



**CHEM Trust**

Protecting humans and wildlife  
from harmful chemicals

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## Comments to call for evidence for Bisphenol A and structurally related bisphenols of similar concern for the environment

Background document: <https://echa.europa.eu/documents/10162/6f7666f4-a30c-7e67-0488-3d6e0f21b56e>

### General comments

CHEM Trust strongly supports development of a restriction proposal to address the risks of BPA and structurally relevant bisphenols to the environment. In 2016 Germany's substance evaluation on BPA had shown that further regulatory measures are necessary. In 2018 CHEM Trust published the report 'From BPA to BPZ – a toxic soup?' <https://chemtrust.org/toxicsoup/>. In this report we highlighted the fact that companies are being allowed to replace the well-known hormone disrupting chemical BPA with chemicals having a similar hazardous profile to BPA.

We have long argued that a group restriction for BPA and structurally related bisphenols is long overdue ([https://chemtrust.org/bisphenol\\_group/](https://chemtrust.org/bisphenol_group/)) and we therefore welcome the approach of covering a group of bisphenols in the restriction.

In this context we would like to make 3 general comments:

#### 1. The restriction needs to cover all relevant bisphenols with a similar hazard profile

The restriction needs to be broad enough to enhance protection, i.e. the group approach should not be taken forward in a too narrow manner. EU regulation needs to be used with more foresight than is currently the case, and BPS serves as a good example why this is needed: at the time of writing the CHEM Trust Toxic Soup report (2018) most notifiers in the CLP inventory did not provide any classification for BPS. In contrast, the joint RAC noted back in 2015 that BPS has a "toxicological profile" similar to BPA and should not be used to replace BPA in products. It took until December 2020 to agree on a harmonised classification: RAC agreed with Belgium's proposal to officially classify BPS as a substance that may damage fertility and the unborn child (cat 1B).

Grouping of substances needs to play a more important role in risk management decisions: it can ensure that a chemical is restricted by applying read-across to similar substances. Otherwise, years will pass to generate (eco)toxicological data for each substance, thus rewarding ignorance, and ultimately meaning that a lack of data helps a chemical to stay on the market. CHEM Trust therefore sees the need to set up a sufficiently large group which covers all relevant substances that are known or suspected as being used as replacements. The default position should be that all bisphenols are viewed as being part of this group, unless there is substantial evidence that a particular bisphenol does not have endocrine disrupting properties. For more details on our proposal see Chapter 6 in 'From BPA to BPZ – a toxic soup?'

## 2. The restriction should address uses for food contact materials

CHEM Trust is very concerned about the bisphenol exposure of the general population from uses of bisphenols in food contact materials. In our view it should be avoided to repeat the mistake that occurred in the joint restriction of 4 phthalates in articles, which omitted the important uses in materials that come into contact with food. For more info see our letter to the Commission in 2018 <https://www.chemtrust.org/wp-content/uploads/chemtrust-fourphthalates-july18.pdf>.

## 3. The restriction should address current exposures, mixture risks and human health concerns

We recommend complementing the analysis by addressing exposure and concerns for human health. Recent human biomonitoring data show decreasing trends for exposure to BPA but increasing levels of substitutes like BPS and BPF. (see e.g. here:

<https://www.sciencedirect.com/science/article/abs/pii/S1438463919305711?via%3Dihub>)

For human health and for the environment it will also be important to consider the fact that exposure takes place to several similarly acting bisphenols at the same time. These combination effects need to be taken into account in the risk considerations.

**In conclusion:** A comprehensive group restriction for the bisphenols would be a very important step forward. It would also be responding to the EU Chemicals Strategy for Sustainability which commits to a ban of EDCs in consumer products as soon as they are identified and allowing their use only, where it is proven to be essential for society. Thus, any derogation should only be granted in exceptional cases based on well-documented reasons and with a time-limit.

### Responses to questions:

#### 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)?

##### 1) Food contact materials (FCM)

Among other things, BPA is used in quite significant volumes in several key food contact applications. It is used to make polycarbonate plastic, which is hard and durable and is therefore produced for articles that are intended to be reused, such as cookware, liquid containers, plates, mugs and other plastic containers. It is also widely used for coatings of food and drink cans. (<https://www.efsa.europa.eu/en/topics/topic/bisphenol>). Exposure from FCM contribute significantly to human exposures - and given the overall volumes of uses in FCM this is also important for addressing environment exposure. There are some EU harmonised rules in place for Bisphenol A in plastic FCM and can coatings, but according to different studies it is doubtful if these are efficient in protecting the consumers (<https://www.foodpackagingforum.org/food-packaging-health/bisphenol-a> and <https://www.sciencedaily.com/releases/2019/10/191024093608.htm>). This is why e.g. France has stricter national rules on BPA in FCM.

Moreover, the EU rules on hazardous chemicals in FCM - including bisphenol A and other bisphenols - focus only on human health and are not designed to take environmental concerns into account (<https://eur-lex.europa.eu/legal->

[content/EN/TXT/PDF/?uri=CELEX:32004R1935&from=EN](#)). We strongly recommend that FCM are included in the restriction proposal. This would also be in line with the recent Chemicals Strategy for Sustainability which recommends REACH restrictions on EDCs in all consumer products, including the FCM.

## 2) Thermal paper

In 2019 the Belgian public authorities (Federal Public Service (FPS) Economy and FPS Health, food chain safety and environment), together with the European Chemical Agency (ECHA) organised the supply chain workshop gathering stakeholders across the thermal paper supply chain. The presentations are available here:

<https://www.health.belgium.be/en/supply-chain-substitution-workshop-alternatives-bisphenol-thermal-paper>

We expect ECHA's reports about changed market trends will also feed into the ongoing restriction process: In June 2020, an [Echa survey](#) found that paper manufacturers have continued to replace BPA with BPS, predicting that 61% of all thermal paper will contain BPS by 2022.

## **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)
- v. 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<sup>[1]</sup>.
- 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 solution to prevent or minimise the releases?

### **CHEM Trust comments:**

*No comments*

**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?**

**CHEM Trust comments:**

*No comments*

**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.

**CHEM Trust comments:**

In our CHEM Trust report 'From BPA to BPZ – a toxic soup?' we give a range of examples and references to bisphenol exposure and uses, in particular on BPA, BPS, BPF, BPAF and BPHF (see Chapters 3 and 4, <https://chemtrust.org/toxicsoup/>). In our view it is important to look not only for other chemicals but also to assess if other materials or other ways of achieving a given function would be workable as substitution. This is particularly true for the bisphenols as many of these seem to have similar hazardous properties.

A review from 2019 included 20 potential BPA-alternatives, which are reported to be used in consumer products. It confirmed a significant lack of data and also indications of endocrine disrupting properties for some of the bisphenol alternatives to BPA: 'Substitution of bisphenol A: a review of the carcinogenicity, reproductive toxicity, and endocrine disruption potential of alternative substances'

<https://www.tandfonline.com/doi/abs/10.1080/10408444.2019.1701986?journalCode=itxc20>

The Canadian government currently runs a technical consultation on 343 substances with structural similarity to BPA to support further information gathering and consideration (ending on 17.2.2021). 343 BPA analogues and functional alternatives were identified and triaged using structural filters into four groups based on structural similarity to BPA; a fifth group was derived based on filtering for evidence as a BPA functional alternative.

<https://www.canada.ca/content/dam/eccc/documents/pdf/pded/technical-consultation-bpa/Technical-consultation-bpa.pdf>

Other potential impacts regarding the transition to alternatives is the exposure of people and wildlife to alternatives, see e.g. recent human biomonitoring data showing a decrease in BPA but increase in bisphenol S (BPS) and bisphenol F (BPF).

<https://www.sciencedirect.com/science/article/abs/pii/S1438463919305711?via%3Dihub>

Moreover, a publication from Wu et al (2018) reported that BPS is already ubiquitous in the environment and has been shown to affect the development of zebrafish larvae

<https://pubmed.ncbi.nlm.nih.gov/28963899/>

#### **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.

#### **CHEM Trust comments:**

*No comments*

#### **6. Available analytical methods and test set up:**

**For detecting the content of 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?**

#### **CHEM Trust comments:**

*No comments*