal) and the loadings were assumed to be equivalent to the active landfills with no treatment

Additionally, no information is available whether a generalization of this information for the whole EU would be an under- or overestimate of the situation for the whole EU.

Further uncertainties:

- Epoxy Europe reports in a factsheet[164] for water pipes a leaching rate of 0.01 – 0.05 mg/L for newly installed pipes. Annual BPA residues for this use are estimated to be <29 kg/a.

Most uncertainties refer to the use of phenolic hardeners where BPA is used as an additive. Some stakeholders submitted information:

- Stakeholder information: Powder coatings are cured with phenolic hardeners. Non-cured resins contain <50 – 1 000ppm free BPA. Non-cured phenolic hardeners may contain up to 5.6% free BPA.

- Stakeholder information: Phenolic hardeners contain up to 35% (350,000ppm) free BPA while solid epoxy resins typically contain <0.1% (SER content <1,000ppm).

- Stakeholder information: Release to the environment from cured powder coatings is expected to be very low but only limited qualitative information is available: Epoxy coated articles for outdoor use exposed to UV are coated with a UV-resistant topcoat. Otherwise, onshore articles are buried (e.g. pipes) and offshore articles are below the sea level.

- Stakeholder information: For phenolic hardeners initial free BPA concentrations of about 6 wt.-% have been analyzed for residual free bisphenol A. After curing max. 200ppm. (relates to a reduction from 17 t free BPA in non-cured products to ca 60 kg in the cured products for Europe)

- Stakeholder information: residual concentration depend on type of ER: LER, SER (solid epoxy resin); 20-30% ER >10ppm residues; few epoxy grades have >200ppm; curing decreases content of BPA.

No further information is available on specific uses. The used quantity for BPA is according to this information 17tpa and the emission potential is according to the same stakeholder 60 kg/a. However, another stakeholder reports higher values for initial BPA concentration in the hardener, as well as up to five times higher concentrations (200 ppm vs. 1,000 ppm) in cured articles, which the dossier submitter understands would implicate five times higher emission potential of up to 300 kg residual free BPA.

P3-P13 – other polymer uses

The research project on BPA investigating values in and releasing from products (Annex H) obtained little to no information on other reported uses. Emission rates greater zero could be extracted for emissions during the production of phenolic resins (P8) to surface water and WWTP (EC JRC 2003, 2008a; Fischer et al. 2014; Groshart et al. 2001). In conclusion and regarding the processing/production of BPA-based polymers, emission rates greater zero could be extracted only for P8 to air, surface water and WWTP. For pathways with no expected emissions, emission rates are assumed to be 0. If no data could be extracted from any of the identified sources, the emission rates are set to be unknown. Groshart et al. (2001, Tab. 1) explicitly state 0 emissions to air and to water for the "use pattern and production data" of P6 and P11.

---

[164] Epoxy Resin Committee 2015: Epoxy resins in water pipes: Assessment of potential BPA emissions, https://epoxy-europe.eu/wp-content/uploads/2015/07/Epoxy_ERC_BPA_WhitePapers_-Water_Pipe.pdf (accessed 2022/30/09)

P14 Emission from syntans and leather (stakeholder Information)

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. 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 tpa (Ramboll Deutschland GmbH, 2021). For BPF, no further information or specifications on the distribution of the total tonnage after use are available. This substance is registered with a tonnage range of 1,000 - 10,000tpa.

50 % of syntans are exported, equivalent to 3,500 to 4,000 t/a BPS (Ramboll Deutschland GmbH, 2021). Import of syntans was estimated as <20% by stakeholders (TEGEWA, 2022), although this is considered a rough estimate based on prior communications (Ramboll Deutschland GmbH, 2021). A German stakeholder association reported, that only one tannery imported 30% of its syntans used for leather production (TEGEWA, 2022).

BosC content of syntans

A measuring campaign conducted by stakeholders (Muppa, 2021) measured BPS and BPF content in sulfone and phenol based syntans. 13 different sulfone based syntans were tested. Of the 13 all were tested for BPS, only 7 were tested for BPF. BPF content ranged between 20 ppm to 600 ppm, with a mean of value of 260 ppm. The BPS content of the same syntans ranged from 75 ppm to 64,000 ppm, with a mean of 27,302 ppm. 11 phenol based syntans were tested. Of the 11 all were tested for BPF, only 9 were tested for BPS. BPF content ranged from 300 ppm to 12,000 ppm, with a mean of 4,708 ppm. BPS content ranged from 0 to 100 ppm, with a mean of 50 ppm. The limit of quantification and detection was not given. It is important to note that BPS and BPF simultaneously occurred in 14 of the 16 fully analysed syntans. The BosC concentration of sulfone based syntans consisted majorly of BPS, whereas the BosC concentration in phenol based syntans consisted majorly of BPF.

Stakeholders reported an equivalent of 1 % residual BPS content in syntans and concluded to calculate this as 2 % unreacted BPS monomer equivalent to be able to take into consideration commonly added auxiliaries during product formulation (Ramboll Deutschland GmbH, 2021). BPF may be produced as a result of using these auxiliaries during the polymerisation of syntans (TEGEWA, 2022). As demonstrated above by Muppa (2021) the BPS and BPF concentrations vary widely between syntans. To compensate for this variation a similar approach was taken by the dossier submitter as stakeholders have used. The mean sum of BPS and BPF concentrations are added up to ΣBPS/BPF and used to express BosC monomer equivalent in further calculations concerning syntans. The numeric values are taken from Muppa (2021). The real case estimate is considered 2.9 % ΣBPS/BPF (sulfon based syntans 27,302 ppm BPS + 260 ppm BPF) and the worst case scenario 4.7 % ΣBPS/BPF (phenol based syntans 50 ppm BPS + 4,708 ppm BPF).

2 % ΣBPS/BPF estimated by stakeholders (Ramboll Deutschland GmbH, 2021) is considered the best case scenario.

Emissions from syntan production

Stakeholders have reported that syntans are produced in a closed loop, however the equipment used for production is washed. The resulting water contains syntan traces and is processed in WWTPs (2 CfE, #57). Further information was not provided and so it is unclear how much BPF/BPS is actually released into surface waters from this step in syntan production.

Emissions from leather tanning

The European Leather Federation submitted information on world leather production. In 2014, this amounted to 558.4 thousand tonnes of heavy (vegetable tanned) leather, 14.540 million square metres of light (Cr and synthetic tanned) cow leather, 5.367 million square metres of light sheep and goat leather, 4,565.8 million pairs of shoes with leather uppers. No quantities for the EU can be derived from this information. In 2011 the production of 224 million m^2 of finished leathers and about 44,000 tons of sole leather was reported by COTANCE (2012). Based on the assumption made by stakeholders (CfE #57) that $10cm^2$ leather are equal to 1 g of leather, EU leather production in 2011 was 224,000 tonnes of finished leather and 44,000 tonnes of sole leather (sum 266,000 tonnes). The dossier submitter assumes that both finished leather and sole leather is treated with syntans.

The syntans can be liquid products or sprayed powders which are added to the leathers in an aqueous float in a tanning drum. During the tanning process BPS from syntans is partially taken up by the leather and partially remains in the processing water. Stakeholders reported this distribution between 80:20 to 65:35 leather: water for BPS, BPF was not considered (Ramboll Deutschland GmbH, 2021; TEGEWA, 2022). An uptake of > 90 % for BPS and BPF was documented by another stakeholder (Muppa, 2021). The OECD (OECD, 2014a) reports an 80 % degree of fixation for re-tanning agents, which would lead to 20 % residue in processing water. The remainder of ΣBPS/BPF in processing water meant for waste water treatment is considered 35 % for the worst case, 20 % for the real case and 10 % for the best case scenario.

Stakeholders shared monitoring data concerning three on-site tannery WWTPs including information on BPS concentration in influent, effluent and river (µg/L) and water volume per year (m^3/a) (Ramboll Deutschland GmbH, 2021), see **Table 87**. The methodical details of BPS measurements are not clear e.g. is the concentration based on a yearly average or on one sampling event.

Table 87: Monitoring data from different WWTP

	BPS (µg/L)	**Volume (m^3/a)**
Tannery A, WWTP in	7,600	300,000
Tannery A, WWTP out	10	226,000
Tannery A, River	< 5	270,000,000
Elimination (%) 99.90		
Tannery B, WWTP in	11,000	n.a.

Tannery B, WWTP out	10	n.a.
Elimination (%) 99.91		
Tannery C, WWTP in	61,000	65,000
Tannery C, WWTP out	< 5	2,737,500
Tannery C, River	< 5	32,000,000
Elimination (%) 99.65		

Tanneries A and B were reported to have above average capacity and use their own on-site WWTP. Tannery C is reported as average EU capacity. It is connected to a municipal WWTP, which explains the disproportionate amount of effluent. Concentrations in the effluent were 10 and < 5 µg/L respectively, whereas the concentration in river water was measured at sties A and C at < 5 µg/L. For Tannery B the ECHA recommended default dilution factor of 10 can be applied to effluent concentration to estimate river concentration. River concentration near tannery B is therefore estimated as 1 µg/L. Although elimination of BPS from waste water at both plants was < 99 % the resulting concentration in river water was in the range of 1 - 5 µg/L. In comparison the highest BPS concentration for surface water monitored in the EU is 210 ng/L (see Annex B.4.2.4.2.). For tannery A the dossier submitter calculated a resulting BPS discharge of 2.26 kg/a from the data given.

No information on waste water treatment of BPF after tanning was provided by stakeholders.

The OECD Emission Scenario Document for leather (OECD, 2014a) allows the calculation of local emissions of tanning chemicals into waste water per day. The **Equation 6** is used in combination with values given in Table 88:

Equation 6: local emissions of tanning chemicals

$E_{localwater} = Q_{rawhide} \times F_{remaining\text{-}mass} \times Q_{chemical\text{-}formulation} \times F_{chemical} \times (1 - F_{fixation}) \times F_{daily\text{-}production} \times (1 - F_{on\text{-}site\text{-}treatment})$

Table 88: symbol explanation for Equation 6

symbol	**explanation**	**Value (default)**
$E_{localwater}$	Local emission of chemical to wastewater per day	
$Q_{rawhide}$	Mass of processed raw hide per day	15 t/d
$F_{remaining\text{-}mass}$	Factor of remaining mass of raw hide	0.35
$Q_{chemical\text{-}formulation}$	Mass of chemical formulation used per mass	150 kg/t
$F_{chemical}$	Content of chemical in formulation	0.5
$F_{fixation}$	Degree of fixation – real case – worst case – best case	0.8 0.65 0.9
$F_{daily\text{-}production}$	Fraction of daily production treated with the product	1
$F_{on\text{-}site\text{-}treatment}$	Fraction of chemical eliminated on-site prior to municipal WWTP	0

All parameters for different scenarios are given in **Error! Reference source not found.**. The following paragraph describes real case scenario I. The local emission of syntans from one average tannery into waste water is 78.75 kg/day. As the concentration of ΣBPS/BPF in syntans is considered 2.9 %, the local emissions of ΣBPS/BPF into waste water would be 2.284 kg/day. Considering that there are about 1,500 tanneries in the EU, the resulting EU wide emissions of ΣBPS/BPF into waste water from tanning would be 3426 kg/day. ECHA (ECHA guidance R.16) considers that only 80 % of waste water is treated in waste water treatment plants. Following this assumption 685.2 kg/day (20% of 3246 kg/day) reaches surface water without any removal rate applied. The remaining 2740.8 kg/day undergo waste water treatment in WWTPs. With a removal rate of 98 % in WWTPs the effluents would receive 54.816 kg/day from this pathway. The overall input into surface water from treated and untreated waste water would therefore be 740.016 kg/day (the sum of 685.2 kg/day and 54.816 kg/day). To calculate the yearly output of ΣBPS/BPF into surface waters 300 days (stakeholder suggestion from Ramboll Deutschland GmbH (2021)) were used to represent the number of days in a year tanning would take place. This resulted is a calculated output of 2220.05 tpa ΣBPS/BPF into European surface waters from tanning. For direct comparison real case scenario II is given in Table 89. For real case scenario II the only parameter changed is the percentage of tannery waste water cleared in waste water treatment plants. The increase from 80 % to 100% reduces ΣBPS/BPF emissions from 222 tpa to 20.56 tpa. It is therefore essential, that all waste water produced during tanning be treated in WWTPs.

Table 89 Results from sytan and ΣBPS/BPF release from leather tanning

Parameter	Worst case scenario	Real case scenario I	Real case scenario II	Best case scenario
$F_{fixation}$	0.65	0.8	0.8	0.9
% ΣBPS/BPF in syntans	4.7 %	2.9 %	2.9 %	2 %
Local emissions (E_{local}) of syntans into waste water by tannery calculated following OECD guidance	137.8 kg/day	78.75 kg/day	78.75 kg/day	39.37 kg/day
Local emissions of ΣBPS/BPF into waste water by tannery	6.477 kg/day	2.284 kg/day	2.284 kg/day	0.787 kg/day
Number of EU tanneries	1,500 (information given by stakeholders)	1,500 (information given by stakeholders)	1,500 (information given by stakeholders)	1,500 (information given by stakeholders)
% of waste water treated in WWTPS	80	80	100	100
Removal rate of ΣBPS/BPF in WWTP	87.8 %	98 %	98 %	99 %
EU wide emissions of	2891.33 kg/day	740.016 kg/day	68.52 kg/day	11.8 kg/day

ΣBPS/BPF into surface water by all tanneries				
Tanning days in a year	365	300 (information given by stakeholders),	300 (information given by stakeholders)	252 (official working days of 2022 in Italy),
Output of ΣBPS/BPF into European surface waters	**1055.34 tpa**	**222 tpa**	**20.56 tpa**	**2.97 tpa**

Uncertainties for this estimation are as follows:

The $Q_{rawhide}$ value in the OECD guideline is representative for Germany (OECD, 2014a) and based on data from 2000 (Böhm, 2000). However, in 2021 80 % of leather in the EU is produced in Italy (Ramboll Deutschland GmbH, 2021), where $Q_{rawhide}$ may differ. Overall production of leather may have increased or decreased since 2000, which would also effect $Q_{rawhide}$.

As stated above, there are large differences in BPS and BPF concentration between syntans. The real and worst case scenario are based on mean values that can only approximate the syntan formulations used in the EU tanning industry.

EU tanneries are very diverse in size and production volume. Therefore, it is an oversimplification to assume the same syntan and ΣBPS/BPF emissions for each of the 1,500 EU tanneries. Emissions for EU surface waters may thus be greatly over or underestimated.

Emissions from the service life of leather articles

The European Leather Industry (2020) reported on the fate of leather in 2019: 37.8 % was used for footwear, 22.3 % for leather goods, 13.4 % for car interiors, 13.3 % for upholstered furniture, 11.4 % for garments and 1.8 % other (see Table 90).

Although detailed numbers are not available stakeholders concurred with the estimation that 80 – 90 % of leather and leather articles contain one or both of BPS and BPF (TEGEWA, 2022). For applications in fashion and upholstery in automobiles the rate is 100 % given by stakeholders. The concentration for leather is presented as the concentration of free BPS/BPF contained in the article, that is not covalently bound and can be fully quantified via extraction (Ramboll Deutschland GmbH, 2021).

In a measuring campaign conducted by stakeholders (Ramboll Deutschland GmbH, 2021), BPS concentrations in leather articles varied widely from non-detects to 1,200 ppm with a mean amount of 120 ppm and 95th percentile of 800 ppm. Values for BPF were estimated to be similar for fashion application but much higher in leather for automotive applications. The German leather industry association (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. For BPF, 50 % of members confirmed a mean concentration of 600 ppm BPF in leather articles. Low concentrations of 100 ppm

BPF were reported for individual cases, high concentrations could reach 3,500 ppm BPF. Stakeholders reported that some leather applications do not contain bisphenols such as cheap chrome leather, leather drive belts and folklore articles.

Imports and export estimations for leather articles were only reported by German stakeholders. Potential imports were estimated between 0 and 90 %, export at 10 to 30 % (TEGEWA, 2022).

Table 90: Tanned leather used for downstream sectors

sector	share
Shoes	37.8%
Furniture	13.3%
Automotive	13.4%
Leather goods	22.3%
Clothes	11.4%
Other	1.8%

Since leather is not thick and is usually porous, it can be assumed that residues of syntans can be easily washed out of the leather. Leathers which are used outdoors, such as shoes or clothes (bikewear), are more prone to this type of release. A theoretical release of 1% original BPS content per day from leather shoes was assumed as worst case scenario by stakeholders. The integrity and functionality of a shoe was assumed to be directly linked to the amount of syntans it retained. The release of syntans (and therefore the release of BPS/BPF) from the shoe would lead to the destruction of the leather material due to mechanical stress, rendering the shoe defect. A real case scenario of BPS release of <0.5% original BPS content per wear cycle was reported (Ramboll Deutschland GmbH, 2021). The dossier submitter assumed, that the same release rates apply to BPF.

As it is unclear to the dossier submitter how many leather products are consumed in the EU per year, leather production was used to estimate leather article consumption.

EU leather production was 266,000 tonnes in 2011 (COTANCE, 2012). 50% of this is estimated to be used for outdoor leather application (shoes, clothes and a small percentage of leather goods), resulting in 133,000 tonnes of leather for outdoor use per year. The mean BPS content of 2600 ppm and BPF content of 600 ppm is assumed for these uses.

Equation 7: calculation of original BosC content in leather articles

*original BosC content in leather = tonnes of leather * concentration of BosC*

*original BPS content in leather = 133,000 t * 2,600 ppm = 345.8 tonnes BPS*

*original BPF content = 133,000 t * 600 ppm = 79.8 tonnes BPF*

For the real case a release rate of < 0.5 % original BPS content per wear cycle was estimated (Ramboll Deutschland GmbH, 2021). The dossier submitter considers 50 wear cycle per year realistic. This results in a release of **86.45 tpa for BPS** and **19.95 tpa for BPF**.

The uncertainty for these numbers is high and related to these factors: amount of leather articles consumed, the percentage of leather applications for outdoor uses, the release rate from leather articles and the wear cycle per year.

In addition to life cycle emissions, the production of syntans, the tanning process and the transport of sludge from processing leather (e.g. landfilling) also have release potential.

Emissions from the end of life of leather articles

The service life of leather and leather articles ranges from 6 months to 50 years (CfE #57). Leather degrades and releases all originally contained BPS and BPF (Ramboll Deutschland GmbH, 2021).

Stakeholders reported, that techniques for leather recycling are available but not commercially established and that some leather waste may be exported to outside of the EU (Ramboll Deutschland GmbH, 2021). As waste incineration in the EU should occur at 850 °C or 900 – 1200 °C, it is considered highly likely that BPS and BPF from leather articles are thermally degraded during waste incineration. Leather articles and production waste from leather articles may additionally be disposed of in landfills (Ramboll Deutschland GmbH, 2021). The risk of leather waste being landfilled was estimated by stakeholders for different categories of waste types (Ramboll Deutschland GmbH, 2021) as described in Table 91.

Table 91 Estimated risk of leather waste being landfilled

Leather waste category	Estimated risk of being landfilled
Textile use, fashion	≥ 5 < 30 %
Automotive use	< 5 %
Furniture	< 5 %
Household use	≥ 5 < 30 %

Monitoring from landfill leachates have reported BPS and BPF concentrations in the µg/L range (see B.4.2.4.2.), but these can not be traced to leather waste.

P15 - Emissions from polyamide colouring

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 a yearly production of BPS of 700 – 800 t for syntan production for this purpose in the EU (Ramboll Deutschland GmbH, 2021).

Although detailed numbers are not available stakeholders concurred with the estimation that 80 - 100 % of polyamide textiles contain one or both of BPS and BPF. 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 years to 20 years, the longer life spans can be observed in specific categories e.g. outdoor articles (2 CfE #8).

In 2018, 3.1 million tonnes of synthetic fibres were produced in the EU (including Turkey). 13 % of which were polyamide, equal to 403,000 tonnes of polyamide fibres being produced in the EU in 2018 (European Environment Agency, 2021).

EU consumption of polyamide was reported by the Joint Research Centre (2014) as 621,368 tpa for clothing and 642,390 t/a for household textiles (calculated from Fig. 1 of the JRC report). Household textiles in this study included interior textiles. Data from 2007 was used and consumption was calculated as: consumption = production + import - export. Technical textiles were not included in this study, although they make up 16 % of EU textile production (Köhler, 2021) and often contain nylon (European Environment Agency, 2021).

Although 403,000 tpa of polyamide fibres were produced in the EU in 2018 (European Environment Agency, 2021) it is unclear if colour fixing of polyamide is performed in the EU or in other countries.

Following the OECD guidance document No. 7 (OECD, 2014b), Equation 8 with parameters given in Table 92 was used to calculate local emissions of syntans into waste water from colour fixing:

Equation 8 local emissions of syntans from clour fixing

$$E_{local} = Q_{textile} \times Q_{product} \times C_{substance} \times (1 - F_{fixation})$$

Parameters and results for the emission calculations are given in **Table 92**.

Table 92 Parameters and results for local emissions of syntans and BPS/BPF from colour fixing

Parameter	symbol	unit	default values	worst case	real case	best case
Mass of textile processed per day	$Q_{textile}$	t/day	13	13	13	13
Mass of auxiliary (preparation agents, sizing agents, biocides) per mass of fabric	$Q_{product}$	kg/day	20 for finishing, exhaust processes 30 for finishing semi-continuous and continuous processes	30	20	20
Content of active substance in preparation	$C_{substance}$	-	1	1	1	1
Degree of fixation	$F_{fixation}$	-	0.8 for auxilliaries intended to fix on the textile 1 for auxilliaries coating	0.8	0.8	1
Local emission of syntans per	$Elocal_{water}$	kg/day	-	78	52	0

day to waste water						
Concentration of ΣBPS/BPF in syntans	-	%	-	4.7	2.9	2
Local emissions of ΣBPS/BPF into waste water by tannery	-	kg/day	-	3.666	1.508	0
Removal rate of ΣBPS/BPF in WWTP	-	%	-	87.8	98	99
Local emissions of ΣBPS/BPF into effluent per day	-	g/day	-	447.252	30.16	0
Working days	-	days	-	365	300	252
Local emissions of ΣBPS/BPF into effluent per year	-	kg/a	-	163.247	9.048	0
capacity of WWTP	-	m^3/day	2,000	2,000	2,000	2,000
Concentration of ΣBPS/BPF in local WWTP effluent	-	µg/L	-	223.62	15.08	0
Dilution factor	-	-	10	10	10	10
Concentration of ΣBPS/BPF in local waterbody	-	µg/L	-	22.36	1.5	0

In the best case scenario all syntans used fix onto the fabric, so no BPS/BPF occurs in the waste water or adjacent surface water ($F_{fixation}=1$). In the estimated real case scenario only 80 % of syntans fix onto the textile. This results in a release of 9.048 kg/a of ΣBPS/BPF during colour fixing of polyamide textiles from one local processing plant and a surface water concentration of 1.5 µg/L. This concentration is again higher than the highest BPS concentration monitored in EU surface waters (210 ng/L) (see Annex B.4.2.4.2.).

As the number of colour fixing plants in the EU are not known, no estimation for the EU wide emissions of ΣBPS/BPF from this processing step can be made.

Emissions from consumer washing of polyamide textiles Stakeholder experiments gave a release of 30 – 50 % of BPS from textiles in one wash at 40°C in the washing machine (TEGEWA, 2022).

The amount of BPS released from washing of polyamide textiles into waste water depends on the number of textiles washed, how often they are washed and the concentration of BPS they contain. The release from household is dependent on the rate of connection to WWTPs and the removal rate of BPS from the WWTPs. All parameters for the estimation of BPS release into surface water from consumer machine washing are given in **Table 93**.

Table 93 parameters for the estimation of BPS release into surface water from consumer machine washing

Parameter	unit	Worst case	Real case	Best case
Polyamide clothes consumed	tpa	621,368	621,368	621,368
Polyamide household textiles consumed	tpa	642,390	642,390	642,390
Number of times clothes are washed *	per year	3	2	1
Amount of polyamide household textiles washed once *	% tpa	30 192,717	20 128,478	10 64,239
BPS concentration clothes	mg/kg	1,000	700 *	200
BPS concentration household textiles *	mg/kg	1,000	400 *	200
Release of original BPS content from textiles	%	50 (first wash) 25 (second wash) * 12.5 (third wash) *	40 (first wash) * 20 (second wash) *	30
Sum of BPS released into waste water	tpa	640.06 (543.7 from clothes + 96.36 from household textiles)	281.53 (260.97 from clothes + 20.56 from home textiles)	41.13 (37.28 from clothes + 3.85 household textiles)
% of waste water treated in WWTPS	%	80	% of waste water treated in WWTPS	%
Removal rate of BPS in the WWTP	%	87.8	98	99
Sum of BPS released into surface water from consumer washing	t/a	190.48	60.81	8.55

* based on common expert judgment, all other data sources are given in the text and chapters above

Emissions from end of life for polyamide

Stakeholders presented data collected from EUROSTAT which indicates that 8 % of textile waste is landfilled and 9 % of textile waste is incinerated in the EU (Ramboll Deutschland GmbH, 2021).

As discussed above waste incineration is regarded to thermally degrade all BPS and BPF in waste, so no release is expected.

Assumptions for landfilling were as followed: all polyamide consumed in a year (data from 2007 from Joint Research Centre (2014)) was considered to turn into textile waste the following year. This is an oversimplification and probable overestimation, as some clothing and household polyamide applications have a much longer life span that 1 year (e.g. carpets, 10 years). 8 % of consumed polyamide was assumed to go to landfill. Parameters for the estimation of BPS release from landfilled polyamide textile waste is listed in **Table 94**.

Table 94 Parameters for the estimation of BPS release from landfilled polyamide textile waste

Parameter	**unit**	**Worst case**	**Real case**	**Best case**
Polyamide clothes consumed	tpa	621368	621368	621368
Polyamide household textiles consumed	tpa	642390	642390	642390
Amount of textile waste landfilled	%	8	8	8
BPS concentration in textiles *	mg/kg	500	275	100
Sum of BPS landfilled from textile waste	**tpa**	**50.55**	**27.8**	**10.11**

* based on expert judgment, all other data sources are given in the text and chapters above

Excursion on carpets

Carpet manufacturing accounts for about 17 % of global polyamide usage (Carmichael, 2015).

It is estimated that, currently, less than 3 % of carpet placed on the market in the EU is recycled (Hilton, 2018), resulting in an estimated 1.5 million tonnes of carpet being landfilled or incinerated annually (European Environment Agency, 2021). If we assume that 17 % of EU polyamide consumption is used for carpets (17% of 642,390 tpa), this equates to 109,206.3 t/a nylon being landfilled or incinerated in the EU. Concentrations in nylon textiles are generally reported to be 200 – 1,000 ppm for BPS and BPF each, but may be lower in carpets as they do not require extensive colour fixing because they are not washed regularly (TEGEWA, 2022). In the best case scenario, no ΣBPS/BPF is landfilled. Either all carpets are incinerated and ΣBPS/BPF is thermally degraded or carpets are landfilled but are not treated with BPS/BPF for colour fixing. In the worst case scenario all nylon carpets are landfilled and have a ΣBPS/BPF concentration of 1000 ppm, which equates to 109.21 t/a of ΣBPS/BPF being landfilled. For the real case scenario following assumptions were made: 50 % of carpets are landfilled. Of these 50 % only half are treated with colour fixing syntans and have a concentration of 200 ppm. As a result, 10.92 t/a ΣBPS/BPF are landfilled in the real case scenario. This excursion exemplifies the high degree of uncertainty pertaining to the landfilling of textiles.

Uncertainties are as follows:

Consumption estimates are based on data from 2007 and may grossly underestimate consumption. Additionally, technical textiles were excluded, which may contribute to underestimation of polyamide consumption.

It is unclear if the default values set in the OECD guidance (OECD, 2014b) reflect modern production processes, as they rely on data from 2000, especially concerning the mass of textile processed per day ($Q_{textile}$). This value may be underestimated as overall textile production increased or overestimated as textile production may have shifted to non-EU countries.

It is not clear how many clothes are dry cleaned and may therefore have a different release of BPS/BPF during dry cleaning in comparison to washing in the washing machine.

The landfill rate for textiles of 8 % is a mean of all member states and is therefore only an approximation. The amount of polyamide textile waste is overestimated.

The BPS and BPF concentrations in polyamide clothes and household textiles are rough estimates derived from stakeholder information. The resulting amounts estimated to be released into surface water may therefore be grossly over or underestimated.

The BPS and BPF concentrations in polyamide textile waste is only a rough estimate. BPS concentrations were considered lower than the original BPS concentrations given by stakeholders, as most polyamide textiles will lose BPS during their service life (e.g. during washing).

The ΣBPS/BPF concentration in nylon carpets and the amount of nylon carpets landfilled in the EU are only rough estimates. The resulting amount of ΣBPS/BPF landfilled may therefore be grossly over or underestimated.

Summary

Table 95 Summary of ΣBPS/BPF releases estimated for leather and textile life cycle steps

release	medium	unit	scale	Worst case	Real case	Best case
syntan production	surface water	tpa	EU	unknown	unknown	0
leather tanning	surface water	tpa	EU	1,055.34	222 (scenario I) 20.56 (scenario II)	2.97
leather articles consumers	environment	tpa	EU	unknown	(86.45 BPS + 19.95 BPF) = 106.4	unknown
polyamide colour fixing [t]	surface water	kg/a	local processing plant	163.247	9.048	0
washing polyamide	surface water	tpa	EU	190.48	60.81	8.55

textiles consumers [t]						
landfilling polyamide textiles [t]	landfill	tpa	EU	50.55	27.8	10.11
landfilling carpets [t]	landfill	tpa	EU	109.21	10.92	0
sum	**overall**	**tpa**	**EU**	**1,405.58**	**321.53 (scenario I or 120.09 (scenario II)**	**14**

[t] data only considers BPS, the same amount may be applied for BPF but information was scarce

In summary, this means that 2.97 to 1,055.34 tpa can be emitted for the processing or production of leather and textiles. In the life cycle of leather and textiles, 106-296tpa are emitted. The EOL is also relevant to emissions and has 10.11-164tpa.

P15 Textile auxillaries (polyamide) (stakeholder information)

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 (P other) and is an unavoidable impurity in products. The duration of service life is from 6 month (clothing) up to 10 years (carpets).

Table 96: additional stakeholder information

use	sector	source	description	emission
P15	textile	CfE	colour fixative for colour fastness - coloured textiles containing e.g. polyamid, polyester, spandex	BosC values from 0,4% to 3% depending on products and type of bisphenol. For finished textiles values from 20 to 170 ppm BosC.
P15	textile	CfE	textile auxillaries	BosC content in Textile auxilary: 3% (=30,000 ppm) measured value.
P15	textile	CfE	textile auxillaries analytics	typical application: 4% textile auxiliary on weight of fibers → 40 g textile auxiliary per kg textile → 1.2 g BosC/kg textile = 1200 mg BosC / kg textile = 1.2 mg BosC / g textile. Extraction of 1 g textile with 100 ml : 1.2 mg BosC / 100 ml if it is completely resolved = 12.0 mg/l The migration limit would be exceeded 100 times if only 30% of BosC is resolved by extraction.

P15	textile	CfE	colour fixative for colour fastness as textile auxiliary - coloured textiles containing e.g. polyamid, polyester, spandex	

The updated SFA (Ramboll Deutschland GmbH, 2022) and the available registration data contain limited additional information on polymeric uses other than P1 and P2:

- P8: Phenoplastic manufacturing (P8) is mentioned: 'Since a quantification of this use is not possible, BPA emissions from Phenoplastics manufacturing sites were not considered in the emissions estimates. However, this emissions pathway is expected to be small based on the manufacturing processes used in Germany.' The dossier submitter assumes that Novolacs are subsumed under this category and points out that according to stakeholder information 8 000tpa resins are produced with Novolacs containing BPA/BPF. Further publicly available information suggests that phenoplastics are used in a wide range of manufacturing process and articles, inter alia microelectronics, building materials, laminates, fiberglass, paper products. Considering this information emissions from the use might as well be significant.

- P6: To support the assessment of BPA in inks and toners, more than 20 local printing shops and large industry-scale printing shops in Munich were contacted. Samples were obtained from six shops with a focus on printing advertising materials. Samples were also collected from major ink producers. Offset printing has the greatest market share in Germany, therefore two offset-colour types were sampled. The relevance of other ink types, such as thermochromic inks, was investigated using an extended literature review and based on inputs from industry members. As the market share of digital printing is significant, toners were also included. The presence of protective varnishes was discovered in the sampled products and articles, representing up to 50% of usage in all printing articles. BPA concentrations in inks, varnishes and toners ranged from below the limit of quantification to as high as 4,605,000 µg/kg.

In addition to information from the SFA, the dossier submitter considered stakeholder information from the CfEs: The maximum typical amount of Free BPA in toners is 40ppm (10-40ppm). Considering the BPA consumption, 154 kg of BPA per year in the EU could be released to the environment, nevertheless, the free BPA is incorporated into the polyester resin, and therefore only a very small part will be released to the environment (matrix of toner particle is barrier) 24% of the toner could be landfilled. Toner content is 70-80% resin and <200ppm BPA as impurity. From the available information it is estimated that 40ppm BPA release from toner which is assumed for a total tonnage of 3,600 tpa.

Further information available from stakeholders and literature that provides statements on emissions for the respective lifecycle stages:

- Stakeholder information for P11: no information available that polyurethane foam was really made by BPA as a monomer

- Literature information on dental resins:Dental waste water/contents in fillings contain BPA. Most likely very small quantities.

- Stakeholder information for P12: Liquid Epoxy Resin is used by UPR [Unsaturated Polyester Resin] sector as starting material in the production of Vinyl ester resins- BPA is used by UPR sector as chain extender in the production of Vinyl ester resins. Epoxy resins and vinyl ester resins are critical ingredients for making blades and spar caps for wind turbine blades. Unsaturated polyester (UP) resins and epoxy vinyl ester (VE) resins are liquid products containing linear unsaturated polyester polymers respectively epoxy vinyl ester polymers (50-70%) and mainly styrene (30-50%). No further information is available. The dossier submitter assumes that potential emissions are already subsumed under the emissions from the use of epoxy resins for the manufacturing of wind turbine blades.

- Stakeholder information for P13: 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, electrodepostion coating, formaldehyde, Halogen free Flame Retardants, Acrylic resins and urethane acrylates as well as phenolic resins. The residue of BPA in Mixtures is <0.1% w/w Formaldehyde resins do not enter the concentration limit, some articles/mixtures will comply with migration limit. Reaction with formaldehye is not 100% complete! It is chemically not possible with this type of resin to comply with the 10ppm Concentration limit. But articles/mixtures can comply with a 0.04 mg/L migration limit! Mixture: (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 (stove-enamelling), 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

- Information on BPA uses in textiles: At the moment only little ist known about the exact content and emissions of BPA in and from textiles and clothes (Xue et al. 2017). In one recent study, 32 pairs of babysocks with different compositions (% cotton,% polyamide,% polyester,% elastan or spandex) and price categories were tested for their BPA content (Xue et al. 2017). All pack labels gave information on the "country of origin" (66% from Spain, 25% from Turkey, and 9% from Italy), although it did not specify whether the country of origin of the fiber was the same. In 90.6% of the investigated samples, BPA could be found in concentrations between <0.7 and 3,736 ng per gram of fabric (median 20.5 ng/g) (Freire et al. 2019).

  In another study by Xue et al. (2017), 77 textiles and infant clothing pieces were analyzed for their potentially toxic chemical content with, among others, BPA and BADGE as target chemicals. It was found that BPA and BADGE derivatives occurred in 82% and 45.8% of all samples at median concentrations of 10.7 ng/g (ranging between <2.21 and 13,300 ng/g) for BPA and up to 2.88 ng/g for BADGE derivatives (ranging between 1.47-62.9 ng/g). BPA was found in 32% of raw textiles (n = 19), 100% of cloth diaper/blanket (n = 6), 98% of analyzed clothes (n = 38) and 100% of analyzed socks (n = 14). BADGE and its derivatives were found in 95% of analyzed raw textiles (n = 19), 27% of analyzed clothes (n = 38) and, 50% of analyzed socks (n = 14). From this data the mean dermal exposure dose (pg/kg BW/d) for infants between 0 and 12 months were calculated ranging between 201 and 248 pg/kg BW/d for BPA and between 20.9 and 25.8 pg/kg BW/d.

  In two further studies by Li et al. (2018) and Wang et al. (2019), 73 and 93 different textile samples were analyzed respectively with an occurrence of BPA in 96% and 99% of all the investigated samples. In these cases, median values of 14.3 ng/g (ranging between <1.3 and 504 ng/g) and 26.9 ng/g (ranging between <3.3 ng/g and 1,823 ng/g) of BPA were obtained.

  In summary, few recent studies in scientific experimental setups detected BPA in textiles but did not report on BPA emissions. Moreover, data on the amounts of BPA used in the production of textiles are missing - especially when trying to distinguish between different BPA uses (A and P). Therefore, the amount of BPA which potentially might be emitted from textiles cannot be estimated and the textile sector could not be considered explicitly in the scenario in Annex H.

Dyeing auxiliaries have different tasks. They are used to dissolve and disperse dyes, to achieve uniform dyeings and certain dyeing effects, and to fix faux dyes. They can also be binders for fixing pigment dyes on fabrics or for the production of nonwovens[165]. Often these auxiliaries consist of surfactants or mixtures of these with other substances, of natural, modified or synthetic colloids (e.g. starch and their ethers, vegetable gums, alginates, cellulose ethers, polyvinyl alcohol, polyacrylates) or even of plastic dispersions.[166] The textile auxiliary is usually referred to as an additive. From a chemical point of view, however, it is a polymer. As a preliminary solution, the average level of BPA, found in textiles (clothing) from Xue et al. (2017) Li et al. (2018) and Wang et al. (2019) (10.7ng/g; 4.3ng/g; 26.9ng/g) was assumed with 17.3ng/g (0.0173ppm). After researching the average tonnage of textile consumed in the EU, an emission potential was derived. As BPA is used for the production of colour fixatives (textile auxilliary), this is attributed to the use "P15".

The EEA recently published a compilation on the consumption of textiles in the EU.[167] In 2020, 6.9 million tonnes of finished textile products were produced in the EU. The focus of EU production is on carpets, home textiles and other textiles (including nonwovens, technical and industrial textiles, ropes and fabrics). In addition to finished products, intermediate textile products such as fibres, yarns and fabrics are also produced in the EU (Köhler et al., 2021). In addition, 8.7 million tonnes of finished textile products were imported into the EU. Clothing accounts for 45% of imports in terms of volume, followed by home textiles, other textiles and footwear (Eurostat, 2021). The average derived textile consumption per person was 6.0 kg of clothing. Taking into account the 448 million inhabitants in the EU, the annual clothing consumption is 2,688,000 tpa.

Equation 9: Emission of BPA from clothing:

$$x = 2{,}688{,}000tpa * 0.0173ppm$$

$$x = 0.05tpa$$

Other textiles may also contain and emit BPA, but no further information is available to consider this impact. It can be assumed that, for example, carpets are not washed in the washing machine, but other home textiles such as curtains are. The upper emission scenario considers the additional textile consumption value of 6.1kg household textiles per person in the EU. Taking into account the 448 million inhabitants in the EU, the annual clothing consumption is 2,860,000 tpa.

Equation 10: Emission of BPA from household textiles

$$x = (2{,}688{,}000tpa * 0.0173ppm) + (2{,}860{,}000tpa * 0.0173ppm)$$

$$x = 0.1tpa$$

As a result, the contribution of BPA from the use phase of textiles can be estimated as low. However, it is completely unclear how much emissions result from the

---

[165] *Ullmann's Encyclopedia of Industrial Chemistry* [Online], Wiley-VCH: Weinheim, (2000) https://onlinelibrary.wiley.com/doi/10.1002/14356007.a26_351 (access 2022/02/05)

[166] Römpp Online Textilhilfsmittel

[167] https://www.eea.europa.eu/publications/textiles-and-the-environment-the/textiles-and-the-environment-the (access 2022/02/05)

processing phase of textile auxiliaries for the production of textiles. The production of textile auxiliaries itself is not registered in the EU. For this reason, no emissions are expected from this process step in the EU.

In sum, it seems most likely that emissions from uses for the other polymers than epoxy resins and polycarbonate is comparably low:

Table 97: Estimated total emissions from P3-P15 per life cycle stage

Code	Life cycle stage	Air (tons)	Soil (tons)	Surface Water[1] (tons)	Total (tons)	Additional information
P3	Manufacturing	n.a.	0	n.a.	0	
	Service life	0	0	n.a.	0	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P4	Manufacturing	n.a.	0	n.a.	0	
	Service life	0	0	0	0	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P5	Manufacturing	n.a.	0	n.a.	0	
	Service life	0	0	n.a.	0	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P6	Manufacturing	0	0	0	0	0.145tpa (40ppm release from toner assumed on total tonnage 3,600tpa)
	Service life	0	0	n.a.	0	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P7	Manufacturing	n.a.	0	n.a.	0	
	Service life	0	0	0	0	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P8	Manufacturing	0	0	0.0259	0.0259	Potentially wide dispersive use, e.g. 8 000tpa Novolacs
	Service life	0	0	n.a.	0	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P9	Manufacturing	n.a.	0	n.a.	0	
	Service life	n.a.	0	n.a.	0	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P10	Manufacturing	n.a.	0	n.a.	0	
	Service life	0	0	0	0	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P11	Manufacturing	n.a.	0	n.a.	0	

	Service life	n.a.	0	n.a.	0	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P12	Manufacturing	n.a.	0	n.a.	0	
	Service life	n.a.	0	n.a.	0	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P13	Manufacturing	n.a.	0	n.a.	0	Unknown but >0 emissions
	Service life	n.a.	0	n.a.	0	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P14	Manufacturing	n.a.	n.a.	2.97 - 1055	2.97 - 1055	
	Service life	n.a.	n.a.	106	106	
	Landfills	n.a.	n.a.	n.a.	n.a.	
P15	Manufacturing	n.a.	n.a.	0 - 163	0 - 163	
	Service life	n.a.	n.a.	8.55 - 191	8.55 - 191	+0,05tpa + 0,1tpa from use of BPA
	Landfills	n.a.	n.a.	10.11 - 160	10.11 - 160	
sum				128 - 1675	**128 - 1675**	

For the polymer uses, the most impacting uncertainty is the potential release during service life and in landfills.

Additionally, the consideration of the application stage especially by professionals and consumers (mostly resins) contributes to emission. In general, it can be said that syntans contribute to environmentally relevant emissions in every cycle step, regardless of whether they are used for leather or textiles.

B.8.6.6. Additional information on Bisphenols of similar concern (BosC)

B.8.6.6.1. BPB

No tonnage and emission relevant information are available. The only information from a stakeholder consultation process is that BPB can replace BPA in some uses, but the substance is probably not relevant to the market in the EU. It can therefore be assumed that imports may contain BPB. This in turn leads to the conclusion that there is a potential for emissions from the consumption of products containing BPB in the EU.

B.8.7. Other sources for BPA/BosC

At this point, reference should be made to other emission events that are known, but whose potential cannot be quantificated because there is no reliable data on them.

B.8.7.1. Natural sources

Natural sources can be botanical extracts. Coeloglossum viride var. bracteatum (rhizome), Galeola faberi (rhizome), Gastrodia elata (rhizome), Xanthium strumarium (seeds) and

Tropidia curculioides (root) were found to contain naturally occurring BPF and are for example used in traditional Chinese medicine(Huang et al., 2019). Zoller et al. (2016) reports concentrations of around 8 mg/kg in mustard. Being probably a reaction product from the breakdown of the glucosinolate glucosinalbin with 4-hydroxybenzyl alcohol, BPF was only found in mild mustard made of the seeds of *Sinapis alba.* Mustard (hot) made of brown mustard seeds (*Brassica juncea*) or black mustard seeds (*Brassica nigra*) contained no BPF. These natural sources are considered as contributing to human exposure rather than a relevant background concentration for the environment.

B.8.7.2. Imports

The information on import of BPA only incorporated in articles is covered by notification (concentration >0.1% w/w). Imported products containing bisphenols and/or made from bisphenols may contribute to environmental exposure of BPA and BosC. Apart from the import figures by use, which are included in the derivation of consumption in the respective uses to P, C or A, it is possible that BPA/BosC is imported in ready-to-use products in partly unknown amounts. But there is no reliable estimation or data on the market share of imported articles in the 3 notified uses for BPA and none for BosC.

Since the notification obligation only applies to companies that contain BPA in products >0.1% and import more than 1 tonne per year, it can be assumed that there will be other imported products (like mixtures ready to use or articles) that are below the quantities triggering the obligation, as known from the call for evidence step and due to response from sector experts during information phase in parallel to the REACH Annex XVII dossier preparation.

ECHA has been notified on the import of automobiles/automotive parts, electrical and electronic equipment, and toys containing >0.1% BPA. From the two calls for evidence that took place from 2020 to 2021 (Appendix G), it also became known that textiles as raw material or for example clothing also contain BPA/BosC. Another example is leather. In both specific applications, the function is quite different. However, it has been regularly added to this information that these are impurities that are not covered. Already for these two application areas, it becomes clear when looking at the sectors that the contained BPA and BosC are used widely. Textiles, for example, can be used for clothing or protective clothing, they are processed in the furniture industry, but can also be used for the production of geotextiles or textile carpets. The use of leather is similarly diverse. Among other things, leather is used for the automotive industry, shoe manufacturing, for the production of clothing and protective equipment, but also for furniture.

With the SCIP[168] notification tool for information on SVHC in articles, it was found that a BPA content of more than 0.1% (w/w) was reported for more than 400,000 articles. The dossier submitter is aware that these notifications are an obligation for downstream users and not all mentions actually indicate BPA or 0.1% w/w BPA. Most entries were registered for electronic articles. The entries for BosC are missing because they either lack an SVHC status or the SVHC identification is pending at the time of the restriction dossier submission (BPS). A large proportion of the electronic goods come from the Asian market and are imported products. However, since it cannot be assumed that all electronic products (made from or with polymers like ER or PESU) are used indoors, it can be concluded that these imports do contribute to environmental emissions.

---

[168] https://echa.europa.eu/de/scip-database?p_p_id=diss_scip_portlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&_diss_scip_portlet_javax.portlet.action=searchArticlesAction (access 2022/30/03)

B.8.7.3. End-of-life stage A1-P15[169]

At the end of the life cycle, all BPA/BosC-containing products become waste and thus reach the last stage within the lifecycle. In general, it is assumed that the articles/mixtures are sent to one of the three processing options:

- incineration
- landfills
- recycling

Regarding the distribution between these options, the mass flow model from the research project on BPA (Annex H) assumes separate values per use and sector. More than 38% of the BPA consumed in Europe were estimated to be incinerated. BPA and BosC are released to the environment (surface water, air, soil), partly via landfills. More than 70% of the BPA consumed in Europe is bound in polymers which were estimated to be recycled.

Incineration

High temperature incineration has been shown to result in the complete destruction of BPA/BosC based on the low thermal stability of BPA, therefore this kind of waste disposal prevents possible BPA/BosC emissions to the environment. Accordingly, no emissions at the EOL stage are assumed across all BPA uses when incinerated.

Landfills

BPA/BosC-containing products at landfills are exposed to environmental conditions leading to decomposition processes, potentially releasing BPA/BosC to air, soil or surface water. Yet, regarding the mass flow model of the research project on BPA (Annex H) it is assumed that the leachate of many municipal landfills in Europe discharge directly into WWTPs, without prior treatment (Brennan et al. 2016; Fischer et al. 2014). This results in environmental spreading. Furthermore, older scientific reports like (Coors et al., 2003) and currently reports like Ramboll Environ (2015, Fig. 3) assume that emissions are due to leaching from landfills into surfacewater.

Recycling of polymer articles

In Europe, plastic waste is currently mainly recycled for energy production. In order to conserve finite resources in the future, efforts are being made worldwide to increase the use of recycled plastics and to increase the proportion of recycled articles in plastic products. All in all, this would lead to lower CO_2 consumption and a reduction in dependence on fossil raw materials.

However, the recycling of plastics is by no means trivial and involves several considerable difficulties. In the best case, plastic waste is collected, milled and, if necessary, after post-stabilisation, used either as 100% recycled material or as an admixture to virgin material. This only works well if the plastics to be recycled are single grade, i.e., consist of only one type of polymer (e.g. only of polycarbonate or only of polypropylene, etc.) and, in the optimum case, come from a single area of application (polycarbonate water tanks or PVC window profiles). This is possible, for example, if plastic waste is directly reused in manufacturing companies (such as sprues in the injection moulding process) or if specific waste paths are developed in which such a single-sort collection of plastic waste is easily

---

[169] Cf. information from research project on BPA in Annex H

possible. A positive example here is the use of rigid PVC from used window profiles as filling material for new windows.

In reality, however, such homogenous plastic waste is very rare. What generally ends up in the waste is a mixture of different plastic articles such as packaging films, electric housings, insulating articles or clothing, consisting of different pure polymers or polymer mixtures. Extreme cases are for example packaging films, which may consist of 8 to 10 layers of different materials. In these cases, where possible, the individual polymer types must be separated from each other, using complex sorting technology in order to be able to use them again in higher-grade applications.[170]

This usually involves either mechanical, manual or automatic separation of the plastics before or after shredding and reuse, or a chemical processing step by solvolysis or thermolysis. Since the reprocessing technology for the production of unmixed plastic recycling material is very expensive, mechanical or feedstock recycling is often not economically viable, which is why energy recovery (incineration for energy generation) is usually resorted to or lower-grade and not entirely unmixed recycling material is processed into lower-grade products such as pedestals for traffic signs or park benches.

Another major barrier to increased recycling of plastics is, the presence of potentially harmful plastic additives added during production, such as BPA, and/or other unintentional contaminants, which are potentially harmful to humans and the environment and come from various sources during use or are generated by polymer degradation. These chemicals can then be emitted from the recycled material when it is reused (Ramboll Environ 2020).

Regarding the mass flow model from the research project on BPA (Annex H), BPA-based products that are being recycled at their end-of-life stage leave the mass flow and are thus not considered for further emissions during their second, third etc. life cycle. At the same time, the mass flow up until that point did not specifically incorporate information on the amount of recycled BPA that enters the cycle – although it is obvious that part of the consumed BPA-based products in Europe must already contain recycled materials. Once more, the reason for this deficiency is the lack of information. Except for BPA in thermal paper (A5), which was not considered further the research project on BPA (Annex H) due to its restriction in 2020, no sources could be identified that provide information on how much of the used/manufactured products in the different BPA uses make use of recycled materials.

Distribution between incineration, landfills and recycling

For each BPA use and sector, it was assessed which fraction goes to incineration, landfills and recycling, respectively. The resulting estimates based on information from all identified sources can be found in Annex H.

General considerations on EOL[171,172]

In addition to the specific information on EOL for BPA, the dossiers submitter includes some general considerations on BPA and BosC. When considering the EOL, different uncertainties with different weightings must be taken into account. On the one hand, there are contributions from contaminating sites, such as landfills, which are not difficult to specify and for which there is no clear data situation in the EU. There are individual measurement campaigns that allow a rough estimate for a site, but cannot be used for correlations in the

---

[170] https://echa.europa.eu/documents/10162/1459379/chem_recycling_final_report_en.pdf/887c4182-8327-e197-0bc4-17a5d608de6e?t=1636708465520 (access 2022/01/10)
[171] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Waste_statistics (access 2022/01/10)
[172] https://www.europarl.europa.eu/news/en/headlines/society/20181212STO21610/plastic-waste-and-recycling-in-the-eu-facts-and-figures (access 2022/01/10)

EU. Factors such as national recycling rates, different waste incineration regulations or landfilling and waste export play a role here. In addition to contaminated sites, there are the more recent substance flows into the waste phase after the end of the use phase and an additional potential for release mainly in the course of landfilling (e.g. municipal waste) and recycling (especially paper recycling). It should be noted that there are also product-specific requirements for recycling quotas, for example in the automotive industry. In addition, process wastewater and process sludge are produced, e.g. in paper processing, which also make a direct contribution to emissions or indirectly through landfilling of process sludge or sewage sludge. The real material flows for BPA and BosC are in any case more complex than previously recorded in substance flow analyses (Fischer et al., 2014) (Ramboll Deutschland GmbH, 2022).

As described in this document, the recycling and landfill processes are basically responsible for additional emissions. Recycling leads to an immediate contribution in emissions during the process. Landfilling leads to a delayed contribution to emissions. Restricting residues in articles would have an impact on emissions, as would the mitigation requirement for effluents from processes. Particularly in the case of recycling and landfilling, it should be noted that large tonnages of products are exported for recycling and landfilling, so that the emissions from these processes do not occur in the EU but in non-EU countries.

Recycling

In Europe, energy recovery is the most commonly used method of disposing of plastic waste, followed by recycling. About 25% of all plastic waste generated is sent to landfill. Half of the plastic collected for recycling is exported to countries outside the EU for further processing. Recycling quotas in the EU differ substantially.

Precise information on other uses such as coatings, paints, varnishes and lubricants, for example, is not available. assuming that paints and varnishes are used close to households, this results in two material flows, for example. on the one hand, there is household waste and on the other hand construction waste.

Landfilling

The information on the topic of landfilling varies widely among EU. In addition to restrictive national regulations stating that crude oil-based plastics may only be landfilled for thermal recycling (e.g. Germany since 2005), there are different regulations elsewhere on the contents and requirements of a landfill. Moreover, there are likely to be major differences between different landfills with regard to the leaching of BPA, as the elution behaviour of organic components is also different.

Evidence on landfill leachates is available e.g. from was e.g. shown by Wilk et al. 2019173 with values up to up to 2,202 µg/L.

According to the Plastic Atlas of 2019,[174] approx. 10% of plastics are directly landfilled. In addition, municipal waste is landfilled[175] in varying proportions across the EU (e.g. Malta 93%, Denmark 1%, Italy 26%) with an average value of 24%. The aim is to reduce the proportion of municipal waste (municipal waste accounts for 8.5% of the total waste

---

173 https://link.springer.com/article/10.1007/s11356-019-05566-4 [Landfill leachates and wastewater of maritime origin as possible sources of endocrine disruptors in municipal wastewater; Barbara K. Wilk, Sylwia Fudala-Ksiazek, Małgorzata Szopińska & Aneta Luczkiewicz; Environmental Science and Pollution Research volume 26, pages25690–25701 (2019)]

[174] https://www.bund.net/fileadmin/user_upload_bund/publikationen/chemie/chemie_plastikatlas_2019.pdf

[175] https://www.europarl.europa.eu/news/de/headlines/society/20180328STO00751/abfallwirtschaft-in-der-eu-zahlen-und-fakten (access 2022/20/04)

generated) landfilled to below 10% until 2035 (and to increase the proportion recycled to above 55% until 2025).

In sum, emissions from legacy uses might contribute significantly to the overall emissions for BosC. The updated SFA (Ramboll Deutschland GmbH, 2022) estimates that approximately 1,080tpa of BPA are emitted from landfills in Germany. The dossier submitter notes high uncertainties regarding this estimation, as well as the uncertainties of extrapolating the results for an estimation of EEA-emission quantities. As already noted above there are major differences in regard to landfilling within the EU. That concerns how much, how, what and when waste has been landfilled currently and/or in the past.

The dossier submitter also notes that the estimated quantity cannot be further analyzed, i.e. it is unknown whether the BPA in the leachate is from more recent or older uses or whether it is from additive or polymer uses. Therefore, the dossier submitter proposes to characterize legacy emissions from landfills as unknown but significant.

Summary of additional Sources for BPA/BosC emission

Table 98: Summary of additional sources for BPA/BosC emission

Bisphenol	Source	Tonnage	Discussion
BPA	Environment via man	0.4 tpa	sources are ordinary e.g. from food contact materials, house dust or consumer goods
	EOL	2 tpa	data from evaluation in annex H (research project on BPA)
	Imports	unknown	Notification obligation under REACH
BosC	Imports	unknown	Currently no notification obligation under REACH
	EOL	unknown	
BPF	Natural source	unknown	

It should therefore be noted that there are other environmentally harmful contributions in addition to the quantified emissions listed. These contributions are not always clearly quantifiable. The natural contribution to BPF by plant parts is rather redundant. The human contribution to BPA has already been quantified and discussed in Section 8.1. Humans are probably exposed to multiple sources of BPA, but also BosC. BPA and BosC are encountered by humans in everyday life in a wide variation, as products made of and containing these substances permeate the whole of everyday life (for example, from food contact materials to consumer goods, toys, furniture, electronics, textiles and building materials - see chapter Emissions 8.6 for more details). The EOL discussed. For bisphenol A, the contribution in the EU is about 2 tpa. However, uncertainties have to be considered for this value. One uncertainty here is that the focus for generating emissions data is not on the EOL. For the BosC, data on this is rather thin. Imports/exports are mainly not about the substances themselves, but about products (articles/mixtures) that contain or can release BPA. There is no reliable data on this, only indications. The SCIP database does not provide a reliable source either, since stakeholders do not fill it correctly according to their own information. For pragmatic reasons, limit values are entered here, even though they have no relevance for the products.

B.8.8. Overall summary on emissions from BPA and BosC

BPA is an endocrine disruptor for aquatic organisms, showing adverse effects at concentrations in the ng/L to low µg/L range. This substance is a chemical produced in large quantities with a variety of different uses. BPA is ubiquitously present in aquatic ecosystems at relevant concentrations (ng/L to high µg/L range) despite inherent degradation. For this reason, the focus is on the primary consideration and discussion of the permanent imission and thus the exposure of the environmental compartment of surface waters. During mass flow modelling, surface waters were also identified as the most relevant compartment (as it is relevant, among other things, through water-rich processing) and the one with the best data situation (for example, through structured monitoring).

Although much data has been analysed and various stakeholders have been consulted during the preparation of this dossier, it is still not possible to attribute the observed environmental concentrations and emissions to specific contributions from individual uses. For this reason, main uses were derived based on the technical function of BPA. The intended technical function, allows conclusions to be drawn about the probability of release under certain conditions. In order to avoid regrettable substitution and also to capture the actual use patterns, the considerations were extended to the BosC (currently BPB, BPS, BPF and BPAF).

Due to the ED properties for environmental organisms, emissions of BPA and also BosC into environmental compartments must be minimised as far as possible in order to follow the precautionary principle and to avoid adverse effects on wildlife. For this reason, the restriction was directed towards maximum limits and migration limitation, with a focus on the investigation of content, release rates and release probability during the lifecycle of BPA/BosC and BPA/BosC containing products (mixtures/articles). These parameters lead to emissions and the estimated emissions were determined and assigned to corresponding uses as follows in Table 99.

Finally, absolute emissions per and across life cycle stages and environmental compartments were estimated and compared to the total BPA used for the processing/production of the respective use where possible.

The following table shows that the ratios for BPA-based additives in PVC (A1-A4), mainly for processing agents are relatively high. Although the amount of BPA consumed for PVC additives on the basis of available data corresponds to only 0,16% of total BPA consumption, the amount of emitted BPA from PVC additives corresponds to 62 tons. Note that the magnitude of these emissions very much depends on whether the use of BPA in PVC has ceased or not.

Table 99: Summary of emissions and outlook

Use	Bisphenols used (tpa)	Bisphenol emissions (tpa)	Best estimate (tpa)	Bisphenol emissions 20 years (tonnes)	Best estimate (tonnes)	Additional information
A1-A4 (PVC manufacturing))	unknown	0 - 62	1 – 5	0 – 1 240	20 - 100	Best estimate is an expert judgement by DS
A1 - A4 (PVC recycling)	45.7	0.782 – 2.7	<2.700	15.64 - 54	<54	BPA content in recycled PVC will decrease over time; recycled

Use	Bisphenols used (tpa)	Bisphenol emissions (tpa)	Best estimate (tpa)	Bisphenol emissions 20 years (tonnes)	Best estimate (tonnes)	Additional information
						quantities increase – no information available how the opposing trends affect future emissions
A5 (Thermal paper production)	4,026	5	5	100	100	Constant use quantities over the next 20 years assumed
A5 (Paper recycling containing TP)	Unknown					115
A6 (hardener)	Unknown					Use quantities and emissions are unknown but are included in use P2
A8 – A10 (Stabilisers in closed loops)	unknown	0		0		Waste is incinerated, therefore no emissions expected
A11 (Lubricants)	unknown	(Up to 100%)		(Up to 100%)		No information submitted in call for evidence
A12 (Tyres)	unknown	0.6	0.6	12	12	Based on one stakeholder calculation
A13 (Fluoroelastomers/FKM)	0.1-1	0.07-2.4	2.4	1.4 - 48	8	Imports are not considered, end of life is not considered.
P1 (Polycarbonate)	1,242,000	<0.900 – 6.0	unknown	<18 - 120	unknown	P1 (Polycarbonate)
P2 (Epoxy Resins)	315,000 275,000 (BPA based) +	<0.526 - >10.551	unknown	<10.52 – >211.02	unknown	P2 (Epoxy Resins)

Use	Bisphenols used (tpa)	Bisphenol emissions (tpa)	Best estimate (tpa)	Bisphenol emissions 20 years (tonnes)	Best estimate (tonnes)	Additional information
	40,000 (BPF based)					
P3 - P13 (polymers)	<10,000					
P14 (syntans used for leather)	8,000	109 – 1,055	328	2,180 – 21,100	6,560	Only emissions from tanning; further significant emissions from service life, waste
P15 (syntans used for polyamide treatment)	0,7-0,8	18.66 – 514	109	373 – 10,280	2,180	Only emissions from service life – significant emissions from application and waste stages not calculated
C1-C7 (production of chemicals)	3,000	unknown		steady		
sum (best estimate)		**251 – 1,773**	**568**			

Overall, bisphenol emissions (best emission estimation) is **568 tpa** (with variations from 251 – 1,773).

It has been shown time and again in the individual applications up to the EOL (see evidence) that the environmental compartments are affected, for example, air (e.g. industrial plants), soil (e.g. spreading sewage sludge, compost) and, in addition to the surface waters on land, of course also the estuaries and marine regions (e.g. ship coatings, wind farms). For this reason, it must be pointed out that it is not only emissions to surface waters that are affected. The actual extent of emissions is estimated to be significantly higher.

BPA is an inherent degradable substance that does not remain stable for a long time even in the air compartment (see therefore chapter 1.2.4). 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 do not need to be derived due to the availability MECs. BPA is emitted always and everywhere. Even if these are small inputs from every single 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. Any exposure of environmental organisms must therefore be avoided. It is imperative to apply the precautionary principle for these SVHC substances.

The monitoring findings do not suggest that the decrease in the environmental concentration would be significant. The withdrawal of the registration of BPA for PVC and the restriction of BPA for thermal paper have led to this trend. Since the environmental concentration (see Annex B.4.) is not decreasing, it cannot be assumed that PVC will no longer be used to the extent it was when this use was still supported by the registrant. Moreover, the tonnage used has increased from 2010 to 2020, which in any case also has greater emission potential. At this point, it remains speculative why there have been no clear decreases in environmental concentrations of BPA with the different regulatory measures. The information obtained in the frame of the two CfE and stakeholder dialogues were also unable to provide clarification in this regard.

Following figures give a visual overview on interrelationships between tonnage used per main use, content and release.

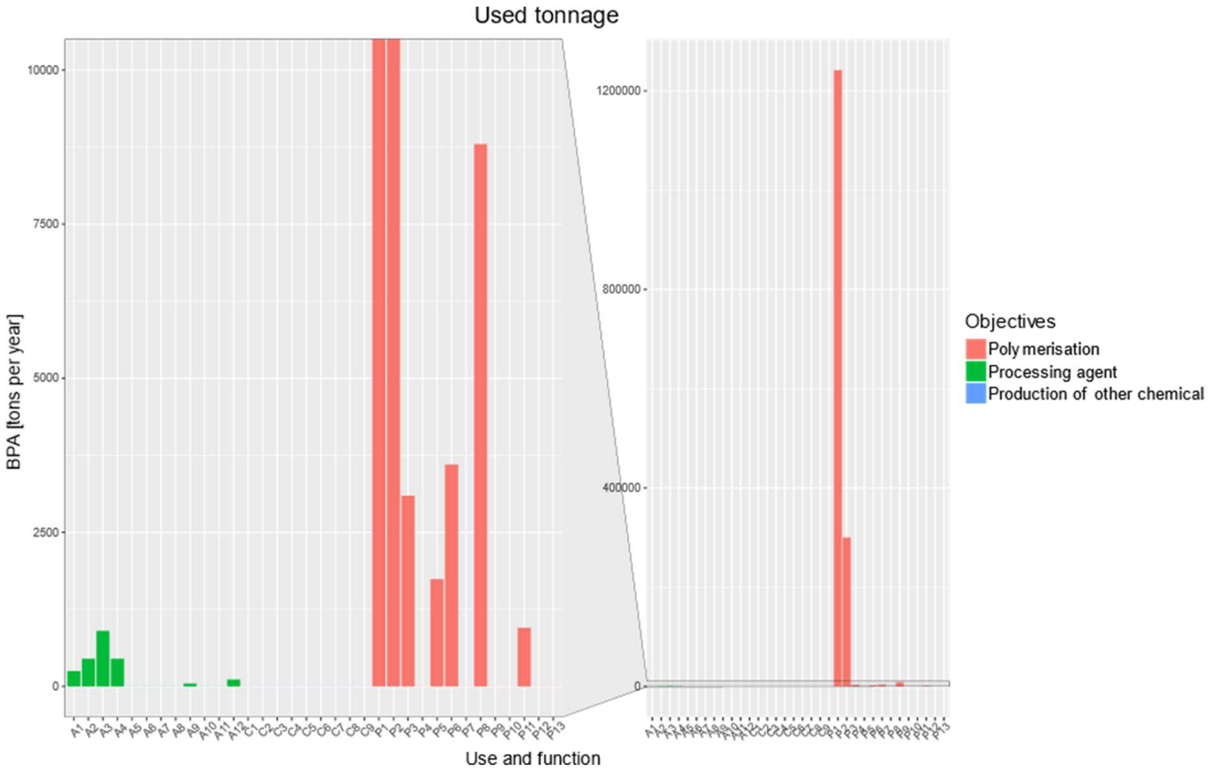


Figure 13: Tonnage distribution on uses BPA (P/A/C)

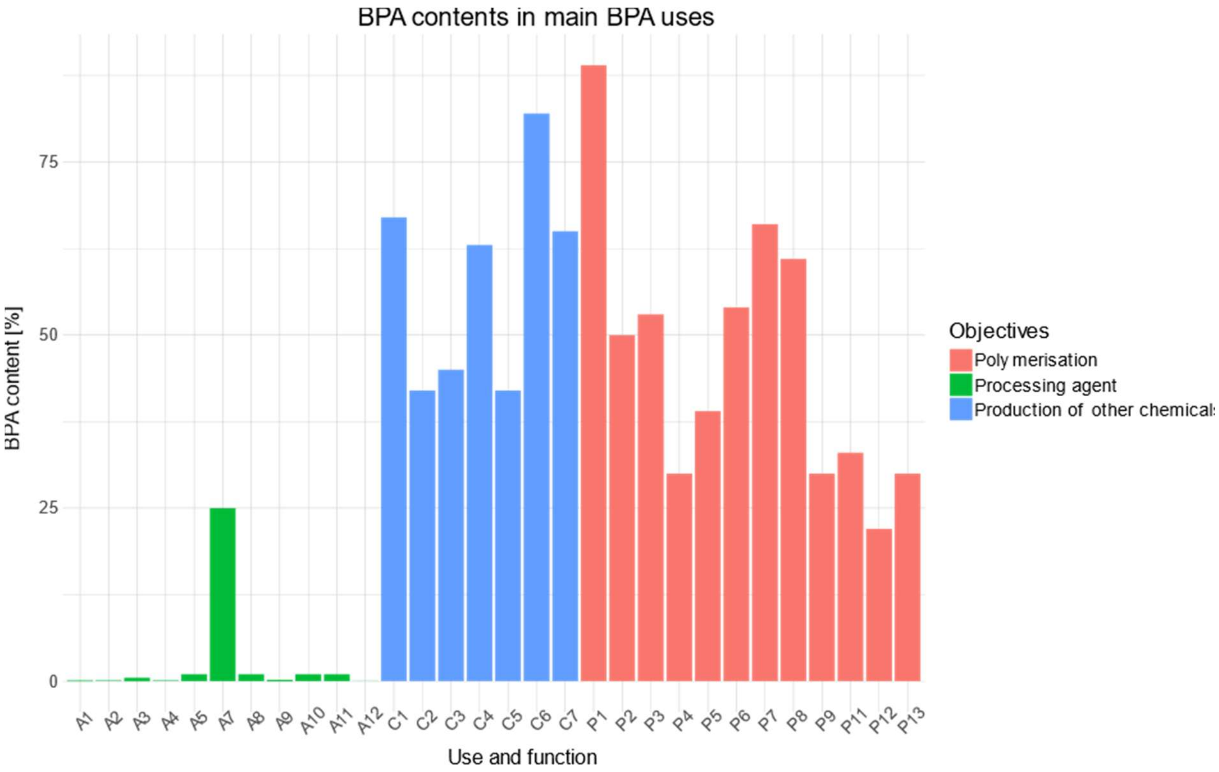


Figure 14: Contents of BPA in uses (P/A/C)

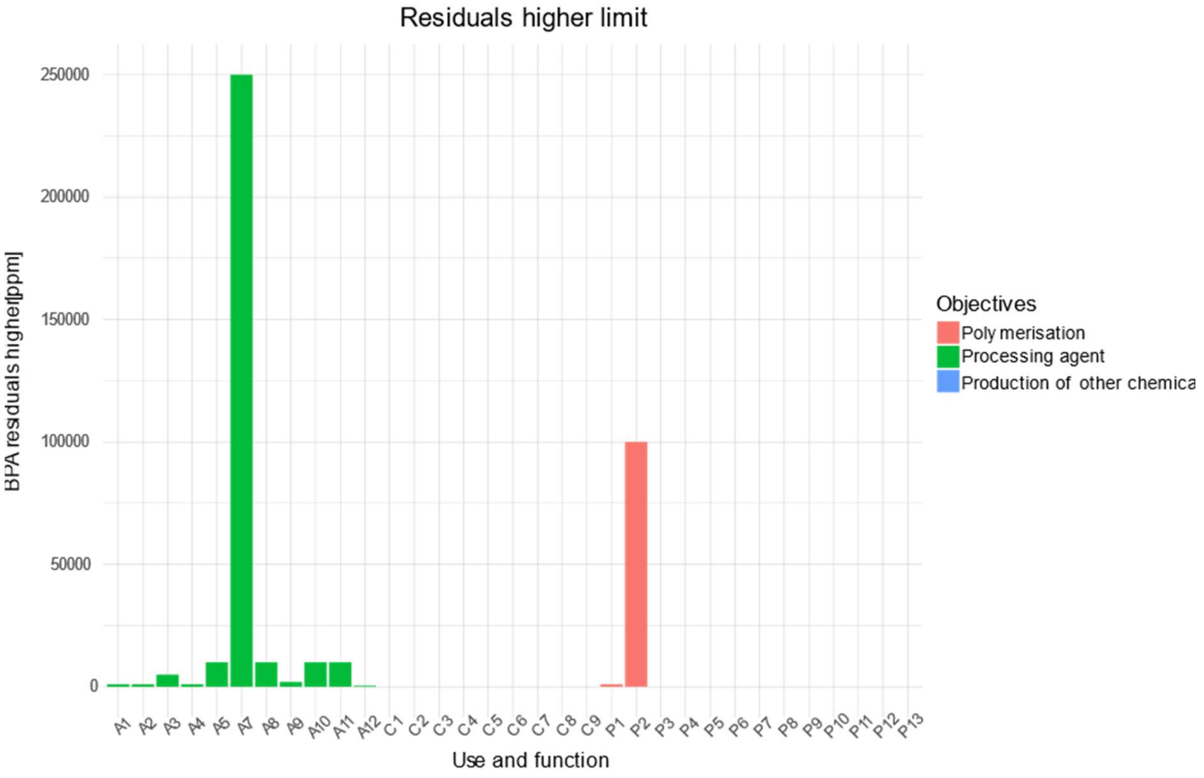


Figure 15: Residuals and free BPA concent in uses

In addition to all the information mixed in with the stakeholder information, it must be mentioned here that the emissions have already been identified in the registration dossier for BPA. This assessment is not contradicted in principle. At this point we also note the estimated regional load quantified as 10,000-100,000 tpa for water, 1,000-10,000 tpa for soil and 10,000-15,000 tpa for air.

As main results the following findings can be summarized:

- Predominant sources: processing and service life
- Major releases in the consumer stage (= consumer uses (e.g. paper products like recycled toilet paper (recently more evident for BPS than for BPA), ready-to-use mixtures, general articles for service life) and professional uses (application));
- Main contributing pathway municipal waste water
- EOL landfill contribution
- Identification of individual contribution of products (used in different sectors) from use phase not possible due to lack of data
- Minor source: 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

The following both graphs show in summary the relative emission and the absolute emission by use for BPA and BosC.

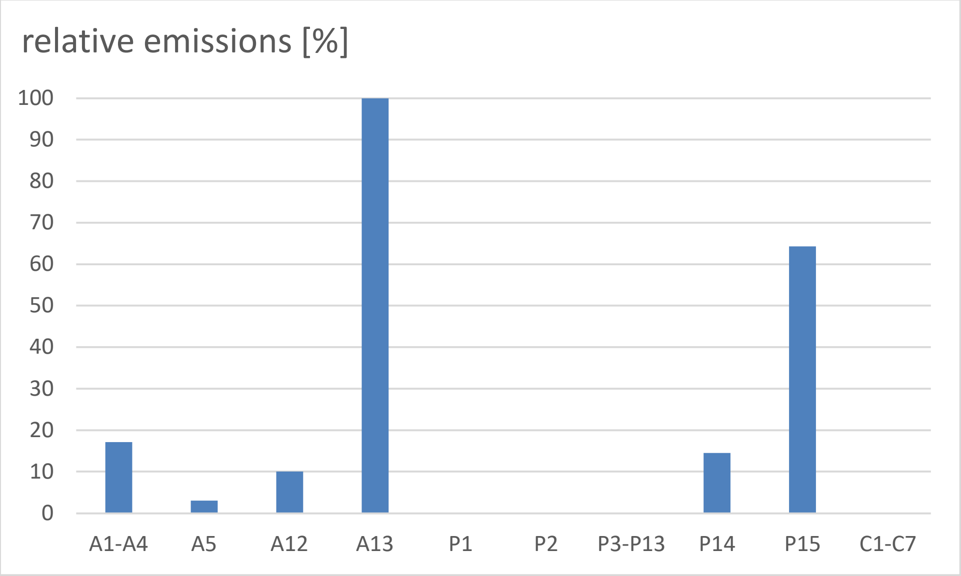


Figure 16 Relative emissions by use for BPA/BosC

In relation to the tonnage used, polymers P1-P13 show a negligible level. The high values for A13 indicate that the emissions exceed the tonnages produced in the EU. For application A12, the tonnage used is unknown and was estimated at 10 times the emitted tonnage based on stakeholder information.

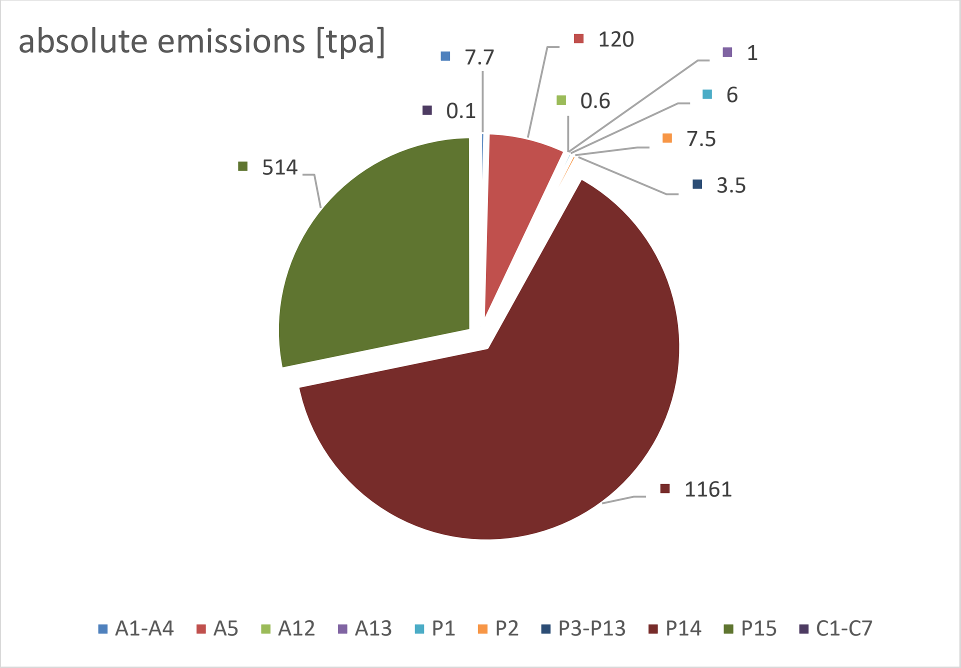


Figure 17 Absolute emissions by use for BPA/BosC

With these figures it become obvious that all uses have an impact on emissions. Some uses have shown a higher release and emission potential. Despite all the clearly recognisable connections, it must not be forgotten that information on releases or the tonnage used was not available and was usually set to zero.

From the available data, it becomes clear that the restriction achieves the greatest effect during service life (use and processing). At the EOL point, recycling can remain possible without restrictions (2 tonnes per year). The application of the requirements under REACH becomes necessary again with the placing on the market or the service life of the recycled product/mixture. For the production of BPA/BosC or processing as isolated intermediate products as a formulation step in industrial plants, the reduction potential seems to be exhausted by the application of risk reduction measures and the demonstration of the respective reduction potential of the individual measures (6 tpa). This area can be monitored by the IED. The adaptation of the BREFs (BAT (Best Available Technique) Reference Documents) for the production/processing of BPA/BosC and the corresponding obligation of monitoring or surveillance harbour an additional reduction potential outside REACH.

In summary, the emitted tonnage of BPA and BosC needs to be drastically reduced. Since surface waters are the most affected by the chemical load of BPA/BosC, the success of the restriction targets this compartment. The goal is to achieve 0.01 µg/L (assumption of the LOD) instead of 0.3 µg/L detectable BPA or 0.4 µg/L for BosC (see here B.4) in surface waters. The objective is thus to reduce the environmental concentration in relation to surface waters by 97% and at least below the quantifiable limit, better below the limit of determination.

As far as the BosC is concerned, the reduction potential is also given. If one considers only the quantity emitted and derives the release potential only in relation to the quantity, the proportion is small. The share of BosC in relation to the tonnage of BPA is only 1%. However, if the most relevant uses for emissions, TP, syntans for leather and textile auxiliaries, are taken into account, a much higher emission in the three- to four-digit range can be assumed due to the high release potential. Since the target of 0.01µg/L in surface waters applies to BPA in sum with the BosCs, it is appropriate to restrict these uses in particular.

The reduction potential is described in detail in Annex E.5 of the restriction dossier (E.5 Risk reduction capacity).

B.9. Risk characterisation

A detailed risk characterization is not considered relevant by the dossier submitter, as both BPA and BosC relate to the same hazard potential (ED substances for the environmental organisms) for which no safe concentration in the environment can be derived (see B.7). Since, based on the current knowledge (i.e. even low-dose exposure in early life stages where homeostatic control is not fully functioning in embryos can have irreversible and adverse effects at later stages) and limited test methods with respect to species and endocrine relevant endpoints available, it is difficult to determine safe exposure levels of EDs in the environment, they should be treated as non-threshold substances. This view is not only supported by a broad scientific community as e.g. documented in the "UNEP-WHO State of the Science, of Endocrine Disrupting Chemicals" report (World Health Organization, 2013) but also by the EU Parliament (European Parliament, 2016), the EU Joint Research Center (2014) and the Commission in its REACH EDC review. This implies that quantitative risk assessment cannot be applied, like it is also established for PBT/vPvB substances, for environmental EDs and it needs to be assumed that any exposure are considered as a proxy for risk (see B.9).

The substances are used widely dispersive and are thus also found ubiquitously as monitoring data (see B.4.2.5) reveal. The regulation of BPA in other substance-, product- and media-oriented areas shows the relevance through the hazard potential (see C). However, it also becomes apparent that further regulatory measures are necessary, as BPA is still found in the environment. Especially for the regrettable substitutes, the BosC, it becomes apparent that these must be co-regulated. These have not been considered so far and harbour a comparably high release potential.[176]

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)[Section 6.2 Fig. 21/22 contained within (Ramboll 2015)] to distinguish between contributions from air and water emissions. It is clear from this 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 are well controlled and in most areas represent only a small fraction of the BPA emissions found in surface waters. The modelling results indicate that a reduction in industrial emissions would only lead to a very modest reductions in BPA concentrations in surface waters, with reductions associated

---

[176] Industrial Emissions vs Consumer Emissions (Final Report; 2015 "SUBSTANCE FLOW ANALYSIS (SFA) AND REGIONALIZED PATHWAY ANALYSIS (RPA) FOR EMISSIONS OF BISPHENOL A (BPA) INTO THE ENVIRONMENT" – FlowEQ model)

with consumer sources are much more likely to lead to significant reductions in surface water BPA concentrations. water.

Annex C: Justification for action on a Union-wide basis

See chapter 1.3 in the main document.

Annex D: Baseline

Emissions of BPA and BosC are estimated to range between 251-1 773 tonnes per year.

Without further regulatory measures the use of Bosc is going to increase as substitution of BPA is likely to increase as e.g. for BPS in thermal paper it can be seen.[177] BPS and BPF are the major BPA substituents with distinct industrial applications. In addition, Bosc are used in a big variety of application as described in Annex A. Monitoring data shows the occurrence of BPA, BPAF, BPB, BPF and BPS in 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.

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 no further BPA emissions from the paper recycling sector after the ban of BPA in thermal paper has become effective. Today, this sector accounts for 77 % - 85 % of the BPA loadings to surface water. Further assumptions are that emissions from PVC recycling will be minimized by 88 %, whereas emissions from the industrial pathway, the recycling of tyres, landfills, the use of polycarbonate and the use of epoxy resins remain stable. In total, 2 tonnes BPA per year are estimated to be released to surface water in Germany in the future with more than 50 % coming from landfills. The Dossier Submitter agrees that a reduction of BPA releases to surface waters can be expected. However, the estimation for remaining BPA releases is considered to be very uncertain and most likely to be an underestimation. Further information on temporal trends and sources of BPA in the German environment is given in section B.4.2.5.

The model does not consider various aspects discussed in Annex B.8 which relate to the specific calculation of emissions from various uses. However, even on a very general level increasing emissions can be expected.

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 ~1.45 million tons. A steady growth is expected during the next years albeit the restriction of its use in thermal paper so that an annual BPA processing of ~1.7 million tons is predicted for 2024 and up to ~ 2 million tons by the end of the decade (**Figure 18**). Most of the BPA processing currently accounts for polycarbonate and epoxy resins and only <5 % to others. Therefore,

---

[177] https://echa.europa.eu/documents/10162/23294236/bpa_thermal_paper_report_2020_en.pdf/59eca269-c788-7942-5c17-3bd822d9cba0

emissions from polycarbonate and emissions from epoxy resins are very likely to increase as well.

Second, emissions from the paper recycling industry cannot be expected to reduce to zero. The use as a photo developer is just one of many uses in the paper industry. Further BPA emissions are still to be expected from coating, inking, recycling residues and processing. In addition, some uses of BPA are predicted to increase. For example, 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 %. In textiles, BPA as TBBPA and articles and chemicals made from BPA find different applications. These use categories are not included in non of the emission estimations so far. Thus, the scenario by Ramboll Deutschland GmbH (2022) is significantly underestimating future emissions.

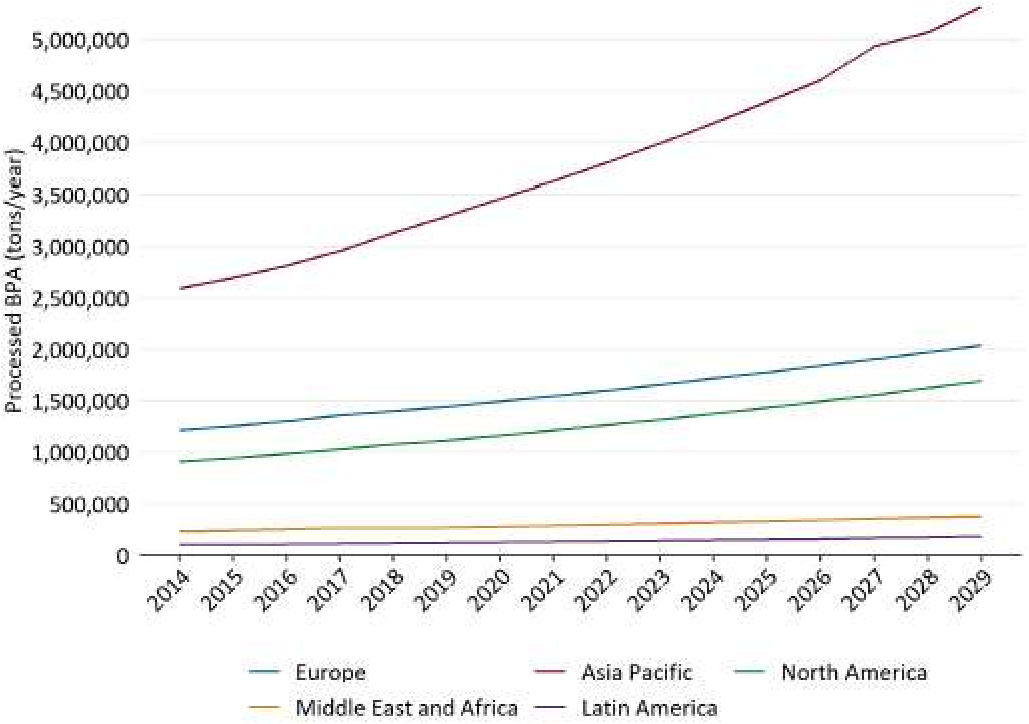


Figure 18: BPA processing 2014 – 2029 by regions

Source: BioMath GmbH, based on (ltd, 2020)

BPA has been subject to regulatory measures at the EU level and also at national level (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. 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, restricted it in those materials intended for children under the age of 3 (Barouki, 2020).

Even though, overall BPA concentrations in surface water have generally decreased in the past decade (see B.4.2.5), 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. Additional emission mitigation in all sectors are necessary.

Annex E: Impact Assessment

E.1. Risk Management Options

E.1.1. Proposed option(s) for restriction

Bisphenol a (BPA) has been the focus of regulatory attention for many years.[178,179] This substance is an SVHC with endocrine disrupting effects on environmental organisms[180] and humans. It is skin sensitising, toxic to reproduction and shows acute and chronic toxicity to environmental organisms. BPA is on the ECHA candidate list.[181] Currently, BPA is ranked with high priority for inclusion in Annex XIV of REACH (Authorisation List).[182]

In a first step, the discussion on a complete ban of BPA took place. Discussion lead to the assumption that BPA and BosC may lead to future materials via innovation and are needed to e.g. reduce CO_2 Emissions. However, the quality of products needs to be increased and/or the circumstances of processing need to be restricted to achieve a reduction on emission into the environment.

As ECHA has already shown in its assessment of regulatory needs on bisphenols that a regrettable substitution of BPA is likely. Regrettable substitution can only be avoided if other bisphenols are also addressed, otherwise this restriction measure would have no meaningful impact on the environment. In conclusion one option to avoid the regrettable substitution was chosen. It is foreseen to address BPA and the bisphenols already identified as ED and the possibility for a subsequent addition of BosC identified via an EU mechanism (e.g. via 57f ED ENV) in one restriction entry. This leads to an effective risk-reduction and reliable risk-assessment. However, SEA and (partly related) legal aspects are unresolved.

There is a need to balance effectiveness considerations and data required for a fit-for-purpose dossier.

As mentioned before, the extension of the restriction also to bisphenols of similar concern, serves to prevent regrettable substitution.[183] The concern, as for BPA in this restriction, relates to endocrine disruption to environmental organisms. For endocrine disruptors, there is no safe threshold of effect in the environment. These substances of similar concern are structurally analogous and are technically applicable as substitutes for BPA for different uses. From 01.01.2020 an additional BPA restriction came into effect. The restriction concerns the concentration of BPA in thermal paper (TP) and was mandated by REACH. Thermal paper products can no longer contain BPA in concentrations equal to or greater than 0.02% by weight. As the paper industry has been detected as an important emitter of BPA,[184] this is a necessary step. Thermal paper is widely used in receipts and although

---

[178] https://echa.europa.eu/de/hot-topics/bisphenol-a (03/03/2020)

[179] https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Downloads/EN/REACH/Verfahren/BPA-Restriction-BAuA-Presentation.pdf?__blob=publicationFile&v=2 (2020)

[180] https://echa.europa.eu/documents/10162/ede153a4-db00-daf6-120f-6b6ccce0c539 (06/07/2021)

[181] https://echa.europa.eu/de/candidate-list-table/-/dislist/details/0b0236e180e22414 (06/07/2021)

[182] https://echa.europa.eu/documents/10162/13640/9th_axiv_recommendation_October2019_en.pdf/d4d55dea-cc36-8f57-0d9f-33b8e64c4f07 (06/30/2021)

[183] https://www.umweltbundesamt.de/publikationen/bewertung-des-endokrinen-potenzials-von-bisphenol

[184] https://www.umweltbundesamt.de/publikationen/identification-of-relevant-emission-pathways-to-the

it is not suitable for recycling, it has probably been fed into the recycling process in large quantities. An indication of this is that processors of recycled paper have emitted BPA without actively adding BPA to production processes and that recycled paper products such as compost bags have contained BPA[185] even though it had not been purposefully added during the production process. With this restriction, BPA will not suddenly disappear from these cycles, but a decrease of BPA concentrations in the recycling cycles is expected. However, this is not true for the use of bisphenol analogues, such as BPS. The increased use of BPS[186] in thermal paper is significant and unaffected by the restriction of BPA. Additionally, as the restriction is limited to thermal paper, other paper treatment processes that could emit BPA are not considered.

The example of BPS as a substitute in thermal paper shows that the technical substitution of BPA with BosC is not a theory. In order to exclude this mechanism, these bisphenols/ BosC should also be addressed with this restriction. The possibility of bypassing the migration limits of this restriction with a combination of bisphenols individually added below the set limit should also be addressed here. The limit proposed by the dossier submitter therefore refers not only to the individual substance BPA, but also to the sum of BPA and BosC. Considering the precautionary principle, it is important to substitute endocrine disruptors without a safe environmental concentration as quickly as possible in areas where this is feasible. Alternatives are available for parts of the broad application range of BPA. The setting of migration limits also recognises that materials and articles made from BPA can, for example, extend the lifetime of construction materials, which saves resources, or save energy, which can reduce emissions of other substances requiring regulation. Nevertheless, it is important to reduce BPA emissions to a minimum with this application- and migration limit, even if this means setting new standards in various sectors.

Currently, targeted restrictions of certain uses and a restriction of BPA and BosC with a migration limit in polymers could be designed and possible emissions from depolymerisation processes could be addressed. Restriction is the only effective regulatory measure to limit release into the environment. Noting that (potential) drop-in substitutes are gaining importance to the same extent as BPA is being restricted, it is imperative that the BPA alternatives, which are also bisphenols, are included in this restriction. Otherwise the current situation will lead to regrettable substitution in the growing markets as it is already the case for BPS in thermal paper. For this reason, it is essential to obtain an overview of the bisphenol alternatives that are ready for the market and already in use, and to apply the same limits to these bisphenols as for BPA, both in mixtures and products.

The restriction intends to reduce all emissions as far as possible. Under this condition, it may still be possible to continue using these SVHC. The aim of the restriction is to reduce the environmental concentration to a maximum of 0.01 µg/L. In doing so, BPA and BosC must be addressed as a sum. This target concentration in the environment applies to BPA and BosC and is not to be regarded as a target for all individually addressed bisphenols. In this case the reference to surface waters was chosen as the effect is most obvious here due to the data available.

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.

---

[185] https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_41_2014_identfifcation_of_relevant_emission_pathways_of_bisphenol_a_0.pdf

[186] https://echa.europa.eu/de/-/bisphenol-s-has-replaced-bisphenol-a-in-thermal-paper (06/30/2021)

E.1.1.1. Proposed restriction option 1: content of max. 10ppm “free BPA+BosC” or 0.04µg/L migration-limit, no specific derogations for polymeric uses

A value-based restriction or migration limit for the use of BPA and/or BosC are considered the most suitable options.

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 (i.e. via functioning as a cross-linker) or are used as intermediates in the manufacture of polymers, and for which contact to aqueous media in any form (i.e. also cleaning) can be excluded during their reasonable and foreseeable use throughout their service life.

3. If contact to water throughout service life cannot be excluded, 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 (i.e. via functioning as a monomer of polymers or a cross-linker) or are used as intermediates in the manufacture of polymers, and for which a migration limit in the respective mixtures and articles does not exceed 0.04 mg/L over the entire service life.

Substances intended to be restricted:

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 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 assessed as fulfilling the criteria for possessing endocrine-disrupting properties with respect to non-target organisms according to Commission Delegated Regulation (EU) 2017/2100[187] in the context of Regulation (EU) No 528/2012.

---

[187] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2100&from=EN

- They have been assessed as fulfilling the criteria for possessing endocrine-disrupting properties with respect to non-target organisms according to Regulation (EU) No 1107/2009, Annex II, 3.6.5.[188]

E.1.1.2. Proposed restriction option 2: content of max. 10ppm "free BPA+BosC" or 0.04µg/L migration-limit and specific derogations for polymeric uses

A value-based restriction or migration limit for the use of BPA and/or BosC are considered the most suitable options.

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 (i.e. via functioning as a cross-linker) or are used as intermediates in the manufacture of polymers, and for which contact to aqueous media in any form (i.e. also cleaning) can be excluded during their reasonable and foreseeable use throughout their service life.

3. If contact to water throughout service life cannot be excluded, 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 (i.e. via functioning as a monomer of polymers or a cross-linker) or are used as intermediates in the manufacture of polymers, and for which a migration limit in the respective mixtures and articles does not exceed 0.04 mg/L over the entire service life.

Substances intended to be restricted:

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 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.

---

[188] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1107-20210327&from=EN

- They have been assessed as fulfilling the criteria for possessing endocrine-disrupting properties with respect to non-target organisms according to Commission Delegated Regulation (EU) 2017/2100[189] in the context of Regulation (EU) No 528/2012.

- They have been assessed as fulfilling the criteria for possessing endocrine-disrupting properties with respect to non-target organisms according to Regulation (EU) No 1107/2009, Annex II, 3.6.5.[190]

E.1.1.3. Proposed restriction option 3: content of max. 1,000ppm "free BPA+BosC"

A value-based restriction or migration limit for the use of BPA and/or BosC are considered the most suitable options.

<u>Conditions of restriction:</u>

1. Shall not be placed on the market as such, as a constituent in other substances, mixtures and articles in a concentration equal to or greater than 1,000ppm (0.1% 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 in which the substances subject to this Annex XVII entry **are used as monomers[191] and** if it can be demonstrated in a migration test representative for the entire service life of the respective mixtures and articles as defined in Appendix Z that the migration of the sum of all these substances does not exceed 1,000ppm.

<u>Substances intended to be restricted:</u>

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 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 assessed as fulfilling the criteria for possessing endocrine-disrupting properties with respect to non-target organisms according to Commission

---

[189] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2100&from=EN
[190] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1107-20210327&from=EN
[191] Monomer/reactant leading to a covalent bonding into the matrix of the derived polymer.

Delegated Regulation (EU) 2017/2100[192] in the context of Regulation (EU) No 528/2012.

- They have been assessed as fulfilling the criteria for possessing endocrine-disrupting properties with respect to non-target organisms according to Regulation (EU) No 1107/2009, Annex II, 3.6.5.[193]

E.1.1.4. Justification for the selected scope (content of max. 10ppm "free BPA/BosC" or 0.04 µg/L migration-limit) of the proposed restriction option

The primary goal of restricting BPA and BosC is to limit the release potential as much as possible. The limits shown (for content and/or migration) apply to BPA and BosC in total. The values are to be considered as sum parameters for the described bisphenols. This is necessary to address possible mixtures of bisphenols or to address a common use.

Bisphenol a is a high tonnage substance which, as such or processed in plastics, permeates all areas of human life.[194] BosC have the same properties of particular concern as BPA. For this reason, BosC must be addressed in the same way. They can also lead to regrettable substitution, which must be prevented. Example uses include consumer goods, food contact materials, furniture, toys and parts of electrical appliances made of polycarbonate, vehicles, construction materials and surface coatings manufactured with epoxy resin, as well as textiles and lubricants that contain BPA/BosC as an additive. These products may also be imported. The regulation of polymers and imported products can only be achieved by a restriction of the substance. A value-based restriction or migration limit for the use of BPA and/or BosC are considered the most suitable options.

As all manufacturers have to provide the same evidence for their products, it would lead to equal treatment under the restriction. This applies equally to European and non-European companies. The obligation to derive an exposure estimate burdened with uncertainties would also be eliminated.

We therefore advocate anchoring the content analysis and/or release (migration) limit within the restriction of the BPA and BosC. The determination of the release potential only becomes necessary when it is clear that the BPA and BosC content in the product (mixture/article) exceeds the limit of 10ppm. The content BPA and BosC here refers to intentionally added additives or also residual amounts (e.g. unreacted monomer, impurity) in polymers/plastics.

The following specific derogations regarding concentration limits are proposed:

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

---

[192] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R2100&from=EN

[193] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02009R1107-20210327&from=EN

[194] Leisewitz A. and Schwarz W. (1997): Stoffströme wichtiger endokrin wirksamer Industriechemikalien (Bisphenol A; Dibutylphtalat/Benzylbutylphthalat;Nonylphenol/Alkylphenolethoxylate). UFOPLAN-No. 106 01 076, date: 1997.

		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.
Polycarbonates	Concentration limit 150 ppm	10 ppm concentration limit can only be met by less of 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.
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.
Leather articles and mixtures used in leather tanning	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 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.

E.1.1.5. Information on testing

For details regarding testing for residual ammounts of BPA and BosC as well as migration testing please refer to section E.7.

E.1.2. Discarded restriction options

A **complete ban on BPA** was discussed. Although this is the best way to reduce the risk, it is necessary to formulate limit values and exemptions from the point of view of proportionality. This has to be considered, as there are obviously uses that do not have a release potential of BPA during the life cycle.

Another option that has been discussed is the **use-specific ban** of all uses **of BPA** with significant emissions. With this option, however, it became clear that use-specific bans alone are not sufficiently minimise environmental concentrations.

Another point to consider in terms of content is that a **ban on BPA alone** could lead to unfortunate substitution. This phenomenon has been observed not least with the thermal paper restriction, with BPA being substituted by BPS (Liao et al., 2012a; Liao et al., 2012c; Liao et al., 2012d).

There is insufficient data for a total restriction. Based on monitoring data, it is evident that BPA can be found in numerous different environmental compartments and organisms. However, not all sources of BPA could be clearly identified so far. Therefore, the aim of the restriction is to avoid known sources and to achieve the technically possible prevention of BPA release from materials.

Table 100: Discussion of restriction options concerning regrettable substitution

Restriction option	Advantages	Disadvantages
Option 1: Only BPA	• Most information with regard to uses and emissions available	• (Most likely) immediate regrettable substitution • Not effective with regard to RAC/SEAC standards
Option 2: BPA + bisphenols for which ED properties have already been established (exhaustive list)	• High degree of legal certainty • (Most likely) immediate substitutes restricted • RAC/SEAC: fact-based assessment	• SEA: How to address unknown (future?) uses of other bisphenols) • High uncertainties with regard to medium-/long-term regrettable substitution • Frequent follow-up restrictions necessary
Option 3: BPA + bisphenols already identified as ED + subsequent addition of bisphenols of similar concern via mechanism (e.g. via 57f ED ENV (open list)	• Avoid regrettable substitution • Evidence-based risk assessment	• High legal uncertainties (no socio-economic assessment) • Ongoing monitoring and assessment of bisphenols necessary • Restriction of unknown uses can be disproportionate (SEAC)
Option 4: All bisphenols of similar concern based on structural similarity	• Regrettable substitution by other bisphenols is avoided	• Difficulties to demonstrate common concern • Lack of data for systematic risk assessment • Lack of data for SEA (additional uses)

- **Option 1:** Most likely very low risk reduction in case of broad regrettable substitution – neither effective (RAC) nor proportionate (SEAC).

- **Option 2:** Likely to be moderately effective and proportionate to justify a restriction – however, the need for frequent follow-up restrictions is burdensome for regulators and industry. Also this approach is outmoded when considering the Chemicals Strategy for Sustainability (CSS).[195]

---

[195] European Commission: Chemicals Strategy for sustainability: Towards a Toxic-Free Environment, 14 October 2020. https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf

- **Option 3:** Effective risk-reduction and reliable risk-assessment. However, SEA and (partly related) legal aspects are unresolved.

- **Option 4:** Most effective option, however unlikely that common concern can be established at the moment → lack of data for systematic structure-activity hazard assessment. Possibly a lot of unknown uses which makes SEA very uncertain.

Option 3 is the most realistic option if we want to balance effectiveness considerations and data required for a fit-for-purpose dossier.

E.1.3. Other Union-wide risk management options than restriction

Authorization:

Currently, BPA is ranked with high priority for inclusion in Annex XIV.[196] It is currently a substance with high priority level, evaluated[197] and set by ECHA[198] according to the "9th recommendation of the European Chemicals Agency of 1 October 2019 for the inclusion of substances in Annex XIV to REACH (List of Substances subject to Authorisation)". It can be safely assumed that bisphenol a will be referred to the REACH regulatory committee by 2024. However, according to the legislation text[199] uses in polymers and imported products are exempt from the authorisation requirement. The regulation of polymers and imported products can only be achieved by a restriction of the substance.

Additionally, Germany submitted a proposal to harmonise the environmental classification of BPA in 2019 as follows:

Hazard class and Category Code	Hazard Statement Code	M-Factor
Aquatic Acute 1	H400	1
Aquatic Chronic 1	H410	10

In October 2020, RAC supported the proposed classification in their opinion on the proposal.

The authorisation procedure might trigger voluntary actions of industry and again strengthen the responsibility of manufacturers to demonstrate and decide on an essential need for BPA and encourage the use of alternative substances or techniques. After an authorisation is set into force article 69(2) of the REACH regulation would trigger the need to consider whether further restrictions are needed for the use of BPA in articles if it can be demonstrated that risks occur which are not adequately controlled. However, the authorisation procedure itself would not address the manufacture of BPA or use of BPA as intermediate, the polymer and the imported articles. Further risk management measures within or outside the scope of the REACH regulation would be necessary to reduce emissions to the environment. Furthermore, if BPA was included in Annex XIV of the REACH

---

[196] https://echa.europa.eu/documents/10162/13640/9th_axiv_recommendation_October2019_en.pdf/d4d55dea-cc36-8f57-0d9f-33b8e64c4f07 (06/30/2021)

[197] https://echa.europa.eu/documents/10162/13640/factsheet_inclusion_annexxiv_de.pdf (06/30/2021)

[198] https://echa.europa.eu/documents/10162/13640/9th_axiv_recommendation_October2019_en.pdf/d4d55dea-cc36-8f57-0d9f-33b8e64c4f07 (06/30/2021)

[199] https://echa.europa.eu/de/regulations/reach/legislation (03/03/2020)

regulation it would not be possible to establish restrictions for mixtures containing BPA. Hence, BPA should not be prioritised for inclusion in Annex XIV of the REACH regulation yet.

Product-specific legislations:

Currently, different product-specific legislations do exist for bisphenol a (BPA) in Europe which set requirements for the use of BPA in different product categories (e.g. food packaging and containers , medical devices, toys, etc.). The main purpose of these regulations is to ensure a high level of protection of human health. Therefore, they specify a migration limit, a maximum amount of substance permitted to migrate from these products (articles under REACH) into e.g. food and the human body. These specific migration limits for BPA were reviewed by EFSA in 2015. As a consequence of uncertainties in respect of potential health effects, EFSA reduced the tolerable daily intake (TDI) for BPA from 50 µg/kg of body weight per day to 4 µg/kg of body weight per day.

An adaptation of product-oriented frameworks could be reasonable and feasible to reduce emissions from articles/mixtures and indirectly also emissions of BPA during the life cycle, the recycling of articles or the waste stage of articles. In addition to product-oriented measures, a consideration of BPA in regulations dealing with disposal and recycling of BPA containing materials could as well reduce emissions to the environment.

Emissions control:

BPA was identified as SVHC for the environment in January 2018.[200] This was the only option to come to an official European wide conclusion on its endocrine disrupting properties for environmental organisms. This conclusion is the basis for further regulatory measures within or outside the scope of the REACH regulation and impact the obligations for a control of emissions e.g. under the Industrial Emissions Directive (IED), may encourage the derivation of an Environmental Quality Standard (EQS) and inclusion of BPA as priority (hazardous) substance under the Water Framework Directive (WFD), or ease the regulation via further product-oriented frameworks. To achieve overall lower concentrations in environmental compartments and protect in particular aquatic organisms, media-oriented frameworks trigger monitoring activities and consequently produce a better data basis and arguments for further reduction measures

E.2. Alternatives

E.2.1. BPA used for production of other chemicals (C)

General remark: While there is some potential for mutual substitution between the BosC included in this dossier for some of the uses described in this chapter, the dossier submitter has refrained from listing them as potential alternatives as there are covered in this restriction dossier.

---

[200] https://echa.europa.eu/documents/10162/ede153a4-db00-daf6-120f-6b6ccce0c539 (06/30/2021)

E.2.1.1. Bisphenol A diglycidyl ether BADGE/DGEBA (C1)

E.2.1.1.1. Research report statements

Bisphenol A diglycidyl ether is an organic compound used as feedstock for epoxy resins. It is synthesized from bisphenol A and epichlorhydrin as raw materials. There are 53 alternatives for BADGE, of which 20 are currently in commercial usage.

Among the most prominent is isosorbide, due to its very good optical clarity, strong resistance to UV irradiation, heat, chemical degradation, impact, and abrasion.

Other possible alternatives are melamine, D4; D5 and CBDO (2,2,4,4 tetramethyl 1,3 cyclobutanediole). Most of these substances were found to be used for (can) coatings, some (D4; D5) also in paints.

E.2.1.1.2. Stakeholder Statements (1st Call for Evidence)

These substances are either used for (can) coatings, or in niche applications in which they have some advantages over BPA. But for many applications there are either no alternatives, or there are inferior regarding necessary characteristics, hazard profiles and/or costs.

Another possible alternative is polyurethane. However, it can contain isocyanates, which is likewise attached to risks.

E.2.1.1.3. Stakeholder Statements (2nd Call for Evidence)

According to one stakeholder (CfE2#161), non-BPA can-linings which satisfy fitness-for-use are expected to be more expensive due to the raw materials being produced on much a much smaller scale than BPA and BADGE. The stakeholder claims to be able to achieve a complete conversion to non-BPA can linings in less than 5 years, which has already been demonstrated for food and beverage cans in France and food cans in the United States.

E.2.1.1.4. Conclusion

Even though the stakeholders express doubt concerning inferior characteristics and lack of versatility, there seem to be sufficient alternatives (like e.g. isosorbide) for many applications. However, melanine is under assessment as being persistent, bioaccumulative and toxic, and is planned to be identified as substance of very high concern. D4; D5 are likewise both identified as substances of very high concern. Polyurethane can contain isocyanates, which is likewise attached to risks. Furtnhermore, the costs may be higher.

Table 101: Potential alternatives for bisphenol A diglycidyl ether BADGE/DGEBA

Alternative	CAS-No.	Type of substance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)
isosorbide	652-67-5	Mono constituen	y	4	

		t			
melamine	108-78-1	Mono constituent	y		Potential: PBT
Octamethylcyclotetrasiloxane (D4)	556-67-2	Mono constituent	y	4	Potential: R Recognised: PBT Potential: POP SVHC Some uses restricted under Annex XVII
decamethylcyclopentasiloxane (D5)	541-02-6	Mono constituent	y	4	Recognised: PBT SVHC Some uses restricted under Annex XVII
2,2,4,4 tetramethyl 1,3 cyclobutanediole (CBDO)	3010-96-6	Multi constituent	y	4	
polyurethane		polymer	y		
n-Alkyl Diphenolate Diglycidyl Ether			n	4	
resorcinol diglycidyl ether	101-90-6	Mono constituent	n	4	Recognised: C Potential: M Recognised: Ss
1,4-cyclohexanedimethanol diglycidyl ether	14228-73-0	Multi constituent	n	4	Broad agreement: Ss
neopentyl glycol diglycidyl ether	17557-23-2		n	4	Recognised: Ss

cardanol	37330-39-5		n	4	
2,2,4,4-tetramethyl-1,3-cyclobutadione (TMCBDI)	3010-96-6		n	4	
trans-1,4-Cyclohexanedimethanol, (trans-CHDM)	3226-48-4		n	4	
2-phenyl-1,3-propanediol	1570-95-2	Mono constituent	n	3	
divinylbenzene	1321-74-0	UVCB	n	3	

Fitness for Purpose according to *"Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials":*
1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA
Asteriks (*) = property relates to cases containing impurities and/or additives
SVHC = Substance of Very High Concern

E.2.1.2. BPA dimethacrylates Bis-GMA, Bis-DMA, Bis-EMA, and dental resins (C3, C4, C5)

E.2.1.2.1. Research report statements

A total number of 28 potential substitutes for BPA-containing dental materials could be found. At least four alternative substances are used commercially already to substitute the BPA-containing dimethacrylates. Among those are BFDGE based dental materials, organically modified ceramic dental composites containing ormocers, silorane based dental composites as well as the relatively new bioactive restoratives which mimic the physical and chemical properties of the natural tooth. Furthermore, current scientific publications are concerned with the study of organic and inorganic biobased and non-biobased components such as, among others, resorcinol, isosorbide, or urethane dimethacrylate (UDMA) compounds.

E.2.1.2.2. Stakeholder Statements (1st Call for Evidence)

The first CfE received no stakeholder claims regarding this application.

E.2.1.2.3. Stakeholder Statements (2nd Call for Evidence)

The BPA-containing dimethacrylate Bis-GMA is used in various dental/orthodontic products, specifically restoratives, adhesives and primers, which are essential to improve and maintain oral health. In these products, Bis-GMA is a vital component to ensure appropriate curing and durability.

E.2.1.2.4. Conclusion

There have been no stakeholder claims contesting the applicability of the alternatives mentioned in the research report. However, both BFDGE and UDMA are agreed to be skin sensitising by a majority of ECHA data submitters.

Table 102: Potential alternatives for BPA dimethacrylates Bis-GMA, Bis-DMA, Bis-EMA, and dental resins

Alternative	CAS-No.	Type of substance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)
organically modified ceramics (Ormocer)			n	4	
Pulpdent activa bioactive restorative			n	4	
Syloran			n	4	
UDMA	72869-86-4	Multi constituent	y	4	Broad agreement: Ss
Barium boro aluminosilicate + Phosphate methacrylate + Mix of methacrylates			Y		
BRUSH DIP (PMMA + several monomers + activator TBB)			y		

Fitness for Purpose according to *"Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials":*
1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA

E.2.1.3. Polyols (C7)

E.2.1.3.1. Research report statements

Although BPA-based polyols are used frequently for the synthesis of polyurethanes for certain applications, there also is a wide variety of other polyols that may be suitable as alternatives for BPA-containing compounds. Four of the most popular are polypropylene glycol, polytetrahydrofuran, polyethylene adipate and polybutylene adipate.

However, a substitution of polyols almost always goes hand in hand with a visible change in the resulting material properties which may lead to more costs to adapt new formulations to existing applications.

E.2.1.3.2. Stakeholder Statements (1st Call for Evidence)

As one potential alternative, alkoxylated (glycerol/sucrose based) products were mentioned. However, they did not duplicate the performance of the existing product nor did they meet the customer's economic expectations (ie. product cost).

E.2.1.3.3. Stakeholder Statements (2nd Call for Evidence)

The second CfE received no stakeholder claims regarding BPA-based polyols.

E.2.1.3.4. Conclusion

There seem to be sufficient alternatives (polypropylene glycol, polytetrahydrofuran, polyethylene adipate and polybutylene adipate) for many applications. One stakeholder additionaly mentioned alkoxylated (glycerol/sucrose based) products, albeit by pointing out that they perform differently, which is also an issue with aforementioned other alternatives.

Table 103: Potential alternatives for polyols

Alternative	**CAS-No.**	**Type of substance**	**Mentioned by Stakeholder**	**Fitness for Purpose according to Research Report**	**Properties of Concern (according to ECHA Substance Infocards)**
polypropylene glycol	25322-69-4	UVCB	y	4	
polytetrahydrofuran	25190-06-1		y	4	
polyethylene adipate	24938-37-2		y	4	
polybutylene adipate	25103-87-1		y	4	
alkoxylated products (glycerol/sucrose based)			y		

Fitness for Purpose according to "*Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials*":
1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA

E.2.2. BPA used as additives (A)

E.2.2.1. PVC stabilisers (A4)

E.2.2.1.1. Research report statements

One of the most common and oldest commercially used PVC stabilisers is BHT which is produced on a hundred thousand ton scale. The relatively low molecular weight and low boiling point of BHT may, however, lead to considerable evaporation of the compound during PVC processing which can lead to potential hazards for people and environment. For this reason, this standard chemical has been further developed and alternatives such as Irganox 1010, Irganox 1076 or mixed (mixed) metal stabilisers with much higher boiling temperatures, are used on a large scale. Those stabilisers are considered standard in current polymer processing and are commercially available in high amounts. The costs of the cheapest potential substitutes are comparable to the costs of BPA.

Most prominent and widely used compounds are metal and mixed metal stabilisers such as organolead, -zinc, -tin, barium/zinc stabilisers or organophosphites. Organolead derivatives were one of the most important (cheap and effective) metal organic compounds used for stabilisation. Due their known toxicity, however, lead stabilisers were banned in Europe in 2015. Nevertheless, a wide variety of substitutes for BPA and lead (such as organotin and barium/zinc stabilisers) are available and used already in high amounts.

E.2.2.1.2. Stakeholder Statements (1st Call for Evidence)

BPA has been used in the formulation of PVC resin, plasticisers and heat stabilizers, but this use was discontinued more than 15 years ago in the EU.

E.2.2.1.3. Stakeholder Statements (2nd Call for Evidence)

BPA is claimed by one stakeholder to be necessary for the fabrication of their polymers, with no suggestion of possible alternatives.

E.2.2.1.4. Conclusion

There have been no stakeholder claims contesting the applicability of the alternatives mentioned in the research report. Note however that the research report addresses concerns regarding BHT, which is under assessment due the potential ED properties, and has been included in the Community Rolling Action Plan.[201] Furthermore, lead stabilisers were banned in Europe in 2015, due their known toxicity.

Table 104: Potential alternatives for PVC additives

Alternative	CAS-No.	Type of substance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)

---

[201] CoRAP section on BHT: https://echa.europa.eu/de/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table/-/dislist/details/0b0236e180b8839d

2,6-di-tert-butyl-p-cresol (BHT)	128-37-0	Mono constituent	y	4	Potential: ED In CoRAP
pentaerythritol tetrakis(3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate)	6683-19-8	Mono constituent	y	4	
octadecyl 3-(3,5-di-tert-butyl-4-hydroxyphenyl)propionate	2082-79-3	Mono constituent	y	4	
4,4',4''-(1-methylpropanyl-3-ylidene)tris[6-tert-butyl-m-cresol]	1843-03-4	Mono constituent	y	4	Broad agreement: Ss
octadecanoic acid	57-11-4	Mono constituent	n	4	
Benzoic acid	65-85-0	Mono constituent	n	4	
Barium/zinc, calcium/zinc, magnesium/zinc stabilisers with co-stabilisers			n	4	
organophosphites (family)			n	4	
Organozinc, organotin stabilisers (families)			n	4	

Fitness for Purpose according to *"Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials":*
1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA
CoRAP = Community Rolling Action Plan

E.2.2.2. Developers in thermal paper (A5)

E.2.2.2.1. Research report statements

N-(p-toluenesulfonyl)-N'-(3-(p-toluenesulfonyloxy)phenyl)urea appears to be the major substituent for BPA in thermal paper. It is the dominating developer in tickets (e.g., for public traffic, events) which are commonly of higher paper quality and grammage.

Besides replacing BPA as a developer in thermal papers, another alternative is the modification of the printing technique. For some applications, the use of thermal printing paper can be replaced by electronic alternatives, which may have an advantage over chemical alternatives with a possibly incomplete or unknown hazard profile. So far, there is only one brand of thermal paper worldwide that has been approved for direct food contact and the recycling through the waste paper cycle is possible.

E.2.2.2.2. Stakeholder Statements (1st Call for Evidence)

Another alternative mentioned is 2,2'-diallyl-4,4'-sulfonyldiphenol, for professional users in tickets, receipts, packaging and logistic labels, et cetera. It shows a significantly higher performance compared to competing alternatives, across a range of parameters including melting point, colour sensitivity, heat and humidity resistance, water resistance and resistance to plasticizer.

E.2.2.2.3. Stakeholder Statements (2nd Call for Evidence)

One stakeholder (CfE2# 115) mentions that their analyses detected the use of BPS and to a lesser extent BPF as alternative to BPA in thermal paper. However, both substances being BosCs, they have to be excluded from taking into consideration as alternatives. It is also pointed out that patents for alternative colour developers are filed by both suppliers and thermal paper manufacturers.

In one study (Banaderakhshan, 2022)[202], another BPA susbstitute found in a thermal paper sample was the biphenyl derivative biphenyl-4,4'-diol (BP4,4, CAS 92-88-6). BP4,4 is usually utilized for polymer production and as laboratory chemical, and can be found in plastic products. This substance is broadly agreed to be skin sensitising.

E.2.2.2.4. Conclusion

There have been no stakeholder claims contesting the applicability of the alternatives mentioned in the research report, and TG-SA has been mentioned as an additional alternative by a stakeholder (CfE#1398). However, aside from the issues concerning the use of BosC as alternatives, 2,2'-diallyl-4,4'-sulfonyldiphenol has been recognised as skin sensitising. The applicability of N-(p-toluenesulfonyl)-N'-(3-(p-toluenesulfonyloxy)phenyl)urea is currently heavily in dispute: The substance was put on the Community Rolling Action Plan, but has been withdrawn again due to studies showing no CMR potential or ED sensitivity.[203] However, the results of those tests are under dispute by experts, and additional tests regarding skin sensitivity are planned.

Table 105: Potential alternatives for developers in thermal paper

Alternative	**CAS-No.**	**Type of substance**	**Mentioned by Stakeholder**	**Fitness for Purpose according to Research Report**	**Properties of Concern (according to ECHA Substance Infocards)**
N-(p-toluenesulfonyl)-N'-(3-(p-toluenesulfonyloxy)phenyl)urea	232938-43-1	Mono constituent	y	4	[withdrawn from CoRAP]
N1,N3-bis(3-methylphenyl)-5-[(3-	2375645-78-4		y		

---

[202] Banaderakhshan, R., et al. (2022). "Bisphenol A and its alternatives in Austrian thermal paper receipts, and the migration from reusable plastic drinking bottles into water and artificial saliva using UHPLC-MS/MS." Chemoshpere 286.

[203] Justification for removing a substance from CoRAP prior to evaluation: https://echa.europa.eu/documents/10162/136d43a3-1ab3-737a-6816-3bb14c3cc6c3

methylphenyl)sulfamoyl]benzene-1,3-dicarboxamide					
2,2'-diallyl-4,4'-sulfonyldiphenol	41481-66-7		y	4	Recognised: Ss
N-[2-[[(phenylamino)carbonyl]amino]phenyl]benzenesulfonamide, -	215917-77-4	Mono constituent	y		
4,4'-isopropylidenedi-o-cresol (BPC)	1571-75-1		y		Potential: ED ENV In CoRAP
1,1-bis(4-hydroxyphenyl)-1-phenylethane (BPAP)	1571-75-1		y	4	
2,2-bis(2-hydroxy-5-biphenylyl)propane (BisOPP-A)	24038-68-4		y		
methyl bis(4-hydroxyphenyl) acetate (MBHA)	5129-00-0		y		
biphenyl-4,4'-diol (BP4,4)	92-88-6	Mono constituent	n		Broad agreement: Ss
4-tert-butylphenol	98-54-4	Mono constituent	n	4	Potential: R Recognised: ED ENV In CoRAP SVHC
Oxalic acid; Ethanedioic acid	144-62-7	Mono constituent	n	4	
Gallic acid; 3,4,5-trihydroxybenzoic acid	149-91-7	Mono constituent	n	4	
2,4-Bis(1-phenylethyl)phenol	2772-45-4	Mono constituent	n	4	
Boric acid	11113-50-1	Mono constituent	n	4	Recognised: R SVHC
3,5-bis-tert-butylsalicylic acid	19715-19-6		n	4	
p-Octadecylphosphonic acid	4724-47-4		n	4	
3,5-bis(α-methylbenzyl)salicylic acid	53721-15-6		n	4	
2,4-BPS	5397-34-2		n	4	

biphenyl-4-ol	92-69-3	Mono constituent	n	4	
BPF - ortho	2467-02-9		n	4	Broad agreement : Ss
BPS-MAE	97042-18-7		y	4	
BPS-MPE	63134-33-8		y	4	
BPZ; bisphenol Z	843-55-0		n	4	
BTUM	151882-81-4		y	4	Potential: C
bisphenol SIP	95235-30-6	Mono constituent	y	4	In CoRAP
BPSIP	191680-83-8		y	4	
DMBPA			n	4	
ethylparaben	120-47-8	Mono constituent	n	4	CoRAP
HPP	599-64-4	Mono constituent	n	4	
PHBB	94-18-8	Mono constituent	y	4	Broad agreement : Ss
phenol, reaction product with 4,4'-sulfonylbis(benzeneamine) and 2,4-TDI (UU)	321860-75-7		y	4	
Ascorbic acid	50-81-7		y	4	
Lauryl gallate	1166-52-5		n	3	Recognised: Ss
ROPAQUE NT-2900 (Polymer containing hollow particles)		Technological substitution	y		

REACH for Bisphenol A - BPA levels in materials":

1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA
SVHC = Substance of Very High Concern
CoRAP = Community Rolling Action Plan

E.2.2.3. Hardeners in epoxy resins (A6)

E.2.2.3.1. Research report statements

There are different alternative substances with different chemical structures, such as aliphatic, aromatic, tertiary and modified amines, imidazoles, polymercaptan, anhydrides and other substances commercially available which are already produced and used in high amounts.

E.2.2.3.2. Stakeholder Statements (1st Call for Evidence)

Besides amines and polyamines, one stakeholder (CfE#1392) also mentions amides and polyamides, which form two-component (2-K) systems with the epoxy resins. The stakeholder claims that these systems are highly important for heavy corrosion protection, i. e. used for large objects such as bridges, marine applications or off-shore wind parks, but also applications such as floor coverings and epoxy resin primers.

E.2.2.3.3. Stakeholder Statements (2nd Call for Evidence)

There are alternatives available in some cases, depending on polymerization velocity and curing degree needed. However, in other cases, there is no alternative available yet. The technical development to seek the best epoxy resin & hardener systems for alternatives can, according to one stakeholder (CfE2#144), cause “huge costs”, and likewise the gathering of safety data regarding alternative epoxy resins and hardeners.

E.2.2.3.4. Conclusion

While one stakeholder (CfE#1418) claims that there is no technical substitution, there are numerous commercially avaiable alternative substances mentioned in the research report. However, some of the anhydrides have been recognised as skin sensitising and respiratory sensitising.

Table 106: Potential alternatives for hardeners in epoxy resins

Alternative	CAS-No.	Type of substance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)
amines (aliphatic; aromatic; tertiary; modified)		Monomers	y		
- VBZMI				2	
polyamines		Polymers	y		
amides		Monomers	y		
polyamides		Polymers	y		
imidazoles			y		
polymercaptan		polymer	y		

anhydrides			y		
- CA	76-32-4			2	
- DPA				2	
- GA	108-55-4	Mono constituent		2	
- IA	2170-03-8	Mono constituent		2	Broad agreement: Ss
- PA	85-44-9	Mono constituent		2	Recognised: Ss Recognised: Sr
- SA	108-30-5	Mono constituent		2	Recognised: Ss Recognised: Sr
diaminophthalocyanine				3	

Fitness for Purpose according to *"Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials":*

1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA

E.2.2.4. Flame retardants in polymers (A7)

E.2.2.4.1. Research report statements

90% of the flame retardants recently investigated for epoxy resins and polycarbonates are phosphorous-containing compounds. DOPO (10-dihydro-9-oxa-10-phosphaphenanthrene-10-oxide) and POSS (polyhedral oligomeric silsesquioxanes) and their derivatives play a particularly important role.

The costs of the cheapest potential substitutes are comparable or slightly higher to the costs for TBBPA.

E.2.2.4.2. Stakeholder Statements (1st Call for Evidence)

Melamine poly(zinc phosphate) (MPZnP) acts as a drop-in substitution for flame retardants. Drop-in replacements are not available for all applications of TBBPA without potentially similar or greater risks for environment and health. Potential alternative substance for BPA/TBBPA in current research are not likely to be available midterm.

E.2.2.4.3. Stakeholder Statements (2nd Call for Evidence)

Brominated organic substances can be used which can be compatible with the relevant matrix. Brominee atoms are needed as radical inhibitors in case of fire.

Alternatives not to be used due to current or future regulatory restrictions: PentaBDE, boric acid and boron oxide. Unless specific provisions and exemptions are to be given for these substances and these specific uses, these could be regrettable substitutions.

Flame retardants based on halogens or phosphorus have other important influence on the environment and safety (e.g. bromine in plastic parts ending in a waste incineration can create dioxins/furans, halogenated flame retardants are often used in combination with antimony- or phosphorus-based flame retardants as well as halogen based complicate waste treatment processes and are under discussion regarding human health).

E.2.2.4.4. Conclusion

The research report names DOPO and POSS as alternatives, and one stakeholder (CfE#1323) adds MPZnP to this list. However, the stakeholder also points out the potential risks to environment and health. Also note that DOPO is agreed by a majority of ECHA data submitters to be skin sensitising.

Similarly, stakeholders voice health concerns regarding not only phosphorus- but also halogen-based (first and foremost Br) flame retardands. Furthermore, some substances (Penta BDE, boric acid and boron oxide) are outright ruled out as alternatives due to current or future regulatory restrictions, and therefore will not be listed in the following table.

Table 107: Potential alternatives for flame retardants in polymers

Alternative	CAS-No.	Type of substance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)
MPZnP melamine poly(zinc phosphate)	1271172-98-5	Mono constituent	y	2	
DOPO (10-dihydro-9-oxa-10-phosphaphenanthrene-10-oxide	35948-25-5	Mono constituent	y	4	Broad agreement: Ss
DOPO (phosphorous- and nitrogen-containing epoxy emulsion with DOPO)			y	2	
POSS (polyhedral oligomeric silsesquioxanes)			n	2	
DOPO-POSS			y		
Aluminium hydroxide	21645-51-2	Mono constituent	n	4	
Magnesium hydroxide	1309-42-8	Mono constituent	n	4	
Phosphorus red	7723-14-0	Mono constituent	y	4	
TBP (2,4,6-tribromophenol)	118-79-6	Mono constituent	y	4	Broad agreement:

					Ss Potential: PBT
TCBBPA (2,2',6,6'-tetrachloro-4,4'-isopropylidenediphenol)	79-95-8		y	4	
boron phosphate	13308-51-5	Mono constituent	y	3	Broad agreement: R*
diboron trioxide	1303-86-2	Mono constituent	y		Recognised: R
Tetraboron disodium heptaoxide, hydrate	12267-73-1		y		Recognised: R
HPCTP (phenoxycycloposphazene) and OGPOSS	1184-10-7		y	3	
Sb (antimony)	7440-36-0	Mono constituent	y		Broad agreement: R*

Fitness for Purpose according to "*Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials":*

1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA
Asteriks (*) = property relates to cases containing impurities and/or additives

E.2.3. BPA used for Polymers (P)

E.2.3.1. Polycarbonate (P1)

E.2.3.1.1. Research report statements

A total of 53 potential alternative materials were identified for polycarbonates. Of these, 38 substances are in commercial use. These include polymers such as silicone, glass, ceramic, polypropylene, polyethylene or polyamides. Also, worth mentioning is a DMT/CBDO/CHDM-based copolyester (Tritan^{TM}) which is often used for bottles or tableware.

Isosorbide has sustainable potential especially for applications such as (food) packaging and electronic displays, optical devices, household, as well as specialty materials for niche areas, particularly in the biomedical field.

E.2.3.1.2. Stakeholder Statements (1st Call for Evidence)

Other material substitutes for PC with actual and known commercial use are methylmethacrylate, acrylonitrile butadiene styrene (ABS), polylactic acid (PLA), the polyamides PA 12 and PA 66 and polypropylene (PP/BORCLEA RC737MOR). Other potential alternatives are PET, polymethylmethacrylate (PMMA), polybutylene terephthalate (PBT), polyphenylene ether (PPE), aliphatic copolyester resins (e.g. wTritan™), PSU, PVC, PA1, PA 6, and other bisphenols.

PLA is intentionally biodegradeable. Aliphatic copolyester resins may be usable in specific packaging applications, e.g. for some food/drink and cosmetics containers, as well as in consumer goods (pens, toys, sporting goods, etc.). Polyamides have comparable heat and mechanical strength to PC. PET and Tritan™ are commonly used for water bottles.

Various stakeholders mention using some of these polymers (ABS, PA, PBT, PPE, PET) as blend partners with PC, often in special electric and electronic applications, in order to achieve other specific performance properties, such as low temperature ductility, improved chemical resistance or flame retardancy. PC-ABS blends for example are used to a large extent as flame retardants and have an outstanding impact strength.

Isosorbide-based PC is a material substitute for PC, with actual and known commercial use of the substance as alternative to BPA/TBBPA.

While PMMA and PA 66 are engineering plastics produced in several million tons globally at multiple sites, the other materials are in many cases specialties which limits their availability and increases their price, often (e.g. for DMT/CBDO/CHDM- or isorbide-based copolymers) only produced by one company.

However, these polymers often do not achieve the desired properties of the polycarbonates for certain applications. The interaction of the property values temperature resistance, dimensional stability, flame retardancy, impact strength, especially in cold conditions, is unique. It should also be guaranteed by a potential alternative. For example, polyamides lack the impact resistance and dimensional stability, polypropylene is not transparent, PLA water sensitive, ABS, PMMA and isorbide-based copolymer not as heat- and impact-resistant, DMT/CBDO/CHDM-based copolymer has a high breakage rate, and mineral glass is even as "gorilla glass" highly brittle in comparison, and not as versatile when a transparent material for 3d applications is needed. For many applications (roofing, machine guards for worker protection, fire regulation compliant multiwall sheets in high-rise buildings), PC is preferred due to PMMA being considered to have inferior properties.

The costs of the cheapest potential substitutes are comparable to the costs of BPA or slightly lower.

E.2.3.1.3. Stakeholder Statements (2nd Call for Evidence)

Several alternatives are mentioned by various stakeholders. There are already other polycarbonates not based on BPA, such as Isosorbid- and limonene-based polycarbonate. However, they show different properties to BPA-based PC, such as inferior impact resistance, heat resistance or flame retardancy, rendering them not suitable for all applications.

Several substances are stated to have a significantly lower temperature resistance than PC, such as cellulose acetate, PMMA, ABS, copolyester, PA, PLA, and polyolefins such as PE-HD, PE-LD and PP.

Cellulose acetate is additionaly said to have lower mechanical strength, along with triacetate (which in turn is on par with PC regarding temperature resistance), while PLA is said to susceptible to hydrolysis and to have brittle behaviour. Grilamid TR 55 and COC (cycloolefine-copolymere) are likewise said to posess lower impact strength, though the latter can replace PC in optical applications.

Though Polyphenylsulphone (PPSU) has higher temperature resistance, it is also mainly made of BPA.

In case of glass and ceramic, weight and shattering are a probem. Likewise, metal can be too heavy.

Additionally, to the aforementioned disadvatages, cellulose acetate, triacetate, PPSU and glass are also more expensive than PC. This is likewise the case for Grilamid TR55/TR90, PES and PEI. Furthermore, PA6.6 is said to have high market volatility.

DuraBio can replace PC for particular uses, however it is more brittle.

Polyamides cause issues regarding high vibrancy during fabrication and high moisture absorption, and have a worse carbon footprint.

Biopolymers are not yet available in the necessary amounts, and Tetrashield polymers are not yet classified for human health and/or environmental toxicity.

Other susbstances mentioned are Wood Plastic Compound (WPC), Polyethylenterephthalat (PET) and Tritan^{TM} copolyester, the latter already being an alternative to PC in many medical applications.

E.2.3.1.4. Conclusion

The stakeholders claim that all alternatives are in some way inferior to BPA-based PC (regarding transparency, mechanical strength, shatter and impact resistance, durability, flame retardancy, heat resistance, toughness, chemical and dimensional stability, sterilizability, ductility and weight) and/or are significantly more expensive. Yet it seems that for many applications alternate substances have already been established or are about to get established.

Glass mixtures can incorporate chemicals which are carcinogenic, while methylmethacrylate has been recognised as skin sensitising and is included in the Community Rolling Action Plan. Furthermore, many of the other bisphenols which are potential alternatives show properties of concern.

Table 108: Potential alternatives for polycarbonate

Alternative	CAS-No.	Type of substance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)
DMT/CBDO/CHDM-based copolyester (aliphatic copolyester resin)		polymer	y		
- cis-CHDM	3236-47-3	Polymer		4	
- trans-CHDM	3226-48-4	Polymer		4	
- copolyester (DMT + CHDM + TMCD = CBDO)		polymer	y	4	

glass	65997-17-3		y	4	Recognised: C
mineral glass			y		
Methylmethacrylate (MMA)	80-62-6	Mono constituent	n	4	Recognised: Ss In CoRAP
polymethylmethacrylate (PMMA)	9011-14-7	polymer	y		
acrylonitrile butadiene styrene (ABS)	9003-56-9		y	4	
polylactide acid (PLA)	26100-51-6	Polymer	y	4	
Poly(methyl acrylate) PA 1	9003-21-8	Polymer	y		
Polyamide PA 6	25038-54-4	Polymer	y		
Polyamide PA 11	25035-04-5	Polymer	y	4	
Polyamide PA 12	24937-16-4	Polymer	y	4	
Polyamide PA 66	32131-17-2	polymer	y	4	
GRILAMID TR 55; GRILAMID TR 90 (polyamide)		polymer	y	4	
RILSAN CLEAR (polyamide)		polymer	y		
TROGAMID (polyamide)		polymer	y		
polypropylene (PP / BORCLEA RC737MOR)	9003-07-0	polymer	y	4	
DURABIO (isosorbide based PC)		polymer	y	4	
limonene	138-86-3	Mono constituent	y		Recognised: Ss
PET	25038-59-9	polymer	y		
polybutylene terephthalate (PBT)	24968-12-5	polymer	y		
polyphenylene ether (PPE)	9041-80-9	polymer	y		

PSU	25135-51-7	polymer	y		
PVC	9002-86-2	polymer	y		
metal			y		
other bisphenols			y		
- BHPF; bisphenol FL	3236-71-3			4	
- BPTMC; bisphenol TMC	129188-99-4			4	
- hydrogenated BPA (cycloaliphatic type)	80-04-6	Mono constituent	y	4	
- PPSU; polyphenylsulfone	92-88-6	Mono constituent	y	4	Broad agreement: Ss
- TMBPA	5613-46-7	Mono constituent		4	
- BGF				2	
- DPA	126-00-1			2	
- IBK; isatin biscresol	47465-97-4			2	
- BPM; bisphenol M	13595-25-0	Mono constituent		1	Potential: R Recognised: Ss Potential: PBT Potential: ED
- BPZ; bisphenol Z	843-55-0			1	
- Alkylated BPA-based polycarbonate		polymer	y		
acrylic acid	79-10-7	Mono constituent	n	4	Broad agreement: Ss*

acrylonitrile	107-13-1	Mono constituent	n	4	Recognised: C Recognised: Ss
CBDO	3010-96-7		n	4	
ceramic	66402-68-4	Multi constituent, UVCB	y	4	
COC; cycloolefin-copolymere / Topas IT X1	26007-43-2	polymer	y	4	
COC; cycloolefin-copolymere; norbornene	498-66-8	Polymer (norbornene: Mono constituent)	n	4	
co-polyester (PTA+CHDM+ethylenglycol + isosorbid) / Ecozen		polymer	y	4	
Cyclic olefin polymer		polymer	n	4	
DMBPA			n	4	
methacrylate acid	79-41-4	Mono constituent	n	4	
PE-HD	9002-88-4	Mono constituent	y	4	
PE-LD	9002-88-4	Mono constituent	y	4	
PES; polyethersulfone	25608-63-3		y	4	
polyurethane / Souplethane WP	67700-43-0	polymer	n	4	Broad agreement: Ss* Broad agreement: Sr*
silicone	7440-21-3	Mono constituent	n	4	
styrene	100-42-5	Mono constituent	n	4	Potential: R

TPA	100-21-0	Mono constituent	n	4	
TDHA	6596-35-6		y	3	
THPE	27955-94-8	Mono constituent	n	3	
cellulose acetate			y		
triacetate			y		
PEI	62929-02-6		y	1	
TSC-M copolymer (based on styrene and butadiene monomer)		polymer	y		
copolyester		polymer	y		
Bioplastic based on marine brown algae / ALGOBLEND			y		
Styrene-Methyl Methacrylate Copolymer (SMMA)	106911-77-7	Polymer	y		
Methyl Methacrylate Butadiene Styrene (MBS)			Y		
Colpolymer of styrene-butadiene		polymer	y		
polyethylene		polymer	y		
Styrene Acrylonitrile (SAN)	9003-54-7		y		
AKESTRA (Co-polyester)		polymer	y		
Methyl methacrylate/Acrylonitrile/Butadiene/Styrene (MABS)			y		
Styrene-Butadiene Copolymer (SBS)		polymer	y		
PLimC (Bio-based polycarbonate made with limonene and CO2)		polymer	y		
Bio-based polycarbonate		polymer	y		
Isosorbide and 1,4-cyclohexanedimethanol			y		

Fitness for Purpose according to "*Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials*":
1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA

Asteriks (*) = property relates to cases containing impurities and/or additives
CoRAP = Community Rolling Action Plan
BosC = Bisphenol of similar Concern

E.2.3.2. Epoxy resins (P2)

E.2.3.2.1. Research report statements

A total of 80 potential alternative substances were identified for epoxy resins. Of these, 42 substances are in commercial use. In addition, two potential technologies (Tetrapack and CANVERA Polyolen Dispersion Technology) that could contribute to BPA substitution and reduction were identified. Alternative substances that were found are used for (can) coatings (e.g., melamine; isosorbid; TMBPF). In addition, substances were identified that can be used for bottles and food packaging (e.g., PET; PE), for electronic and electrical applications (2,2'-bis-(4-hydroxycyclohexyl)propane; bismaleimides resins), for paints (PPC, D4; D5) or other uses e.g., optical devices or sealing films.

For the use of coatings in particular, other bisphenols such as BFDGE, BHPF, BPE, BPP, BPTMC or TMBPF can replace the BPA in the epoxy resin. However, there are still uncertainties regarding the potential endocrine disrupting effects. Molecules that have a similar cross-linking functionality as BPA include isosorbide; 1,4-cyclohexanedimethanol (CHDM) or 2,2,4,4-tetramethyl-1,3-cyclobutanediol (CBDO), which are commercially used already as a substitute for epoxy resins. For use in coatings, polyester resins, polyurethane or sustainable molecules such as oleoresins, cardanol (from cashew nutshell liquid) or isosorbide are alternatives worth mentioning.

Isosorbid appears to be a very promising substance. Substances that are currently already being produced in high tonnages and used commercially (isosorbid, hydrogenated BPA, melamine, D4; D5) show significant price advantages compared to the other substances identified.

The costs of the cheapest potential substitutes are partly comparable to the costs of BPA or slightly higher.

E.2.3.2.2. Stakeholder Statements (1st Call for Evidence)

Besides isosorbid, other material substitutes for epoxy resins mentioned are polyester and polyester resins, (CBDO) 2.2.4.4- tetramethyl-1.3-cyclobutadione, alkyds, polyurethanes, zinc silicates, vinyl esters, various other bisphenols, and (can) coating resins with the monomers CHDM - 1,4-Cyclohexanedimethanol, TMCD 2,2,4,4-tetramethyl-1,3-cyclobutanediol, NPG Glycol - 2,2-Dimethyl-1,3-Propanediol, TMPD Glycol - 2,2,4-Trimethyl-1,3-Pentanediol and HPHP Glycol - Hydroxypivalyl Hydroxypivalate.

Substitutions to epoxy resins can differ in properties such as in viscosity, heat resistance or adhesiveness. In EP resin printed circuit boards, the electrical properties such as dielectric strength and impedances are matched to this epoxy material. EP potting and encapsulation compounds have very low coefficients of thermal expansion, which ensure that no components on the circuit board are damaged under thermal cycling. Furthermore, circular connectors are often potted to achieve the necessary push-through resistance.

Polyester resins could be an excellent alternative in most coating applications (polyester acrylic resins are already used together with epoxy resins to form 1 K systems of high chemical resistance for coil coating, metal packing and primer, corrosion protection of bulk material and technical surfaces) but are not drop-in replacements. BPA-NI perform better over BPA resins when applied over metal without Cr(VI) pre-treatment. There are also no acceptable alternatives for anticorrosive coatings.

In low corrosivity environments, alkyd primers and direct-to-metal polyurethanes are to some extent alternatives. However, globally the use of alkyd primers is decreasing due to their high solvent content which results in high VOC emissions, while polyurethane coatings contain isocyanates. The costs for alkyds range from lower to higher compared to epoxy primers, and require more coats to be applied due to lower dry film thickness and 10-33% higher total thickness required. Polyurethane typically has a 30-50% higher cost.

Zinc silicate primers are alternatives to zinc epoxies in high corrosivity atmospheric environments but their cost is much higher, curing depends on humidity and overcoating is complicated due to their porosity. Also epoxy coatings are today widely used as a safe second coat when the primer is zinc silicate. For certain speciality chemicals zinc silicates are likewise used as alternatives, as well as vinyl esters. Zinc silicates are however not resistant to alkaline and acidic chemicals and vinyl esters are in general not liked due to their high content of styrene monomer which has an unpleasant smell and is a health concern. Vinyl esters also require special application equipment. Zinc silicates have an approximately 50% higher than zinc epoxies and are 5-10 times more expensive than zinc free epoxy primers. Zinc silicate solutions are 2-4 times more expensive than epoxy solutions, while vinyl esters are 3-5 times more expensive than epoxy solutions.

Hazards and risks of monomers and reactants of potential alternative polymers to BPA based Epoxy Resins, such as other non-BPA based glycidyl ethers, polyurethanes, polyesters, vinyl esters, phenolic resins or acrylates, have been assessed and described in the respective REACH Chemical Safety Reports. All of them exhibit their own inherent hazards and risks, some similar to BPA some different.

No alternative has the equivalent product performance and versatility with comparable cost and less hazardous to the environment and human health.

E.2.3.2.3. Stakeholder Statements (2nd Call for Evidence)

Coatings based on copolyester can be used safely and in compliance with EU regulations in food contact applications. Typically unit cost is higher and more usage is required to achieve the same technical performance. Everything is known on the toxicology of copolyesters to ensure a thorough risk assessement evaluation regulatory requirements and customers needs.

Tetramethyl bisphenol F (TMBPF) is a monomer used in the production of food contact metal can coating. The chemical properties and behavior of TMBPF are distinct from many bisphenols, including BPA and BPF. According to one stakeholder (CfE #1410; CfE2 #139), TMBPF has been found to exhibit physical properties critical for high-performance epoxy-based can coatings without the endocrine and estrogen activity or migration concerns associated with other bisphenols. It should be pointed out however that there are studies (a fish short term reproduction assay after OECD 229 and an amphibian metamorphosis assay after OECD 231)[204] showing effects that may point to an endocrine actvity after all (significant decrease of fecundity in female fish and reduced fertilization success, as well as significant effects on the thyroid gland in amphibians). TMBPF, like other bisphenol-based alternatives mentioned in this section, might therefore in principle be a candidate for inclusion in this restriction via the extension mechanism (based on an EU-wide consensus on the environmental ED properties), potentially requiring TMBPF-containing mixtures and articles to comply with the restriction conditions.

---

[204] Accessible online at https://sherwin-williams.app.box.com/s/yf7t38ohj95zfonbtojddwgblbduw4dw - with the two studies in question being *TMBPF Short-Term Repro (Fisch - FSTRA).pdf* and *TMBPF Amphibian Metamorphosis (Frog – AMA).pdf*

Isosorbide glycidylether has very bad resistance to water, and can fully decompose if cured with some common hardeners.

In the semiconductor industry and its supply chain, potential alternatives that provide the specific required functionalities are still based upon BosC, and thus will not be further discussed here.

Some polyesters, polyurethanes or thermoplastic based coatings could be a substitute for limited applications. This will not cover the range of all the different performances that are required (e.g. chemical, heat, corrosion, hardness). Many of the alternatives would not be equivalent in terms of performance, durability, or environmental footprint.

Polyurethane and polyurea cured with isocyanates will pose similar or more severe health hazards compared to BPA.

Other hydrocarbon based technologies do not meet the standards such as BS476, UL1709 and NORSOK due to the harsh fire and durability requirements.

E.2.3.2.4. Stakeholder Statements (Others)

A case study[205] provided by one stakeholder evaluates various epoxy resin alternatives regarding their suitability for lining food containers. It comes to the conclusion that MMA, ethylene-acrylic acid copolymer and isosorbide based resins are worth further testing, while excluding acylic, a mixture of acrylic & styrene and acrylic resins from acrylates (including phenolic resins) from further testing due to high concerns regarding carcinogenity and sensitisation. Interestingly, a number of the substances cited in this case study already cropped up in the CfEs as alternatives for other uses, most notably PC.

E.2.3.2.5. Conclusion

There are a number of substances that have already been established or are about to get established as substitute for epoxy resins, such as TMBPF, isororbite or copolyester.

Also often mentioned are various other bisphenols, of which however many show properties of similar concern.

Table 109: Potential alternatives for epoxy resins

Alternative	**CAS-No.**	**Type of substance**	**Mentioned by Stakeholder**	**Fitness for Purpose according to Research Report**	**Properties of Concern (according to ECHA Substance Infocards)**
isosorbid/POLYSORB	652-67-5	Mono constituent	y	4	
Isosorbide glycidylether			y		
PRIPOL F® (Polysester)		polymer	y	4	

---

[205] LIFE / FIT FOR REACH substitution of bisphenol A in epoxy resins for lining food containers https://www.fitreach.eu/sites/default/files/editor/Images/publiacations/Case%20story_%20Bisphenol%20A_ENG_final_updated15_02_2017.pdf

PE /EcoCare™ (Polyester)		Polymer	y	4	
POLYKOAT® (polyester)		polymer	y	4	
DYNAPOL® L (polyester)		polymer	y		
DUROFTAL PE 6160/50MPAC resin (saturated polyester)		polymer	y		
DUROFTAL VPE 6104/60MPAC resin (hydroxylated polyester)		polymer	y		
unsaturated polyester		Polymer	y		
Polyester extracted from skin of tomatoes		polymer	y		
copolyester		Polymer	y		
Copolyester (PTA+CHDM+ethylene glycol + isosorbide)		polymer	Y		
alkyds			y		
Polyurethane / Souplethane WP		Polymer	y	4	
polyurea		Polymer	y		
zinc silicates			y		
vinyl esters			y		
unsaturated vinyl esters			y		
isocyanates			y		
other bisphenols					
n-Alkyl Diphenolate Diglycidyl Ether				4	
BFDGE	2095-03-6			4	Broad agreement: Ss
BHPF; bisphenol FL	3236-71-3			4	
BPE; bisphenol E	2081-08-5			4	
BPP; bisphenol P	2167-51-3			4	
BPTMC; bisphenol TMC	129188			4	

	- 99-4				
hydrogenated BPA (cycloaliphatic type)	80-04-6	Mono constituent	Y	4	
TMBPF; tetramethyl bisphenol F	5384-21-4	Mono constituent	Y	4	Potential: ED
ferulic and sinapic acids				2	
BGF				2	
BTFMEP				2	
DPA	126-00-1			2	
BPM; bisphenol M	13595-25-0	Mono constituent		1	Potential: R Recognised: Ss Potential: PBT Potential: ED In CoRAP
propoxylated bisphenol A / Bicom 03PO	37353-75-6	UVCB		1	Potential: ED In CoRAP
Epoxy resin based on alkylated BPA		polymer	Y		
Tetrashield MP2100			Y		
CHDM - 1,4-Cyclohexanedimethanol	105-08-8	Multi constituent	Y		
TMCD 2,2,4,4-tetramethyl-1,3-cyclobutanediol	3010-96-6	Multi constituent	Y		
NPG Glycol - 2,2-Dimethyl-1,3-Propanediol	126-30-7	Mono costituent	Y		
TMPD Glycol - 2,2,4-Trimethyl-1,3-Pentanediol	144-19-4	Mono constituent	Y		
HPHP Glycol - Hydroxypivalyl Hydroxypivalate	1115-20-4	Mono constituent	Y		
(CBDO) 2.2.4.4-tetramethyl-1.3-	3010-		Y	4	

cyclobutadiol	96-7				
resorcinol diglycidyl ether	101-90-6	Mono constituent	N	4	Recognised: C Potential: M Recognised: Ss
neopentyl glycol diglycidyl ether	17557-23-2		N	4	Recognised: Ss
1.4-Cyclohexanedimethanol diglycidyl ether	14228-73-0	Multi constituent	N	4	Broad agreement: Ss
ORTHOPOXY®			N	4	
LigaTurf; Poligras; Ligagrass			N	4	
acrylic			Y	4	
BMI			N	4	
cardanol (from cashew nutshell liquid)	37330-39-5		N	4	
casein based plastics			N	4	
ceramic	66402-68-4	Multi constituent, UVCB	Y	4	
D4	556-67-2	Mono constituent	N	4	Potential: R Recognised: PBT Potential: POP SVHC Some uses restricted under Annex XVII
D5	541-02-6	Mono constituent			Recognised: PBT SVHC Some uses restricted under Annex XVII

melamine	108-78-1	Mono constituent	N	4	Potential: PBT
oleoresins	8023-77-6	polymer	Y	4	
PET	25038-59-9	Polymer	N	4	
polyacrylates	9003-01-4	Polymer	y	4	
Polypropylene carbonate (PPC)		polymer	y	4	
PROVALIN (Thermoplastic elastomer)			y	4	
resin ChemSuD		Polymer	N	4	
Resin SPR		polymer	y	4	
Tetrapack / Tetra Recart® (cardboard packaging)		Technological substitution	y	4	
DOYPACK® PET/Aluminium/Polyethylene or polypropylene		Technological substitution	y		
TMCBDI			N	4	
trans-CHDM	3226-48-4		N	4	
UV-L Eco Resin (Thermosetting resin obtained from linseed oil)		polymer	y	4	
Verdanol (based on derivates of epoxy resins and vegetal polyols)		polymer	y	4	
vinyle			N	4	
Divinylbenzen	1321-74-0	UVCB	N	3	
CANVERA Polyolen Dispersion Technology		Technological substitution	N	3	
2-phenyl-1,3-propanediol	1570-95-2		N	3	
Aromatic epoxy resins based on flavonoid extracts, tannins or phenolic acids		polymer	Y		
Copolymer based on styrene and butadiene monomer		polymer	Y		

Polymers based on Tetradecahydroanthracene (TDHA)	6596-35-6	polymer	Y		
Resins produced from natural oils, fatty acids and gelatin		polymer	Y		
Coating based on methacrylic acid (MMA)	80-62-6	Mono constituent	Y		Recognised : Ss In CoRAP
Mixture of acrylic acids & styrene			Y		
Ethylene-acrylic acid copolymer		polymer	Y		
Co-polymers of acrylates & styrene		polymer	Y		
Acrylic resins from acrylates, including phenolic resins		polymer	Y		
Diphenolic acid	126-00-1		Y		
Lauryl gallate	1166-52-5		Y		Recognised : Ss
BIOLIGNINE (biopolymer)		polymer	y		
Composite polymer based on polypropylene carbonate polyol (PPC) combined to modified amidon		polymer	y		
Technology based on derivative of cyclohexanediol		Technological substitution			
Epoxy resins produced from biobased tannins		polymer			
Casein-based bioplastic from milk protein			y		
Polymerized rosin resin	8050-09-7	UVCB	y		
RILSAN (polyamide)		polymer	y		
Soy-PK Resin (Biosourced resin obtained from acetoacetylation of soybean oil)		polymer	y		

Fitness for Purpose according to *"Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials":*

1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA
SVHC = Substance of Very High Concern
CoRAP = Community Rolling Action Plan
BosC = Bisphenol of similar Concern

E.2.3.3. Polysulfones (P3)

E.2.3.1. Research report statements

Polyethersulfone, with its monomer 1,4-bis(4-Chlorophenyl)sulfone, is a potential substitute for HC hard-and-clear plastics-products. It is commercially used e.g., for baby bottles. However, even if they are BPA-free, they also consistently release chemicals having estrogenic potential.

Costs can be assumed to be between 12-75 USD (25/500 g).

E.2.3.3.2. Stakeholder Statements (1st Call for Evidence)

Polyethersulfone (PESU) is used as raw materials to produce the PEPA hollow fiber membrane for dialysate purification.

Other possible alternatives are various cellulose-based products, polyphenylsulfone (PPSU), polyoxymethylene (POM), impact modified polyphenylene sulphide (PPS) and polyethylene terephthalate (PET). Like PESU, PPSU is likewise used for dialysis-related medical applications.

There are alternatives for power cables and plug cables. Other alternatives must be evaluated case-by-cases.

E.2.3.3.3. Stakeholder Statements (2nd Call for Evidence)

Alternatives to polysulfone polymer are available for some uses. However, the performance is not the same which causes risks for the applications.

PESU (produced out of Bisphenol S) is a possible alternative to PSU. However, a relevant difference is the glass transition temperature (PSU = 187°C vs. PESU 223°C) which is important in applications with a long-term exposure to high temperatures. For medical device uses of PESU, one stakeholder estimates that a development process, including intensive medical approvals, would at least take 7-8 years based on indicative customer input.

E.2.3.3.4. Conclusion

PESU is the substitute most often refered to. However, its derivate PEPA is recognised as being skin sensitising. Furthermore, PESU is produced out of Bisphenol S, which is a BosC. The alternative 1,4-bis(chlorophenyl)sulfon (BCPS) has been evaluated by the AT CA and according to their assessment fulfils the criteria for very persistent and very bioaccumulative (vPvB) according to REACH Annex XIII.[206]

---

[206] Substance evaluation conclusion and report for BCPS: https://echa.europa.eu/documents/10162/c63c93be-c901-864f-1d5a-9e21a35c81f8

Table 110: Potential alternatives for polysulfones

Alternative	CAS-No.	Type of substance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)
PEPA	68131-73-7	UVCB	y		Recognised: Ss
PESU (polyethersulfone)		Polymer	y		Produced out of BPS
cellulose acetate	9004-35-7		y		
cellulose triacetate	9012-09-3		y		
polyphenylsulfone (PPSU)		Polymer	y		
polyoxymethylene (POM)	30525-89-4	Polymer	y		Broad agreement: Ss Minority position: Sr
polyphenylene sulphide (PPS)		Polymer	y		
polyethylene terephthalate (PET)	25038-59-9	polymer	y		
1,4-bis(chlorophenyl)sulfon	80-07-9	Mono constituent	n	4	Potential: PBT

Fitness for Purpose according to "*Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials*":
1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA

E.2.3.4. Unsaturated polyesters (P6)

E.2.3.4.1. Research report statements

A total of eight different candidates were found as alternatives for BPA in unsaturated polyesters, six of them are in the research stage and two of them are candidates to be used as alternatives in BPA free polyesters. Polyesters containing isosorbide or BPTMC instead of BPA can, for example, be used as components for optical and general applications. Especially isosorbid based polymers such as Polysorb (Roquette) are biobased and thus environmentally friendly and can be applied in different polyester applications. Costs can be assumed by 27 $/25g.

Similar to PEIs, BPTMC can be used as base monomer for polyesters used in films. However, it has similar endocrine disruption effects to BPA what might be problematic since it might be subject to future regulations.

E.2.3.4.2. Stakeholder Statements (1st Call for Evidence)

Alternative matrix resins such as unsaturated polyesters, phenolics, epoxies, cyanate esters, and others cannot uphold the stringent standards of the aerospace industry.

E.2.3.4.3. Stakeholder Statements (2nd Call for Evidence)

The second CfE received no stakeholder claims regarding this application.

E.2.3.4.4. Conclusion

BPTMC has similar endocrine disruption effects to BPA, which might be problematic since it might be subject to future regulations.

Table 111: Potential alternatives for unsaturated polyesters

Alternative	CAS-No.	Type of subtance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)
isosorbid	652-67-5	Mono constituent	y	4	
BPTMC	129188-99-4		y	4	
unsaturated polyesters		polymer	y		
epoxies			y		
cyanate esters			y		
propoxylated bisphenol A	37353-75-7		n	4	

Fitness for Purpose according to "*Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials*":
1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA

E.2.3.5. Phenolic resins (P8)

E.2.3.5.1. Research report statements

There are a wide variety of other compounds suitable as alternatives for BPA monomers in phenolic resin synthesis. However, an exchange of the phenol compound almost always goes hand in hand with a not negligible change in the resulting material properties which may lead to more costs to adapt new formulations to existing applications.

E.2.3.5.2. Stakeholder Statements (1st Call for Evidence)

One application of BPA based phenolic resins is the production of special prepregs for ballistic protection. According to stakeholder CfE #1374 there is no technical alternative for the purpose of ballistic protection.

Hazards and risks of monomers and reactants of potential alternative polymers to BPA based Epoxy Resins, amongst others phenolic resins, have been assessed and described in the respective REACH Chemical Safety Reports. All of them exhibit their own inherent hazards and risks, some similar to BPA some different.

E.2.3.5.3. Stakeholder Statements (2nd Call for Evidence)

The second CfE received no stakeholder claims regarding this application.

E.2.3.5.4. Conclusion

The stakeholders acknowledged the existence of alternatives, but didn't provide further details, aside from the notion that an exchange of the phenol compound also leads to a change of the material properties.

It should also be pointed out that several of the alternatives mentioned in the research report are noted as having properties of concern.

Table 112: Potential alternatives for phenolic resins

Alternative	CAS-No.	Type of substance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)
2,3-Xylenol	526-75-0	Mono constituent	n	4	
2,4-Xylenol	105-67-9	Mono constituent	n	4	Broad agreement: Ss
2,5-Xylenol	95-87-4	Mono constituent	n	4	Broad agreement: Ss
2,6-Xylenol	576-26-1	Mono constituent	n	4	
3,4-Xylenol	95-65-8	Mono constituent	n	4	
3,5-Xylenol	108-68-9	Mono constituent	n	4	
m-Cresol	108-39-4	Mono constituent	n	4	
Novolake		Phenol resins	n	4	

o-Cresol	95-48-7	Mono constituent	n	4	
p-Cresol	106-44-5	Mono constituent	n	4	In CoRAP
Phenol	108-95-2	Mono constituent	n	4	Potential: M In CoRAP
Resorcinol	108-46-3	Mono constituent	n	4	Broad agreement: Ss Potential: ED In CoRAP

Fitness for Purpose according to "*Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials":*
1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA
CoRAP = Community Rolling Action Plan

E.2.3.6. Polyurethanes (P11)

E.2.3.6.1. Research report statements

Most polyurethanes are BPA-free. Therefore, a large number of alternatives, specific for certain applications, could be shown. Also, in case of further alternatives, the targeted applications need to be specifically addressed. Depending on the formulation of the polymer, a wide range of applications are conceivable, such as flexible foams (mattresses, upholstered furniture, carpet underlays and car parts such as cushions, backs and armrests), rigid foams (insulating materials for commercial and residential buildings, insulation for tanks, pipes, water heaters, refrigerators and freezers), solid elastomers (tires for forklifts, skateboards, roller coasters and escalators), extrusion and injection moulded parts, coatings, sealants, adhesives and for the production of synthetic fibres (spandex).

Polyurea-urethane was identified as a potential BPA substitute for polyurethanes. Furthermore, polyols can react to form polyurethanes.

E.2.3.6.2. Stakeholder Statements (1st Call for Evidence)

Polyurethane contains isocyanates which is another health concern.

E.2.3.6.3. Stakeholder Statements (2nd Call for Evidence)

Polyurethane is cured with isocyanates and poses the same or more severe health hazard in comparison to BPA.

E.2.3.6.4. Conclusion

In both CfEs, polyurethanes are mentioned as an alternative to BPA uses like epoxy coatings, rather than as a substance an alternative has to be found for. (It has to be considered that most polyurethanes are BPA-free, and alternatives have to be found for those that are not.) Both CfEs also point out the health concerns regarding polyurethanes due to isocyanates.

Table 113: Potential alternatives for polyurethanes

Alternative	CAS-No.	Type of substance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)
BPA-free polyurethanes		polymer	y		
polyurea-urethane		polymer		4	
isocyanates			y		Resp. Sens.

Fitness for Purpose according to *"Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials":*
1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA

E.2.3.7. Vinyl ester resins (P12)

E.2.3.7.1. Research report statements

A total of 10 potential alternative substances were identified for vinyl ester resins (VERs). Of these, four substances are in commercial use. There are several bio-based substitutes for the production of VERs that are considered to become replacements for BPA, though some of them show properties of concern. Cardanol-based vinyl esters are used extensively in the marine sector for coatings and corrosion. Epoxidised soybean oil has been commercialised and is expected to stay pretty cheap at 29.5 to 32.5 cents a pound. Overall, cellulosic polymers are showing the most promising results, with isosorbide (27$/25g) showing the greatest potential for VERs.

E.2.3.7.2. Stakeholder Statements (1st Call for Evidence)

Vinyl ester resins are critically important for many chemicals and gasoline containment vessels, chemical processing operations, seawater desalination operations, marine applications and renewable energy applications (e.g., blade used in wind turbines). In many cases no feasible alternatives to Vinyl esters are known that can be used in these applications that do not also employ a bisphenol at some stage of their production.

E.2.3.7.3. Stakeholder Statements (2nd Call for Evidence)

Vinyl ester resins in many cases are the only material system that can resist harsh chemical environments. In other areas they are highly cost-effective systems compared to expensive stainless steel and alloys.

E.2.3.7.4. Conclusion

Though the existence of BPA-free alternatives to vinyl esther resins gets aknowledged, it is also claimed that there is no alterative that can resist the harsh conditions in their applications. Metal alloys are mentioned as far less cost-effective in comparison.

Table 114: Potential alternatives for vinyl ester resins

Alternative	CAS-No.	Type of substance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)
bio-based substitutes			y		
- cardanol (from cashew nutshell liquid)	37330-39-5			4	
- ESO				4	
- Sucrose esters of fatty acids				4	
- lignin	9005-53-2			3	
- Dipentene	138-86-3			2	Recognised: Ss
- FA	98-00-0	Mono constituent		2	Potential: C
- FDCA	3238-40-2	Mono constituent		2	
- Phloroglucinol	108-73-6	Mono constituent		2	
- rosin	8050-09-7	UVCB		2	Recognised: Ss
Isosorbid	652-67-5	Mono constituent	n	4	
stainless steel	12597-68-1		y		

Fitness for Purpose according to *"Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials":*
1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost
2 = Potential alternative substance for BPA in current research not likely to be available midterm
3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market
4 = Actual and known commercial use of the substance as alternative to BPA

E.2.3.8. Polyacrylates (P13)

E.2.3.8.1. Research report statements

Three sustainable potential substitutes were identified for polyacrylates. Tannins, epoxidised soybean oil and vanillyl alcohol cardanol (methacrylated) are currently still being researched for the use of polyacrylates. Although e.g. epoxidised soybean oil has been and is expected to stay pretty cheap at 29.5 to 32.5 cents a pound and therefore the availability of sustainable raw materials offers great potential for commercial use, it cannot be assumed that it will be used as a substitute in the medium term. In addition, for use in inks and overprint varnishes, polyester / polyether acrylates are described as potential replacements for epoxy acrylates. However, they are more expensive than the BPA analogue.

E.2.3.8.2. Stakeholder Statements (1st Call for Evidence)

The first CfE received no stakeholder claims regarding any alternatives for polyacrylates. To the contrary, polyacrylates receive a mention as alterative to epoxy resins.

E.2.3.8.3. Stakeholder Statements (2nd Call for Evidence)

The second CfE received no stakeholder claims regarding alternatives for polyacrylates. To the contrary, polyacrylates receive a mention as alterative to BPA-based tanning agents.

E.2.3.8.4. Conclusion

None of the stakeholders delivered any statements regarding the alternatives mentioned by the research report. The notion of their use is therefore neither supported nor contested by the stakeholders.

Table 115: Potential alternatives for polyacrylates

Alternative	**CAS-No.**	**Type of substance**	**Mentioned by Stakeholder**	**Fitness for Purpose according to Research Report**	**Properties of Concern (according to ECHA Substance Infocards)**
Tannins	1401-55-4	Mono constituent substance		2	
epoxidised soybean oil				2	
vanillyl alcohol cardanol (methacrylated)				2	
polyester / polyether acrylates		polymer		4	

Fitness for Purpose according to *"Data collection to support the restriction of substances of very high concern under REACH for Bisphenol A - BPA levels in materials":*

2 = Potential alternative substance for BPA/TBBPA in current research not likely to be available midterm

4 = Actual and known commercial use of the substance as alternative to BPA1 = Unknown or very unlikely use of substance as alternative to BPA also due to potential health risks or cost

2 = Potential alternative substance for BPA in current research not likely to be available midterm

3 = Potential alternative to BPA not yet placed, newly placed or about to be placed on the market

4 = Actual and known commercial use of the substance as alternative to BPA

E.2.4. Uses of other bisphenols with similar concern

E.2.4.1. BPS for Syntans

E.2.4.1.1. Research report statements

There have been no statements in the research report regarding this application.

E.2.4.1.2. Stakeholder Statements (1st Call for Evidence)

There have been no stakeholder claims in the 1st Call for Evidence regarding this application.

E.2.4.1.3 Stakeholder Statements (2nd Call for Evidence)

Synthetic polymers based on bisphenol structures are called syntans. Starting with antimony potassium tartrate, the industry switched to naphthalene based syntans, later to phenole based polymers and after that to BPS based syntans.

Synthetic tanning agents based on bisphenol structures are especially used in re-tanning processes to reach the final character of the leather articles. Almost all leather articles, chromium- or chrom-free tanned or tanned with vegetable tanning agents or glutaraldehyde are re-tanned with syntans. BPS respectively Phenol are used for polycondensation with formaldehyde to result in syntan, which has been developed to mimic the structure of plant based tannins while improving their performance. Polycondensates without aromatic hydroxy functions do not demonstrate the same performance. Such products are available on the market as auxiliaries.

Bisphenol F (BPF) can be an impurity in synthetic tannin. Likewise, bisphenol S (BPS) is a monomer that is used to manufacture synthetic tannins, which can lead to residues in the final product.

A number of leathers have already been "free of BPS". All those leathers relate to "niche" or "low end" articles in which already today no syntans are used because of cost reasons. Recipees without syntans are not acceptable / present in mid- to high-end articles because of a combination of cost/performance ratio.

Synthetic tanning agents are an alternative to vegetable tanning agents (phenolics of natural origin) as they have very good lightfastness properties and enable leather dyeing in all desired colors which isn’t possible with vegetable tanning agents. Furthermore, they are providing leather physical properties such as fullness and dye distribution. Leathers threated with vegetable tanning agents can only be used as very hard bag leathers or for shoe soles. Another stakeholder claims that gloves could still work without syntans, but not shoes.

Plant tannins are poorly investigated and not registered under REACH. Available studies however indicate a tox- and ecotox-profile as would be expected from a poly-phenolic with the respective molecular weight

Leather tanned with vegetable tanning agents have low biodegreadability.

Furthermore, in order to produce enough vegetable tanning agents for all leather, vast areas of monocultures of the respective trees would be necessary. Also, the time to grow the crops in sufficient quantities needs to be taken into account.

Chrome(III) tanning salts have a low tox- and eco-tox profile. However, unfortunately, chrome can be oxidized if tanners and/or article manufacturers do not follow best practices and this remains a permanent challenge.

Glutaraldehyde and other reactive tannig agents do show a substantially tox profile, mainly focussed on workplace safety issues, but sometimes consumer and environment as well.

Chrome tanning salts and/or reactive tannins like glutaraldehyde do have a strong tanning ability, but miss other properties which are essential to manufacture a leather, and as such are commonly combined with syntans to compensate the deficiencies.

Naphtalene produce certain effects that BPS achieves but not all oft hem or not with the same properties or with the same efficiency.

Other possible alternatives include polyacrylates and melamine urea substances.

While these alternatives may impart some of the physical effects needed during the re-tanning process, most of them cannot match the physical qualities imparted by sulfone- and phenol-based synthetic tanning agents.

For polyamide dye-fixing agents (nylon and nylon blends) there are non-phenolic alternatives.

An alternative to leather altogether would be plastics, which carry its own environmental issues, such as being non-biodegradable, creating microplastic, being based on fossil fuels, containing high amounts of other BosC, or made of other harmful substances.

E.2.4.1.4 Conclusion

Syntans are primarily used in re-tannings (thus after the prior usage of other tanning agents), in order to gain additional properties that improve the quality of the leather.

The most often mentioned alternative are vegetable tanning agents. However, aside from these not being on par with the syntans regarding the delivery of the desired leather properties, many stakeholders also point out that vegetable tanning agents come with their own plethora of environmental and other problematic issues.

Other alternative tanning agents mentioned (chrome, glutaraldehyde, naphthalene, polyacrylates, melamine urea) are likewise considered disadvantageous.

There are non-phenolic alternatives for nylon and nylon blends.

Table 116: Potential alternatives for syntans

Alternative	**CAS-No.**	**Type of substance**	**Mentioned by Stakeholder**	**Fitness for Purpose according to Research Report**	**Properties of Concern (according to ECHA Substance Infocards)**
antimony potassium tartrate	11071-15-1	Mono constituent	y		Broad agreement: Ss

naphthalene based syntans	91-20-3	mono constituent (naphthalene)	y		Potential: C
phenole based polymers		Polymers	y		
vegetable tanning agents (phenolics of natural origin)			y		
Chrome(III) tanning salts			y		
Glutaraldehyde			y		
polyacrylates		polymers	Y		
melamine urea	25036-13-9		Y		
plastics			y		

E.2.4.2. BPAF for Fluoroelastomers

E.2.4.2.1. Research report statements

There have been no statements in the research report regarding this application.

E.2.4.2.2. Stakeholder Statements (1st Call for Evidence)

BPAF (fluorinated organic compound related to BPA) one of the most commonly used cross linkers fluoroelastomer rubber (FKM). Fluoro rubber parts are used in many applications for equipment, machinery, industry, aviation, mining, processing and transportation.

Alternative systems use peroxide or diamine instead of BPAF. Alternatives are available in sufficient quantities, however there are limitations regarding high temperature stability, ease of processing and increased scrap rate, with hazards like skin and eye irritation, acute chronical toxicity for water organism. Furthermore, FKMs cannot be substituted by lower value elastomers.

E.2.4.2.3. Stakeholder Statements (2nd Call for Evidence)

There are two alternative crosslinking mechanisms available: Diamines and peroxides. However, both are unsuitable in dynamic application, high wear and very high temperatures.

Crosslinking fluoroelastomers with diamines does not produce seals or hoses that meet today’s performance standards and was replaced by the BPAF cure system. Fluoroelastomers with diamines should not be considered as alternative due to property and processing deficiencies.

Peroxid-cured Fluoroelastomers showed improved resistance to steam but do not exhibit the high thermal stability of BPAF cured. Moreover, peroxid-cured and BPAF-cured Fluorelastomers are frequently used in different applications. BPAF-cured fluoroelastomers are commonly less expensive Peroxides also create new risks of fire and explosion if not handled properly.

In applications where peroxide (PO)-cured and BPAF-cured Fluoroelastomers are both technically feasible, BPAF-cured Fluoroelastomers are commonly less expensive.

FFKM is different type of perfluorinated elastomer and cannot replace all uses of FKM cured with BPAF. BPAF-cured FKM has better low-temperature property and metals bonding properties compared to FFKM. FFKM is also 10-100x more expensive than FKM, and supply of FFKM is limited due to production capacity of suppliers.

Non-PFAS elastomer has poorer heat resistance and chemical resistance compared to PFAS elastomers such as BPAF-cured FKM or FFKM.

E.2.4.2.4. Conclusion

Curing systems using peroxide or diamines are the commonly cited alternatives to BPAF. However, stakeholders view both as inferior in comparison to the BPAF system.

Other types of elastomers which are considered by one stakeholder as possible but subpar alternatives, are FFKM and non-PFAS eleastomers.

Table 117: Potential alternatives for fluoroelastomers

Alternative	CAS-No.	Type of substance	Mentioned by Stakeholder	Fitness for Purpose according to Research Report	Properties of Concern (according to ECHA Substance Infocards)
peroxides			Y		
diamines	302-01-2	Mono constituent	y		Recognised: C Recognised: Ss SVHC
FFKM			y		

SVHC = Substance of Very High Concern

E.3. Restriction scenario(s)

E.3.1. General

Under the proposed restriction option (**Error! Reference source not found.**), it is necessary to examine how the relevant uses can be recorded and how the goal of reducing the environmental concentration to a minimum, in this case to the level of detection, can be achieved.

The restriction intends to reduce all emissions as far as possible. Under this condition, it may still be possible to continue using these SVHC. Currently, an environmental concentration of 0.27 µg/L - 0.53 µg/L is recorded[207]. The aim of the restriction is to reduce the environmental concentration to a maximum of 0.01µg/L. The reduction from average 0.3µg/L to 0.01µg/L in surface water is a value of >95% (reduction potential). In this case the reference to surface waters was chosen as the effect is most obvious here due to the data available. If these substances of very high concern are to be limited to a maximum, but their use is partly indispensable from a socio-economic point of view, the release of BPA/BosC into the environment must be specifically investigated.

E.3.2. Background

In order to be able to assess the release potential of BPA and BosC, various sources were investigated, discussions held with stakeholders, own research[208] carried out and two calls for evidence launched.[209]

All sources confirm that release to the environment is possible. However, they vary significantly in the estimated magnitude of released emissions, or to what they refer to, e.g. surface of the article or article weight. Generic emission estimates as in the Registrant´s Dossier indicate a tonnage in the five-digit range (10,000-99,999 tpa). Only by applying the refinement of evidence-based data, the theoretical release is shifted into a range of 60 tpa (Ramboll Deutschland GmbH, 2022) to 79 tpa for BPA (without taking into account the uncertainties in the estimate for both estimates). Such detailed environmental assessments are not available for BosC.

As evidence-based data have shown, during the processing phase and the use phase 90% (related to portion of total in Table 118) of the emissions are caused and thus that is where the greatest potential for reduction lies. The remaining 10% relates to the manufacturing phase and the end-of-life phase.

Table 118: Estimated total emissions for BPA and data gaps per life cycle stage

(evidence-based scenario comprising publicly available data) (Source: BioMath)

Life cycle stage	Absolute[1]	Relative[2]	Portion of Total
Production	6.0	6.0 t = 0.00048% of 1,242,000 t	7.6%
Processing	44.1	44.1 t = 0.0036% of 1,242,000 t	55.5%
Use	27.3	27.3 t = 0.0022% of 1,242,000 t	34.4%
End-of-life	2.0	2.0 t = 0.00016% of 1,242,000 t	2.5%

[1]: Values are given in tons as lifetime emissions from products that had entered the market in the reference year 2020 (see **Error! Reference source not found.**). Several values may be interpreted as lower boundaries, as for some emission pathways no emission rate could be extracted from the identified sources (see **Error! Reference source not found.**, **Error! Reference source not found.**, **Error! Reference source not found.**, **Error! Reference source not found.**).
[2]: Emission as the portion of the amount of BPA that was consumed for the respective use (see **Error! Reference source not found.**, **Error! Reference source not found.**, **Error! Reference source not found.**)

---

[207] See chapter B.4
[208] See Annex H; Registration Dossier (ECHA dissemination site); Ramboll SFA (Ramboll I-III)
[209] Via ECHA: https://echa.europa.eu/de/hot-topics/bisphenol-a

The way to reduce the environmental concentration is to limit the release potentials from the whole life cycle of bisphenol A and BosC. This can be achieved through the limitation of the content of BPA/BosC in articles and mixtures and/or through the specification of maximum release (migration) levels from products. In this context, the determination of marketability through content and/or release analytics has been developed. Various investigations of toys, food contact materials and products made of polycarbonate show that it is possible to comply with such limits. Due to the lack of knowledge about the safety of imported goods, this regulatory step should also apply to imported goods that may release BPA/BosC to the environment. A wide range of products for DIY applications, e.g. epoxy resins, are also under concern. No protective measures can be prescribed in a binding manner, nor can the production or the disposal of residues be guaranteed to a safe or precautionary extent. Thus, regulation should also apply here. However, since no analysis can be carried out, it is advisable to manufacture DIY products BPA-free, unless the pre-formulations fall below 10ppm BPA.

E.3.3. Proposed Restriction Option

Against this background, a straight-forward approach to estimate the emission behaviour of BPA from materials is described here. The approach is based on the assumption that all materials have either the same threshold value for residual BPA or are “free” of BPA. Product-specific emission calculations based on residual BPA content, specific leaching rates and extrapolated emission quantities for exposure estimation could then be dispensed with. Since the main emission sources are shifting away from the processing phase to the use phase, large emission quantities from PVC production and also thermal paper production/recycling (use of BPA as an additive) are eliminated. However, in terms of environmental concentrations, there has been little change. The majority of surface waters, for example, are exposed at a level of 0.3 µg/L (for details see Annex B.4). Possible explanations may be the following:

- Even though PVC is not registered, processing/application still takes place
- TP is still in the recycling loop
- TP/paper products continue to release BP
- emissions occur from the use phase of products, possibly because the material varies in quality or equipment
- or more goods are imported than known, which could increase total emissions from products

The mitigation options for releases from the BPA manufacturing process and formulation appear to be exhausted due to the measures taken at the facilities. They are thus less within the scope of the regulatory options under REACH (but rather implementation IED), as are the emissions from the EOL step (subject to the WFD (Water Framework Directive)) of articles consisting of or containing/releasing BPA. However, the proposed regulatory measure under REACH has indirect consequences for all life cycle stages and especially in the EOL, as the release potential is also reduced there in consequence.

E.3.4. Expected use of BPA/BosC and behavioural responses to restriction

The proposed restriction is designed in such a way that the use of BPA/BosC as an additive is virtually impossible, since the list of BPA contents in Annex B.8, for example, shows that a technical function is only possible with a concentration of approx. 0.1% or more in the mixture (e.g. lubricant). The use as monomer for the production of polymers as well as the use as reactant for the production of chemicals (both intermediates) remains possible. What changes are the requirements for placing articles and mixtures on the market via the regulation of the release potential. This applies indirectly through compliance with maximum BPA/BosC concentrations in the polymer/chemical or directly through the recording of the release potential through, for example, migration testing. Not only the service life, but the entire life cycle should be examined to determine at which point a release relevance or migration relevance exists. In the case of polymers, not only polycarbonates, epoxy resins, polymer blends, co-polymers and other polymers that are not used as plastics (e.g. in or as components) should also be examined, but also polymers that are used in the production of functional mixtures (e.g. syntans).

The derivation of the impact of this most appropriate and feasible measure on the release potential of BPA/BosC is as follows:

Restricting use as Additives (e.g. in technical mixtures, PVC, TP)

Under the proposed restriction the application of BPA/BosC as additives no longer has any relevance. This is due to the fact that when the restriction and thus the maximum amount of 10ppm is applied, BPA/BosC lose the ability to exert a technical additive function. A functionality, for example as an antioxidant in lubricants, will only be achieved by a concentration of 0.1% or 1,000ppm in relation to the amount of mixture.

The production of PVC with BPA/BosC will also be phased out - this greatly reduces the main input pathway during processing triggered by additives. Since 2018, the use of BPA in PVC has not supported in the REACH registrations. However, this polymer still has great relevance in the electrical industry. In a consultation process with ZVEI (the German Electro and Digital Industry Association) it was discussed that especially soft PVC is still relevant in the electrical and electronics industry and that the substitutes for application are still at a low stage of development, acceptance or market penetration. So, at present it is still assumed that BPA-containing PVC will continue to be manufactured and processed, but also recycled in the EU.

With the restriction of the use of BosC as an additive, it is also no longer possible to use thermal paper with other bisphenols as photo-developers. This finally leads to the elimination of these ED substances (also of the more frequently used substitute BPS) from the paper recycling cycle. This substitution increases the paper recyclability. In addition, less BPA/BosC enters the wastewater treatment plant pathway and thus also the surface waters.

Regrettable substitution and alternatives

The inclusion of BosC in this restriction is intended to prevent "regrettable substitution". It would not be sufficient to restrict only BPA, as this would have promoted these undesirable substitutes in any case, as could be seen in the example of TP, not only in the EU[210] but also for example in the USA and Japan.

During the preparation of the restriction, the potentials of BP-free alternatives were also surveyed in the course of the research project in 2020 and during the stakeholder processes of the two subsequent calls for evidence in 2020 and 2021. The aim of the restriction is also to identify and promote BPA/BosC-free alternatives. Not only alternatives on the substance level (e.g. BPA-free TP), but also the use of alternative materials

---

[210] https://echa.europa.eu/de/-/bisphenol-s-has-replaced-bisphenol-a-in-thermal-paper

(different plastics or also silicate-based materials, Blue4Est in TP) or the switch to new technologies should be considered.

Consideration of future-oriented material solutions

With this restriction, a further use of e.g. polymers is foreseen, but with an improved quality. This way, the further marketing of the promising material PC (e.g. for the automotive industry) or the indispensable ER (e.g. GRP (glass fibre-reinforced plastics) for rotor blades) can continue to be guaranteed.

In a factsheet provided by Plastics Europe[211] it was shown that the contribution of PC is only 1% of total emissions (approx. 60tpa) and the contribution of ER is 6%. This study was highly informative in this process, but also shows that it is important to investigate a relationship to the other materials and processes. Moreover, it remained unclear until the end how the materials such as the investigated PC are equipped to withstand stressors. Thus, it remains unclear whether this is an ideally finished material and which quality is common for all products in the EU. For this reason, the industry's results cannot be reconstructed at this point.

Concerning information like the residuals for the polymers in service life (PC 150ppm and ER 25ppm), the extent of outdoor use for PC and ER (about 20% according to the registration dossier) and the corresponding amounts (in this case the article surface) exposed to outdoor stressors, deviating release reduction potential is estimated when assuming restriction of content (BPA+BosC):

PC 150ppm → 10ppm: reduction of 93%

ER 25ppm → 10ppm: reduction of 60%

Based on the data for ER and PC in the service life (processing and application are not addressed), the application of the residual content may mean a small change (in relation to the total environmental concentration). In any case, the obligation to analyse leads to the assurance that these materials are safe for their intended uses.However, taking into account the given uncertainties (e.g. deviating height of the outdoor use for ER and PC), a higher emission from this path must be taken into account.

Indirect Impact

On EOL

There is no direct restriction of the EOL. Inputs from the EOL occur, for example, through inputs into surface waters from landfills. Through recycling, for example, contents in materials are retained or can increase through processing. The restriction has an indirect influence here, as the reduction of BPA or BosC that can migrate ensures that the release into the environment is also reduced. according to research by Ramboll, landfilling in particular appears to contribute a significant amount. Ramboll's results also confirm the data that the greatest release potential (90%) comes from additive uses and the main release pathway is the municipal wastewater. The release is split between 85% from TP recycling processes and 5% from PVC recycling processes.

On "environment via man"

---

[211] Plastics Europe: Bisphenol A und Umwelt – Quellen, Eintragspfade und Wege zur Minimierung. August 2021.

This restriction of BPA/BosC may reduce exposure of man and the resulting environment. The magnitude of the effect cannot be described in detail here, as humans are affected by a variety of sources. A re-evaluation of human exposure to BPA is currently taking place. This assessment was initiated because the TDI has been reduced by a factor of 100,000 from 4µg/kg body weight/d (EFSA Panel on Food Contact Materials, 2015) to 0.04ng/kg body weight/d (EFSA, 2021).

Additionally, it can be assumed that the share of additive uses approaches 0. The share of additive uses accounts for 2% of the total consumption amount of BPA + estimated shares of BosC (1% of BPA).

E.4. Impact Assessment

E.4.1. PVC (additive uses A1-A4)

E.4.1.1. Use (summary)

BPA has historically been used as polymerization inhibitor for the manufacturing of PVC as well as antioxidant in PVC formulations to protect the plasticizer against thermal oxidation during the processing as well during the manufacturing and service life of the PVC article. According to stakeholder information BPA is no longer uses as polymerization inhibitor in the EEA.

Limited information is available that BPA might still be used as an antioxidant in the manufacturing of wires and cables. Stakeholders reported (see Annex **Error! Reference source not found.**) possible uses in the automotive and medical sectors. Stakeholders reported that uses of BPA in the automotive industry are declining in their quantities. Alternatives already exist, so that the use of BPA in PVC is no longer necessary and will be phased out in the near future. Alternatives are technically feasible and are already used in many cases, say the stakeholder.

European PVC manufacturers have reported to the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) that they no longer use BPA in PVC production. This would indicate that this ingredient was only used in the medical sector to a certain extent before the switch.

Information on imported articles has not been submitted in the two stakeholder consultations and could also not be obtained via other means. It is worth noting that no stakeholder submitted information on current actual uses of BPA and no stakeholder provided information that substitution for certain uses is not possible.

Due to its former wide use as an additive BPA is present in PVC waste which is recycled. Especially in PVC-P (plasticized) recyclates BPA can be present via old stabilizer formulations. One stakeholder provided detailed information on the presence of BPA in plastic/rubber cable sheathing waste generated after stripping cables for copper/metal recovery and the sorted PVC fraction: The PVC fraction from cable sheathing is mainly processed for the direct production of articles in traffic management (e.g. road cones, pedestals, cable bridges) by compression moulding. Other uses include riding tracks, stable equipment and industrial mats. No additional detailed information on recycled PVC uses is available. However, some stakeholder suggested widespread use of recycled materials in all sectors where PVC is used.

E.4.1.2. Impact Assessment

Additive uses A1-A4 for manufacturing of 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 but presented no further information to back up this claim.

Two stakeholder organization for the automotive industry stated 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. The dossier submitter could not obtain any information why BPA is or might still be in use. No technical or economic reasons were presented. However, stakeholders for both industries stressed that the use of PVC is declining and expected to be phased out within the next few years.

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. However, information is available that films made in Europe do not contain phthalates to give them their suppleness and elasticity, but adipates (especially DEHA).[212]

In the 2nd Call for Evidence the dossier submitter asked stakeholders to comment on a list of potential alternatives for the uses A1-A4 (see Annex E2). Stakeholders did not object to the list but agree that alternatives are commercially available and technically and economically feasible.

Considering the limited information, a restriction on the uses A1-A4 will be proportionate. According to the available information substitution is already mostly completed and ongoing or expected for the near future for current limited uses. No information has been submitted regarding the required transition period. The dossier submitter therefore proposes a transition period of 18 months. The stakeholder information that substitution will soon be completed is from 2021. Entry into force of the restriction is expected for end of 2023/beginning of 2024, meaning that 4-5 years will have passed from the time when stakeholders commented that substitution will happen soon until the end of the transition period. Stakeholders can submit additional information in case a longer transition period is needed.

Only limited information is available with regard to to the residual BPA content in articles that are placed on the market. Umweltbundesamt (2010) states that in soft PVC, such as cables, bisphenol A can account for 0.5% of the employed plasticizer; the actual concentration in the product is accordingly in most cases less than 0.1%. One stakeholder informed that the average concentration in 12 post-consumer cable samples were 30ppm with outliers at 58ppm and 102ppm. Concentrations in old beacon bases range up to 1000ppm. Lopez-Cervantes and Paseiro-Losada (2003) measured concentrations from 43-483ppm in PVC stretch film.

The limited information suggests that a restriction with a concentration limit of 10ppm would restrict the further use of BPM additives in PVC. A concentration limit of 150ppm would most likely be effective to ban the use of BPA-containing plastizers for PVC in the EEA. However, a potentially large share of imported articles might meet the 150ppm. A similar conclusion can be drawn regarding a concentration limit of 1,000ppm. While the use of plasticizers in the EEA might no longer be possible, the effect of a restriction with this high concentration might have no or a very limited effect on imported articles.

Recycled PVC

BPA is present as an impurity when PVC is recycled. Stakeholder information regarding the impact of a restriction on the recycling of PVC was mostly limited to basic information that recycled soft PVC (PVC-P) will not be able to comply with a 10ppm concentration limit for BPA. Historically, PVC containing high concentrations of BPA has been used in several long-lasting applications (e.g. Cables, Building materials, etc.) which enter the recycling process now.

---

[212] https://www.elipso.org/en/preconceived-ideas-on-plastic-packaging/, accessed 23 August 2022.

One stakeholder organization provided more detailed information on the impact of a restriction on the PVC recycling industry during the two calls for evidence and during personal meetings:

BPA is expected to only be found as legacy additive in recycled applications. A sharp decrease in BPA concentrations in recycled articles is expected in the next 5 to 10 years. Technical and compliance challenges are likely, because batch to batch variability should be expected.

Testing in 2018 and 2020 resulted in maximum concentrations in recycled articles from 100 ppm in cable sheathing to 1,000ppmppm in traffic management components.

The 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. The Dossier Submitter does not understand how this would reduce the number of tests because in order to determine the average concentration still every batch has to be tested.

The stakeholder estimates that within 5-10 years the concentration of BPA in recycled articles will be less than 100ppm. Considering the submitted information it is the Dossier Submitters understanding that this concentration is already met today in the majority of recycled PVC and will be much lower in 5-10 years.

The majority of mixed PVC waste and flexible PVC (e.g. flooring, cables) are not likely to be converted into pellets or flakes but directly pressed into thick-walled products such as traffic products for road traffic safety (Vinylplus 2017) (BiPRO 2002) these waste streams are considered to be recycled in an open-loop. According to the association Plastics Recyclers Europe this kind of open-loop recycling (see Annex 3.1) is not seen as generally "bad" as there is a need for material for traffic products and the use of recyclate can displace virgin material production in this sector (input PlasticsRecyclers Europe 2021). However, originally included additives are not removed during this kind of recycling either (European and Directorate-General for, 2022).

The stakeholder also submitted socioeconomic information prepared for the public consultation of the SEAC opinion for the restriction of lead in PVC. The dossier submitter notes that this information has already been critically examined by the dossier submitter for that restriction proposal (ECHA) and by the SEAC rapporteurs in their final opinion and assessed as an overstimateion of the costs in case of a restriction. Nevertheless, SEAC finally agreed that a derogation for the use of lead in recycled PVC would be proportionate, the main reason being that the increasing incineration of waste materials would result in higher lead emissions than recycling.

The dossier submitter notes that lead is mainly used in rigid PVC. BPA, on the other hand, in PVC-P. Therefore, a restriction on BPA in recycled articles would not affect the recycling of rigid PVC containing lead. Conclusions from the restriction proposal on lead in PVC cannot be applied to determine whether a corresponding derogation for this restriction proposal on bisphenols would be proportionate.

One should note that concentrations up to 1,000ppm have been found in older already installed beacon bases (Ramboll Deutschland GmbH, 2021), but the stakeholder does not expect those to be found in new articles placed on the market. In his view it is however important to understand better the extent of the variability of BPA concentration in currently recycled streams.

No additional information has been submitted in the two calls for evidence to assess the economic impact in case recycling is no longer possible. The dossier submitter therefore uses information provided in the background document from the lead in PVC restriction.

ECHA estimated that PVC waste that no longer can be recycled would be disposed of via landfill (25%), Incineration (56%) and Export (19%). The dossier submitter estimates a minimum of 111,000tpa flexible PVC waste (see Annex B9) would need to be disposed of in a similar manner in case of a concentration limit of 10ppm. Costs for landfilling and incineration given in the lead dossier are € 125 and € 150 respectively (for 2020). Costs for export are not available. That would result in the following annual costs:

Landfill: 111 000 t x 25% x €125 = €3.5 million

Incineration: 111 000 t x 56% x €150 = €9.3 million

Export: not available

Total costs: €12.8 million

Additionally, the proposed restriction with a 10ppm limit for BPA in PVC recycling is likely to increase prices of PVC articles that can no longer use the cheaper recycled PVC material. The background document for lead in PVC estimated an additional cost of €350/t if virgin material replaces the cheaper recycled PVC. If all 111 000tpa are replaced with virgin PVC the resulting additional costs amount to €38.9 million. Of course, the exact scenario is unknown. It might be possible that users would partly switch to other materials that are cheaper.

But in absence of further information a total cost estimate of €51.7 million/year is used here. Considering 2.7 t BPA avoided emissions from the service life of the recycled PVC this would result in a cost effectiveness of

€51.7 million / 2 700 kg = €19 148/kg

On the one hand this cost can be considered as an underestimation as additional emissions from landfilling are likely thereby reducing the avoided emissions. It also needs to be considered that the exported PVC would be recycled outside the EEA and result in external negative environmental effects.

On the other hand this number will be an overestimation of the costs as the available information suggests that post-consumer PVC waste with lower concentrations of BPA can be mixed with pre-consumer PVC waste and would then be able to meet a 10 ppm concentration limit. It is therefore unknown which share of PVC waste needs to be disposed of and which share can still be recycled.

Within the next few years the share of PVC waste with comparably higher BPA concentrations will be reduced considerably which means that the potential emissions will be smaller but also that the share of non-recycable PVC waste will be reduced.

In the absence of more robust information the Dossier Submitter proposes to interpret the above cost estimate of € 19 148/kg as a high estimate of the potential costs of a restriction with a 10 ppm concentration limit. Recycling of an unknwon but significant share of post-cooncumer will still be possible and increase over time. The recycling industry in general might face costs for a limited time but in general can continue as the majority of waste consists of pre-consumer waste without BPA content.

Whether this cost effectiveness of < € 19 148/kg is considered as proportionate is not a completely scientific question. It is the Dossier Submitters understanding that SEAC considers cost-effectiveness ratios of this magnitude as potentially proportionate.

In case the costs of a restriction on the use of BPA with a concentration limit of 10ppm are considered as too high, the dossier submitter proposes a concentration limit of 150ppm and a transition period of three years.

Stakeholder information confirmed that this limit value will be achievable within the next few years. It was pointed out that there might be problems achieving specific concentration limits over all recycled articles. For cable sheating/jacketing measurements suggest that a limit value of 100 ppm might be exceeded slightly in a small number of cases. The dossier submitter considers a 50% higher limit value as sufficient and assumes that this will be met by all recycled articles and compounds, especially considering the large share of pre-consumer waste.

No stakeholder submitted information regarding the number of tests that are necessary to ensure compliance with the restriction. In general, one stakeholder organization suggests that regular migration testing would be too expensive. They do not argue the same for a testing of concentration limits. Additionally, it can be argued that concentration limit testing is already needed for lead in PVC and was deemed as negligible for that restriction. The dossier submitter understands that testing for lead in PVC is less expensive (according to the lead in PVC dossier €15 - €140). SEAC deemed the statements on the negligibility of the costs as uncertain, however, and did neither confirm nor question them. No further information is available.

Regarding the limit value for recycled articles SEAC proposed a 'safety margin' in the concentration limit that would facilitate the smooth operations of the processing of post-consumer PVC waste and decrease the efforts spent by recycling companies on testing.

The dossier submitter proposes an extended transition period of three years. Stakeholders informed in 2021 that they expect the BPA content in PVC waste to decrease significantly within the next few years. This restriction proposal will most likely not enter into force before 2024. A three-year transition period until mid to end 2027 would ensure that recyclers comply with the concentration limit of 150 ppm.

In case a derogation with a higher concentration limit is deemed as most proportionate the dossier submitter proposes a labelling requirement for recycled PVC. Articles should be visibly labelled as containing BPA. SEAC concluded for lead in PVC that with regard to articles containing recycled PVC, the labelling requirement is crucial, because without a label it will be hardly possible for enforcement authorities to clearly identify recycled articles and articles where lead was added intentionally. SEAC noted that the labelling requirement will impose a cost on recyclers and PVC converters. SEAC considered the label as proposed by the Dossier Submitter does enable enforcement in a cost-efficient way.

The BD for lead in PVC argues:

'A derogation for recycling may raise enforceability issues concerning scope and traceability (in particular of imported PVC articles that are claimed by importers to be produced using recycled PVC). As previously discussed, in order to facilitate the enforceability aspects of the derogation, ECHA recommends that:

- Not all PVC articles, but rather an exhaustive list of rigid PVC articles, should be derogated. As previously discussed, such list should include PVC articles that would not be expected to lead to significant human exposure to lead during their service life (e.g. via dust inside the buildings or direct and prolonged contact);

- Producers of PVC articles should be obliged to clearly indicate thepercentage of recycled PVC in their products (as well as where in the article the recycled PVC is used, e.g. in case of multi-layered or co-extruded PVC articles86);

- Importers of PVC articles could be asked to provide documentation (from their suppliers/contractors) proving that articles were produced using PVC recyclate (with any essential details on% recycled PVC; location of recycled material, etc.);

- In addition, there could be an additional requirement, specifying that PVC articles containing recycled PVC are visibly, legibly, and indelibly marked as follows (contains recycled PVC) in analogy to the labelling requirement for recycled PVC containing cadmium (entry 23 of Annex XVII to REACH).'

The first aspect is human health related and therefore not relevant for this proposal. In accordance with the other aspects mentioned the dossier submitter for the restriction proposal on BPA and BosC proposes a labelling requirement in which the producers of PVC articles should be obliged to clearly indicate thepercentage of recycled PVC in their products, Importers of PVC articles need to provide documentation (from their suppliers/contractors) proving that articles were produced using PVC recyclate (with any essential details on recycled PVC); PVC articles containing recycled PVC are visibly, legibly, and indelibly marked as follows (contains recycled PVC) in analogy to the labelling requirement for recycled PVC containing cadmium (entry 23 of Annex XVII to REACH).'

E.4.1.3. Uncertainties

One major uncertainty is whether additives are still used in the EEA to manufacture PVC. No stakeholder reported actual uses or reasons why a continued use is needed. And the stakeholder who reported his suspicion that BPA might be used in limited quantities in the EEA did not present further explanations in regard to the assessment.

The only indication on imported PVC containing BPA was provided by a stakeholder representing the Japanese automotive industry. However, it cannot be excluded that significant quantities of other imported articles contain PVC where BPA is used as an additive.

Stakeholders from automotive industry and the medical sector commented that the phase-out of BPA-containing PVC is expected soon. No further details where given. Therefore, it is a medium uncertainty whether a longer transition period is necessary to complete the phase-out.

For recycled articles a minor uncertainty remains, whether the concentration limit can always be met and if that is not the case, what the additional costs for disposal of those quantities would be.

E.4.1.4. Proposed action

The dossier submitter proposes a concentration limit of 10 ppm for BPA and BosC in PVC articles. As discussed, for manufacturing in the EEA a concentration limit of 150 ppm would suffice because the plasticizers would already contain more than 150 ppm BPA. However, it remains unclear whether the final articles always contain above 10 ppm BPA. In order to ensure a level playing field for EEA-manufactured and imported articles the dossier submitter therefore proposes the lower limit value.

The dossier submitter discussed only two options for recycling because stakeholders indicated that they will meet the 150 ppm limit in the near future for recycled PVC. The Dossier Submitter agrees that in case of a restriction with a 10 ppm concentration limit costs will arise. The costs cannot be fully quantified but considering previous discussions might be considered as proportionate.

The dossier submitter discussed only two options for recycling because stakeholders indicated that they will meet the 150ppm limit in the near future for recycled PVC.

Considering the discussions in this chapter and the environmental impact of the three options, costs and benefits are summarized in Table 119.

Table 119: Restriction options for A1-A4 - PVC additive uses

	Costs per year (million €)	**Emissions reduced per year (tonnes)**	**Cost effectiveness €/kg emissions reduced**
PVC articles (10ppm)	Unknown: Use in the EEA is possible. Substitution costs expected to be affordable, because competitors already substituted before 2010. Stakeholders from automotive industry do not expect a price-increase for BPA-free PVC. Unknown but expected to be affordable.	Unknown. Expert judgement in B9 is 1-5tpa emissions	Not available
Recycled PVC articles RO1 (10ppm)	51.7 million	<2,7	<19,148
Recycled PVC articles RO2 (150ppm)	Costs for labelling and testing are unknown but expected to be affordable	unknown	Not available

E.4.2. Thermal Paper (additive use A5)

E.4.2.1. Use (summary)

BPA or structurally related bisphenols have been employed as colour developers which, together with other components of the reactive layer, i.e. dyes, sensitisers and stabilisers, generate the print result on the thermal paper when processed through a printing device. Colour developer systems consist of one substance or a formulation of different substances. Different products made from thermal paper exist on the market (Stakeholder information). The use of BPA in thermal paper in a concentration equal to or greater than 0.02% by weight is restricted since January 2020 based on Annex XVII Entry 66.[213]

---

[213] Commission Regulation (EU) 2016/2235 of 12 December 2016 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards bisphenol A: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.337.01.0003.01.ENG&toc=OJ:L:2016:337:TOC

For this reason, annual usage tonnages of BPA for thermal paper production decreased significantly over the last few years and are considered zero in 2020 in Europe as the concentration limit set in the restriction precludes the use of BPA or any other colour developer in thermal paper for reasons of technical feasibility.

The use of BPA-based thermal paper was almost entirely offset by an increase in the use of BPS-based thermal paper, thereby making BPS the most widely used colour developer for the manufacture of thermal paper in the EU's history. Other developers on the market are used in lower quantities.

E.4.2.2. Baseline

E.4.2.2.1. Thermal Paper manufacturing

The European Chemicals Agency has been issuing annual updates following the publication of the Commission Regulation (EU) 2016/2235 concerning the restriction of BPA in thermal paper (see above). The last report (ECHA 2020) covers the period up to 2019 and projected, in cooperation with the European Thermal Paper Association, use numbers for BPA and alternative developers up to 2022 for the EU.

ECHA (2020) reports that overall consumption of thermal paper in the EU has witnessed a decrease of roughly 3% from 2018 to 2019, totalling 477 kilotonnes. Nevertheless, they assumed that the EU thermal paper market will continue to grow at an annual rate of 2% from 2020 to 2022. This is consistent with the past trend (2014-19) of a 2% average increase in the consumption of thermal paper.

They further assume that 75% of the BPA-based thermal paper will switch to BPS-based thermal paper until 2022, and the remaining 25% to other alternative developers. This scenario has been confirmed by European paper manufacturers to be the most likely scenario.

For the baseline the dossier submitter decided to assume a constant thermal paper market with no growth. The three main uses for thermal printing are point-of-sale receipts (highest usage volume), tickets, and labelling (bar codes, pallet labels, etc.). It is expected that over the next 20 years the use of paper receipts and tickets will continually drop and be replaced by digital receipts and tickets. It seems more likely that thermal paper use will decrease, however, as no further information is available the dossier submitter assumes a constant use over 20 years compared to the year 2022.

The imports of thermal paper into the EU from the five largest exporting countries saw an increase of 8% in 2019, amounting to about 119 kilotonnes (i.e. a quarter of the total thermal paper market). (ECHA 2020).

The resulting estimate for thermal paper to be placed on the market in 2022 and beyond is:

Bisphenol A: 0tpa

Bisphenol S: 307 000tpa

Other developers: 199 000tpa

Total: 506 000tpa

E.4.2.2.2. Paper Recycling

In 2021, 71.4% of all paper and board consumed in Europe was recycled. Both consumption of new paper and board and collection of Paper for Recycling (PfR) have increased. The consumption of paper and board has strongly recovered after the lifting of many pandemic-related restrictions. It reached a level higher than in 2019, before the Covid-19 pandemic. With regard to the collection of PfR, there has also been growth, but collection levels recovered more slowly. As a result, the recycling rate slightly decreased in 2021 compared to 2020 (European, 2022).

In a year to year comparison, the total amount of paper and board collected and recycled in the paper sector in 2021 increased by 2% to 57.1 million tonnes, while consumption of paper and board increased by 4.8% to 80 million tonnes. The recycling rate is defined as the ratio between the recycling of used paper, including net trad of PfR, and paper and board consumption. The net trade of PfR is included in the European paper recycling rate (71.4% in 2021). As consumption of paper and board grew more than the recycling of paper and board within and outside Europe, the recycling rate decreased from 73.3% in 2020 to 71.4% in 2021. Looking back at the progress made since 1998 - the base year for the first voluntary commitment set in the European Declaration on Paper Recycling - recycling has increased by 43% (17.1 million tonnes). In strong contrast, consumption since 1998 increased up until 2007 and dropped back below the initial level in the following years. 2020 (European, 2022).

E.4.2.3. Impact Assessment

E.4.2.3.1. 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 a very limited number of stakeholders commented on this use and only one stakeholder representing the European manufacturers of thermal paper presented detailed information. Regarding the economic impact of a restriction they stated that 'The SEAC opinion for the BPA restriction estimated that overall substitution costs would range between 1 Mio € and 22 Mio € per year when considering BPS, D8 and PergafastTM 201. In addition, compliance costs of 150 000 and 250 000 € per year are expected. These values are still deemed to be valid.'

It is noted that the cited cost range was not the estimation by SEAC but by the French dossier submitter. The range for the non-bisphenolic alternatives was given as €19-€22 Mio per year. SEAC estimated costs to be in a range from €43s - €151 Mio per year.[214] As mentioned the most recent stakeholder information confirms the estimations from the background document of that older restriction not the higher estimations calculated by SEAC.

The SEAC opinion summed up the relevant parts of the background document as follows:

---

[214] Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC): Opinion on an Annex XV dossier proposing restrictions on Bisphenol A; ECHA/RAC/RES-O-0000001412-86-56/F ECHA/SEAC/ RES-O-0000001412-86-82/F Compiled version prepared by the ECHA Secretariat of RAC's opinion (adopted 5 June 2015) and SEAC's opinion (adopted 4 December 2015). https://echa.europa.eu/documents/10162/6ad9418c-d781-c26b-4332-47dd75127bad

The Dossier Submitter's approach to cost estimation is based on estimating the substitution costs and compliance control costs for the thermal paper producers. This includes thermal paper production both for EU use (58%) and for export (42%). The size of the import market of BPA containing thermal paper is unknown, and the costs to importers are thus not included[215]*.*

To calculate the substitution costs, the Dossier Submitter has considered the expected price increase for thermal paper, when switching from BPA to other dye developers. The alternatives included in the analysis are: BPS, D8, and Pergafast 201. Three scenarios were constructed (low, medium and high) varying all the input prices as well as the concentration of the dye developers (loading) used in the thermal paper.

The main assumptions used in the substitution cost calculations included:

- *Only costs for "ecopaper" POS tickets and receipts are calculated*
- *Period of analysis 2019-2030*
- *Growth in thermal paper market 5-7%*
- *Price decrease in alternatives of 8% between 2013 and 2023, and then 5% decrease from 2023-2030.*
- *All alternatives are treated as "drop-in" used in the same concentration as BPA*

Based on these assumptions, as well as additional industry consultations performed by the ECHA secretariat and the Dossier Submitter (see Annex 9 to the BD), the medium scenario substitution costs are estimated to be in the range €1 million to €22 million per year. Excluding BPS the range is €19 million to €22 million per year.

In addition to the substitution costs compliance control costs in the range €150 000 – €250 000 per year are expected.

<u>Proportionality</u>

In the BD, proportionality is evaluated under two extreme scenarios:

All companies will move from Bisphenol A to Bisphenol S

No company will move to BPS and instead will move to non-bisphenol alternatives, including D8 (4-hydroxyphenyl 4-isoprooxyphenylsulfone) and Pergafast 201.

A summary of the Dossier Submitters' assessment is presented for the two scenarios in Table 24 (i.e. the table number of the background document for the previous restriction proposal).

---

[215] *The need to include costs for export in the cost estimate depends on whether industry will produce BPA free thermal paper for export as a consequence of the restriction or whether a separate production line for BPA containing thermal paper remains in place for export after the restriction. In the latter case, no costs for export would occur, and the costs would be overestimated. On the other hand, the costs borne by importers are not included, which will underestimate the costs. As long it is unknown whether the EU is a net exporter or a net importer of BPA containing thermal paper, it is not possible to determine whether the costs are under- or overestimated in this respect.*

Table 120: Costs and benifits ratio in two scenarios (taken from section E.2.1.1.2.1 in the BD)

	Human health benefits (B)	*Costs (substitution+control) (C)*
Scenario 1 (BPS)	*(likely) ≈ 0*	*medium cost = €1.4 million*
Scenario 2 (nonbisphenol alternatives – D8 and Pergafast)	*> €3.5 million and €5.2 million (not all benefits quantified and valued)*	*medium cost = [€19.3 million; €25.3 million]* *(upper bound likely to be overestimated)*

The Dossier Submitter concludes that scenario 1 is not considered proportionate, but that the benefits may outweigh the costs for scenario 2 (if unquantified benefits would be large enough) and the restriction may thus be deemed proportionate.

Key elements underpinning SEAC's conclusion

[…]

<u>Costs</u>

SEAC in principle agrees with the approach taken by the Dossier Submitter to estimate the costs of the proposed restriction. SEAC however made some modifications in order to correct for some errors identified, to include new cost information received, as well as to incorporate other changes considered necessary by SEAC. In particular, the following assumptions are different from the Dossier Submitter assumptions:

New information was obtained from industry by the ECHA secretariat and the Dossier Submitter (Annex 9 to the BD) late in the opinion making process. This additional information from several stakeholders indicates that Pergafast-containing thermal paper is only 10-35% more expensive than BPA-containing thermal paper. SEAC has used this new information as a basis for producing new cost estimates.

The Dossier Submitter had assumed that the thermal paper market would grow by 5-7% per year. Although SEAC found some justification for assuming a growing thermal paper market, evidence on specific growth rates was lacking. Furthermore, there are aspects like the growing paperfree alternatives market, which might lead to a decrease in market size, but, SEAC has no corroborating evidence to support this. In the public consultation for the SEAC draft opinion, an additional report was brought to SEAC's attention, stating that the European market is increasing between 0-10% per year (Danish EPA 2014). Nevertheless, since no conclusions would change, SEAC has for simplicity not changed its assumption that the tonnages will be constant during the period of analysis, though this means that the resulting costs are likely to be underestimated.

The Dossier Submitter assumed an 8% (followed by 5%) yearly price decline for the alternatives. SEAC could not find any justification for this assumption. Furthermore, new information obtained from industry (Annex 9 to the BD) indicated that raw material inputs were the main driver of the cost of alternatives, and that no significant economies of scale *were to be expected. As such, the price difference when using an alternative dye developer in the manufacture of thermal paper is expected to persist over time. Based on this information, SEAC has assumed a constant price difference over time between the alternatives and BPA.*

The scope of the restriction includes both thermal paper used for Point-of-Sale (POS) and non-Point-of-Sale (non-POS) applications:

Table 121: Applications of thermal paper in Europe (Table 6 from the BD)

Application	***Share over total thermal paper (2008-2012)***
Point-of-sale receipts	*50% - 65%*
Self-adhesive labels	*20% - 30%*
Lottery tickets	*≈10%*
Fax	*≈5% - 10%*
Other	*< 0.5%*
TOTAL	*100%*

However, the costs estimates derived by the Dossier Submitter only included the POS applications. SEAC could not find any justification for assuming that there would be no costs connected to non-POS applications, so the cost estimates produced by SEAC were extended to include the entire scope. SEAC assumed that the cost of using an alternative in non-POS thermal paper would be the same as using alternatives in POS thermal paper[216]*.*

The Dossier Submitter estimated that a switch to D8 or Pergafast 201 would lead to a 13.5% or 15% price increase in thermal paper respectively (medium cost scenario). SEAC has based its cost assessment on three different cost scenarios using 10%, 20% and 35% as the respective increases in the price of thermal paper, which will cover both these alternatives. This range corresponds to the range of price increases for Pergafast reported in the new information gathered by the ECHA Secretariat and the Dossier Submitter, which showed a price increase between 10-35% (Annex 9 to the Background Document).[217]

Based on these updates, as well as the price and tonnage information from the dossier, SEAC has estimated the cost of the restriction as presented in Table 122*.*

---

[216] *As noted above, a narrower scope would be worth investigating. However, SEAC does not have the necessary information about potential costs or risks associated with a narrower scope, and is thus only evaluating the proposed restriction. Please also see the section on benefits for a discussion of the uncertainties surrounding the population at risk.*

[217] *SEAC does not distinguish between D8 and Pergafast in calculating the price increase scenarios, since both are within the same thermal paper price increase interval.*

Table 122: Three cost scenarios for the average yearly costs in € over the period 2019-2030

Alternative	*Cost scenarios*		
Cost scenario	***low (10%)***	***medium (20%)***	***high (35%)***
Average yearly costs over the period 2019 - 2030	*43 000 000*	*86 000 000*	*151 000 000*

(End of excerpt of the background document)

The Dossier Submitter for this restriction proposal points out that the most recent stakeholder information supports the initial cost estimate of €19.15 – €22.25 Mio per year which is why this estimate is considered as best and central estimation of the cost of a restriction on the the use of BPS in thermal paper.

Further the Dossier Submitter notes that additional evaluation of the data from the previous restriction dossier is difficult as several input variables cannot be confirmed, for example:

- The background document estimates the consumption of 2 400tpa BPA for the manufacturing of over 500 000tpa thermal paper. More recent stakeholder information suggests that the average BPA use for the manufacturing of thermal paper amounts to approximately 1.3% of the paper mass.

- SEAC (see table above) assumed 20% price increase as the central cost scenario. Information in Annex 9 of that dossier suggests otherwise: 'the price/cost increase of Pergafast-containing thermal paper compared with BPA containing thermal paper seems to be between 10% and 20%.'

- SEAC assumed a constant price difference over time between the alternatives and BPA thereby deliberately neglecting information from the background document. Information given in Annex 9 suggests that a yearly price decrease of 8% is unlikely however small effects from economies of scale still can be expected.

- Stakeholder information for this new restriction proposal states that additional non-phenolic alternatives entered the market recently (e.g. Blue4est® Pro). These are also more expensive than BPA, however in order to be competitive they must be less expensive than established alternatives like Pergafast.

Considering that

- SEACs evaluation is based on partially unreliable data,

- and that SEAC, in the Dossier Submitters view, analysed available information only insufficiently,

- and that stakeholders did not present more reliable data in the two calls for evidence

the dossier submitter proposes to use the most recent expert cost estimate given by an industry association representing manufacturers accounting for approximately 65% of the EU thermal paper market.

Regarding the availability of sufficient quantities of the alternatives the previous SEAC opinion concluded:

For ecopaper, some of the alternatives seem to be widely available and already in use. This means that at least to some extent there exist technically and economically feasible alternatives. For the remaining 35% of the thermal paper market, which is not categorized as ecopaper, there is little information in the dossier. It is thus uncertain whether the conclusion that technically and economically feasible alternatives exist and are available applies to the entire thermal paper market.

However, based on the draft Forum's Advice, which states that the proposed restriction is practicable and enforceable, SEAC concludes that the proposed restriction can be considered implementable, enforceable and manageable.

The dossier does not present any information on the time it will take to sell out of existing stock nor did the public consultation reveal any new information about the transition period. According to the information gathered by the ECHA Secretariat and the Dossier Submitter (see Annex 9 to the BD) some industry actors indicated that 3 years would be sufficient time to adjust the production of phenol free thermal paper to an increase in demand. Albeit based on limited evidence, SEAC thus considers it likely that 3 years would be sufficient time for industry to complete the substitution process.

The Dossier Submitter for this restriction proposal points out that stakeholder information in the background document indicated that 'should a restriction on BPA come into force, time is needed to adjust production of phenol free paper to an increase in demand. This would take 2-3 years.' However, stakeholder information from the first CfE states: 'The patent of PF201 has expired since the end of 2019, so several suppliers are ready to export material to EU in addition of the historical producer and importer. Other new Non-phenolic color developers are either already present or will soon hit the market.'

Considering the current availability of a larger variety of alternatives the Dossier Submitter considers the general transition period of 18 months to be sufficient to phase out the use of bisphenols in thermal paper, however, it is proposed to confirm this in the public consultation.

All three restriction options RO1-RO3 would effectively ban the use of BPS in thermal paper, considering that in order to function properly BPS needs to be used in quantities of 1-3% in relation to the paper mass.

E.4.2.3.2 Paper Recycling

No stakeholders commented on the economic impacts of a restriction on BPA and BosC in regards 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 million 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 <1ppm to >10ppm.

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 an unknown 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.

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.9), however the following main arguments are considered as substantial negative impacts in case of a 10ppm limit value:

- Either industry ceases to manufacture recycling paper in the EEA for up to 10 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 significant negative environmental impacts, especially with regard to CO2 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 elsewhere.

Only a qualitative assessment of the expected impacts resulting from the different restriction options is possible. RO1 would lead to large economic impacts possibly resulting in the cessation of European paper recycling or in activities to bypass an effective regulation that reduces emissions.

RO2 would allow the continuation of paper recycling in the EEA. It is expected that within 5 years after the end of the transition period for the restriction on the additive use of BPA in thermal paper concentrations of BPA and BosC in recycling paper will be less than 10 ppm (see Annex B9). However, it would be possible that new BPA and BosC quantities continue to enter the recycling loop in case European recyclers import paper waste from outside the EEA. In the dossier submitters view it is necessary to avoid this and therefore a time-limited higher concentration limit of 150 ppm for 78 months for paper recycling is proposed.

E.4.2.4. Uncertainties

The major uncertainties have already been discussed:

Additive use in the manufacturing of thermal paper

- The availability of alternatives in sufficient quantities.
- The price of alternatives and future price developments.
- Substitution costs: only one rough estimation has been provided in the two calls for evidence which is based on flawed data from 2013/2014 used in the previous

restriction proposal on BPA in thermal paper. Additionally, the adjusted estimation by SEAC is based on incorrect data and assumptions and therefore very likely to be an overestimation of the costs.

Paper recycling

- A quantification or further qualification of the costs resulting from RO1 is not possible. The assumption that impacts would be disproportionate is based on expert judgement considering the current large share of paper recycling in the EEA and the two scenarios that might result from a restriction: a) cessation of paper recycling in the EEA; b) continued recycling with unchanged emissions.
- Current import of paper waste for recycling and impacts stemming from a ban are unknown.
- The time needed for the removal of BPA and BosC from the recycling loop in sufficient quantities to meet a concentration limit of 10 ppm is a minor uncertainty. However in absence of further information 5 years is considered a reliable estimation.

E.4.2.5. Proposed action

Considering the discussions in this chapter and the environmental impact of the three options, costs and benefits for the restriction on additive uses of BPS are summarized in Table 123.

Table 123: Restriction options for A5 - additive use in thermal paper

	Costs 1 000 €/a	**Costs total 20 years 1 000 €**	**Emissions reduced over 20 years (tonnes)**	**Cost effectiveness €/kg emissions reduced**
RO1 (10ppm)	19 000– 22 000	265 000 – 307 000	1 720	154 - 178
RO2 (150ppm)	As RO1			
RO3 (1000ppm)	As RO1			

- Costs are presented using a discount rate of 4%, an analytical period of 20 years

Considering previous restrictions on PBT and vPvB substances as comparison the cost resulting from RO1 is considered as proportionate. Even if the stakeholder information underestimates the costs a restriction would still be proportionate.

For the recycling of paper the three different restriction options cannot be assessed quantitatively or even qualitatively in detail. Considering the assumption that resulting from RO1 the paper recycling would either be no longer possible or paper recyclers could bypass effective regulation resulting in ongoing and unchanged emissions of BPA and BPS RO1 is considered disproportionate. RO2 would enable manufacturers to continue the recycling of paper waste. However, it would also result in the possibility that paper waste imported into the EEA leads to additional influx of BPA and BPS into the recycling loop even after BPA and BPS have been initially removed from the recycling loop. Therefore, a time-limited derogation of 78 months from the 10 ppm concentration limit is considered the most proportionate restriction option. For 78 months after entry into force of the restriction the concentration limit for BPA and BosC in recycled paper articles shall amount to 150 ppm.

E.4.3. Hardener in epoxy resins (A6)

For this application, no information is available on the percentage of hardener for epoxy resins cured with BPA. For the estimation of environmentally relevant emissions, information on the share of environmentally relevant uses, i.e. rather outdoor, is necessary, which is not available. The step of application (by professional user and consumer) is also assumed to be emission-relevant. Here, too, no information is available. According to stakeholders the professional use of epoxy resin hardeners is a dry process and no water is generated.

The dossier submitter obtained only very sparse information in the two Calls for Evidence on this use. Apparently phenolic hardeners are used as curing agents for epoxy resins in molding compounds, copper clad laminates, electrical applications and potting as well as powder coatings. Epoxy resins made of and containing Bisphenols are usually needed to accelerate curing if fast curing is needed (no post-curing process). Depending on the cure conditions, BPA catalyzes and takes part in the reaction with epoxy resins. 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. Limited stakeholder information suggests that epoxy resins that are cured with low BPA containing phenolic hardeners comply with a 150ppm limit but exceed the 10ppm concentration limit for BPA/BosC.

One stakeholder reported that some work has been initiated including: 1) Avoid use of phenolic hardeners in new products and 2) Evaluation of low BPA containing phenolic hardeners for existing products. The stakeholder reports that the main obstacle for powder coatings is the residual BPA in the solid epoxy resins. For a complete transition to alternative hardeners (non and low phenolic) at least a transition period of 5-10 years is needed. It is not clear whether 10ppm in the cured product can be met for all applications.

The dossier submitter proposes a derogation with a BPA/BosC concentration limit of 65ppm for semi-solidepoxy resins (see discussion for P2 – epoxy resins). Based on the limited information it seems likely that epoxy resins cured with phenolic hardeners can meet this limit. Information from the same stakeholder suggests that in the future it might be possible to meet lower concentration limits. The dossier submitter proposes to ask for additional information in the public consultation to get a better understanding what limits can be achieved and what time frame for substitution is required.

In sum, the Dossier Submitter possesses a limited understanding on this use and corresponding socio-economic impacts. In absence of further information it is assumed that the proposed concentration limit of 65 ppm for BPA/BosC in semi-solid epoxy resin articles enables users to continue the use of phenolic hardeners if needed.

E.4.4. Stabiliser in liquids used in closed loops (A8 – A10)

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

E.4.5. Lubricants (A11)

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

E.4.6. Tyres (A12)

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

Considering information from the stakeholder consultation no impacts on recycling processes are expected. One stakeholder submitted information that granulates from used tyres from four different European producers were tested for BPA contents. BPA concentrations ranged between 0.1 and 1ppm. A literature search undertaken by the same stakeholder suggests that the average concentration of BPA in tyre shred might even be one order of magnitude lower (SFA, (Ramboll Deutschland GmbH, 2022)).

E.4.7. Fluoroelastomers (FKM) (A13)

E.4.7.1. Use

BPAF is an essential component of FKM. FKM are highly fluorinated polymers that exhibit a very good thermostability but are not flexible at low temperature. Various grades of FKM are available. BPAF is one of the most commonly used cross linkers for BP-curable fluoroelastomers in the rubber industry. Normally, BPAF is used along with accelerators such as quaternary phosphonium salts (n.b.: several quaternary phosphonium salts of BPAF have been registered as separate substances under the NONS regimen and under REACH, c.f. Table 21, section B.1.1).

General rubber goods such as o-rings, gaskets, hoses, pads, where technical performance and safety play the major role require the use of FKM rubber and other fluoropolymers that contain BPAF as cross linking agent. They are used in the following sectors: Automotive, Aerospace, machinery, oil and gas.

According to stakeholder information, the use of fluoropolymers containing BPAF in rubber is essential to meet technical expectations on product performance. To date there are not chemicals, nor technological alternatives, that could substitute the use of fluoropolymers in the industry.

Regarding the use of BPAF to manufacture FKM it is necessary to have a clear distinction between products and articles/mixtures: A: The pure FKM polymer does not contain BPAF as it is added at a different value step. B: For the FKM precompound curative BPAF is intentionally added/mixed/encapsulated with FKM. In case B, BPAF is added intentionally and will be present in the article.

E.4.7.2. Baseline

Stakeholders estimate that 14,000 - 50,000tpa of rubber goods require the use of ,luoropolymers, accounting for 0,5 to 2% of the overall production of rubber goods in

Europe – among those FKM rubber containing BPAF. Rubber goods containing fluoropolymers are used in automotive, aviation, oil and gas sectors.

Rubber goods containing fluoropolymers are used inside other complex objects, such as aviation or automotive, in industrial controlled environments. Although a significant number of uses is linked to the use of combustion engines in transportation, the industry expects steady demand for FKM as there might be new uses in the future as well as continued demand for certain uses also in electric cars. In sum, it seems reasonable to assume steady demand in the foreseeable future.

The use of BPAF in the rubber industry is limited to the production of FKM rubber. The content of BPAF in uncured rubber mixtures containing FKM is estimated by one industry association in the range of 5% w/w. Other estimates are in the range of 0.3 % w/w – 3 % w/w depending on the performance needs of the final FKM-article. It is estimated that the amount of BPAF present in uncured rubber articles is in the range of 42 t/a (0.3 percent of 14 000 t/a FKM) to 2 500 t/a (5 percent of 50 000 t/a). One stakeholder stated that in finished rubber articles the content of Bisphenol AF is limited to impurities not reacted during the vulcanization process. Yet, it is unknown whether the overall quantities would be lower than 10 ppm in all cases.

According to another industry estimate the market volume of BPAF used in the EU is ca.120 tons of BPAF. It is not clear whether this information encompasses only the intentional use of BPAF to manufacture masterbatches or whether this includes imported masterbatches, FKM and articles containing FKM. The dossier submitter assumes that this number only includes manufacturing of masterbatches in the EU.

With regard to emissions potential during the processing stage, stakeholders describe the use as follows: Uncured rubber mixtures containing Bisphenols are not used by professional workers, but only used at industrial sites. Bisphenols, produced as granulates or powder, are delivered to industrial sites in bags made of paper bags or plastic drums. The raw material is stored in dedicated facilities at ambient temperature with stable conditions, controlled levels of humidity and temperature. The packing of the raw material is disposed according to the on-site requirements for hazardous waste.

The boiling points of the Bisphenols used in the rubber industry are in the range of 343 to 500 °C , temperatures much higher the process steps where exposure could happen via inhalation – rubber process temperatures maximums are in the range of 220 °C.

Stekeholders do not expect releases to the environment of Bisphenols during the production of general rubber goods as they are used in close bags and duly stored. Bisphenols are embedded in the uncured rubber mixture and no release to the environment can occur on the industrial site.

Stakeholders provided heterogeneous information regarding BPAF present in the final (cured) FKM. Information ranged from the statement that rubber articles are not expected to contain Bisphenols so releases during use are not expected. Other information suggested that articles can meet a 10 ppm concentration limit and some stakeholders expect that articles might contain BPA residues of 50 ppm or more. The different responses might be explained by different FKM formulations as well as by differing testing methods. The dossier submitter concludes that although most of BPAF reacts with the polymer and incorporates into the polymer after cross-linking to make an article, residue of unreacted BPAF in articles will be present. The assumed number of residues is 5-50 ppm.

The emissions estimate in B.9 considered the available information and concluded that emissions during manufacturing are expected to be comparably low. Main uses in semi-conductors and other electronics and in automotive/aerospace suggest that emissions during service-life are according to the available stakeholder information very low, too because no significant water contact is expected. However, anecdotal information of publicly available information suggests that there are additional uses with water contact: FKM rubber straps, e.g. used in sports equipment; Tubing, hoses, seals and gaskets made from FKM rubber are according to one supplier a popular choice for outdoor applications because they are resistant to oxygen and ozone.

The dossier submitter expects the largest emission potential in the waste phase. If the assumption that virtually all uses are in electronics and automotive uses is correct it can be expected that significant quantities of the waste end up in landfills as part of the shredder faction/ASR (automotive shredder residue). The dossier submitter expects that ultimately all residues will leach out of the waste and only part of it will be eliminated in WWTPs.

The dossier submitter received limited information from stakeholders concerning future demand for FKM. Considering that a large share of the uses is related to the use of internal combustion engines in vehicles and machinery it might be possible that demand will decrease continually as the share of electric cars increases. However, in a personal meeting in March 2022 stakeholders expressed their expectation that use of FKM will be steady in the foreseeable future.

E.4.7.3. Impact assesment

Examples of representative uses of fluorelastomers that could contain BPA and end use markets are presented in the table:

Table 124: FKM uses

Type of polymers that can contain BP-AF	**End use application (ex: automotive, food contact…)**	**Type of article**
FKM	Automotive Applications	O-Rings and sealing gaskets for Fuel connectors, Tank seals, Fuel injector, Air Admission, Turbocharger, Engine seals, sensors
	Oil&Gas (gas transportation)	valves and seals
	Industrial application	industrial valves, pneumatic cylinders, pumps
	Aerospace Applications	Fuel line, Hydraulic systems, Engine seals

The addition of BPAF to uncured FKM rubber is needed to achieve rubber goods that are resistant to high temperatures and chemical resistance. The potential presence of impurities of BPAF in rubber articles made out of FKM rubber does not have any technical use.

There are two alternative crosslinking mechanisms available: Diamines and peroxides. However, stakeholders argue that both are unsuitable in dynamic application, high wear and very high temperatures. There are limitations regarding high temperature stability, ease of processing and increased scrap rate, with hazards like skin and eye irritation, acute chronical toxicity for water organism. Furthermore, FKMs cannot be substituted by lower value elastomers.

According to stakeholders, crosslinking fluoroelastomers with diamines does not produce seals or hoses that meet current performance standards and has therefore been replaced by the BPAF curing system. Fluoroelastomers with diamines should not be considered as a suitable alternative due to property and processing deficiencies of the resulting materials.

Peroxide (PO)-cured fluoroelastomers showed improved resistance to steam but do not exhibit the high thermal stability of BPAF-cured analogues. Moreover, PO-cured and BPAF-cured Fluorelastomers are frequently used in different applications. Peroxides also create new risks of fire and explosions if not handled properly.

In applications where PO-cured and BPAF-cured fluoroelastomers are both technically feasible, BPAF-cured fluoroelastomers are commonly less expensive.

In sum, curing systems using peroxide or diamines are the commonly cited alternatives to BPAF. However, stakeholders view both as inferior and not applicable in comparison to the BPAF system.

Other types of elastomers which are considered by one stakeholder as possible but subpar alternatives, are FFKM (perfluorinated rubber/perfluoroelastomer) and non-PFAS elastomers.

In the 2nd Call for Evidence the dossier submitter received general information describing the EEA-market of rubber articles containing fluoropolymer that includes FKM rubber. It is estimated to be in the range of €50 - €70 million. An estimated 18% share of all rubber articles are fluoroelastomers. The turnover share of FKM-based articles might be significantly larger as they are regarded as very expensive materials in comparison to other fluoropolymer articles.

Impacts with regard to articles

The dossier submitter received conflicting information on the question whether the 10ppm concentration limit can be met for articles in general. Some stakeholders stated that the concentration limit can be met for cured articles. Others stated that it is possible to meet a 50ppm concentration limit in cured articles. However, one stakeholder stated that cured articles sometimes contain several hundredppm unreacted BPAF residues. No information is available what the reasons are for the large differences in measured residues.

Another open question is which share of articles has water contact during service life and how much emissions can be expected at the end of life of the articles. The submitted information suggests that FKM-articles containing BPAF are mainly used in industrial applications with no or very limited water contact. However, stakeholders indicated that there might be several outdoor uses, e.g. in chemical plants, substations/transformer stations, etc.

Some stakeholders stated that BPAF cannot be released into the environment unless exposed to extremely high temperatures. In practice, FKM is processed, and FKM components are used, at lower temperatures. Stakeholders also stated that their materials need to withstand stressors for very long periods of time, e.g. in case of automotive, at least 20 years, which is as long as a vehicles' service life. However, in a personal meeting, stakeholders also presented data to the dossier submitter from a testing of two articles (each with four test runs) where migration of BPAF from the FKM material was up to more than one magnitude higher than the proposed migration limit. Stakeholders were cautious regarding the results, arguing that no standard method for measuring BPAF in FKM has been established and that it should be noted that the measurement results may change if the measurement method is changed.

The dossier submitter received no information on the number of necessary tests resulting from this restriction. However, in the EU the number of manufacturers of fluoroelastomers is less than five. It is the understanding of the dossier submitter that manufacturers offer several different fluoroelastomers which are used depending on the stressors. Several migration tests might be necessary per manufacturer. However, it was stressed by stakeholders that fluoroelastomers need to be extremely reliable. Therefore, the dossier submitter assumes that production processes, especially with a view to the curing step, are strictly controlled and that testing is not needed for individual batches but only needed once for every grade that is placed on the market.

Impacts of a restriction on mixtures

Stakeholders claim that FKM uncured rubber mixtures contain BPAF in the range of 0.3 - 5% and consequently do not meet the proposed content threshold. They claim that the migration threshold is extremely low and requires specific test methods. Importers of uncured rubber mixtures would have little incentives to import to Europe, affecting the availability of FKM mixtures for EU-based rubber manufacturers and creating a disadvantage compared to non-EU manufacturers who would have better access to raw materials.

As discussed in Annex B.9, FKM uncured rubber mixtures are manufacturered and processed in industrial settings under controlled conditions where it can be demonstrated that on site measures are adequate to control the risk of potential emissions to air and water of BPAF from the use on uncured rubber mixtures, i.e. that the conditions as per paragraph 2 concerning the provision that contact to aqueous media throughout the service life can be excluded applies.

The dossier submitter expects that the necessary documentation (description of production process, emissions control, waste management and transportation) is already available, meaning that no additional cost arises.

The use of BPAF in the manufacture of FKM is within the dossier submitter's definition of an additive use. However, some aspects have to be considered:

- Stakeholders expect no or very limited emissions during manufacture of mixtures and the FKM curing step. The dossier submitter is not aware of contradicting information.
- An unknown but large share of the uses will be without water contact. i.e. no emissions during service life are expected. An unlikely worst case approach for emissions during service life would life assume the following:

  20%% unprotected outdoor uses of 50,000tpa FKM

  50ppm BPAF

  with 25%% emitted during service life

  with 61%% elemination of BPAF in WWTP

That scenario would result in 48.75 kg/a emissions of BPAF. A quantity that is comparably low but not a negligible quantity over 20 years: 975 t.

- Large shares of uses in transportation, industrial machinery and electronics make it likely that a large share of FKM ends up in landfills where the remaining BPAF residues can easily migrate into the leachate. The end of life of those articles are regulated by Directive 2012/19/EU and Directive 2000/53/EC. However, small plastic parts can end up in the shredder fraction. Recycling of the plastic share within the shredder fraction is still very difficult and expensive and it is the Dossier Submitters understanding that ultimately a large share is landfilled. In landfills it is possible that over time 100 percent of the unbound residues emit from the waste. If 50 percent of 50 000 t/a FKM uses end up in landfills the emission potential is 487.5 t/a or 9.750 tonnes over 20 years.

- For certain uses alternatives are not available. Considering confidential information from stakeholders the direct revenue loss for manufacturers of FKM could be in the range of 500 – 1,000 million €/a. More importantly, however, other costs resulting from not being able to use BPAF for FKM manufacturing could be much larger: Accorting to stakeholder information the automotive sector is by far the most important sector for BPAF-cured FKMs since FKM products are designed to achieve the highest requirements in extreme environments. This includes high temperatures in a combination of contact with fuel, diesel and manufactured substances. The very low permeation rate of the pre-compounds allows components to meet current environmental regulations, which without BPAF would not be possible (European limits for exhaust gas emissions of ICEVs: Euro6d).

The Dossier Submitter cannot verify the statements and doubts that stakeholder views are correct that the economic loss in whole sectors such as automotive, oil & gas would be total. Stakeholders stated that they will not be able to manufacture their final products anymore without FKMs compounded with BPAF. It seems more likely that there would be a quality loss in regard to certain properties with unknown concequences. For example, articles might be unsafer, but perhaps this could be avoided by more maintenance and more frequent replacement of parts. However, considering the large uncertainties, especially in regard to the competitiveness of EU-manufactured articles on the world market, the dossier submitter agrees with stakeholder information that economic impacts on downstream user are potentially very large.

The dossier submitter points out that the SEAC, in its opinion on the restriction proposal for PFHxA,[218] did not conclude on the economic impacts of restricting the use of fluoroelastomers : '*No information available on substitution costs. Information available indicates that functional losses are likely to occur and would negatively impact engine performance, safety and emissions in the automotive sector*.' Basically, the information submitted in the two Calls for Evidence did provide the same information that was submitted to SEAC in the public consultation on the restriction proposal on PFHxA in 2020. Therefore, information on the magnitude of impacts is still inconclusive.

---

[218] Committee for Risk Assessment (RAC) Committee for Socio-economic Analysis (SEAC) Opinion on an Annex XV dossier proposing restrictions on undecafluorohexanoic acid (PFHxA), its salts and related substances ECHA/RAC/RES-O-0000006976-57-01/F ECHA/SEAC/RES-O-0000007039-72-01/F. 8 December 2021. https://echa.europa.eu/documents/10162/97eb5263-90be-ede5-0dd9-7d8c50865c7e

E.4.7.4. Proposed action and uncertainties

Agreeing that there are large uncertainties regarding potentially disproportionate costs the dossier submitter proposes to derogate the use of BPAF in the manufacturing of FKM from the restriction on additive uses of BPA and BosC. However, considering the large variety of information on the number of residues in the cured articles he proposes a concentration limit for BPAF residues in cured articles placed on the market. Some stakeholders commented that it is possible to comply with a 10ppm limit. Other stakeholders referenced a 30 to 50ppm limit for residues. One stakeholder stated that he cannot comply with a limit value of under several hundredppm. The reasons where not discussed and considering that other stakeholders manufacture basic materials and/or articles for comparable end uses it is reasonable to assume that alternatives with less residues are available.

Stakeholder information also suggests that optimization in the formulation and/or curing process can reduce the amount of BPAF. Considering the large emissions potential from the waste stage and the more limited emissions potential during service life emissions reduction can mostly be achieved by limiting the BPAF residues. Other measures like coatings or encapsulation etc. would only reduce the emission potential during service life.

The dossier submitter proposes to derogate the use of BPAF in cured articles for 10 years after entry into force of the restriction if the content of unbound BPAF monomers does not exceed 50ppm.

This proposal is based on the information that the BPAF content for some uses is larger than 10ppm at the moment but that the content can be reduced in the future through optimization of formulations and curing steps. The dossier submitter proposes a transitional period of ten years for this application considering information from stakeholders that in the automotive industry testing of long-term performances due to safety, environment and warranties takes 4-5 years. In absence of further information, the dossier submitter assumes that an additional 4-5 years for R&D on process optimization is proportionate.

No more information in regard to monetary impacts is available. Considering that also no information is available on the average residues that are currently in FKM it is not possible to give more detailed information on environmental impacts of this proposal. The illustrative example above on potential emissions during the end of life of FKM articles demonstrates that a large amount of emissions can be avoided when BPAF residues are minimized to less than 10ppm.

Additional uncertainties:

- No information regarding the costs for development of optimized production processes is available.
- No information on costs for optimized formulations or additional curing steps is available.
- Minor uncertainties on testing costs: One stakeholder stated that in his view testing is possible and affordable. Other stakeholders did not comment on this issue.
- Large uncertainties in regard to emission potential from outdoor uses
- Large uncertainties in regard to end of life-emissions – the exact share of articles that are landfilled, incinerated, used for mining, heated when metals are recycled, etc is unknown. The assumption suggested by stakeholders that all plastic and rubber used in vehicles and electronics materials are destroyed at their end of life is not correct.

- The dossier submitter suggests to ask stakeholders specific questions on the most important uncertainties during the public consultation.

E4.8. Polycarbonate (P1)

E4.8.1. Use (summary)

Polycarbonates (PC) are polyesters of carbonic acid. Although other synthesis routes are possible, the most commonly used polycarbonates are synthesised from BPA and phosgene. 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).

In Annex **Error! Reference source not found.** the production of polycarbonate is described as the largest use of BPA. Considering the large use quantities and the multitude of applications it is possible to summarize the various end uses in broad main categories (see **Error! Reference source not found.** H) but it is not possible to analyze all individual sub-uses in more detail. Accordingly, a more generic approach has been chosen to identify proportionate risk management options.

E.4.8.2. Baseline

Use-specific quantities and emissions are discussed in Annex B.8.6.5. The dossier submitter discussed data provided by Annex H, the currently available registration data as well as the updated SFA (Ramboll Deutschland GmbH, 2022) and considered additional stakeholder information. Annex H mainly considered data provided by industry stakeholders between 2015 and 2020. BPA registration data and the SFA provided used the same data and additional refinements. The dossier submitter discussed the two data sets and concluded that large uncertainties as well as questionable assumptions might have lead to a significant underestimation of emissions in those two analyses. This conclusion is especially related to emissions from the use and waste phase.

Uncertainties are large regarding future use quantities. According to PlasticEurope polycarbonate use in the EU more than tripled between 1990 and 2010. However, no reliable data is available regarding future trends. For some sectors it seems likely that use will grow (e.g. construction); other sectors might shrink (e.g. optical media); and for some sectors change is likely but the direction is not evident (e.g. automotive). Therefore, in the absence of reliable data on trends the dossier submitter assumes for the impact assessment constant use numbers for the baseline scenario as well as constant emissions.

E.4.8.3. Impact Assessment

Annex H identified several potential bisphenol-free alternatives for polycarbonate uses. However, in two calls for evidence several stakeholders submitted information that led the dossier submitter to the following conclusions:

Many alternatives are mentioned by various stakeholders.

- There are already other polycarbonates not based on BPA. However, they show different properties to BPA-based PC, such as inferior impact resistance, heat resistance or flame retardancy, rendering them not suitable for all applications.

- The stakeholders claim that all alternatives are inferior to BPA-based PC (regarding transparency, mechanical strength, shatter and impact resistance, durability, flame retardancy, heat resistance, toughness, chemical and dimensional stability, sterilizability, ductility and weight) and/or are significantly more expensive.

- Some alternatives, bisphenols and others, show properties of concern.

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. It is not possible to conclude whether substitution cost would be proportionate considering the comparatatively low emissions from at least some individual uses (i.e. uses with no or negligible water contact) and the large range of uses.

However, resulting from the very large overall use of BPA-based polycarbonate BPA is likely to be emitted to the environment in significant quantitites. As discussed in Annex B9 emissions might be larger than 6tpa. Stakeholders argue that emissions are significantly lower. They stress that for uses with known stressors like UV and weathering polycarbonate uses are protected to extend the service-life of the article, e.g. with coatings. Further, stakeholders argue that BPA is emitted from the surface area of the articles thereby limiting the total emission potential. Additionally, stakeholders claim that BPA is released from stressed polymers only for a limited initial exposure period on the very surface exposed to weathering/water. In the waste phase stakeholders predict only very small emission quantities.

In sum, the dossier submitter argues in Annex B9 that the available information on emissions from polycarbonate uses is not conclusive and estimates a possible range of BPA emissions from all uses of polycarbonate between 0.9 and >6tpa.

Emission potential is considered low when (i) the proposed concentration limit can be met, or (ii) the proposed migration limit can be met, or c) contact to water is limited thereby limiting the potential emissions of substances within the scope of this restriction to a low level.

In order to estimate the potential impact of different restriction options the following information provided by stakeholders has been considered:

- Stakeholder information suggests that more than 60% but less than 80% of polycarbonate used in the EEA does not meet a concentration limit of 10ppm for BPA.

- Stakeholder information suggests that all PC uses can meet a concentration limit of 150ppm for BPA. Several stakeholders specifically reported that meeting the 150ppm limit is possible. Some stakeholders reported that real values are 'typically' significantly lower. Some (downstream) stakeholders discussed a limit value of 200ppm and did not reference the limit value of 150ppm. Therefore, some minor uncertainty remains. However, the dossier submitter points out that the information from PC manufacturers makes it seem very unlikely that PC contains above 150ppm BPA for specific technical or practical reasons.

- Relevant uses are defined by stakeholders as the "volume of applications which are deemed to be regularly in intense contact with water, which is a pre-requisite for BPA releases from polycarbonate (BPA registration data, 2022). According to information contained therein, approx 195,000 t PC are used in applications where intense water contact is possible:

Table 125: Uses with water contact

[6] Confidential information is contained in a separate annex which is not available in the published version of the dossier.

- The potential applications of polycarbonates are so manifold and different uses need different material properties and thus material formulations. Therefore, a wide variety of polycarbonate formulations and polycarbonate blends are commercially obtainable. The number of different formulations available can be accessed via electronic databases such as UL Prospector or CAMPUS. For Annex H, a simple search in these databases revealed more than 1,200 different accessible polycarbonate formulations. ALBIS (MOCOM) offers more than 250 different polycarbonate formulations (ALCOM and ALTECH series), Covestro more than 250 (APEC and Bayblend Series), SABIC more than 580 (Cycoloy, LNP and LEXAN Series) and smaller amounts are offered by, INEOS Styrolution, LANXESS Mitsubishi EP, Lyondell Basell and Celanese. Approx. 850, i.e., about 2/3 of these more than 1,200 polycarbonate formulations are specifically designed for injection moulding applications. These are often used, among other general applications, for automotive lighting components, electronic and electric as well as thin-walled applications for medical products.

- Confidential stakeholder information suggests that overall 30,000 – 50,000 batches of PC (sum of batches for all different formulations from all manufacturers) are manufactured per year.

- No information is available on the number of formulations that meet/do not meet the concentration limit of 10ppm. In absence of further information, the same split is assumed as for total quantities of PC used in the EEA, i.e. 60-80% of formulations do not meet the concentration limit. The central estimate is 70% of 1 200 formulation: 840 formulations with a BPA concentration > 10ppm.

- The same logic applies to the fraction of batches that are above/below 10ppm: 9,000 – 15,000 batches can be expected to meet 10 ppm. 21,000 – 35,000 can be expected to not meet the 10ppm limit.

E.4.8.3.1.: RO1 - 10ppm concentration limit or migration limit

The dossier submitter assumes that economic impacts from of this restriction option mainly arise from

- the testing requirement resulting from the proposed concentration limit. It is assumed that 30% of formulations need to be tested for the concentration of BPA in the article. The dossier submitter assumes that only those formulations need to be tested where manufacturers intend to certify that the 10ppm limit is met for the article.

- the testing requirements resulting from the proposed migration limit. It is assumed that migration tests are necessary for 70% of the formulations but not for individual batches.

- administrative costs. 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 mainly one-off and for a) most likely negligible. However, for b) the number of formulations that do not meet the proposed migration limit is unknown. The costs might be significant considering the large number of formulations above 10ppm BPA but it is possible that a large share already meets the migration limit without further use-specific measures.

- measures necessary to comply with the migration limit value. Stakeholder input regarding this topic has been very scarce. Industry repeatedly expressed the opinion that PC 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 polycarbonate materials from stressors and thereby minimizing the migration potential of BPA. However, this information is mainly based on articles with a long expected service life (e.g. automotive uses, construction). In absence of further information, the dossier submitter cannot quantify this potential cost but assumes it to be minor.

- a shift to lower quality PC (with less than 10 ppm BPA). Stakeholders expressed concern that the increasing use of PC that meets the limit value might occur, thereby shortening the durability and service-life of an article. No further information is available but the dossier submitter agrees in theory that this could happen and therefore needs to be considered as an uncertainty.

Testing cost for concentration limit:

Several stakeholders confirmed in the second Call for Evidence that a cost per test of €200 is realistic. A small number of stakeholders assumed the costs to be slightly higher. A 25% higher cost (€250/test) is assumed for the the uncertainties discussion.

If 30% of batches need to be tested then the resulting cost would be

9,000 – 15,000 batch tests x €200 = €1,800,000 - €3,000,000

However, in the dossier submitter’s view it is not necessary to test every batch. As pointed out above, applications of polycarbonates are manifold and different uses need different material properties. It is likely that polycarbonates are produced under controlled conditions to meet specific requirements and that therefore concentrations of unreacted BPA monomers are constant over batches.

If every formulation only needs to be tested once a year it would result in testing costs of an estimated

360 formulations x €200 = €72,000.

As no further stakeholder input is available in this regard, the annual testing costs for the concentration limit are estimated to be in the

cost range: €72,000 – €3,000,000.

Testing cost for migration limit testing:

The cost of testing for complex scenarios with simulation of several different stressors and long service-life is potentially very high. Stakeholders reported on theit own research and indicated full testing cost of above €100,000 for one material. The dossier submitter considered this information and decided to propose a testing requirement where only a limited number of stressors need to be accounted for and where only a limited service-life needs to be tested even if the expected service-life of the manufactured article is longer and realistic worst-case scenarios imply more severe stressors.

The dossier submitter estimates that due to such a limited migration testing requirement most, if not all, tests can be performed by manufacturers of the formulations and that for the individual formulations guidelines are prepared to clarify under which conditions and with which additional protective measures the migration limit can be met.

Therefore, if 70% of batches need to be tested:

21,000 to 35,000 tests x (€3,000 to €5,000) = €63,000,000 to €175,000,000

Accordingly, as discussed above it is unknown to the dossier submitter whether it is necessary to test every batch. Testing formulations only once a year would result in a testing cost of

840 formulations x (€3,000 to €5,000) = €2,520,000 to €4,200,000.

As no further stakeholder input is available in this regard the annual testing costs for the concentration limit are estimated to be in the

cost range: €2,520,000 to €175,000,000.

Administrative cost:

a) Documentation: Stakeholders were asked in the second Call for Evidence to comment on the most economical way to communicate the compliance of their article in the value chain and towards enforcement authorities. Several stakeholders suggested that ideally a Certificate of Analysis or Declaration of Compliance issued by the supplier of the material should suffice as proof for the enforcement authorities.

The dossier submitter agrees with stakeholders that there are already established tools such as compliance statement for ROHS, routine customer communication, certificate of analysis, material safety data sheets, etc. The dossier submitter proposes to use the safety data sheet according to Regulation (EU) No. 1907/2006 to communicate information on BPA concentration in the article and, if applicable, to inform the downstream users on measures for which the supplier certifies that the migration limit will be met. This information could be added to Section 16 of the SDS: Other information. The administrative cost of this measure is unknown but most likely negligible.

b) Technical documentation of suitable measures to adhere to the migration limit: The selection and documentation of suitable protective measures for articles which contain BPA above the concentration limit of 10 ppm entails unknown cost. Several stakeholders commented that they do not have data on the current emission potential of their articles and do not have the expertise to make any informed statements.

According to one stakeholder it seems likely that even the migration potential of their unprotected PC will meet the proposed limit of 0.04 mg/L. Some stakeholders suppose or have already shown via inhouse testing that regardless of the residual BPA concentration in the final article the migration amount can be considered to be near zero for outdoor uses, if the surface is coated. During personal meetings, stakeholders from industry stressed repeatedly that it seems likely that the vast majority of materials for outdoor applications are coated because otherwise the quality of the article could deteriorate and put the longevity in question.

Stakeholder comments stated that PC indoor applications have hardly any potential for BPA release. It has also been mentioned that the use of PC resins on industrial sites and articles should be exempted from the restriction. This has already been considered by the dossier submitter with the proposal to waive information requirements on intermediate uses of bisphenols for which aqueous exposure can be excluded.

Some stakeholders suggested that for other applications representative testing or suitable approaches (e.g. modelling) should be allowed. The testing requirements are in their view very demanding and are only proportionate if e.g. representative testing and clustering of applications is explicitly granted. One stakeholder suggested testing based on reasonable worst-case scenario analysis of a single material representative to the final product. Only in cases where there is a reasonable concern that the migration limit might be exceeded, should a full test be imposed.

In sum, available information suggests that stakeholders agree that the testing of the migration limit can be done by the manufacturers of the PC. In case the migration limit is exceeded the manufacturers of PC can propose suitable measures for protection of the article. In this case additional testing, evaluation and documentation and most likely communication with downstream users would lead to additional costs. The magnitude of which is unknown. However, most likely those will be one-time costs.

Measures necessary to meet the migration limit value:

Considering the high number of different uses and that no stakeholders explicitely commented on this subject the dossier submitter cannot conclude on this potential cost of the restriction proposal. Of course, the dossier submitters assumption is that there might be uses where articles with BPA concentrations above 10 ppm lead to migration of BPA above the limit of 0.04 mg/L. However, no stakeholder commented in the two calls for evidence on this subject matter. The dossier submitter can only derive from available information that most users buy protected/coated articles or apply protection/coating by themselves when severe stressors are expected during sevice life. Therefore, at least for the majority of such uses the benefit of protecting the article already outweighs the additional costs.

Shift to lower quality PC (with less than 10 ppm BPA):

For some uses protective measures might not be possible or it may be that users cannot use the proposed measures from PC manufacturers resulting in individual testing requirements. Users might then shift to PC that meets the limit value thereby shortening the durability and service-life of an article. No further information is available but the dossier submitter agrees that this could happen.

E.4.8.4.2.: RO2 – 150 ppm concentration limit or migration limit

The dossier submitter assumes that economic impacts from of this restriction option mainly arise from

- the testing requirement resulting from the proposed concentration limit. It is assumed that only those formulations need to be tested where the residue content is expected to be higher. No information is available in that regard but considering that several stakeholders repeatedly stated that a 150 ppm residues limit can be met it seems likely that only a small share of formulations is expected to be near that limit. Therefore, the dossier submitter assumes that only <10 perecent of formulations need to be tested to ensure that the 150 ppm limit is met for the article.

- the testing requirements resulting from the proposed migration limit. It is assumed that migration tests are not needed. However, to allow for uncertainties a sensitivity analysis will consider migration testing for 5% of the formulations but not for individual batches.

- administrative costs. 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 mainly one-off and for a) most likely negligible. However, for b) the number of formulations that do not meet the proposed migration limit is unknown. The costs might be zero considering stakeholder information but it is possible that some materials contain aabove 150ppmppm BPA residues and cannot meet the migration limit without further use-specific measures.

- measures necessary to meet the migration limit value. Stakeholder input regarding this topic has been very scarce. Industry repeatedly expressed the opinion that PC 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 polycarbonate materials from stressors and thereby minimizing the migration potential of BPA. In absence of further information, the dossier submitter cannot quantify this potential cost but assumes it to be negligible.

- a shift to lower quality PC (with less than 10ppm BPA). Stakeholders expressed concern that the increasing use of PC that meets the limit value might occur thereby shortening the durability and service-life of an article. The information concerned a concentration limit of 10ppm BPA: No information suggested that the same scenario is likely in case of a higher concentration limit of 150ppm.

Testing cost for concentration limit:

Several stakeholders confirmed in the second call for evidence that a cost per test of €200 is realistic. A small number of stakeholders assumed the costs to be slightly higher. A 25% higher cost (€250/test) is assumed for the the uncertainties discussion.

Sensitivity analysis:

If 10% of batches need to be tested then the resulting cost would be

3 000 – 5 000 batch tests x €200 = €600 000 - €1 000 000

If every formulation only needs to be tested once a year it would result in testing costs of an estimated

120 formulations x €200 = €24 000.

As no further stakeholder input is available in this regard the testing costs for the concentration limit are estimated to be in the

cost range: €24 000 – €1 000 000.

Testing cost for migration limit:

No migration testing costs are expected when all formulations meet the concentration limit of 150ppm BPA. However, for sensitivity, costs would be as follows if 10% of formulations cannot meet the concentration limit and all batches are tested:

3 000 – 5 000 tests x €3 000 - €5 000 = €9 000 000 – €25 000 000

Accordingly, as discussed above it is unknown to the dossier submitter whether it is necessary to test every batch. Testing formulations only once a year would result in a testing cost of

120 formulations x €3 000 – 5 000 = €360 000 – €600 000.

If up to ten% of formulations cannot meet the 150ppm limit, then the testing costs for the concentration limit are estimated to be in the

cost range: €600 000 – €25 000 000.

Administrative cost:

a) Documentation: The administrative cost of this measure is unknown but most likely negligible (see above).

b) Technical documentation of suitable measures to adhere to the migration limit: No cost in case all formulations met the 150ppm limit as suggested by several stakeholders.

In case that the information is not correct, the selection and documentation of suitable protective measures for articles which contain BPA above the concentration limit of 15ppm entails unknown cost. However, most likely those will be one-time costs.

Measures necessary to meet the migration limit value: Considering the high number of different uses and that no stakeholders explicitely commented on this subject the dossier submitter cannot conclude on this potential cost of the restriction proposal. The dossier submitters assumption is that there might be a comparably small number of uses where articles with BPA-concentrations above 150ppm lead to migration of BPA above the limit of 0,04 mg/l. However, no stakeholder commented in the two calls for evidence on this subject matter. The dossier submitter can only hypothesize from available information that most users buy protected/coated articles or apply protection/coating by themselves when severe stressors are expected during service life. Therefore at least for the majority of such uses the benefit of protecting the article outweighs the additional costs.

Shift to lower quality PC (with less than 150ppm BPA): It is unknown whether for some uses protective measures might not be possible or it may be that users cannot use the proposed measures from PC manufacturers resulting in individual testing requirements. Users might then shift to PC that meets the limit value thereby shortening the durability and service-life of an article. No further information is available but the dossier submitter agrees that this could happen.

E.4.8.3.3.: RO3 – 1 000ppm concentration limit

The dossier submitter assumes that all polycarbonate formulations/articles already comply with a concentration limit of 1 000ppm for BPA. Accordingly, negligible economic impacts arise from this restriction option.

Testing cost for concentration limit:

No stakeholder information suggests that this concentration limit cannot be met for all uses. It will not be necessary to test formulations or articles to ensure that the concentration limit is met.

Testing cost for migration limit:

No testing costs are expected when all formulations meet the concentration limit of 1,000ppm BPA.

Administrative cost:

a) Documentation: The administrative cost of this measure is unknown but most likely negligible (see above).

b) Technical documentation of suitable measures to adhere to the migration limit will not be necessary.

Measures necessary to meet the migration limit value:

No cost.

Shift to lower quality PC (with less than 1,000ppm BPA):

No substitution with lower quality PC is expected.

E.4.8.4. Uncertainties

Several uncertainties make it difficult to assess the proportionality of the three proposed restriction options. Some have already been discussed above as well as in B.8, some others are:

- Imports/Exports: The dossier submitter is not aware of reliable and detailed data on imported and exported quantities of PC, neither as starting material (e.g. polycarbonate sheets) or as processed articles (e.g. polycarbonate in imported cars). Annex H analysed different data sources and estimated that 300 000tpa PC are exported from and 100 000tpa PC are imported into the EU. This is a highly uncertain estimate. However, if correct at least three uncertainties arise from this:

    a) Information is missing whether imported articles are comparable regarding residue content and protection of material from stressors.

    b) It is unknown whether manufacturers of PC outside the EU and their downstream customers can comply with the testing requirements respectively with the corresponding requirements to protect materials and to communicate through the supply chain.

    c) The materials used and the specific uses (share of uses with stressor contact) are unknown for imports and exports. Therefore, it is unknown how imports and exports of PC impact the calculated emissions within the EU. However, considering the export surplus it is more likely that emissions for the EU are overestimated.

- The dossier submitter concluded that alternatives are not available. Limited information suggests that at least for some uses alternatives are available and affordable. Therefore it is possible that some uses of PC will be substituted with alternative materials, meaning that compliance costs resulting from testing and and additional protection of the material will not arise.

- Major uncertainties remain in regard to testing requirements: is it sufficient when testing is done upstream? Are there uses for which upstream testing and recommendations for protection of the material are not sufficient. In that case additional costs for individual testing of the migration limit might be necessary for some uses. However, no additional information is available to assess this.

- The impact of additional protective measures like coating of PC is very uncertain. No information is available regarding the potential cost of this additional effort in the manufacturing of an article. However, stakeholders repeatedly argued that BPA-leaching from articles is not desirable, because it results in a rapidly declining condition of the article and often the necessity for early replacement. Therefore, there is also a benefit resulting from need to improve protection of PC articles, however, the magnitude of this is unknown.

E.4.8.5. Proposed action

Considering the discussions in this chapter and the environmental impact of the three options, costs and benefits are summarized in Table 126. Costs are not discounted.

Table 126: Restriction options for P1 - Polycarbonates

	Costs 1 000 €/a	**Costs total** **20 years 1 000 €**	**Emissions reduced over 20 years (tonnes)**	**Cost effectiveness €/kg emissions reduced**
RO1 (10ppm)	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)	Unknown but up to 120 tonnes.	-
RO2 (150ppm)	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 150ppm limit.	Unknown but very small if all formulations already comply with 150ppm limit.	-
RO3 (1,000ppm)	A: very low one-time cost	Unknown but very low	0	-

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

High uncertainties regarding the current and future emissions of BPA from polycarbonate uses make it difficult to come to a clearcut conclusion which of the three proposed restriction options are proportionate and effective.

a) RO1 would be proportionate if a) the worst case estimate for emissions during service life is a realistic scenario, b) only limited testing is necessary and c) additional protection of materials is possible at limited cost. Considering the available information this seems unlikely. While the dossier submitter considers it likely that only limited testing of formulations is necessary he also considers it likely that an emission estimate that assumes that 60-80% of PC that does not meet the 10ppm concentration limit is averaging a concentration limit near 150ppm is very unlikely. Whether only limited additional coating of materials is required depends on whether all or most of the materials exceeding the proposed concentration limit comply with the proposed migration limit of 0,04 mg/l. Some stakeholders confirmed that this might be the case, however, overall information is inconclusive and it also has to be considered that if migration potential is limited the overall emissions from the use phase will be considerably less than the high estimate presented in the table above.

In sum, cost-effectiveness for this restriction option might fall within the so-called "grey zone" where action on environmental pollutants (PBT or vPvB) of between €1 000 and €50 000 per kg of emission avoided may or may not be approved by regulators {Oosterhuis, 2017 #1105}. There are too many unknown and uncertain variables. However, the dossier submitter argues that emissions avoided that fall between 25-50% of the worst-case estimate are a reasonable assumption. It is also reasonable to assume that only a limited number of batches need to be tested. Finally, in absence of further information additional protection of materials is assumed to be associated with affordable costs and some additional benefits (i.e. durability). Stakeholders commented that several customers already prefer coated material, meaning that additional benefits outweigh the additional costs.

b) RO2 will result in limited cost and benefit. Manufacturers of PC confirmed that they can comply with this proposed option. Therefore, the dossier submitter assumes that in principle no testing is required to certify that articles comply with this restriction option. It might be possible that manufacturers test some formulations at least once to ensure REACH-conformity. There will be no emission reductions in case the submitted information is certain. The dossier submitter argues that RO2 leads to continued emissions that are not as substantial as emissions of BPA/BosC from some others uses (e.g. thermal paper, textiles, legacy landfills). However, RO2 ensures that uncertainties in regard to imported articles will be minimized. At the moment only very limited information is available that imported PC articles comply with a 150ppm limit. In case RO2 enters into force importers need a certification that imported PC and articles containing PC comply with the concentration limit. In sum, small uncertainties in regard to PC manufactured in the EEA and larger uncertainties in regard to imported articles can be eliminated at an affordable cost making this RO proportionate.

c) RO3 has been considered because uncertainties are high regarding the proportionality of RO1 and the effectiveness of RO2. No costs and benefits are expected with a view to the use of BPA in the manufacturing of PC. Nevertheless, in case RO1 and RO2 are deemed to be not proportionate, the dossier submitter considers this concentration limit to be necessary to avert the potential use of additives especially in imported PC.

In case additional information is submitted during the public consultation for this Annex VX report that adds certainty regarding a potentially limited emission potential from PC uses and/or regarding disproportionately high costs for RO1 the dossier submitter deems RO2 to be an effective and affordable measure to ensure that current and future emissions into the environment are limited.

E.4.9. Epoxy Resins (P2)

E.4.9.1. Use (summary)

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

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

E.4.9.2. Impact Assessment

The information provided by stakeholders is not sufficient to determine whether a restriction with a concentration limit of 10ppm BPA/BosC in epoxy resins would be proportionate. The dossier submitter considers the following information provided by stakeholders in the two calls for evidence as relevant:

Stakeholder (downstream user)

- little exposure expected for adhesive products (cured, bonded and coated, or small exposable surface)
- most products contain 0.1% BPA
- no alternative due to unique performance
- products used in highly regulated and safety driven markets (e.g.automotive)
- approval time 10y - 30y (aviation)
- >100mio€ annual sales would in 3y be affected, in 10y >150 mio€

Stakeholder (trade association)

- LERs in general meet the 10ppm limit of residual BPA. SER generally contain more than 10ppm of free BPA which may result in coatings formulated with SER having a content of BPA above the 10ppm proposed limit.
- Information on weathering tests for protective coatings. Information on standards for these uses. Testing requires 6 months to one year.
- Many coatings systems have a non epoxy top coating layer. In general the coating comprises a small part of the total weight of the article.
- Some polyesters, polyurethanes or thermoplastics-based coatings could be a substitute for a limited range of applications.
- In general, the restriction leads to performance losses and related maintenance costs (no quantitative data).
- Alternatives will not be available in the short to medium term.
- Downstream users need information from suppliers on residual content to calculate worst case amount of residual BPA content.
- New standards need to be developed to cover the wide range of coating applications and service life conditions
- Compliance with performance testing today (e.g. ISO12944 /20340) is around 1 MM € per coating system.

Stakeholder (trade association)

- Claim that ER are important for Green Deal - Curing decreases content of residual BPA .

- The residual amount of BPA in BPA type Epoxy resins, which are used in wide range of application, is from below 10ppm, or exceeding 200ppm.

- At least seven parameters should be considered for comparison with alternatives: 1) Handling 2) Functionality 3) Reactivity 4) Protective properties 5) Mechanical properties - for example strength and toughness in composites. 6) Thermal properties 7) Adhesive properties.

- A large cost is required to get safety data regarding alternative epoxy resins and hardeners, too.

Stakeholder (coatings)

- In non-phenolic cured formulations, a reduction of the free BPA level to proposed levels is believed not to affect curing and performance. When replacing phenolic hardeners with low content BPA phenolic hardener it is expected that products need to be reformulated. Performance may be influenced.

- Alternatives do not offer same properties or are considered as regrettable substitution.

- Requalification costs apply for eg pipes in case of reformulation.

- Some work has been initiated including: 1) Avoid use of phenolic hardeners in new products and 2) Evaluation of low BPA containing phenolic hardeners for existing products.

- Complete transition to alternative hardeners (non-phenolic and low-phenolic) at least transition period of 5-10 years. Not clear whether 10ppm in the cured product can be met for all applications.

Stakeholder (coatings)

- Some alternatives might work in specific coatings. In some special cases, alternatives might be found but certainly not in all cases. So-called 1:1 replacement does not exist in coatings.

- If BPA will become restricted and only alternatives are available, there is no choice and prices will adapt to the new situation. In the end customers will decide if the on-costs are worth the resulting performance of the alternative. Prices of paints will increase and certain technologies may no longer be available.

- Specifications are set by customers, eg marine and aerospace coatings. Approval takes 2-5 years.

Stakeholder (trade association)

- Cured Epoxy resins which are processed into final articles do not contain nor release any significant amount of BPA. Recycling of cured resins (“thermosets”) should not lead to any significant release of BPA as BPA is chemically bound as part of a polymer matrix

- Residual concentration of BPA in uncured Liquid Epoxy Resin (LER) are below 0.00005% or 0.5ppm (see Annex f of the 1st Call for Evidence). In uncured Solid

Epoxy Resin the weighted average residual concentration of BPA is less than 0.0065% or 65 pm Annex I) Some solid Epoxy Resins in targeted applications may exceed this level. As such residual content of BPA in the vast majority of solid epoxy resins exceed the limit of 10ppm referenced as part of 2nd call for Evidence. During the curing process, residual BPA will chemically react and bind to the polymer matrix. There are no agreed upon methods to determine 'residual' BPA content in the cured resin/article.

- Solid epoxy resins contain, on average, 65ppm of residual BPA. It is not technically feasible with today's industrial scale technology to lower this content to below 10ppm. Liquid and solid epoxy resins are used in fundamentally different technology and cannot be replaced.

- Alternatives: BPF based epoxy resins have a strong tendency to crystallize which makes them unsuitable for use without heating equipment. They have a lower viscosity compared to BPA based epoxy resin, a higher epoxy number and a higher average epoxy functionality. This results in a higher resistance to solvents. They cannot be used as drop-in solutions for BPA based epoxies, even though the molecule seems nearly identical. Isosorbide glycidylether has very bad resistance to water, cured with some common hardeners, it even fully decomposes.

- Epoxy products have unique characteristics but also have an elevated price versus other solutions such as thermoplastics. If users chose an Epoxy product, they recognize and are willing to pay for the superior performance versus alternatives.

- Many possible candidates for alternatives are experimental in nature.

- As quite a significant portion of BPF-based ER is handled in a professional setting (construction, anti-corrosion coatings) the adherence to SSC is not possible and as well not required due to the very low residual content.

- BPF-based epoxy resins are used in mixtures or mixed oligomers with BPA-based epoxy resins as they confer better temperature stability at lower temperature. BPF in epoxy resins is generally not used as a replacement of BPA in epoxy resins, but as a complementary building block.

- Only a very small number of grades of semi-solid and solid epoxy resin can meet the 10-ppm residual BPA limit. A 10ppm concentration limit would affect 20 - 30% of Epoxy Resins. For the downstream value chain this could be a few 100000 tons of formulated product and dozens of applications (end uses). A limit of residual BPA of 200pm would affect a few Epoxy grades but would be more feasible.

- Cost for migration testing: A more realistic estimate for a realistic migration testing for finished articles made from newly developed epoxy resin products and over the service life of the article is likely around 50 000€.

- The stakeholder provided a very general socio-economic analysis:

- Energy Sector: The EU wind turbine manufacturing sector employs 77,800 people and over €11 billion in revenues and comprises a growing share of energy generation. In the absence of epoxy resins, blade and component manufacturers would adopt alternatives where feasible, with adverse effects on ongoing product development, with particular adverse effects on longer turbine blades and on operational and maintenance costs of the turbine itself. An estimated €4 billion market would be potentially affected.

- In electrical and energy distribution systems, they are used as sealants, coatings and adhesives, and in the manufacture of primary components such as transformers, insulators and bushings. They provide durability and performance in high-voltage systems and increase component lifetimes, decreasing the likelihood of blackouts. Direct economic costs from a 1-hour blackout in two EU regions are estimated at between €20 million and €150 million, for example. In the absence of epoxy resins, at worst these risks may increase, or be offset by increased costs from more frequent inspection and replacement

- Food and Water Sector: As protective coatings, epoxies prevent corrosion in production machinery and in cans, prolonging food shelf-life, without affecting flavor. In their absence, alternatives would be adopted where feasible. This is expected to increase food waste, where even a 0.1% increase in waste could impose costs of over €360 million per year: and

- In water infrastructure, epoxy resins prevent corrosion and leaks and extend operational lifetimes of pipes, including in-situ repair to underground pipes use of a 'sock'. Road works caused by utility companies 'activities are estimated to cost €5 billion in delays and loss of business per year in the UK alone; suggesting costs in the order of several tens of billions across the EU – even a small increase would result in significant costs.

- Transport Sector: Epoxy resins are used in cars, trucks, motorcycles, trains, boats and aircraft. They prevent corrosion, enabling lighter and more durable internal parts. In aerospace, epoxy resins have supported increased use of composite materials with improved strength, durability alongside weight reductions, improving fuel and CO2 efficiency whilst reducing repair, maintenance and replacement costs. EU manufacture and repair of various vehicles and aircraft supports turnover of €1,300 billion and employs some 3.5 million people; and without current composite materials, weight, fuel consumption and emissions of aircraft may be affected. Comparing epoxy resin savings with historical use of aluminum, for instance, suggests in the order of 4,400 million kg of fuel savings, €2,600 million in fuel costs and 14 million tons of CO2 emitted across the EU fleet of operational aircraft. In practice, in the absence of epoxy resins, both aircraft and automotive sectors would be exposed to non-EU import of final articles, if possible, with the associated loss of EU economic activity.

- Home, leisure, information & communications technology (ICT) and medical Sector

- Epoxy resins are used in various sporting equipment, in composites with glass or carbon fiber. In DIY, they are used in sealants, adhesives, mortars and for the repair of woods and plastics. Providing a strong, durable, chemical and heat-proof seal, they prolong the useful life of various products, ultimately saving expenditure on replacement goods and preventing damage from leaks; and

- Found in ICT applications, such as internal circuits, transistors and smartphones, they protect vital components from light, humidity, dust and electrical and physical shocks. In the medical sector, epoxy resins are widely used in surgical instruments, diagnostic equipment (e.g. x-ray and magnetic resonance machines) and prosthetics. In their absence, alongside economic losses amongst the manufactures, downstream users would use alternatives where feasible. This is expected to increase costs and affect the quality of final products, imposing additional costs on final consumers from damage and/or more frequent repair, including in medical applications.

- Construction Sector: Epoxies are used extensively in flooring, protecting against wear, preventing slippage and providing high chemical and abrasion resistance. In commercial construction, they provide particularly strong bonding adhesives, sealants and fillers, often marketed as replacements for mechanical fixings they are also used to repair bridge decks; and in their absence, alternatives would be used by downstream users, where feasible. This is expected to lead to loss of functionality in certain demanding applications. In turn this may affect some building maintenance frequencies – particularly high rise - with associated costs and risk from working at height. For illustration, for the 28 buildings above 200 m height in the EU, assuming epoxy resins are used in around half, just a 1% increase in repair costs could mean an additional €0.5 million cost per year. If this is extrapolated to all office floorspace in the EU28, the equivalent costs would be in the order of €350 million.

Stakeholder (coatings/paints)

- can accept traces of ~30ppm of free BPA/BosC in the epoxy resin and still achieve the <10ppm limit in the finished coating product.

- Epoxy resins are available with very low levels of free BPA (<5ppm). Cost of BPA resins with low free BPA levels is app. 20% higher than "standard" free BPA level which is up to 100ppm. Stakeholder does not expect that the suppliers can supply sufficient volume of the low free BPA level at this time.

Stakeholder (manufacturer FCM)

- Epoxy based coatings can meet the proposed limit values.

- Coatings based on copolyester can be used safely and in compliance with EU regulations in food contact applications. Typically unit cost is higher and more usage is required to achieve the same technical performance.

E.4.9.3. Proposed action

The dossier submitter cannot give a cost estimate for RO1 at the moment:

- No reliable information is available on the share of cured sSER and 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 could 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 present only a few specific hardeners with standardized curing processes and defined protection to which all downstream users then adhere to meet the migration limit.

- Stakeholders provided information that BPA and BPS residues in articles made of liquid epoxy resins amount to less than 10ppm. Residues in articles made with solid epoxy resins contain less than 65ppm 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. This means that the use of phenolic hardeners and SER shall be restricted for consumer uses.

E.4.10. Other uses of BPA in the manufacturing of polymers (P3-P13)

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

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

Polyarylates (P4): The use of polyarylates is reported by an 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.

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

Unsaturated BPA Polyesters / Polyester resins (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 – 40ppm. 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 that BPA-free alternatives exists and/or are in development. For example, alternatives are reported to be available for printing on food contact materials.

Polybenzoxazine resins (P7): No information submitted in the two Calls for Evidence. No further information available.

Phenolic resins (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 10ppm 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 10ppm limit cannot be met only refers to the mixtures or also to the enamel baked final articles.

Dental resins (P9): No information was submitted in the two Calls for Evidence. Publicly available information suggests that up to 80% of dental resins contain residual BPA. Exact concentrations in cured materials are not available to the dossier submitter. However, some information suggests that they are well below 10ppm.

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

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

Vinyl ester resins (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.

Polyacrylate (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 any uses.

E.4.11. Leather tanning (P14)

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

50% of syntans are exported, equivalent to 3,500 to 4,000tpa BPS (Ramboll Deutschland GmbH, 2021). Import of syntans was estimated as < 20% by stakeholders (TEGEWA, 2022), although this is considered a rough estimate based on prior communications (Ramboll Deutschland GmbH, 2021). A German stakeholder association reported that only one tannery imported 30% of its syntans used for leather production (TEGEWA, 2022).

According to the report provided by one stakeholder, the majority of syntan production within EU happens in three to four large sites (two of them in Germany). Approx. 3500 – 4000tpa of syntans are exported, with 700 – 800tpa being delivered to the textile industry, the rest to approx. 1,500 EU tanneries. (With approx. 2/3 of them being in Italy.) The tanneries and the textile industry are also importing an unknown amount of syntans from outside EU.

Many stakeholders state the value of BosC (BPS and BPF) residues in the finished syntan within the range of 0.1 – 3%. In cases in which BPF is mentioned separately, the concentration in syntans is usually stated to be 0.1 - 1% by weight.

The German leather industry association (TEGEWA, 2022) confirmed a 2,600ppm mean concentration of BPS in leather articles for 75% of their members. Few articles with lower concentrations at 100 – 200ppm BPS were reported in split or soft leather applications such as gloves. The stakeholder considered the share of applications with lower concentrations as very limited.

(Ramboll Deutschland GmbH, 2021) reports data from a measuring campaign that reports considerably lower concentrations of BPS in leather articles, BPS concentrations in leather articles varied widely from non detect to 1200 ppm with a mean amount of 120 ppm and 95th percentile of 800 ppm. Values for BPF were estimated to be similar for fashion application but much higher in leather for automotive applications. In sum, typical DHDPS content in leather articles is therefore below 800 ppm.

In case of entry into force of RO1 more than 80% 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. Considering the reported mean concentration of 2,600ppm BPS in leather articles RO3 would also likely result in a situation where more than 50% of leather articles can no longer be sold. However, according to the measuring campaign reported by Ramboll more than 95% of leather might comply with RO3.

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 billion.

Publicly available information suggests that syntan manufacturers are actively working on reducing the content of bisphenols in their products.

In the second call for evidence approximately 100 stakeholders from the textiles sector commented. Most of the information received is company specific. Some stakeholders provided more general input considering the European leather industry. One stakeholder provided the following information:

- Both mixtures and articles (leather and textiles, including recycled material) produced in Europe and importedproducts are affected.

- Synthetic tanning agents (syntans) have been developed to either replace or complement vegetable tanning agents (all of which contain phenolic structural elements) to reduce chemical consumption and improve leather quality. Therefore, at a minimum, 80% of chrome-free, chrome-tanned, or alternatively tanned leathers are treated with BPS- or phenol-based syntans, at least in the re-tanning step. Therefore, almost all leather products manufactured in the EU or imported into the EU market are affected by a restriction on BosC. The impact on the leather industry will have significant implications upstream (animal breeding and upcycling of animal skin versus waste arisings) as well as downstream (e.g. shoe-, furniture- and automotive industry).

- Any known technical or consumer use of leather is affected, e.g. clothing, shoes, furniture, automotive industry, machinery, etc.

- When tanning without synthetic polymers based on BPS or phenol, the resulting leather article would no longer be equivalent to the original article: Surface texture, inner fullness, softness and dyeing behaviour would change. In addition, the fastness properties and thus the ageing profiles of the leather articles would deteriorate. These are the central characteristics of a leather article.

- As more than 80% of manufactured or imported leather articles are affected, the proposed limits of 10ppm and the proposed migration limit pose a major threat to the European leather industry. The majority of current leather articles can no longer be used, which means that the small proportion of leather products that may still be compliant can no longer be economically produced and marketed.

- A Replacement of syntanes would mean a considerable step backwards in leather quality.

- In case of quality changes in products the typical approval times are between 3 and 12 months. Typical lead times to bring leather or textile articles to market are 1 - 3 years, in case of extensive testing procedures (e.g. in the automotive industry) the lead time can be even longer.

- If polyacrylates were used as an alternative to bisphenol-based leather auxiliaries, the resulting leather article would no longer be equivalent to the original article: surface texture, inner fullness, softness and dyeing behaviour would change. These are the key characteristics of a leather article. If they will be replaced by vegetable tanning agents, the fastness properties and thus the ageing profiles of the leather articles would deteriorate significantly. The low fastness profiles of vegetable tanning agents have created the need for BosC-based leather auxiliaries. In addition, the availability of vegetable tanning agents would have to be considered. On the one hand, additional farmland would be needed for cultivation, and on the other hand, the majority of these plants grow slowly. Acacia trees, from whose bark mimosa can be extracted, are ready for harvesting after seven years.

The dossier submitter asked the stakeholder to clarify some of the information provided in the Call for Evidence:

- The stakeholder clarified that roughly 80-90% of all leather articles contain BPS and/or BPF. For sub-uses 'fashion' and upholstery', 100% would be affected by a restriction.

- Only very few articles meet a concentration limit of <200ppm.

- Approximately 75% of manufacturers confirmed average concentrations of BPS of 2,600ppm for BPS and 50% confirmed an average concentration of 600ppm for BPF.

- Currently the tanning performance is directly related to the concentration of phenols in the syntans. The stakeholder reported that syntan manufacturers are currently undertaking research and development to reduce the contents of BPF and BPS. New. products are already on the market and further advancements are expected within the next 3-5 years. However, they stress that meeting a concentration limit of 10ppm is generally not possible.

- BPS and BPF content in syntans shows a large variance from less than 100ppm to more than 20,000ppm.[219] The dossier submitter asked the stakeholder to comment on whether the different syntans are for specific product groups, i.e. whether it is possible to differnitiate between product groups with typical BosC contents. The stakeholder pointed out that this is not possible and stressed that often a combination of different syntans are used to achieve specific performances and to account for different properties of the raw materials.

- No reliable data is available in regard to imported and exported leather articles.

Relevant additional information on impacts from a restriction from individual manufacturers and associations:

- Global market for synthetic tanning agents is roughly 160,000 t with a value of 240 mio €. Roughly 30% is located in Europe. BPS / BPF is only an impurity in those formulations. Global leather manufacture for which the syntans are applied is around 2 mio tpa or 2 billion m^2/a.

- In a study done in 2016 a number of leathers have already been "free of BPs". All those leathers relate to "niche" or "low end" articles like leather working gloves

---

[219] See for example https://www.smitzoon.com/en/sustainability/chemicals-bisphenol/#, 04 October 2022.

made from wet blue split, in which already today no syntans are used because of cost reasons.

- Glutaraldehyde and other reactive tannig agents do show a substantially toxicity profile, mainly focussed on workplace safety issues, but sometimes consumer and environment as well.
- Roughly 20% of global leather manufacture is sold into automotive, public transport, aerospace and similar industries. Approval schemes have to be considered.
- Economic impact will be driven by business loss and/or redevelopment of production processes and be bigger by several orders of magnitude.
- On top of a more redundant residue control at the site of the chemicals manufacturer, analysis will need to be established at the leather / textile manufacturer or importer resulting in a more complex analytical matrix. Systems in principle are in place from voluntary commitments in the textile & shoe industry (e. g. Öko-Tex), an additional analytical run would need to be added.
- Syntans are water-soluble formulations of chemicals. Migration testing is equivalent to concentration testing.
- Time for substitution required is estimated 12 years when alternatives are available.
- Stocks can be used for up to 10 years: exemption for this timeframe needed.
- Restriction as it stands would end the leather industry in the EU and cost 392,000 jobs.
- Syntane manufacturers may be able to provide syntans with <500ppm BosC: this would lead to cost increase of chrome tanned leather of 0.08€ per m^2 and 0.15€ per m^2 chrome-free leather.
- If syntans stay the same, but tanning process is optimized to meet limit value, high quality leather for automotives, aircrafts and furniture could no longer be produced in the EU, export of hides and import of leather products increase CO_2 emissions, disadvantage of EU tanneries.
- The high-end segment is estimated to be 25% of Europe’s production, followed by the medium-to-high-end segment with 34%. The use of European leather acts as a driver in the creation of value by downstream manufacturers.
- Almost €8 billion of leather manufactured in the EU generates a turnover of around 125 billion, providing work for over 40 thousand companies and 2 million employees.
- The cost for testing would be unsustainable for most SME leather companies. 1 tonne of hides may produce 150 m^2 leather to be sold at 20€/m^2 amounting to 3000€ salesprice, with 1000€ costs for migration testing sales prices would become unsustainable.
- Syntans manufacturer: possibilities for reduction of bisphenol F residues are known. According to the stakeholder’s calculations, the 0.04 mg/L migration limit can not be reached. Since most of the leather articles could not be made, stakeholder would sell much less chemicals. A decline of about 80% is estimated.

- One Stakeholder reports on R&D trials that are focused at reducing the content to <1,000ppm from leather. First investigation showed that the BPS content could be decreased to 100-1,000ppm from leather with some modification on the chemistry of the syntans. However, it still debatable wether such modification can allow the technicians to obtain the leather article in compliance with the technical requests. By 2024 a possible technical solution to decrease the BPS content to 500ppm from the syntans could be feasible and that could be implemented at an industrial scale. Alternatively, it is possible to reconsider the utilisation of natural tannins, although this will bring issues on costs and sustainability of the entire process. If the stakeholder would actually switch to natural tannins the costs and the production of the leather articles will change (technical issues).

- If the concentration limits will pass into regulation, additional cost increase can be estimated to +7% for the purchasement of the alternative raw material. In addition, it is still debateble wether the alternative raw materials might be available to satisfy the chemicals demand.

- One stakleholder currently can't comply with 10ppm concentration limit, since current BosC values are in a higher range of mg/kg. This can be reduced in the next few years, but it is unclear to exactly which quantity. However, this depends on the tanning, less for chrome leathers, more for pure chrome-free leathers. Stakeholder cannot comply with it if they want to achieve fastnesses.

- One trade association stated that concentration limits are impossible to reach without impairing the fastnesses and performance of chrome-free, chrome or any alternative tanned leathers which are all retanned with sulphone and phenol based syntans. Available technology can ensure at best mixtures containing up to 3,000 mg/kg, which would make some 200 mg/kg in leather. Chrome-based tanning processes may need less BosC than chrome-free ones. Such leathers will significantly exceed the proposed limits, but possibly less significantly than chrome-free and vegetable tanned leathers. Vegetable tanning processes also rely on retanning with BPF and BPS and show concentrations of BosC above the 10ppm limit.

- This means that today - except for very small niches - all sales of leather in the EU risks not to be compliant with the proposal.

- Global leather production in 2014 was 558,4 thousand tons of heavy (vegetable) tanned leather, 14,540 million sqft of light (Cr and Synthetic tanned) bovine leather, 5,367 million sqft of light sheep & goat leather, 4,565.8 million pairs of shoes with leather uppers. Value of the leather and leather footwear trade in some 76 billion USD on average every year (2012-2014). Today the trade in these goods has increased; the data are outdated. They do not include the production and value of leather clothing and gloves, leathergoods, leather furniture and leather car, yacht and train interiors. The value of the goods that will be affected by the proposed restrictions on BosC can reach several hundreds million Euro and put the livelihood of millions of people working in this sector at risk.

- The restriction as it is proposed risks to reduce substantially the types of leather that are currently produced, sold and consumed in the EU. European Tanning Industry has about 1,600 tanneries generating an annual turnover of 7-8 billion Euro and providing direct employment to some 34,000 people. It is estimated that the inability to produce leathers with the qualities that are demanded by their customers will lead to a substantial reduction of these figures. Individual tanneries losing about 50% of their turnover will not be able to survive.

Considering the available information, the dossier submitter notes:

- RO1 and RO2 would according to the majority of stakeholders lead to the cessation of most leather production in the EEA considering current practices. Most likely the vast majority manufactured and placed on the market exceeds a concentration limit for BosC of >150ppm.

- Impacts cannot be quantified. Stakeholders predict job losses of >10 000 – 2 000 000. Turnover for leather products manufactured in the EU is >8 billion €. Information on profits is not available.

- Several stakeholders provide information that BosC content in leather articles can be reduced considerably. A general concentration limit of less than 500ppm is considered as not achievable. According to some stakeholders a reduction can be achieved in 5-10 years. Some articles might still not meet a concentration limit of 500ppm. Time needed for certification and re-qualification is estimated to be 1-3-years for most uses.

Considering the very large emissions of BosC from leather textiles and considering that no other options are available to minimize direct emissions to the environment the Dossier Submitter considers a restriction on the manufacturing and placing on the market of leather articles exceeding a concentration limit of 500ppm for BosC as necessary. However, current stakeholder information is inconclusive. Although several stakeholders stated that they expect to be able to reduce the BosC content only some stakeholders stated the value of 500ppm as achievable. Some stakeholders argued that for uses where higher performance standards are required higher BosC concentrations are required. The dossier submitter received no helpful information that describes for which specific uses a higher concentration limit would be justified.

The dossier submitter therefore proposes a higher concentration limit of 500 ppm for a transition period of 5 years. Syntan manufacturers and tanneries are already working on reducing the BosC content in syntans and leathers. Considering that the restriction is not likely to enter into force before 2025 the Dossier Submitter assumes that the economic impacts will be limited. Syntans with reduced BosC content will be available to comply with the proposed concentration limit.

However, in order to assess the proportionality and whether specific additional derogations are justified stakeholders (leather tanners and syntans manufacturers) must provide additional information on ongoing research and development and timelines. On the basis of this additional information it can be discussed whether the derogation with the higher concentration limit needs to be extended.

No derogation is needed for the manufacturing and placing on the market of the syntans since it is expected that syntans are processed in closed loops.

As discussed in Annex B.8, during the tanning process BPS from syntans is partially taken up by the leather and partially remains in the processing water. In case the processing water is processed in WWTP emissions can be reduced considerably. Therefore the dossier submitter proposes that process waste water must either be pre-treated and/or treated via waste water treatment plants to ensure a high removal rate before it can be delivered to surface water bodies. No stakeholder information is available on current wastewater treatment practices.

E.4.12. Colour fixers for Polyamides and other texiles (P15)

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

In 2018, 3.1 million tonnes of synthetic fibres were produced in the EU (including Turkey). 13% of which were polyamide, equal to 403,000 tonnes of polyamide fibres being produced in the EU in 2018 (European Environment Agency, 2021).

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 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 polyamide (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.

The dossier submitter concludes that RO1 would lead to the complete loss of business for 80% of polyamides. RO2 most likely would lead to the same impact. The concentration limit proposed for RO3 is achievable for polyamide articles, possibly partly at the expense of colourfastness.

The following information from the two Calls for Evidence was considered:

- As there are no alternatives for the post-treatment of bisphenol-based polyamide, the use of polyamide fibres in Europe is in question
- Closure of textile companies specialized in polyamide finishing is expected (U.B. medical sector, postoperative tromobosis stockings).
- In the textile industry the proposed restriction could affect the recycling of Polyamide. If there would be an impact, it will depend on which type of recycled polyamide is considered. Recycled polyamide is often dope dyed (in that case no impact).
- Residues of unreacted BPS in the final mixtures amount typically to 1 – 5%. In Phenol-based products the concentration of free BPF can be over 0,5%. There is no data available on the amount of BPF which is incorporated in the polymer.
- One stakeholder expects that the concentration of BPS residues in the chemical products cannot be reduced to level which allows a use on polyamide below the limit values. Therefore, stakeholders do currently not attempt to minimise BosC residues. No information on what would be possible is available.

- Typically articles are apparel, home textiles and outdoor articles. The service life ranges from a few years to 20 years for e.g. outdoor articles.

- Typical conditions which could lead to fatigue are e.g. washing, water (e.g. sweat, rain, etc) and sun light. Free BosC in the articles are expected to be released during the initial period of use, e.g. by washing. The stakeholder does not expect that it will be possible to minimise the release of BosC in an economic way.

- The dyeing of polyamide in medium to deep shades requires any kind of after-treatment in most cases. Otherwise, the colour fastness will not meet common expectations of the market. Without improving the fastness, a consumer would face a rapid fade-out and possibly a staining of other articles during laundry. A shift from polyamide to polyester articles might be the result. But polyamide cannot be replaced in a wide range of applications. Due to the expected unavailability of PA after-treatment agents the market of polyamide dyestuffs will likely see a massive decline.

- It should be noted that the textile market is strongly driven by inhouse requirements of the major brands. They maintain own so-called Restricted Substances Lists (RSLs). The RSL limits have to comply with the legal requirements for all their markets. The brands do not differ between the sales region but want to have aligned global requirements. If the proposed limit will come into effect, probably many major brands will list this requirement in their RSLs. The transition phase is often < 1 year.

- Phenol-based after-treatment agents are available as alternative to BPS. But they contain a certain level of BPF. Although the concentration is somewhat lower than for BPS, they will also not be able to meet the proposed limits on textile. Furthermore, they contain free phenol that is of concern for the human health.

- Total world market of textiles made out of polyamide - 5.6 mio metric tons.

- The residual concentration does not lead to any effect or function on textile materials. The values of BPS are in the range of 100 – 1,000ppm.

- One stakeholder reports use for polyamid/polyester/spandex textiles, as an additive, dye fixation agent. No further information was submitted if those are separate uses or whether polyamide textiles containing also elastan/polyester/spandex are meant.

- Polyamides restriction lead to a rejection of products certified via standards (e.g. no longer suitable for Standard 100 by OEKO-TEX, bluesign, GOTS, etc.).

- Elastan fibres have also a problem with residues of BosC.

- Impacts: Closure of textile companies specialized in polyamide finishing (U.B. medical sector, postoperative tromobosis stockings...) - Ban on wind power, aircraft construction ......(CFK materials)- Ban on textile recycling or a textile circular economy.

- Imported goods may be able to meet threshold values for products via washing processes.

- Main use of polyamide fibers in the EU are: Outdoor garments, sports and swimwear, underwear, corsetry, fine stockings, socks, medical products (e.g. compression stockings), home textiles (with carpet and automotive sector).

- No more fixation of the dyes on the polyamide fiber will be possible. Since there are no alternatives to anionic after-treatment agents based on BPS or phenol, polyamide dyeing may no longer be after-treated (fixed) in the EU, then the result is: No high quality PA articles can be produced; No high color fastness achievable; Strong color lightening after a few household washes, with household washing detergents, color transfer by soiling of the detached dye onto other garments, Poor contact fastnesses such as perspiration, water, seawater and chlorine fastnesses. Probable skin irritation due to detached dye when worn.

- Considering the very large emissions of BosC from polyamide textiles and considering that no other options are available to minimize direct emissions to the environment the dossier submitter considers a restriction on the manufacturing and placing on the market of polyamide articles exceeding a concentration limit of 10 ppm for BosC as necessary. However, current stakeholder information is inconclusive. Some stakeholders stated that they expect to be able to reduce the BosC content only one stakeholder stated a value of 100 ppm as achievable. Some stakeholders argued that a reduction of BosC content would result in severe losses of quality and possible side-effects like skin irritation or color transfer onto other garments during washing. However, in order to assess the proportionality and whether specific additional derogations are justified stakeholders (leather tanners and syntans manufacturers) must provide additional information on ongoing research and development and timelines. The dossier submitter needs more information:

- - Why are natural fibers such as organic cotton, linen, and hemp, regenerated cellulosic fibers[220] such as lyocell, cupro, and modal no feasible alternatives?

- - Are derogations needed for certain technical textiles? Why do these technical textiles need to be of high colour fastness?

- - Stakeholders cited concentrations between 100-1 000 ppm. What are the technical reasons for the higher concentrations?

E.4.13. Additional uses

The dossier submitter received inconclusive information on some other uses. In order to evaluate the socioeconomic impacts more information is required. The dossier submitter expects that stakeholders will submit additional information in the publich consultation.

- One stakeholder reported the use of BPA and BPF in abrasives. No further information on concentrations is available. However, it might be possible that this use is related to epoxy resins and that impacts in regard to RO1-3 are already covered in the corresponding chapter.

- Stakeholders reported the use of BPS as a monomer to manufacture polyethersulfone resins. A concentration limit of 200ppm is considered as achiveable (actual >1,000ppm). 10ppm is technically not feasible. There are no

---

[220] Cf. e.g. https://www.panaprium.com/blogs/i/sustainable-synthetic-fabrics

existing non-BosC-alternatives. The stakeholder currently tests if 40 ppb are achievable.

- Use of polyarylene sulfones for membrane manufacturing, filters are used for (industrial) watertreatment purposes; no information onpercentage of BPS present as residual in the product is available, BPS polymers play an essential role in the membrane filtration market. BPS offers a better chemical stability (in oxidizing conditions) as BPA. The majority of membrane filters are based on BPS/BPA type polymers. Alternatives are not technically feasible for the stakeholder if BPS is to be restricted company is expected to cease to exist. Alternatives would be PFAS-based.

E.4.14. Spare Parts

Stakeholders stated that complete derogations for spare parts in automotive uses, electronis and medical devices are necessary. No additional information on costs and use quantities were provided. The environmental impacts are unknown. The dossier submitter notes that similar derogations were justified in previous restrictions but is of the opinion that a derogation cannot be justified without further information.

E.5. Human health and environmental impacts

E.5.1. Risk reduction capacity

The focus of this chapter is on processing and service life and the resulting environmental emissions. In the use phase, the (ready-to-use) mixtures and their application are addressed as well as articles. The reduction potential in the manufacture and formulation of BPA lies more with the IED. The EOL step is also, in terms of the process, outside REACH. Only when the recycled materials re-enter the service life are they subject to the specifications of this restriction.

BPA is an inherent degradable substance that does not remain stable for a long time even in the air compartment (see therefore chapter B.4.1.1). 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 do not need to be derived due to the availability MECs, which is sufficient for the presentation of the evidence at this point, as any emission carries a risk. BPA is emitted always and everywhere. Even if these are small inputs from every single possible use, no main input pathway or use can be identified, but it is clear that the totality of all uses of wide dispersive leads to this unacceptable situation. For the protection of the environment, no safe emission level can be derived due to its endocrine disrupting properties. Any exposure of environmental organisms must be avoided. It is imperative to apply the precautionary principle for these SVHC substances.

As main results the following findings on what is known about emission sources can be summarized:

- Predominant sources: processing and service life (Annex H)

- Major releases in the consumer stage (= consumer uses and professional uses – continuous wide dispersive);

- Main contributing pathway is municipal waste water

- EOL landfill contribution
- Identification of individual contribution of product classes from use phase not possible due to lack of data
- Minor source: Industrial processes (shown by Registrant´s Dossier)
- Release is likely in all three main uses (P, A, C)

From the available data for BPA, it becomes clear that the restriction at the lifecycle steps service life and processing, achieves the greatest effect (90%). At the EOL point (2%), recycling can remain possible without restrictions. The application of the requirements under REACH becomes necessary again with the placing on the market or the service life of the product/mixture made from recycled material. At the point of production of BPA or processing as an isolated intermediate product as a formulation step in industrial plants, the reduction potential seems to be exhausted by applying risk reduction measures and showing the respective reduction potential of the individual measures (8%). This area can be monitored by the IED. The adaptation of the BREFs for the production/processing of BPA/BosC and the corresponding obligation of monitoring or surveillance harbour an additional reduction potential outside REACH.

90% of the emitted tonnage must be avoided. As surface waters are most affected by chemical pressure from BPA/BosC, the restriction success targets this compartment. The target is to achieve 0.01 µg/L (assumption of the LOD) instead of 0.3 µg/L detectable BPA in surface water. The goal is thus to reduce the environmental concentration in relation to surface waters by 97%."

Impact discussion

Starting level: Monitored environmental concentration (MEC): [see B.4]

BPA - Surface water: 0.27 – 0.53µg/L [95th%ile **0.3 µg/L**]

BosC – Surface water: **0.4 µg/L** [highest BosC concentration of BPS]

Target level:

BPA/BosC – Surface water: **0.01 µg/L**

Theorethical reduction capacity:

97%

In order to be able to investigate the reduction potential of BPA/BosC, it must be clarified in advance at which life cycle step the release occurs, to what extent and whether this restriction applies accordingly. The following table visualises this necessary information.

E.5.1.1. BPA

Table 127: Estimated total emissions per life cycle stage base scenario comprising publicly available data without use for thermal paper

Life cycle stage	Absolute	Portion of Total
Manufacture	**6.0tpa**	**7.6%**
Processing	44.1tpa	55.5%
Service life	**27.3tpa**	**34.4%**
End-of-life	2.0tpa	2.5%
sum	**79tpa**	

Reduceable tonnage during processing and service life (considering data from Annex H):

79 tpa – 6 tpa (manufacture) – 2 tpa (EOL) = 71 tpa

79 tpa result in 0.3µg/L MEC

71 tpa therefore result in 0.27 µg/L PEC

With ca. 97% reduction required, only 3% of the tonnage can still be allowed to enter the environment!

3% corresponds to *2.3 tpa*

Contribution estimation on emission

After main use (according base sceanario):

P - 13%

A - 86%

C - unknown

After lifecycle-step

Manufacture: 8%

Processing: 56%

Service life: 34%

EOL: 2%

1) ***Proposed restriction option 1: content of max. 10ppm "free BPA+BosC" or 0.04 mg/L migration-limit***

- PC 15% outdoor use, 150ppm residues → 10 ppm: means reduction of 95% (Migration 0.04 mg/L → 5ppm: means 97%) for 15% articles during service life:

  - **tonnage based PC** (1,242,000 tpa consumption 150 ppm): 1,242,000tpa *0.00015*0.15 = 28 tpa

  - **tonnage based PC** (1,242,000 tpa consumption 10 ppm): 1,242,000tpa *0.00001*0.15 = 2 tpa

  - **evidence based** (emission from PC 1tpa): 1tpa from polymers containing 150ppm → x tpa from 10ppm; x=10*1/150= 0.07 tpa

- ER 21% outdoor use, 25 ppm residues → 10ppm: means reduction of 60% (Migration 0.04mg/L → 5ppm: means 80%) for 21% ER articles during service life:

  - **tonnage based ER** (300,000tpa [sumBPA+BPF] consumption 25ppm): 300,000tpa *0.000025*0.21 = 1.6 tpa

  - **tonnage based ER** (300,000tpa [sumBPA+BPF] consumption 10ppm): 300,000tpa *0.00001*0.21 = 0.6 tpa

  - **evidence based ER** (emission from ER 10tpa): 10tpa from articles/coats containing 25ppm → x tpa from 10ppm; x=10*1/25= 0.4 tpa

- Other:

  - use as additive impossible (except covalently bound additives like e.g. crosslinkers)

  - other polymer materials: no deviating residuals known

  - imported products addressed

  - processing exemption if no water contact, no direct release to environment

  - indoor use: no water contact, no emission

- Impact additives: total restriction additive use BPA/BosC (known impact on TP, leather, lubricant, greases…) – unknown impact on textiles → additives includes into matrix addressed but residuals varying (e.g. hardener 400 ppm - 6%)

- point sources (processing): only considered if process water considered with mitigation measures

- indoor use: like washing textiles – considered assuming maximum residuals, but unknown impact, due to small amounts in textile but huge impact on environment due to 100% leaching [only impacted if additives are restricted namely]

2) Proposed restriction option 2: content of max. 200 ppm "free BPA+BosC" or 0.04 mg/L migration-limit

  - **tonnage based PC** (1,242,000 tpa consumption 150 ppm): 1,242,000 tpa *0.00015*0.15 = 28 tpa

  - **evidence based** (emission from PC 1tpa): 1tpa from polymers containing 150 ppm → x tpa from 150 ppm; x = 200*1/150 = 1.0 tpa

  - **tonnage based ER** (300,000 tpa [sumBPA+BPF] consumption 150 ppm): 300,000 tpa *0.00015*0.21 = 9.5 tpa
  - **evidence based ER** (emission from ER 10 tpa): 10 tpa from articles/coats containing 25 ppm → x tpa from 50 ppm; x=200*1/25= 8 tpa

- Other:
  - use as additive impossible (except covalently bound additives like crosslinker)
  - other polymer materials: no deviating residuals known
  - imported products adressed
  - processing exemption if no water contact, no direct release to environment
  - indoor use: no water contact, no emission
- Impact additives: total restriction additive use BPA/BosC (known impact on TP, leather, lubricant, greases…) – unknown impact on textiles → additives includes into matrix addressed but residuals varying (e.g. hardener 400ppm - 6%)
- point sources (processing): only considered if process water considered with mitigation measures
- indoor use: like washing textiles – considered assuming maximum residuals, but unknown impact, due to small amounts in textile but huge impact on environment due to 100% leaching [only impacted if additives are restricted namely]

3) total restriction additive use (restriction content <1,000 ppm)

- no/low impact on Polymer use (syntans may still cause emissions qualitatively)
- 100% addressing additives (87% total emission BPA – BosC data in progress)

  → ***0.86*71 tpa = 61 tpa BPA addressed (concern ENV concentration: 0.3 µg/L*0.86=0.26 µg/L – measurable: 0.04 mg/L)***

- Exemptions needed for inclusion into matrix e.g. hardeners (crosslinker)

Table 128: Estimated total emissions with lower and upper values concerning additional available data for BPA

use	Base scenario	Lower scenario	Upper scenario
(A) Additive use	128 tpa	121tpa	185tpa (but may qualitatively significant higher)
(P) Polymer use	unknown	1.5tpa	17tpa
(C) Chemical use	unknown	unknown	unknown

These emission data differ from the results in Appendix H, as additional information from stakeholders was taken into account. However, these data still show the relevance of BPA from TP in the recycling loop.

E.5.1.2. BosC

Table 129:Summary of emissions of BosC general estimate (base scenario)

Life cycle stage	Absolute	Portion of Total	Life cycle stage
Manufacture	0.06tpa	**7.6%**	Manufacture
Processing	0.44tpa	55.5%	Processing
Service life	0.27tpa	**34.4%**	Service life
End-of-life	0.02tpa	2.5%	End-of-life
sum	0.79tpa		sum

With the input of the information from the stakeholders, the assumptions could be specified and the emissions were also derived more precisely.

Table 130: Summary of emissions of BosC with stakeholder information

BosC	Main use	best estimate
manufacture BosC		0.06tpa
BPS	P	437tpa
	A	120tpa
BPF	P	437tpa
BPAF	A	2.4tpa
BPB	P/A/C	
Sum*	P/A	559.4tpa
share P 78%		
share A 22%		

* Since the shares in P14 and P15 are not clearly attributed to BPS or BPF, 328tpa correspond to either BPS or BPF.

A best estimate value of **560 tpa** 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 accounting for a mixture of BosC was depicted here.

E.5.2. Human health impacts

Not considered in the scope of this dossier.

E.5.3. Environmental impacts

The visualisation of emission paths and distribution pathways shown below can help to show the determination of the restriction at this point. In principle, the 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.

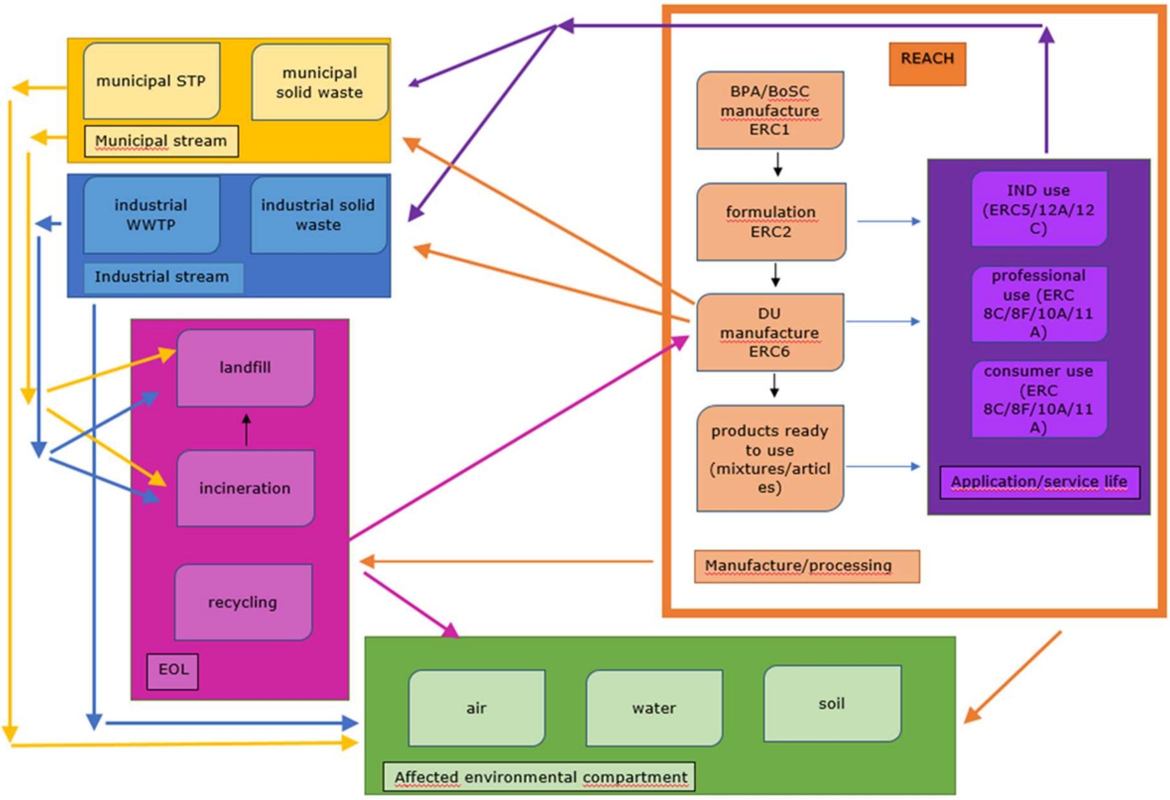


Figure 19: BPA/BosC pathways or corridors of influence during lifecycle

In order to arrive at a comprehensive assessment of the contents in materials and to obtain an overview of the release potentials of BPA, a research project was initiated in the run-up to the restriction, which was primarily intended to work out these questions in a structured manner. This resulted in the following data, which serve to derive the base scenario data.

Using the additional scientific data and stakeholder information, the lower and upper scenarios for the individual uses were derived below.

Direct-indirect

Reduction of the environmental pressure

Against this background, a straight-forward approach to estimate the emission behaviour of BPA from materials is described here. The approach is based on the assumption that all materials have either the same threshold value for residual BPA or are "free" of BPA. Product-specific emission calculations based on residual BPA content, specific leaching rates and extrapolated emission quantities for exposure estimation could then be dispensed with. Since the main emission sources are shifting away from the processing phase to the use phase, large emission quantities from PVC production and also thermal paper production/recycling (use of BPA as an additive) are eliminated. However, in terms of environmental concentrations, there has been little change. The majority of surface waters, for example, are exposed at a level of 0.3 µg/L (for details see Annex B.4). Possible explanations may be:

- Even though PVC is not registered, processing/application still takes place
- TP is still in the recycling loop
- TP/paper products continue to release BP
- emissions occur from the use phase of products, possibly because the material varies in quality or equipment
- or more goods are imported than known, which could increases emissions from products

The mitigation options for releases from the BPA manufacturing process and formulation appear to be exhausted due to the measures taken at the facilities. They are thus less within the scope of the regulatory options under REACH (but rather implementation IED), as are the emissions from the EOL step (subject to WFD) of articles consisting of or containing/releasing BPA. However, the proposed regulatory measure under REACH has indirect consequences for all life cycle stages and especially in the EOL, as the release potential is reduced there.

E.6. Other impacts, practicability and monitorability

E.6.1. Social impacts

No additional information is available.

E.6.2. Wider economic impacts

No additional information is available.

E.6.3. Distributional impacts

No additional information is available.

E.7. Practicality and monitorability

In order to be able to assess the release potential of BPA and Bosc, various sources were investigated, discussions held with stakeholders, own research[221] carried out and two calls for evidence launched.[222]

All sources confirm that release to the environment is possible. However, they vary significantly in the estimated magnitude of released emissions, or to what they refer to, e.g. surface or article weight. Generic emission estimates as in the RegDossier and Annex H indicate a tonnage in the five-digit range (10,000-99,999 tpa). Only by applying the refinement of evidence-based data, the theoretical release is shifted into a range of 60 (Ramboll Deutschland GmbH, 2022) to 79 tpa. This was also shown by Ramboll working for Plastics Europe Publication. When these input values are applied to distribution simulation models, the results are comparable to the concentrations in surface water as found in monitoring data (Annex B.4).

As evidence-based data have shown, during the processing phase and the use phase 90% (related to portion of total in table 2) of the emissions are caused and thus that is where the greatest potential for reduction lies. The remaining 10% relates to the manufacturing phase and the end-of-life phase.

Table 131: Estimated total emissions for BPA and data gaps per life cycle stage (evidence-based scenario comprising publicly available data)[223]

Life cycle stage	Absolute[1]	Relative[2]	Portion of Total
Production	6.0	6.0 t = 0.00048% of 1,242,000 t	7.6%
Processing	44.1	44.1 t = 0.0036% of 1,242,000 t	55.5%
Use	27.3	27.3 t = 0.0022% of 1,242,000 t	34.4%
End-of-life	2.0	2.0 t = 0.00016% of 1,242,000 t	2.5%

---

[221] See Annex H; registration Dossier (ECHA dissemination site); Ramboll SFA (Ramboll I-III)
[222] Via ECHA: https://echa.europa.eu/de/hot-topics/bisphenol-a
[223] See Table 18 in Annex H (Annex H)

; 1: Values are given in tons as lifetime emissions from products that had entered the market in the reference year 2020 (see **Error! Reference source not found.**). Several values may be interpreted as lower boundaries, as for some emission pathways no emission rate could be extracted from the identified sources (see **Error! Reference source not found.**, **Error! Reference source not found.**, **Error! Reference source not found.**, **Error! Reference source not found.**).
2: Emission as the portion of the amount of BPA that was consumed for the respective use (see **Error! Reference source not found.**, **Error! Reference source not found.**, **Error! Reference source not found.**)
Source: BioMath

The way to reduce the environmental concentration is to limit the release potentials from the whole life cycle of bisphenol A and BosC. This can be achieved through the limation of the content of BPA/BosC in articles and mixtures and/or through the specification of maximum release (migration) levels from products. In this context, the determination of marketability through content and/or release analytics has been developed. Various investigations of toys, food contact materials and products made of polycarbonate show that it is possible to comply with such limits. Due to the lack of knowledge about the safety of imported goods, this regulatory step should also apply to imported goods that may release BPA/BosC. A wide range of products for DIY applications, e.g. epoxy resins, are also under concern. No protective measures can be prescribed in a binding manner, nor can the production or the disposal of residues be guaranteed to a safe or precautionary extent. Thus, regulation should also apply here. However, since no analysis can be carried out, it is advisable to manufacture DIY products BPA-free, unless the pre-formulations fall below 10ppm BPA.

E.7.1. Methods for determining the content and/or release of substances from articles/mixtures into the environment during their service life

E71.1 Background

For the determination of the contents in articles or mixtures, only batch to batch analysis shall be applied.

When recording the release potential (due to migration/leaching) in the event of the present content of BPA/BosC in the article/mixture being exceeded by >10ppm, three steps must be taken.

a) In the first step, the stressing must be carried out according to the foreseen use,
b) followed by the recording of the release, in particular the migration.
c) Finally, the medium, in particular the eluate, must be analyzed for the analyte to determine the content.

E7.1.2 Methodology for determining the release (migration/leaching)

A number of different experimental methods can be used to estimate emissions during the life cycle of chemicals from articles and mixtures These include laboratory tests under standardized conditions and field tests under natural weather conditions. Based on this, mathematical models are also available to describe the migration of substances to the surface of articles and ultimately into the environment. Such models can be used to support migration test design or if plausible to argue that the conditions of the restriction are met. Concrete experimental experience is already available for numerous chemical compounds in different articles.

In order to test the emission behavior of substances of concern from articles, tests are usually performed in the laboratory, with the test methods being primarily directed at the suitability and durability of the articles/materials (performance). In some cases, these methods were then further developed to also determine the emission behavior of hazardous substances into the environment.

In laboratory experiments, small test specimens of the material or glass plates coated with a material (e.g. paints, coatings, films) are usually immersed in water at certain intervals and dried again, or else continuously exposed to water over specified periods. From the measured substance concentrations of the eluate (mg/l), the emissions over a short period of time (e.g. 30 days, time-lapse test) can be represented graphically as a cumulative emission for this period. Likewise, the emission of the target substance can be calculated in relation to the area of the test specimen (mg/m^2) and a flux rate ($mg/m^2/d$) can be derived for the target substance per unit of time.

Laboratory tests cannot reflect the real environmental conditions to which a material and the substances it contains are exposed during the use phase. However, they do provide, as a first step, an idea of the degree of release from the material under test conditions. However, they can be used to describe the leaching behaviour of a substance depending on the nature of the matrix and also allow comparisons in the retention behaviour of different substances.

A number of experimental studies are available for the assessment of the leaching of biocides from different material (Schoknecht et al., 2016) and priority chemicals from urban catchments (Björklund et al., 2009; Rule et al., 2006). In addition, there are also results on emission behaviour additives from construction materials, where the leached chemicals are measured in run-off after rain events (Burkhardt et al., 2011). These methods should be adequate to simulate stressors for BPA containing materials too since they also test factors such as the composition of the product, the availability and transport of water and the UV exposure of the coatings and they are also suitable for comparing the emission behaviour of different substances under standardized conditions (Schoknecht et al., 2009).

Leaching tests could be developed from performance testing. One example is the CEN standard EN 84 (EN 84, 1997) which tests the ecotoxicity of a wood preservative to fungi and insects after repeated water contact using small wood samples. If the resulting leachate is analyzed for the biocides applied, information is also obtained on their emission behaviour. These simple tests were later used as a starting point to derive specifications for the emission behaviour of hazardous substances under laboratory conditions and in the field (ECHA, 2017b).

Semi-field tests follow the same principles as the leaching tests in the laboratory, but here larger test specimens of various materials are exposed on a weathering rack (Schoknecht et al., 2012). Depending of the materials of interest and the data required, the test specimens are exposed horizontally or vertically (NT Build 509). The duration of the field or semi-field study should reflect the exposure situation and enable an extrapolation to the service life of the treated article. For polymers, it has to be taken into account that leaching rates can vary quite significantly depending on the type of polymer, the type of incorporation or coating and of the use (ECHA, 2017a).

Overall, field and semi-field tests are more complex to perform and require a longer period of time as well as a larger number of analyses of the substances of interest. However, since they are carried out under actual environmental conditions and other stressors are involved in addition to water contact, the emissions determined are more realistic than those from laboratory tests (higher tier assessment). Results from the field experiments by Schoknecht et al. (Schoknecht et al., 2016) indicate that competing processes mainly occur during summer, and increased amounts of target substances can be observed in runoff samples during autumn again. Moreover, the analyses of the field test data have shown that the runoff is the most crucial influence factor on the emission in field experiments. The analyses have also shown that the temperature and the global radiation have a crucial influence as well.

In addition, there are a number of different approaches beyond data from leaching studies to calculate emissions of substances during the life cycle of different materials by extrapolation. Schoknecht et al. (Schoknecht et al., 2016) investigated the leaching behaviour of various biocidal substances on a range of different materials and used a mathematical model to extrapolate data from laboratory tests. The semi-analytical model fits the specific emission curves obtained in laboratory experiments for almost all substances investigated and treated articles as well. Emission curves from field data can be fitted well by means of linear weighted regression models. Burkhardt et al. (2019) developed the COMLEAM software to derive the emissions of pollutants from building facades under the prevailing environmental conditions into different environmental compartments. Tietje et al. (2018) used this simulation model for different field tests with plastered facades and concluded that a prediction of emissions was most successful with a logarithmic emission function.

The experimental methods and extrapolations presented here can also be applied or further developed in a similar way to describe the emission behaviour of the substance group of bisphenols.

Example test developed for BPA

Vermeirssen et al. (2017) used eluates of BPA from anti-corrosion coatings based on epoxy resins for testing in bioassays against various endpoints with specific effects (e.g. nuclear receptor transactivation, inhibition of photosynthesis, water flea reproduction).

Tests developed for stability assessment of plastics

To predict the service life of plastics, they are either aged in time-lapse tests or examined directly in the open air. As a rule, these tests are necessary to check the respective stability requirements depending on the application and to better equip the materials against stressors in the respective areas of application. Testing the stability of a plastic is considered an ageing criterion in practice. From these tests, the eluates can also be examined.

There are several stability, leaching and analytical standards for determining stability and material equipment requirements. Therefore, if levels of BP(A) in articles need to be analyzed to ensure marketability during service life, some standards are available. A single example are International standards and tests for material testing in the construction sector according to the purpose of use (ASTDM or ISO).

E.7.1.3 Testing – for residuals and migration

Analysing residual content[224]

Residual levels of BPA/BosC need to be determined in all samples in order to estimate the potential diffusion-controlled release of BPA/BosC from each sample. Subsamples (double determinations) of about 1 g of each polymer should be dissolved in 20 ml methylene chloride according to Biles et al. (1997). The solutions can be left at room temperature for 24 hours until complete dissolution of the polymers. Precipitation of dissolved polymer needs to be done by addition of 20 ml methanol (MeOH). The extracts then should be centrifuged (4500 rpm in 10 min, 10 °C) and filtered. The level of BPA/BosC can be determined in the extracts by liquid chromatography mass spectrometry, LC-MS/MS after dilution of sample extracts with MeOH and addition of internal standard (IS) of (BPA- d16). Quantification can be done by the use of external standard calibration in MeOH/methylene chloride with addition of IS of BPA-d16. The level of BPA in the polymer samples then can be calculated as μg/g polymer and in μg/dm^2 sample.

Migration Testing – a generic approach

The release of BPA/BosC from the samples should as a worst case be tested by exposure into hot water (a potential worst-case food in contact with e.g. PC or precipitation after high global radiation event for weathering of building materials outdoor) at selected worst case time and temperature conditions. For worst case outdoor use the water needs the pH of 5-6 and for other application pH 8. Testing with water at high temperature is assumed to represent worst case testing (as e.g. PC is sensitive to hydrothermal effects according to technical literature and results from several studies (Mercea et al., 2009; Cao et al., 2009)). The testing was performed in accordance with the regulation of EU 10/2011 for plastic food contact materials and following relevant parts of the *European standards for migration testing* (CEN, 2004). The migration test should last 1 hour. Samples were tested by 3 times repeated exposure and all samples were tested as double determinations (two samples). The level of BPA/BosC should be analysed by LC-MS/MS. Surface area of each sample was measured and the results were calculated in μg BPA/dm^2 surface area of the sample.

Modelling

In order to make migration tests economically justifiable, they are standardised and the data thus obtained can be subjected to lifetime modelling. So field or semi-field tests do not necessarily have to be carried out to determine the conditions and duration of use and the resulting release. Modelling is an option to calculate migration.

As an example, the JRC (Joint Research Centre) issued a guidance document[225] on migration modelling. Several companies offer software systems for migration modelling

---

[224] Pedersen, G. A., Hvilsted, S., & Petersen, J. H. (2015). Migration of bisphenol A from polycarbonate plastic of different qualities: Environmental project No. 1710 , 2015. Danish Ministry of the Environment. Miljoeprojekter No. 1710 http://mst.dk/service/publikationer/publikationsarkiv/2015/maj/migration-of-bisphenol-a-from-polycarbonate-plastic

[225] E. J. Hoekstra, R. Brandsch, C. Dequatre, P. Mercea, M. R. Milana, A. Störmer, X. Trier, O. Vitrac, A. Schäfer and C. Simoneau, "Practical guidelines on the apllication of migration modelling for the estimation of specific migration," EUR 27529 EN, doi:10.2788/04517.

(non-exhaustive list of tools) such as: INRA Safe Food Packaging Portal version 335, FABES MIGRATEST Software or AKTSSML Software, FACET, among others.[226]

E.71.4. Non-exhaustive list for sector specific tests

A number of standardized methods are available to simulate weathering conditions and thus release potential of substances such as BPA.

In Germany, a test for outdoor weathering may be carried out according to DIN EN ISO 877. ISO/DIS 15314 is available for testing under maritime conditions. With artificial weathering, a time reduction of approx. 8.5 times can be achieved. For example, DIN 75220 is available for artificial weathering simulation. Specific test methods have been derived for the various areas of application, such as DIN 75220 for vehicle parts in Germany. In addition, following methods are available (non-exhaustive list):

- 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)
- 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

---

[226] https://www.eupia.org/fileadmin/FilesAndTradExtx_edm/2020-08-14_EuPIA_Guidance_on_Migration_Test_Methods.pdf

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

The tests listed are each suitable for different steps in either content testing or release testing. This list is provided as an example to show that there are test requirements in a number of sectors. In the 2nd Call for Evidence, however, it was also shown that there are no standardized tests for various sectors or specific applications. In some sectors tests are developed, for others this is not yet planned.

Due to the large number of different uses of BPA and the different products made from it, suitable test methods do not yet exist for all areas of application. In this respect, 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) 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 effort and costs required to check the migration limit can be significantly reduced.

E71.5. Tiered approach migration testing

If the residual content or the content of free BPA in the matrix exceeds 10 ppm, the release of BPA/BosC need to be determined for these articles/mixtures. The release, measured as migration, shall not exceed 0.04 mg/L during the service life.

The tiered approach is intended to save costs with a generic test proposal on the one hand and to allow existing in-house tests (like performance tests) with exhaustive justification to be approved on the other.

Tier 1: Generic testing

Exemplary, within this tier the aging of polymer or plastic may be simulated in the laboratory (simulation global radiation and T). See therefore *E.7.1.3 Migration Testing – a generic approach.* For modelling the service life see *E.7.1.3 Modelling.*

Tier 2: Specific laboratory test or field/semi-field-test

Exemplary, the ageing of polymer or plastic is simulated in the laboratory (simulation of global radiation, temperature and precipitation). The migration during the ageing process is constantly examined and a flux calculated. As a result, the migration limit (≤0.04 mg/L) may not be exceeded during service life. For modelling see *E.7.1.3 Modelling* and for methods see *E.71.4. Non-exhaustive list for sector* specific tests*.*

Exemplary, the ageing of polymer or plastic takes place in a field or semi-field test according to the conditions of use. During this test, the use phase is partly or completely depicted and the global radiation, change in temperature and the precipitation value completely correspond to reality. The migration is evaluated here with the help of the flux rate. As a result, the migration limit (≤0.04 mg/L) may not be exceeded during service life. For modelling see *E.7.1.3 Modelling* and for methods see *E.71.4. Non-exhaustive list for sector specific tests.*

E.7.1.6 Use description to derive stressor condition information – applicable decision tool

The use descriptor system (ECHA R.12)[227] can be used to determine the appropriate stressors for life cycle testing. To derive an adequate test, two questions need to be addressed in advance: how long is the foreseen life cycle and what stressors, for example, is the article exposed to in its intended use. So, what are the framework conditions of my use. The contributing activity name and the title of the contributing scenario are information requirements in the supply chain. For this reason, every actor in the supply chain should have access to the relevant data on the contributing activity. The market descriptors are sector of use category (SU), Product category (PC) and Article category (AC). Alone they only inadequately describe the entire life cycle. For each individual use, at least one contributing activity must be reported in IUCLID for, in this case, the environment. When carrying out an exposure assessment for the use, each contributing activity is evaluated to demonstrate that its conditions of use are safe. Each contributing activity should be linked to a standardized use descriptor category: in this case, with the environmental release category (ERC) that describes the activity. An ERC is associated with a contributing activity (environmental perspective), but can be associated with one or more contributing activities from an occupational perspective (e.g. several PROCs per ERC). This means that a set of environmental conditions for a use applies with several sets of operational conditions (OCs)/risk management measures (RMMs) for the different activities of workers at that site. In addition, the product category (PC) describes the contributing consumer activities and the article category (AC) also describes the contributing consumer lifetime activities.

This life cycle analysis serves to determine whether a release is possible and if so, at what stage in the life cycle it takes place. If the material is suitable for the intended use, the duration of service life must be determined to then derive the conditions for stressing the material. The duration of the service life changes the intensity of the stressors, such as the duration of irradiation, the stress due to temperature fluctuations, the probability of leaching due to precipitation events, among others, which must be simulated in the laboratory tests or semi-field tests. Taking these points into account, it is possible to derive scenarios according to the ERCs or to derive a worst case and a best case for the stressors. A worst-case example would entail a long service life over years and correspondingly long exposure to weathering due to outdoor use or constant water contact (as is relevant for

---

[227] https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf/ea8fa5a6-6ba1-47f4-9e47-c7216e180197 (accessed 11/2021)

coatings, for example). A best-case example would entail a negligent migration with a rather short life cycle but possible release potential despite indoor use (e.g. paper product).

E.8. Proportionality (comparison of options)

No additional information.

E.9.1. Comparison of Restriction Options

In order to assess the appropriateness of different possible restriction options several variables and uncertainties need to be considered:

Scope: Bisphenol A and BosC are used in very high tonnages in numerous mixtures and articles. The Dossier Submitter distinguishes the additive use, the use in the production of other chemicals and the use in the production of polymers. In chapter B9 emissions from these use categories and sub-uses are estimated. Despite large uncertainties for most uses it is concluded that (a) the majority of emissions into the environment result from additive uses of the bisphenols and the use in textiles, (b) no empirical evidence or information from the information gathering puts into question the conclusion that emissions resulting from the use of bisphenols in the the production (and during the use) of other chemicals are negligible, (c) the emissions resulting from the use of bisphenols in the production of polymers (and the subsequent processing and use) are very uncertain. The central estimate in Annex B9 suggests that environmental emissions from polymer uses are comparably lower but still significant:

Processing of materials: Emission potential via wastewater from the processing of polymers is significant (see Annex B9). According to information from industry emissions can be reduced significantly (80-90%) when wastewater is treated on site and additionally treated in municipal waste water treatment facilities.

Emissions during service life: Emission potential during service life depends on the concentration of BPA in the mixture or article and whether it will be extracted/eluted via contact with water. For articles/mixtures without or with negligible water contact no BPA emissions are expected.

The dossier submitter considers that for articles/mixtures containing less than 10ppm BPA the emission potential is low. However, stakeholders' information suggests that an estimated 20-30% of polymers cannot meet such a comparably low concentration limit for BPA and BosC. Other stakeholders are uncertain whether they can meet this limit but are confident that they could meet a slightly higher concentration limit. It is the dossier submitter's understanding that almost all polymer uses can comply with a concentration limit of 150ppm.

Additive uses of BPA cannot meet low concentration limit values. The submitted information during the CfE suggests BPA contents are significantly higher than 1 000 ppm. For some additive uses, reported BPA concentrations in the mixture/article are in the range of 1-3% (10 000 – 30 000 ppm).

The information submitted for chemicals manufactured using BPA claims that unreacted BPA is not present in the chemicals.

End-of-life emissions: Emission potential at the end of service life depends on waste disposal method and BPA concentration in an article/mixture. In 2017, 24% of municipal waste was disposed via landfill disposal. Therefore, only for uses where (a) the BPA concentration is low or (b) a specific waste management system is in place the dossier submitter expects negligible emissions.

Minimization of emissions during service life/migration testing:

The leaching of BPA from articles containing BPA (which water contact) can be minimized through various means. Stakeholder information suggests that even articles with comparably high BPA concentrations can be protected in a way that any remaining emission potential during service life is negligible. Such a limited emission potential of an article can be tested via laboratory migration testing that emulates the stressors from the expected service life.

E.9.2. Comparison of costs and benefits

No additional information is available.

Annex F: Assumptions, uncertainties and sensitivities

F.1. Release and measured data

Measured data from monitoring programmes or various projects reflect the release potential of BPA from processes and products. The best studied environmental matrix is water. However, available data also show that BPA is regularly found in biota, soils and sediments. The latest environmental findings continue to show exposure to BPA. What cannot be explained at this point are the differences in concentrations from measurement to measurement. Some sites show changing environmental concentrations. this may be due to seasonal differences, or fluctuations in the use of BPA-containing products, whereby the causal relationship is not always given. A clear upward or downward trend in environmental concentrations is also not discernible. Although the production rates of BPA are increasing both EU-wide and internationally (estimated growth of 6% per year), the release rates appear to be decreasing. the lower release can be explained by the steadily decreasing migration limits from product-specific regulations, for example.

F.2. Uncertainties Life-Cycle

F.2.1. Mass flow from import/export articles/mixtures

As SVHC BPA needs to be notified according to Art 7(2)[228]. The substance is used in the following articles. Since only BPA and BPB has been identified as an SVHC so far (formally taken up to ECHA´s candidate list), for the other BosC no obligation for notification exists.[229]

Table 132: Notification of use in imported articles and mixtures

No of notification	article categories	Use and function
3	machinery, mechanical appliances, electrical/electronic articles	articles used by consumers and in workplaces

Further consideration in the exposure assessment does not take place as precise tonnages of imported BPA-containing/releasing articles/mixtures are not available. Additionally,

---

[228] https://echa.europa.eu/regulations/reach/candidate-list-substances-in-articles/notification-of-substances-in-articles (2021/23/08)

[229] https://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles-table (2021/23/08)

since the notification obligation only applies to companies that contain BPA in products <0.1% and import more than 1 tpa, it can be assumed that there will be other imported products that are below the quantities triggering the obligation, as known from the call for evidence step and due to response from sector experts during information phase in parallel to the REACH Annex XVII dossier preparation. Because of this uncertainty these shares can not be considered concerning the European mass flow of BPA.

F.2.2. uses not registered

The most prominent use is BPA for manufacturing, processing and stabilizing during service life of PVC. This use is not supported by registrants anymore but still occurs as demonstrated during consultation of industries affected and during the Call for Evidence. Soft PVC is still used in the EU and therefore, the release potential is considered.

F.3. Uncertainties of Exposure

Table 133: uncertainties of exposure at different lifecycle stages

Lifecycle stage	description
EOL	- plastic used in many sectors, but the respective shares unclear - EOL more generic due to limited data
Release	- Release from materials is not investigated in great detail, or the equipment of the plastics is largely unclear (trade secret), so few conclusions can be drawn between the same types of polymer/plastic. - in consequence, the same release was nevertheless assumed for one type of material (polymer) (only a distinction was made between indoor and outdoor application). - In the first instance, worst case scenario according to default parameters corresponding to R.16, since hardly any data are available. - so far, the release has only been related to the proportion of residues, although it is clear that the polymer can be superficially stressed and degraded/fragmented (hydrolysis, photolysis, etc.). - release was considered for entire polymer
STP	- Data for access to stp/wwtp are available on a rudimentary basis for individual countries; it is known that the availability of an STP varies in the EU states. - Similar for bypass events
Degradation	- little stable under environmental conditions, but constant environmental concentration to be found - therefore no consideration of degradation
emission	- conceivable through human ingestion not only from drinking water and food contact materials, but also from food, consumer goods, clothing and dust inhalation - studies rare
Emission scenarios	- worst case (R.16) - real case (IND data without refinements)

Annex G: Stakeholder information

During the preparation phase, the dossier submitter conducted several consultations to gather further information on the uses of BPA and BosC and alternatives.

Table 134: Stakeholder consultations and exchange on BPA and BosC

Consultation	Date	Remark
RMOA consultation on BPA	January to March 2017	Webropol survey (two monts duration) hosted via the website of the DE REACH/CLP/Biocides Helpdesk
Meeting with stakeholders	2 May 2017	Follow-up meeting based on the comments received during the RMOA consultation
Public consultation within the context of SVHC identification of BPA	March to May 2017	Formal stakeholder consultation hosted via ECHA website
Written consultation of 263 stakeholder (producers, associations, scientists, authorities) by BioMath GmbH (see Annex H)	1 July 2020 to 5 August 2020	
Follow-up interviews of 18 manufacturers of alternative materials of BPA with regard to application areas, quantities, feasibility, substitution costs, etc. by BioMath GmbH (see Annex H)		
Meetings with individual stakeholders	2017: two meetings 2018: two meetings 2019: one meeting 2020: four meetings 2021: two meetings 2022:six meetings	Meetings took place virtually from 02/2020 on due to COVID-19 pandemic restrictions
Stakeholder information on planned restriction	15 September 2020	Virtual meeting
1st Call for Evidence	14 October 2020 until 15 February 2021	Hosted via the website of ECHA (ECHA, 2020b)
2nd Call for Evidence	22 October 2021 until 22 December 2021	Hosted via the website of the DE REACH/CLP/Biocides Helpdesk

Regulatory Management Option Analysis (RMOA) consultation on BPA

Following the finalisation of the substance evaluation on BPA and publication of the conclusion and evaluation report (BAuA, 2017b; BAuA, 2018), the Dossier Submitter conducted an EU-wide two-month consultation of stakeholders of BPA in 2017 via the website of the national REACH/CLP/Biocides Helpdesk (BAuA). The invitation to participate in the consultation was sent to registrants, down-stream users, C&L notifiers of BPA as well as associations and interested third parties. Following conclusion of the consultation, the RMO analysis on BPA was finalised by the Dossier Submitter and the conclusion published on ECHA's website on 13 June 2017 (BAuA, 2017a).

Calls for Evidence (CfE)

The objective of the survey was to increase the information basis on:

1) Manufactured and imported amounts of BPA and BosC;

2) manufactured and imported amounts of their potential alternatives;

3) the type of uses the substances are applied to;

4) the economic effects that are linked to the use of the substances.

The invitations to the CfEs were sent (EU-wide) to substance manufactures; formulators of mixtures; end users of substances or mixtures; importers of substances, mixtures or articles as well as article assemblers in the EU; and associations, NGOs or other interested third parties. Furthermore, the first CfE was promoted via ECHA's Weekly (ECHA, 2020a).

At the start of each of the CfEs, around 1,000 stakeholders were contacted directly via email by the dossier submitter and invited to participate in the CfEs and to share information through the respective online survey.

The first CfE was originally planned to run from 14 October 2020 until 15 January 2021 but was extended upon requests by stakeholders to 15 February. Overall, 80 stakeholders provided input to the first CfE via ECHA's webform or via direct submission of documents to the dossier submitter.

The contributing stakeholders were:

- Companies (n = 40; 50%)
- Industry & trade associations (n = 34; 43%)
- NGOs (n = 3; 4%)
- Member States (n = 3; 4%)

The second CfE took place from 22 October 2021 until 22 December 2021. Herein, over 180 stakeholders provided input to the CfE via the Webropol webform or via directly providing documents to the Dossier Submitter.

The contributing stakeholders were:

- Companies (n = 124; 68%)
- Industry & trade associations (n = 47; 25%)
- Research institutes and laboratories (n = 5; 2%)
- NGOs and private individuals (n = 4; 2%)

- Member States (1)

Stakeholders provided the following information on the topics of the second CfE:

- BPA Use: Manufacture and downstream use of polymers (n = 76; 42%)
- BPA Use: Production and downstream use of other chemicals (10%)
- BPA Use: Additive use (12%)
- BPA-like BosC uses (19%)
- BosC discrete uses (58%)

The responses covered following industries and uses:

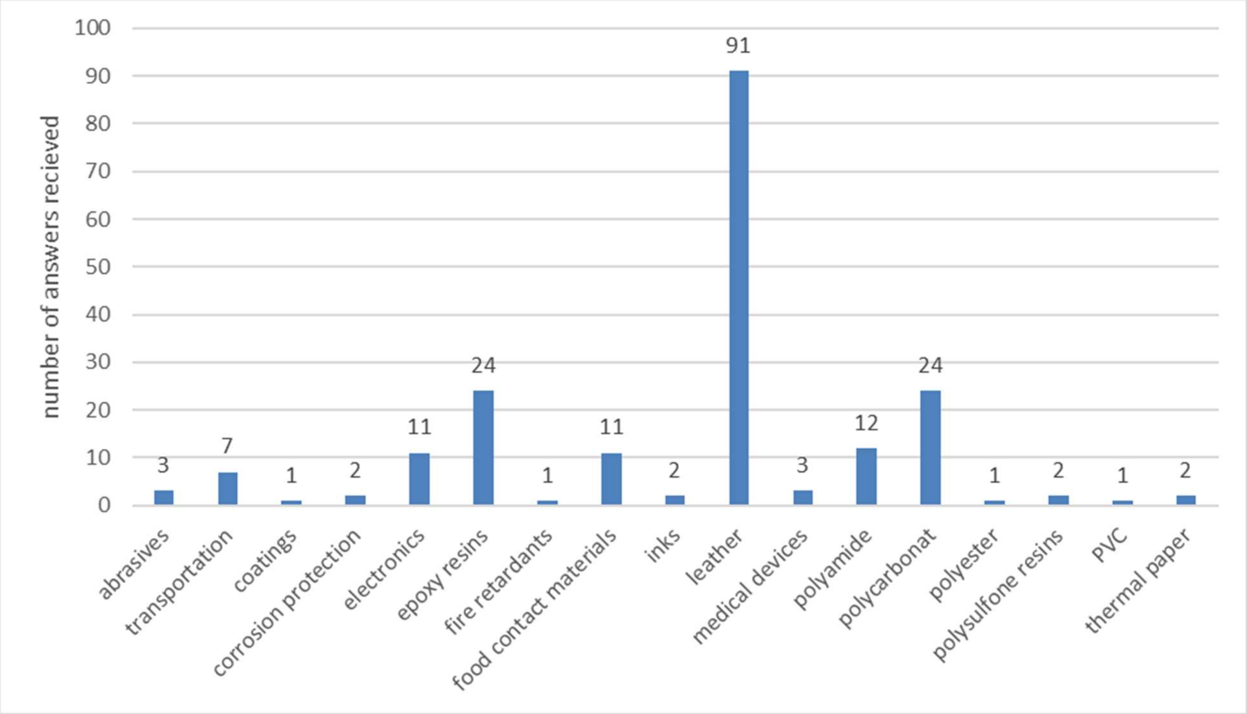


Figure 20: industries/uses covered by answers from both CfE

The main contributions from the participating industry sectors for both CfE were:

- Chemical manufacturers / importers
- Formulators of chemical mixtures
- Producers of polymers containing BPA and BosC (e.g. polycarbonate, epoxy resins, polyols, polyesters, polyacrylates)
- End users of substances, mixtures or polymers containing BPA and BosC (e.g. coating and paints, leather and textiles, printing, rubber, paper)
- Producers of articles made from polymers containing BPA and/or BosC (e.g. automotive, electrical engineering, electronics, construction)
- Generally, the second CfE saw a marked increase in responses from the textile and leather sector (around 60 companies and associations and ca. 30% of the overall feedback of the second CfE).

The answers of the first call for evidence could be further categorized as:

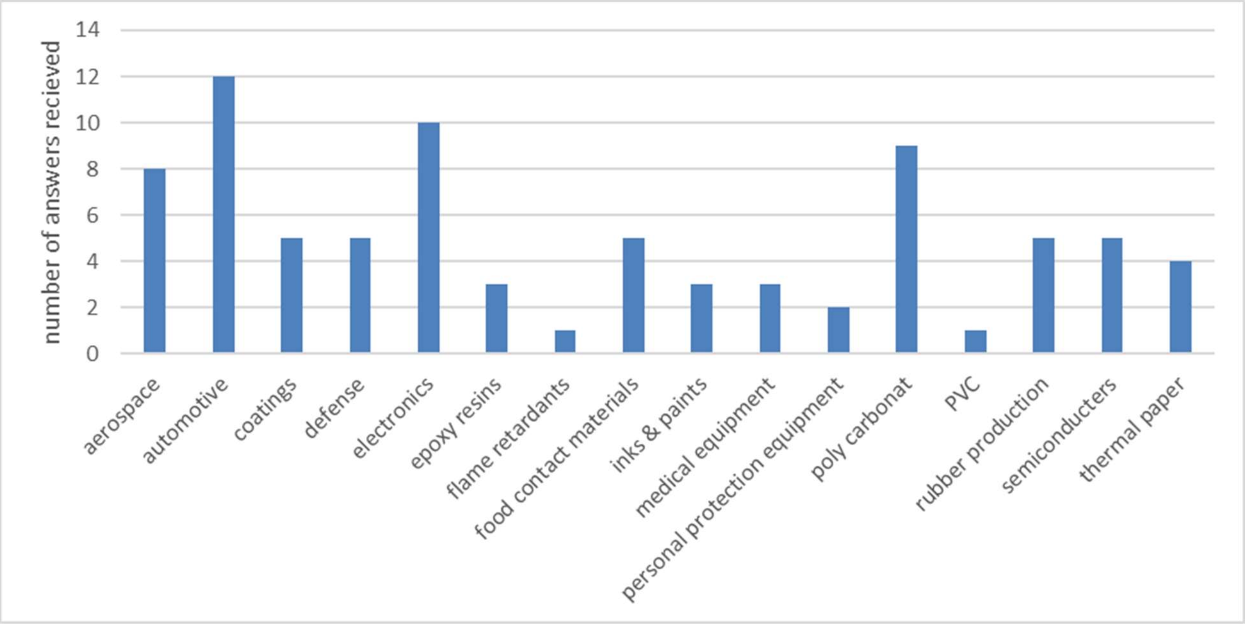


Figure 21: category of answers of the 1st CfE

Appendix G-1: Survey structure of the first Call for Evidence (via ECHA website): *Call for evidence on a possible restriction on 4,4'-isopropylidenediphenol (Bisphenol A) and structurally related bisphenols of similar concern for the environment*

1. Sectors and processing of BPA and/or structurally related bisphenols: Please provide information on which sectors BPA and/or structurally related bisphenols are used including how it is transferred and processed, e.g. as a mixture of granules or article (materials/subassembly)?

2. The specific use of Bisphenol A and/or structurally related bisphenols in (i) articles and (ii) mixtures (which are used, for example, to manufacture articles or mixtures):

For which articles/mixtures are BPA and/or structurally related bisphenols used. Is/Are they used as an additive or a monomer? Which technical function does BPA or structurally-related bisphenols have in the process or the material/article matrix (e.g. dye fixation agent, stabilizer, plasticizer)? Please provide the following additional information, where possible:

- *i.* *The identity of the mixtures/articles containing BPA or structurally related bisphenols (intended e.g. as an additive and not intended e.g. as residual)*
- *ii.* *Concentration of BPA or structurally related bisphenol in these products (differentiated into concentration total used, reacted, i.e. chemically bound, and unreacted BPA)*
- *iii.* *Who are the users: are they consumers, professional or industrial users and how are the users processing the mixture/article?*

- *iv.* *Quantity of BPA or structurally related bisphenols used in these products (e.g. as annual tonnage)*

- *iv.* *Are measures in place to minimise releases during manufacture and handling of mixtures/articles and their life cycle? Do strictly controlled conditions exist* *or can they be implemented? If yes, please specify the measure(s) in place and if possible, the resulting release reduction.*

v. How long is the common service life for the mixture/article?

vii. What are the known stressors (e.g. UV-radiation, pH, temperature, moisture) for your article / mixture and how can they influence releases? What are your solution to prevent or minimise the releases?

3. Quality and testing of products (mixtures/articles): In the entry of the Registry for Intention, certain concentration limit values are proposed. Formerly, discussions were often about quality differences between imported products and products manufactured in the EU. Are the proposed concentration limit values technically feasible?

4. What are potential alternative substances, alternative materials or technical alternatives to the use of BPA and structurally related bisphenols in mixtures and articles. Please provide the following additional information:

i. Identity of existing or emerging alternatives and any information on the existing market share

ii. Technical and economic feasibility of potential alternatives, including information on product performance, the price differences between BPA, structurally related bisphenols and their alternatives, the number of products that could require reformulation, expected costs and timelines for reformulation and transitioning to a full-scale production using the alternatives, etc.

iii. Hazard and risk profile of the alternatives,

iv. Availability of alternatives in sufficient quantities on the market: current and future trends

v. Other potential impacts stemming from the transition to alternatives, e.g. discontinuation of certain articles/mixtures, changes in product performance, article/mixture approval, etc.

5. Socio-economic impacts on society:

i. Costs and benefits to any affected actors, e.g. producers, professional or industrial users, consumers, or any other relevant actors (such as the producers of alternatives).

ii. Key economic parameters such as turnover of the concerned sector(s), the number of people employed, current share of products containing BPA or structurally related bisphenols, etc.

iii. Information on possible functional losses in case alternatives do not provide equal performance. Information should include quantitative or qualitative description of the overall impact of such functional losses.

iv. Information on imports and exports of substitutes and whether the actors will be impacted differently by a restriction.

6. Available analytical methods and test set up: For detecting the content pf BPA and structurally related bisphenols in and release from products, i.e. methods to determine the amount of residual or free BPA in different matrices as well as potential release of previously chemically bound BPA from articles/mixtures during the life cycle of articles/mixtures. Within the framework of stability tests prior to market launch or to certify the safety of articles/mixtures, there are specifications and standards for test setups. Which standards or test designs (e.g. for migration and leaching test) are you connected to?

Appendix G-2: Survey structure of the first Call for Evidence (via national Helpdesk): *2nd Stakeholder Consultation on a Restriction for Bisphenol A and Bisphenols of similar concern (BPAF, BPB, BPF, BPS)*

Reasons and aims of this analysis

Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA), the competent authority for REACH of Germany, and Umweltbundesamt (UBA), hereafter referred to as 'the authorities', are currently preparing a REACH Annex XV Restriction Dossier for bisphenol A (BPA) + bisphenols of similar concern (BosC - as defined under Section II.) since all these substances are considered to have endocrine disrupting properties in the environment.

Endocrine disrupting substances (EDs) in the environment interfere with the hormone system of wildlife animals and can thereby cause adverse and population relevant effects (i.e. by impairing reproductive functions or altering sex ratios). Thus, exposure to EDs endanger the survival of populations or subpopulations in the affected ecosystems. Due to the still limited knowledge on e.g. the endocrine system of invertebrates and hence their sensitivities to EDs exposure, the decoupling of exposure and adverse effects (even transient exposure during sensitive juvenile life stages can result in adverse effects in adult animals or in subsequent generations) and missing test systems for addressing specific endocrine mediated modes of action (e.g. thyroid active chemicals in fish), it is not possible to predict and derive a safe threshold for EDs in the environment that is sufficiently protective.

BPA and BosC act via several endocrine pathways that are conserved among a broad range of vertebrate species and taxa. Hence, environmental exposure to these chemicals not only affects single species and populations but directly whole ecosystems.

Based on these considerations any exposure of the environment with BPA and BosC is subject to the minimization requirement.

The tonnage bands for BPA and the BosC manufacture and use within the EEA are:

BPA	*1,000,000*	*– 10,000,000*	*tonnes per year*
BPB	*1*	*– 10*	*tonnes per year*
BPF	*1,000*	*– 10,000*	*tonnes per year*
BPAF	*100*	*– 1,000*	*tonnes per year*
BPS	*10,000*	*– 100,000*	*tonnes per year*

The use of BPA and BosC as a monomer or additive, in mixtures or in polymers can result in emissions to the environment when taking the whole life cycle of articles and products into account. Monitoring data for BPA and BPS show that these substances are ubiquitously distributed in the environment, whereas other BosC show environmental exposures as well. Exposures of BosC are assumed to significantly increase if BosC are used as substitutes for high volume bisphenols like BPA and BPS.

In view of these concerns, the authorities plan to propose EU-wide measures covering BPA, BPB, BPS, BPF, BPAF and BosC identified in the future to reduce their environmental exposure. The authorities consider to introduce limit values to minimize the release potential and in consequence *the emissions in the environment. The limit of 10ppm has proven to be target-oriented and feasible, especially for articles. If the residue levels are higher, but significantly less migration from articles (max. 40ppb per year in relation to the service life) is expected through protective measures, we require a relevant migration test. This value, 40ppb, is used, for example, in the context of the Toys Directive. Restricting releases on the basis of residual limits or a migration limit allows the continued use of bisphenols where such limits are feasible, while reducing environmental exposure as much as possible.*

This survey is intended to offer an opportunity for stakeholders to provide updated information, on uses, including tonnages, emissions, alternatives and transition costs, and limit values. By checking the presented data and providing feedback you/the respondents can ensure that the correct information is used for the assessment and preparation of a REACH Annex XV Restriction Dossier. Furthermore, you/the respondents can provide currently still lacking information to the authorities.

Disclaimer:

The purpose of the five 'report summaries' (download is possible on the next page) is to present our current knowledge and understanding regarding the uses of BPA and BosC with a focus on the use, tonnages, releases, alternatives and substitution costs. Additionally, we want to better understand costs and practical consequences of introducing a limit value and/or a migration limit for the bisphenol content in products. The data are important for both risk assessment and socio-economic analysis (SEA).

It should be noted that these investigation report summaries should not be considered to be equivalent to the Annex XV restriction report, which is currently in a preparation phase.

The presented data reflect the current knowledge of the authorities but during the project new data might become available. It is not guaranteed that the information presented here will be used in the Annex XV restriction report or in the presented way. For instance: presented quantities or costs could be higher or lower.

The information provided is largely of a general nature and is not intended to address the specific circumstances of any particular individual or entity. Further, the information is not professional or legal advice. In case respondents fill out the survey several times, only the latest entry will be considered.

This survey is not intended as an opportunity to provide feedback on the (chemical) scope of the proposed restriction. The Dossier Submitter has enough data to demonstrate the hazards of the substances in the scope of the restriction.

Stakeholders are invited to add information on uses not mentioned in the report summaries.

Scope of the restriction:

The scope of the restriction aims to minimize the release potentials from all uses. To reach this goal, a tiered approach is used:

A) the residual content in articles and mixtures is restricted by setting a limit value for BPA and BosC residues which may not be exceeded.

B) a migration limit is set for articles not fulfilling the residual limit value which must not be exceeded during the entire life cycle.

If the residual content limit value cannot be achieved a migration limit must be fulfilled which ensures that migration from articles is minimized during the entire life cycle. This results in a tiered restriction. If point A cannot be complied with, point B must be checked further.

A transition period of 24 months is considered to be proportionate for most manufacturing processes and uses:

The period allows for the implementation of testing and certification requirements.

Substitution processes can be performed where necessary when alternatives are already available.

The authorities will consider longer transition periods, e.g. for uses where alternatives are not market-ready, where legal requirements requiring the use are in place and where a restriction would result in disproportionate impacts.

BPA/BosC	*Shall not be placed on the market in mixtures and articles in a concentration equal to or greater than 10ppm (0.001% by weight). This limit value refers to the sum of BPA and all BosC present in the respective mixtures and articles. If the concentration in mixtures and articles exceeds 10ppm, a migration test to determine the migration value needs to be conducted (2.).*
	Shall not be placed on the market in articles showing a migration value greater than 0.04 mg/l (migration limit) over the entire service life. This migration limit refers to the sum of BPA and all BosC present in the respective mixtures and articles.
	Paragraphs 1 and 2 shall apply 24 months from entry into force of the restriction.

Please find supplementary material containing information on the concentration limit, on how migration can occur, and how to deal with such products (articles, mixtures): supplemental_material_on_concentration_limit_and_migration[230]

Public sources / literature references:

Presented numbers (i.e. tonnages & emissions) represent the situation in the European Economic Area (EEA). If you have a different view, please provide this information on EEA level with reference to public sources.

In case transition times are impacted by legal requirements (e.g. certification/testing procedures), please refer to the respective legal text if possible. In instances where the information presented in the investigation report summaries is challenged, but no reference to literature or public sources are made to justify such challenges, we are unlikely to be able to take the comments into account.

Others:

In case no information is available, the authorities will follow a reasonable worst-case approach when estimating emissions to the environment. Concerning the presented summaries, the authorities do not accept any liability with regard to the use that may be made of the information contained.

---

[230] https://www.reach-clp-biozid-helpdesk.de/media/Helpdesk/download/supplemental-material-on-concentration-limit-and-migration2.pdf

Use of the information in these summaries remains the sole responsibility of the reader. Even though, the information provided in the summaries have been prepared with the utmost care, we cannot exclude potential errors or omissions. The authorities do not accept any liability with regards to any such errors or omissions.

<u>Bisphenols in scope</u>

Bisphenol A and Bisphenol B were identified as substances of very high concern according to Art 57(f) of the REACH regulation because they showed endocrine disrupting effects in the environment. For BPS, BPF and BPAF, the available data from in vitro as well as from in vivo mammalian and fish studies show that they also fulfill the WHO/IPCS criteria for an ED in the environment. For more details please refer to the background document on BosC provided with this call, which can be downloaded further below.

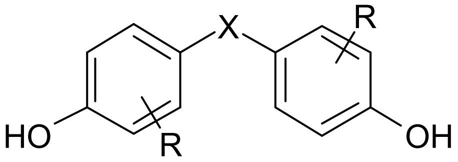


Figure 1: Basic structure of bisphenols that are in the scope of the restriction

BPA, BPB and the other BosC within the scope all share specific structural features that are shown in figure 1. They act via various modes of action based on their characteristic structure-activity relationships. Thus, it is very likely that further bisphenols matching the structural features shown in figure 1 as well as substances that can degrade to BPA or BosC under environmental conditions may also be identified as EDs for the environment in the future (if further data and knowledge becomes available). These substances shall also be included within the scope of this restriction via an extension clause to prevent regrettable substitutions.

Hence, all bisphenols showing endocrine disrupting properties in the environment will be considered for regulation and the present scope should be read as a non-exhaustive list of those bisphenols where the available data already suffice to demonstrate that these substances are environmental EDs.

Target group of this questionnaire

Questions are addressed to the entire supply chain including industry associations, manufacturers, importers, distributors and downstream users.

Information on bisphenols of concern and alternatives to bisphenols is of interest. Both, BPA and BosC contained in mixtures and articles are relevant. Alternatives include chemical as well as technical replacements for BPA and BosC.

Please note that this questionnaire will allow you to navigate through blocks of questions depending on your type of information or data. Hence, you will be able to specifically respond to the questions relevant to you.

Questions can be answered for up to five different uses:

Uses of BPA with regard to Polymers

Uses of BPA with regard to the production of other chemicals

Uses of BPA as an additive

Uses of BosC where the use can be regarded as a substitute use for BPA (for example the use of BPS in thermal paper)

Uses of BosC where there are no comparable uses of BPA

In the table below, the hyperlinks on the right side will allow you to download summary reports for the different uses for which further information is requested. Please note that information for BosC, Use (P), (C), (A) and additional BosC uses are reported in one summary report. However, two specific sets of questions have been prepared for

The use of BosC as alternative to BPA use (P), (C) or (A), in the following called: BPA-like BosC uses

The use of BosC outside the use pattern of BPA, in the following called: BosC discrete uses

Use	*Hyperlinks to report summaries*
BPA Use (P): Manufacturing and downstream use of Polymers (P)	*Report summary BPA use for polymers.pdf* [231]
BPA Use (C): Manufacturing and downstream use of other chemicals (C)	*Report summary on BPA use for chemicals.pdf* [232]
BPA Use (A): Additives use (A)	*Report summary on BPA use as additives.pdf* [233]
BPA-like BosC uses	*Report summary on uses of BosC* [234]
BosC discrete uses	

For all stakeholders who plan to continue using BPA or BosC the proposed limit value and migration limit will be relevant. You can download a supplemental report explaining the concentration limit and migration limit here:

Supplemental material on	*Supplemental_material_on_concentration_limit_and_*

---

[231] https://www.reach-clp-biozid-helpdesk.de/media/Helpdesk/download/report-summary-on-BPA-use-for-polymers2.pdf

[232] https://www.reach-clp-biozid-helpdesk.de/media/Helpdesk/download/report-summary-on-BPA-use-for-chemicals2.pdf

[233] https://www.reach-clp-biozid-helpdesk.de/media/Helpdesk/download/report-summary-on-BPA-use-as-additives2.pdf

[234] https://www.reach-clp-biozid-helpdesk.de/media/Helpdesk/download/report-summary-on-BosC-uses2.pdf

concentration limit and migration	*migration.pdf*

Information on institute/organisation/person & data protection rights

Information on institute/organisation/person & data protection rights can be downloaded via the following link: GDPR[235] information bisphenols

*Fields marked with * on this page are mandatory fields.*

PERMISSION FOR INFORMATION PURPOSES: I agree to the personal data I provide in the present survey, including my name and my e-mail address, to be collected, processed and stored for potential follow-up questions regarding this survey by the service provider of the Federal Institute for Occupational Safety and Health (BAuA), namely Webropol Deutschland GmbH, and to these being subsequently stored in the database of the Federal Office for Chemicals.

*Information on institute/organisation/person**

Name	*Surname*	*Name of institute/organisation*	*E-Mail*

*Can we contact you with follow-up questions?**

Yes	*No*

Note on Confidentiality of information and data

*I understand that it is my responsibility not to include confidential information in responses to general comments and in any responses to requests for specific information (e.g. company name, properties, assets, costs etc.). The competent authorities for REACH will not be held liable for any damages caused.**

Yes

*I understand that it is my responsibility to mark confidential data and attachments as confidential. **

Yes

I. General questions

---

[235] https://www.reach-clp-biozid-helpdesk.de/media/Helpdesk/download/GDPR-BPA.pdf

For which report(s) would you like to submit information? Please select all topics on which you would like to provide information.[236]

BPA Use (P): Manufacturing and downstream use of Polymers
BPA Use (C): Manufacturing and downstream use of other chemicals
BPA Use (A): Additives use
BPA-like BosC uses
BosC discrete uses

For all stakeholders who plan to continue using BPA or BosC the proposed concentration limit value and migration limit will be relevant. The final set of questions aims at a better understanding of this topic. Do you want to provide information?

Yes	*No*

If relevant, please further specify your use by giving a short description (e.g. additive use as a polymerisation inhibitor in order to terminate the polymerisation reaction; use in chemical production of tetrabromobisphenol A (TBBPA); use of polycarbonate for building applications, manufacture of epoxy resins).

Free text field (400 characters left)

In this questionnaire we ask for information for example on uses, emissions, availability of alternatives, costs and testing methods. How can company-specific information provided by you be best described:

Information on mixtures/articles manufactured and/or used in the EEA
Information on imported mixtures/articles
Information on imported mixtures/articles that are further processed in the EEA
Other (please describe)
Free text field (400 characters left)

Do you have information on practical and/or economic impacts resulting from the proposed restriction with regard to recycling and/or the broader circular economy? Can you provide data that demonstrates if/if not the proposed limit values would impact the recycling industry? Can you provide any data on potential costs (e.g. when recycling is no longer possible or when additional costs to comply with limit values become necessary)? In case you want to submit detailed information in this regard, you can provide a link to the information or submit a separate document. Please indicate which parts of the submitted information are relevant to recycling/the circular economy.

---

[236] Depending on the ticked boxes, stakeholders were guided to the respective segments of the survey (i.e. ticking of the "BPA Use (P)" box unlocked Segment II of the survey, "BPA Use (C)" unlocked Segment III etc.).

Free text field (500 characters left)
Option to upload attachment

Are certain uses of BPA and BosC missing that do not fit in the main use categories (A), (P) and/or (C)? If yes: Please describe the use shortly.

Free text field (500 characters left)

II. BPA Use (P): Manufacturing and downstream use of Polymers (P)

The following linked information presents the status quo based on information available to the authorities: report_summary_on_BPA_use_for_polymers.pdf231

<u>Information on use, release and emission</u>

EEA tonnages & emissions presented in the background report for polycarbonate (table 1), epoxy resins (table 2) and other polymers (table 3) represent the European perspective. If relative shares, tonnages or emissions are challenged, please do so at European level, not at individual company level. For alternatives (and transition costs) this is slightly different and individual companies likely have valuable information.

<u>Polycarbonate</u>

In the report summary, Table 1: EU use of PC by sector presents available information and information gaps on uses of polycarbonate. Review of information and input to fill these gaps (preferably with non-confidential information) is highly appreciated. Some additional confidential data is available but cannot be reproduced here.

Please indicate which data you agree with and specify where you disagree with information on relative shares, tonnages and expected trends.

Free text field (2000 characters left)

Please indicate which year(s) the provided data refers to. Please specify and/or refer to literature/public sources

Free text field (1000 characters left)

In the report summary, Table 2: EU use of epoxy resins by sector presents available information and information gaps on uses of epoxy resins. Review of information and input to fill these gaps *(preferably with non-confidential information) is highly appreciated. Some additional confidential data is available but cannot be reproduced here.*

Please indicate which data you agree with and specify where you disagree with information on relative shares, tonnages and expected trends.

Free text field (2000 characters left)

Please indicate which year(s) the provided data refers to. Please specify and/or refer to literature/public sources

Free text field (1000 characters left)

In the report summary, Table 3: EU use of other polymers presents available information and information gaps on other polymers manufactured with BPA. Review of information and input to fill these gaps (preferably with non-confidential information) is highly appreciated. Some additional confidential data is available but cannot be reproduced here.

Please indicate which data you agree with and specify where you disagree with information on relative shares, tonnages and expected trends.

Free text field (2000 characters left)

Please indicate which year(s) the provided data refers to. Please specify and/or refer to literature/public sources

Free text field (1000 characters left)

How much BPA do you use annually (as mixture or in articles)? If the exact amount is not known, estimates can be provided.

Free text field (1000 characters left)

Do you have information on thepercentage of BPA outlined in the question above that is released into the environment? Can specify possible exposure pathways to the environmental media (e.gt. water, air and soil)?

Free text field (1000 characters left)

Do you have/provide information on thepercentage of BPA present as residual in the product (article e.g. sheets or ready to use article or mixture e.g. pre-formulated bulk) If yes, please give a description summarizing such information.

Free text field (1000 characters left)

Are you able to apply or do you have access to methods to simulate and analyse the migration behaviour of BPA during the service life of your article? Please describe.

Free text field (1000 characters left)

The environmental release category (ERC) is a key REACH descriptor to define release factors of a chemical substance in a use-specific exposure scenario. The category is used in various modelling tools to derive environmental exposure estimates. ERC default factors may be used to estimate emissions of BPA in three major life-cycle stages, namely the production stage including manufacture of substances, formulation of mixtures and production of articles, the 'in-use' stage, and the waste stage.

Please indicate if you have information on specific emission rates (refinements or specific environmental release categories - SPERCs) for BPA, based on measurements and / or model calculations.

Free text field (1000 characters left)

Information on the availability of alternatives

In the background report, the authorities present stakeholder information from a previous public consultation as well as data compiled for a research project in which alternatives to the use of BPA were identified. The data suggests that for several uses alternatives are already available or will soon be available. For most other uses potential alternatives for BPA are currently researched. With regard to the use of BPA in polymers the authorities understand that most uses meet the proposed limit values of 10ppm for the total of BPA and BosC residuals and/or the migration limit of 0,04 mg/l in total during its service life. However, the authorities would like to learn about your views with regard to the availability of alternatives in case you cannot meet the proposed limit values.

Do you have information on alternatives? (answer no if you want to skip questions on alternatives completely)

Yes	*No*

Is there a specific application/functionality of BPA in your product(s)/processes that cannot meet the proposed limit values? What is the specific application/functionality of BPA in your product(s)/processes that cannot meet the proposed limit values?

Free text field (2000 characters left)

Are in your view the non-bisphenol alternatives listed in the background report technically feasible in your product(s)/processes?

Yes	*No*

Please specify why.

Free text field (1000 characters left)

Are in your view the non-bisphenol alternatives listed in the background document economically feasible in your product(s)/processes?

Yes	*No*

Please specify why.

Free text field (1000 characters left)

Do you have information on the alternatives' risk profile?

Yes	*No*

Please describe.

Free text field (1000 characters left)

Are there legal approval schemes for your product(s)/processes, which have to be taken into account in case non-bisphenol alternatives will be used?

Yes	*No*

Please specify and/or refer to literature/public sources.

Free text field (1000 characters left)

What is the average approval time?

Free text field (1000 characters left)

Do you actively work on finding alternatives?

Yes	*No*

Please specify.

Free text field (1000 characters left)

If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain.

Free text field (2000 characters left)

Do you have information on additional alternatives for any of the described applications that have not been disclosed in the attached information?

Free text field (2000 characters left)

Information on Economic Impacts

What is the economic impact (euro) and social impact (jobs) on your business/company if the use of BPA is prohibited?

In 3 years.

Free text field (2000 characters left)

In 10 years.

Free text field (2000 characters left)

Please explain by providing your calculations.

Free text field (2000 characters left)

III. BPA Use (C): Production and downstream use of other chemicals (C)

The following linked information presents the status quo based on information available to the authorities: Report summary on BPA use for chemicals.pdf [232]

Information on use, release and emission

EEA tonnages & emissions presented in the background report depict the European perspective. If relative shares, tonnages or emissions are challenged, please do so at European level, not at individual company level. For alternatives (and transition costs) this is slightly different and individual companies likely have valuable information.

In the background report, the authorities describe that only very limited information is available. At the moment, for the production of other chemicals from BPA a yearly tonnage of only 1,000-10,000 tonnes is assumed. Input to improve information is highly appreciated.

Do you have information on the use of BPA in the production of other chemicals in general or specific information with regard to individual chemicals (TBBPA, BIS-GMA/DMA/EMA, BADCy, BADGE, Polyols). Please state tonnages and expected future trends.

Free text field (2000 characters left)

How much BPA do you use annually? If the exact amount is not known, estimates can be provided.

Free text field (2000 characters left)

Do you have information on thepercentage of BPA outlined in the question above that is released into the environment?

Free text field (1000 characters left)

Do you have/provide information on thepercentage of BPA as residual in the chemicals synthesized based on BPA as an educt? If yes, please provide respective background information (e.g. literature data, analytical reports).

Free text field (1000 characters left)

Are you able to apply or do you have access to methods to simulate and analyse the migration behaviour of BPA during the service life of articles produced by residual BPA containing chemicals?

Free text field (1000 characters left)

The environmental release category (ERC) is a key REACH use descriptor to define the release factors of a chemical substance in a specific use exposure scenario. It is used in various modelling tools to derive environmental exposure estimates. ERC default factors may be used to estimate emissions of BPA in three major life-cycle stages, namely the production stage including manufacture of substances, formulation of mixtures and production of articles, the 'in-use' stage, and the waste stage.

Please indicate if you have information on specific emission values (refinements or specific environmental release categories - SPERCs) for BPA used in the production of other chemicals and subsequent production of products, based on measurements and / or model calculations.

Free text field (1000 characters left)

Information on the availability of alternatives

In the background report, the authorities present stakeholder information from a previous public consultation as well as data compiled for a research project in which alternatives to the use of BPA where identified. The data suggests that for several uses alternatives are already or soon will be available and for most other uses potential alternatives for BPA are currently researched. The authorities would like to learn about your views with regard to the availability of alternatives in case needed because the proposed limit values cannot be met.

Do you have information on alternatives? (answer no if you want to skip questions on alternatives completely)

Yes	*No*

What is the specific application/functionality of possibly residual BPA containing chemicals in your product(s)/processes?

Free text field (1000 characters left)

In your view, are the listed non-bisphenol alternatives technically feasible in your chemicals?

Yes	*No*

Please specify why.

Free text field (1000 characters left)

In your view, are the listed non-bisphenol alternatives economically feasible in your chemicals?

Yes	*No*

Please specify why.

Free text field (1000 characters left)

Do you have information on the alternatives' risk profile?

Yes	*No*

Please describe.

Free text field (1000 characters left)

Are there legal approval schemes for your product(s)/processes, which have to be taken into account in case BPA alternatives have to be used?

Yes	*No*

Please specify and/or refer to literature/public sources.

Free text field (1000 characters left)

What is the average approval time?

Free text field (1000 characters left)

Do you actively work on finding alternatives?

Yes	*No*

Please specify.

Free text field (1000 characters left)

If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain.

Free text field (1000 characters left)

Do you have information on additional alternatives for any of the described applications that have not been disclosed in the attached information?

Free text field (1000 characters left)

Information on Economic Impacts

What is the economic impact (euro) and social impact (jobs) on your business/company if the use of BPA is prohibited?

a) In 3 years.

Free text field (1000 characters left)

b) In 10 years.

Free text field (1000 characters left)

c) Please explain by providing your calculations.

Free text field (1000 characters left)

IV. BPA Use (A): Additive Use (A)

The following linked information presents the status quo based on information available to the authorities: Report summary on BPA use as additives.pdf233

<u>Information on use, release and emission</u>

EEA tonnages & emissions presented in the background report depict the European perspective. If relative shares, tonnages or emissions are challenged, please do so at European level, not at individual company level. For alternatives (and transition costs) this is slightly different and individual companies likely have valuable information.

In the report summary Table 1: BPA uses as an additive in the EEA presents available information and information gaps. Review of information and input to fill these gaps (preferably with non-confidential information) is highly appreciated.

Please indicate which information you agree with and specify where you disagree with information on relative shares and tonnages. Do you have additional information on data and expected trends?

Free text field (2000 characters left)

How much BPA do you use annually? If the exact amount is not known, estimates can be provided.

Free text field (1000 characters left)

Do you have information on thepercentage of BPA outlined in the question above that is released into the environment?

Free text field (1000 characters left)

Do you have/provide information on thepercentage of BPA present as residual in the product (article e.g. sheets or ready to use article or mixture e.g. pre-formulated bulk) If yes, please give a description where do you find such information.

Free text field (1000 characters left)

Are you able to apply or do you have access to methods to simulate and analyse the migration behavior of BPA during the service life of your article?

Free text field (1000 characters left)

The environmental release category (ERC) is a key REACH use descriptor to define the release factors of a chemical substance in a specific use exposure scenario. It is used in various modelling tools to derive environmental exposure estimates. ERC default factors may be used to estimate emissions of BPA in three major life-cycle stages, namely the production stage including manufacture of substances, formulation of mixtures and production of articles, the 'in-use' stage, and the waste stage.

Please indicate if you have information on specific emission values (refinements or specific environmental release categories - SPERCs) for BPA, based on measurements and / or model calculations.

Free text field (1000 characters left)

Information on the availability of alternatives

In the background report the authorities present stakeholder information from a previous public consultation as well as data compiled for a research project in which alternatives to the use of BPA where identified. The data suggests that for several uses alternatives are already available or soon will be available and that for most other uses potential alternatives for BPA are currently researched. The authorities would like to learn about your views with regard to the availability of alternatives in case you cannot meet the proposed limit values.

Do you have information on alternatives?

Yes	*No*

What is the specific application/functionality of BPA in your product(s)/processes?

Free text field (1000 characters left)

In your view, are the listed non-BPA alternatives technically feasible in your product(s)/processes?

Yes	*No*

Please specify why.

Free text field (1000 characters left)

In your view, are the listed non-BPA alternatives economically feasible in your product(s)/processes?

Yes	*No*

Please specify why.

Free text field (1000 characters left)

Do you have information on the alternatives' risk profile?

Yes	*No*

Please describe.

Free text field (1000 characters left)

Are there legal approval schemes for your product(s)/processes, which have to be taken into account in case BPA alternatives will be used?

Yes	*No*

Please specify and/or refer to literature/public sources.

Free text field (1000 characters left)

What is the average approval time?

Free text field (1000 characters left)

Do you actively work on finding alternatives?

Yes	*No*

Please specify.

Free text field (1000 characters left)

If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain.

Free text field (1000 characters left)

Do you have information on additional alternatives for any of the described applications that have not been disclosed in the attached information?

Free text field (1000 characters left)

Information on Economic Impacts

What is the economic impact (euro) and social impact (jobs) on your business/company if the use of BPA is prohibited?

a) In 3 years.

Free text field (1000 characters left)

b) In 10 years.

Free text field (1000 characters left)

c) Please explain by providing your calculations.

Free text field (1000 characters left)

V. BosC Use (P), (C), (A) (bisphenols of similar concern BPF, BPS, BPB, BPAF): BPA-like BosC uses

The following linked information presents the status quo based on information available to the authorities: report_summary_on_BosC_uses.pdf

General Information

It is well documented that BPA has been substituted in the recent past with other bisphenols (namely BPS) for the use as an additive in the manufacturing of thermal paper. The available information suggests that BosC substitute several other former BPA uses, too. In order to assess the impacts resulting from a restriction on manufacturing and downstream use of BPF, BPS, BPB and BPAF the authorities invite you to share information on uses where these BosC already substitute former uses of BPA.

Only limited information could be gathered in the first Call for Evidence on uses of BosC. Therefore, the authorities invite you to submit general as well as detailed information on manufacture and use of BosC for polymers (P), production of chemicals (C) and additive uses (A).

Information on use, release and emission

Please provide information on which sectors your information for the BosC relates to, including how it is transferred and processed, e.g. as a mixture of granules or article (materials/subassembly)?

Free text field (2000 characters left)

For which articles/mixtures are the BosC used. Are they used as an additive or a monomer? Which technical function do they have in the process or in the material/article matrix (e.g. dye fixation agent, stabilizer, plasticizer)? Please provide the following additional information, where possible:

i. The identity of the mixtures/articles containing BosC (intended e.g. as an additive and not intended e.g. as residual)
ii. Concentrations of BosC in these products (if possible: differentiated into concentration used in total, reacted, i.e. chemically bound, and unreacted BosC)
iii. Who are the users: are they consumers, professional or industrial users and how are the users processing the mixture/article?
iv. Quantity of BosC used in these products (e.g. as annual tonnage)
v. Are measures in place to minimize releases during manufacture and handling of mixtures/articles and their life cycle? Do strictly controlled conditions exist or can they be implemented? If yes, please specify the measure(s) in place and if possible, the resulting release reduction
vi. How long is the common service life for the mixture/article?
vii. What are the known stressors (e.g. UV-radiation, pH, temperature, moisture) for your article / mixture and how can they influence releases? What are your solutions to prevent or minimize the releases?
viii.

Free text field (1000 characters left)

If possible, please provide any additional information on the overall market for your use(s), e.g. relevant statistical data on EEA-market(s) in which you act, share of articles manufactured in your market(s) with BPA/BosC, time trends regarding substitution of BPA with BosC..

Free text field (1000 characters left)

In case you use BosC in a use/uses where it is technically possible to use BPA. Can you describe why?

Free text field (1000 characters left)

Do you have information on other uses where BPA has been substituted with BosC?

Free text field (1000 characters left)

Are you able to apply or do you have access to methods to simulate and analyse the migration behaviour of BPA and BosC during the service life of your article?

Free text field (1000 characters left)

Information on the availability of alternatives

In the background report the authorities present stakeholder information from a previous public consultation as well as data compiled for a research project in which alternatives to the use of BPA where identified. It should be noted here that such alternatives also comprise BosC in the scope of the restriction proposal. Such substitutes will not be taken as suitable alternatives in the sense of the presented restriction strategy here. The data suggests that for several uses alternatives are already available or soon will be available and that for most other uses potential alternatives for BPA are currently researched. The authorities would like to learn about your views with regard to the availability of non-phenolic alternatives in case you cannot meet the proposed limit values for BPA and BosC.

Do you have information on alternatives? (answer no if you want to skip questions on alternatives completely)

Yes	*No*

What is the specific application/functionality of the BosC in your product(s)/processes?

Free text field (1000 characters left)

In your view, are the listed non-phenolic alternatives technically feasible in your product(s)/processes?

Yes	*No*

Please specify why.

Free text field (1000 characters left)

In your view, are the listed non-phenolic alternatives economically feasible in your product(s)/processes?

Yes	*No*

Please specify why.

Free text field (1000 characters left)

Do you have information on the alternatives' risk profile?

Yes	*No*

Please describe.

Free text field (1000 characters left)

Are there legal approval schemes for your product(s)/processes, which have to be taken into account in case non-phenolic alternatives will be used?

Yes	*No*

Please specify and/or refer to literature/public sources.

Free text field (1000 characters left)

What is the average approval time?

Free text field (1000 characters left)

Do you actively work on finding alternatives?

Yes	*No*

Please specify.

Free text field (1000 characters left)

If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain.

Free text field (1000 characters left)

Do you have information on additional alternatives for any of the described applications that have not been disclosed in the attached information?

Free text field (1000 characters left)

<u>Information on Economic Impacts</u>

What is the economic impact (euro) and social impact (jobs) on your business/company if the use of BPA and BosC is prohibited?

a) In 3 years.

Free text field (1000 characters left)

b) In 10 years.

Free text field (1000 characters left)

c) Please explain by providing your calculations.

Free text field (1000 characters left)

VI. BosC Use (P), (C), (A) (bisphenols of similar concern BPF, BPS, BPB, BPAF): Discrete BosC uses

The following linked information presents the status quo based on information available to the authorities: report_summary_on_BosC_uses.pdf

<u>General Information</u>

According to available information BosC are mainly used or might be used as drop-in substitutes for uses where they replace BPA. For example, it is well documented that BPA has been substituted in the recent past with other bisphenols (namely BPS) for the use of BPA as an additive in the manufacturing of thermal paper . The available information suggests that BosC substitute or will substitute several other former BPA uses, too. However, in order to assess potential uses where BPF, BPS, BPB and BPAF do not function as direct substitute for BPA the authorities invite you to share information on such uses. Only limited information could be gathered in the first Call for Evidence on uses of BosC. Therefore, the authorities ask for general as well as detailed information on manufacture and use

Please provide information to which sectors your information for the BosC relates to, including how it is transported and processed, e.g. as a mixture of granules or article (materials/subassembly)?

Free text field (2000 characters left)

<u>Information on use, release and emission</u>

For which articles/mixtures are the BosC used. Are they used as an additive or a monomer? Which technical function do they have in the process or the material/article matrix (e.g. dye fixation agent, stabilizer, plasticizer)? Please provide the following additional information, where possible:

- *i. The identity of the mixtures/articles BosC (intended e.g. as an additive and not intended e.g. as residual)*
- *ii. Concentrations of BosC in these products (if possible: differentiated into concentration used in total, reacted, i.e. chemically bound, and unreacted BosC*
- *iii. Who are the users: are they consumers, professional or industrial users and how are the users processing the mixture/article?*
- *iv. Quantity of BosC used in these products (e.g. as annual tonnage)*
- *v. Are measures in place to minimize releases during manufacture and handling of mixtures/articles and their life cycle? Do strictly controlled conditions exist or can they be implemented? If yes, please specify the measure(s) in place and if possible, the resulting release reduction*
- *vi. How long is the common service life for the mixture/article?*
- *vii. What are the known stressors (e.g. UV-radiation, pH, temperature, moisture) for your article / mixture and how can they influence releases? What are your solutions to prevent or minimize the releases?*

Free text field (1000 characters left)

If possible, please provide any additional information on the overall market for your use(s)?

Free text field (2000 characters left)

Are you able to apply or do you have access to methods to simulate and analyse the migration behaviour of BosC during the service life of your article?

Free text field (1000 characters left)

Do you know simulation testing and analytical methods to conduct migration of BosC during service life of your product?

Free text field (1000 characters left)

Information on the availability of alternatives

In the background reports on uses of BPA the authorities present stakeholder information from a previous public consultation as well as data compiled for a research project in which alternatives to the use of BPA where identified. The data suggests that for several uses alternatives are already available or soon will be available and that for most other uses potential alternatives for BPA are currently researched. No information is available with regard to additional uses of BosC. The authorities would like to learn about your views with regard to the availability of non-phenolic alternatives in case you cannot meet the proposed limit values for BPA and BosC.

Do you have information on alternatives? (answer no if you want to skip questions on alternatives completely)

Yes	*No*

What is the specific application/functionality of the BosC in your product(s)/processes?

Free text field (1000 characters left)

Are in your view non-phenolic alternatives technically feasible in your product(s)/processes?

Yes	*No*

Please specify why.

Free text field (1000 characters left)

Are in your view non-phenolic alternatives economically feasible in your product(s)/processes?

Yes	*No*

Please specify why.

Free text field (1000 characters left)

Do you have information on the alternatives' risk profile?

Yes	*No*

Please describe.

Free text field (1000 characters left)

Are there legal approval schemes for your product(s)/processes, which have to be taken into account in case non-phenolic alternatives will be used?

Yes	*No*

Please specify and/or refer to literature/public sources.

Free text field (1000 characters left)

What is the average approval time?

Free text field (1000 characters left)

Do you actively work on finding alternatives?

Yes	*No*

Please specify.

Free text field (1000 characters left)

If alternatives have been identified as potentially suitable, which timescale do you foresee for a complete transition to those? Please explain.

Free text field (1000 characters left)

Information on Economic Impacts

What is the economic impact (euro) and social impact (jobs) on your business/company if the use of BPA and BosC is prohibited?

a) In 3 years.

Free text field (1000 characters left)

b) In 10 years.

Free text field (1000 characters left)

c) Please explain by providing your calculations.

Free text field (1000 characters left)

VII. Limit value for bisphenol content in mixtures and articles; Concentration limit and Migration limit

The following linked information presents the current picture: supplemental_material_on_concentration_limit_and_migration.pdf

<u>Information on the concentration limit</u>

The authorities consider setting a concentration limit of 10ppm (0.001% by weight) for the sum of BPA and BosC.

Can the articles/mixtures you produce comply with a 10ppm (0.001% by weight) concentration limit?

Yes	*No*

Please specify.

Free text field (1000 characters left)

If you expect to comply with the concentration limit: Do you expect any technical or practical issues with regard to the implementation of the concentration limit in general and/or specifically with regard to your business. Please specify.

Free text field (2000 characters left)

What is the economic impact (euro) on your business/company if testing for a concentration limit were passed into regulation?

Free text field (2000 characters left)

Please explain by providing your calculations.

Free text field (1000 characters left)

Do you agree with the cost estimation presented in the background document?

Yes	*No*

Please specify.

Free text field (1000 characters left)

Which is the most economical way to communicate the compliance of your article in the value chain and towards enforcement authorities?

Free text field (2000 characters left)

Information on the migration limit

The authorities consider setting a migration limit of 0.04 mg/L (BPA in the eluate, as single analyte or as sum with other bisphenols of concern) over the entire service life for articles/mixtures (e.g. as mixtures of granules) that cannot comply with a 10ppm residue limit for the sum of BPA and BosC.

Can the articles/mixtures you produce comply with a 0.04 mg/L migration limit?

Yes	*No*

Please specify.

Free text field (1000 characters left)

The authorities provide different migration testing methods in the background document. Which of these tests are appropriate for your article/mixture?

Free text field (2000 characters left)

Please specify.

Free text field (1000 characters left)

If the testing methods are not appropriate for your article/mixture which testing methods would you use to confirm your articles/mixtures compliance with the migration limit?

Free text field (1000 characters left)

What is the economic impact (euro) on your business/company if testing for a migration limit were passed into regulation?

Free text field (1000 characters left)

Please explain by providing your calculations.

Free text field (1000 characters left)

Do you agree with the cost estimation presented in the background document?

Yes	*No*

Please specify.

Free text field (1000 characters left)

Which is the most economical way to communicate the compliance of your article in the value chain and towards enforcement authorities?

Free text field (2000 characters left)

In case you want to submit additional confidential information you can upload your document here.

Option to upload attachment

Please specify where the relevant confidential information can be found in the document.

Free text field (1000 characters left)

[End of questionnaire]

Bibliography

A. M.-G.A.W. (2022): Problems Regarding the Calculation of Recycling and Recovery Rates for End-of-life Vehicles in the European Union Member States. European Research Studies Journal Volume XXV (Issue 1, 2022), 752-764.

Abraham E., Palevitch O., Gothilf Y., and Zohar Y. (2010): Targeted gonadotropin-releasing hormone-3 neuron ablation in zebrafish: effects on neurogenesis, neuronal migration, and reproduction. Endocrinology 151 (1), 332-340. DOI: 10.1210/en.2009-0548

Ahsan N., Ullah H., Ullah W., and Jahan S. (2018): Comparative effects of Bisphenol S and Bisphenol A on the development of female reproductive system in rats; a neonatal exposure study. Chemosphere 197, 336-343. DOI: https://doi.org/10.1016/j.chemosphere.2017.12.118

Akahori Y., Nakai M., Yamasaki K., Takatsuki M., Shimohigashi Y., and Ohtaki M. (2008): Relationship between the results of in vitro receptor binding assay to human estrogen receptor α and in vivo uterotrophic assay: Comparative study with 65 selected chemicals. Toxicology in Vitro 22 (1), 225-231. DOI: https://doi.org/10.1016/j.tiv.2007.08.004

Akhbarizadeh R., Moore F., Monteiro C., Fernandes J.O., and Cunha S.C. (2020): Occurrence, trophic transfer, and health risk assessment of bisphenol analogues in seafood from the Persian Gulf. Marine Pollution Bulletin 154, 111036. DOI: https://doi.org/10.1016/j.marpolbul.2020.111036

Anjali V., Remya V., Suma R., S S., and Aruna C. (2019): Impact of Bisphenol S as an Endocrine Disruptor in a Freshwater Fish, Oreochromis mossambicus 23, 49-63. DOI: 10.18311/jer/2019/27184

Anonymous (1998): Biodegradation and Bioaccumulation Data of Existing Chemicals based on the CSCL Japan. Chemicals Inspection & Testing Institute Japan; Japan Chemical Industry Ecology-Toxicology & Information Center (JETOC)

Arancio A.L., Cole K.D., Dominguez A.R., Cohenour E.R., Kadie J., Maloney W.C., Cilliers C., and Schuh S.M. (2019): Bisphenol A, Bisphenol AF, di-n-butyl phthalate, and 17beta-estradiol have shared and unique dose-dependent effects on early embryo cleavage divisions and development in Xenopus laevis. Reprod Toxicol 84, 65-74. DOI: 10.1016/j.reprotox.2018.12.005

Artacho-Cordón F., Arrebola J., Nielsen O., Hernández P., Skakkebaek N., Fernández M., Andersson A., Olea N., and Frederiksen H. (2017): Assumed non-persistent environmental chemicals in human adipose tissue; matrix stability and correlation with levels measured in urine and serum. Environmental Research 156, 120-127

Ashrap P., Watkins D.J., Calafat A.M., Ye X., Rosario Z., Brown P., Velez-Vega C.M., Alshawabkeh A., Cordero J.F., and Meeker J.D. (2018): Elevated concentrations of urinary triclocarban, phenol and paraben among pregnant women in Northern Puerto Rico: Predictors and trends. Environment International 121, 990-1002

Asimakopoulos A.G., Elangovan M., and Kannan K. (2016): Migration of Parabens, Bisphenols, Benzophenone-Type UV Filters, Triclosan, and Triclocarban from Teethers and Its Implications for Infant Exposure. Environ Sci Technol 50 (24), 13539-13547. DOI: 10.1021/acs.est.6b04128

Aykut H. and Kaptaner B. (2021): In vitro effects of bisphenol F on antioxidant system indicators in the isolated hepatocytes of rainbow trout (Oncorhyncus mykiss). Molecular Biology Reports 48 (3), 2591-2599. DOI: 10.1007/s11033-021-06310-3

Balicco A., Bidondo M., Fillol C., and GANE J. (2019): Imprégnation De La Population Française Par Les Bisphénols A, S Et F: Programme National De Biosurveillance, Esteban 2014–2016. Santé Publique France: Ile-de-France, France, 57

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: RMOA Section of the German REACH/CLP/Biozid Helpdesk. https://www.reach-clp-biozid-helpdesk.de/EN/Home/Home_node.html (last accessed 16.03.2022)

BAuA (2017a): Risk Management Option Analysis Conclusion Document (published), date: 13.06.2017. Bundesanstalt für Arbeitsschutz und Arbeitsmedizin. Risk Management Option Analysis Conclusion Document

BAuA (2017b): SUBSTANCE EVALUATION CONCLUSION as required by REACH Article 48 and EVALUATION REPORT for 4,4'-Isopropylidenediphenol, date: May 2017. Evaluating Member State Competent Authority: BAuA. https://echa.europa.eu/documents/10162/2e8ac666-fae6-2e54-f0eb-ef4a5da819ed

BAuA (2018): CORRIGENDUM to the Part B of the SUBSTANCE EVALUATION CONCLUSION as required by REACH Article 48 and EVALUATION REPORT for 4,4'-Isopropylidenediphenol date: 02.10.2018. Evaluating Member State Competent Authority: BAuA. Germany E.M.S. https://echa.europa.eu/documents/10162/3cd2972c-7758-1cff-929f-ca35f9dae511

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

Berkner S., Streck G., and Herrmann R. (2004): Development and validation of a method for determination of trace levels of alkylphenols and bisphenol A in atmospheric samples. Chemosphere 54 (4), 575-584

Bicchi C., Schilirò T., Pignata C., Fea E., Cordero C., Canale F., and Gilli G. (2009): Analysis of environmental endocrine disrupting chemicals using the E-screen method and stir bar sorptive extraction in wastewater treatment plant effluents. Science of The Total Environment 407 (6), 1842-1851

Bidleman T. (1988): Wet and dry deposition of organic compounds are controlled by their vapor-particle partitioning. Environ. Sci. Technol. 22, 361-367

Bizarro C., Ros O., Vallejo A., Prieto A., Etxebarria N., Cajaraville M.P., and Ortiz-Zarragoitia M. (2014): Intersex condition and molecular markers of endocrine disruption in relation with burdens of emerging pollutants in thicklip grey mullets (Chelon labrosus) from Basque estuaries (South-East Bay of Biscay). Mar Environ Res 96, 19-28. DOI: 10.1016/j.marenvres.2013.10.009

Bjermo H.G., I.; Lindh, C.H. (2019): Concentrations of phthalates and phenolic substances in urine from first-time mothers in Uppsala, Sweden: temporal trends 2009-2018. Livsmedelsverket

Björklund K., Cousins A.P., Strömvall A.-M., and Malmqvist P.-A. (2009): Phthalates and nonylphenols in urban runoff: Occurrence, distribution and area emission factors. Science of the Total Environment 407 (16), 4665-4672. DOI: https://doi.org/10.1016/j.scitotenv.2009.04.040

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

Brion F., Le Page Y., Piccini B., Cardoso O., Tong S.K., Chung B.C., and Kah O. (2012): Screening estrogenic activities of chemicals or mixtures in vivo using transgenic (cyp19a1b-GFP) zebrafish embryos. PLoS ONE 7 (5), e36069. DOI: 10.1371/journal.pone.0036069

Brueller W., Inreiter N., Boegl T., Rubasch M., Saner S., Humer F., Moche W., Schuhmann A., Hartl W., Brezinka C., Wildt L., and Allerberger F. (2018): Occurrence of chemicals with known or suspected endocrine disrupting activity in drinking water, groundwater and surface water, Austria 2017/2018. Die Bodenkultur: Journal of Land Management, Food and Environment 69 (3), 155-173. DOI: doi:10.2478/boku-2018-0014

Burkhardt M., Engelke D., Gehrig S., Hochstrasser F., Rohr M., and Tietje O. (2019): Introduction and application of the software COMLEAM – Manual Version 2.0 (Rapperswil H.U.o.A.S., ed.), Switzerland. https://comleam.com/en/home/_comleam-benutzen/COMLEAM_Manual_V2.pdf

Burkhardt M., Zuleeg S., Vonbank R., Schmid P., Hean S., Lamani X., Bester K., and Boller M. (2011): Leaching of additives from construction materials to urban storm water runoff. Water Science and Technology 63 (9), 1974-1982. DOI: 10.2166/wst.2011.128 (last accessed 9/2/2021)

Caban M. and Stepnowski P. (2020): Determination of bisphenol A in size fractions of indoor dust from several microenvironments. Microchemical Journal 153, 104392

Cai M., Li Y.Y., Zhu M., Li J.B., and Qin Z.F. (2020): Evaluation of the effects of low concentrations of bisphenol AF on gonadal development using the Xenopus laevis model: A finding of testicular differentiation inhibition coupled with feminization. Environ Pollut 260, 113980. DOI: 10.1016/j.envpol.2020.113980

Campen K.A., Lavallee M., and Combelles C. (2018): The impact of bisphenol S on bovine granulosa and theca cells. Reprod Domest Anim 53 (2), 450-457. DOI: 10.1111/rda.13130

Cano-Nicolau J., Vaillant C., Pellegrini E., Charlier T.D., Kah O., and Coumailleau P. (2016): Estrogenic Effects of Several BPA Analogs in the Developing Zebrafish Brain. Front Neurosci 10, 112. DOI: 10.3389/fnins.2016.00112

Cao S., Wang S., Zhao Y., Wang L., Ma Y., Schäffer A., and Ji R. (2020): Fate of bisphenol S (BPS) and characterization of non-extractable residues in soil: Insights into persistence of BPS. Environment International 143, 105908

Cao X.-L. and Popovic S. (2015): Bisphenol A and three other bisphenol analogues in canned fish products from the Canadian market 2014. Journal of food protection 78 (7), 1402-1407

Casas M., Basagaña X., Sakhi A.K., Haug L.S., Philippat C., Granum B., Manzano-Salgado C.B., Brochot C., Zeman F., and de Bont J. (2018): Variability of urinary concentrations of non-persistent chemicals in pregnant women and school-aged children. Environment International 121, 561-573

Casatta N., Mascolo G., Roscioli C., and Viganò L. (2015): Tracing endocrine disrupting chemicals in a coastal lagoon (Sacca di Goro, Italy): Sediment contamination and bioaccumulation in Manila clams. Science of The Total Environment 511, 214-222

Česen M., Ahel M., Terzić S., Heath D.J., and Heath E. (2019): The occurrence of contaminants of emerging concern in Slovenian and Croatian wastewaters and receiving Sava river. Science of The Total Environment 650, 2446-2453

Česen M., Lenarčič K., Mislej V., Levstek M., Kovačič A., Cimrmančič B., Uranjek N., Kosjek T., Heath D., Dolenc M.S., and Heath E. (2018): The occurrence and source identification of bisphenol compounds in wastewaters. Science of The Total Environment 616-617, 744-752. DOI: https://doi.org/10.1016/j.scitotenv.2017.10.252

Chang B.V., Liu J.H., and Liao C.S. (2014): Aerobic degradation of bisphenol-A and its derivatives in river sediment. Environ Technol 35 (1-4), 416-424. DOI: 10.1080/09593330.2013.831111

Chen D., Kannan K., Tan H., Zheng Z., Feng Y.L., Wu Y., and Widelka M. (2016): Bisphenol Analogues Other Than BPA: Environmental Occurrence, Human Exposure, and Toxicity-A Review. Environ Sci Technol 50 (11), 5438-5453. DOI: 10.1021/acs.est.5b05387

Chen P., Wang R., Chen G., An B., Liu M., Wang Q., and Tao Y. (2022): Thyroid endocrine disruption and hepatotoxicity induced by bisphenol AF: Integrated zebrafish embryotoxicity test and deep learning. Sci Total Environ 822, 153639. DOI: 10.1016/j.scitotenv.2022.153639

Chin Y.-P., Miller P.L., Zeng L., Cawley K., and Weavers L.K. (2004): Photosensitized degradation of bisphenol A by dissolved organic matter. Environmental Science & Technology 38 (22), 5888-5894

Choi Y.J. and Lee L.S. (2017a): Aerobic soil biodegradation of bisphenol (BPA) alternatives bisphenol S and bisphenol AF compared to BPA. Environmental Science & Technology 51 (23), 13698-13704

Choi Y.J. and Lee L.S. (2017b): Partitioning Behavior of Bisphenol Alternatives BPS and BPAF Compared to BPA. Environmental Science & Technology 51 (7), 3725-3732. DOI: 10.1021/acs.est.6b05902

CITI (1998): Study of bio-accumulation of dihydroxydiphenyl Sulfone (include nucleic methyl substituted compounds) [4,4'-sulfonyldiphenol (K-1328)]. 51328 (in Japanese), Japan

Coors A., Jones P.D., Giesy J.P., and Ratte H.T. (2003): Removal of estrogenic activity from municipal waste landfill leachate assessed with a bioassay based on reporter gene expression. Environ Sci Technol 37 (15), 3430-3434. DOI: 10.1021/es0300158

Corrales J., Kristofco L.A., Steele W.B., Yates B.S., Breed C.S., Williams E.S., and Brooks B.W. (2015): Global assessment of bisphenol A in the environment: review and analysis of its occurrence and bioaccumulation. Dose-Response 13 (3), 1559325815598308

Couderc M., Poirier L., Zalouk-Vergnoux A., Kamari A., Blanchet-Letrouvé I., Marchand P., Vénisseau A., Veyrand B., Mouneyrac C., and Le Bizec B. (2015): Occurrence of POPs and other persistent organic contaminants in the European eel (Anguilla anguilla) from the Loire estuary, France. Science of The Total Environment 505, 199-215

Coumailleau P., Trempont S., Pellegrini E., and Charlier T.D. (2020): Impacts of bisphenol A analogues on zebrafish post-embryonic brain. J Neuroendocrinol 32 (8), e12879. DOI: 10.1111/jne.12879

Covington (2011): Tanning Chemistry: The Science of Leather. ISBN: 978-1-84973-434-9

Danzl E., Sei K., Soda S., Ike M., and Fujita M. (2009): Biodegradation of bisphenol A, bisphenol F and bisphenol S in seawater. Int J Environ Res Public Health 6 (4), 1472-1484. DOI: 10.3390/ijerph6041472

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

Desdoits-Lethimonier C., Lesné L., Gaudriault P., Zalko D., Antignac J.P., Deceuninck Y., Platel C., Dejucq-Rainsford N., Mazaud-Guittot S., and Jégou B. (2017): Parallel assessment of the effects of bisphenol A and several of its analogs on the adult human testis. Hum Reprod 32 (7), 1465-1473. DOI: 10.1093/humrep/dex093

Doucette W.J. (2000): Soil and sediment sorption coefficients, 141-188. CRC Press LLC: Boca Raton, Florida

Dualde P., Pardo O., Corpas-Burgos F., Kuligowski J., Gormaz M., Vento M., Pastor A., and Yusà V. (2019): Biomonitoring of bisphenols A, F, S in human milk and probabilistic risk assessment for breastfed infants. Science of The Total Environment 668, 797-805

Duan Y., Yao Y., Wang B., Han L., Wang L., Sun H., and Chen L. (2018): Association of urinary concentrations of bisphenols with type 2 diabetes mellitus: A case-control study. Environmental Pollution 243, 1719-1726. DOI: https://doi.org/10.1016/j.envpol.2018.09.093

Dueñas-Mas M.J., Ballesteros-Gómez A., and Rubio S. (2019): Supramolecular solvent-based microextraction of emerging bisphenol A replacements (colour developers) in indoor dust from public environments. Chemosphere 222, 22-28. https://www.sciencedirect.com/science/article/pii/S004565351930102X?via%3Dihub

Dvořáková M., Kejlová K., Bendová H., Rucki M., Kohout P., Vavrouš A., and Jírová D. (2016): Alternative methods in vitro for screening of endocrine disruptors. Neuro Endocrinol Lett 37 (Suppl1), 123-131

ECHA (2017a): 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

ECHA (2017b): Member State Committee Support Document for Identification of 4,4'-Isopropylidenediphenol (Bisphenol A, BPA) as a Substance of Very High Concern because of its endocrine disrupting properties (Article 57(f)) causing probable serious effects to the environment which give rise to an equivalent level of concern to those of CMR and PBT/vPvB properties, date: 14.12.2017. European Chemicals Agency, https://echa.europa.eu/documents/10162/769b2777-19cd-9fff-33c4-54fe6d8290d5

ECHA (2020a): ECHA Weekly - 14 October 2020. https://echa.europa.eu/de/view-article/-/journal_content/title/echa-weekly-14-october-2020 (last accessed 16.03.2022)

ECHA (2020b): Previous calls for comments and evidence. https://echa.europa.eu/previous-calls-for-comments-and-evidence/-/substance-rev/57001/term (last accessed 16.03.2022)

ECHA (2021): 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

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

EFSA (2021): Bisphenol A: EFSA draft opinion proposes lowering the tolerable daily intake. https://www.efsa.europa.eu/en/news/bisphenol-efsa-draft-opinion-proposes-lowering-tolerable-daily-intake (last accessed 25.01.2022)

EFSA Panel on Food Contact Materials E., Flavourings Processing Aids, (2015): Scientific opinion on the risks to public health related to the presence of bisphenol A (BPA) in foodstuffs. EFSA Journal 13 (1), 3978

Eladak S., Grisin T., Moison D., Guerquin M., N'Tumba-Byn T., Pozzi-Gaudin S., Benachi A., Livera G., Rouiller-Fabre V., and Habert R. (2015): A new chapter in the bisphenol A story: bisphenol S and bisphenol F are not safe alternatives to this compound. Fertil Steril 103 (1), 11-21. DOI: 10.1016/j.fertnstert.2014.11.005

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

Eriksson J., Rahm S., Green N., Bergman Å., and Jakobsson E. (2004): Photochemical transformations of tetrabromobisphenol A and related phenols in water. Chemosphere 54 (1), 117-126

European C. and Directorate-General for E. (2022): The use of PVC (poly vinyl chloride) in the context of a non-toxic environment : final report. Publications Office of the European Union. DOI: doi/10.2779/375357

European Chemicals Agency (2019): Use of bisphenol A and its alternatives in thermal paper in the EU – 2018 update. ECHA-2019-R-12-EN. DOI: 10.2823/258259

European Chemicals Agency (2020): The use of bisphenol A and its alternatives in thermal paper in the EU during 2014-2022. DOI: DOI: 10.2823/592282

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 Commission (2008): Updated European Risk Assessment Report 4,4'-ISOPROPYLIDENEDIPHENOL (BISPHENOL-A), date: 2/1/2008. Communities O.f.O.P.o.t.E., Luxembourg

European Commission (2010): European Union Risk Assessment Report 4,4-ISOPROPYLENEDIPHENOL (Bisphenol-A) complete risk assessment in one document, date: 2/10/2010. 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

European P., Recycling, Council (2022): Monitoring Report 2021 - European Declaration on Paper Recycling 2021-2030, Brussels. https://www.paperforrecycling.eu/publications/

European Parliament (2016): European Parliament resolution of 14 March 2013 on the protection of public health from endocrine disrupters (2012/2066(INI)). Official Journal of the European Union C 36, 85-91. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52013IP0091

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

Feng Y., Jiao Z., Shi J., Li M., Guo Q., and Shao B. (2016): Effects of bisphenol analogues on steroidogenic gene expression and hormone synthesis in H295R cells. Chemosphere 147, 9-19. DOI: 10.1016/j.chemosphere.2015.12.081

Fenichel P., Dechaux H., Harthe C., Gal J., Ferrari P., Pacini P., Wagner-Mahler K., Pugeat M., and Brucker-Davis F. (2012): Unconjugated bisphenol A cord blood levels in boys with descended or undescended testes. Human Reproduction 27 (4), 983-990

Fenlon K.A., Johnson A.C., Tyler C.R., and Hill E.M. (2010): Gas–liquid chromatography–tandem mass spectrometry methodology for the quantitation of estrogenic contaminants in bile of fish exposed to wastewater treatment works effluents and from wild populations. Journal of Chromatography A 1217 (1), 112-118

Fent G., Hein W.J., Moendel M.J., and Kubiak R. (2003): Fate of 14C-bisphenol A in soils. Chemosphere 51 (8), 735-746

Fernandez M., Arrebola J., Taoufiki J., Navalón A., Ballesteros O., Pulgar R., Vilchez J., and Olea N. (2007): Bisphenol-A and chlorinated derivatives in adipose tissue of women. Reprod Toxicol 24 (2), 259-264

Fischer B., Milunov M., Floredo Y., Hofbauer P., and Joas A. (2014): Identification of relevant emission pathways to the environment and quantification of environmental exposure for Bisphenol A. https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_41_2014_identfifcation_of_relevant_emission_pathways_of_bisphenol_a_0.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

France (2021): Annex XV report PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE OF VERY HIGH CONCERN ON THE BASIS OF THE CRITERIA SET OUT IN REACH ARTICLE 57 4,4'-(1-methylpropylidene)bisphenol (bisphenol B; BPB). https://echa.europa.eu/documents/10162/00872c55-2827-a6d7-273d-78ac4391906b

Frankowski R., Zgoła-Grześkowiak A., Smułek W., and Grześkowiak T. (2020): Removal of bisphenol A and its potential substitutes by biodegradation. Applied Biochemistry and Biotechnology 191 (3), 1100-1110

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

Fu P. and Kawamura K. (2010): Ubiquity of bisphenol A in the atmosphere. Environmental Pollution 158 (10), 3138-3143

Gao C.-J. and Kannan K. (2020): Phthalates, bisphenols, parabens, and triclocarban in feminine hygiene products from the United States and their implications for human exposure. Environment International 136, 105465

García-Córcoles M., Cipa M., Rodríguez-Gómez R., Rivas A., Olea-Serrano F., Vílchez J., and Zafra-Gómez A. (2018): Determination of bisphenols with estrogenic activity in plastic packaged baby food samples using solid-liquid extraction and clean-up with dispersive sorbents followed by gas chromatography tandem mass spectrometry analysis. Talanta 178, 441-448. https://www.sciencedirect.com/science/article/pii/S0039914017310093?via%3Dihub

Gatidou G., Vassalou E., and Thomaidis N.S. (2010): Bioconcentration of selected endocrine disrupting compounds in the Mediterranean mussel, Mytilus galloprovincialis. Marine Pollution Bulletin 60 (11), 2111-2116

Geens T., Goeyens L., and Covaci A. (2011): Are potential sources for human exposure to bisphenol-A overlooked? Int J Hyg Environ Health 214 (5), 339-347. DOI: 10.1016/j.ijheh.2011.04.005

Geens T., Neels H., and Covaci A. (2012): Distribution of bisphenol-A, triclosan and n-nonylphenol in human adipose tissue, liver and brain. Chemosphere 87 (7), 796-802

Gehring M. (2004): Verhalten der endokrin wirksamen Substanz Bisphenol A bei der kommunalen Abwasserentsorgung., Technische Universität Dresden

Gercken J. C.M., Petterssson M., Wickman T., Futter M., Ahrens L. (2018): HAZARDOUS SUBSTANCE OCCURRENCE IN BALTIC SEA PILOT MUNICIPALITIES - MAJOR OUTPUT FROM THE TRACKING AND RANKING FOR PRIORITISATION OF SOURCES IN NONHAZCITY PROJECT. City of Stockholm Stockholm

Gewurtz S.B., Tardif G., Power M., Backus S.M., Dove A., Dubé-Roberge K., Garron C., King M., Lalonde B., and Letcher R.J. (2021): Bisphenol A in the Canadian environment: A multimedia analysis. Science of The Total Environment 755, 142472

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

GmbH R.D. (2021): Additional information on the leather tanning agent use of 4,4'-Dihydroxydiphenylsulfone (DHDPS) as described in the CSR

Goldinger D.M., Demierre A.L., Zoller O., Rupp H., Reinhard H., Magnin R., Becker T.W., and Bourqui-Pittet M. (2015): Endocrine activity of alternatives to BPA found in thermal paper in Switzerland. Regul Toxicol Pharmacol 71 (3), 9. DOI: 10.1016/j.yrtph.2015.01.002

González-Rubio S., Ballesteros-Gómez A., Asimakopoulos A.G., and Jaspers V.L.B. (2021): A review on contaminants of emerging concern in European raptors (2002−2020). Science of The Total Environment 760, 143337. DOI: https://doi.org/10.1016/j.scitotenv.2020.143337

González-Rubio S., Vike-Jonas K., Gonzalez S.V., Ballesteros-Gómez A., Sonne C., Dietz R., Boertmann D., Rasmussen L.M., Jaspers V.L., and Asimakopoulos A.G. (2020): Bioaccumulation potential of bisphenols and benzophenone UV filters: A multiresidue approach in raptor tissues. Science of The Total Environment 741, 140330. https://www.sciencedirect.com/science/article/pii/S0048969720338523?via%3Dihub

González N., Cunha S.C., Monteiro C., Fernandes J.O., Marquès M., Domingo J.L., and Nadal M. (2019): Quantification of eight bisphenol analogues in blood and urine samples of workers in a hazardous waste incinerator. Environmental Research 176, 108576. DOI: https://doi.org/10.1016/j.envres.2019.108576

Gonzalez N., Marques M., Cunha S.C., Fernandes J.O., Domingo J.L., and Nadal M. (2020): Biomonitoring of co-exposure to bisphenols by consumers of canned foodstuffs. Environment International 140, 105760

Grignard E., Lapenna S., and Bremer S. (2012): Weak estrogenic transcriptional activities of Bisphenol A and Bisphenol S. Toxicol In Vitro 26 (5), 727-731. DOI: 10.1016/j.tiv.2012.03.013

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

Grumetto L., Gennari O., Montesano D., Ferracane R., Ritieni A., Albrizio S., and Barbato F. (2013): Determination of five bisphenols in commercial milk samples by liquid chromatography coupled to fluorescence detection. Journal of food protection 76 (9), 1590-1596

Grung M., Jartun M., Bæk K., Ruus A., Rundberget T., Allan I., Beylich B., Vogelsang C., Schlabach M., Hanssen L., Borgå K., and Helberg M. (2021): Environmental Contaminants in an Urban Fjord, 2020. vannforskning N.i.f. https://hdl.handle.net/11250/2838804

Gu J., Wu J., Xu S., Zhang L., Fan D., Shi L., Wang J., and Ji G. (2020): Bisphenol F exposure impairs neurodevelopment in zebrafish larvae (Danio rerio). Ecotoxicology and Environmental Safety 188, 109870. DOI: https://doi.org/10.1016/j.ecoenv.2019.109870

Guerranti C., Martellini T., Fortunati A., Scodellini R., and Cincinelli A. (2019): Environmental pollution from plasticiser compounds: Do we know enough about atmospheric levels and their contribution to human exposure in Europe? Current Opinion in Environmental Science & Health 8, 1-5. DOI: https://doi.org/10.1016/j.coesh.2018.10.004

Gyllenhammar I., Glynn A., Darnerud P.O., Lignell S., van Delft R., and Aune M. (2012): 4-Nonylphenol and bisphenol A in Swedish food and exposure in Swedish nursing women. Environment International 43, 21-28

Gyllenhammar I., Glynn A., Jönsson B.A., Lindh C.H., Darnerud P.O., Svensson K., and Lignell S. (2017): Diverging temporal trends of human exposure to bisphenols and plastizisers, such as phthalates, caused by substitution of legacy EDCs? Environmental Research 153, 48-54. https://www.sciencedirect.com/science/article/pii/S0013935116310854?via%3Dihub

Han Y., Fei Y., Wang M., Xue Y., Chen H., and Liu Y. (2021): Study on the Joint Toxicity of BPZ, BPS, BPC and BPF to Zebrafish. Molecules 26 (14). DOI: 10.3390/molecules26144180

Hansen A.B. and Lassen P. (2008): Screening of phenolic substances in the Nordic Environments. Nordic Council of Ministers, Copenhagen

Hartmann C. (2021): Human-Biomonitoring in sensiblen Bevölkerungsgruppen - Kindersurvey. REP-0780. Bundesministerium für Klimaschutz U., Energie, Mobilität, Innovation und and Technologie, Wien

Haug L.S., Sakhi A.K., Cequier E., Casas M., Maitre L., Basagana X., Andrusaityte S., Chalkiadaki G., Chatzi L., and Coen M. (2018): In-utero and childhood chemical exposome in six European mother-child cohorts. Environment International 121, 751-763

Heffernan A.L., Thompson K., Eaglesham G., Vijayasarathy S., Mueller J.F., Sly P.D., and Gomez M.J. (2016): Rapid, automated online SPE-LC-QTRAP-MS/MS method for the simultaneous analysis of 14 phthalate metabolites and 5 bisphenol analogues in human urine. Talanta 151, 224-233. DOI: https://doi.org/10.1016/j.talanta.2016.01.037

Holbech H., Petersen G.I., Norman A., Örn S., Norrgren L., and Bjerregaard P. (2001): Comparison of vitellogenin in plasma and whole body homogenate from zebrafish (Danio rerio) and rainbow trout (Oncorhynchus mykiss). In: Suitability of Zebrafish as Test Organism for Detection of Endocrine Disrupting Chemicals (Petersen G.I., ed.), chapter 6, pp. 48-51. Nordic Council of Ministers. ISBN: 9789289307215. https://books.google.de/books?id=Ibivl-Sb_HIC

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

Huang C., Wu L.-H., Liu G.-Q., Shi L., and Guo Y. (2018): Occurrence and ecological risk assessment of eight endocrine-disrupting chemicals in urban river water and sediments of South China. Archives of Environmental Contamination and Toxicology 75 (2), 224-235. https://link.springer.com/content/pdf/10.1007/s00244-018-0527-9.pdf

Huang G.M., Tian X.F., Fang X.D., and Ji F.J. (2016): Waterborne exposure to bisphenol F causes thyroid endocrine disruption in zebrafish larvae. Chemosphere 147, 188-194. DOI: 10.1016/j.chemosphere.2015.12.080

Huang T., Danaher L.A., Brüschweiler B.J., Kass G.E.N., and Merten C. (2019): Naturally occurring bisphenol F in plants used in traditional medicine. Archives of Toxicology 93 (6), 1485-1490. DOI: 10.1007/s00204-019-02442-5

Huang Z., Zhao J.-L., Yang Y.-Y., Jia Y.-W., Zhang Q.-Q., Chen C.-E., Liu Y.-S., Yang B., Xie L., and Ying G.-G. (2020): Occurrence, mass loads and risks of bisphenol analogues in the Pearl River Delta region, South China: Urban rainfall runoff as a potential source for receiving rivers. Environmental Pollution 263, 114361. DOI: https://doi.org/10.1016/j.envpol.2020.114361

Husøy T., Andreassen M., Hjertholm H., Carlsen M.H., Norberg N., Sprong C., Papadopoulou E., Sakhi A.K., Sabaredzovic A., and Dirven H. (2019): The Norwegian biomonitoring study from the EU project EuroMix: Levels of phenols and phthalates in 24-hour urine samples and exposure sources from food and personal care products. Environment International 132, 105103. https://www.sciencedirect.com/science/article/pii/S0160412019306944?via%3Dihub

Ihde E.S., Zamudio S., Loh J.M., Zhu Y., Woytanowski J., Rosen L., Liu M., and Buckley B. (2018): Application of a novel mass spectrometric (MS) method to examine exposure to Bisphenol-A and common substitutes in a maternal fetal cohort. Hum Ecol Risk Assess 24 (2), 331-346. DOI: 10.1080/10807039.2017.1381831

Ijaz S., Ullah A., Shaheen G., and Jahan S. (2020): Exposure of BPA and its alternatives like BPB, BPF, and BPS impair subsequent reproductive potentials in adult female Sprague Dawley rats. Toxicology Mechanisms and Methods 30 (1), 60-72. DOI: 10.1080/15376516.2019.1652873

Ike M., Chen M.Y., Danzl E., Sei K., and Fujita M. (2006): Biodegradation of a variety of bisphenols under aerobic and anaerobic conditions, 153-159. ISBN: 02731223 (ISSN). DOI: 10.2166/wst.2006.189

Ike M., Jin C., and Fujita M. (2000): Biodegradation of bisphenol A in the aquatic environment. Water Science and Technology 42 (7-8), 31-38

Jacobson M.H., Woodward M., Bao W., Liu B., and Trasande L. (2019): Urinary bisphenols and obesity prevalence among US children and adolescents. Journal of the Endocrine Society 3 (9), 1715-1726

Ji K., Hong S., Kho Y., and Choi K. (2013): Effects of bisphenol s exposure on endocrine functions and reproduction of zebrafish. Environ Sci Technol 47 (15), 8793-8800. DOI: 10.1021/es400329t

Jin H. and Zhu L. (2016): Occurrence and partitioning of bisphenol analogues in water and sediment from Liaohe River Basin and Taihu Lake, China. Water Research 103, 343-351. https://www.sciencedirect.com/science/article/pii/S0043135416305735?via%3Dihub

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

Jørgensen N.: Danish Young Men Study - cross sectional study (Dept. of Growth and Reproduction R., Region Hovedstaden, ed.). https://ipchem.jrc.ec.europa.eu/RDSIdiscovery/ipchem/index.html#showmetadata/DYMS (last accessed 08.07.2022)

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.

Jurek A. and Leitner E. (2018): Analytical determination of bisphenol A (BPA) and bisphenol analogues in paper products by LC-MS/MS. Food Addit Contam Part A Chem Anal Control Expo Risk Assess 35 (11), 2256-2269. DOI: 10.1080/19440049.2018.1524157

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

Kallivretaki E., Eggen R., Neuhauss S., Alberti M., Kausch U., and Segner H. (2006): Aromatase in zebrafish: A potential target for endocrine disrupting chemicals. Marine Environmental Research 62, S187-S190. DOI: https://doi.org/10.1016/j.marenvres.2006.04.003

Kang J.-H. and Kondo F. (2002): Bisphenol A degradation by bacteria isolated from river water. Archives of Environmental Contamination and Toxicology 43 (3), 0265-0269

Kang J.H. and Kondo F. (2005): Bisphenol A degradation in seawater is different from that in river water. Chemosphere 60 (9), 1288-1292. DOI: 10.1016/j.chemosphere.2005.01.058

Kang J.S., Choi J.S., Kim W.K., Lee Y.J., and Park J.W. (2014): Estrogenic potency of bisphenol S, polyethersulfone and their metabolites generated by the rat liver S9 fractions on a MVLN cell using a luciferase reporter gene assay. Reprod Biol Endocrinol 12, 102. DOI: 10.1186/1477-7827-12-102

Karthikraj R. and Kannan K. (2017): Mass loading and removal of benzotriazoles, benzothiazoles, benzophenones, and bisphenols in Indian sewage treatment plants. Chemosphere 181, 216-223. https://www.sciencedirect.com/science/article/pii/S0045653517306112?via%3Dihub

Kinch C.D., Ibhazehiebo K., Jeong J.-H., Habibi H.R., and Kurrasch D.M. (2015): Low-dose exposure to bisphenol A and replacement bisphenol S induces precocious hypothalamic neurogenesis in embryonic zebrafish. Proceedings of the National Academy of Sciences. DOI: 10.1073/pnas.1417731112

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

Klečka G.M., Gonsior S.J., West R.J., Goodwin P.A., and Markham D.A. (2001): Biodegradation of bisphenol A in aquatic environments: river die-away. Environ Toxicol Chem 20 (12), 2725-2735. http://www.ncbi.nlm.nih.gov/pubmed/11764155

Klečka G.M., Staples C.A., Clark K.E., van der Hoeven N., Thomas D.E., and Hentges S.G. (2009): Exposure analysis of bisphenol A in surface water systems in North America and Europe. Environmental Science & Technology 43 (16), 6145-6150

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

Koch H.M., Kolossa-Gehring M., Schröter-Kermani C., Angerer J., and Brüning T. (2012): Bisphenol A in 24 h urine and plasma samples of the German Environmental Specimen Bank from 1995 to 2009: A retrospective exposure evaluation. Journal of Exposure Science & Environmental Epidemiology 22 (6), 610-616. DOI: 10.1038/jes.2012.39

Kojima H., Takeuchi S., Sanoh S., Okuda K., Kitamura S., Uramaru N., Sugihara K., and Yoshinari K. (2019): Profiling of bisphenol A and eight its analogues on transcriptional activity via human nuclear receptors. Toxicology 413, 48-55. DOI: 10.1016/j.tox.2018.12.001

Kovačič A., Česen M., Laimou-Geraniou M., Lambropoulou D., Kosjek T., Heath D., and Heath E. (2019): Stability, biological treatment and UV photolysis of 18 bisphenols under laboratory conditions. Environmental Research 179, 108738

Kwon B., Kho Y., Kim P.-G., and Ji K. (2016): Thyroid endocrine disruption in male zebrafish following exposure to binary mixture of bisphenol AF and sulfamethoxazole. Environmental Toxicology and Pharmacology 48, 168-174. DOI: https://doi.org/10.1016/j.etap.2016.10.018

Larsson K., Lindh C.H., Jönsson B.A., Giovanoulis G., Bibi M., Bottai M., Bergström A., and Berglund M. (2017): Phthalates, non-phthalate plasticizers and bisphenols in Swedish preschool dust in relation to children's exposure. Environment International 102, 114-124. https://www.sciencedirect.com/science/article/pii/S0160412016307929?via%3Dihub

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

LAWA (2020): Bund/Länder-Arbeitsgemeinschaft Wasser (LAWA) - Ausschuss Oberirdische Gewässer und Küstengewässer (AO) (German federal monitoring programs). https://www.lawa.de/English-About-LAWA.html

Laws S.C., Yavanhxay S., Cooper R.L., and Eldridge J.C. (2006): Nature of the binding interaction for 50 structurally diverse chemicals with rat estrogen receptors. Toxicol Sci 94 (1), 46-56. DOI: 10.1093/toxsci/kfl092

Le Fol V., Aït-Aïssa S., Sonavane M., Porcher J.-M., Balaguer P., Cravedi J.-P., Zalko D., and Brion F. (2017): In vitro and in vivo estrogenic activity of BPA, BPF and BPS in zebrafish-specific assays. Ecotoxicology and Environmental Safety 142, 150-156. DOI: https://doi.org/10.1016/j.ecoenv.2017.04.009

Lee S., Kim C., Shin H., Kho Y., and Choi K. (2019): Comparison of thyroid hormone disruption potentials by bisphenols A, S, F, and Z in embryo-larval zebrafish. Chemosphere 221, 115-123. DOI: https://doi.org/10.1016/j.chemosphere.2019.01.019

Lee S., Liao C., Song G.-J., Ra K., Kannan K., and Moon H.-B. (2015): Emission of bisphenol analogues including bisphenol A and bisphenol F from wastewater treatment plants in Korea. Chemosphere 119, 1000-1006

Lehmler H.-J., Liu B., Gadogbe M., and Bao W. (2018): Exposure to bisphenol A, bisphenol F, and bisphenol S in US adults and children: The national health and nutrition examination survey 2013–2014. ACS omega 3 (6), 6523-6532

Li A., Zhuang T., Shi W., Liang Y., Liao C., Song M., and Jiang G. (2020): Serum concentration of bisphenol analogues in pregnant women in China. Science of The Total Environment 707, 136100

Li A.J. and Kannan K. (2018): Elevated Concentrations of Bisphenols, Benzophenones, and Antimicrobials in Pantyhose Collected from Six Countries. Environmental Science & Technology 52, 10812–10819. https://pubs.acs.org/doi/10.1021/acs.est.8b03129

Li Y., Burns K.A., Arao Y., Luh C.J., and Korach K.S. (2012): Differential estrogenic actions of endocrine-disrupting chemicals bisphenol A, bisphenol AF, and zearalenone through estrogen receptor α and β in vitro. Environ Health Perspect 120 (7), 1029-1035. DOI: 10.1289/ehp.1104689

Li Y., Luh C.J., Burns K.A., Arao Y., Jiang Z., Teng C.T., Tice R.R., and Korach K.S. (2013): Endocrine-Disrupting Chemicals (EDCs): In Vitro Mechanism of Estrogenic Activation and Differential Effects on ER Target Genes. Environmental Health Perspectives 121 (4), 459-466. DOI: 10.1289/ehp.1205951

Liao C. and Kannan K. (2013): Concentrations and profiles of bisphenol A and other bisphenol analogues in foodstuffs from the United States and their implications for human exposure. J Agric Food Chem 61 (19), 4655-4662. DOI: 10.1021/jf400445n

Liao C. and Kannan K. (2014): A survey of bisphenol A and other bisphenol analogues in foodstuffs from nine cities in China. Food Additives & Contaminants: Part A 31 (2), 319-329

Liao C. and Kannan K. (2019): Species-specific accumulation and temporal trends of bisphenols and benzophenones in mollusks from the Chinese Bohai Sea during 2006–2015. Science of The Total Environment 653, 168-175. DOI: 10.1016/j.scitotenv.2018.10.271

Liao C., Liu F., Alomirah H., Loi V.D., Mohd M.A., Moon H.B., Nakata H., and Kannan K. (2012a): Bisphenol S in urine from the United States and seven Asian countries: occurrence and human exposures. Environ Sci Technol 46 (12), 6860-6866. DOI: 10.1021/es301334j

Liao C., Liu F., Guo Y., Moon H.-B., Nakata H., Wu Q., and Kannan K. (2012b): Occurrence of Eight Bisphenol Analogues in Indoor Dust from the United States and Several Asian Countries: Implications for Human Exposure. Environmental Science & Technology 46 (16), 9138-9145. DOI: 10.1021/es302004w

Liao C., Liu F., and Kannan K. (2012c): Bisphenol s, a new bisphenol analogue, in paper products and currency bills and its association with bisphenol a residues. Environ Sci Technol 46 (12), 6515-6522. DOI: 10.1021/es300876n

Liao C., Liu F., Moon H.-B., Yamashita N., Yun S., and Kannan K. (2012d): Bisphenol analogues in sediments from industrialized areas in the United States, Japan, and Korea: spatial and temporal distributions. Environmental Science & Technology 46 (21), 11558-11565

Liao C., Shi J., Wang X., Zhu Q., and Kannan K. (2019): Occurrence and distribution of parabens and bisphenols in sediment from northern Chinese coastal areas. Environmental Pollution 253, 759-767. https://www.sciencedirect.com/science/article/pii/S0269749119311789?via%3Dihub

Lin J., Deng L., Sun M., Wang Y., Lee S., Choi K., and Liu X. (2021): An in vitro investigation of endocrine disrupting potentials of ten bisphenol analogues. Steroids 169, 108826. DOI: 10.1016/j.steroids.2021.108826

Liu M., Jia S., Dong T., Han Y., Xue J., Wanjaya E.R., and Fang M. (2019a): The occurrence of bisphenol plasticizers in paired dust and urine samples and its association with oxidative stress. Chemosphere 216, 472-478. DOI: https://doi.org/10.1016/j.chemosphere.2018.10.090

Liu W.-X., Donatella F., Tan S.-J., Ge W., Wang J.-J., Sun X.-F., Cheng S.-F., and Shen W. (2021): Detrimental effect of Bisphenol S in mouse germ cell cyst breakdown and primordial follicle assembly. Chemosphere 264, 128445. DOI: https://doi.org/10.1016/j.chemosphere.2020.128445

Liu X., Sakai H., Nishigori M., Suyama K., Nawaji T., Ikeda S., Nishigouchi M., Okada H., Matsushima A., Nose T., Shimohigashi M., and Shimohigashi Y. (2019b): Receptor-binding affinities of bisphenol A and its next-generation analogs for human nuclear receptors. Toxicol Appl Pharmacol 377, 114610. DOI: https://doi.org/10.1016/j.taap.2019.114610

Liu Y., Zhang S., Song N., Guo R., Chen M., Mai D., Yan Z., Han Z., and Chen J. (2017): Occurrence, distribution and sources of bisphenol analogues in a shallow Chinese freshwater lake (Taihu Lake): Implications for ecological and human health risk. Science of The Total Environment 599, 1090-1098. https://www.sciencedirect.com/science/article/pii/S0048969717311695?via%3Dihub

Liv Bruås Henninge R.M.K., Roman Grabic, Martin Ferenčík, Per-Anders Bergqvist, Elisabeth Lyngstad, Janne Berger (2020): Screening programme 2019 - Suspected PBT compounds, date: 27.10.2020. The Norwegian Environment Agency C.A., Report

Lobos J.H., Leib T.K., and Su T.M. (1992): Biodegradation of bisphenol A and other bisphenols by a gram-negative aerobic bacterium. Appl Environ Microbiol 58 (6), 1823-1831

Lopez-Cervantes J. and Paseiro-Losada P. (2003): Determination of bisphenol A in, and its migration from, PVC stretch film used for food packaging. Food Addit Contam 20 (6), 596-606. DOI: 10.1080/0265203031000109495

Lopez-Espinosa M.J., Granada A., Araque P., Molina-Molina J.M., Puertollano M.C., Rivas A., Fernández M., Cerrillo I., Olea-Serrano M.F., López C., and Olea N. (2007): Oestrogenicity of paper and cardboard extracts used as food containers. Food Additives & Contaminants 24 (1), 95-102. DOI: 10.1080/02652030600936375

ltd M.R.C. (2020): Bisphenol A 2020 world market outlook and forecast up to 2029.

Lucarini F., Krasniqi T., Rosset G.B., Roth N., Hopf N.B., Broillet M.C., and Staedler D. (2020): Exposure to new emerging bisphenols among young children in Switzerland. International Journal of Environmental Research and Public Health 17 (13), 1-15. DOI: 10.3390/ijerph17134793

Lucia M., Gabrielsen G.W., Herzke D., and Christensen G.N. (2016): Screening of UV chemicals, bisphenols and siloxanes in the Arctic. 039. Norwegian Polar Institute, Tromsø

Lyman W.J., Reehl W.F., and Rosenblatt D.H. (1990): Harris JC (1990) Rate of hydrolysis. . In: Handbook of chemical property estimation methods

Machtinger R., Berman T., Adir M., Mansur A., Baccarelli A.A., Racowsky C., Calafat A.M., Hauser R., and Nahum R. (2018): Urinary concentrations of phthalate metabolites, bisphenols and personal care product chemical biomarkers in pregnant women in Israel. Environ Int 116, 319-325. DOI: 10.1016/j.envint.2018.04.022

Markiewicz A., Björklund K., Eriksson E., Kalmykova Y., Strömvall A.-M., and Siopi A. (2017): Emissions of organic pollutants from traffic and roads: Priority pollutants selection and substance flow analysis. Science of The Total Environment 580, 1162-1174. DOI: https://doi.org/10.1016/j.scitotenv.2016.12.074

Martínez Steele E., Khandpur N., da Costa Louzada M.L., and Monteiro C.A. (2020): Association between dietary contribution of ultra-processed foods and urinary concentrations of phthalates and bisphenol in a nationally representative sample of the US population aged 6 years and older. PLoS ONE 15 (7), e0236738

Matsushima A., Liu X., Okada H., Shimohigashi M., and Shimohigashi Y. (2010): Bisphenol AF is a full agonist for the estrogen receptor ERalpha but a highly specific antagonist for ERbeta. Environ Health Perspect 118 (9), 1267-1272. DOI: 10.1289/ehp.0901819

McPherson A.D., Barrios J.P., Luks-Morgan S.J., Manfredi J.P., Bonkowsky J.L., Douglass A.D., and Dorsky R.I. (2016): Motor Behavior Mediated by Continuously Generated Dopaminergic Neurons in the Zebrafish Hypothalamus Recovers after Cell Ablation. Curr Biol 26 (2), 263-269. DOI: 10.1016/j.cub.2015.11.064

Mesnage R., Phedonos A., Arno M., Balu S., Corton J.C., and Antoniou M.N. (2017): Editor's Highlight: Transcriptome Profiling Reveals Bisphenol A Alternatives Activate Estrogen Receptor Alpha in Human Breast Cancer Cells. Toxicol Sci 158 (2), 431-443. DOI: 10.1093/toxsci/kfx101

Michałowicz J. (2014): Bisphenol A–sources, toxicity and biotransformation. Environmental Toxicology and Pharmacology 37 (2), 738-758

Miege C., Peretti A., Labadie P., Budzinski H., Le Bizec B., Vorkamp K., Tronczyński J., Persat H., Coquery M., and Babut M. (2012): Occurrence of priority and emerging organic compounds in fishes from the Rhone River (France). Analytical and Bioanalytical Chemistry 404 (9), 2721-2735

Migeot V., Dupuis A., Cariot A., Albouy-Llaty M., Pierre F., and Rabouan S. (2013): Bisphenol A and its chlorinated derivatives in human colostrum. Environmental Science & Technology 47 (23), 13791-13797

Milla S., Terrien X., Sturm A., Ibrahim F., Giton F., Fiet J., Prunet P., and Le Gac F. (2008): Plasma 11-deoxycorticosterone (DOC) and mineralocorticoid receptor testicular expression during rainbow trout Oncorhynchus mykiss spermiation: implication with 17alpha, 20beta-dihydroxyprogesterone on the milt fluidity? Reprod Biol Endocrinol 6, 19. DOI: 10.1186/1477-7827-6-19

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

Mita L., Bianco M., Viggiano E., Zollo F., Bencivenga U., Sica V., Monaco G., Portaccio M., Diano N., and Colonna A. (2011): Bisphenol A content in fish caught in two different sites of the Tyrrhenian Sea (Italy). Chemosphere 82 (3), 405-410

MITI (1992): Biodegradation and Bioaccumulation of Existing Chemical Substances under the Chemical Substance Control Law. National Institute of Technology and Evaluation, Japan.

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

Molina-Molina J.M., Jimenez-Diaz I., Fernandez M.F., Rodriguez-Carrillo A., Peinado F.M., Mustieles V., Barouki R., Piccoli C., Olea N., and Freire C. (2019): Determination of bisphenol A and bisphenol S concentrations and assessment of estrogen- and anti-androgen-like activities in thermal paper receipts from Brazil, France, and Spain. Environ Res 170, 406-415. DOI: 10.1016/j.envres.2018.12.046

Moreman J., Lee O., Trznadel M., David A., Kudoh T., and Tyler C.R. (2017): Acute Toxicity, Teratogenic, and Estrogenic Effects of Bisphenol A and Its Alternative Replacements Bisphenol S, Bisphenol F, and Bisphenol AF in Zebrafish Embryo-Larvae. Environmental Science and Technology 51 (21), 12796-12805. DOI: 10.1021/acs.est.7b03283

Morin N. A.H.P., Hale S.E. (2015): Bisphenol A in Solid Waste Materials, Leachate Water, and Air Particles from Norwegian Waste-Handling Facilities: Presence and Partitioning Behavior. Environmental Science & Technology 49 (13), 7675-7683 DOI: 10.1021/acs.est.5b01307

Mu X., Huang Y., Li X., Lei Y., Teng M., Li X., Wang C., and Li Y. (2018): Developmental Effects and Estrogenicity of Bisphenol A Alternatives in a Zebrafish Embryo Model. Environ Sci Technol 52 (5), 3222-3231. DOI: 10.1021/acs.est.7b06255

Mu X., Liu J., Yuan L., Yang K., Huang Y., Wang C., Yang W., Shen G., and Li Y. (2019): The mechanisms underlying the developmental effects of bisphenol F on zebrafish. Sci Total Environ 687, 877-884. DOI: 10.1016/j.scitotenv.2019.05.489

Muppa R.P.W., P. B.; Özcan, K. (2021): Phenolic monomers in aromatic syntans and their influence on leather: (Pending) Restricted compounds. Smit & zoon, Weesp, The Netherlands. https://allpi.int/phocadownload/2021/WLC-IULTCS/oral/022.pdf

Naderi M., Puar P., JavadiEsfahani R., and Kwong R.W.M. (2022): Early developmental exposure to bisphenol A and bisphenol S disrupts socio-cognitive function, isotocin equilibrium, and excitation-inhibition balance in developing zebrafish. NeuroToxicology 88, 144-154. DOI: 10.1016/j.neuro.2021.11.009

Naderi M., Salahinejad A., Attaran A., Chivers D.P., and Niyogi S. (2020): Chronic exposure to environmentally relevant concentrations of bisphenol S differentially affects cognitive behaviors in adult female zebrafish. Environmental Pollution 261, 114060. DOI: https://doi.org/10.1016/j.envpol.2020.114060

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

National Center for Biotechnology Information (2021): PubChem Compound Summary for CID 12111, 4,4'-Methylenediphenol. National Center for Biotechnology Information. https://pubchem.ncbi.nlm.nih.gov/compound/4_4_-Methylenediphenol.

Ndaw S., Remy A., Denis F., Marsan P., Jargot D., and Robert A. (2018): Occupational exposure of cashiers to bisphenol S via thermal paper. Toxicology Letters 298, 106-111. DOI: https://doi.org/10.1016/j.toxlet.2018.05.026

Ndaw S., Remy A., Jargot D., and Robert A. (2016): Occupational exposure of cashiers to Bisphenol A via thermal paper: urinary biomonitoring study. International Archives of Occupational and Environmental Health 89 (6), 935-946

Nevoral J., Kolinko Y., Moravec J., Žalmanová T., Hošková K., Prokešová Š., Klein P., Ghaibour K., Hošek P., Štiavnická M., Řimnáčová H., Tonar Z., Petr J., and Králíčková M. (2018): Long-term exposure to very low doses of bisphenol S affects female reproduction. Reproduction 156 (1), 47-57. DOI: 10.1530/rep-18-0092

Nilsen B.M., Berg K., Eidem J.K., Kristiansen S.I., Brion F., Porcher J.M., and Goksøyr A. (2004): Development of quantitative vitellogenin-ELISAs for fish test species used in endocrine disruptor screening. Anal Bioanal Chem 378 (3), 621-633. DOI: 10.1007/s00216-003-2241-2

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

Niu Y., Wang B., Zhao Y., Zhang J., and Shao B. (2017): Highly sensitive and high-throughput method for the analysis of bisphenol analogues and their halogenated derivatives in breast milk. Journal of Agricultural and Food Chemistry 65 (48), 10452-10463

Niu Y., Zhu M., Dong M., Li J., Li Y., Xiong Y., Liu P., and Qin Z. (2021): Bisphenols disrupt thyroid hormone (TH) signaling in the brain and affect TH-dependent brain development in Xenopus laevis. Aquat Toxicol 237, 105902. DOI: 10.1016/j.aquatox.2021.105902

NORMAN (2022): EMPODAT database. Accessed on 10/02/2022 for surface waters and 16/09/2021 for other matrices. https://www.norman-network.com/nds/empodat/

Norwegian Environment Agency T., K.; Schlabach, M.; Langford, K.; Fjeld, E.; Øxnevad, S.; Rundberget, T.; Bæk, K.; Rostkowski, P.; Harju, M. (2014): Screening program 2013. New bisphenols, organic peroxides, fluorinated siloxanes, organic UV filters and selected PBT substances. NIVA rapport, 6696-2014. Norwegian Environment Agency,. http://hdl.handle.net/11250/2359203

Noszczyńska M. and Piotrowska-Seget Z. (2018): Bisphenols: application, occurrence, safety, and biodegradation mediated by bacterial communities in wastewater treatment plants and rivers. Chemosphere 201, 214-223

OECD (2004): Leather Processing, Series on Emission Scenario Documents, No. 8. In: OECD Publishing. https://read.oecd-ilibrary.org/environment/leather-processing_9789264221178-en#page1

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

Olsén L., Lampa E., Birkholz D.A., Lind L., and Lind P.M. (2012): Circulating levels of bisphenol A (BPA) and phthalates in an elderly population in Sweden, based on the Prospective Investigation of the Vasculature in Uppsala Seniors (PIVUS). Ecotoxicology and Environmental Safety 75, 242-248

Orn S., Yamani S., and Norrgren L. (2006): Comparison of vitellogenin induction, sex ratio, and gonad morphology between zebrafish and Japanese medaka after exposure to 17alpha-ethinylestradiol and 17beta-trenbolone. Arch Environ Contam Toxicol 51 (2), 237-243. DOI: 10.1007/s00244-005-0103-y

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

Pang L., Yang H., Lv L., Liu S., Gu W., Zhou Y., Wang Y., Yang P., Zhao H., and Guo L. (2019): Occurrence and estrogenic potency of bisphenol analogs in sewage sludge from wastewater treatment plants in Central China. Archives of Environmental Contamination and Toxicology 77 (3), 461-470. https://link.springer.com/content/pdf/10.1007/s00244-019-00663-4.pdf

Park C., Song H., Choi J., Sim S., Kojima H., Park J., Iida M., and Lee Y. (2020): The mixture effects of bisphenol derivatives on estrogen receptor and androgen receptor. Environmental Pollution 260, 114036. DOI: https://doi.org/10.1016/j.envpol.2020.114036

Park C.B., Kim G.E., On J., Pyo H., Park J.W., and Cho S.H. (2022): Sex-specific effects of bisphenol S with tissue-specific responsiveness in adult zebrafish: The antiandrogenic and antiestrogenic effects. Ecotoxicol Environ Saf 229, 113102. DOI: 10.1016/j.ecoenv.2021.113102

Pelch K., Wignall J.A., Goldstone A.E., Ross P.K., Blain R.B., Shapiro A.J., Holmgren S.D., Hsieh J.-H., Svoboda D., Auerbach S.S., Parham F.M., Masten S.A., Walker V., Rooney A., and Thayer K.A. (2019a): A scoping review of the health and toxicological activity of bisphenol A (BPA) structural analogues and functional alternatives. Toxicology 424, 152235. DOI: https://doi.org/10.1016/j.tox.2019.06.006

Pelch K.E., Li Y., Perera L., Thayer K.A., and Korach K.S. (2019b): Characterization of Estrogenic and Androgenic Activities for Bisphenol A-like Chemicals (BPs): In Vitro Estrogen and Androgen Receptors Transcriptional Activation, Gene Regulation, and Binding Profiles. Toxicological Sciences 172 (1), 23-37. DOI: 10.1093/toxsci/kfz173 (last accessed 11/3/2020)

Pettersson M., Hahlbeck E., Katsiadaki I., Asplund L., and Bengtsson B.-E. (2007): Survey of estrogenic and androgenic disruption in Swedish coastal waters by the analysis of bile fluid from perch and biomarkers in the three-spined stickleback. Marine Pollution Bulletin 54 (12), 1868-1880

Philips E.M., Jaddoe V.W., Asimakopoulos A.G., Kannan K., Steegers E.A., Santos S., and Trasande L. (2018a): Bisphenol and phthalate concentrations and its determinants among pregnant women in a population-based cohort in the Netherlands, 2004–5. Environmental Research 161, 562-572

Philips E.M., Kahn L.G., Jaddoe V.W.V., Shao Y., Asimakopoulos A.G., Kannan K., Steegers E.A.P., and Trasande L. (2018b): First Trimester Urinary Bisphenol and Phthalate Concentrations and Time to Pregnancy: A Population-Based Cohort Analysis. J Clin Endocrinol Metab 103 (9), 3540-3547. DOI: 10.1210/jc.2018-00855

Pivnenko K., Laner D., and Astrup T.F. (2018): Dynamics of bisphenol A (BPA) and bisphenol S (BPS) in the European paper cycle: Need for concern? Resources, Conservation and Recycling 133, 278-287. DOI: https://doi.org/10.1016/j.resconrec.2018.01.021

Pivnenko K., Pedersen G.A., Eriksson E., and Astrup T.F. (2015): Bisphenol A and its structural analogues in household waste paper. Waste management 44, 39-47

Planas J.V. and Swanson P. (1995): Maturation-associated changes in the response of the salmon testis to the steroidogenic actions of gonadotropins (GTH I and GTH II) in vitro. Biol Reprod 52 (3), 697-704. DOI: 10.1095/biolreprod52.3.697

Punt A., Aartse A., Bovee T.F.H., Gerssen A., van Leeuwen S.P.J., Hoogenboom R.L.A.P., and Peijnenburg A.A.C.M. (2019): Quantitative in vitro-to-in vivo extrapolation (QIVIVE) of estrogenic and anti-androgenic potencies of BPA and BADGE analogues. Archives of Toxicology 93 (7), 1941-1953. DOI: 10.1007/s00204-019-02479-6

Puy-Azurmendi E., Ortiz-Zarragoitia M., Kuster M., Martínez E., Guillamón M., Domínguez C., Serrano T., Barbero M.C., Alda M.L.d., Bayona J.M., Barceló D., and Cajaraville M.P. (2010): An integrated study of endocrine disruptors in sediments and reproduction-related parameters in bivalve molluscs from the Biosphere's Reserve of Urdaibai (Bay of Biscay). Marine Environmental Research 69, S63-S66. DOI: https://doi.org/10.1016/j.marenvres.2009.10.003

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

Qiu W., Shao H., Lei P., Zheng C., Qiu C., Yang M., and Zheng Y. (2018a): Immunotoxicity of bisphenol S and F are similar to that of bisphenol A during zebrafish early development. Chemosphere 194, 1-8. DOI: https://doi.org/10.1016/j.chemosphere.2017.11.125

Qiu W., Zhan H., Tian Y., Zhang T., He X., Luo S., Xu H., and Zheng C. (2018b): The in vivo action of chronic bisphenol F showing potential immune disturbance in juvenile common carp (Cyprinus carpio). Chemosphere 205, 506-513. DOI: 10.1016/j.chemosphere.2018.04.105

Qiu W., Zhao Y., Yang M., Farajzadeh M., Pan C., and Wayne N.L. (2016): Actions of bisphenol A and bisphenol S on the reproductive neuroendocrine system during early development in zebrafish. Endocrinology 157 (2), 636-647. DOI: 10.1210/en.2015-1785

Rajendiran P., Jaafar F., Kar S., Sudhakumari C., Senthilkumaran B., and Parhar I.S. (2021): Sex Determination and Differentiation in Teleost: Roles of Genetics, Environment, and Brain. Biology (Basel) 10 (10). DOI: 10.3390/biology10100973

Ramboll Deutschland GmbH (2019): Investigation on main input pathways and sources of BPA in surface waters - Final report. Intended for PlasticsEurope. Project number: 327000467_Conv

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

Reich Prof. Dr. G. T.D.T. (2009): Chemikalien für die Lederherstellung. Vom Kollagen tierischer Häute zum Werkstoff Leder. Wiley Online Library. DOI: https://doi.org/10.1002/ciuz.200900473

Ren W.J., Wang Z., Wang L., Yang Q., and Liu J.N. (2017): Effects of Bisphenol A and its analogues on zebrafish embryos and larvae. Asian J. Ecotox. 12 (1), 184-192. https://www.scopus.com/inward/record.uri?eid=2-s2.0-85052465560&partnerID=40&md5=c9972f0e30222193a85de305b5b9f3b7

Roelofs M.J.E., Berg M.V.D., Bovee T.F.H., Piersma A.H., and Duursen M.B. (2015): Structural bisphenol analogues differentially target steroidogenesis in murine MA-10 Leydig cells as well as the glucocorticoid receptor. Toxicology 329, 10-20. http://www.scopus.com/inward/record.url?eid=2-s2.0-84921528943&partnerID=40&md5=78f58d10dc3200d8c1681318ca73c8ee

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

Ruan T., Liang D., Song S., Song M., Wang H., and Jiang G. (2015): Evaluation of the in vitro estrogenicity of emerging bisphenol analogs and their respective estrogenic contributions in municipal sewage sludge in China. Chemosphere 124, 150-155. DOI: https://doi.org/10.1016/j.chemosphere.2014.12.017

Rule K.L., Comber S.D.W., Ross D., Thornton A., Makropoulos C.K., and Rautiu R. (2006): Sources of priority substances entering an urban wastewater catchment—trace organic chemicals. Chemosphere 63 (4), 581-591. DOI: https://doi.org/10.1016/j.chemosphere.2005.08.016

Russo G., Barbato F., and Grumetto L. (2017): Monitoring of bisphenol A and bisphenol S in thermal paper receipts from the Italian market and estimated transdermal human intake: A pilot study. Sci Total Environ 599-600, 68-75. DOI: 10.1016/j.scitotenv.2017.04.192

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

Ruus A., Bæk K., Rundberget T., Allan I., Beylich B., Schlabach M., Warner N.A., Borgå K., and Helberg M. (2019): Environmental Contaminants in an Urban Fjord, 2018. vannforskning N.i.f. http://hdl.handle.net/11250/2624207

Ruus A., Bæk K., Rundberget T., Allan I., Beylich B., Vogelsang C., Schlabach M., Götsch A., Borgå K., and Helberg M. (2020): Environmental Contaminants in an Urban Fjord, 2019. vannforskning N.i.f. https://hdl.handle.net/11250/2718861

Sajiki J. Y.J. (2003): Leaching of bisphenol A (BPA) to seawater from polycarbonate plastic and its degradation by reactive oxygen species. DOI: 10.1016/s0045-6535(02)00789-0

Sakai K., Yamanaka H., Moriyoshi K., Ohmoto T., and Ohe T. (2007): Biodegradation of bisphenol A and related compounds by Sphingomonas sp. strain BP-7 isolated from seawater. Bioscience, Biotechnology and Biochemistry 71 (1), 51-57. DOI: 10.1271/bbb.60351

Sakhi A.K., Sabaredzovic A., Papadopoulou E., Cequier E., and Thomsen C. (2018): Levels, variability and determinants of environmental phenols in pairs of Norwegian mothers and children. Environment International 114, 242-251. DOI: https://doi.org/10.1016/j.envint.2018.02.037

Salahinejad A., Attaran A., Meuthen D., Rachamalla M., Chivers D.P., and Niyogi S. (2022): Maternal exposure to bisphenol S induces neuropeptide signaling dysfunction and oxidative stress in the brain, and abnormal social behaviors in zebrafish (Danio rerio) offspring. Science of The Total Environment 830. DOI: 10.1016/j.scitotenv.2022.154794

Salahinejad A., Naderi M., Attaran A., Meuthen D., Niyogi S., and Chivers D.P. (2020): Effects of chronic exposure to bisphenol-S on social behaviors in adult zebrafish: Disruption of the neuropeptide signaling pathways in the brain. Environmental Pollution 262, 113992. DOI: https://doi.org/10.1016/j.envpol.2020.113992

Salapasidou M., Samara C., and Voutsa D. (2011): Endocrine disrupting compounds in the atmosphere of the urban area of Thessaloniki, Greece. Atmospheric Environment 45 (22), 3720-3729. DOI: https://doi.org/10.1016/j.atmosenv.2011.04.025

Sánchez-Brunete C., Miguel E., and Tadeo J.L. (2009): Determination of tetrabromobisphenol-A, tetrachlorobisphenol-A and bisphenol-A in soil by ultrasonic assisted extraction and gas chromatography–mass spectrometry. Journal of Chromatography A 1216 (29), 5497-5503

Sanchis Y., Coscollà C., Corpas-Burgos F., Vento M., Gormaz M., and Yusà V. (2020): Biomonitoring of bisphenols A, F, S and parabens in urine of breastfeeding mothers: exposure and risk assessment. Environmental Research 185, 109481

Sarmah A.K. and Northcott G.L. (2008): Laboratory degradation studies of four endocrine disruptors in two environmental media. Environ Toxicol Chem 27 (4), 819-827. DOI: 10.1897/07-231.1

Šauer P., Švecová H., Grabicová K., Gönül Aydın F., Mackuľak T., Kodeš V., Blytt L.D., Henninge L.B., Grabic R., and Kocour Kroupová H. (2021): Bisphenols emerging in Norwegian and Czech aquatic environments show transthyretin binding potency and other less-studied endocrine-disrupting activities. Science of The Total Environment 751, 141801. DOI: https://doi.org/10.1016/j.scitotenv.2020.141801

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

Schmidt N., Castro-Jiménez J., Fauvelle V., Ourgaud M., and Sempéré R. (2020): Occurrence of organic plastic additives in surface waters of the Rhône River (France). Environmental Pollution 257, 113637. DOI: https://doi.org/10.1016/j.envpol.2019.113637

Schoknecht U., Gruycheva J., Mathies H., Bergmann H., and Burkhardt M. (2009): Leaching of Biocides Used in Façade Coatings under Laboratory Test Conditions. Environmental Science & Technology 43 (24), 9321-9328. DOI: 10.1021/es9019832

Schoknecht U., Mathies H., Wegner R., Uhlig S., Baldauf H., and Colson B. (2016): Emissions of material preservatives into the environment-realistic extimation of environmental risks through the improved characterisation of the leaching of biocides from treated materials used outdoors

Servili A., Le Page Y., Leprince J., Caraty A., Escobar S., Parhar I.S., Seong J.Y., Vaudry H., and Kah O. (2011): Organization of two independent kisspeptin systems derived from evolutionary-ancient kiss genes in the brain of zebrafish. Endocrinology 152 (4), 1527-1540. DOI: 10.1210/en.2010-0948

Shang J., Corriveau J., Champoux-Jenane A., Gagnon J., Moss E., Dumas P., Gaudreau E., Chevrier J., and Chalifour L.E. (2019): Recovery From a Myocardial Infarction Is Impaired in Male C57bl/6 N Mice Acutely Exposed to the Bisphenols and Phthalates That Escape From Medical Devices Used in Cardiac Surgery. Toxicological Sciences 168 (1), 78-94. DOI: 10.1093/toxsci/kfy276 (last accessed 7/8/2022)

Shi J., Jiao Z., Zheng S., Li M., Zhang J., Feng Y., Yin J., and Shao B. (2015): Long-term effects of bisphenol AF (BPAF) on hormonal balance and genes of hypothalamus-pituitary-gonad axis and liver of zebrafish (Danio rerio), and the impact on offspring. Chemosphere 128, 252-257. DOI: 10.1016/j.chemosphere.2015.01.060

Shi J., Yang Y., Zhang J., Feng Y., and Shao B. (2016): Uptake, depuration and bioconcentration of bisphenol AF (BPAF) in whole-body and tissues of zebrafish (Danio rerio). Ecotoxicol Environ Saf 132, 339-344. DOI: 10.1016/j.ecoenv.2016.05.025

Shi M., Sekulovski N., MacLean J.A., 2nd, and Hayashi K. (2017): Effects of bisphenol A analogues on reproductive functions in mice. Reprod Toxicol 73, 280-291. DOI: 10.1016/j.reprotox.2017.06.134

Shi M., Sekulovski N., MacLean J.A., 2nd, and Hayashi K. (2018): Prenatal Exposure to Bisphenol A Analogues on Male Reproductive Functions in Mice. Toxicol Sci 163 (2), 620-631. DOI: 10.1093/toxsci/kfy061

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

Shi M., Whorton A.E., Sekulovski N., MacLean J.A., and Hayashi K. (2019b): Prenatal exposure to bisphenol A, E, and S induces transgenerational effects on male reproductive functions in mice. Toxicological Sciences 172 (2), 303-315

Sidorkiewicz I., Czerniecki J., Jarząbek K., Zbucka-Krętowska M., and Wołczyński S. (2018): Cellular, transcriptomic and methylome effects of individual and combined exposure to BPA, BPF, BPS on mouse spermatocyte GC-2 cell line. Toxicol Appl Pharmacol 359, 1-11. DOI: https://doi.org/10.1016/j.taap.2018.09.006

Song M., Liang D., Liang Y., Chen M., Wang F., Wang H., and Jiang G. (2014a): Assessing developmental toxicity and estrogenic activity of halogenated bisphenol A on zebrafish (Danio rerio). Chemosphere 112, 275-281. DOI: 10.1016/j.chemosphere.2014.04.084

Song S., Song M., Zeng L., Wang T., Liu R., Ruan T., and Jiang G. (2014b): Occurrence and profiles of bisphenol analogues in municipal sewage sludge in China. Environmental Pollution 186, 14-19

Song Y., Tao B., Chen J., Jia S., Zhu Z., Trudeau V.L., and Hu W. (2017): GABAergic Neurons and Their Modulatory Effects on GnRH3 in Zebrafish. Endocrinology 158 (4), 874-886. DOI: 10.1210/en.2016-1776

Staniszewska M., Falkowska L., Grabowski P., Kwaśniak J., Mudrak-Cegiołka S., Reindl A.R., Sokołowski A., Szumiło E., and Zgrundo A. (2014): Bisphenol A, 4-tert-octylphenol, and 4-

nonylphenol in the Gulf of Gdańsk (Southern Baltic). Archives of Environmental Contamination and Toxicology 67 (3), 335-347

Staniszewska M., Koniecko I., Falkowska L., Burska D., and Kiełczewska J. (2016): The relationship between the black carbon and bisphenol A in sea and river sediments (Southern Baltic). Journal of Environmental Sciences 41, 24-32

Staples C., van der Hoeven N., Clark K., Mihaich E., Woelz J., and Hentges S. (2018): Distributions of concentrations of bisphenol A in North American and European surface waters and sediments determined from 19 years of monitoring data. Chemosphere 201, 448-458. DOI: https://doi.org/10.1016/j.chemosphere.2018.02.175

Stasinakis A.S., Petalas A.V., Mamais D., and Thomaidis N.S. (2008): Application of the OECD 301F respirometric test for the biodegradability assessment of various potential endocrine disrupting chemicals. Bioresour Technol 99 (9), 3458-3467. DOI: 10.1016/j.biortech.2007.08.002

Stone C.M. and Watkinson R.J. (1983): Diphenylol Propane: An Assessment of Ready Biodegradability. Research Report SBGR.83.425. Shell Group

Sun Q., Wang Y., Li Y., Ashfaq M., Dai L., Xie X., and Yu C.-P. (2017): Fate and mass balance of bisphenol analogues in wastewater treatment plants in Xiamen City, China. Environmental Pollution 225, 542-549

Sun X., Peng J., Wang M., Wang J., Tang C., Yang L., Lei H., Li F., Wang X., and Chen J. (2018): Determination of nine bisphenols in sewage and sludge using dummy molecularly imprinted solid-phase extraction coupled with liquid chromatography tandem mass spectrometry. Journal of Chromatography A 1552, 10-16. DOI: https://doi.org/10.1016/j.chroma.2018.04.004

Suzuki T., Nakagawa Y., Takano I., Yaguchi K., and Yasuda K. (2004): Environmental Fate of Bisphenol A and Its Biological Metabolites in River Water and Their Xeno-estrogenic Activity. Environmental Science & Technology 38 (8), 2389-2396. DOI: 10.1021/es030576z

Tang H., Chen Y., Liu Y., Yin Y., Li G., Guo Y., Liu X., and Lin H. (2017a): New Insights Into the Role of Estrogens in Male Fertility Based on Findings in Aromatase-Deficient Zebrafish. Endocrinology 158 (9), 3042-3054. DOI: 10.1210/en.2017-00156

Tang H., Chen Y., Wang L., Yin Y., Li G., Guo Y., Liu Y., Lin H., Cheng C.H.K., and Liu X. (2017b): Fertility impairment with defective spermatogenesis and steroidogenesis in male zebrafish lacking androgen receptor†. Biology of Reproduction 98 (2), 227-238. DOI: 10.1093/biolre/iox165 (last accessed 7/21/2022)

Tang S., He C., Thai P.K., Heffernan A., Vijayasarathy S., Toms L., Thompson K., Hobson P., Tscharke B.J., O'Brien J.W., Thomas K.V., and Mueller J.F. (2020): Urinary Concentrations of Bisphenols in the Australian Population and Their Association with the Per Capita Mass Loads in Wastewater. Environ Sci Technol 54 (16), 10141-10148. DOI: 10.1021/acs.est.0c00921

Tang T., Yang Y., Chen Y., Tang W., Wang F., and Diao X. (2015): Thyroid Disruption in Zebrafish Larvae by Short-Term Exposure to Bisphenol AF. Int J Environ Res Public Health 12 (10), 13069-13084. DOI: 10.3390/ijerph121013069

Tanner E.M., Hallerbäck M.U., Wikström S., Lindh C., Kiviranta H., Gennings C., and Bornehag C.-G. (2020): Early prenatal exposure to suspected endocrine disruptor mixtures is associated with lower IQ at age seven. Environment International 134, 105185

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

Teil M.-J., Moreau-Guigon E., Blanchard M., Alliot F., Gasperi J., Cladière M., Mandin C., Moukhtar S., and Chevreuil M. (2016): Endocrine disrupting compounds in gaseous and particulate outdoor air phases according to environmental factors. Chemosphere 146, 94-104

Tello J.A., Wu S., Rivier J.E., and Sherwood N.M. (2008): Four functional GnRH receptors in zebrafish: analysis of structure, signaling, synteny and phylogeny. Integr Comp Biol 48 (5), 570-587. DOI: 10.1093/icb/icn070

Téteau O., Jaubert M., Desmarchais A., Papillier P., Binet A., Maillard V., and Elis S. (2020): Bisphenol A and S impaired ovine granulosa cell steroidogenesis. Reproduction 159 (5), 571-583. DOI: 10.1530/rep-19-0575

Thayer K.A., Taylor K.W., Garantziotis S., Schurman S.H., Kissling G.E., Hunt D., Herbert B., Church R., Jankowich R., Churchwell M.I., Scheri R.C., Birnbaum L.S., and Bucher J.R. (2016): Bisphenol A, Bisphenol S, and 4-Hydroxyphenyl 4-Isoprooxyphenylsulfone (BPSIP) in Urine and Blood of Cashiers. Environ Health Perspect 124 (4), 437-444. DOI: 10.1289/ehp.1409427

Theodore Mill W.M. (1991): Environmental Exposure From Chemicals Volume I (W. Brock Neely G.E.B., ed.), chapter Photochemical Transformations, Boca Raton

Tian L., Verreault J., Houde M., and Bayen S. (2019): Suspect screening of plastic-related chemicals in northern pike (Esox lucius) from the St. Lawrence River, Canada. Environmental Pollution 255, 113223. DOI: https://doi.org/10.1016/j.envpol.2019.113223

Tietje O., Burkhardt M., Rohr M., Borho N., and Schoknecht U. (2018): Emissions-und Übertragungsfunktionen für die Modellierung der Auslaugung von Bauprodukten. 28/2018, Dessau-Roßlau. https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2018-04-11_texte_28-2018_auslaugung-bauprodukte.pdf

Tisler T., Krel A., Gerzelj U., Erjavec B., Dolenc M.S., and Pintar A. (2016): Hazard identification and risk characterization of bisphenols A, F and AF to aquatic organisms. Environ Pollut 212, 472-479. DOI: 10.1016/j.envpol.2016.02.045

Tkalec Ž., Kosjek T., Snoj Tratnik J., Stajnko A., Runkel A.A., Sykiotou M., Mazej D., and Horvat M. (2021): Exposure of Slovenian children and adolescents to bisphenols, parabens and triclosan: Urinary levels, exposure patterns, determinants of exposure and susceptibility. Environment International 146, 106172. DOI: https://doi.org/10.1016/j.envint.2020.106172

U.S. EPA (2021): Bis(4-hydroxyphenyl)methane, Bisphenol F. https://comptox.epa.gov/dashboard/chemical/details/DTXSID9022445

Ullah A., Pirzada M., Jahan S., Ullah H., Razak S., Rauf N., Khan M.J., and Mahboob S.Z. (2019): Prenatal BPA and its analogs BPB, BPF, and BPS exposure and reproductive axis function in the male offspring of Sprague Dawley rats. Hum Exp Toxicol 38 (12), 1344-1365. DOI: 10.1177/0960327119862335

Ullah A., Pirzada M., Jahan S., Ullah H., Shaheen G., Rehman H., Siddiqui M.F., and Butt M.A. (2018a): Bisphenol A and its analogs bisphenol B, bisphenol F, and bisphenol S: Comparative in vitro and in vivo studies on the sperms and testicular tissues of rats. Chemosphere 209, 508-516. DOI: https://doi.org/10.1016/j.chemosphere.2018.06.089

Ullah A., Pirzada M., Jahan S., Ullah H., Turi N., Ullah W., Siddiqui M.F., Zakria M., Lodhi K.Z., and Khan M.M. (2018b): Impact of low-dose chronic exposure to bisphenol A and its analogue bisphenol B, bisphenol F and bisphenol S on hypothalamo-pituitary-testicular activities in adult rats: A focus on the possible hormonal mode of action. Food and Chemical Toxicology 121, 24-36. DOI: https://doi.org/10.1016/j.fct.2018.08.024

Ullah H., Jahan S., Ain Q.U., Shaheen G., and Ahsan N. (2016): Effect of bisphenol S exposure on male reproductive system of rats: A histological and biochemical study. Chemosphere 152, 383-391. DOI: 10.1016/j.chemosphere.2016.02.125

Ullah H., Ullah F., Rehman O., Jahan S., Afsar T., Al-Disi D., Almajwal A., and Razak S. (2021): Chronic exposure of bisphenol S (BPS) affect hypothalamic-pituitary-testicular activities in adult male rats: possible in estrogenic mode of action. Environ Health Prev Med 26 (1), 31. DOI: 10.1186/s12199-021-00954-0

Umweltbundesamt (2010): Bisphenol A, Massenchemikalie mit unerwünschten Nebenwirkungen. http://www.umweltbundesamt.de/uba-info-medien/mysql_medien.php?anfrage=Kennummer&Suchwort=3782

van Es D.D.S. (2014): Analysis of alternatives for BPA in thermal paper. 1515, date: 12.12.2014. Wageningen UR Food & Biobased Research. https://www.rivm.nl/sites/default/files/2018-11/Analysis%20of%20alternatives%20for%20BPA%20in%20thermal%20paper.pdf

van Leeuwen S.P.J., Bovee T.F.H., Awchi M., Klijnstra M.D., Hamers A.R.M., Hoogenboom R.L.A.P., Portier L., and Gerssen A. (2019): BPA, BADGE and analogues: A new multi-analyte LC-ESI-MS/MS method for their determination and their in vitro (anti)estrogenic and (anti)androgenic properties. Chemosphere 221, 246-253. DOI: https://doi.org/10.1016/j.chemosphere.2018.12.189

Vandenberg L.N., Maffini M.V., Sonnenschein C., Rubin B.S., and Soto A.M. (2009): Bisphenol-A and the great divide: a review of controversies in the field of endocrine disruption. Endocr Rev 30 (1), 75-95. DOI: 10.1210/er.2008-0021

Vasiljevic T. and Harner T. (2021): Bisphenol A and its analogues in outdoor and indoor air: Properties, sources and global levels. Science of The Total Environment 789, 148013. DOI: https://doi.org/10.1016/j.scitotenv.2021.148013

Vela-Soria F., Ballesteros O., Camino-Sánchez F., Zafra-Gómez A., Ballesteros L., and Navalón A. (2015): Matrix solid phase dispersion for the extraction of selected endocrine disrupting chemicals from human placental tissue prior to UHPLC-MS/MS analysis. Microchemical Journal 118, 32-39

Vela N., Calín M., Yáñez-Gascón M.J., Garrido I., Pérez-Lucas G., Fenoll J., and Navarro S. (2018a): Photocatalytic oxidation of six endocrine disruptor chemicals in wastewater using ZnO at pilot plant scale under natural sunlight. Environmental Science and Pollution Research 25 (35), 34995-35007

Vela N., Calín M., Yáñez-Gascón M.J., Garrido I., Pérez-Lucas G., Fenoll J., and Navarro S. (2018b): Solar reclamation of wastewater effluent polluted with bisphenols, phthalates and parabens by photocatalytic treatment with TiO2/Na2S2O8 at pilot plant scale. Chemosphere 212, 95-104

Velázquez-Gómez M., Hurtado-Fernández E., and Lacorte S. (2019): Differential occurrence, profiles and uptake of dust contaminants in the Barcelona urban area. Science of The Total Environment 648, 1354-1370

Vermeirssen E.L.M., Dietschweiler C., Werner I., and Burkhardt M. (2017): Corrosion protection products as a source of bisphenol A and toxicity to the aquatic environment. Water Research 123, 586-593. DOI: https://doi.org/10.1016/j.watres.2017.07.006

Vermeirssen E.L.M.D., C; Werner, I.; Burkhardt, M. (2017): Corrosion protection products as a source of bisphenol A and toxicity to the aquatic environment. DOI: https://doi.org/10.1016/j.watres.2017.07.006

Vinggaard A.M., Körner W., Lund K.H., Bolz U., and Petersen J.H. (2000): Identification and quantification of estrogenic compounds in recycled and virgin paper for household use as determined by an in vitro yeast estrogen screen and chemical analysis. Chem Res Toxicol 13 (12), 1214-1222. DOI: 10.1021/tx000146b

VinylPlus: PROGRESS REPORT 2022. https://www.vinylplus.eu/wp-content/uploads/2022/05/VinylPlus-Progress-Report-2022.pdf

Voordeckers J.W., Fennell D.E., Jones K., and Haggblom M.M. (2002): Anaerobic biotransformation of tetrabromobisphenol A, tetrachlorobisphenol A, and bisphenol A in estuarine sediments. Environ Sci Technol 36 (4), 696-701. http://www.ncbi.nlm.nih.gov/pubmed/11878385

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

Wan Y., Huo W., Xu S., Zheng T., Zhang B., Li Y., Zhou A., Zhang Y., Hu J., Zhu Y., Chen Z., Lu S., Wu C., Jiang M., Jiang Y., Liu H., Yang X., and Xia W. (2018a): Relationship between maternal exposure to bisphenol S and pregnancy duration. Environ Pollut 238, 717-724. DOI: 10.1016/j.envpol.2018.03.057

Wan Y., Xia W., Yang S., Pan X., He Z., and Kannan K. (2018b): Spatial distribution of bisphenol S in surface water and human serum from Yangtze River watershed, China: Implications for exposure through drinking water. Chemosphere 199, 595-602. https://www.sciencedirect.com/science/article/pii/S004565351830242X?via%3Dihub

Wang J., Ma S., Zhang Z., Zheng M., Dong Y., and Ru S. (2017a): Vitellogenin induction in caudal fin of guppy (Poecilia reticulata) as a less invasive and sensitive biomarker for environmental estrogens. Sci Rep 7 (1), 7647. DOI: 10.1038/s41598-017-06670-6

Wang Q., Chen M., Qiang L., Wu W., Yang J., and Zhu L. (2020): Toxicokinetics and bioaccumulation characteristics of bisphenol analogues in common carp (Cyprinus carpio). Ecotoxicology and Environmental Safety 191, 110183. DOI: https://doi.org/10.1016/j.ecoenv.2020.110183

Wang Q., Chen M., Shan G., Chen P., Cui S., Yi S., and Zhu L. (2017b): Bioaccumulation and biomagnification of emerging bisphenol analogues in aquatic organisms from Taihu Lake, China. Science of The Total Environment 598, 814-820. DOI: https://doi.org/10.1016/j.scitotenv.2017.04.167

Wang W., Abualnaja K.O., Asimakopoulos A.G., Covaci A., Gevao B., Johnson-Restrepo B., Kumosani T.A., Malarvannan G., Minh T.B., and Moon H.-B. (2015): A comparative assessment of human exposure to tetrabromobisphenol A and eight bisphenols including bisphenol A via indoor dust ingestion in twelve countries. Environment International 83, 183-191. https://www.sciencedirect.com/science/article/pii/S0160412015300039?via%3Dihub

Wang Y.-X., Liu C., Shen Y., Wang Q., Pan A., Yang P., Chen Y.-J., Deng Y.-L., Lu Q., and Cheng L.-M. (2019): Urinary levels of bisphenol A, F and S and markers of oxidative stress among healthy adult men: Variability and association analysis. Environment International 123, 301-309

Wang Y., Wang B., Wang Q., Liu Y., Liu X., Wu B., and Lu G. (2021): Intestinal toxicity and microbial community disorder induced by bisphenol F and bisphenol S in zebrafish. Chemosphere 280, 130711. DOI: 10.1016/j.chemosphere.2021.130711

Wang Z., Yu J., Yao J., Wu L., Xiao H., Wang J., and Gao R. (2018): Simultaneous identification and quantification of bisphenol A and 12 bisphenol analogues in environmental samples using precolumn derivatization and ultra high performance liquid chromatography with tandem mass spectrometry. J Sep Sci 41 (10), 2269-2278

Wei P., Zhao F., Zhang X., Liu W., Jiang G., Wang H., and Ru S. (2018): Transgenerational thyroid endocrine disruption induced by bisphenol S affects the early development of zebrafish offspring. Environmental Pollution 243, 800-808. DOI: 10.1016/j.envpol.2018.09.042

West R.J., Goodwin P.A., and Klecka G.M. (2001): Assessment of the Ready Biodegradability of Bisphenol A. Bulletin of Environmental Contamination and Toxicology 67 (1), 0106-0112. DOI: 10.1007/s00128-001-0097-8

Williams G.P. and Darbre P.D. (2019): Low-dose environmental endocrine disruptors, increase aromatase activity, estradiol biosynthesis and cell proliferation in human breast cells. Molecular and Cellular Endocrinology 486, 55-64. DOI: https://doi.org/10.1016/j.mce.2019.02.016

Witmer G. and Shiels A. (2017): Ecology, Impacts, and Management of Invasive Rodents in the United States, pp. 193-220. ISBN: 978-1-4987-0482-3. DOI: 10.1201/9781315157078-11

World Health Organization (2013): State of the science of endocrine disrupting chemicals 2012 : summary for decision-makers, date: 2013. World Health Organization, Geneva. https://apps.who.int/iris/handle/10665/78102

Wu N.C. and Seebacher F. (2021): Bisphenols alter thermal responses and performance in zebrafish (Danio rerio). Conserv Physiol 9 (1), coaa138. DOI: 10.1093/conphys/coaa138

Wu P., Cai Z., Jin H., and Tang Y. (2019): Adsorption mechanisms of five bisphenol analogues on PVC microplastics. Science of The Total Environment 650, 671-678

Xue J. and Kannan K. (2019): Mass flows and removal of eight bisphenol analogs, bisphenol A diglycidyl ether and its derivatives in two wastewater treatment plants in New York State, USA. Sci Total Environ 648, 442-449. DOI: 10.1016/j.scitotenv.2018.08.047

Xue J., Wan Y., and Kannan K. (2016): Occurrence of bisphenols, bisphenol A diglycidyl ethers (BADGEs), and novolac glycidyl ethers (NOGEs) in indoor air from Albany, New York, USA, and its implications for inhalation exposure. Chemosphere 151, 1-8. DOI: 10.1016/j.chemosphere.2016.02.038

Yamasaki K., Noda S., Imatanaka N., and Yakabe Y. (2004): Comparative study of the uterotrophic potency of 14 chemicals in a uterotrophic assay and their receptor-binding affinity. Toxicol Lett 146 (2), 111-120. http://www.ncbi.nlm.nih.gov/pubmed/14643963

Yamazaki E., Yamashita N., Taniyasu S., Lam J., Lam P.K., Moon H.B., Jeong Y., Kannan P., Achyuthan H., Munuswamy N., and Kannan K. (2015): Bisphenol A and other bisphenol analogues including BPS and BPF in surface water samples from Japan, China, Korea and India. Ecotoxicol Environ Saf 122, 565-572. DOI: 10.1016/j.ecoenv.2015.09.029

Yan Z., Liu Y., Yan K., Wu S., Han Z., Guo R., Chen M., Yang Q., Zhang S., and Chen J. (2017): Bisphenol analogues in surface water and sediment from the shallow Chinese freshwater lakes: occurrence, distribution, source apportionment, and ecological and human health risk. Chemosphere 184, 318-328. https://www.sciencedirect.com/science/article/pii/S0045653517309128?via%3Dihub

Yang F., Qiu W., Li R., Hu J., Luo S., Zhang T., He X., and Zheng C. (2018): Genome-wide identification of the interactions between key genes and pathways provide new insights into the toxicity of bisphenol F and S during early development in zebrafish. Chemosphere 213, 559-567. DOI: 10.1016/j.chemosphere.2018.09.133

Yang Q., Yang X., Liu J., Ren W., Chen Y., and Shen S. (2017): Effects of BPF on steroid hormone homeostasis and gene expression in the hypothalamic–pituitary–gonadal axis of zebrafish. Environmental Science and Pollution Research 24 (26), 21311-21322. DOI: 10.1007/s11356-017-9773-z

Yang X., Liu Y., Li J., Chen M., Peng D., Liang Y., Song M., Zhang J., and Jiang G. (2016): Exposure to Bisphenol AF disrupts sex hormone levels and vitellogenin expression in zebrafish. Environ Toxicol 31 (3), 285-294. DOI: 10.1002/tox.22043

Yang Y., Guan J., Yin J., Shao B., and Li H. (2014a): Urinary levels of bisphenol analogues in residents living near a manufacturing plant in south China. Chemosphere 112, 481-486. https://www.sciencedirect.com/science/article/pii/S0045653514006055?via%3Dihub

Yang Y., Lu L., Zhang J., Yang Y., Wu Y., and Shao B. (2014b): Simultaneous determination of seven bisphenols in environmental water and solid samples by liquid chromatography-electrospray tandem mass spectrometry. Journal of Chromatography A 1328, 26-34. DOI: 10.1016/j.chroma.2013.12.074

Yang Y., Wang Z., and Xie S. (2014c): Aerobic biodegradation of bisphenol A in river sediment and associated bacterial community change. Sci Total Environ 470-471, 1184-1188. DOI: 10.1016/j.scitotenv.2013.10.102

Yao Y., Shao Y., Zhan M., Zou X., Qu W., and Zhou Y. (2018): Rapid and sensitive determination of nine bisphenol analogues, three amphenicol antibiotics, and six phthalate metabolites in human urine samples using UHPLC-MS/MS. Analytical and Bioanalytical Chemistry 410 (16), 3871-3883. DOI: 10.1007/s00216-018-1062-2

Ye X., Wong L.-Y., Kramer J., Zhou X., Jia T., and Calafat A.M. (2015): Urinary concentrations of bisphenol A and three other bisphenols in convenience samples of US adults during 2000–2014. Environmental Science & Technology 49 (19), 11834-11839

Ying G.G. and Kookana R.S. (2003): Degradation of Five Selected Endocrine-Disrupting Chemicals in Seawater and Marine Sediment. Environmental Science & Technology 37 (7), 1256-1260. DOI: doi: 10.1021/es0262232

Ying G.G. and Kookana R.S. (2005): Sorption and degradation of estrogen-like-endocrine disrupting chemicals in soil. Environmental Toxicology and Chemistry: An International Journal 24 (10), 2640-2645

Ying G.G., Kookana R.S., and Dillon P. (2003): Sorption and degradation of selected five endocrine disrupting chemicals in aquifer material. Water Research 37 (15), 3785-3791. DOI: doi: DOI: 10.1016/S0043-1354(03)00261-6

Yu X., Xue J., Yao H., Wu Q., Venkatesan A.K., Halden R.U., and Kannan K. (2015): Occurrence and estrogenic potency of eight bisphenol analogs in sewage sludge from the US EPA targeted national sewage sludge survey. Journal of Hazardous Materials 299, 733-739. https://www.sciencedirect.com/science/article/pii/S0304389415005415?via%3Dihub

Yuan L., Qian L., Qian Y., Liu J., Yang K., Huang Y., Wang C., Li Y., and Mu X. (2019): Bisphenol F-Induced Neurotoxicity toward Zebrafish Embryos. Environmental Science & Technology 53 (24), 14638-14648. DOI: 10.1021/acs.est.9b04097

Zhan M., Yang X., Xian Q., and Kong L. (2006): Photosensitized degradation of bisphenol A involving reactive oxygen species in the presence of humic substances. Chemosphere 63 (3), 378-386

Zhang B., He Y., Zhu H., Huang X., Bai X., Kannan K., and Zhang T. (2020a): Concentrations of bisphenol A and its alternatives in paired maternal-fetal urine, serum and amniotic fluid from an e-waste dismantling area in China. Environ Int 136, 105407. DOI: 10.1016/j.envint.2019.105407

Zhang D.H., Zhou E.X., and Yang Z.L. (2017a): Waterborne exposure to BPS causes thyroid endocrine disruption in zebrafish larvae. PLoS ONE 12 (5), e0176927. DOI: 10.1371/journal.pone.0176927

Zhang H., Quan Q., Zhang M., Zhang N., Zhang W., Zhan M., Xu W., Lu L., Fan J., and Wang Q. (2020b): Occurrence of bisphenol A and its alternatives in paired urine and indoor dust from Chinese university students: Implications for human exposure. Chemosphere 247, 125987. DOI: https://doi.org/10.1016/j.chemosphere.2020.125987

Zhang H., Zhang Y., Li J., and Yang M. (2019): Occurrence and exposure assessment of bisphenol analogues in source water and drinking water in China. Science of The Total Environment 655, 607-613

Zhang Y.F., Ren X.M., Li Y.Y., Yao X.F., Li C.H., Qin Z.F., and Guo L.H. (2017b): Bisphenol A alternatives bisphenol S and bisphenol F interfere with thyroid hormone signaling pathway in vitro and in vivo. Environ Pollut. DOI: 10.1016/j.envpol.2017.11.027

Zhang Y.F., Ren X.M., Li Y.Y., Yao X.F., Li C.H., Qin Z.F., and Guo L.H. (2018): Bisphenol A alternatives bisphenol S and bisphenol F interfere with thyroid hormone signaling pathway in vitro and in vivo. Environmental Pollution 237, 1072-1079. DOI: 10.1016/j.envpol.2017.11.027

Zhang Z., Lau S.W., Zhang L., and Ge W. (2015a): Disruption of Zebrafish Follicle-Stimulating Hormone Receptor (fshr) But Not Luteinizing Hormone Receptor (lhcgr) Gene by TALEN Leads to Failed Follicle Activation in Females Followed by Sexual Reversal to Males. Endocrinology 156 (10), 3747-3762. DOI: 10.1210/en.2015-1039

Zhang Z., Zhu B., and Ge W. (2015b): Genetic analysis of zebrafish gonadotropin (FSH and LH) functions by TALEN-mediated gene disruption. Mol Endocrinol 29 (1), 76-98. DOI: 10.1210/me.2014-1256

Zhao N., Hu H., Zhao M., Liu W., and Jin H. (2021): Occurrence of Free-Form and Conjugated Bisphenol Analogues in Marine Organisms. Environmental Science & Technology 55 (8), 4914-4922

Zhao X., Qiu W., Zheng Y., Xiong J., Gao C., and Hu S. (2019): Occurrence, distribution, bioaccumulation, and ecological risk of bisphenol analogues, parabens and their metabolites in the Pearl River Estuary, South China. Ecotoxicology and Environmental Safety 180, 43-52. DOI: https://doi.org/10.1016/j.ecoenv.2019.04.083

Zhao Y., Singh C., Prober D.A., and Wayne N.L. (2016): Morphological and Physiological Interactions Between GnRH3 and Hypocretin/Orexin Neuronal Systems in Zebrafish (Danio rerio). Endocrinology 157 (10), 4012-4020. DOI: 10.1210/en.2016-1381

Zheng C., Liu J., Ren J., Shen J., Fan J., Xi R., Chen W., and Chen Q. (2019): Occurrence, Distribution and Ecological Risk of Bisphenol Analogues in the Surface Water from a Water Diversion Project in Nanjing, China. International Journal of Environmental Research and Public Health 16 (18), 3296. DOI: 10.3390/ijerph16183296

Zheng J.-L., Guan D.-X., Luo J., Zhang H., Davison W., Cui X.-Y., Wang L.-H., and Ma L.Q. (2015): Activated charcoal based diffusive gradients in thin films for in situ monitoring of bisphenols in waters. Analytical chemistry 87 (1), 801-807

Zhou N., Liu Y., Cao S., Guo R., Ma Y., and Chen J. (2020): Biodegradation of bisphenol compounds in the surface water of Taihu Lake and the effect of humic acids. Science of The Total Environment 723, 138164

Zhou X., Kramer J.P., Calafat A.M., and Ye X. (2014): Automated on-line column-switching high performance liquid chromatography isotope dilution tandem mass spectrometry method for the quantification of bisphenol A, bisphenol F, bisphenol S, and 11 other phenols in urine. Journal of Chromatography B 944, 152-156. DOI: https://doi.org/10.1016/j.jchromb.2013.11.009

Zhu H., Wang L., Liu C., Stryker Z., Loganathan B.G., and Kannan K. (2019a): Phthalate Metabolites, Hydroxy-Polycyclic Aromatic Hydrocarbons, and Bisphenol Analogues in Bovine Urine Collected from China, India, and the United States. Environmental Science & Technology 53 (19), 11524-11531. DOI: 10.1021/acs.est.9b04178

Zhu M., Chen X.Y., Li Y.Y., Yin N.Y., Faiola F., Qin Z.F., and Wei W.J. (2018): Bisphenol F Disrupts Thyroid Hormone Signaling and Postembryonic Development in Xenopus laevis. Environ Sci Technol 52 (3), 1602-1611. DOI: 10.1021/acs.est.7b06270

Zhu Q., Jia J., Wang Y., Zhang K., Zhang H., Liao C., and Jiang G. (2019b): Spatial distribution of parabens, triclocarban, triclosan, bisphenols, and tetrabromobisphenol A and its alternatives in municipal sewage sludges in China. Science of The Total Environment 679, 61-69

Zoller O., Brüschweiler B.J., Magnin R., Reinhard H., Rhyn P., Rupp H., Zeltner S., and Felleisen R. (2016): Natural occurrence of bisphenol F in mustard. Food Additives & Contaminants: Part A 33 (1), 137-146

Annex H

Note: The content of Annex H, the report 'BioMath/SKZ - Data collection to support the restriction of substances of very high concern under REACH for bisphenol A - BPA levels in materials - Final Report' (Project No. (FKZ) 3719654060), is provided as a separate document to the restriction dossier.