

# Call for evidence on a possible restriction on 1,4-dioxane

## Background document

### Introduction and problem identification

The German competent authority for REACH has identified a potential risk to sources of Europe's drinking water from 1,4-dioxane. Due to its substance properties, 1,4-dioxane is easily distributed in the aquatic environment and is difficult to remove from raw water in the drinking water purification processes. The substance has a harmonized classification as a category 2 carcinogen under CLP (Regulation (EC) No. 1272/2008) and an even more stringent classification as Carc. 1B has been proposed and included in the draft 17th ATP to CLP<sup>1</sup>.

The persistency and mobility of 1,4-dioxane lead to a wide spatial distribution. In addition, 1,4-dioxane is a toxic substance according to the REACH Annex XIII criteria. These properties led the German competent authority to recently propose 1,4-dioxane as an SVHC. The consultation for this process started on 9 March 2021<sup>2</sup>. A potential SVHC identification according to Art. 57f will trigger information requirements to consumers and for industry supply chains (Art. 7 and Art. 33) and promote substitution<sup>3</sup>.

During the RMOA process it became obvious that the major sources of emissions were not solely related to uses of 1,4-dioxane as such or in mixtures, but also to uses of substances that contain 1,4-dioxane as a constituent or as an impurity<sup>4</sup>. Chemicals that came into focus for example belong to the group of ethoxylates, which are often used as surfactants in cleaning products. Another group is the thermoplastic polyethylene terephthalate (PET), where 1,4-dioxane is a by-product in the polymerisation process. In all cases reviewed so far, the occurrence of 1,4-dioxane is unpreventable due to the underlying reaction processes.

This information leads to the conclusion that inclusion of 1,4-dioxane into REACH Annex XIV as such will only have a marginal effect on the emissions to the environment.

Based data from industry, and in coherence with the requirements of the European Cosmetics Regulation (regulation (EC) No. 1223/2009) which is defining tolerable thresholds for 1,4-dioxane in cosmetic products, there is sufficient evidence of existing techniques capable to reduce the residual concentration of 1,4-dioxane in substances, respectively in specific products such as mixtures.

### Scope

The German competent authority for REACH intends to submit a restriction proposal according to REACH Article 69(4) and to restrict the placing on the market of 1,4-dioxane as such, or as a constituent or impurity in other substances or mixtures.

The restriction proposal will also introduce requirements, i.e. concentration limit values, for contaminated waters from application processes of 1,4-dioxane or substances and mixtures containing

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<sup>1</sup> [https://ec.europa.eu/growth/tools-databases/tbt/en/search/?tbtaction=search.detail&Country\\_ID=EU&num=729&dspLang=en&basdatedeb=&basdatefin=&basdays=EU&basnotifnum=&basnotifnum2=&bastypepays=&baskeywords](https://ec.europa.eu/growth/tools-databases/tbt/en/search/?tbtaction=search.detail&Country_ID=EU&num=729&dspLang=en&basdatedeb=&basdatefin=&basdays=EU&basnotifnum=&basnotifnum2=&bastypepays=&baskeywords)

<sup>2</sup> <https://www.echa.europa.eu/web/guest/substances-of-very-high-concern-identification/-/substance-rev/27506/term>

<sup>3</sup> <https://www.echa.europa.eu/web/guest/registry-of-svhc-intentions/-/dislist/details/0b0236e1857f0d76>

<sup>4</sup> <https://echa.europa.eu/rmoa/-/dislist/details/0b0236e183e78201>

1,4-dioxane, which are intended to be released – regardless of whether directly emitted into the environment or into the public sewer system.

However, it is intended that the substance used as transported isolated intermediate on its own, in mixtures or in other substances as a constituent or impurity under strictly controlled conditions in accordance with article 18 of the REACH regulation will not fall under the restriction, if it is ensured that process effluents and effluents resulting from maintenance processes do not contain 1,4-dioxane.

Please note that concentration limit values are not yet specified. The restriction conditions will be elaborated in more detail during the development of the proposal including the socio-economic analysis, taking into account the information received in the call for evidence.

### **Elements of an Annex XV restriction proposal**

The elements that need to be considered during the preparation of a restriction proposal are set out in Annex XV of REACH and further elaboration can be found in ECHA Guidance documents<sup>5</sup>. These can be summarised, as follows:

- a characterisation of exposure and resulting risks to human health from a use of a substance, including via food and water;
- a characterisation of exposure and resulting risks to the environment and wildlife from a use of a substance;
- a justification that risks are not adequately controlled and occur on a Union-wide basis;
- an analysis of the availability, technical and economic feasibility of alternatives to the substance to be restricted;
- a socio-economic analysis (e.g. costs and benefits to society) that would arise from a restriction

### **Evidence and information to be collected**

This call for evidence is intended to gather information on 1,4-dioxane as well as substances and mixtures containing 1,4-dioxane as a constituent or an impurity, specifically on:

- manufacture (including tonnage information and market trends),
- uses (including use descriptions, tonnage information and market trends),
- emissions related to the manufacture and uses of these chemicals,
- the feasibility of removal of 1,4-dioxane from other substances/mixtures and process waters,
- the socio-economic impacts of a REACH restriction

The call for evidence further aims at understanding which chemical or technical alternatives exist and which voluntary measures or substitution processes etc. are ongoing. Any information provided will be used, amongst other evaluation criteria, to determine if any derogations may need to be granted for any potential restriction that is proposed. However, derogations cannot be proposed without adequate information on risk and socio-economic information, including information on alternatives. If a derogation is not proposed in the initial restriction proposal then it will be incumbent on relevant stakeholders to provide a full justification based on a comprehensive information on risk, socio-economic elements and alternatives, during the opinion-making process.

The objective of this call is to gather information or receive comments for the subsequent aspects:

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<sup>5</sup> ECHA information on the preparation of Annex XV restriction dossiers:

<https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions>

1. Sectors and processing of 1,4-dioxane as well as 1,4-dioxane containing substances and mixtures:

Please indicate if you are

(a) manufacturer/importer and/or

(b) using 1,4-dioxane as a substance itself and/or you are

(c) formulator/importer of mixtures or substances containing 1,4-dioxane and/or

(d) using substances containing 1,4-dioxane

2. If you are (a) manufacturer/importer of 1,4-dioxane as a substance itself please specify production/import volume 1,4-dioxane, and uses of the substance. What are the end products?

If you are (c) formulator/importer of mixtures or substances containing 1,4-dioxane, please specify production/import volume of the mixture/substance containing 1,4-dioxane, typical concentration range of 1,4-dioxane in your mixture/substances, the technical function of 1,4-dioxane in your mixture/substance, and uses of your mixture/substance.

If you are (b) using 1,4-dioxane and/or (d) using substances containing 1,4-dioxane, please specify typical concentrations of 1,4-dioxane in your mixture/substances, the technical function of 1,4-dioxane or the substance containing 1,4-dioxane in your process or in your mixture/substance. What are the end products?

3. Does your manufacturing process or your application of 1,4-dioxane/-containing mixture(s) or substance(s) lead to emissions into the environment? (Note: This also covers emissions occurring as consequence of intended cleaning and maintenance activities.)

If yes, please specify the environmental media(s) of initial emission. In case of on-site emission reduction measures ("end-of-pipe-technology") being applied at your site: Please provide a robust description of the measures you are utilising at your site to reduce emissions of 1,4-dioxane into the environment. Do you operate a sewage treatment plant at your site? If the answer is yes, do your sewage treatment processes put a focus on the reduction of 1,4-dioxane in the waste water?

If available to you, please provide data from monitoring or a qualified estimate regarding the amount of 1,4-dioxane released per year from your plant into receiving waters, respectively into the public sewer system. Please quantify the degree of efficiency of the emission reduction measures.

4. Please describe alternative technologies or alternative substances for the uses of 1,4-dioxane or the uses of your mixtures/substances containing 1,4-dioxane. Please estimate the technical and economic (costs where possible) implications for substitution and an expected duration for the implementation of the alternatives.

5. Would it be possible to switch to a 1,4-dioxane-based application without emissions into the environment?

Do you know of any possibility of reducing the 1,4-dioxane content of the substance(s) or mixtures you manufacture, import or use? Would this affect the intended use of this substance? If such a reduction is possible, which reduced level of 1,4-dioxane contained in your substance might be achieved? Please provide data for the achievable concentration (range) to underline your estimate.

What would be the technical implications for you and your customers if you (intend to) use the alternative substance/technology? What time frame would the transition take? Please provide information on product performance. Please provide key economic parameters such as turnover of the concerned sector(s), the number of people employed, current share of products with substances containing 1,4-dioxane, etc. Please try to quantify costs and describe the expected benefits to any affected actor, e.g. producers, professional or industrial users, consumers, or any other relevant actors (such as the producers of alternatives).

6. Please provide information on economic implications including the price differences between substances used containing 1,4-dioxane and alternatives, the number of products that could require reformulation, expected costs and timelines for reformulation and transitioning to a full-scale production using the alternatives, etc.

### **Who should participate in the call for evidence?**

This call for evidence is addressed to the whole supply chain including manufacturers, importers, distributors, formulators, and downstream users of 1,4-dioxane and substances containing 1,4-dioxane (as constituent or impurity) and of alternatives for these substances as well as trade associations, scientific organisations, NGOs and other stakeholders or Member State Authorities holding relevant information. Information can be submitted confidentially and will be treated as such by the Federal Institute for Occupational Safety and Health (BAuA) and the German Environment Agency (UBA).

Please note that the consultation on an SVHC proposal for 1,4-dioxane started on 9 March 2021 and that information relevant for the SVHC process needs to be submitted to that consultation in order to be taken into account. Information submitted to this call for evidence cannot be considered during the SVHC process.

ECHA invites interested parties to respond to the call for evidence by 17 June 2021.

<https://echa.europa.eu/calls-for-comments-and-evidence>

For any clarifications, please contact: [chemg@baua.bund.de](mailto:chemg@baua.bund.de)