



EUROPEAN COMMISSION

DG Employment, Social Affairs and Inclusion

Employment and Social Legislation, Social Dialogue

Health and Safety

The Advisory Committee on Safety and Health at Work

Opinion

**Opinion on an EU Binding Occupational Exposure Limit Values (BOELs) for
Nickel compounds within the scope of
the Carcinogens and Mutagens Directive 2004/37/EC.**

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Nickel and its 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 Carcinogens and Mutagens Directive (CMD) 2004/37/EC, and, in addition, for the specific case of nickel the Chemical Agents Directive 98/24/EC.

In the meetings of the Working Party of Chemicals on 19th – 20th March 2019 and 29th – 30th April 2019, the adopted RAC Opinion ECHA/RAC/ A77-O-0000001412-86-189/F¹ of March 2018 was discussed.

The three Interest Groups agreed on limit values as presented below for nickel and its compounds.

The ACSH strongly recommends the Commission to adopt as soon as possible OELs for this substance under Directive 2004/37/EC.

The ACSH recommends that the date of application of the OEL for nickel compounds should be 17th January 2025 to ensure alignment with the date of application of the OEL for chromium (VI) compounds adopted in Directive 2017/2398/EU².

The three Interest Groups agreed on a transition period that ends in January 2025, as adopted for Chromium VI, since both groups of substances (nickel compounds and Chromium VI compounds) are frequently occurring in the same sectors and, often, in the same processes. As a consequence, actions to reduce the exposure to chromium VI and nickel compounds must be coordinated and can benefit from synergies.

All three Interest Groups agree that in a limited number of sectors or processes, including specifically smelting, refineries and welding, face particular difficulties for complying with the proposed OELs. In these sectors or processes, and possibly in other sectors, there may be a need for using respiratory protective equipment (RPE) to ensure that the workers are appropriately protected.

In addition, the three Interest Groups agreed that it would be appropriate to introduce an OEL under the Chemical Agents Directive (CAD) for Nickel. The limit value should be set at the same level and size fraction (respirable) for Nickel compounds under CMD.

The entries in the Directive should be:

¹https://echa.europa.eu/documents/10162/13641/nickel_opinion_en.pdf/9e050da5-b45c-c8e5-9e5e-a1a2ce908335

²OJ L 345, 27.12.2017, p.87.

| 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 | | |
| several | several | Nickel compounds measured as nickel: | | | | | | |
| | | Respirable fraction | 0.01 | | | | Skin and respiratory sensitisation | The limit value for the respirable fraction shall apply from 17 th January 2025. |
| | | Inhalable fraction | 0.05 | | | | Skin and respiratory sensitisation | The limit value for inhalable fraction shall apply from 17 th January 2025. Until then a limit value of 0.1 mg/m ³ shall apply. |

Specific comments of the Government Interest Group (GIG):

None.

Specific comments of the Employers Interest Group (EIG):

The socio- economic analysis on nickel compounds deals only with the costs and benefit of potential BOELVs for the inhalable fraction as there is a principal lack of data on the respirable fraction. The EIG emphasizes that the agreement on the rather strict BOELV for the respirable fraction is therefore built on quite some limited information on the implementation difficulties. This is added by the fact that, at present, measuring the respirable fraction of nickel compounds at the workplace is a challenge. The currently available methods are not easily suitable for personal sampling (due to the necessary apparatus and practicalities of sampling) and require a very dedicated and expensive analysis. EIG suggests that compilation work be done during the transition period to provide an adequate method for the measurement of respirable fraction of nickel compounds that companies and institutes can adopt to check compliance with the BOELV for the respirable fraction. In situations where industries work on huge or irregular shaped pieces, it might be difficult to meet the thresholds since closed-batched processes are not feasible.

Specific comments of the Workers Interest Group (WIG):

The WIG would like to further explain the rationale behind the date of 17th January 2025. Based on the assumption that CMD4 will probably enter into force at the latest early 2021, we estimate that a transitional period ending on 17th January 2025 would be more than enough to comply with the agreed OELs for nickel compounds in all sectors of industry. Indeed, the date of 17 January 2025 coincides with the date of application of the OEL for chromium VI compounds adopted in Directive (EU) 2017/2398 and, as the same protective measures can be used for chromium VI and nickel compounds in the welding/surface treatment sectors, all necessary tools should already be in place to comply with these different limit values.

Should the entry into force of CMD4 be delayed for whatever reason, the WIG is of the opinion that the date of 17th January 2025 should therefore remain the end of the transition period for complying with the agreed OELs for nickel and its compounds.

The WIG would like to stress that where this is technically possible employers should work towards achieving exposures below the limit values proposed by RAC (0.005 mg/m³ for respirable fraction and 0.03 mg/m³ for inhalable fraction). These are the exposure levels recommended by RAC in 2018 under which no adverse effects are expected on exposed workers.

The WIG would like also to emphasize that no measurement difficulties are foreseen for the inhalable and respirable OELs proposed by RAC, let alone for the agreed OELs. This means that air measurement techniques are currently available to measure, as required for compliance, 10% of the agreed OELs.