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INFORMATION NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee/Council
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. - Outcome of the European Parliament's first reading (Strasbourg, 14-17 February 2022)

I. INTRODUCTION

In accordance with the provisions of Article 294 of the TFEU and the Joint declaration on practical arrangements for the codecision procedure¹, a number of informal contacts have taken place between the Council, the European Parliament and the Commission with a view to reaching an agreement on this file at first reading.

In this context, the Chair of the Committee on Employment and Social Affairs, Dragoş PÎSLARU (RE, RO), presented on behalf of the Committee a compromise amendment (amendment number 75) to the abovementioned proposal for a Directive and two amendments (amendments number 76 and 78) to the legislative resolution containing statements. These amendments had been agreed during the informal contacts referred to above.

¹ OJ C 145, 30.6.2007, p. 5.

II. VOTE

When it voted on 17 February 2022, the plenary adopted the compromise amendment (amendment number 75) to the abovementioned proposal for a Directive, as well as amendments 76 and 78 to the legislative resolution. No other amendments were adopted. The Commission's proposal as thus amended constitutes the Parliament's first-reading position which is contained in its legislative resolution as set out in the Annex hereto².

The Parliament's position reflects what had been previously agreed between the institutions. The Council should therefore be in a position to approve the Parliament's position.

The act would then be adopted in the wording which corresponds to the Parliament's position.

² The version of the Parliament's position in the legislative resolution has been marked up to indicate the changes made by the amendments to the Commission's proposal. Additions to the Commission's text are highlighted in *bold and italics*. The symbol "■" indicates deleted text.

Protection of workers from the risks relating to exposure to carcinogens, mutagens and reprotoxins at work *I**

European Parliament legislative resolution of 17 February 2022 on the 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 (COM(2020)0571– C9-0301/2020 – 2020/0262(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

- having regard to the Commission proposal to Parliament and the Council (COM(2020)0571),
- having regard to Article 294(2) and in particular Article 153(2)(b), in conjunction with Article 153 (1)(a) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C9-0301/2020),
- having regard to Article 294(3) of the Treaty on the Functioning of the European Union,
- having regard to the opinion of the European Economic and Social Committee of 16 February 2021¹,
- after consulting the Committee of the Regions,
- having regard to the provisional agreement approved by the responsible committee under Rule 74(4) of its Rules of Procedure and the undertaking given by the Council representative by letter of 22 December 2021 to approve Parliament’s position, in accordance with Article 294(4) of the Treaty on the Functioning of the European Union,
- having regard to Rule 59 of its Rules of Procedure,
- having regard to the opinion of the Committee on Legal Affairs;
- having regard to the report of the Committee on Employment and Social Affairs (A9-0114/2021)

¹ OJ C 56, 16.2.2021, p. 63.

1. Adopts its position at first reading hereinafter set out;
2. Approves the joint statement by Parliament and the Council annexed to this resolution, which will be published in the L series of the *Official Journal of the European Union* together with the final legislative act;
3. Takes note of the Commission statement annexed to this resolution,;
4. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;
5. Instructs its President to forward its position to the Council, the Commission and the national parliaments;

Position of the European Parliament adopted at first reading on 17 February 2022 with a view to the adoption of Directive (EU) 2022/... 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 Article 153(2), point (b), in conjunction with Article 153(1), point (a), 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 Committee¹,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure²,

¹ OJ C 56, 16.2.2021, p. 63.

² Position of the European Parliament of 17 February 2022.

Whereas:

- (1) Directive 2004/37/EC of the European Parliament and the Council¹ aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the place of work. 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.
- (2) *By setting minimum requirements for workers' protection across the Union, Directive 2004/37/EC improves clarity and contributes to a more level playing field for the economic actors in the sectors that use the substances falling within the scope of that Directive, thereby demonstrating the importance of Union action in this field.*

¹ 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) *According to the latest scientific evidence, reprotoxic substances can cause adverse effects on sexual function and fertility in adult males and females, as well as on the development of their offspring. Similarly to carcinogens or mutagens, reprotoxic substances are substances of very high concern which may have serious and irreversible effects on workers' health. Therefore, reprotoxic substances should also be regulated under Directive 2004/37/EC in order to improve consistency with, inter alia, Regulation (EC) No 1907/2006 of the European Parliament and of the Council¹ and to ensure a similar level of minimum protection at Union level.*
- (4) *For most reprotoxic substances, it is scientifically possible to identify levels below which exposure would not lead to adverse health effects. The exposure minimisation requirements laid down in Directive 2004/37/EC should apply only to reprotoxic substances for which it is not possible to identify a safe level of exposure and which are identified as 'non-threshold' in the notation column of the Annex III to Directive 2004/37/EC. With regard to all other reprotoxic substances, employers should ensure that the risk related to the exposure of workers is reduced to a minimum.*

¹ *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).*

- (5) *According to the latest scientific data, biological limit values may be necessary in specific cases to protect workers from exposure to some carcinogens, mutagens or reprotoxic substances. Biological limit values and relevant related provisions should therefore be included in Directive 2004/37/EC.*
- (6) Principle 10 of the European Pillar of Social Rights¹, 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 for the right of workers to a high level of protection of their health and safety at work, which includes protection from the exposure to carcinogens, mutagens *and reprotoxic substances* at the place of work.
- (7) 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 carcinogens, mutagens *and reprotoxic substances* for which the available information, including *up-to-date* scientific and technical data, make it possible to do so.

¹ OJ C 428, 13.12.2017, p. 10.

- (8) *For mutagens and most carcinogens, it is not scientifically possible to identify levels below which exposure would not lead to adverse health effects. Although setting limit values for exposure at the place of work in relation to carcinogens and mutagens in Directive 2004/37/EC 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 by means of the stepwise and goal-setting approach that was adopted in that Directive.*
- (9) Binding occupational exposure limit values are without prejudice to other employers' obligations pursuant to Directive 2004/37/EC, such as the reduction of the use of carcinogens, mutagens *and reprotoxic substances* at the place of work, the prevention or reduction of workers' exposure to carcinogens, mutagens *and reprotoxic substances*, or to 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, mutagen *and reprotoxic substance* by a substance, mixture or process which is not dangerous or which is less dangerous to workers' health, the use of a closed system, or other measures aiming to reduce the level of workers' exposure.

- (10) *There is a need for workers to receive sufficient and appropriate training when they are exposed or are likely to be exposed to carcinogens, mutagens or reprotoxic substances, including those contained in certain hazardous medicinal products. The training that the employer is required to provide pursuant to Article 11 of Directive 2004/37/EC should be adapted to take account of a new or changed risk, in particular when workers are exposed to new carcinogens, mutagens or reprotoxic substances or to a number of different carcinogens, mutagens or reprotoxic substances, including in hazardous medicinal products, or in the case of changing circumstances related to work.*
- (11) *Certain hazardous medicinal products contain one or more substances which meet the criteria for classification as carcinogenic (category 1A or 1B), mutagenic (category 1A or 1B) or toxic for reproduction (category 1A or 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council¹ and therefore fall within the scope of Directive 2004/37/EC. However, clear and updated information concerning whether a medicinal product meets those criteria is not easily accessible to workers, employers or enforcement authorities. In order to ensure the proper implementation of Directive 2004/37/EC and to provide clarity with regard to the use of and risks relating to the handling of those hazardous medicinal products, it is necessary to take steps to help employers to identify them. The Commission, in line with the Commission communication of 28 June 2021 on an EU strategic framework on health and safety at work 2021-2027, is to provide guidelines, including on training, protocols, surveillance and monitoring, for protecting workers against exposure to hazardous medicinal products.*

¹ *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 the risk assessment provided in Article 3 of Directive 2004/37/EC, when assessing exposure to hazardous medicinal products falling within the scope of that Directive, employers should pay specific attention to ensure that the requirement to replace such products would not be to the detriment of patients' health.*
- (13) This Directive strengthens the protection of workers' health and safety at the place of work. New limit values should be set out in Directive 2004/37/EC in light of available information, including *up-to-date* 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 place of work. 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 established by Regulation (EC) No 1907/2006 (ECHA) and opinions of the Advisory Committee on Safety and Health at Work established by a Council Decision of 22 July 2003¹ (ACSH). Information related to residual risk that has been made publicly available at Union level is valuable for any future work to limit risks from occupational exposure to carcinogens, mutagens *and reprotoxic substances*.

¹ Council Decision of 22 July 2003 setting up an Advisory Committee on Safety and Health at Work (OJ C 218, 13.9.2003, p. 1).

- (14) *The Commission should task the ACSH with further exploring the possibility to adopt a risk-based methodology on the basis of available information, including scientific and technical data, with the aim of setting limit values at an exposure level corresponding to a risk of developing an adverse health effect, such as cancer, including the option of establishing them in the range between an upper and a lower risk level.*
- (15) 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, mutagens *and reprotoxic substances* 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.
- (16) It is also necessary to consider **█** absorption pathways *other* than inhalation for all carcinogens, mutagens *and reprotoxic substances*, including the possibility of uptake through the skin, in order to ensure the best possible level of protection. *Further notations for hazardous substances and mixtures are laid down in Regulation (EC) No 1272/2008.*

- (17) The assessment of health effects of the carcinogens subject to this Directive is based on the relevant scientific expertise *provided by* the RAC. Pursuant to a Service Level Agreement signed by the Commission's Directorate-General for 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 effects on workers' health.
- (18) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 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 within the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed that biological monitoring for acrylonitrile would be useful. This should be considered when developing guidance on the practical use of biological monitoring.

- (19) 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 comply with in the short term. A transitional period of four years after entry into force of this Directive from which those Occupational Exposure Limit (OEL) values apply *should* be introduced.
- (20) 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 the place of work may also result in dermal sensitisation and sensitisation of the respiratory tract. It is therefore appropriate to establish limit values for both the inhalable and respirable fractions of the nickel compounds within the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.

- (21) 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 comply with in a number of sectors or processes, in particular 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. The transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive (EU) 2017/2398 of the European Parliament and of the Council¹.
- (22) 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 light of more recent scientific data and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, agreed that the biological monitoring for benzene would be useful. This should be considered when developing guidance on the practical use of biological monitoring.

¹ 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*).

- (23) With regard to benzene, a revised limit value of 0,2 ppm (0,66 mg/m³) may be difficult to comply with in some sectors in the short term. A transitional period of four 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 of the European Parliament and the Council¹ should continue to apply until ... [OJ: 2 years after the date of entry into force of this amending Directive] and a transitional limit value of 0,5 ppm (1,65 mg/m³) should apply from ... [OJ: 2 years after the date of entry into force of this amending Directive] until ... [OJ: 4 years after the date of entry into force of this amending Directive].*
- (24) *The limit value for respirable crystalline silica dust set out in Annex III to Directive (EU) 2017/2398 should be revised in light of the Commission's evaluations pursuant to Directive 2004/37/EC and recent scientific and technical data.*
- (25) 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*.

¹ *Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 30, 31.1.2019, p. 112).*

- (26) 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. *In particular, with regard to benzene, the Commission, in close cooperation with the ACSH, will assess the feasibility of a further reduction of the OEL, taking into account the RAC opinion of 2018 and any new relevant information.*
- (27) Since the objective of this Directive, namely to protect workers against risks to their health and safety arising from or likely to arise from exposure to carcinogens, mutagens *or reprotoxic substances* at work, including the prevention of such risks, 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.
- (28) *Since* this Directive concerns the protection of the health and safety of workers at the place of work, it should be transposed within two years of the date of its entry into force.
- (29) Directive 2004/37/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2004/37/EC

Directive 2004/37/EC is amended as follows:

(1) *the title is replaced by the following:*

‘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, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC)’;

(2) *in Article 1(1), the first subparagraph is replaced by the following:*

‘1. This Directive has as its aim the protection of workers against risks to their health and safety arising from or likely to arise from exposure to carcinogens, mutagens or reprotoxic substances at work, including the prevention of such risks.’;

(3) *Article 2 is amended as follows:*

(a) *the following points are inserted:*

‘(ba) ‘reprotoxic substance’ means a substance or mixture, which meets the criteria for classification as a category 1A or 1B reproductive toxicant set out in Annex I to Regulation (EC) No 1272/2008;

(bb) ‘non-threshold reprotoxic substance’ means a reprotoxic substance to which there is no safe level of exposure for workers’ health and which is identified as such in the notation column of Annex III;

(bc) *'threshold reprotoxic substance' means a reprotoxic substance for which a safe level of exposure exists below which there is no risk to workers' health and which is identified as such in the notation column of Annex III;'*

(b) *point (c) is replaced by the following:*

'(c) 'limit value' means, unless otherwise specified, the limit of the time-weighted average of the concentration for a carcinogen, mutagen or reprotoxic substance in the air within the breathing zone of a worker in relation to a specified reference period as set out in Annex III;'

(c) *the following points are added:*

'(d) 'biological limit value' means the limit of the concentration in the appropriate biological medium of the relevant agent, its metabolite, or an indicator of effect;

'(e) 'health surveillance' means the assessment of an individual worker to determine the state of health of that individual, as related to exposure to specific carcinogens, mutagens or reprotoxic substances at work.'

(4) *Article 3 is amended as follows:*

(a) *paragraph 1 is replaced by the following:*

'1. This Directive shall apply to activities in which workers are or are likely to be exposed to carcinogens, mutagens or reprotoxic substances as a result of their work.';

(b) *in paragraph 2, the first and second subparagraphs are replaced by the following:*

'2. In the case of any activity likely to involve a risk of exposure to carcinogens, mutagens or reprotoxic substances, the nature, degree and duration of workers' exposure shall be determined in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken.

The assessment shall be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens, mutagens or reprotoxic substances.';

(c) *paragraph 4 is replaced by the following:*

'4. When the risk assessment is carried out, employers shall give particular attention to any effects concerning the health or safety of workers at particular risk and shall, inter alia, take account of the desirability of not employing such workers in areas where they may come into contact with carcinogens, mutagens or reprotoxic substances.';

(5) *in Article 4, paragraph 1 is replaced by the following:*

'1. The employer shall reduce the use of a carcinogen, mutagen or reprotoxic substance at the place of work, in particular by replacing it, in so far as is technically possible, by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to workers' health or safety, as the case may be.'

(6) *Article 5 is amended as follows:*

(a) *paragraphs 2, 3 and 4 are replaced by the following:*

- '2. Where it is not technically possible to replace the carcinogen, mutagen or reprotoxic substance by a substance, mixture or process which, under its conditions of use, is not dangerous or is less dangerous to health or safety, the employer shall ensure that the carcinogen, mutagen or reprotoxic substance is, in so far as is technically possible, manufactured and used in a closed system.*
- 3. Where a closed system is not technically possible, the employer shall ensure that the level of exposure of workers to the carcinogen, mutagen or non-threshold reprotoxic substance is reduced to as low a level as is technically possible.*
- 3a. Where it is not technically possible to use or manufacture a threshold reprotoxic substance in a closed system, the employer shall ensure that the risk related to the exposure of workers to that threshold reprotoxic substance is reduced to a minimum.*

- 3b. *The employer shall, with regard to reprotoxic substances other than non-threshold reprotoxic substances and threshold reprotoxic substances, apply paragraph 3a of this Article. In such a case, when carrying out the risk assessment referred to in Article 3, the employer shall duly take into account the possibility that a safe level of exposure for workers' health for such a reprotoxic substance might not exist and shall lay down appropriate measures in that regard.*
4. *Exposure shall not exceed the limit value of a carcinogen, mutagen or a reprotoxic substance as set out in Annex III.’;*
- (b) *paragraph 5 is amended as follows:*
- (i) *the introductory wording is replaced by the following:*
- ‘5. *Wherever a carcinogen, mutagen or reprotoxic substance is used, the employer shall apply all the following measures:’;*
- (ii) *point (a) is replaced by the following:*
- ‘(a) *limitation of the quantities of a carcinogen, mutagen or reprotoxic substance at the place of work;’;*
- (iii) *points (c), (d) and (e) are replaced by the following:*
- ‘(c) *design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens, mutagens or reprotoxic substances into the place of work;*
- (d) *evacuation of carcinogens, mutagens or reprotoxic substances at source, local extraction system or general ventilation, all such methods to be appropriate and compatible with the need to protect public health and the environment;*
- (e) *use of existing appropriate procedures for the measurement of carcinogens, mutagens or reprotoxic substances, in particular for the*

early detection of abnormal exposures resulting from an unforeseeable event or an accident;’;

(iv) *point (j) is replaced by the following:*

‘(j) demarcation of risk areas and use of adequate warning and safety signs including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens, mutagens or reprotoxic substances;’;

(7) *in Article 6, first paragraph, points (a) and (b) are replaced by the following:*

‘(a) the activities and/or industrial processes carried out, including the reasons for which carcinogens, mutagens or reprotoxic substances are used;

(b) the quantities of substances or mixtures manufactured or used which contain carcinogens, mutagens or reprotoxic substances;’;

(8) *Article 10(1) is amended as follows:*

(a) the introductory wording is replaced by the following:

‘1. Employers shall be obliged, in the case of all activities for which there is a risk of contamination by carcinogens, mutagens or reprotoxic substances, to take appropriate measures to ensure that:’;

(b) point (a) is replaced by the following:

‘(a) workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens, mutagens or reprotoxic substances;’;

(9) *Article 11 is amended as follows:*

(a) *in paragraph 1, the second subparagraph is replaced by the following:*

‘The training shall be:

- adapted to take account of new or changed risk, in particular when workers are or are likely to be exposed to new carcinogens, mutagens or reprotoxic substances or to a number of different carcinogens, mutagens or reprotoxic substances, including those contained in hazardous medicinal products, or in case of changing circumstances related to work,*
- provided periodically in healthcare settings to all workers who are exposed to carcinogens, mutagens or reprotoxic substances, in particular where new hazardous medicinal products containing those substances are used, and*
- repeated periodically in other settings if necessary.’;*

(b) *paragraph 2 is replaced by the following:*

‘2 Employers shall inform workers of installations and related containers containing carcinogens, mutagens or reprotoxic substances, ensure that all containers, packages and installations containing carcinogens, mutagens or reprotoxic substances are labelled clearly and legibly, and display clearly visible warning and hazard signs.

Where a biological limit value has been set in Annex IIIa, health surveillance shall be mandatory for working with the carcinogen, mutagen or reprotoxic substance in question, in accordance with the procedures laid down in that Annex. Workers shall be informed of that requirement before being assigned to the task involving the risk of exposure to the carcinogen, mutagen or reprotoxic substance indicated.’;

(10) *Article 14 is amended as follows:*

(a) *in paragraph 3, the first subparagraph is replaced by the following:*

‘3. If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens, mutagens or reprotoxic substances, or if a biological limit value is found to have been exceeded, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.’;

(b) *paragraph 4 is replaced by the following:*

‘4. In cases where health surveillance is carried out, an individual medical record shall be kept and the doctor or authority responsible for health surveillance shall propose any protective or preventive measures to be taken in respect of any individual workers. Biological monitoring and related requirements may form part of health surveillance.’;

(c) *in paragraph 8, the first subparagraph is replaced by the following:*

‘8. All cases of cancer, adverse effects on sexual function and fertility in adult male and female workers or developmental toxicity in their offspring identified in accordance with national law or practice as resulting from occupational exposure to a carcinogen, mutagen or reprotoxic substance shall be notified to the competent authority.’;

(11) *in Article 15, paragraph 1 is replaced by the following:*

- ‘1. With regard to carcinogens and mutagens, the list referred to in Article 12, point (c), and the medical record referred to in Article 14(4) shall be kept for at least 40 years following the end of exposure, in accordance with national law or practice.*
- 1a. With regard to reprotoxic substances, the list referred to in Article 12, point (c), and the medical record referred to in Article 14(4) shall be kept for at least five years following the end of exposure, in accordance with national law or practice.’;*

(12) *Article 16 is amended as follows:*

(a) *paragraph 1 is replaced by the following:*

- ‘1. The European Parliament and the Council shall, in accordance with the procedure laid down in Article 153(2), point (b), of the Treaty on the Functioning of the European Union (TFEU), set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens, mutagens or reprotoxic substances for which this is possible, and, where necessary, other directly related provisions.’;*

(b) *the following paragraphs are added:*

- ‘3. The European Parliament and the Council shall, in accordance with the procedure laid down in Article 153(2), point (b), TFEU, set out biological limit values in Directives on the basis of the available information, including scientific and technical data, together with other relevant health surveillance information.*
- 4. Biological limit values and other health surveillance information are set out in Annex IIIa.’;*

(13) *the following Article is inserted:*

‘Article 16a

Identification of non-threshold and threshold reprotoxic substances

The European Parliament and the Council shall, in accordance with the procedure laid down in Article 153(2), point (b), TFEU, identify, on the basis of the available scientific and technical data, in the notations column of Annex III to this Directive whether a reprotoxic substance is a non-threshold reprotoxic substance or a threshold reprotoxic substance.’;

(14) *in Article 17, the first paragraph is replaced by the following:*

‘The Commission is empowered to adopt delegated acts in accordance with Article 17a to make strictly technical amendments to Annex II, in order to take account of technical progress, changes in international regulations or specifications and new findings with regard to carcinogens, mutagens or reprotoxic substances.’;

(15) *Article 18a is replaced by the following:*

‘Article 18a

Evaluation

The Commission shall, as part of the next evaluation of the implementation of this Directive in the context of the evaluation referred to in Article 17a of Directive 89/391/EEC, also evaluate the need to modify the limit value for respirable crystalline silica dust. The Commission shall launch this process in 2022 and, where appropriate, shall subsequently propose necessary amendments and modifications related to that substance in a subsequent revision of this Directive.

No later than 11 July 2022, the Commission shall assess the option of amending this Directive to add provisions on a combination of an airborne occupational exposure limit and a biological limit value for cadmium and its inorganic compounds.

No later than 31 December 2022, where appropriate, after consulting the Advisory Committee for Safety and Health at Work (ACSH) and taking into account the existing recommendations of different agencies, stakeholders and the World Health Organization, on priority carcinogens, mutagens and reprotoxic substances for which limit values are needed, the Commission shall present an action plan to achieve new or revised occupational exposure limits values for at least 25 substances, groups of substances or process-generated substances. Where appropriate, taking into account that action plan, the latest developments in scientific knowledge, and after consulting the ACSH, the Commission shall present legislative proposals pursuant to Article 16 without delay.

Where appropriate and no later than ... [OJ: three years after the date of entry into force of this amending Directive], taking into account the latest developments in scientific knowledge and after appropriate consultation of relevant stakeholders, the Commission shall develop a definition and establish an indicative list of hazardous medicinal products or the substances contained therein, which meet the criteria for classification as a category 1A or 1B carcinogen set out in Annex I to Regulation (EC) No 1272/2008, a mutagen or a reprotoxic substance.

No later than 31 December 2022, the Commission shall, after appropriate consultation of relevant stakeholders, prepare Union guidelines for the preparation, administration, and disposal of hazardous medicinal products at the place of work. Those guidelines shall be published on the website of EU-OSHA and shall be disseminated in all Member States by the relevant competent authorities.

Where appropriate, after receipt of an opinion from the ACSH, the Commission shall, taking into account the existing methodology for setting limit values for carcinogens in some Member States and the opinion of the ACSH, establish upper and lower risk levels. No later than 12 months after receipt of the ACSH opinion, the Commission shall, after appropriate consultation of relevant stakeholders, prepare Union guidelines on the methodology establishing risk-based limit values. Those guidelines shall be published on the EU-OSHA website and disseminated in all Member States by the relevant competent authorities.

No later than 31 December 2024, the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation of relevant stakeholders, propose, where appropriate, a limit value for cobalt and inorganic cobalt compounds.’;

(16) *in Annex II, point 1 is replaced by the following:*

‘1. The doctor and/or authority responsible for the health surveillance of workers exposed to carcinogens, mutagens or reprotoxic substances must be familiar with the exposure conditions or circumstances of each worker.’;

(17) Annex III 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 ... [OJ: two years after the date of entry into force of this amending 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 shall be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main measures 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 ...,

For the European Parliament

For the Council

The President

The President

ANNEX

The Annexes to Directive 2004/37/EC are amended as follows:

(1) in Annex III, point A is amended as follows:

(a) the row related to benzene is replaced by the following:

Name of agent	EC No (¹)	CAS No (²)	Limit values						Notat ion (⁸)	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)	<i>Limit value 1 ppm (3,25 mg/m³) until ...[OJ: two years after the date of entry into force of this amending Directive]. Limit value 0,5 ppm (1,65 mg/m³) from ... [OJ: two years after the date of entry into force of this amending Directive] until ... [OJ: 4 years after the date of entry into force of this amending Directive].</i>

(b) 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/m ³ ⁽⁵⁾	ppm ⁽⁶⁾	f/ml ⁽⁷⁾	mg/m ³	ppm	f/ml		
Acrylonitrile	203-466-5	107-13-1	1	0,4 5	–	4	1,8	–	Skin ⁽⁸⁾ Dermal sensitisation ⁽⁹⁾	The limit values shall apply from ... [OJ: four years after the date of entry into force of this amending Directive].
Nickel compounds	–	–	0,01 ⁽¹⁰⁾ 0,05 ⁽¹¹⁾	–	–	–	–	–	Dermal and respiratory sensitisation ⁽¹²⁾	The limit value ⁽¹⁰⁾ shall apply from 18 th January 2025 The limit value ⁽¹¹⁾ shall apply from 18 th January 2025. Until then a limit value of 0,1 mg/m ³ ⁽¹¹⁾ shall apply.

<i>Inorganic lead and its compounds</i>			0,15							
<i>N,N-Dimethylacetamide</i>	204-826-4	127-19-5	36	10		72	20		Skin ⁽⁸⁾	
<i>Nitrobenzene</i>	202-716-0	98-95-3	1	0,2					Skin ⁽⁸⁾	
<i>N,N Dimethylformamide</i>	200-679-5	68-12-2	15	5		30	10		Skin ⁽⁸⁾	
<i>2-Methoxyethanol</i>	203-713-7	109-86-4		1					Skin ⁽⁸⁾	
<i>2-Methoxyethyl acetate</i>	203-772-9	110-49-6		1					Skin ⁽⁸⁾	
<i>2-Ethoxy ethanol</i>	203-804-1	110-80-5	8	2					Skin ⁽⁸⁾	

<i>2-Ethoxyethyl acetate</i>	203-839-2	111-15-9	11	2					Skin ⁽⁸⁾	
<i>1-Methyl-2-pyrrolidone</i>	212-828-1	872-50-4	40	10		80	20		Skin ⁽⁸⁾	
<i>Mercury and divalent inorganic mercury compounds including mercuric oxide and mercuric chloride (measured as mercury)</i>			0,02							
<i>Bisphenol A; 4,4'-Isopropylidenediphenol</i>	201-245-8	80-05-7	2 ⁽¹³⁾							
<i>Carbon monoxide</i>	211-128-3	630-08-0	23	20		117	100			

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- (¹) EC No, i.e. Einescs, 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/m³ = 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/m³).
- (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.
- (¹³) ***Inhalable fraction.***’;

(2) *the following annex is inserted:*

‘ANNEX IIIa

BIOLOGICAL LIMIT VALUES AND HEALTH SURVEILLANCE MEASURES

(Article 16(4))

1. Lead and its ionic compounds

1.1 Biological monitoring must include measuring the blood-lead level (PbB) using absorption spectrometry or a method giving equivalent results. The binding biological limit value is:

70 µg Pb/100 ml blood

1.2 Medical surveillance is carried out if exposure to a concentration of lead in air is greater than 0,075 mg/m³, calculated as a time-weighted average over 40 hours per week, or a blood-lead level greater than 40 µg Pb/100 ml blood is measured in individual workers.’

1. ANNEX TO THE LEGISLATIVE RESOLUTION

2. Joint statement of the European Parliament and the Council related to the scope of Directive 2004/37/EC

[to be published in the L series immediately after the legislative act]

3. The European Parliament and the Council share the common understanding that hazardous medicinal products which contain substances which meet the criteria for classification as carcinogenic (categories 1A or 1B), mutagenic (categories 1A or 1B) or reprotoxin (categories 1A or 1B) in accordance with Regulation (EC) No 1272/2008 fall under the scope of Directive 2004/37/EC. All requirements of Directive 2004/37/EC apply to hazardous medicinal products accordingly.

4.

Commission Statement – Action plan and legislative proposals

The obligations imposed on the Commission in Article 18a, third paragraph, regarding the presentation of an action plan and the presentation of a legislative proposal cannot go against the institutional prerogatives of the Commission and its right of initiative deriving directly from the Treaties.

Article 18a, third paragraph, refers to Article 16 of Directive 2004/37/EC, which lays down an obligation to set limit values on the basis of the available information, including scientific and technical data, in respect of all those substances for which this is possible. In implementing this provision, the Commission is also invited to present the action plan referred to in Article 18a, third paragraph. For reasons of transparency, this action plan will consist of a listing of the next 25 new or revised substances to be scientifically evaluated. The evaluations of the listed substances will form part of the established procedure including consultation of social partners, the opinion of the ACSH and impact assessment preparing any necessary legislative proposals in due time.