



EUROPEAN COMMISSION
DG Employment, Social Affairs and Inclusion
Working Conditions and Social Dialogue
Health and Safety at Work Unit

The Advisory Committee on Safety and Health at Work

Opinion

**Opinion on an update of the EU Binding Occupational Exposure Limit Value
(BOEL) for
Chromium VI 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)**

Doc.014-23

Adopted on 29/11/2023

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 meeting of the Working Party of Chemicals held on 27-28 September 2023, the need to re-evaluate the existing limit value of Chromium VI compounds was discussed.

Taking into consideration that:

- A limit value for Chromium VI compounds which are carcinogens within the meaning of point (i) of Article 2(a) (as chromium) of Directive 2004/37/EC has been adopted in Directive (EU) 2017/2398.
- The BOEL is 0.010 mg/m³ (0.025 mg/m³ for welding or plasma cutting processes or similar work processes that generate fumes) until 17 January 2025 which is the end of a transitional period. After that date, the generally applicable BOEL will be 0.005 mg/m³ (8hTWA).
- The BOEL adopted in Directive (EU) 2017/2398 is based on the SCOEL scientific assessment published in 2004¹, the Impact Assessment carried out by the European Commission published in 2016² and the ACSH opinion adopted on 19/10/2017³.
- RAC/ECHA in 2013⁴ and SCOEL in 2017⁵ re-evaluated the existing information on the carcinogenicity of Hexavalent Chromium compounds and both scientific bodies came to the conclusion that the excess risk level associated with exposure to Chromium VI were much higher than those calculated in the SCOEL 2004 evaluation, due to new scientific information.
- On the basis of these new convergent assessments, the calculated excess risk level of additional lung cancer associated with the BOEL of 0.005 mg/m³ adopted in the CMRD is of 20 additional lung cancer cases in 1000 exposed workers (20:1000) in 40 years occupational exposure.
- In 2022, the ACSH adopted an opinion on a Risk-based approach for OEL setting of non-threshold carcinogens in the CMRD⁶ where the three Interest Groups agreed on the principle that limit values should not be set with a residual cancer risk higher than 4:1000.
- The residual cancer risk level of 4:1000 for workers exposed to Chromium VI compounds would be met at the OEL level of 0.001 mg/m³ which is the 8h TWA OEL currently enforced in France, Denmark and the Netherlands.

In order to limit the workers' exposure to Chromium VI in the EU, Chromium VI is not only regulated under the CMRD but also under the European regulation (EC 1907/2006) on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). According to the provisions of REACH, authorisation may be granted for non-threshold carcinogens if the socio-economic benefits outweigh the risk to human health and the environment which is linked to the exposure levels. For granted authorisations of uses of Chromium VI in surface treatment, the levels of workers' exposure are up to 0.001-0.003 mg/m³.

¹ Recommendation from the Scientific Committee on Occupational Exposure Limits: Risk assessment for Hexavalent Chromium, [SCOEL/SUM/86](#), December 2004.

² Commission Staff Working Document Impact Assessment accompanying the document Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC, [SWD \(2016\) 152 final](#) of 13/05/2016.

³ Advisory Committee on Safety and Health at Work, Opinion on an EU Occupational Limit value for Chromium VI compounds under Directive 204/37/EC, [Doc 1335/17](#) adopted on 19/10/2017.

⁴ ECHA, Application for Authorisation: establishing a reference dose response relationship for carcinogenicity of Hexavalent Chromium [RAC/27/2013/06 Rev.1](#).

⁵ Recommendation from the Scientific Committee on Occupational Exposure Limits, [SCOEL/REC/386](#) Chromium VI compounds adopted on 22/05/2017.

⁶ Advisory Committee on Safety and Health at Work, Opinion on limit value setting for non-threshold carcinogens, a Risk-based Approach, [Doc. 005-22](#) adopted on 31/11/2022.

- According to the recent chromates study, carried out by HBM4EU⁷, air levels of Chromium VI are achievable below the future EU BOEL of 0.005 mg/m³ for both welding and surface treatment and therefore further lowering of the limit value for Chromium VI is needed.

The three Interests Groups therefore agreed the following points concerning the limit value for Chromium VI and the approach for its setting:

The generally applicable BOEL of 0.005 mg/m³ for Chromium VI compounds in the CMRD after 17 January 2025 is still associated with a significant residual risk for lung cancer. This is reflected both by the 2013 ECHA/RAC assessment and the 2017 SCOEL recommendation, which show an associated excess risk level of lung cancer of 20:1000 in 40 years occupational exposure.

The three Interest Groups consider that a high priority is to revise the BOEL applicable after 17 January 2025. In order to do this in a timely way, it is advisable to act on the basis of the existing exposure risk relationship in RAC 2013 assessment and SCOEL 2017 Recommendation.

Since the previous impact assessment study was carried out, the situation has changed with entry into force of transitional binding limit values for Chromium VI compounds under the CMRD and the granting of numerous authorisations for specific uses of Chromium VI compounds under REACH. Therefore, a new evaluation of the feasibility and socio-economic impacts is required to enable the ACSH to prepare an opinion and for the Commission to carry out its impact assessment to further reduce the BOEL below 0.005 mg/m³ after a reasonable period of time of entering into force.

The ACSH strongly recommends the Commission to carry out a study in order to evaluate the feasibility and socio-economic impacts of the possible lowering of the BOEL for Chromium VI compounds to 0.001 mg/m³, which is within the range of residual risks indicated in the ACSH opinion on the Risk-based Approach for OEL setting. The impact assessment study should also take into account the results of the HBM4EU chromates study report whilst recognising that the HBM4EU is not fully representative of the situation of all Member States and evaluate the possible added value of biomonitoring of exposed workers.

This study should be launched at the earliest opportunity. Taking the Commission's internal administrative procedures into account it seems feasible to launch the procurement phase of the study during 2024 with the active phase of the study being started and, if possible, carried out the same year.

After receiving the results of the impact assessment study, as well as the results of the ongoing evaluation referred to in Article 17a of Directive 89/391/EEC, the ACSH will prepare its opinion on the revision of the limit value for Chromium VI compounds.

⁷ Tiina Santonen et al, The HBM4EU chromates study – Outcomes and impacts on EU policies and occupational health practices, International Journal of Hygiene and Environmental Health, Volume 248, 2023, <https://doi.org/10.1016/j.ijheh.2022.114099>.