

**Risk Management Option Analysis Conclusion Document**

**Substance Name: 4,4'-methylenediphenol (Bisphenol F)**

**EC Number:** **210-658-2**

**CAS Number: 620-92-8**

**Authority: Swedish Chemicals Agency**

**Date: 24 March 2021**

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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]](#footnote-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. 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.

### OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

### 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.

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

### Need for follow-up regulatory action at EU level

### Harmonised classification and labelling

Bisphenol F, a BPA-analogue, is currently not a registered substance under REACH. There are some data available on BPF’s toxicity and its endocrine disrupting (ED) effects have been evaluated. Based on an assessment of the available ED data, it was concluded that the current evidence may not be strong enough to be used as basis for SVHC identification (ED HH). Evaluation of ED properties for the environment has not been the main focus of this RMOA, however, available data indicate effects on relevant parameters such as in zebrafish.

BPF is found in human urine, serum, and breast milk, thus confirming exposure to humans. ED properties might be expected based on BPF’s similarities with BPA, thus indicating concern. Some available reprotoxicity data also indicate similarities between BPA and BPF and read across from BPA might be possible, to propose a harmonised classification as Repr. 1B. It is proposed to further explore the read-across approach, based on structural similarities between BPA and BPF, and currently available data on fertility parameters. The more detailed assessment will provide advice on the possibility of proceeding with a classification proposal without the need for new data.

The need for other regulatory risk management actions will be revisited once the assessment of a read-across approach is finalized.

### 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.

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| **Follow-up action** | **Date for follow-up** | **Actor** |
| Harmonised classification and labelling | 2021-2022 | Sweden |

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> [↑](#footnote-ref-1)