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AMENDMENTS

12 - 119

Draft opinion

Joëlle Mélin

(PE661.850v01-00)

Opinion on proposal for a directive amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work

Proposal for a directive

(COM(2020)0571 – C9-0301/2020 – 2020/0262(COD))

Amendment 12
Sirpa Pietikäinen

Proposal for a directive
Recital 1

Text proposed by the Commission

(1) Directive 2004/37/EC of the European Parliament and the Council⁴⁵ 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.

⁴⁵ 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).

Amendment

(1) Directive 2004/37/EC of the European Parliament and the Council⁴⁵ aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens **and reprotoxic substances** at the workplace. A consistent level of protection from the risks related to the occupational exposure to carcinogens and mutagens **and reprotoxic substances** 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.

⁴⁵ 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).

(This amendment applies throughout the text)

Or. en

Amendment 13
Manuel Bompard

Proposal for a directive
Recital 1

Text proposed by the Commission

(1) Directive 2004/37/EC of the European Parliament and the Council⁴⁵ 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.

⁴⁵ 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).

Amendment

(1) Directive 2004/37/EC of the European Parliament and the Council⁴⁵ aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens ***and reprotoxic substances*** at the workplace. A consistent level of protection from the risks related to the occupational exposure to carcinogens and mutagens ***and reprotoxic substances*** 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.

⁴⁵ 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).

(This amendment applies throughout the text)

Or. en

Amendment 14
Manuel Bompard

Proposal for a directive
Recital 1 a (new)

Text proposed by the Commission

Amendment

(1a) It is necessary to highlight the importance of protecting workers against exposure to carcinogens, mutagens and reprotoxic substances. In the workplace,

men and women are often exposed to a cocktail of substances, which can increase health risks, cause adverse effects on their reproductive systems and impaired fertility or infertility, and have a negative impact on foetal development and lactation. Substances which are toxic to reproduction are of very high concern and the organisation of workplace prevention should apply the same approach as for carcinogens and mutagens. As not all reprotoxic substances are threshold substances, it is of utmost importance to enlarge the scope of Directive 2004/37/EC to reprotoxic substances in order to bring it into line with Regulation (EC) 1907/2006 of the European Parliament and of the Council^{1a} and to better protect workers and their offspring and ensure the safer participation of women in the workplace.

^{1a} 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).

Or. en

Amendment 15
Sirpa Pietikäinen

Proposal for a directive
Recital 1 a (new)

Text proposed by the Commission

Amendment

(1a) Every worker has a right to a safe and healthy working environment. In order for the right to a safe and healthy working environment to be realised, the precautionary principle needs to be fully implemented with regard to carcinogenic substances;

Or. en

Amendment 16
Sirpa Pietikäinen

Proposal for a directive
Recital 1 b (new)

Text proposed by the Commission

Amendment

(1b) It is necessary to highlight the importance of protecting workers against exposure to carcinogens, mutagens and reprotoxic substances. In the workplace, men and women are often exposed to a cocktail of substances, which can increase health risks, cause adverse effects on their reproductive systems and impaired fertility or infertility, and have a negative impact on foetal development and lactation. Substances which are toxic to reproduction are of very high concern and the organisation of workplace prevention should apply the same approach as for carcinogens and mutagens. As not all reprotoxic substances are threshold substances, it is of utmost importance to enlarge the scope of Directive 2004/37/EC to reprotoxic substances in order to bring it into line with Regulation (EC) No 1907/2006 of the European Parliament and of the Council^{1a} and to better protect workers and their offspring and ensure the safer participation of women in the workplace.

^{1a} 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).

Or. en

Amendment 17
Sirpa Pietikäinen

Proposal for a directive
Recital 1 c (new)

Text proposed by the Commission

Amendment

(1c) As exposure to endocrine disrupting chemicals (EDCs) has been associated with variety of rare cancers, impaired reproduction, osteoporosis, thyroid disease, metabolic illnesses, birth defects, neurodevelopmental disorders and numerous other diseases or impairments, it is vital to protect EU citizens and workers from their harmful effects. The Commission should therefore provide science-based, reliable, clear and comprehensive information on EDCs to Union citizens through a portal, as promised in its Communication COM(2018)0734^{1a} and the present regulations on EDCs^{2a}, to protect workers from the carcinogenic impacts of EDCs.

^{1a} Communication from the Commission

to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - Towards a Comprehensive European Union Framework on Endocrine Disruptors (COM(2018)734)

2^a Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products and Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

Or. en

Amendment 18 **Manuel Bompard**

Proposal for a directive **Recital 2**

Text proposed by the Commission

(2) Principle 10 of the European Pillar of Social Rights⁴⁶, 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.

⁴⁶ 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

Amendment

(2) Principle 10 of the European Pillar of Social Rights⁴⁶, 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 **and reprotoxic substances** at the workplace.

⁴⁶ 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

Amendment 19
Sirpa Pietikäinen

Proposal for a directive
Recital 2

Text proposed by the Commission

(2) Principle 10 of the European Pillar of Social Rights⁴⁶, 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.

⁴⁶ 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

Amendment

(2) Principle 10 of the European Pillar of Social Rights⁴⁶, 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, mutagens *and reprotoxic substances* at the workplace.

⁴⁶ 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

Amendment 20
Sirpa Pietikäinen

Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission

Amendment

(2a) *Hazardous Medicinal Products can cause adverse health effects such as certain types of cancer (breast cancer, haematopoietic cancer) and reproductive disorders (infertility, miscarriages, congenital malformations) in workers*

who are exposed to them through work resulting from the preparation, administration, or disposal of hazardous drugs. Hazardous Medicinal Products thus affect workers that handle such agents, both directly and indirectly. They include healthcare workers using cytostatic drugs to treat cancer patients in hospitals or at home but also workers in services related to cleaning, transport, laundry, or waste disposal of hazardous drugs or of material contaminated by such drugs. It is therefore important to protect all exposed workers by including relevant pharmacotherapeutic groups of Hazardous Medicinal Products in Annex I of the Directive. The elimination and substitution obligations defined in Article 4 do not apply to Hazardous Medicinal Products because these substances are needed and essential to treat patients. The other provisions, in particular Articles 5 to 18a, are therefore the added value of the Directive to protect exposed workers.

Or. en

Amendment 21
Manuel Bompard

Proposal for a directive
Recital 3

Text proposed by the Commission

(3) Binding occupational exposure limit values are 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.

Amendment

(3) Binding occupational exposure limit values are 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 **or reprotoxic substances** for which the available information, including scientific and technical data, make this possible.

Amendment 22
Sirpa Pietikäinen

Proposal for a directive
Recital 3

Text proposed by the Commission

(3) Binding occupational exposure limit values are 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.

Amendment

(3) Binding occupational exposure limit values are 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 ***or reprotoxic substances*** for which the available information, including scientific and technical data, make this possible.

Amendment 23
Joanna Kopcińska

Proposal for a directive
Recital 3

Text proposed by the Commission

(3) Binding occupational exposure limit values are 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.

Amendment

(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.

Amendment 24
Manuel Bompard

Proposal for a directive
Recital 4

Text proposed by the Commission

(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.

Amendment

(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, mutagens **and reprotoxic substances** at the workplace, the prevention or reduction of workers' exposure to carcinogens, mutagens **or reprotoxic chemicals** 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, mutagen **or reprotoxic substance** 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.

Or. en

Amendment 25
Sirpa Pietikäinen

Proposal for a directive
Recital 4

Text proposed by the Commission

(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

Amendment

(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, mutagens **and**

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.

reprotoxic substances at the workplace, the prevention or reduction of workers' exposure to carcinogens, mutagens *or reprotoxic chemicals* 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, mutagen *or reprotoxic substance* 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.

Or. en

Amendment 26
Joanna Kopcińska

Proposal for a directive
Recital 5

Text proposed by the Commission

(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

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, ***also differentiating and analysing impacts and available infrastructures in different regions and member states of the Union.*** 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

and mutagens.

valuable for any future work to limit risks from occupational exposure to carcinogens and mutagens.

Or. en

Justification

Infrastructural market realities differ greatly throughout the Union and a thorough impact assessment ought to be sufficiently nuanced.

Amendment 27 **Manuel Bompard**

Proposal for a directive **Recital 5**

Text proposed by the Commission

(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.

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 ***using a risk-based methodology. All*** available information ***should be considered***, including new scientific and technical data, a thorough assessment of the socioeconomic impact and ***the*** 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, mutagens ***and reprotoxic substances***.

Or. en

Amendment 28
Sirpa Pietikäinen

Proposal for a directive
Recital 5

Text proposed by the Commission

(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.

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 **using a risk-based methodology. All** available information **should be considered**, including new scientific and technical data, a thorough assessment of the socioeconomic impact and **the** 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, mutagens **and reprotoxic substances**.

Or. en

Amendment 29
Manuel Bompard

Proposal for a directive
Recital 6

Text proposed by the Commission

(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

Amendment

(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.

hours time-weighted average (long-term exposure limit values) and, for certain carcinogens, mutagens *or 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.

Or. en

Amendment 30 **Sirpa Pietikäinen**

Proposal for a directive **Recital 6**

Text proposed by the Commission

(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.

Amendment

(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, mutagens *or reprotoxic chemicals* 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.

Or. en

Amendment 31 **Joanna Kopcińska**

Proposal for a directive **Recital 7**

Text proposed by the Commission

(7) It is also necessary to consider other absorption pathways than inhalation

Amendment

(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.

of all carcinogens and mutagens, including the possibility of uptake through the skin, in order to ensure the best possible level of protection. ***Encourages the Commission, in close cooperation with the Member States and relevant authorities to continue their close cooperation with research centers, academia and other relevant stakeholders, to ensure the most up to date information available.***

Or. en

Amendment 32
Manuel Bompard

Proposal for a directive
Recital 7

Text proposed by the Commission

(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.

Amendment

(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens, mutagens ***and reprotoxic substances***, including the possibility of uptake through the skin, in order to ensure the best possible level of protection.

Or. en

Amendment 33
Sirpa Pietikäinen

Proposal for a directive
Recital 7

Text proposed by the Commission

(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

Amendment

(7) It is also necessary to consider other absorption pathways than inhalation of all carcinogens, mutagens ***and reprotoxic substances***, including the possibility of uptake through the skin, in order to ensure the best possible level of

protection.

protection.

Or. en

Amendment 34
Sirpa Pietikäinen

Proposal for a directive
Recital 7 a (new)

Text proposed by the Commission

Amendment

(7a) In the workplace, workers are often exposed to a cocktail of hazardous substances, which can increase risks and cause adverse health effects. In case of combined exposure to substances acting by the same mode of action and/or at the same target cell or tissue, it is necessary to adapt the implementation of their eventual limit values to take into account the combined effects.

Or. en

Amendment 35
Manuel Bompard

Proposal for a directive
Recital 7 a (new)

Text proposed by the Commission

Amendment

(7a) In the workplace, workers are often exposed to a cocktail of hazardous substances, which can increase risks and cause adverse health effects. In case of combined exposure to substances acting by the same mode of action and/or at the same target cell or tissue, it is necessary to adapt the implementation of their eventual limit values to take into account the combined effects.

Or. en

Amendment 36
Joanna Kopcińska

Proposal for a directive
Recital 10

Text proposed by the Commission

(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.

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 **at least** four years after entry into force of this Directive should be introduced from which these Occupational Exposure Limit (OEL) values shall apply, **allowing for full adaptation in all member states**.

Or. en

Amendment 37
Joanna Kopcińska

Proposal for a directive
Recital 12

Text proposed by the Commission

(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

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 **mining**, smelting, **welding, casting, and** refineries. 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

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/EU⁴⁸.

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/EU⁴⁸.

⁴⁸ 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>.

⁴⁸ 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. en

Amendment 38 **Joanna Kopcińska**

Proposal for a directive **Recital 13**

Text proposed by the Commission

(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 biomonitoring.

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 ***and has in particular been found to also be a cause of various types of leukemia***. 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.

Or. en

Amendment 39
Manuel Bompard

Proposal for a directive
Recital 13

Text proposed by the Commission

(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 biomonitoring.

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 ***no later than 1 January 2030 in accordance with the ACSH opinion*** and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, ***also*** agreed on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of biomonitoring.

Or. en

Amendment 40
Sirpa Pietikäinen

Proposal for a directive
Recital 13

Text proposed by the Commission

(13) Benzene meets the criteria for classification as carcinogenic (category 1A) in accordance with Regulation (EC) No 1272/2008 and is therefore carcinogen

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 biomonitoring.

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 ***no later than 1 January 2030 in accordance with the ACSH opinion*** and it is appropriate to keep the skin notation. The ACSH, based on the RAC opinion, ***also*** agreed on the usefulness of the biomonitoring for benzene. This should be considered when developing guidance on the practical use of biomonitoring.

Or. en

Amendment 41
Manuel Bompard

Proposal for a directive
Recital 14

Text proposed by the Commission

(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.

Amendment

(14) With regard to benzene, a revised limit value of **0.05 ppm (0.16 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.

Or. en

Amendment 42
Manuel Bompard

Proposal for a directive
Recital 14 a (new)

(14a) Cobalt and cobalt compounds meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008^{1a} and are therefore carcinogens within the meaning of Directive 2004/37/EC^{1b}. 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 cobalt and cobalt 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 cobalt and its compounds under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.

^{1a} 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

^{1b} 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)

Or. en

Amendment 43
Sirpa Pietikäinen

Proposal for a directive
Recital 14 a (new)

Text proposed by the Commission

Amendment

(14a) Cobalt and cobalt compounds meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008^{1a} and are therefore carcinogens within the meaning of Directive 2004/37/EC^{1b}. 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 cobalt and cobalt 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 cobalt and its compounds under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.

^{1a} 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

^{1b} 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)

Or. en

Amendment 44
Manuel Bompard

Proposal for a directive
Recital 14 b (new)

Text proposed by the Commission

Amendment

(14b) Hazardous Medicinal Products can cause adverse health effects such as certain types of cancer (breast cancer, haematopoietic cancer) and reproductive disorders (infertility, miscarriages, congenital malformations) in workers who are exposed to them through work resulting from the preparation, administration, or disposal of hazardous drugs. Hazardous Medicinal Products thus affect workers that handle both, directly and indirectly, such agents. They include healthcare workers using cytostatic drugs to treat cancer patients in hospitals or at home but also workers in services related to cleaning, transport, laundry, or waste disposal of hazardous drugs or of material contaminated by such drugs. It is therefore important to protect all exposed workers by including relevant pharmacotherapeutic groups of Hazardous Medicinal Products in Annex I of the Directive. The elimination and substitution obligations defined in Article 4 do not apply to Hazardous Medicinal Products because these substances are needed and essential to treat patients. The other provisions, in particular Articles 5 to 18a, are therefore the added value of the Directive to protect exposed workers.

Or. en

Amendment 45
Sirpa Pietikäinen

Proposal for a directive
Recital 17

Text proposed by the Commission

(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.

Amendment

(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, mutagens *or reprotoxic substances* 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.

Or. en

Amendment 46
Manuel Bompard

Proposal for a directive
Recital 17

Text proposed by the Commission

(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

Amendment

(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, mutagens *or reprotoxic substances* 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,

go beyond what is necessary in order to achieve that objective.

this Directive does not go beyond what is necessary in order to achieve that objective.

Or. en

Amendment 47
Joanna Kopcińska

Proposal for a directive
Recital 18

Text proposed by the Commission

(18) Given that 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.

Amendment

(18) Given that this Directive concerns the protection of the health and safety of workers at their workplace, it should be transposed within **four** years of the date of its entry into force, **allowing for another two years of transitional phase for all member states to adapt accordingly.**

Or. en

Amendment 48
Manuel Bompard

Proposal for a directive
Article -1 (new) – point 1
Directive 2004/37/EC
Title

Present text

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)

Amendment

(-1a) 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)

Amendment 49
Sirpa Pietikäinen

Proposal for a directive
Article -1 (new)
Directive 2004/37/EC
Title

Present text

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)

Amendment

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)

Amendment 50
Manuel Bompard

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

Present text

1. This Directive has as its aim the protection of 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.

Amendment

(-1a) Article 1, paragraph 1, sub paragraph 1 is amended as follows:

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

Amendment 51
Sirpa Pietikäinen

Proposal for a directive

Article -1 a (new)

Directive 2004/37/EC

Article 1 – paragraph 1 – subparagraph 1

Present text

1. This Directive has as its aim the protection of 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.

Amendment

(-1a) Article 1, paragraph 1, subparagraph 1 is amended as follows:

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

Or. en

Amendment 52
Sirpa Pietikäinen

Proposal for a directive

Article -1 b (new)

Directive 2004/37/EC

Article 2 – paragraph 1 – point (ba) (new)

Text proposed by the Commission

(ba)

'reprotoxic substance' means: a substance or mixture which meets the criteria for being classified as toxic to reproduction category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008;

Amendment

(-1b) In Article 2, the following point is added:

'reprotoxic substance' means: a substance or mixture which meets the criteria for being classified as toxic to reproduction category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008;

Or. en

Amendment 53
Manuel Bompard

Proposal for a directive

Article -1 b (new)

Directive 2004/37/EC

Article 2 – paragraph 1 – point (c)

Present text

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

Amendment

(3) Article 2, point (c) is amended as follows:

(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 to this Directive.

Or. en

Amendment 54

Sirpa Pietikäinen

Proposal for a directive

Article -1 c (new)

Directive 2004/37/EC

Article 2 – paragraph 1 – point (c)

Present text

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

Amendment

(3) Article 2, point (c) is amended as follows:

(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 to this Directive.

Or. en

Amendment 55
Manuel Bompard

Proposal for a directive

Article -1 c (new)

Directive 2004/37/EC

Article 2 – paragraph 1 – point (ca) (new)

Text proposed by the Commission

Amendment

(-1 c) In Article 2, the following point is added:

"(ca) 'risk-based limit value' means a limit value set at an exposure level corresponding to a risk of developing an adverse health effect (e.g. cancer) in the range between an upper and lower risk level. These risk levels are to be set out in accordance with the procedure laid down in Article 137(2) of the Treaty."

Or. en

Amendment 56
Sirpa Pietikäinen

Proposal for a directive

Article -1 d (new)

Directive 2004/37/EC

Article 2 – paragraph 1 – point (ca) (new)

Text proposed by the Commission

Amendment

(-1 d) In Article 2, the following point is added:

"(ca) 'risk-based limit value' means a limit value set at an exposure level corresponding to a risk of developing an adverse health effect (e.g. cancer) in the range between an upper and a lower risk level. These risk levels are to be set out in accordance with the procedure laid down in Article 137(2) of the Treaty."

Or. en

Amendment 57
Manuel Bompard

Proposal for a directive

Article -1 d (new)

Directive 2004/37/EC

Article 2 – paragraph 1 – point (cb) (new)

Text proposed by the Commission

Amendment

(-1 d) In Article 2, the following point is added:

"(cb) 'reprotoxic substances' means all substances or mixtures which meet the criteria for being classified as toxic to reproduction category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008."

Or. en

Amendment 58
Manuel Bompard

Proposal for a directive

Article -1 e (new)

Directive 2004/37/EC

Article 3 – paragraph 1

Present text

Amendment

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

(-1 e) Article 3, paragraph 1 is amended as follows:

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.

Or. en

Amendment 59
Sirpa Pietikäinen

Proposal for a directive
Article -1 e (new)
Directive 2004/37/EC
Article 3 – paragraph 1

Present text

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

Amendment

(-1 e) Article 3, paragraph 1 is amended as follows:

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.

Or. en

Amendment 60
Manuel Bompard

Proposal for a directive
Article -1 f (new)
Directive 2004/37/EC
Article 3 – paragraph 2 – subparagraph 1

Present text

In the case of any activity likely to involve a risk of exposure to carcinogens *or* mutagens, 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.

Amendment

(-1 f) Article 3, paragraph 2, subparagraph 1 is amended as follows:

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.

Or. en

Amendment 61
Sirpa Pietikäinen

Proposal for a directive

Article -1 f (new)

Directive 2004/37/EC

Article 3 – paragraph 2 – subparagraph 1

Present text

In the case of any activity likely to involve a risk of exposure to carcinogens *or* mutagens, 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.

Amendment

(-1 f) Article 3, paragraph 2, subparagraph 1 is amended as follows:

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.

Or. en

Amendment 62
Manuel Bompard

Proposal for a directive

Article -1 g (new)

Directive 2004/37/EC

Article 3 – paragraph 2 – subparagraph 2

Present text

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

Amendment

(-1 g) Article 3, paragraph 2, subparagraph 2 is amended as follows:

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*.

Or. en

Amendment 63
Sirpa Pietikäinen

Proposal for a directive

Article -1 g (new)

Directive 2004/37/EC

Article 3 – paragraph 2 – subparagraph 2

Present text

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

Amendment

(-1 g) Article 3 paragraph 2, subparagraph 2 is amended as follows:

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*.

Or. en

Amendment 64
Sirpa Pietikäinen

Proposal for a directive

Article -1 h (new)

Directive 2004/37/EC

Article 3 – paragraph 4

Present text

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 *or* mutagens.

Amendment

(-1 h) Article 3, paragraph 4 is amended as follows:

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*.

Or. en

Amendment 65
Manuel Bompard

Proposal for a directive

Article -1 h (new)

Directive 2004/37/EC

Article 3 – paragraph 4

Present text

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 *or* mutagens.

Amendment

(-1 h) Article 3, paragraph 4 is amended as follows:

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*.

Or. en

Amendment 66
Manuel Bompard

Proposal for a directive

Article -1 i (new)

Directive 2004/37/EC

Article 4 – paragraph 1

Present text

1. The employer shall reduce the use of a carcinogen *or* mutagen 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.

Amendment

(-1 i) Article 4, paragraph 1 is amended as follows:

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.

Amendment 67
Sirpa Pietikäinen

Proposal for a directive
Article -1 i (new)
Directive 2004/37/EC
Article 4 – paragraph 1

Present text

1. The employer shall reduce the use of a carcinogen *or* mutagen 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.

Amendment

(-1 i) Article 4, paragraph 1 is amended as follows:

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.

Amendment 68
Manuel Bompard

Proposal for a directive
Article -1 j (new)
Directive 2004/37/EC
Article 4 – paragraph 2

Present text

2. The employer shall, upon request, submit the findings of his investigations to the relevant authorities.

Amendment

(-1 j) Article 4, paragraph 2 is amended as follows:

2. The employer shall, upon request, submit the findings of his investigations to the relevant authorities *and exposed workers*.

Amendment 69
Sirpa Pietikäinen

Proposal for a directive

Article -1 j (new)

Directive 2004/37/EC

Article 5 – paragraph 2

Present text

2. Where it is not technically possible to replace the carcinogen *or* mutagen 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 *or* mutagen is, in so far as is technically possible, manufactured and used in a closed system.

Amendment

(-1 j) Article 5, paragraph 2 is amended as follows:

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.

Or. en

Amendment 70
Manuel Bompard

Proposal for a directive

Article -1 k (new)

Directive 2004/37/EC

Article 5 – paragraph 2

Present text

2. Where it is not technically possible to replace the carcinogen *or* mutagen 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 *or* mutagen is, in so far as is technically

Amendment

(-1 k) Article 5, paragraph 2 is amended as follows:

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,

possible, manufactured and used in a closed system.

mutagen or reprotoxic substance is, in so far as is technically possible, manufactured and used in a closed system.

Or. en

Amendment 71
Manuel Bompard

Proposal for a directive
Article -1 l (new)
Directive 2004/37/EC
Article 5 – paragraph 4

Present text

4. Exposure shall not exceed the limit value of a carcinogen as set out in Annex III.

Amendment

(-1 l) Article 5, paragraph 4 is amended as follows:

4. Exposure shall not exceed the limit value of a carcinogen, mutagen or reprotoxic substance as set out in Annex III. ***In case of combined exposure to substances acting by the same mode of action and/or at the same target cell or tissue, the implementation of their eventual limit values shall be adapted to take into account the combined effects.***

Or. en

Amendment 72
Sirpa Pietikäinen

Proposal for a directive
Article -1 k (new)
Directive 2004/37/EC
Article 5 – paragraph 4

Present text

4. Exposure shall not exceed the limit value of a carcinogen as set out in Annex

Amendment

(-1 k) Article 5, paragraph 4 is amended as follows:

4. Exposure shall not exceed the limit value of a substance as set out in Annex

III.

III. *In case of combined exposure to substances acting by the same mode of action and/or at the same target cell or tissue, the implementation of their eventual limit values shall be adapted to take into account the combined effects.*

Or. en

**Amendment 73
Sirpa Pietikäinen**

**Proposal for a directive
Article -1 l (new)**

Directive 2004/37/EC

Article 5 – paragraph 5 – introductory part

Present text

5. Wherever a carcinogen, mutagen *or* reprotoxic substance is used, the employer shall apply all the following measures:

Amendment

(-1 l) Article 5, paragraph 5, introductory part is amended as follows:

5. Wherever a carcinogen, mutagen *or reprotoxic substance is used*, the employer shall apply all the following measures:

Or. en

**Amendment 74
Manuel Bompard**

**Proposal for a directive
Article -1 m (new)**

Directive 2004/37/EC

Article 5 – paragraph 5 – introductory part

Present text

5. Wherever a carcinogen, mutagen *or* reprotoxic substance is used, the employer shall apply all the following measures:

Amendment

(-1 m) Article 5, paragraph 5, introductory part is amended as follows:

5. Wherever a carcinogen, mutagen *or reprotoxic substance is used*, the employer shall apply all the following measures:

Or. en

Amendment 75
Sirpa Pietikäinen

Proposal for a directive

Article -1 m (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point (a)

Present text

(a) limitation of the quantities of a carcinogen *or* mutagen at the place of work;

Amendment

(-1 m) Article 5, paragraph 5, point (a) is amended as follows:

(a) limitation of the quantities of a carcinogen, mutagen *or reprotoxic substance* at the place of work;

Or. en

Amendment 76
Manuel Bompard

Proposal for a directive

Article -1 n (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point (a)

Present text

(a) limitation of the quantities of a carcinogen *or* mutagen at the place of work;

Amendment

(-1 n) Article 5, paragraph 5, point (a) is amended as follows:

(a) limitation of the quantities of a carcinogen, mutagen *or reprotoxic substance* at the place of work;

Or. en

Amendment 77
Sirpa Pietikäinen

Proposal for a directive

Article -1 n (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point (c)

Present text

(c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens *or* mutagens into the place of work;

Amendment

(-1 n) Article 5, paragraph 5, point (c) is amended as follows:

(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;

Or. en

Amendment 78
Manuel Bompard

Proposal for a directive

Article -1 o (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point (c)

Present text

(c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens *or* mutagens into the place of work;

Amendment

(-1 o) Article 5, paragraph 5, point (c) is amended as follows:

(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;

Or. en

Amendment 79
Manuel Bompard

Proposal for a directive

Article -1 o (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point (d)

Present text

(d) evacuation of carcinogens *or* mutagens 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;

Amendment

(-1 o) Article 5, paragraph 5, point (d) is amended as follows:

(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;

Or. en

Amendment 80
Sirpa Pietikäinen

Proposal for a directive

Article -1 o (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point (d)

Present text

(d) evacuation of carcinogens *or* mutagens 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;

Amendment

(-1 o) Article 5, paragraph 5, point (d) is amended as follows:

(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;

Or. en

Amendment 81
Sirpa Pietikäinen

Proposal for a directive

Article -1 p – (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point (e)

Present text

(e) use of existing appropriate procedures for the measurement of carcinogens *or* mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;

Amendment

(-1 p) Article 5, paragraph 5, point (e) is amended as follows:

(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;

Or. en

Amendment 82
Manuel Bompard

Proposal for a directive

Article -1 q– (new)

Directive 2004/37/EC

Article 5 –paragraph 5 – point (e)

Present text

(e) use of existing appropriate procedures for the measurement of carcinogens *or* mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;

Amendment

(-1 q) Article 5, paragraph 5, point (e) is amended as follows:

(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;

Or. en

Amendment 83
Sirpa Pietikäinen

Proposal for a directive

Article -1 q (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point (j)

Present text

Amendment

(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 *or* mutagens;

(-1 q) Article 5, paragraph 5, point (j) is amended as follows:

(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*;

Or. en

**Amendment 84
Manuel Bompard**

Proposal for a directive

Article -1 r (new)

Directive 2004/37/EC

Article 5 – paragraph 5 – point (j)

Present text

Amendment

(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 *or* mutagens;

(-1 r) Article 5, paragraph 5, point (j) is amended as follows:

(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*;

Or. en

**Amendment 85
Manuel Bompard**

Proposal for a directive

Article -1 s (new)

Directive 2004/37/EC

Article 6 – title

Present text

Amendment

Information for the competent authority

(-1 s) Article 6, title is amended as follows:

Information for the competent authority
and exposed workers

Or. en

Amendment 86
Manuel Bompard

Proposal for a directive

Article -1 t (new)

Directive 2004/37/EC

Article 6 – introductory part

Present text

Amendment

Where the results of the assessment referred to in Article 3(2) reveal a risk to workers' health or safety, employers shall, when requested, make available to the competent authority appropriate information on:

(-1 t) Article 6, introductory part is amended as follows:

Where the results of the assessment referred to in Article 3(2) reveal a risk to workers' health or safety, employers shall, when requested, make available to the competent authority ***and exposed workers*** appropriate information on:

Or. en

Amendment 87
Manuel Bompard

Proposal for a directive

Article -1 u (new)

Directive 2004/37/EC

Article 6 – paragraph 1 – point (a)

Present text

Amendment

(a) the activities and/or industrial processes

(-1 u) Article 6, point (a) is amended as follows:

(a) the activities and/or industrial

carried out, including the reasons for which carcinogens or mutagens are used;

processes carried out, including the reasons for which carcinogens, mutagens *or reprotoxic substances* are used;

Or. en

Amendment 88
Sirpa Pietikäinen

Proposal for a directive

Article -1 r (new)

Directive 2004/37/EC

Article 6 – paragraph 1 – point (a)

Present text

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

Amendment

(-1 r) Article 6, point (a) is amended as follows:

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

Or. en

Amendment 89
Sirpa Pietikäinen

Proposal for a directive

Article -1 s (new)

Directive 2004/37/EC

Article 6 – paragraph 1 – point (b)

Present text

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

Amendment

(-1 s) Article 6, point (b) is amended as follows:

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

Or. en

Amendment 90
Manuel Bompard

Proposal for a directive

Article -1 v (new)

Directive 2004/37/EC

Article 6 – paragraph 1 – point (b)

Present text

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

Amendment

(-1 v) Article 6, point (b) is amended as follows:

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

Or. en

Amendment 91
Manuel Bompard

Proposal for a directive

Article -1 w (new)

Directive 2004/37/EC

Article 10 – paragraph 1 – introductory part

Present text

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

Amendment

(-1 w) Article 10, paragraph 1, introductory part is amended as follows:

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:

Or. en

Amendment 92
Sirpa Pietikäinen

Proposal for a directive

Article -1 t (new)

Directive 2004/37/EC

Article 10 – paragraph 1 – introductory part

Present text

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

Amendment

(-1 t) Article 10, paragraph 1, introductory part is amended as follows:

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:

Or. en

Amendment 93

Manuel Bompard

Proposal for a directive

Article -1 x (new)

Directive 2004/37/EC

Article 10 – paragraph 1 – point (a)

Present text

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

Amendment

(-1 x) Article 10, paragraph 1, point (a) , is amended as follows:

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

Or. en

Amendment 94

Sirpa Pietikäinen

Proposal for a directive

Article -1 u

Directive 2004/37/EC

Article 10 – paragraph 1 – point (a)

Present text

Amendment

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

(-1 u) Article 10, paragraph 1, point (a) is amended as follows:

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

Or. en

Amendment 95
Sirpa Pietikäinen

Proposal for a directive
Article -1 v (new)
Directive 2004/37/EC
Article 11 – paragraph 2

Present text

Amendment

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

(-1 v) Article 11, paragraph 2 is amended as follows:

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.

Or. en

Amendment 96
Manuel Bompard

Proposal for a directive
Article -1 y (new)
Directive 2004/37/EC
Article 11 – paragraph 2

Present text

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

Amendment

(-1 y) Article 11, paragraph 2 is amended as follows:

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.

Or. en

Amendment 97
Manuel Bompard

Proposal for a directive

Article -1 z (new)

Directive 2004/37/EC

Article 14 – paragraph 3 –subparagraph 1

Present text

If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens *or* mutagens, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.

Amendment

(-1 z) Article 14, paragraph 3, subparagraph 1 is amended as follows:

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*, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.

Or. en

Amendment 98
Sirpa Pietikäinen

Proposal for a directive

Article -1 w (new)

Directive 2004/37/EC

Article 14 – paragraph 3 – subparagraph 1

Present text

If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens *or* mutagens, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.

Amendment

(-1 w) Article 14, paragraph 3, subparagraph 1 is amended as follows:

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*, the doctor or authority responsible for the health surveillance of workers may require other workers who have been similarly exposed to undergo health surveillance.

Or. en

Amendment 99

Manuel Bompard

Proposal for a directive

Article -1 aa (new)

Directive 2004/37/EC

Article 14 – paragraph 8 – subparagraph 1

Present text

All cases of cancer identified in accordance with national law *or* practice as resulting from occupational exposure to a carcinogen *or* mutagen shall be notified to the competent authority.

Amendment

(-1 aa) Article 14, paragraph 8, subparagraph 1 is amended as follows:

All cases of cancer or reproductive disorder identified in accordance with national laws *and/or* practice as resulting from occupational exposure to a carcinogen, mutagen *or reprotoxic substance* shall be notified to the competent authority.

Or. en

Amendment 100

Sirpa Pietikäinen

Proposal for a directive

Article -1 x (new)

Directive 2004/37/EC

Article 14 – paragraph 8 – subparagraph 1

Present text

All cases of cancer identified in accordance with national law *or* practice as resulting from occupational exposure to a carcinogen *or* mutagen shall be notified to the competent authority.

Amendment

(-1 x) Article 14, paragraph 8, subparagraph 1 is amended as follows:

All cases of cancer or reproductive disorder identified in accordance with national laws *and/or* practice as resulting from occupational exposure to a carcinogen, mutagen *or reprotoxic substance* shall be notified to the competent authority.

Or. en

Amendment 101

Sirpa Pietikäinen

Proposal for a directive

Article -1 y (new)

Directive 2004/37/EC

Article 15 – paragraph 2a (new)

Text proposed by the Commission

Amendment 102

Manuel Bompard

Amendment

(-1 y) In Article 15, the following paragraph is added:

"2a. The Member States shall provide the Commission with the information referred to in Article 14(8) of this Directive as part of the implementation reports referred to in Article 17a of Council Directive 89/391/EEC."

Or. en

Proposal for a directive
Article -1 ab (new)
Directive 2004/37/EC
Article 15 – paragraph 2a (new)

Text proposed by the Commission

Amendment

(-1 ab) In Article 15, the following paragraph is added:

"2a. The Member States shall provide the Commission with the information referred to in Article 14(8) of this Directive as part of the implementation reports referred to in Article 17a of Directive 89/391/EEC."

Or. en

Amendment 103
Manuel Bompard

Proposal for a directive
Article -1 ac (new)
Directive 2004/37/EC
Article 16 – paragraph 1

Text proposed by the Commission

Amendment

(-1 ac) Article 16, paragraph 1 is amended as follows:

1. The Council shall, in accordance with the procedure laid down in Article 137(2) of the Treaty, set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens or mutagens for which this is possible, and, where necessary, other directly related provisions.

1. The Council shall, in accordance with the procedure laid down in Article 137(2) of the Treaty, set out risk-based limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens or mutagens ***or reprotoxic substances*** for which this is possible, and, where necessary, other directly related provisions.

Or. en

Amendment 104
Sirpa Pietikäinen

Proposal for a directive

Article -1 z (new)

Directive 2004/37/EC

Article 16 – paragraph 1

Text proposed by the Commission

1. The Council shall, in accordance with the procedure laid down in Article 137(2) of the Treaty, set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens **or** mutagens for which this is possible, and, where necessary, other directly related provisions.

Amendment

(-1 z) Article 16, paragraph 1 is amended as follows:

1. The Council shall, in accordance with the procedure laid down in Article 137(2) of the Treaty, set out **risk-based** 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.

Or. en

Amendment 105
Sirpa Pietikäinen

Proposal for a directive

Article -1 aa (new)

Directive 2004/37/EC

Article 16 – paragraph 1

Present text

1. The Council shall, in accordance with the procedure laid down in Article 137(2) of the Treaty, set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens **or** mutagens for which this is possible, and, where necessary, other directly related provisions.

Amendment

(-1 aa) Article 16, paragraph 1 is amended as follows:

1. The Council shall, in accordance with the procedure laid down in Article 137(2) of the Treaty, 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.

Or. en

Amendment 106
Manuel Bompard

Proposal for a directive
Article -1 ad (new)
Directive 2004/37/EC
Article 16 a (new)

Text proposed by the Commission

Amendment

(-1 ad) the following Article is inserted:

"Article 16a

Legal requirements and transparency

1. No later than 1 June 2022, the Commission shall, taking into account the existing methodology to set limit values for carcinogens, mutagens or reprotoxic substances in some Member States and the opinion of the ACSH, define the upper and lower risk levels referred to in Article

2. No later than 1 December 2022, the Commission shall, after appropriate consultation with relevant stakeholders, prepare EU guidelines on the methodology establishing risk-based limit values under this Directive. These guidelines shall be published on the website of the European Agency for Safety and Health at Work (EU-OSHA).

2. No later than 1 March 2022, the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation with relevant stakeholders, in particular health practitioners and health professionals, prepare a definition of Hazardous Medicinal Products and establish the list of substances covered by the related entry in Annex I. This list shall be reviewed every two years. No later than 1 December 2022, the Commission shall,

after appropriate consultation with relevant stakeholders, prepare EU guidelines and standards of practice for the preparation, administration, and disposal of Hazardous Medicinal Products. These non-legislative tools shall be published on the website of the European Agency for Safety and Health at Work (EU-OSHA).

3. No later than 1 December 2022, the Commission shall, taking into account the latest developments in scientific knowledge, the opinion of RAC and after appropriate consultation with relevant stakeholders, prepare EU guidelines on how the implementation of the limit values referred to in Article 5(4) should be adapted in case of combined exposure. These guidelines shall be published on the website of the European Agency for Safety and Health at Work (EU-OSHA).

4. No later than 1 January 2028, the Commission shall, taking into account the RAC opinion of 2018 and the latest developments in scientific knowledge, start evaluating the feasibility of a further reduction of the limit value for Benzene. No later than 1 January 2030, the Commission shall propose, where appropriate, necessary amendments and modifications related to that substance."

Or. en

Amendment 107
Sirpa Pietikäinen

Proposal for a directive
Article -1 ab (new)
Directive 2004/37/EC
Article 17 – paragraph 1 – subparagraph 1

Present text

Amendment

(-1 ab) Article 17, paragraph 1 is

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 or mutagens.

amended as follows:

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*.

Or. en

Amendment 108
Manuel Bompard

Proposal for a directive
Article -1 ae (new)
Directive 2004/37/EC
Article 17 – paragraph 1

Present text

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 *or* mutagens.

Amendment

(-1 ae) Article 17, paragraph 1 is amended as follows:

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 and reprotoxic substances*.

Or. en

Amendment 109
Sirpa Pietikäinen

Proposal for a directive
Article -1 ac (new)
Directive 2004/37/EC
Article 18a – paragraph 4 a (new)

Text proposed by the Commission

Amendment

(-1 ac) In Article 18a, the following paragraph is added:

"No later than 1 January 2028, the Commission shall, taking into account the RAC opinion of 2018 and the latest developments in scientific knowledge, start evaluating the feasibility of a further reduction of the limit value for Benzene. No later than 1 January 2030, the Commission shall propose, where appropriate, necessary amendments and modifications related to that substance."

Or. en

Amendment 110
Sirpa Pietikäinen

Proposal for a directive

Article -1 ad

Directive 2004/37/EC

Article 18a – paragraph 4 b (new)

Text proposed by the Commission

Amendment

(-1 ad) In Article 18a, the following paragraph is added:

"No later than 1 December 2022, the Commission shall, taking into account the latest developments in scientific knowledge, the opinion of RAC and after appropriate consultation with relevant stakeholders, prepare EU guidelines on how the implementation of the limit values referred to in Article 5(4) should be adapted in case of combined exposure. These guidelines shall be published on the website of the European Agency for Safety and Health at Work (EU-OSHA)."

Or. en

Justification

Workers are often exposed simultaneously to several hazardous chemicals used in or generated by industrial processes. Occupational exposure limit values are established substance by substance with no consideration of possible combined exposure (e.g., different carcinogenic substances present at the workplace). In such situations, health risks can be increased, and compliance with individual limit values cannot suffice to protect workers' health. It is necessary to adapt the implementation of the different limit values to consider the combined exposure.

Amendment 111 **Sirpa Pietikäinen**

Proposal for a directive

Article -1 ae

Directive 2004/37/EC

Article 18a – paragraph 4c (new)

Text proposed by the Commission

Amendment

(-1 ae) In Article 18a, the following paragraph is added:

"No later than 1 March 2022, the Commission shall, taking into account the latest developments in scientific knowledge, and after appropriate consultation with relevant stakeholders, in particular health practitioners and health professionals, prepare a definition of Hazardous Medicinal Products and establish the list of substances covered by the related entry in Annex I. This list shall be reviewed every two years. No later than 1 December 2022, the Commission shall, after appropriate consultation with relevant stakeholders, prepare EU guidelines and standards of practice for the preparation, administration, and disposal of Hazardous Medicinal Products. These non-legislative tools shall be published on the website of the European Agency for Safety and Health at Work (EU-OSHA)."

Or. en

Justification

Inclusion in Annex I of work involving exposure to Hazardous Medicinal Products from the

three proposed pharmacotherapeutic groups covers most of the exposure situations and ensures effective protection by requiring the MS to introduce preventative and risk management measures. The other provisions of the directive will also apply, such as mandatory training and health surveillance. The inclusion in Annex I will also add legal certainty that the directive covers Hazardous Medicinal Products that are carcinogenic, mutagenic and/or toxic for reproduction category 1A or 1B.

Amendment 112
Sirpa Pietikäinen

Proposal for a directive

Article -1 af (new)

Directive 2004/37/EC

Article 18a – paragraph 4 d (new)

Text proposed by the Commission

Amendment

(1 af) In Article 18a, the following paragraph is added:

"No later than 1 June 2022, the Commission shall, taking into account the existing methodology to set limit values for carcinogens in some Member States and the opinion of the ACSH, define the upper and lower risk levels referred to in Article 2. No later than 1 December 2022, the Commission shall, after appropriate consultation with relevant stakeholders, prepare EU guidelines on the methodology establishing risk-based limit values under this Directive. These guidelines shall be published on the website of the European Agency for Safety and Health at Work (EU-OSHA)."

Or. en

Justification

Today, there is a broad consensus among stakeholders and governments that the current system to set limit values under the CMD should be revamped to move towards the risk-based methodology successfully applied in some Members States like The Netherlands and Germany (see the report of the conference "Working together on the future of the limit values for carcinogens in Europe" organized on 10-11 February 2020 by the Dutch Social and Economic Council).

Amendment 113
Manuel Bompard

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

Text proposed by the Commission

Amendment

1 a. In Annex I, the following point is added:

"8a. Work involving exposure to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of hazardous drugs, and work involving exposure to carcinogenic, mutagenic and/or reprotoxic substances in cleaning, transport, laundry and waste disposal of hazardous drugs or materials contaminated by hazardous drugs and in personal care for patients under treatment of hazardous drugs."

Or. en

Amendment 114
Sirpa Pietikäinen

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

Text proposed by the Commission

Amendment

(-1 ag) In Annex I, the following point is added:

"8a. Work involving exposure to Hazardous Medicinal Products from the three following pharmacotherapeutic groups: antineoplastic drugs, immunosuppressant drugs and antiviral drugs and, meeting the criteria for classification as carcinogenic, mutagenic

and/or toxic for reproduction category 1A or 1B set out in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council."

Or. en

Amendment 115
Manuel Bompard

Proposal for a directive
Article -1 ag (new)
Directive 2004/37/EC
Annex II – point 1

Present text

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

Amendment

(-1 ag) In Annex II to Directive 2004/37/EC, point 1 is amended as follows:

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.

Or. en

Amendment 116
Sirpa Pietikäinen

Proposal for a directive
Article -1 ah (new)
Directive 2004/37/EC
Annex II – point 1

Present text

1. The doctor and/or authority responsible for the health surveillance of workers

Amendment

(-1 ah) In Annex II to Directive 2004/37/EC, point 1 is amended as follows:

1. The doctor and/or authority responsible for the health surveillance of

exposed to carcinogens *or* mutagens must be familiar with the exposure conditions or circumstances of each worker.

workers exposed to carcinogens, mutagens *or reprotoxic substances* must be familiar with the exposure conditions or circumstances of each worker.

Or. en

Justification

Legislative protection of workers from substances toxic for reproduction is for now weak, being limited to the general provisions of the Chemical Agents Directive CAD (98/42/EC). Extending the scope of the Carcinogens and Mutagens Directive CMD by including reprotoxic substances would strengthen the current OSH system and add legal coherence. Limit values adopted under this Directive are always binding and obligation remains to reduce the levels as far as technically possible. The CMD is, therefore, more demanding than the CAD in terms of reducing exposure levels in the workplace.

Amendment 117 **Manuel Bompard**

Proposal for a directive **Article -1 ah (new)**

Text proposed by the Commission

Amendment

Article -1 ah

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

Or. en

Amendment 118 **Joanna Kopcińska**

Proposal for a directive **Article 2 – paragraph 1**

Text proposed by the Commission

Amendment

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 at the latest. They shall forthwith communicate to the Commission the text

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [**four** years] after the date of entry into force of this Directive at the latest. They shall forthwith communicate to the Commission the text

of those provisions.

of those provisions.

Or. en

Amendment 119
Sirpa Pietikäinen

Proposal for a directive

Annex I – point 2

Directive 2004/37/EC

Annex III – Point A – rows 2 a (new) and 2 b(new)

Text proposed by the Commission

Name of agent	Limit values / 8 hours	Notation
...
...

Amendment

Name of agent	Limit values / 8 hours	Notation
Cobalt	0,0005(9a)	Derma and respiratory sensitisation 11
Cobalt compounds	0,001 (10a)	
	<hr/> 9a Respirable fraction, measured as cobalt	<hr/> 11 The substance can cause sensitisation of the skin and of the respiratory tract.
	10a Inhalable fraction, measured as cobalt	

Or. en

Justification

The ECHA's Risk Assessment Committee (RAC) proposed a harmonised limit value of 1 µg Cobalt/m³ (as 8 h TWA, for inhalable fraction) and 0.5 µg Cobalt/m³ (as 8 h TWA, for

respirable fraction) in its 17/02/2020 opinion about a restriction under REACH for five cobalt salts within the EU. This restriction does not cover Cobalt and other cobalt compounds, also widely used in the EU. RAC supports the restriction targeted at the five soluble cobalt salts, but also recommends that the Commission derives a binding occupational exposure limit value for cobalt and its compounds under the CMD.