European Parliament
2019-2024

Committee on the Environment, Public Health and Food Safety

2020/0262(COD)

22.12.2020

DRAFT OPINION

of the Committee on the Environment, Public Health and Food Safety:

for the Committee on Employment and Social Affairs

on the proposal for a directive of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
(COM(2020)0571 – C9-0301/2020 – 2020/0262(COD))

Rapporteur for opinion: Joëlle Mélin

PA_Legam

SHORT JUSTIFICATION

Background

As the Commission has pointed out, 'each year in the European Union, around 120 000 cases of work-related cancer are caused by exposure to carcinogens at work, with around 80 000 people dying every year as a result. So as better to protect workers against cancer, today the Commission is proposing to further limit workers' exposure to cancer-causing chemicals. This fourth overhaul of the Carcinogens and Mutagens Directive sets new or revised limit values for three important substances: acrylonitrile, nickel compounds and benzene. Estimates suggest that more than 1.1 million workers in a wide range of sectors will enjoy better protection thanks to these new rules. The proposal that has been announced today is the first initiative the Commission has taken as part of its commitment to fighting cancer under Europe's plan to beat the disease, which is to be unveiled very soon.'

Subject

There are three new or revised limit values.

The Carcinogens and Mutagens Directive is regularly updated in the light of new scientific and technical data. Three previous updates have focused on workers' exposure to 26 chemicals. The proposal announced today sets new or revised occupational exposure limit values for the following substances:

- acrylonitrile (new limit value set);
- nickel compounds (new limit value set);
- benzene (existing limit value has been lowered).

Potential contributions to this fourth review

Following the three previous reviews, the rapporteur has preferred to focus on factual and technical aspects.

She accepts the three limit values for substances on which there was consensus, as reported in the extremely detailed working documents provided to MEPs. This consensus was confirmed to the rapporteur by a number of professionals.

She would also like to take the opportunity to call for a better definition of the risks involving the skin, beyond the term 'Skin'. Arrangements need to be made to provide systematic calculations for all substances that might pass through the skin.

The rapporteur also calls for the provisions in place to be assessed on a regular basis, at least every five years – not in view of an increase in new cases, which is unlikely to happen in such a short time, but in the light of technological progress and innovation with regard to finding alternative substances and/or the processing of substances.

AMENDMENTS

The Committee on the Environment, Public Health and Food Safety calls on the Committee on Employment and Social Affairs, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a directive
Recital 1

Text proposed by the Commission	*Amendment*
(1) Directive 2004/37/EC of the European Parliament and the Council[3] aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A consistent level of protection from the risks related to the occupational exposure to carcinogens and mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States.	(1) Directive 2004/37/EC of the European Parliament and the Council[3] aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. A consistent level of protection from the risks related to the occupational exposure to carcinogens and mutagens is provided for in that Directive by a framework of general principles to enable Member States to ensure the consistent application of minimum requirements. The aim of these minimum requirements is to protect workers at Union level. More stringent provisions can be set by Member States. ***At the same time, however, the impact on businesses should not be too drastic, to ensure that related businesses and jobs can be maintained.***
[3] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).	[3] Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

Or. fr

Amendment 2

Proposal for a directive
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) Research should also be carried out on a larger scale as part of the European recovery plan and the Member States' recovery plans in order to support companies wishing to either change their processes or find alternative materials.

Or. fr

Amendment 3

Proposal for a directive
Recital 7 a (new)

Text proposed by the Commission	*Amendment*
	(7a) Clearer, more systematic criteria for defining absorption through the skin or mucous membranes should be introduced: product concentration, surface area of skin, duration and frequency of exposure, i.e. mg/cm^2/h.

Or. fr

Amendment 4

Proposal for a directive
Recital 9

Text proposed by the Commission	*Amendment*
(9) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council[5] and is therefore carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a long- and short-term limit value for that	(9) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council[5] and is therefore ***a*** carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a long- and short-term limit value for that

carcinogen. Acrylonitrile ***can also be*** absorbed through the skin. It is therefore appropriate to establish a limit value for acrylonitrile under the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for acrylonitrile. This should be considered when developing guidance on the practical use of biomonitoring.

---

[5] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272.

carcinogen. Acrylonitrile ***is very easily*** absorbed through the skin***: 0.6 mg/cm²/h⁴ for human*** skin. It is therefore appropriate to establish a limit value for acrylonitrile under the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for acrylonitrile. This should be considered when developing guidance on the practical use of biomonitoring.

---

[5] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008R1272.

Or. fr

Amendment 5

Proposal for a directive
Recital 9 a (new)

Text proposed by the Commission	*Amendment*
	(9a) Acrylonitrile has also been recognised as a reprotoxic substance.

Or. fr

Amendment 6

Proposal for a directive
Recital 11

Text proposed by the Commission	*Amendment*
(11) Nickel ***compounds*** meet the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to	(11) Nickel ***salts*** meet the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to

set limit values for that group of carcinogens. Exposure to nickel ***compounds*** at workplaces may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish two limit values for both the inhalable and respirable fractions of the nickel ***compounds*** under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.	set limit values for that group of carcinogens. Exposure to nickel ***salts*** at workplaces may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish two limit values for both the inhalable and respirable fractions of the nickel ***salts*** under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation. *(This amendment applies throughout the text)* Or. fr

Amendment 7

Proposal for a directive
Recital 11 a (new)

Text proposed by the Commission	*Amendment*
	(11a) The hazardousness of salts deriving from nickel processing varies depending on the ore-processing method, its use in alloys and the size of its particles, which when equal to or greater than 60µ are not easily taken up by cells. Or. fr

Amendment 8

Proposal for a directive
Recital 12

Text proposed by the Commission	*Amendment*
(12) With regard to nickel ***compounds***, limit values of 0.01 mg/m³ for the respirable fraction and 0.05 mg/m³ for the inhalable fraction may be difficult to be complied with in a number of sectors or processes, including specifically smelting, refineries and welding. Furthermore, since identical risk management measures can be used both for chromium (VI) and nickel	(12) With regard to nickel ***salts***, limit values of 0.01 mg/m³ for the respirable fraction and 0.05 mg/m³ for the inhalable fraction may be difficult to be complied with in a number of sectors or processes, including specifically smelting, refineries and welding. Furthermore, since identical risk management measures can be used both for chromium (VI) and nickel

compounds, the transitional measures aiming to reduce the exposure to these two groups of carcinogens should be aligned. Therefore, a transitional period until 17 January 2025 inclusive should be introduced during which a limit value of 0.1 mg/m³ for the inhalable fraction of the nickel ***compounds*** should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU[6]

[6] Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571906530859&uri=CELEX:32017L2398

compounds, the transitional measures aiming to reduce the exposure to these two groups of carcinogens should be aligned. Therefore, a transitional period until 17 January 2025 inclusive should be introduced during which a limit value of 0.1 mg/m³ for the inhalable fraction of the nickel ***salts*** should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU[6]

[6] Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1571906530859&uri=CELEX:32017L2398

Or. fr

Amendment 9

Proposal for a directive
Recital 13

Text proposed by the Commission	*Amendment*
(13) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. The limit value set out in Annex III to Directive 2004/37/EC for benzene should be revised in the light of more recent scientific data and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of	(13) Benzene***, a very widely used raw material in a number of sectors and professions,*** meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore ***a*** carcinogen within the meaning of Directive 2004/37/EC. Benzene can also be absorbed through the skin. The limit value set out in Annex III to Directive 2004/37/EC for benzene should be revised in the light of more recent scientific data and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for

biomonitoring.	benzene. This should be considered when developing guidance on the practical use of biomonitoring.

Or. fr

Amendment 10

Proposal for a directive
Recital 16

Text proposed by the Commission	*Amendment*
(16) The limit values established in this Directive are to be kept under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006[7].	(16) The limit values established in this Directive are to be kept under regular scrutiny and review to ensure consistency with Regulation (EC) No 1907/2006[7] ***at least every five years to take account of technological progress, while allowing for a stable regulatory framework***.
[7] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006R1907	[7] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals. Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006R1907

Or. fr

Amendment 11

Proposal for a directive
Annex I – point 2
Directive 2004/37/EC
Annex III – point A

Text proposed by the Commission	*Amendment*
Nickel compounds	Nickel ***salts***

Or. fr