

## GERMANY PROPOSES A RESTRICTION ON BISPHENOL A AND OTHER BISPHENOLS WITH ENDOCRINE DISRUPTING PROPERTIES FOR THE ENVIRONMENT<sup>1</sup>

### Summary

Germany proposes to restrict bisphenols with endocrine disrupting properties for the environment.

The proposal concludes that it is not possible, based on current scientific knowledge, to set sufficiently safe threshold values for endocrine disrupting chemicals in the environment. There is a large variety of emission sources with wide dispersive and wide spread uses. Therefore, the proposed restriction aims to minimise the emissions of bisphenols with endocrine disrupting properties to the environment.

The substances in the scope of the proposed restriction are

- Bisphenol A (4,4'-isopropylidenediphenol, EC 201-245-8)
- Bisphenol B (4,4'-(1-methylpropylidene)bisphenol, EC 201-025-1)
- Bisphenol S (4,4'-sulphonyldiphenol, EC 201-250-5)
- Bisphenol F (4,4'-methylenediphenol, EC 210-658-2)
- Bisphenol AF (4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol, EC 216-036-7)
- Bisphenols that will in the future be:
  - identified as substances of very high concern (SVHC) due to their endocrine disrupting properties for the environment according to Article 57 and Article 59 of the REACH Regulation, or
  - classified as endocrine disruptors for the environment category 1 in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or
  - identified as endocrine disruptors for the environment according to the Biocidal Products Regulation (EU) No 528/2012 or the Plant Protection Products Regulation (EC) No 1107/2009.
- Salts of any of the above.

Considering the risks associated with Bisphenol A and other bisphenols of similar concern (BoSC), the Dossier Submitter proposes a ban on placing on the market of articles and mixtures containing a concentration of bisphenols in the scope of the restriction equal to or greater than 10 ppm (0.001 % by weight) with the following derogations:

- a derogation for mixtures and articles where the bisphenols are either covalently bound to any type of matrix (e.g. via functioning as a cross-linker) or are used as intermediates in the manufacture of polymers, and for which
  - i) contact to aqueous media in any form can be excluded during their reasonable and foreseeable use throughout their service life or

---

<sup>1</sup> The information note has been prepared based on the Annex XV report prepared by Germany.

INFORMATION NOTE ON RESTRICTION REPORT ON  
BISPHENOL A

- ii) the migration limit in the respective mixtures and articles does not exceed 0.04 mg/L over the entire service life.
- Five product specific derogations, under which the following concentrations limits are also proposed:
  - o 150 ppm for the recycling of paper for 78 months
  - o 50 ppm for fluoroelastomers for 10 years
  - o 150 ppm for polycarbonates
  - o 65 ppm for the placing on the market of articles manufactured with solid and semi-solid epoxy resins and concentration limit of 1 ppm for epoxy resin mixtures intended for consumer use
  - o 500 ppm for leather articles and mixtures used for the tanning of leather for 5 years.

The consultation on this proposed restriction will start on 21/12/2022 and ends on 22/06/2023

When responding to the consultation, stakeholders should ensure that they are referring to the most recent version of the Annex XV report and any annexes (i.e. those published alongside the consultation).

Respondents are also encouraged to take into account when certain aspects of the proposal are planned to be discussed in the committee's plenary meetings (see table below) and time their submissions accordingly (multiple submissions are possible throughout the consultation).

	<b>Committee</b>	
<b>Plenary meeting of the Committee (timing)</b>	<b>Risk Assessment Committee (RAC)</b>	<b>Socio-Economic Assessment Committee (SEAC)</b>
<b>1 (2.5 months after PC starts)</b>	Verify scope  Conclude evaluation of hazard assessment  Preliminary evaluation of exposure and risk	Verify scope  Preliminary evaluation of AoA  Conclusion on other regulatory RMOs  Conclude that action is required on an EU-wide basis  Preliminary evaluation of costs  Preliminary evaluation of benefits  Preliminary evaluation of practicality and monitorability
<b>2 (5.5 months after PC starts)</b>	Conclude evaluation of exposure and risk and that action is required on an EU-wide basis  Preliminary evaluation that the	Conclude evaluation of AoA  Preliminarily conclude evaluation of costs and benefits  Preliminary evaluation of

INFORMATION NOTE ON RESTRICTION REPORT ON  
BISPHENOL A

	proposed restriction is the most appropriate EU-wide measure	proportionality
<b>3 (8.5 months after PC starts)</b>	Conclude evaluation that the proposed restriction is the most appropriate EU-wide measure  Conclude on uncertainties  Adopt opinion	Conclude evaluation that the proposed restriction is the most appropriate EU-wide measure  Conclude on uncertainties  Agree draft opinion
<b>4</b>	Not relevant.	Conclude on issues raised during SEAC draft opinion consultation  Adopt opinion

Information on the hazards of the substance(s), exposure/risk, costs of the proposal, benefits and derogations would make the most impact if submitted by month two of the consultation. This early submission would also allow the information to be considered at the appropriate time. This timing takes into account that stakeholders have access to the dossier much earlier than in the past, as it is published two weeks after submission or more than six weeks in advance of the start of the consultation.

It is possible to submit more than one consultation response during the six month period so please take this into account when deciding when to submit information.

### **How to submit a comment in the consultation on the proposed restriction**

Firstly please read the consultation guidance that describes the relevant information that should be submitted. It is available here:

[https://echa.europa.eu/documents/10162/13641/public\\_consultation\\_guidance\\_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c](https://echa.europa.eu/documents/10162/13641/public_consultation_guidance_en.pdf/7c4705d5-ad01-43ed-a611-06f1426a595c).

When you are ready to make your comments, click on the appropriate link on the ECHA website. Please be aware that it is not possible to save your submission and come back to it, so you should already have your comments prepared in an attachment or saved in some other format in advance.

The web form contains five main parts:

- Introduction: containing some general information on the restriction and a link to this note and the PC guidance.
- Section 1: Personal information
- Section 2: Organisational information
- Section 3: Non-confidential comments on the proposal - both general comments and information on specific issues (see below). Your responses can be entered directly into the form or through section 4 as an attachment. However, please do not submit the same comments via both means. General comments can be on any aspect of the Annex XV restriction proposal, including on issues related to socio-economic analysis.

## INFORMATION NOTE ON RESTRICTION REPORT ON BISPHENOL A

- Section 4: Non-confidential attachments can be added here.
- Section 5: Confidential attachments can be added here. Confidential information will only be available to the ECHA Secretariat, the Committees and Member State Competent Authorities. However, if ECHA receives an Access to Documents request, we may come back to you for justifications why the information is confidential. You can also add this information already in the relevant part of the webform.

Once you have finished your submission press the submit button and your comments will be submitted. You will receive a submission number via e-mail and you should refer to this in any communication with ECHA on this issue.

It is not possible for you to retrieve your submission so you may want to take a screen shot, or printed copy for your future reference.

### Specific information requests

In addition to the general comments, outlined above, the consultation includes several specific questions to gather information that is considered to be particularly relevant to the evaluation of the proposal, as follows:

#### Restriction conditions and testing

1. Do you consider that the restriction conditions (including derogations listed in Appendix Y) and the conditions and methods for migration testing (as described in Annex Z) are clear? Are there conditions that require further clarification? Do you consider that the conditions and methods for migration testing as described in Annex Z are representative to assess migration during the entire article service life? If not, can you propose a more reliable testing?
2. Which analytical methods exist for your sector to test:
  - a. the **content** of BPA and BoSC in article or mixtures that are covered in the scope of the restriction?
  - b. **migration** of bisphenols from your articles, part of articles and/or mixtures?

In your answer, please specify the aim and purpose of the testing (for example, testing in the context of testing REACH conformity, characterising performance or stability).

Which solvent do you use to extract BPA and/or BosC in either content or migration testing?

3. Do you see any challenge in the supply chain communication on the presence of BPA/BoSC in mixtures and articles? Are you aware of any liquid mixture containing more than 10 ppm of BPA/BoSC and for which contact to water cannot be excluded during its service life (and for which according to the proposed restriction conditions migration testing would be required)? Do established methods for the BPA/BosC content analysis for liquids exist in your application at your sector? Please specify.

#### Alternatives

4. The Dossier Submitter identified different alternatives for the different uses of Bisphenol A and BoSC (e.g. in PVC, thermal paper, hardeners for epoxy resins, polycarbonates, epoxy resins, polysulfones, polyesters, phenolic resins,

INFORMATION NOTE ON RESTRICTION REPORT ON  
BISPHENOL A

polyurethanes, vinyl ester resins, polyacrylates, syntans, fluoroelastomers). These are described in section E.2 of the Appendix. Do you agree with the Dossier Submitter's conclusion regarding the availability of alternatives? Do you have additional information on alternatives that should be considered as part of the Impact Assessment.

5. The Dossier Submitter assessed the impacts of the examined restriction options (See Annex E and section 2.4 of the Annex XV report). Please provide additional information on the economic impacts of the proposed restriction. Please consider both the restriction conditions as described in paragraph 1 and 2, as well as the derogations described in Appendix Y. If the derogations are relevant for your sector, please also describe the economic impacts you would expect in case the derogations are removed.

### **Product specific questions**

#### **Epoxy resins**

6. For manufacturers or importers of epoxy resins: do you have information on the presence of BPF or BoSC in your products? If BPF or BoSC are present in your products, please can you indicate the concentration, the methods used for the testing and the volumes of epoxy resins produced per year in the EU. Do you have information on the expected growth in demand for epoxy resins in the EU in the next 5 years and more (e.g. up to 20 years)?

#### **Synthetic tanning agents (Syntans)**

7. You are invited to provide information on:
  - a. volumes of syntans produced in the EU in 2020 and 2021
  - b. the volumes of leather (e.g. tonnes or m<sup>2</sup>) that were tanned using syntans
  - c. information on alternatives
  - d. whether it is possible to remove the "free BoSC" from syntans, e.g. by excess reaction
  - e. the concentration of BPS and BPF in the leather
  - f. the relevant sectors (e.g. fashion, automotive, furniture, personal protection, other) that are supplied with leather treated with syntans
  - g. economic impacts you expect for the producers of syntans and leather articles (e.g. impacts on profit and jobs) of the examined restriction options as well as of the proposed restriction option (with the latter being described on pages 5-7 of the Annex XV report)

#### **Synthetic tanning agents used for polyamide treatment (textile auxiliaries)**

8. You are invited to provide information on:
  - a. on the share of the annually produced polyamide (e.g. in 2020 and in 2021) that is processed with textile auxiliaries (synthetic tanning agents used for polyamide treatment) containing BPF or BPS
  - b. whether colour fastness is a requirement for all polyamide articles or some specific product categories
  - c. how textile auxiliaries are applied (e.g. are the auxiliaries used only at industrial settings or also by professionals? What measures are

INFORMATION NOTE ON RESTRICTION REPORT ON  
BISPHENOL A

implemented to treat the chemical waste generated during the processing of textiles and textile auxiliaries containing BPA or BoSC)

- d. whether the use of BoSC in textile auxiliaries and textile production should be considered as an additive use
- e. function of BPS and BPF in textile auxiliaries and textile production
- f. the content of BPS and BPF in polyamide textile articles (the Dossier Submitter collected information on the content of BPS and BPF in polyamide textile articles and this appears to range from 200 – 1 000 ppm)
- g. whether there are technical constraints that prevent the achieving of a lower concentration limit
- h. tested concentration of BPA or BoSC in polyamide textile articles (if you have tested your polyamide textile articles for BPA or BoSC, please could you share the concentration and methods and indicate also how regularly the textile is analysed for residues of BPS/BPF or another BoSC?)
- i. the economic impacts for polyamide producers and downstream sectors in terms of impacts on profit and jobs of each of the three concentration limits (10 ppm under the proposed restriction, 150 ppm and 1 000 ppm)

## Emissions

- 9. During the manufacture of your products or their use, which measures do you employ to minimise the amount of “free” BPA/BosC in them?
- 10. Emission estimates are provided in Annexes B8 and H. Please provide any additional information regarding the emission estimates. For example, information on release from the use of hardener as an additive in epoxy resins would be appreciated.

The final opinions of both Committees are scheduled to be available by December 2022. ECHA will send the joint opinion of the Committees to the European Commission, which will take the decision whether to include the proposed restriction in Annex XVII of the REACH Regulation.

The Dossier Submitter and the Rapporteurs will all respond to the issues raised in the consultation and these responses will be published with the launch of the consultation on the SEAC draft opinion in month nine of the process.