European Parliament
2019-2024

Committee on Employment and Social Affairs

2020/0262(COD)

10.01.2020

***I
DRAFT REPORT

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))

Committee on Employment and Social Affairs

Rapporteur: Stefania Zambelli

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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 Article 153(2)(b) and (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 Rules 59 of its Rules of Procedure,

– having regard to the opinions of the Committee on the Environment, Public Health and Food Safety and of the Committee on Legal Affairs;

– having regard to the report of the Committee on Employment and Social Affairs (A9-0000/2020)

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments;

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	(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.

[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).

carcinogens***,*** mutagens ***or reprotoxic substances*** 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.

[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. en

Amendment 2

Proposal for a directive
Recital 2

Text proposed by the Commission	*Amendment*
(2) ***Principle 10 of*** the European Pillar of Social Rights[4]***, 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.	(2) ***On 17 November 2017,*** the European Pillar of Social Rights ***(the 'Pillar')*** [4] ***was*** proclaimed ***jointly*** by the European Parliament, the Council and the Commission ***as a response to*** social ***challenges in the Union. The Pillar sets out 20 principles, which are divided into three categories: equal opportunities and access to the labour market; fair working conditions; and social protection and inclusion. Principle No 10 of the Pillar*** provides ***for*** a high level of protection of ***workers'*** health and safety at work***. This should include*** the protection ***of workers*** from exposure to carcinogens and mutagens at the workplace.

[4] European Pillar of Social Rights, November 2017, available at: https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf

[4] European Pillar of Social Rights, November 2017, available at: https://ec.europa.eu/commission/sites/beta-political/files/social-summit-european-pillar-social-rights-booklet_en.pdf

Or. en

Amendment 3

Proposal for a directive
Recital 5

Text proposed by the Commission	*Amendment*
(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 ***socioeconomic*** 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.	(5) ***The amendments to Directive 2004/37/EC provided for by*** this Directive ***are intended to strengthen*** the protection of workers' health and safety at ***the*** workplace. ***They provide for the setting of*** new limit values in Directive 2004/37/EC***,*** in light of ***the latest*** available information, including new scientific and technical data and ***are*** 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.

Or. en

Amendment 4

Proposal for a directive
Recital 10

Text proposed by the Commission	*Amendment*
(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 ***shall*** apply.	(10) With regard to acrylonitrile, ***it may be difficult in the short term to comply with*** a limit value of 1 mg/m³ (***0,45 ppm***) and a short-term limit value of 4 mg/m³ (***1,8 ppm***)***. It is therefore appropriate to introduce*** a transitional period of four years after entry into force of this Directive***, after*** which ***those*** occupational exposure limit values ***should*** apply.

Or. en

Amendment 5

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 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].	(12) With regard to nickel compounds, ***it may be difficult to comply with the*** limit values of ***0,01 mg/m³*** for the respirable fraction and ***0,05 mg/m³*** for the inhalable fraction 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 ***those*** two groups of carcinogens should be aligned. ***It is*** therefore ***appropriate to introduce*** a transitional period until 17 January 2025***,*** during which a limit value of ***0,1 mg/m³*** for the inhalable fraction of the nickel compounds should apply. ***That*** transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU ***of the European Parliament and the Council***[6].
[6] Directive (EU) 2017/2398 of the European Parliament and of the Council of 12 December 2017 amending Directive	[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.

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. en

Amendment 6

Proposal for a directive
Recital 14

Text proposed by the Commission	*Amendment*
(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 be introduced***. From two years up to four years after entry into force, a transitional limit value of ***0.5 ppm*** (***1.65 mg/m³***) should apply.	(14) With regard to benzene, ***it may be difficult to comply with*** a revised limit value of ***0,2 ppm*** (***0,66 mg/m³***) in some sectors in the short term. ***It is therefore appropriate to introduce*** a transitional period of ***four*** years after entry into force of this Directive. From two years up to four years after entry into force, a transitional limit value of ***0,5 ppm*** (***1,65 mg/m³***) should apply.

Or. en

Amendment 7

Proposal for a directive
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) Exposure to hazardous medicinal products (HMPs) can result in adverse health effects in healthcare workers and patients, including both acute and chronic health effects, such as skin rashes, adverse reproductive outcomes (including infertility, spontaneous abortions, and congenital disorders), as well as leukaemia, breast cancer and other cancers. The substitution or replacement of HMPs is not normally an option as access to the best available treatments for

patients should not be jeopardised. Workers and patients can be protected from exposure to HMPs by the manufacture and use of such products in a closed system and by the use of engineering and administrative controls and proper protective equipment.

Or. en

Amendment 8

Proposal for a directive
Recital 14 b (new)

Text proposed by the Commission	*Amendment*
	(14b) HMPs are defined and listed in the National Institute for Occupational Safety and Health List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, of September 2016, as amended (NIOSH List). The NIOSH List includes antineoplastic, immunosuppressant and antiviral HMPs and their active substances. Those three pharmacotherapeutic groups of HMPs are primarily used to treat patients undergoing treatment for cancer, organ transplants, arthritis, human immunodeficiency viruses and hepatitis B and C and can have genotoxic, carcinogenic, mutagenic or reprotoxic properties. It is therefore important to protect workers and patients who are exposed to the HMPs listed in the NIOSH List in the context of the manufacture, preparation, administration or disposal of such products, of the provision of services related to cleaning, transport, laundry or waste disposal of, or of materials and surfaces contaminated by, such products, and of the personal care of patients who are treated with such products.

Or. en

Amendment 9

Proposal for a directive
Recital 14 c (new)

Text proposed by the Commission	*Amendment*
	(14c) To supplement and complement the inclusion of antineoplastic, immunosuppressant and antiviral HMPs and their active substances in Annex I to Directive 2004/37/EC, the Commission should, taking into account the latest developments and scientific knowledge, and after consulting the relevant stakeholders, including the social partners, issue guidelines to ensure the occupational safety of workers exposed to HMPs with respect to best practices for the handling of HMPs, surface, environmental and biological monitoring of occupational exposure to such products and the provision of information, education, training, and awareness-raising by employers. The Commission should also establish and regularly update a Union register, comprising a definition of HMPs and a list of antineoplastic, immunosuppressant and antiviral HMPs and their active substances.

Or. en

Amendment 10

Proposal for a directive
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) In implementing this Directive, Member States should avoid imposing administrative, financial and legal constraints in a way which would discourage the creation and development of small and medium-sized enterprises (SMEs). In that regard, Member States and relevant bodies at Union and national level are encouraged to provide

incentives, guidance and advice to microenterprises and SMEs to facilitate compliance with this Directive. In that context, the social partners are encouraged to conclude agreements, issue guidance and undertake other joint actions, which identify and develop best practices.

Or. en

Amendment 11

Proposal for a directive
Article 1 – paragraph -1 (new)
Directive 2004/37/EC
Article 18 b (new)

Text proposed by the Commission	*Amendment*
	-1. The following article is inserted in Directive 2004/37/EC:
	"Article 18b
	Commission guidelines and Union register
	By the fourth quarter of 2021, the Commission shall, on the basis of scientific data and after consulting the relevant stakeholders, including the social partners, issue guidelines with respect to at least the following:
	(a) best practices for the manufacture, preparation, administration and disposal of hazardous medicinal products;
	(b) surface, environmental and biological monitoring of occupational exposure to hazardous medicinal products;
	(c) the provision of information, education, training, information and awareness-raising by employers to prevent occupational exposure to hazardous medicinal products.
	By the deadline referred to in the first subparagraph, the Commission shall establish a Union register containing a

definition of hazardous medicinal products and a list of antineoplastic, immunosuppressant and antiviral hazardous medicinal products and their active substances. The Commission shall update that register on a regular basis.";

Or. en

Amendment 12

Proposal for a directive
Article 1 – paragraph -1 a (new)
Directive 2004/37/EC
Annex I – point 8 a (new)

Text proposed by the Commission	*Amendment*
	-1a. In Annex I to Directive 2004/37/EC, the following point is added:
	"8a. Work involving exposure to antineoplastic, immunosuppressant and antiviral hazardous medicinal products and their active substances*[*]*.
	****. National Institute for Occupational Safety and Health List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, September 2016, as amended.".***

Or. en

EXPLANATORY STATEMENT

Cancer is the first cause of work-related deaths in the European Union. According to the data, some 52% of annual occupational deaths are attributed to work-related cancers, compared to 24% to cardiovascular diseases and 22% to other diseases.

The Commission has made the fight against cancer one of its priorities for 2019-2024. Indeed, according to the Commission, 40 % of cancer cases in Europe can be prevented. Greater protection for workers, together with a reduction or elimination of work-related risks, goes in the right direction in terms of preventing workers' exposure to mutagenic or carcinogenic substances.

The Commission has already addressed the issue of occupational exposure to mutagens and carcinogens through the adoption of three proposals with a view to updating Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work – the first in May 2016, the second in January 2017 and the third in April 2018.

This is the fourth legislative proposal relating to the directive, and it seeks to establish new occupational exposure limits for three substances: acrylonitrile, nickel compounds and benzene.

Your rapporteur welcomed the Commission's proposal and the revision of the new occupational exposure limits. The aim of the new changes to the directive is to ensure a new level of occupational protection for more than one million workers across the EU in many different sectors, including the oil, textile, manufacturing, construction and chemical sectors. The distinction between respirable and inhalable fraction for nickel compounds is also to be welcomed, with different limit values given the different types of exposure and hazard.

Furthermore, the proposal allows for an appropriate transition period for companies, varying according to the substance, so that they can adapt to the new limit values adopted. Your rapporteur considered it important to take an approach that facilitates this transition for small and medium-sized enterprises and micro-enterprises. In attaining the new limit values, a specific approach must be taken for SMEs, which have limited financial and human capacity. Incentives, support and digital tools may be the right way of meeting the needs of these companies.

Lastly, your rapporteur considered it advisable to address the issue of hazardous medicinal products (HMPs) in an ambitious manner. Indeed, every year, more than 12.7 million healthcare workers in Europe, including 7.3 million nurses, are potentially exposed to dangerous drugs. The handling, preparation and administration of these drugs exposes healthcare workers to high health risks, which means that, according to studies, they are three times more likely to get cancer. That is why your rapporteur has opted not only to amend Annex 1 to the directive, in order to include HMPs, but has also called for the introduction of guidelines enabling the exchange of information and best practices between Member States and the establishment of an EU register, comprising a definition of HMPs and a regularly updated list of antineoplastic, immunosuppressant and antiviral HMPs and their active substances. Indeed, studies show that legislative measures are only effective if they are

properly accompanied by non-binding guidelines and explanatory measures.
Lastly, your rapporteur sought to reiterate Parliament's willingness also to address the issue of reprotoxic substances, which had already been discussed during previous revisions but was still deadlocked. In reopening this discussion, the hope is that co-legislators will be able to find an appropriate and balanced solution to this problem.