# Call for evidence on a possible restriction on 4,4'-isopropylidenediphenol (Bisphenol A) and structurally related bisphenols of similar concern for the environment

## Background document

### *Introduction*

Germany conducted a REACH substance evaluation on 4,4'-isopropylidenediphenol (Bisphenol A, BPA) and, in 2016, determined that further regulatory measures are necessary with respect to environmental releases of BPA.[1] In the subsequent Regulatory Management Option Analysis (RMOA),[2] Germany concluded that BPA ought to be identified as a Substance of Very High Concern (SVHC) due to its endocrine disrupting properties for the environment. In a subsequent step, a targeted restriction should follow to minimise the environmental releases of BPA. BPA was subsequently identified as an SVHC due to its endocrine disrupting properties for humans and the environment and was added to the candidate list in 2017 and 2018, respectively. Our objective is to submit a proportionate and enforceable restriction proposal that adequately addresses the potential risks to the environment from relevant uses and functions of Bisphenol A and other bisphenols with similar hazard profiles, particularly those that might be used as drop-in alternatives.

### *Elements of an Annex XV restriction proposal*

The elements that need to be considered during the preparation of a restriction proposal are set out in Annex XV of REACH and further elaboration in ECHA Guidance documents[3]. These can be summarised, as follows:

- A characterisation of exposure and resulting risks to human health from a use of a substance, including via food and water;
- A characterisation of exposure and resulting risks to the environment and wildlife from a use of a substance;
- A justification that risks are not adequately controlled and occur on a Union-wide basis;
- An analysis of the availability, technical and economic feasibility of alternatives to the substance to be restricted;
- A socio-economic analysis (e.g. costs and benefits to society) that would arise from a restriction.

[1] Substance evaluation conclusion and report on BPA: https://echa.europa.eu/documents/10162/2e8ac666-fae6-2e54-f0eb-ef4a5da819ed

[2] Documentation on the RMOA process on BPA performed by the German agencies: https://echa.europa.eu/documents/10162/f39eafc1-f58d-de22-7be3-2cd64eef62a7

[3] ECHA information on the preparation of Annex XV restriction dossiers: https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions

**Problem identification**

BPA is a high production volume chemical which is used mainly as a monomer in the production of polymers (e.g. polycarbonate or epoxy resins) but which is also used as an additive in plastics. The use as a developing agent in thermal paper has previously been restricted (Entry 66 to Annex XVII). Steady EU-wide emissions of BPA into the environment via sewage treatment plant have been detected with peak emissions near, for example, paper recycling/production plants and professional laundries. Traffic security systems (for example, traffic cones and barriers) are often made of recycled materials and show high residues of BPA leaching directly into the environment. Products containing BPA (indoor and outdoor use) may lead to continuous release into wastewater treatment plants.

To avoid regrettable substitution of Bisphenol A, especially with regard to drop-in alternatives, it is planned to also address other bisphenol substances that exhibit similar concern for the environment based on their structural similarity.

A restriction is proposed, rather than authorisation, to allow releases from all relevant substances to be considerd as well as releases from both imported articles and intermediate uses.

***Scope***

The concerns for BPA leading to the restriction proposal are based on its endocrine disrupting properties for the environment. Structurally similar bisphenols may have a similar hazard to BPA and 'drop-in' substitution to these would limit the effectiveness of a restriction on BPA to address risks to the environment. A restriction proposal on a group of substances is, therefore, intended to minimise emissions of BPA, and structurally related bisphenols, to the environment. An example, non-exhaustive, list of structurally related bisphenols potentially within the scope of the restriction is provided in an Annex to this note.

This may be achieved via restricting the residual amount of free BPA, or BPA related substances, in mixtures and articles as well as via limiting the release rate of BPA, or BPA related substances, from articles throughout their life cycle. Currently, the entry made to the registry of intention for the restriction is as follows:

A) Restricting the use as an additive and the content in articles (0.02% by weight)
B) Restricting content of residues (unreacted monomer) in articles – also for imported goods (0.02% by weight)
C) Restricting the use of mixtures with content of 0.02% by weight for non-automated processes
D) Introducing release rates for BPA from articles (products and subassemblies) during service life (weathering, leaching due to cleaning action) preventing release into the environment and/or (direct) migration to organisms

Please note that the concentration limit values specified are provisional. The restriction conditions will be elaborated in more detail during the development of the proposal including the socio-economic analysis, taking into account the information received in the call for evidence.

***Evidence and information to be collected***

The objective of this call is to gather information or comments on:

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)
   v. Are measures in place to minimise releases during manufacture of mixtures/articles and their life cycle? 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 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?

Additional information that could also be potentially relevant is also welcome and should be submitted. We have undertaken and will continue to undertake our own research for relevant scientific and other literature and information on the potential release of BPA and structurally related bisphenols to the environment but we would be interested in being informed of any ongoing research that might be published during the course of 2020 and 2021 (e.g. ongoing research or submitted but unpublished literature).

***Who should participate in the call for evidence?***

This call for evidence is intended for interested parties such as private companies (manufacturers, suppliers, recyclers, downstream users, distributors, importers etc.), trade associations, scientific organisations, NGOs and other stakeholders or Member State Authorities holding relevant information. Information can be submitted confidentially and will be treated as such by ECHA, the Federal Institute for Occupational Safety and Health (BAuA) and the German Environment Agency (UBA).

Any information provided will be used, amongst other issues, to determine if any derogations are required for any potential restriction that is proposed. However, derogations cannot be proposed without adequate information on risk and socio-economic information, including alternatives. If a

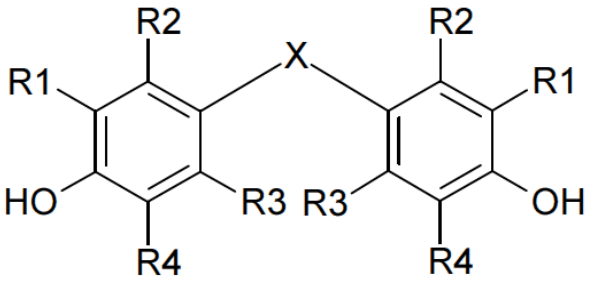
derogation is not proposed in the initial restriction proposal then it will be incumbent on relevant stakeholders to provide a full justification based on a comprehensive information on risk, socio-economic elements and alternatives, during the opinion-making process.

ECHA invites interested parties to respond to the call for evidence by 15 January 2021.

https://echa.europa.eu/calls-for-comments-and-evidence

For any clarifications, please contact: chemg@baua.bund.de

**Annex - Exemplary, non-exhaustive, list of bisphenols for which information is asked during the call for evidence and which may be addressed by the Restriction**




This is an exemplary basic structure of a symmetric bisphenol derivative – two phenol rings are connected via a **bridge (X)** in the 4,4'-/double *para*-position (2,2'(double *ortho*) or 2,4' (*ortho*/*para*) substitution patterns may also be found).

The **bridge** can contain solely carbon and hydrogen atoms (the simplest example would be a methylene ($CH_2$) bridge) or also hetero atoms (e.g. a sulphonyl group in BPS). Structures with more than one bridging atom are also available.

Either of the bisphenols rings may contain **further substituents ($R_1$ to $R_4$)**. In the simplest case, the rings will only bear hydrogens as further substituents but they may also bear alkyl chains or heteroatoms (e.g. bromine in TBBPA). Usually, the substitution pattern will be symmetrical but asymmetric patterns may also be possible (where $R_1$ to $R_4$ on the first ring do not correspond to $R_1$ to $R_4$ on the second ring).

The **hydroxyl (OH)** groups of the phenol rings are reactive and may be covalently bound to further groups either during the use of the bisphenols as a monomer for the manufacture of polymers or during the manufacture of further related substances. These may be mono-constituent substances or even substances of more variable composition (UVCBs).

| Trivial name / Abbreviation | Name | EC No | CAS No | Molecular Formula |
|---|---|---|---|---|
| Bisphenol A / BPA | 4,4'-isopropylidenediphenol | 201-245-8 | 80-05-7 | C15H16O2 |
| Bisphenol S / BPS | 4,4'-sulphonyldiphenol | 201-250-5 | 80-09-1 | C12H10O4S |
| Tetrabromobisphenol A / TBBPA | 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol | 201-236-9 | 79-94-7 | C15H12Br4O2 |
| Bisphenol C / BPC | 4,4'-isopropylidenedi-o-cresol | 201-240-0 | 79-97-0 | C17H20O2 |
| | 6,6'-di-tert-butyl-4,4'-butylidenedi-m-cresol | 201-618-5 | 85-60-9 | C26H38O2 |
| | 1,1'-isopropylidenebis(p-phenyleneoxy)dipropan-2-ol | 204-137-9 | 116-37-0 | C21H28O4 |
| | 2,2',6,6'-tetra-tert-butyl-4,4'-methylenediphenol | 204-279-1 | 118-82-1 | C29H44O2 |
| | 2,2'-isopropylidenebis(p-phenyleneoxy)diethanol | 212-985-6 | 901-44-0 | C19H24O4 |
| | 4,4'-isopropylidenediphenyl dicyanate | 214-590-4 | 1156-51-0 | C17H14N2O2 |

| Trivial name / Abbreviation | Name | EC No | CAS No | Molecular Formula |
|---|---|---|---|---|
| BPAF | 4,4'-[2,2,2-trifluoro-1-(trifluoromethyl)ethylidene]diphenol | 216-036-7 | 1478-61-1 | C15H10F6O2 |
| Diallyl BPA / DAB | 4,4'-isopropylidenebis[2-allylphenol] | 217-121-1 | 1745-89-7 | C21H24O2 |
| | 4,4',4''-(1-methylpropanyl-3-ylidene)tris[6-tert-butyl-m-cresol] | 217-420-7 | 1843-03-4 | C37H52O3 |
| DMBPC | 4,4'-cyclohexylidenedi-o-cresol | 219-110-7 | 2362-14-3 | C20H24O2 |
| Tetramethyl BPA / TMBPA | 4,4'-isopropylidenedi-2,6-xylol | 227-033-5 | 5613-46-7 | C19H24O2 |
| | 4,4'-[isopropylidenebis(4,1-phenyleneoxy)]dianiline | 235-985-8 | 13080-86-9 | C27H26N2O2 |
| | 2,2'-[(1-methylethylidene)bis(4,1-phenyleneoxy)]bisethyl diacetate | 242-895-2 | 19224-29-4 | C23H28O6 |
| | (1-methylethylidene)bis(4,1-phenyleneoxy-3,1-propanediyl) bismethacrylate | 248-607-1 | 27689-12-9 | C29H36O6 |
| | 4,4'-[(isopropylidene)bis(p-phenyleneoxy)]diphthalic dianhydride | 253-781-7 | 38103-06-9 | C31H20O8 |
| | 4,6-bis[2-(4-hydroxyphenyl)isopropylidene]resorcinol | 432-380-2 | 147504-92-5 | C24H26O4 |
| | $2^5,3^5$-(1,1,1-trifluoropropane-2,2-diyl)di([$1^1,2^1$:$2^3,3^1$-terphenyl]-$2^2$-ol) | 610-104-3 | 43100-47-6 | C39H29F3O2 |
| | 4,4'-(2-ethylhexane-1,1-diyl)diphenol | 680-046-1 | 74462-02-5 | C20H26O2 |
| | 2,2'-[cyclohexane-1,1-diylbis(4,1-phenyleneoxymethylene)]dioxirane | 810-464-3 | 13446-84-9 | C24H28O4 |
| | phenolphthalein | 201-004-7 | 77-09-8 | C20H14O4 |
| | 6,6'-di-tert-butyl-4,4'-thiodi-m-cresol | 202-525-2 | 96-69-5 | C22H30O2S |
| | 4,4'-dihydroxybenzophenone | 210-288-1 | 611-99-4 | C13H10O3 |
| | 4,4',4''-(ethan-1,1,1-triyl)triphenol | 405-800-7 | 27955-94-8 | C20H18O3 |
| | 4-[1-(4-hydroxyphenyl)-1-{4-[2-(4-hydroxyphenyl)propan-2-yl]phenyl}ethyl]phenol | 425-600-3 | 110726-28-8 | C29H28O3 |
| | 3,5-Dihydroxy-4-[3-(4-hydroxyphenyl)propanoyl]phenyl 2-O-(6-deoxy-α-D-mannopyranosyl)- β-D-gulopyranoside | 700-320-7 | 18916-17-1 | C27H34O14 |
| | ethylenebis(oxyethylene) bis[3-(5-tert-butyl-4-hydroxy-m-tolyl)propionate] | 253-039-2 | 36443-68-2 | C31H46O7 |
| | 2,2'-diallyl-4,4'-sulfonyldiphenol | 411-570-9 | 41481-66-7 | C18H20O4S |
| D8 | 4-(4-isopropoxyphenylsulfonyl)phenol | 405-520-5 | 95235-30-6 | C15H16O4S |
| BPS-MAE | 4-(4-Allyloxy-benzenesulfonyl)-phenol | 479-880-7 | 97042-18-7 | C15H14O4S |