



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR EMPLOYMENT, SOCIAL AFFAIRS AND INCLUSION  
Working Conditions and Social Dialogue  
Health and Safety at Work Unit, EU-OSHA

## **The Advisory Committee on Safety and Health at Work**

<b>Opinion</b>
----------------

**Opinion on an EU Binding Occupational Exposure Limit Value (BOEL), Short Term Exposure Limit (STEL), Biological Limit Value (BLV) and skin notation for**

**1,4-dioxane**

**under the Directive on the protection of workers from the risks related to  
exposure to carcinogens, mutagens or reprotoxic substances at work  
(2004/37/EC)**

**Doc. 007/23**

**Adopted on 22/09/2023**

## 1,4-Dioxane

This Opinion is one of a series of chemical specific Opinions adopted by the ACSH in support of the forthcoming Commission proposal on amending the Directive on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (2004/37/EC).

1,4-Dioxane was already under the scope of the Chemical Agents Directive (98/24/EC) and was associated with an Indicative Occupational exposure limit of 73mg/m<sup>3</sup>. Due to its classification as a carcinogen category 1B (COM delegated Regulation (EU) 2021/849 of 11 March 2021), 1,4-dioxane needed to be assessed under the CMRD.

In the meetings of the Working Party of Chemicals on 11<sup>th</sup> - 12<sup>th</sup> May and 05<sup>th</sup> - 06<sup>th</sup> September, in three technical meetings with the consultant and in one technical exchange meeting on 28<sup>th</sup> August 2023, 1,4-dioxane has been discussed taking into account the RAC report (ECHA/RAC/OEL-O-0000007101-89-01/F of 22 March 2022) and the external study on the socioeconomic and environmental impacts.

The three Interest Groups agree that workers will benefit from setting a binding limit value for 1,4-Dioxane at the EU level and therefore the three Interests Groups agreed the following points concerning limit values and notations for 1,4-dioxane:

- 1,4-Dioxane is considered a threshold carcinogen for which no cancer burden could be identified resulting from the current exposure situation.
- The RAC proposal of an OEL of 7.3mg/m<sup>3</sup> and a STEL of 73mg/m<sup>3</sup> is supported.
- RAC further proposed a BLV of 45mg HEAA in urine/g Creatinine (at the end of exposure or shift), which is supported as well.
- Furthermore, a skin notation is very important.

Taking into consideration that:

- Tumor formation caused by 1,4-Dioxane is only observed above saturation levels of metabolism (in humans 180mg/m<sup>3</sup>) and therefore 1,4-Dioxane can be regarded a threshold carcinogen.
- The current (estimated) exposure levels across all sectors of use are way below the saturation level. Therefore, no incidences for cancer development could be derived despite the fact that 1,4-dioxane is classified as carcinogenic. The lower policy options will prevent other adverse health effects (mainly for local irritation of the nasal cavity, and also for liver, kidney) to occur.
- Given the very likely contribution of dermal exposure to the total uptake of 1,4-Dioxane, a skin notation will have a positive effect. Dermal and inhalational exposure are both relevant routes for the uptake of 1,4-Dioxane into the human body. The BLV and the OEL complement each other, and both have to be complied with.

The ACSH recommends the Commission to adopt the below new BOEL, STEL, BLV and a skin notation for 1,4-Dioxane under Directive 2004/37/EC. The ACSH strongly believes that the benefits associated with the below limit values and notation justify their costs.

**Annex:**

EC No	CAS No	NAME OF THE CHEMICAL AGENT	LIMIT VALUES				BIOLOGICAL LIMIT VALUE	Notation	Transitional measures
			8 hours		Short-term				
			mg/ m³	ppm	mg/m³	ppm	mg HEAA in urine/g Creatinine, at the end of exposure or shift		
204-661-8	123-91-1	1,4-Dioxane	7,3	2,0	73	20	45	Skin	-