1 October 2019

Background document for 4,4'-isopropylidenediphenol (bisphenol A, BPA)

Document developed in the context of ECHA's ninth recommendation for the inclusion of substances in Annex XIV

ECHA is required to regularly prioritise the substances from the Candidate List and to submit to the European Commission recommendations of substances that should be subject to authorisation. This document provides background information on the prioritisation of the substance, as well as on the determination of its draft entry in the Authorisation List (Annex XIV of the REACH Regulation). Information comprising confidential comments submitted during public consultation, or relating to content of registration dossiers which is of such nature that it may potentially harm the commercial interest of companies if it was disclosed, is provided in a confidential annex to this document.

Information relevant for prioritisation and/or for proposing Annex XIV entries provided during the public consultation on the inclusion of 4,4'-isopropylidenediphenol (bisphenol A) on the Authorisation List or in the registration dossiers[1] as well as the MSC opinion[2] were taken into consideration when finalising the recommendation and are reflected in the present document.

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[1] As of the last day of the public consultation, i.e. 5 December 2018
[2] Opinion of the Member State Committee on the draft ninth recommendation of the priority substances to be included in Annex XIV, adopted on 26 June 2019

1. Identity of the substance

Identity of the substance as provided in the Candidate List[3]:

Name: 4,4'-isopropylidenediphenol
EC Number: 201-245-8
CAS Number: 80-05-7

2. Background information for prioritisation

Priority was assessed by using the General approach for prioritisation of SVHCs for inclusion in the list of substances subject to authorisation[4]. Results of the prioritisation of all substances included in the Candidate List by January 2018 and not yet included or recommended in Annex XIV of the REACH Regulation are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_en.pdf.

The prioritisation results of the substances included in the draft 9th recommendation have been updated as necessary after the public consultation. The updated results are available at https://echa.europa.eu/documents/10162/13640/prioritisation_results_draft9threc_substances_October2019_en.pdf.

2.1. Intrinsic properties

4,4'-isopropylidenediphenol (bisphenol A) was identified as a Substance of Very High Concern (SVHC) according to Article 57(c) as it is classified in Annex VI, part 3, Table 3.1 (the list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008 as Toxic for Reproduction, Category 1B, H360F ("May damage fertility"), and was therefore included in the Candidate List for authorisation on 12 January 2017, following ECHA's decision ED/01/2017.

Taking into account all available information on the intrinsic properties of bisphenol A and their adverse effects, it was concluded that the substance can be regarded as substance with endocrine disrupting properties for which in accordance with Article 57(f) of REACH there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57. Bisphenol A was identified as a Substance of Very High Concern (SVHC) according to Article 57(f) and the entry in the Candidate List for authorisation was updated accordingly[5] on 7 July 2017, following ECHA's decision ED/30/2017.

Similarly, it was concluded that the substance can be regarded as substance with endocrine disrupting properties for which in accordance with Article 57(f) of REACH there is scientific evidence of probable serious effects to the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57. Bisphenol A was identified as a Substance of Very High Concern (SVHC) according to Article 57(f) and the entry in the Candidate List for authorisation was updated accordingly[6] on 15 January 2018, following ECHA's decision ED/01/2018.

[3] For further information please refer to the Candidate List and the respective support document at https://www.echa.europa.eu/candidate-list-table.
[4] Document can be accessed at http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf
[5] Additional intrinsic property of concern: Endocrine disrupting properties (Article 57(f) - human health)
[6] Additional intrinsic property of concern: Endocrine disrupting properties (Article 57(f) - environment)

In summary, bisphenol A was identified as SVHC according to Article 57(c) as it is classified as toxic for reproduction (category 1B) and according to Article 57(f) as it demonstrates probable serious effects to human health and the environment, due to its endocrine disrupting properties, which are of an equivalent level of concern.

There is currently one Court case (T-207/18) pending on the identification of bisphenol A as SVHC due to its endocrine disrupting properties for the environment. This Court case has no suspensive effect. According to the judgements of the General Court of the European Union in cases T-185/17[7] and T-636/17[8] ECHA was entitled to identify bisphenol A as a SVHC, based on its classification for reproductive toxicity and its endocrine disrupting properties for human health.

2.2. Volume used in the scope of authorisation

The amount of 4,4'-isopropylidenediphenol (bisphenol A) manufactured and/or imported into the EU is according to registration data (ECHA, 2018) above 1,000,000 t/y. Part of the tonnage reported in registrations relates to the monomer imported as part of polymers and is therefore not considered for priority assessment.

Some uses appear not to be in the scope of authorisation, such as uses as intermediate (in e.g. the manufacture of polycarbonate, epoxy resins, coating materials, substances or polymers) and to the extent it falls under the generic exemptions from authorisation requirement uses as laboratory reagent.

Based on the registration information on volumes provided for most of these uses, which were confirmed by comments received during the public consultation (ComRef, 2019), the volume in the scope of authorisation is estimated to be in the range of 1,000 - 10,000 t/y.

More detailed information on the main uses is provided in Annex I.

2.3. Wide-dispersiveness of uses

Registered uses of 4,4'-isopropylidenediphenol (bisphenol A) in the scope of authorisation include uses at industrial sites (formulation and use of epoxy resin hardeners) and uses by professional workers (e.g. use of epoxy resin hardeners).

The substance is reported for use in the production of various types of articles, however this seems not to be relevant for the WDU assessment: For thermal paper, the use will be limited to concentrations <0.02% by 2020 due to a restriction (entry no. 66 of REACH Annex XVII). In epoxy resin articles cured with bisphenol A-containing hardeners the substance seems to react and releases are considered unlikely (see Annex I).

It is noted that some uses are reported by members of the joint registration, which are not (any more) covered by the joint CSR of the lead registrant (e.g. industrial and professional use as anti-oxidant for processing PVC, production and recycling of thermal paper) (ECHA, 2018 and RCOM, 2016). Therefore, these uses were not considered for priority assessment.

More detailed information on uses is provided in Annex I.

[7] See http://curia.europa.eu/juris/documents.jsf?num=T-185/17
[8] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:62017TJ0636

2.4. Further considerations for priority setting

None

2.5. Conclusion

Verbal descriptions and scores			Total score
Inherent properties (IP)	Volume (V)	Wide dispersiveness of uses (WDU)	(= IP + V + WDU)
Bisphenol A is classified as toxic for reproduction 1B and has endocrine disrupting properties with effects to human health and the environment meeting the criteria of Article 57(c) and (f) Score: 7	The amount of bisphenol A used in the scope of authorisation is in the range of 1,000 - 10,000 t/y Score: 12	Bisphenol A is used at industrial sites and by professional workers. Score: 10	29

Conclusion

On the basis of the prioritisation criteria, bisphenol A receives priority among the substances on the Candidate List (see link to the prioritisation results above). Therefore, bisphenol A is recommended for inclusion in Annex XIV.

3. Background information for the proposed Annex XIV entry

Draft Annex XIV entries were determined on the basis of the General approach for preparation of draft Annex XIV entries for substances to be included in Annex XIV[9] and as further specified in the practical implementation document[10]. The draft Annex XIV entries for all the substances that underwent public consultation are available at https://www.echa.europa.eu/documents/10162/13640/9th_recom_draft_axiv_entries_en.pdf.

The final draft Annex XIV entries that ECHA recommends are available at https://echa.europa.eu/documents/10162/13640/9th_axiv_recommendation_October2019_en.pdf.

[9] General approach can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf

[10] Practical implementation document can be accessed at https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf

3.1. Latest application and sunset dates

ECHA recommends the following transitional arrangements for bisphenol A:

Latest application date (LAD):	Date of inclusion in Annex XIV plus 24 months
Sunset date:	18 months after LAD

The LAD slots are set in 3 months intervals (normally 18, 21 and 24 months after inclusion in Annex XIV).

Allocation of (groups of) substances to LAD slots aims at an even workload for all parties during the opinion forming and decision making on the authorisation applications. All substances can therefore not be set at the same LAD. ECHA proposes to allocate those substances to the “later” LAD slots (21 months or more) for which the available information indicates a relatively higher complexity of supply chain. Groups of substances are considered together.

During the public consultation, comments were received arguing for longer timeframes due to time consuming research and substitution activities. Other comments favoured an early LAD, which would benefit companies already replacing bisphenol A (ComRef, 2019).

ECHA made the final LAD allocation using all available relevant information including that received in the public consultation.

A summary of the information available is provided in Annex I.

3.2. Review period for certain uses

In its draft recommendation ECHA had seen no ground to include in Annex XIV any review period for bisphenol A.

During the public consultation ECHA did not receive comments requesting upfront review period for specific uses.

ECHA therefore does not recommend to include in Annex XIV any review periods for uses of bisphenol A.

3.3. Uses or categories of uses exempted from authorisation requirement

3.3.1 Exemption under Article 58(2)

In its draft recommendation ECHA had not proposed any exemptions for (categories of) uses of bisphenol A on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

During the public consultation ECHA received requests for exemptions which were however not referring to any existing Community legislation.

In its opinion MSC expresses the view that there is currently not a sufficient basis for recommending exemptions for a use or a category of uses for this substance.

ECHA has assessed the requests made (see detailed assessment in Section C, in particular C.2 of the response document (RCOM, 2019)) and concluded that there is no ground to recommend

an exemption from the authorisation requirement under Article 58(2) for a use or a category of uses of bisphenol A.

ECHA therefore does not recommend exemptions for uses of bisphenol A on the basis of Article 58 (1)(e) in combination with Article 58(2) of the REACH Regulation.

3.3.2 Exemption of product and process oriented research and development (PPORD)

In its draft recommendation ECHA had not proposed to include in Annex XIV any exemption from authorisation for the use of bisphenol A for PPORD.

During the public consultation ECHA did not receive any requests for exemptions from the authorisation requirement for PPORD for the substance.

No PPORD notifications had been submitted by the end of the public consultation.

ECHA therefore does not recommend exempting any use of bisphenol A for PPORD from authorisation.

4. References

Annex XV SVHC report (2016): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. 4,4'-isopropylidenediphenol (Bisphenol A) Submitted by France, August 2016.

https://www.echa.europa.eu/documents/10162/93f7f325-8bc0-a772-7e4d-15a1dbdde15c

Annex XV SVHC report (2017a): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. 4,4'-isopropylidenediphenol (Bisphenol A) Submitted by France, March 2017.

https://www.echa.europa.eu/documents/10162/93bf4be3-9af6-d7ca-8b07-4e8fb42bad11

Annex XV SVHC report (2017b): Proposal for identification of a substance of very high concern on the basis of the criteria set out in REACH Article 57. 4,4'-isopropylidenediphenol (Bisphenol A; BPA) Submitted by Germany, August 2017.

https://www.echa.europa.eu/documents/10162/12d03565-e386-c6cd-0f5b-4851d2dd2767

ComRef (2019): "Comments and references to responses" document. Document compiling comments and references to respective answers from commenting period 05/09/2018 – 05/12/2018 on ECHA's proposal to include bisphenol A in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/9th_recom_comref_bisphenol_a_en.rtf

ECHA (2018): 4,4'-isopropylidenediphenol. ECHA's dissemination website on registered substances. Accessed on 5 December 2018.

https://echa.europa.eu/search-for-chemicals

RCOM (2016): "Responses to comments" document. Document compiled by France from the commenting period 06/09/2016 – 21/10/2016 on the proposal to identify 4,4'-isopropylidenediphenol (bisphenol A) as a Substance of Very High Concern.

https://www.echa.europa.eu/documents/10162/2cf952cc-a366-fe92-d87c-306f71dfc19b

RCOM (2017): "Responses to comments" document. Document compiled by France from the commenting period 09/03/2017 – 24/04/2017 on the proposal to identify 4,4'-isopropylidenediphenol (bisphenol A) as a Substance of Very High Concern.

https://www.echa.europa.eu/documents/10162/ffc0a157-d90e-05f9-aa7b-d300d81bb6e7

RCOM (2017): “Responses to comments” document. Document compiled by Germany from the commenting period 05/09/2017 – 20/10/2017 on the proposal to identify 4,4'-isopropylidenediphenol (bisphenol A) as a Substance of Very High Concern.

https://www.echa.europa.eu/documents/10162/1d07be7f-20d2-659c-5ca1-58c285a4d217

RCOM (2019): “Responses to comments” document. Document compiling the responses to comments from commenting period 05/09/2018 – 05/12/2018 on ECHA’s proposal to include bisphenol A in its 9th recommendation of priority substances for inclusion in the list of substances subject to authorisation (Annex XIV).

https://echa.europa.eu/documents/10162/13640/9th_recom_respdoc_bisphenol_a_en.pdf

RMOA (2017): Risk management option analysis conclusion document. 4,4'-isopropylidenediphenol (Bisphenol A; BPA) Submitted by Germany, June 2017.

https://www.echa.europa.eu/documents/10162/f39eafc1-f58d-de22-7be3-2cd64eef62a7

Annex I: Further information on uses

1. Further details on the type of applications and main (sector of) uses

Bisphenol A is manufactured and/or imported in very high volumes and used in a broad range of applications. A detailed overview of its uses (e.g. manufacture of polycarbonate and epoxy resins) can be found in the Annex XV SVHC reports (2016, 2017 a, b). However, most of the uses seem to be outside the scope of authorisation and will therefore not be described in this background document.

Uses of bisphenol A that appear to be in the scope of authorisation are the formulation and use of epoxy resin hardeners, both at industrial sites and by professional workers, which correspond to less than 1% of the total tonnage. The corresponding volume in the scope of authorisation is estimated to be in the range of 1,000 - 10,000 t/y (see Section 2.2).

Some uses reported in registrations were not considered for priority assessment. The industrial and professional uses of bisphenol A as anti-oxidant for processing polyvinylchloride (PVC) as well as the use of articles made of PVC are not any more covered by the joint chemical safety report of the lead registrant. Furthermore, comments received during the public consultation (ComRef, 2019) indicate that bisphenol A can be present in mixtures used as lubricants, greases or brake fluids. However, these uses are not covered by chemical safety reports of any registrant. The production and recycling of thermal paper and the use of thermal paper were disregarded due to an existing restriction (entry no. 66 in REACH Annex XVII), which will limit the content of bisphenol A in thermal paper to concentrations below 0.02% by weight after 2 January 2020.

Bisphenol A is used as monomer for the manufacture of polymers (e.g. polycarbonate) and epoxy resins. These uses are considered intermediate uses and therefore outside the scope of authorisation.

Furthermore epoxy resins can be cross-linked with bisphenol A-containing hardeners (RCOM, 2016 and 2017). In this case the use of bisphenol A is considered within the scope of authorisation. The reported uses of articles made of these materials were not taken into account for prioritisation as bisphenol A seems to react during use and release is considered unlikely.

However, epoxy resins can as well be cured with hardeners that do not contain bisphenol A. According to comments recently received (ComRef, 2019) epoxy resins seem to be in most cases cured with BPA-free hardeners. Nonetheless, it was also confirmed in comments that for special uses hardeners containing bisphenol A are usually applied to accelerate the curing of epoxy resins. Final products resulting from this use are polymer materials used in the following applications and sectors: turbine blades for the generation of wind energy, electronic components for electrical energy generation, distribution and supply, composite materials and coatings for cars, trucks motorcycles, trains, aircrafts and aerospace applications, coatings, sealants, fillers and chemical anchors used in construction as well as composites, adhesives and coatings for furniture or sport articles.

In the Substances in Preparations in Nordic Countries database (SPIN)[11] bisphenol A was reported in 2015 for the use categories (according to UC62 codes): Paints, lacquers and varnishes, process regulators, stabilizers, adhesives, binding agents, surface-active agents, construction materials, softeners, reprographic agents, lubricants and additives, insulating materials, laboratory chemicals, intermediates, hydraulic fluids and additives, fillers, surface treatment and colouring agents. The relevant products can be found mainly in following sectors: Building and construction, crop and animal production, hunting, extraction of crude petroleum

[11] SPIN database can be found at http://spin2000.net/

and natural gas, metals and metal products, manufacture of chemicals and chemical products, computer, electronic and optical products, electrical equipment, vehicles, non-metallic mineral products, transport equipment, paper and paper products, wood and wood products, printing and reproduction of recorded media, retail trade, warehousing, wholesale trade.

Furthermore, BPA is permitted for use in food contact materials in the EU under Regulation (EU) 10/2011 (amended by Regulation (EU) 2018/213) relating to plastic materials and articles intending to come into contact with foodstuff. However, there are prohibitions on the use of BPA in certain food contact materials e.g. for the manufacture of polycarbonate baby bottles and infant 'sippy' cups. EFSA is currently re-evaluating the risks to public health related to the presence of BPA in foodstuffs.

Bisphenol A is ubiquitously and regularly found in all environmental compartments indicating continuous emissions of the substance which, however, cannot be traced back to single uses (RMOA, 2017). According to a comment from the public consultation the German Competent Authority is exploring a potential restriction to limit emissions of Bisphenol A to the environment (ComRef, 2019). However, the possible impact of such a restriction on the priority of the substance could not be considered for this recommendation due to the very early stage of this regulatory activity (RCOM, 2019).

2. Structure and complexity of supply chains

The following assumptions were made to allocate the substance to a specific LAD slot.

Bisphenol A is manufactured and/or imported by more than 50 registrants (ECHA, 2018). Generic information on number of sites provided in registrations for the formulation and industrial use of epoxy resin hardeners indicate that these uses could take place at more than 100 industrial sites within the EU.

The supply chain can be characterised[12] by the following actors: formulators, users at industrial sites and professional workers as well as article assemblers (multi-layer assembling chain) (relevant life cycle stages: F, IS, PW, SL (multi-layer).

Bisphenol A seems to be used in the following product categories: Polymer preparations and compounds, adhesives, sealants, coatings and paints, thinners, paint removers, paper and board treatment products, processing aids, lubricants, greases, release products, welding and soldering products and flux products (relevant product categories: PC1, PC9a, PC20, PC24, PC26, PC32 and PC38).

A number of sectors is relying on the substance in some of their uses including manufacturers of plastic products, paper, fabricated metal products, computer, electronic and optical equipment, furniture, machinery, equipment, vehicles and transport equipment as well as the building and construction sector (relevant sector of use categories: SU6a, SU12, SU15, SU16, SU17, SU18 and SU19).

Uses of bisphenol A in the scope of authorisation seem to be relevant for the production of a number of article types such as plastic, paper, metal and wood articles as well as machinery, mechanical appliances, electrical/electronic equipment and vehicles (relevant article categories: AC1, AC2, AC7, AC8, AC11, AC13).

The majority of categories mentioned are not explicitly reported in registrations but could be derived from information on uses available in registration dossiers, information from substance

[12] Categories listed here after (life cycle stage, SU, PC and AC) make reference to the use descriptor system described in ECHA's guidance on use description: https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf

in article notifications, comments received during the public consultation (ComRef, 2019), the Annex XV SVHC reports (2017 a, b) and the SPIN database.