



CHEMTrust

Protecting humans and wildlife
from harmful chemicals

Submission

CHEM Trust comments on the restriction proposal for 4,4'-isopropylidenediphenol (Bisphenol A) and bisphenols of similar concern for the environment

Consultation Risk Assessment Committee, ECHA, January 2023

General comments - Introduction

CHEM Trust would like to thank the dossier submitter for all the work on the restriction proposal for 4,4'-isopropylidenediphenol (Bisphenol A) and bisphenols of similar concern for the environment. Germany's substance evaluation on BPA had already shown in 2016 that further regulatory measures are necessary to reduce exposure to bisphenols. The presented proposal can contribute to this reduction. However, we find that several aspects are likely to limit the effectiveness of this restriction and this calls for improvement. Therefore, we would like to make the following comments below as input to the first RAC discussions.

We note that the intention with the dossier is to minimise the emissions to the environment, which is an important goal. In addition, bisphenols are also frequently found in the general population.¹ Recent human biomonitoring data from the EU research programme HBM4EU have once again demonstrated the relevance of human exposure to BPA as well as to other bisphenols, and data on bisphenol S and bisphenol F showed that median levels of urinary BPA alternatives are increasing in all European regions.² We therefore call on the Commission to follow up on its commitment in the Restrictions roadmap³ to act on the concerns for human health from BPA and additional bisphenols.

Scope

Grouping approach to BPA and bisphenols of similar concern (BoSC)

We agree very much with the need to choose a grouping approach to increase protection and avoid regrettable substitution of bisphenols. In 2018 CHEM Trust published the report 'From BPA to BPZ – a toxic soup?'.⁴ 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 as BPA. We have argued for many years that a group restriction for BPA and structurally related bisphenols is long overdue.⁵

¹ <https://www.sciencedirect.com/science/article/abs/pii/S1438463919305711?via%3Dihub>

² https://chemtrust.org/hbm4eu_conference/

³ <https://ec.europa.eu/docsroom/documents/49734>

⁴ <https://chemtrust.org/toxicsoup>

⁵ https://chemtrust.org/bisphenol_group/

As stated in our comments submitted to the call for evidence in 2021⁶ 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. 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. Looking at the example of BPS: RAC already 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 to officially classify BPS as a substance that may damage fertility and the unborn child (Rep cat 1B) and it has only just been included in the Candidate List as an SVHC in January 2023.⁷

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 for BPA and BoSC. 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.

The proposed restriction takes a rather narrow approach by just including 5 bisphenols that have been officially identified in the EU as meeting the WHO/IPCS criteria for an endocrine disrupter in the environment. This selection requires a high level of evidence and data availability for each substance, as well as an overall identification process among EU experts that the substance is indeed an endocrine disrupter for the environment. Instead, it would be important to define larger boundaries by building on specific molecular structures expected to lead to ED effects. This would reflect a more inclusive future-proof approach, which also contributes to reducing animal tests, so that all relevant bisphenols that could become regrettable substitutes are included in the group from the start.

Moreover, while the general idea of an extension mechanism for adding future BoSC to the restriction makes sense, we are concerned that the currently proposed mechanism requires a too high burden for adding substances to the group restriction.

CHEM Trust recommendation:

Expand the scope of the group: add more bisphenols to enlarge the group, by building on ECHA’s grouping of bisphenols⁸ to ensure that the restriction delivers fast and effective reduction measures. The benefit of the group approach is the ability to take regulatory action, even in the absence of all specific hazard data (and before many years of EU identification discussions have passed), and build the appropriate group based on read-across/structural similarity.

Expand the extension mechanism: Also in the future, data gaps on ED properties are likely to remain a limiting factor in ED assessment. Therefore, we see it as absolutely crucial that the proposed extension mechanism will not only include Cat 1 EDs of the future CLP ED hazard classes (known and presumed) but also Cat 2 EDs (suspected). Otherwise, the stated goal of the EU Chemicals Strategy to deliver better and faster protection will not be met.

⁶ https://chemtrust.org/wp-content/uploads/CT-comments-call-for-evidence-bisphenols-restriction_Feb21.pdf

⁷ <https://echa.europa.eu/de/-/echa-adds-nine-hazardous-chemicals-to-candidate-list>

⁸ <https://echa.europa.eu/de/-/group-assessment-of-bisphenols-identifies-need-for-restriction>

For a straightforward application of the extension mechanism, we also recommend direct inclusion of substances identified as EDCs in the restriction. Otherwise, the effect of the restriction may be undermined or delayed through drawn-out discussions on exceptions or transition periods.

Hazard

The presented hazard part on the five bisphenols is performed very well and the risks from adverse effects to a very large number of species are well described. The restriction of the 5 bisphenols, all EDs for the environment, are important targets for the restriction to prevent regrettable substitution (even if we argue for a larger group, see above). We support the dossier submitter in applying a non-threshold approach, as no safe concentration can be set with sufficient certainty for EDCs and therefore emission minimisation is needed.

Information on benefits

Without the group restriction it would be likely that other bisphenols would be replaced by similar bisphenols because of the high structural similarity – as sadly happened with the increased use of BPS in thermal paper following the ban of BPA for this use.⁹ Important benefits to be expected from the restriction are the prevention of regrettable substitution with one of the other bisphenols within the scope of the restriction. This sends signals to the market, and the resulting emission reductions/avoidance will also provide benefits for human health.

Transition times and proposed derogations

The concentration limits proposed for the five product-specific derogations seem rather high. For example, if the dossier states that EU manufacturers can comply with the proposed 150 ppm concentration limit for polycarbonates, there is basically no trigger for any substitution. In particular, as it comes without a time-limit.

The derogation for recycling paper has a too long transition time of 6,5 years and needs a shorter deadline. It has been very clear for years that bisphenol in till receipts was a problem for recycling.¹⁰ So therefore companies should have been responding to try and avoid/limit recycling thermal paper, thus reducing emissions to the environment.

CHEM Trust recommendation: The proposed five product-specific derogations should be carefully re-assessed and lowered, especially since the proposed concentration limits have been provided by the same (industry) stakeholders affected by the measures! In the case that derogations are deemed absolutely necessary, it is important that the concentrations limits remain a driver for substitution. Also, the transition times seem very long and should be shortened/introduced unless there is convincing arguments/evidence against this.

⁹ <https://echa.europa.eu/de/-/bisphenol-s-has-replaced-bisphenol-a-in-thermal-paper>

¹⁰ <https://chemtrust.org/bps-thermal-paper-action/>

Conclusion

As the dossier well describes, many different emission sources lead to environmental emissions from endocrine disrupting bisphenols and therefore, EU wide measures are needed to improve protection of the environment from bisphenol emissions.

In CHEMTrust`s view, the proposed restriction option RO1 should be the basis of the RAC discussions – and it should be considered to lower the migration limit of 0,04 mg/L. Options 2 and 3 are inappropriate as they would achieve too little risk reduction and thus miss the restriction goal.

Overall, we find that a much more protective approach should be taken by including a larger group of bisphenols in the group restriction proposal. Based on the points above, we strongly recommend

- expanding the scope of the group of bisphenols and the extension mechanism,
- reworking some of the derogations to achieve a more significant impact of reducing the environmental emissions of BPA and BoSC.

While we support the proposed restriction of additive uses, we miss a stronger emphasis on substituting the polymeric uses and setting clear incentives. In fact, several companies have already started to move away from bisphenols in materials such as coatings, in particular in the food contact material sector, as described in the recent White paper from Akzo Nobel.¹¹

It is important to increase the effectiveness of this restriction, also to the EU`s 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.

¹¹ <https://packagingcoatings.akzonobel.com/content/dam/akzonobel-packagingcoatings/en/homepage/c43395-akzonobel-whitepaperpackaging-v13.pdf>