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From:	General Secretariat of the Council
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Subject:	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work *- Mandate for negotiation with the European Parliament*

Delegations will find in the Annex the mandate on the above mentioned Proposal for a Directive approved by the Permanent Representatives Committee on 25 November 2020.

ANNEX

2020/0262 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work[…]

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular point (b) of Article 153(2), in conjunction with point (a) of Article 153(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(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.

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1 OJ C , , p. .

2 OJ C , , p. .

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).

(2) Principle 10 of the European Pillar of Social Rights**[…]**, jointly proclaimed by the European Parliament, the Council and the Commission at the Social Summit for Fair Jobs and Growth on 17 November 2017, provides workers' right to a high level of protection of their health and safety at work, which includes the protection from the exposure to carcinogens and mutagens at the workplace.

(3) Binding occupational exposure limit values are **an** important component of the general arrangements for the protection of workers established by Directive 2004/37/EC and must not be exceeded. Limit values and other directly related provisions should be established for all those carcinogens or mutagens for which the available information, including scientific and technical data, make this possible.

(3a) For mutagens and most of the carcinogens, it is not scientifically possible to identify levels below which exposure would not lead to adverse effects. While setting the limit values at the workplace in relation to carcinogens and mutagens pursuant to this Directive does not completely eliminate risks to the health and safety of workers arising from exposure at work (residual risk), it nonetheless contributes to a significant reduction of risks arising from such exposure in the stepwise and goal-setting approach adopted in Directive 2004/37/EC. For some carcinogens, it is scientifically possible to identify levels below which exposure will not lead to adverse effects.

(4) Compliance with binding occupational exposure limit values is without prejudice to other employers' obligations pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens and mutagens at the workplace, the prevention or reduction of workers' exposure to carcinogens or mutagens and the measures which should be implemented to that effect. Those measures should include, as far as it is technically possible, the replacement of the carcinogen or mutagen by a substance, mixture or process which is not dangerous or is less dangerous to workers' health, the use of a closed system or other measures aiming to reduce the level of workers' exposure.

(5) This Directive strengthens the protection of workers' health and safety at their workplace. New limit values should be set out in Directive 2004/37/EC in the light of available information, including new scientific and technical data and should also be based on a thorough assessment of the socio-economic impact and availability of exposure measurement protocols and techniques at the workplace. That information should, if possible, include data on residual risks to the health of workers, opinions of the Committee for Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH). Information related to residual risk, made publicly available at Union level, is valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens.

(6) In accordance with the recommendations of the RAC and the ACSH, where possible, limit values for the inhalation route of exposure are established in relation to a reference period of eight hours time-weighted average (long-term exposure limit values) and, for certain carcinogens or mutagens to a shorter reference period, in general fifteen minutes time-weighted average (short-term exposure limit values), in order to limit, to the extent possible, the effects arising from short-term exposure.

(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection. **Further notations for hazardous substances and compounds can be found in Regulation (EC) No 1272/2008.**[4]

(8) The assessment of health effects of the carcinogens subject to this Directive was based on the relevant scientific expertise **provided by** the RAC. Pursuant to a Service Level Agreement signed by DG Employment, Social Affairs and Inclusion and ECHA, RAC provides scientific evaluations on the toxicological profile of each of the selected priority chemical substances in relation to their adverse health effects on workers.

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[4] **Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008).**

(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.

(10) With regard to acrylonitrile, a limit value of 1 mg/m³ (0.45 ppm) and a short-term limit value of 4 mg/m³ (1.8 ppm) may be difficult to be complied with in the short term. A transitional period of four years after entry into force of this Directive should be introduced from which these Occupational Exposure Limit (OEL) values **should** apply.

(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 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.

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[5] Regulation (EC) No 1272/2008 **of the European Parliament and of the Council of 16 December 2008** on classification, labelling and packaging of substances and mixtures, **amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)**. **[…]**

(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 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].

(13) Benzene 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 benzene. This should be considered when developing guidance on the practical use of biomonitoring.

(14) With regard to benzene, a revised limit value of 0**,**2 ppm (0**,**66 mg/m³) may be difficult to be complied with in some sectors in the short term. A transitional period of 4 years after entry into force of this Directive should **therefore** be introduced. **As a transitional measure, the limit value of 1 ppm (3,25 mg/m³) provided for in Directive (EU) 2019/130 should continue to apply until [OJ: the first 2 years after entry into force of this Directive] and** a **new** transitional limit value of 0**,**5 ppm (1.65 mg/m³) should **then** apply **until [OJ: the second 2 years after entry into force of this Directive].**

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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 **(OJ L 345, 27.12.2017, p. 87)**. **[…]**

(15) The Commission has carried out a two-stage consultation of management and labour at Union level in accordance with Article 154 of the Treaty on the Functioning of the European Union. It has also consulted the ACSH, which has adopted opinions for all priority substances concerned by this Directive, recommended one or several binding occupational exposure limit values for each of them, as well as notations, **where appropriate**.

(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]. **In particular, with regard to benzene, the Commission, in close cooperation with the Advisory Committee for Safety and Health,[8] will assess the feasibility of a further reduction of the BOEL, taking into account the RAC opinion of 2018 and any new relevant information.**

(17) Since the objective of this Directive, namely to protect workers against risks to their health and safety, including the prevention of such risks, arising or likely to arise from exposure to carcinogens or mutagens at work, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality~~,~~ as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

(18) **Since** this Directive concerns the protection of the health and safety of workers at their workplace, it should be transposed within two years of the date of its entry into force.

(19) Directive 2004/37/EC should therefore be amended accordingly,

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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 **(REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).**

8 **OJ C 218, 13.9.2003, p. 1**

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendment of Directive 2004/37/EC

Annex III to Directive 2004/37/EC is amended in accordance with the Annex to this Directive.

Article 2

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by **...** [two years after the date of entry into force of this Directive**] […]**. They shall **immediately** communicate **the text of those measures** to the Commission **[…]**.

   When Member States adopt those **measures**, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

Addressees

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

Appendix

ANNEX

The **Annex to Directive 2004/37/EC is amended as follows:**

(1) in point A of Annex III to Directive 2004/37/EC, the row related to benzene is replaced by the following row:

Name of agent	EC No ([1])	CAS No ([2])	Limit values						Notation	Transitional measures
			8 hours ([3])			Short-term ([4])				
			mg/m^3 ([5])	ppm ([6])	f/ml ([7])	mg/m^3	ppm	f/ml		
Benzene	200-753-7	71-43-2	0,66	0,2	–	–	–	–	Skin ([8])	**Limit value 1 ppm (3,25 mg/m³) until [OJ: 2 years after the entry into force]. Limit value 0,5 ppm (1,65 mg/m³) until [OJ: 4 years after the entry into force].**

(2) in point A of Annex III to Directive 2004/37/EC, the following rows are added

Name of agent	EC No ([1])	CAS No ([2])	Limit values						Notation	Transitional measures
			8 hours ([3])			Short-term ([4])				
			mg/m³ ([5])	ppm ([6])	f/ml ([7])	mg/m³	ppm	f/ml		
Acrylonitrile	203-466-5	107-13-1	1	0,45	–	4	1,8	–	Skin ([8]) **Dermal sensitisation ([9])**	The limit values shall apply from **... [OJ: 4 years after the entry into force of this Directive].**
Nickel compounds	–	–	0,01**([10])** 0,05**([11])**	–	–	–	–	–	Dermal and respiratory sensitisation **([12])**	The limit value **([10])** shall apply from 18th January 2025 The limit value **([11])** shall apply from 18th January 2025. Until then a limit value of 0,1 mg/m³ **([11])** shall apply.

(1) EC No, i.e. Einecs, ELINCS or NLP, is the official number of the substance within the European Union, as defined in Section 1.1.1.2 in Annex VI, Part 1, to Regulation (EC) No 1272/2008.
(2) CAS No: Chemical Abstract Service Registry Number.
(3) Measured or calculated in relation to a reference period of eight hours time-weighted average (TWA).
(4) Short-term exposure limit (STEL). A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.
(5) mg/m^3 = milligrams per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure).
(6) ppm = parts per million by volume in air (ml/m^3).
(7) f/ml = fibres per millilitre.
(8) Substantial contribution to the total body burden via dermal exposure possible.
(9) The substance can cause sensitisation of the skin.
(10) Respirable fraction, measured as nickel
(11) Inhalable fraction, measured as nickel
(12) The substance can cause sensitisation of the skin and of the respiratory tract.