Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Risk Management Option Analysis Conclusion Document

Substance Name:	**4,4'-isopropylidenediphenol (Bisphenol A, BPA)**
EC Number:	**201-245-8**
CAS Number:	**80-05-7**
Authority:	**Germany**
Date:	**2017-06-13**

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority (aMSCA). In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

A Risk Assessment Report for BPA was prepared by the United Kingdom in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances. A complete risk assessment in one document was prepared in 2010.

A proposal to restrict the use of BPA in thermal paper under REACH Annex XVII was submitted by France in January 2014. This proposal aims to address the risks for human health of pregnant workers and consumers exposed to BPA contained in thermal paper they may handle. The final background document taking into account the opinions of RAC and SEAC has been published in December 2015. The restriction has been adopted on 12 December 2016. BPA shall not be placed on the market in thermal paper in a concentration equal to or greater than 0.02% by weight after 2 January 2020.

Since the start of the evaluation, a harmonised classification of BPA for reproductive toxicity (Repr. 1B) has been adopted according to Commission Regulation (EU) 2016/1179.

BPA was identified as a substance of very high concern according to REACH Article 57c due to its effects as a reproductive toxicant and added to the candidate list in December 2016 based on a proposal by France. In June 2017, agreement on a proposal to identify BPA as an SVHC according to REACH Article 57f based on its properties as an endocrine disruptor for human health was sought in the Member State Committee.

A substance evaluation process was started in March 2012 and a decision requesting further information was sent to the registrants after the first year of evaluation. The decision required the concerned registrants of BPA to update their registration dossiers until 20 December 2015 with use-specific information regarding environmental exposure as well as information from a skin absorption study[2]. Updates of the lead registration dossier and the joint chemical safety report as well as a portion of member dossiers have been received until December 2015 and in some cases with considerable delay in 2016.

The evaluating MSCA (eMSCA) assessed the available information and concluded on the concerns without requiring further information from the registrants.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC	X
Restriction under REACH	X
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

[2] "Decision on substance evaluation pursuant to article 46(1) of Regulation (EC) No 1907/2006 for 4,4'-isopropylidenendiphenol (Bisphenol A), CAS No 80-05-7 (EC No 201-245-8)" accessible via https://echa.europa.eu/documents/10162/84dbe057-2950-487a-8c72-aee0aacaf215

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

3.1 Harmonised classification and labelling

Endocrine disruption is not an endpoint for which harmonised classification and labelling according to CLP can be applied.

However, the aMSCA will consider to propose a harmonized classification as Aquatic Chronic 1 to account for the identified high ecotoxicity and adverse effects of BPA to aquatic organisms.

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

Based on an in-depth assessment during substance evaluation, it is the opinion of the aMSCA that BPA meets the SVHC criteria due to its endocrine disrupting properties for the environment which are considered to be of very high concern.

BPA is an endocrine disruptor for aquatic organisms with adverse effects occurring at concentrations in the ng/L to low µg/L-range. Based on the available data for fish, amphibians and further vertebrate and invertebrate species it can be concluded that BPA meets the WHO/IPCS criteria of an endocrine disruptor for the environment. BPA is a substance of equivalent concern to PBT/vPvB chemicals. From an environmental perspective there is enough scientific evidence to conclude on its endocrine properties for the environment and to identify BPA as SVHC according to Art. 57 (f) of the REACH Regulation.

Additionally, based on the uncertainties connected to the predictability of endocrine mediated effects on wildlife populations, a safe threshold of BPA, such as a predicted no effect concentration (PNEC) in the environment, cannot be derived based on the currently available data and methods.

BPA is a high production volume chemical with a broad variety of different uses. However, the majority of uses is out of scope of authorization. Nevertheless, BPA is ubiquitously present in relevant concentrations (ng/L to high µg/L range) in aquatic ecosystems. However, it is not possible to allocate the observed environmental concentrations and emissions to specific contributions of single uses. But, like for PBT/vPvB substances the emissions of BPA to environmental compartments must be minimized as much as possible to follow the precautionary principle in avoiding adverse effects in wildlife animals.

The identification of BPA as SVHC would increase the pressure that BPA is to be progressively replaced by suitable alternative substances or technologies. The SVHC identification itself would trigger information duties of the industry for consumers on the BPA contents in articles and would furthermore be an important political signal triggering voluntary risk reduction actions of industry. Moreover, an identification of BPA as SVHC is the only option to come to an official European wide conclusion on its endocrine disrupting properties. Such conclusion can be the basis for further regulatory measures within or outside the scope of the REACH regulation and impact the obligations for a control of emissions under the Industrial Emissions Directive (IED), encourage the

derivation of an Environmental Quality Standard (EQS) and inclusion of BPA as priority (hazardous) substance under the Water Framework Directive (WFD), or ease the regulation via product-oriented frameworks.

The authorisation procedure might trigger voluntary actions of industry and again strengthen the responsibility of manufacturers to demonstrate and decide on an essential need for BPA and encourage the use of alternative substances or techniques. After an authorisation is set into force article 69(2) of the REACH regulation would trigger the need to consider whether further restrictions are needed for the use of BPA in articles if it can be demonstrated that risks occur which are not adequately controlled.

However, the authorisation procedure itself would not address the manufacture of BPA or use of BPA as intermediate. Further risk management measures within or outside the scope of the REACH regulation would be necessary to reduce emissions to the environment. Furthermore, if BPA was included in Annex XIV of the REACH regulation it would not be possible to establish restrictions for mixtures containing BPA. Hence, BPA should not be prioritised for inclusion in Annex XIV of the REACH regulation yet.

3.3 Restriction under REACH

Currently, targeted restrictions of certain uses are difficult as environmental concentrations and emissions cannot be traced back to single uses due to lack of reliable exposure estimates in the registration dossiers. The possibility of restrictions on certain categories of uses, such as consumer uses, will be further elaborated. In this case, it is also necessary to examine how a restriction of BPA as a residue in polymers could be designed and how possible emissions from depolymerisation processes could be addressed.

3.4 Other Union-wide regulatory measures

To achieve overall lower concentrations in environmental compartments and protect in particular aquatic organisms, media-oriented frameworks trigger monitoring activities and consequently produce a better data basis and arguments for further reduction measures. It would be important to include BPA as priority (hazardous) substance in Annex X of the WFD. This might be encouraged by the identification of BPA as SVHC.

Technical measures to reduce emissions site-specific and control emissions in effluents or local surface waters need to be encouraged to reduce occasionally high emissions. It might be possible that an identification of BPA as SVHC could lead to a review of installation permits under the IED and imply further monitoring and the control of emissions of BPA from point sources in the scope of the IED. As the manufacture of BPA and the production of polymers could not be regulated via the authorisation procedure the enforcement and strengthening of the IED could be an option.

The identification of BPA as SVHC could support the need for further regulatory measures under product-oriented frameworks. An adaptation of product-oriented frameworks could be reasonable to reduce emissions from articles and indirectly also emissions of BPA during the life cycle, the recycling of articles or the waste stage of articles.

In addition to product-oriented measures, a consideration of BPA in regulations dealing with disposal and recycling of BPA containing materials could as well reduce emissions to the environment.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

Not applicable.

5. NO ACTION NEEDED AT THIS TIME

Not applicable.

6. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for follow-up	Actor
Annex XV Dossier for SVHC identification (Art 57f with regard to the environment)	08/2017	Germany