

# CALL FOR EVIDENCE AND INFORMATION ON 1,4-DIOXANE AS WELL AS SUBSTANCES AND MIXTURES CONTAINING 1,4-DIOXANE AS A CONSTITUENT OR AN IMPURITY

## Introduction and problem identification

The German competent authority for REACH has identified a potential risk to sources of Europe's drinking waters 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 1B carcinogen under CLP (Regulation (EC) No. 1272/2008).

The persistence and mobility of 1,4-dioxane lead to a wide spatial distribution. In addition, 1,4-dioxane is a toxic substance. In 2021, 1,4-dioxane was identified as SVHC according to REACH Art. 57 (a) and (f). This triggers information requirements to consumers and for industries' supply chains (REACH Art. 7 and Art. 33) and promotes substitution<sup>1</sup>.

The substance 1,4-dioxane is mainly used as solvent for the synthesis of chemicals, and as an intermediate. In addition, 1,4-dioxane is contained as constituent or impurity in other substances registered under REACH<sup>2</sup>. Currently, it is concluded that significant overall emissions of 1,4-dioxane across the EU result from uses of substances containing 1,4-dioxane as constituent or impurity, even in case 1,4-dioxane does not exceed the concentration threshold of 0.1 % (w/w) in the specific substance.

Among those substances containing 1,4-dioxane, a number of organic surfactants are important sources for environmental emissions of 1,4-dioxane. This is due to the high annual production volumes of those surfactants, their wide dispersive uses by industry, professional workers and consumers, together with their predominant release into the sewage system at the final application stage. Therefore, due to its intrinsic properties, the release of 1,4-dioxane via sewage treatment plants is dependent on the application conditions of the respective surfactants and is expected to occur throughout the whole life cycle.

Based on previously provided data from industry and to comply with the European Cosmetics Regulation (regulation (EC) No. 1223/2009) on 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 of the call for evidence

The German competent authority for REACH intends to submit a restriction proposal according to REACH Article 69(4) and to restrict the manufacture, use and placing on the market of 1,4-dioxane containing surfactants.

The planned restriction proposal will also introduce requirements, i.e. limit values, for contaminated waters from application processes of 1,4-dioxane or substances and mixtures containing 1,4-dioxane, which are intended to be released – regardless of whether directly emitted into the environment or into the public sewer system.

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<sup>1</sup> <https://echa.europa.eu/de/registry-of-svhc-intentions/-/dislist/details/0b0236e1857f0d76>

<sup>2</sup> <https://echa.europa.eu/de/rmoa/-/dislist/details/0b0236e183e78201>

## BACKGROUND NOTE - CALL FOR EVIDENCE AND INFORMATION

### 1,4-DIOXANE

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.

The current proposal would restrict the manufacture and use of surfactants containing more than 1 mg 1,4-dioxane in 1 kg (1 ppm) surfactant active matter.

### **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:

- the 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.

### **Who should participate to 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 containing surfactants (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).

Interested parties are invited to respond to the call for evidence by the 20th of June 2023.

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