



Amendment of the Carcinogens- Mutagens Directive, 4th batch

COM (2020) 571

Executive summary

Under the 4th proposal for amendment to the Carcinogens and Mutagens Directive ([COM \(2020\) 571 final](#)), binding Occupational Exposure Limit values (OELs) for acrylonitrile, benzene, as well as nickel and nickel compounds, should be reset or revised. However, the proposed limit values are associated with unacceptable health risks.

The Austrian Chamber of Labour (AK) is calling in principle for the EU to introduce the system of risk-based limit values similar to the ones in Germany when setting limit values for carcinogens. The goal must be to create limit values which are associated with an additional risk of cancer over a 40-year working life, initially determined as a maximum of four in 10,000, and a maximum of four in 100,000 in the medium term. This means that, from a statistical standpoint, among 2,500 or 25,000 workers, at most one person was diagnosed with cancer over a period of more than 40 years because of working with the agent.

The Austrian Chamber of Labour (AK) is calling for limit values of the working substances of the 4th proposal amending the Directive to be revised downwards in relation to the figures proposed. The limit values need to be based on threshold values that are safe for workers or based on a barely acceptable working life cancer risk (initially four in 10,000 and four in 100,000 in the medium term):

- Setting the limit value for acrylonitrile at an initial level of 0.1 mg/m³ or 0.045 ppm instead of 1 mg/m³ or 0.45 ppm (eight hour time weighted average). In the medium term, the limit value should be revised downwards to 0.028 mg/m³ and 0.012 ppm respectively.
- Lowering the limit value for benzene initially to 0.05 ppm instead of 0.2 ppm or 0.66 mg/m³. In the medium term, the limit value should be revised downwards to 0.006 ppm or 0.02 mg/m³ respectively.
- Setting the limit value for nickel and its compounds for the inhalable fraction at 0.03 Ni mg/m³ (I) instead of 0.05 Ni mg/m³ (I). For

the respirable fraction the limit value should not be 0.01 Ni mg/m³ (R), but 0.005 mg/m³ (R) for metallic nickel and 0.006 Ni mg/m³ (R) for nickel compounds initially and, in the medium term, 0.001 Ni mg/m³ (R).

In addition to the introduction of risk-based limit values, a fundamental change in the Carcinogens and Mutagens Directive should be to indicate the residual risk of cancer also in cases where limit values are merely observed. This creates transparency regarding cancer risk in companies and increases motivation to stay below the limit values as much as possible.

The year-long transition period proposed for the limit values should be cut in half in favour of swifter health protection.

Due to the high health risks associated with working with such dangerous drugs and substances as reprotoxins, these substances need to be urgently included within the scope of the Carcinogens and Mutagens Directive.

The AK's position

1. Initial situation

According to a [study by the European Trade Union Institute \(ETUI\)](#), an estimated 147,000 workers in the EU develop cancer every year because they are exposed to carcinogens in the workplace. Every year around [100,000](#) people die of work-related cancer in the European Union.

In the fight against work-related cancer, the European Commission has so far made three amendments to the Carcinogens and Mutagens Directive 2004/37/EC. As a result, 22 binding occupational exposure limits for carcinogenic substances were introduced and two existing limit values were revised downwards. In view of the explosive figures on work-related cancer, the pace for introducing new limit values needs to be increased urgently.

Under the 4th proposal to amend the Carcinogens and Mutagens Directive (COM 2020/5710), limit values need to be redefined for only two carcinogens and an existing limit value needs to be revised downwards:

- New limit value for acrylonitrile (33,000 exposed workers, e.g. in plastics manufacturing)
- New limit value for nickel and nickel compounds (79,000 exposed workers, e.g. in metalworking)
- Adjustment of the limit value for benzene (1,000,000 exposed workers, e.g. in plastics processing or the automotive industry)

2. Lower limit values required

2.1. Priority for the protection of health

The limit values in the Carcinogens and Mutagens Directive relate to uptake through inhaling and describe the maximum concentration of a certain airborne chemical agent at the workplace. It is required that the average exposure of workers in a certain period of time does not to exceed this value.

The Austrian Chamber of Labour (AK) is essentially calling for the EU to introduce the system of risk-based limit values similar to the ones in Germany when setting limit values for carcinogens. The Netherlands, France, and Poland also already have binding risk-based limit values. This system includes carcinogens for which reliable scientific data on the so called exposure-risk relationship are available. With risk-based limit values, the risk of cancer for these agents should be equally low for all employees who are exposed to these substances over a working life of 40 years. The acceptable risk that has been politically determined in Germany means that the limit values reduce the working life cancer risk to a maximum of four in 10,000 for the time being, and to a maximum of four in 100,000 in the medium term. This means that, from a statistical standpoint, among 2,500 or 25,000 workers, at most one person, was diagnosed with cancer over a period of more than 40 years because of working with the agent. The German system is not restricted to setting limit values; employers are required to prepare concrete action plans to reach the acceptable values in the workplace and to maintain them as low as possible.

Regarding the introduction of the risk-based limit value, it should be cited together with the associated residual cancer risk limit values in Annex III of the Directive, providing clear numerical values. This is intended to create transparency in companies. Unfortunately, in operational practice, there is often a misconception, that simply adhering to the limit value is sufficient for protecting health. To increase the motivation to implement protective measures so that the actual values are as much as possible below the limit values, corporate operators involved in worker protection, as well as the affected workers, have a need for clarity concerning residual cancer risks.

Long-term transition periods for the limit values are proposed in the draft: for acrylonitrile, a period of four years was established and for benzene, two or four years after the Directive came into force, while for nickel and its compounds, the transition period runs until 18 January 2025. These transition periods are based on purely economic considerations.

However, health protection must be given priority. Shortening of the transition periods to half of the proposed length is sufficient for businesses.

2.2. Acrylonitrile

The proposed limit value of 1 mg/m³ or 0.45 ppm (daily average) far exceeds a corresponding working life cancer risk of four in 10,000.

It should be noted that the [European Chemicals Agency \(ECHA\)](#) submitted a recommendation for a limit value of 0.1 mg/ m³ or lower for carcinogenic and non-carcinogenic effects (see, specifically, Chapter 8.5). A maximum risk of 0.00018 for malignant brain tumours was assumed for this value. The limit value now proposed, based on the recommendation of the ECHA Risk Assessment Committee (RAC), is now ten times that!

The [German Committee on Hazardous Substances \(AGS\)](#) has specified 0.26 mg/m³ or 0.12 ppm as the interim acceptable value. This would mean that the working life cancer risk would be less than four in 10,000. In the medium term, a limit value that is associated with a risk of four in 100,000 is the ultimate goal to be aimed for, namely, 0.028 mg/m³ or 0.012 ppm.

The Austrian Chamber of Labour (AK) therefore calls for a limit value of 0.1 mg/m³ or 0.045 ppm for the time being, and 0.028 mg/m³ or 0.012 ppm in the medium term, meaning barely acceptable cancer risks.

2.3. Benzene

The draft provides for a limit value of 0.2 ppm or 0.5 mg/m³. The Austrian Chamber of Labour (AK) supports revising the limit value for benzene downwards to 0.05 ppm initially. This is the value recommended by the [Risk Assessment Committee \(RAC\)](#), below which no health damage for workers is to be feared.

A limit value of 0.05 ppm would roughly correspond to the interim acceptable value (risk of four in 10,000) specified by the [German Committee on Hazardous Substances \(AGS\)](#). In the medium term, the limit should be revised downwards so that it corresponds to a risk of four in 100,000, namely, to 0.006 ppm or 0.02 mg/m³.

2.4. Nickel and its compounds

The proposal provides for a limit value of 0.01 Ni mg/ m³ (R) for the respirable fraction and 0.05 Ni mg/m³ (I) for the inhalable fraction for nickel and its compounds. The respirable fraction (R) is part of the inhalable fraction (I) and it is so fine that it can penetrate into the lung alveoli.

The [German Committee on Hazardous Substances \(AGS\)](#) derived a health-based occupational exposure limit of 0.03 mg Ni mg/m³ (I) for the inhalable fraction from nickel compounds and from metallic nickel. The recommendation of the [Risk Assessment Committee \(RAC\)](#) also corresponds to 0.03 Ni mg/m³ (I). The Austrian Chamber of Labour (AK) therefore calls for a limit value of 0.03 Ni mg/m³ (I) instead of 0.05 Ni mg/ m³ (I) for the inhalable fraction.

Regarding the limit value for the A dust of metallic nickel and nickel compounds, recommendations of the [European Chemicals Agency \(ECHA\)](#) (specifically, Chapter 8.2) and of the [Risk Assessment Committee \(RAC\)](#), agree with 0.005 Ni mg/m³ (A).

In terms of the limit value for the respirable fraction, however, a distinction needs to be made between metallic nickel and nickel compounds to guarantee adequate health protection. For the respirable fraction of metallic nickel, the Austrian Chamber of Labour (AK) calls for the previously mentioned limit value of 0.005 Ni mg/m³. This corresponds roughly to the health-based occupational exposure limit value adopted in [Germany](#), at which there is generally no health risk.

For the respirable fraction of nickel compounds, the interim acceptable concentration based on a working life cancer risk is four in 10,000, according to the [Committee on Hazardous Substances \(AGS\)](#) and contained in the "Rationale for nickel compounds in the Technical Rules for Hazardous Substances 910 - TRGS 910" but 0.006 Ni mg/m³ (R). For a risk of four in 100,000, a value of 0.001 Ni mg/m³ (R) is provided. The Austrian Chamber of Labour (BAK) therefore calls for a limit value for the respirable fraction of nickel compounds of initially 0.006 Ni mg/m³ (R) and of 0.001 Ni mg/m³ (R) in the medium term.

3. Intake of hazardous drugs

As discloses the [European Trade Union Institute \(ETUI\)](#), 12 million workers in the health sector in the EU are exposed to hazardous drugs. Specifically, cytotoxic, cytostatic or anti-neoplastic drugs can have carcinogenic, mutagenic or reprotoxic effects.

For example, cytostatic agents used to treat cancer and other diseases may themselves be carcinogenic. In view of this high-risk potential, hazardous drugs (especially cytotoxic, cytostatic and anti-neoplastic drugs) should be included in Appendix I of the Carcinogens and Mutagens Directive. The addition should be worded as recommended by the European Trade Union Institute (ETI): “Work involving exposure to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of hazardous drugs, including cytotoxic drugs, and work involving exposure to carcinogenic or mutagenic substances in cleaning, transport, laundry and waste disposal of hazardous drugs or materials contaminated by hazardous drugs and in personal care for patients under treatment of hazardous drugs.”

4. Intake of reprotoxins

Reprotoxins may impair the ability of workers to conceive or the development of the child during pregnancy and after birth. According to the [European Trade Union Institute \(ETUI\)](#), these include phthalates, which serve as plasticisers, or endocrine disruptors, such as bisphenol A. Affected workers include, for example, those working in agriculture and care, hairdressers and beauticians. The Carcinogens and Mutagens Directive urgently needs to be expanded to include reprotoxins. Several Member States, such as Austria, have long included these substances in their national legislation on dangerous substances in workplaces. In 2017, the European Parliament (EP) called for an amendment to extend the scope of the Carcinogens and Mutagens Directive to reprotoxins. The European Commission has not yet complied with this recommendation. The European Parliament (EP) is now being asked to exert pressure and call for the inclusion of reprotoxins under a new proposal.



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About us

The Austrian Chamber of Labour (AK) is by law representing the interests of about 3.8 million employees and consumers in Austria. It acts for the interests of its members in fields of social-, educational-, economical-, and consumer issues both on the national and on the EU-level in Brussels. Furthermore, the Austrian Chamber of Labour is a part of the Austrian social partnership. The Austrian Chamber of Labour is registered at the EU Transparency Register under the number 23869471911-54.

The main objectives of the 1991 established AK EUROPA Office in Brussels are the representation of AK vis-à-vis the European Institutions and interest groups, the monitoring of EU policies and to transfer relevant Information from Brussels to Austria, as well as to lobby the in Austria developed expertise and positions of the Austrian Chamber of Labour in Brussels.