baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

Risk Management Option Analysis Conclusion Document

Substance Name: 1,4-dioxane
EC Number: 204-661-8
CAS Number: 123-91-1

Authority: DE CA
Date: 17.06.2020

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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. 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

1,4-Dioxane is listed in Annex VI of the CLP regulation. ECHAs Risk Assessment Committee (RAC) adopted an opinion in March 2019 to classify 1,4-dioxane as Carc. 1B instead of the current classification as Carc. 2. The corresponding inclusion into Annex VI of the CLP regulation is still pending.

For 1,4-dioxane a risk assessment was performed under Regulation EEC 793/93 – Existing Substances Regulation.

1,4-Dioxane is listed in Annex II of the Regulation (EC) No 1223/2009 on cosmetic products and therefore prohibited in cosmetic products. The Scientific Committee on Consumer Safety (SCCS) concluded in their scientific opinion about an acceptable trace level in cosmetic products that residual concentrations of 1,4-dioxane below 10 ppm are considered as safe for consumers.

An indicative occupational exposure limit value (IOELV) was adopted in the Directive 2009/161/EU in 2009 (in implementation of Directive 98/24/EC (Chemical Agent Directive). IOELV for 1,4-dioxane amounts to 73 mg/m^3 or 20 ppm (8 hours)[2].

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 (without subsequent authorisation)	x
Authorisation under REACH	
Restriction under REACH	x
Other EU-wide regulatory measures	x
Need for action other than EU regulatory action	
No action needed at this time	

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

3.1 Identification as a substance of very high concern, SVHC

Environment and indirect exposure of the general population

The SVHC Roadmap aims to have all relevant substances of very high concern in the Candidate List by 2020. 1,4-Dioxane can be considered a relevant substance of very high concern from the environmental perspective. 1,4-Dioxane is a persistent, mobile and toxic substance and thus considered to be of equivalent level of concern (ELOC) to PBT/vPvB substances. A SVHC identification according to Art. 57f will trigger communication

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32009L0161&from=EN

requirements to consumers and for industries supply chains (Art. 7 and Art. 33) and promotes substitution.

The Authorisation duty would be a potential second step after inclusion in the Candidate List. Current knowledge on uses of 1,4-dioxane implies that authorisation of 1,4-dioxane may give control to emissions of this substance to a limited extent. Authorisation addresses the use of a substance as such as well as in mixtures. However, 1,4-dioxane is also present as an unintended constituent (impurity) in many other substances in relevant concentrations which, although the concentration of the impurities is very low (<0.1%) in sum result in relevant emissions to the environment. Such substances are used in various applications and according to the aMSCAs knowledge contribute significantly to emissions of 1,4-dioxane to the environment. Additionally, inclusion of 1,4-dioxane into Annex XIV could hamper later restriction efforts (Art. 58 (5)). Further, imported articles containing 1,4-dioxane at relevant concentrations are not covered by the inclusion of 1,4-dioxane into Annex XIV, although information obligations as described earlier would persist.

Therefore, authorisation of 1,4-dioxane would not be an effective risk management measure in this case.

Occupational Safety and Health

From the perspective of occupational safety and health the identification as SVHC & Inclusion in Annex XIV is considered as an effective RMO, when a substance is intended to become substituted over the medium or longer term (sunset chemicals). Based on the upcoming Carc. 1B-classification an identification with regard to Art. 57a is possible.
However, it should be kept in mind that some applications are exempted from authorisation (see above). In the case of 1,4-dioxane, there is no additional benefit for the protection of workers by the RMO authorisation. Risk management measures at the workplace are already triggered by harmonised classification. We therefore consider authorisation on the current basis of information as disproportionate regulatory measure. Further risk management options, like setting an EU-BOELV under CMD should be considered first.
When these primary risk management tools are not efficiently implemented, the need for an authorisation will be re-evaluated.

3.2 Restriction under REACH

Restriction shall address an unacceptable risk to human health or the environment arising from the manufacture, use or placing on the market of substances (Art 68). This option would also cover imported articles. A restriction can be scoped differently: either as general restriction covering all products which contain 1,4-dioxane above a certain concentration, or as a restriction to cover relevant emission sources from specific uses selectively.

Environment and indirect exposure of the general population

1,4-Dioxane is produced to be intentionally used as a solvent. Furthermore, it is an impurity or constituent of substances of high economic impact produced in large annual quantities, e.g. surfactants.

A restriction for specific uses of 1,4-dioxane and/or substances, containing 1,4-dioxane which lead to significant releases into the environment is considered the most appropriate regulatory option. For this purpose, those uses need to be addressed precisely. 1,4-Dioxane as an impurity - even if it occurs in low concentrations - could be addressed in a restriction by defining a concentration level of 1,4-dioxane which should not be exceeded with a careful consideration of techniques available to reduce the level of 1,4-dioxane in a substance and their impact on emissions to the environment. Further elaboration on the knowledge of additional uses of substances containing 1,4-dioxane is needed in order to

ensure that all uses resulting in relevant releases should be adequately addressed in the restriction proposal.

Occupational safety and health

Concerning occupational safety and health a restriction under REACH is a powerful risk management tool to regulate occupational risks. However, one prerequisite is an unacceptable risk for human health (Article 68 of REACH-regulation). Thus, it is not only based on a hazard, exposure has to be so high, that an unacceptable risk can be identified. The currently valid IOELV revealed to be outdated and a BOELV would be needed instead for the evaluation of exposure. Furthermore, the upcoming Carc. 1B classification is expected to change the exposure profile implying that a quantitative risk assessment based on current exposure information could be questionable. Thus, it appears somewhat premature to prepare a restriction from the perspective of occupational safety and health.

When other primary risk management tools are not efficiently implemented, the need for a restriction will be re-evaluated.

3.3 Other Union-wide regulatory measures

Derivation of a binding occupational exposure limit value (BOELV) under the Carcinogens and Mutagens Directive (CMD)

The currently valid IOELV turned out to be obsolete and should not be used from now on as basis for risk assessment. In light of the upcoming Carc. 1B classification the provisions of CMD become relevant and a BOELV should be derived. The adoption of a BOELV is pending on the initiative of the Commission.

Update of Registration dossier by the Registrants

Though updating the registration dossier is not an RMO it is considered important that an updated dossier is available. The Registrants are in charge of updating their registration dossier considering the more recent information (e. g. (Kano, 2009), (Kasai et al., 2009)) and the upcoming classification as Carc. 1B. The current registration data cannot demonstrate that a safe use is possible and unacceptable risks can be avoided effectively.

4. 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)	February 2021	DE CA
Annex XV dossier for restrictions	September 2021	DE CA