



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

Opinion

**Opinion on an EU Binding Occupational Exposure Limit Value (BOEL) and
notations for
Cobalt and its inorganic compounds
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)**

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Cobalt and its inorganic compounds

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).

In the meetings of the Working Party of Chemicals on 11th - 12th May and 05th - 06th September, in three technical meetings with the consultant and in two technical exchange meeting on 19th July and 29th August 2023 the need to establish the limit values for cobalt and its inorganic compounds in the scope of the CMRD was discussed. At this moment, no binding occupational exposure limit values (BOELs) exist at EU level.

The three Interest Groups recognize that the exposure of workers to cobalt and its inorganic compounds in the European Union is of concern. They agree that this issue should be tackled at the EU level.

The three Interests Groups agreed the following points concerning limit values and notations for cobalt and its inorganic compounds:

- There is consensus agreement on the need to establish OELs for both the inhalable and the respirable fraction. The inhalable fraction OEL addresses non-carcinogenic effects (in particular decrease in lung function, upper airways irritation) and the respirable fraction OEL addresses carcinogenic effects. Both the inhalable fraction OEL and respirable fraction OEL will be binding and need to be complied with.
- The RAC opinion did not give a BLV because the air levels corresponding to the OELs proposed by RAC are likely to result in urinary levels which are very close to the background level of the general population and considered a STEL not to be relevant for the case of cobalt and its inorganic compounds. Therefore, the three interest groups agree not to establish a STEL or a BLV at the moment.
- Notations for skin and respiratory sensitization are relevant and should be included.
- A limit value of 20 $\mu\text{g}/\text{m}^3$ for the inhalable fraction and 4.2 $\mu\text{g}/\text{m}^3$ for the respirable fraction (the latter corresponding to a residual cancer risk of 4 : 1000 according to RAC, based on animal studies) could apply.
- 6 years after entry into force of the Directive, a limit value of 10 $\mu\text{g}/\text{m}^3$ for the inhalable fraction and 2.5 $\mu\text{g}/\text{m}^3$ for the respirable fraction (the latter corresponding to a residual cancer risk of approximately 2 : 1000) will apply.
- At the latest 13 years after entry into force of the Directive the ACSH advises that the Commission should have the result of a study assessing the feasibility to further reduce the respirable OEL to a level corresponding to a residual risk of 4 : 10000 and to check the need of reducing further the inhalable fraction. This enables gaining experience with the OELs of 10 $\mu\text{g}/\text{m}^3$ for the inhalable fraction and 2.5 $\mu\text{g}/\text{m}^3$ for the respirable fraction. This study should take into account the RAC opinion of 2022 and any new relevant information. Based on the results of this study the ACSH advises that the Commission should propose, where appropriate, necessary amendments and modifications related to cobalt and its inorganic compounds without delay.
- All three Interest Groups agree that some sectors may face particular difficulties for complying with the proposed OELs. In these sectors there is a need for using respiratory protective equipment (RPE) to ensure that the workers are appropriately protected.

The ACSH strongly recommends the Commission to adopt as soon as possible the below new BOELs, and the relevant notations for this group of chemicals under Directive 2004/37/EC. The ACSH strongly believes that the benefits associated with the below limit values and notations justify their costs.

Annex:

EC No	CAS No	NAME OF THE CHEMICAL AGENT	LIMIT VALUES				Notation	Transitional measures
			8 hours		Short-term			
			mg/m ³	ppm	mg/m ³	ppm		
-	-	Cobalt and its inorganic compounds	µg/m ³ 10 ¹¹ 2.5 ⁹				Dermal and respiratory sensitisation ¹³	Limit Values 20 ¹¹ µg/m ³ and 4.2 ⁹ µg/m ³ until 6 years after entry into force of the Directive

(⁹) Respirable fraction.

(¹¹) Inhalable fraction.

(¹³) Dermal and respiratory sensitisation