

**5 September 2018**

## **Draft 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 (as of the last day of the public consultation, i.e. 5 December 2018) will be taken into consideration when finalising the recommendation and will be reflected in the final background document.**

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## 1. Identity of the substance

Identity of the substance as provided in the Candidate List<sup>1</sup>:

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<sup>2</sup>. 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 is available at [https://echa.europa.eu/documents/10162/13640/prioritisation\\_results\\_cl\\_substances\\_sept\\_2018\\_en.pdf](https://echa.europa.eu/documents/10162/13640/prioritisation_results_cl_substances_sept_2018_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<sup>3</sup> 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<sup>4</sup> on 15 January 2018, following ECHA's decision ED/01/2018.

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.

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<sup>1</sup> For further information please refer to the Candidate List and the respective support document at <https://www.echa.europa.eu/candidate-list-table>.

<sup>2</sup> Document can be accessed at

[http://echa.europa.eu/documents/10162/13640/gen\\_approach\\_svhc\\_prior\\_in\\_recommendations\\_en.pdf](http://echa.europa.eu/documents/10162/13640/gen_approach_svhc_prior_in_recommendations_en.pdf)

<sup>3</sup> Additional intrinsic property of concern: Endocrine disrupting properties (Article 57(f) - human health)

<sup>4</sup> Additional intrinsic property of concern: Endocrine disrupting properties (Article 57(f) - environment)

There are currently three Court cases (T-185/17, T-636/17 and T-207/18) pending on the identification of bisphenol A as Substance of Very High Concern (SVHC). These Court cases have no suspensive effects.

## **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, 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 and the relative share of the total tonnage 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) (RCOM, 2016). Therefore, these uses were not considered for priority assessment.

More detailed information on uses is provided in Annex I.

## **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, it is proposed to prioritise bisphenol A for inclusion in Annex XIV.

## 3. Background information for the proposed Annex XIV entry

### 3.1. Latest application and sunset dates

ECHA proposes the following transitional arrangements:

Latest application date (LAD):      Date of inclusion in Annex XIV plus **18, 21 or 24 months**

Sunset date:                              18 months after LAD

ECHA will make the final LAD allocation when finalising the recommendation and will use all available relevant information including that received in the public consultation. ECHA will apply the Annex XIV entries approach<sup>5</sup> and the criteria described in the implementation document<sup>6</sup>. According to these documents, substances for which the available information indicates a relatively high number of uses and/or complex supply chain(s) are allocated to the "later" LAD slots.

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

<sup>5</sup> General approach can be accessed at [https://echa.europa.eu/documents/10162/13640/recom\\_general\\_approach\\_draft\\_axiv\\_entries.pdf](https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries.pdf)

<sup>6</sup> Practical implementation document can be accessed at [https://echa.europa.eu/documents/10162/13640/recom\\_general\\_approach\\_draft\\_axiv\\_entries\\_draft\\_implementation\\_en.pdf](https://echa.europa.eu/documents/10162/13640/recom_general_approach_draft_axiv_entries_draft_implementation_en.pdf)

Time needed to prepare an authorisation application of sufficient quality has been estimated to require 18 months in standard cases. When setting the LADs ECHA has also to take into account the anticipated workload of ECHA's Committees and Secretariat to process authorisation applications. This is done by allocating the substances proposed to be included in the final recommendation in slots, normally 3, and setting the application dates with 3 months intervals in between these slots (standard LAD slots: 18, 21 and 24 months).

For substances to be included in the 9<sup>th</sup> recommendation, ECHA sees currently no reason to deviate from these standard LAD slots.

### 3.2. Review period for certain uses

ECHA proposes not to include in Annex XIV any review period for bisphenol A.

In general, ECHA does not propose any upfront specific review periods in its draft recommendations for inclusion in the Authorisation List. Setting review periods in Annex XIV for any uses would require that ECHA had access to adequate information on different aspects relevant for a decision on the review period. Such information is generally not available to ECHA at the recommendation step. It is to be stressed that, in the next step of the authorisation process, i.e. during the decision on whether authorisation is granted based on specific applications by manufacturers, importers or downstream users of the substance, all authorisation decisions will include specific review periods which will be based on concrete case-specific information provided in the applications for authorisation.

### 3.3. Uses or categories of uses exempted from authorisation requirement

#### 3.3.1 Exemption under Article 58(2)

ECHA proposes not to 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.

According to Article 58(2) of REACH it is possible to exempt from the authorisation requirement uses or categories of uses *'provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled'*.

ECHA considers the following elements in deciding whether to recommend an exemption of a use of a substance:

- There is existing EU legislation (i.e., rules of law adopted by a European Union entity intended to produce binding effects) addressing the specific use (or categories of use) that is proposed to be exempted;
- The existing EU legislation properly controls the risks to human health and/or the environment from the use of the substance arising from the intrinsic properties of the substance that are specified in Annex XIV; generally, the legislation in question should specifically refer to the substance to be included in Annex XIV either by naming the substance or by referring to a group of substances that is clearly distinct from other substances;
- The existing EU legislation imposes minimum requirements for the control of risks of the use. The piece of legislation (i) has to define the minimum standard to be adopted in the interest of public health or the environment and (ii) allows EU Member States to impose more stringent requirements than the specific minimum requirements set out in the EU legislation in question. Legislation setting only a general framework of requirements or

the aim of imposing measures or not clearly specifying the actual type and effectiveness of measures to be implemented is not regarded as sufficient to meet the requirements under Article 58(2). Furthermore, it can be implied from the REACH Regulation that attention should be paid as to whether and how the risks related to the life-cycle stages resulting from the uses in question (i.e. service-life of articles and waste stage(s), as relevant) are covered by the legislation.

*Where interested parties are considering making a request for exemption from authorisation under Art. 58(2) for a particular use, it is strongly recommended that they take into account ECHA's previous responses to Art. 58(2) exemption requests<sup>7</sup>. It is noted that any Art. 58(2) request is assessed case-by-case.*

*Furthermore, it should be noted that if a use falls under the generic exemptions from authorisation<sup>8</sup>, there is no need to propose an additional specific exemption.*

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

ECHA proposes not to recommend to include in Annex XIV any exemption from authorisation for the use of bisphenol A for PPORD.

So far, ECHA has not considered it appropriate to recommend specific exemptions for PPORD for any substance. ECHA notes that an operator may use a substance included in Annex XIV for a PPORD activity if that operator has obtained authorisation for that use of the substance in accordance with Articles 60 to 64 of the REACH Regulation.

No PPORD notifications have been submitted for bisphenol A<sup>9</sup>.

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<sup>7</sup> See analysis of most relevant pieces of legislation e.g. in sections C.2.8 – C.2.12 in <https://echa.europa.eu/documents/10162/b80fccc0-c055-7cd7-4743-8d3c26956b15>, or in section C.2 in <https://echa.europa.eu/documents/10162/b1820209-b7f4-4f87-998a-a996729c7375>

<sup>8</sup> Generic exemptions from the authorisation requirement: [https://echa.europa.eu/documents/10162/13640/generic\\_exemptions\\_authorisation\\_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc](https://echa.europa.eu/documents/10162/13640/generic_exemptions_authorisation_en.pdf/9291ab2a-fe2f-418d-9ce7-4c5abaaa04fc)

<sup>9</sup> As of 1 February 2018.

## 4. References

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>

ECHA (2018): 4,4'-isopropylidenediphenol. ECHA's dissemination website on registered substances. Accessed on 1 February 2018.

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

RCOM (2016): "*Responses to comments*" document. Document compiled by ECHA 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 ECHA 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>

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/10162/816f026b-e24c-5600-3beb-6696976d5044>

## 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 (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. The production and recycling of thermal paper and the use of thermal and recycled 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.

In the Substances in Preparations in Nordic Countries database (SPIN)<sup>10</sup> 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 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.

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).

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<sup>10</sup> SPIN database can be found at <http://spin2000.net/>

## 2. Structure and complexity of supply chains

The following assumptions are made based on currently available information and will be used, together with any relevant information from public consultation, to allocate the substance to a specific LAD slot in the final recommendation.

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 use of epoxy resin hardeners indicate that these uses could take place at more than 100 sites within the EU.

The supply chain can be characterised<sup>11</sup> by the following actors: formulators, users at industrial sites and professional workers (relevant life cycle stages: F, IS, PW).

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, SU10, 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).

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 in article notifications, the Annex XV SVHC reports (2017 a, b) and the SPIN database.

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<sup>11</sup> 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](https://echa.europa.eu/documents/10162/13632/information_requirements_r12_en.pdf)