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| European Parliament2014-2019 |  |

<Commission>{EMPL}Committee on Employment and Social Affairs</Commission>

<RefProc>2018/0081</RefProc><RefTypeProc>(COD)</RefTypeProc>

<Date>{29/06/2018}29.6.2018</Date>

<RefProcLect>\*\*\*I</RefProcLect>

<TitreType>DRAFT REPORT</TitreType>

<Titre>on the proposal for a directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work</Titre>

<DocRef>(COM(2018)0171 – C8-0130/2018 – 2018/0081(COD))</DocRef>

<Commission>{EMPL}Committee on Employment and Social Affairs</Commission>

Rapporteur: <Depute>Laura Agea</Depute>

PR\_COD\_1amCom

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| Symbols for procedures |
|  \* Consultation procedure \*\*\* Consent procedure \*\*\*I Ordinary legislative procedure (first reading) \*\*\*II Ordinary legislative procedure (second reading) \*\*\*III Ordinary legislative procedure (third reading)(The type of procedure depends on the legal basis proposed by the draft act.) |

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| Amendments to a draft act |
| **Amendments by Parliament set out in two columns**Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.**Amendments by Parliament in the form of a consolidated text**New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced. By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted. |

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

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

(COM(2018)0171 – C8-0130/2018 – 2018/0081(COD))

(Ordinary legislative procedure: first reading)

*The European Parliament*,

– having regard to the Commission proposal to Parliament and the Council (COM2018/0171),

– having regard to Article 294(2) and Articles 153(2)(b) and 153(1)(a) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0130/2018),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the report of the Committee on Employment and Social Affairs and also the opinions of the Committee on the Environment, Public Health and Food Safety and the Committee on Legal Affairs (A8-0000/2018),

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

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

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

<RepeatBlock-Amend><Amend>Amendment <NumAm>1</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 1</Article>

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| Text proposed by the Commission | Amendment |
| (1) Principle 10 of the European Pillar of Social Rights43, proclaimed at Gothenburg on 17 November 2017, provides that every worker has the right to healthy, safe and well-adapted work environment***. The right to*** a high level of protection of ***the*** health and safety at work***,*** ***as well as to*** a working environment adapted to ***the*** professional needs ***of workers and which enables*** them to prolong their participation in the labour market ***includes also protection from carcinogens and mutagens at the*** ***workplace***. | (1) Principle 10 of the European Pillar of Social Rights43, proclaimed at Gothenburg on 17 November 2017, provides that every worker has the right to healthy, safe and well-adapted work environment***,*** a high level of protection of health and safety at work ***and*** a working environment adapted to professional needs***, irrespective*** ***of*** ***the arrangements for, and duration of, the period of employment, such as to enable*** them to prolong their participation in the labour market. |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 43 European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights\_en | 43 European Pillar of Social Rights, November 2017, https://ec.europa.eu/commission/priorities/deeper-and-fairer-economic-and-monetary-union/european-pillar-social-rights\_en |

Or. <Original>{IT}it</Original>

</Amend>

<Amend>Amendment <NumAm>2</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 2</Article>

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| Text proposed by the Commission | Amendment |
| (2) Directive 2004/37/EC of the European Parliament and of the Council44 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 carcinogens and mutagens is provided for in Directive 2004/37/EC by a framework of general principles to enable Member States to ensure the consistent application of the minimum requirements.*** Binding occupational exposure limit values established on the basis of available information***, including scientific*** and technical data, economic feasibility, a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace, are important components of the general arrangements for the protection of workers established by Directive 2004/37/EC. The minimum requirements provided for in Directive 2004/37/EC aim to protect workers at Union level. More stringent binding occupational exposure limit values can be set by Member States. | (2) Directive 2004/37/EC of the European Parliament and of the Council44 aims to protect workers against risks to their health and safety from exposure to carcinogens or mutagens at the workplace. ***Directive 2004/37/EC lays down*** ***the*** ***relevant minimum requirements on the basis of acquired scientific evidence, and is subject*** ***to*** ***periodic review in order*** ***to*** ***improve protection from risks arising from carcinogens and mutagens***. Binding occupational exposure limit values established on the basis of available ***scientific*** information and technical data, economic feasibility, a thorough assessment of the socioeconomic impact and availability of exposure measurement protocols and techniques at the workplace, are important components of the general arrangements for the protection of workers established by Directive 2004/37/EC. The minimum requirements provided for in Directive 2004/37/EC aim to protect workers at Union level. More stringent binding occupational exposure limit values can be set by Member States. |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 44 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). | 44 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50). |

Or. <Original>{IT}it</Original>

</Amend>

<Amend>Amendment <NumAm>3</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 3</Article>

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| Text proposed by the Commission | Amendment |
| (3) Occupational exposure limit values are part of risk management under Directive 2004/37/EC. Compliance with those limit values is without prejudice to other obligations of employers 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. In that context, it is essential to take the precautionary principle into account where there are uncertainties. | (3) Occupational exposure limit values are part of risk management under Directive 2004/37/EC. Compliance with those limit values is without prejudice to other obligations of employers 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***, such as organisational modelling of work or individual protection provisions,*** aiming to reduce the level of workers’ exposure. In that context, it is essential to take the precautionary principle into account where there are uncertainties. |

Or. <Original>{IT}it</Original>

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<Amend>Amendment <NumAm>4</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 3 a (new)</Article>

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| Text proposed by the Commission | Amendment |
|  | ***(3a)*** ***In pharmacology, hazardous drugs are drugs that are known to cause harm, because of their genotoxicity, carcinogenicity, teratogenicity, reprotoxicity and other developmental toxicity and organ toxicity at low doses. Those drugs include cytotoxic agents, biologic agents, antiviral agents and immunosuppressive agents. Cytotoxic drugs inhibit or prevent the function of cells. Cytotoxic drugs are primarily used to treat cancer, frequently as part of a chemotherapy regime. Cytotoxic drugs can prevent the rapid growth and division of cancer cells. However, the cytotoxic drugs available for current use are generally nonselective and are therefore likely to damage normal (nontumour) cells too. Thus, many cytotoxic drugs are known to be genotoxic, carcinogenetic or mutagenic;*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>5</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 3 b (new)</Article>

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| Text proposed by the Commission | Amendment |
|  | ***(3b)*** ***The International Agency for Research on Cancer (IARC) has actually identified a number of cytotoxic drugs as having an association with several forms of cancer. In particular, on the basis of epidemiological findings in patients with cancer as well as data from animal studies, IARC has listed the cytotoxic drugs that it considers to be definitely carcinogenic in humans (IARC category 1), among which thiotepa or tamoxifen. A large number of other cytotoxic drugs are considered probably carcinogenic (IARC category 2A) - for instance teniposide-, or possibly carcinogenic (IARC category 2B), for example streptozocin1a;*** |
|  | ***–––––––––––––––––––––––––––––––––*** |
|  | ***1a IARC monographs on the evaluation of carcinogenic risks to humans, volumes 1-121 http://monographs.iarc.fr/ENG/Classification/index.php*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>6</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 3 c (new)</Article>

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| Text proposed by the Commission | Amendment |
|  | ***(3c)*** ***As regards occupational risk, studies have shown that health workers who are occupationally exposed to cytotoxic agents have a higher risk of contracting leukemia. Other studies have found an increased risk of particular kinds of cancer (e.g. breast cancer and cancer of the rectum) in healthcare workers handling such drugs1a. Exposure may occur through skin contact, skin absorption, inhalation of aerosols and drug particles, ingestion and needle stick injuries when preparing, administering, or transporting drugs, handling patient waste, transporting and disposing of waste, or cleaning spills. Threshold levels of exposure (below which there is no risk) cannot be predicted on the basis of current knowledge, and therefore contact with genotoxic carcinogens (which include almost all alkylating agents) by operators should be avoided at all levels. The same applies to non-cytotoxic hazardous drugs which have also carcinogenic or mutagenic effects.*** |
|  | ***––––––––––––––––––––––––––––––––––*** |
|  | ***1a See: Skov T, Lynge E, Maarup B, et al. Risks for physicians handling antineoplastic drugs. Lancet. 1990;336:1446; S. Martin, The adverse health effects of occupational exposure to hazardous drugs, Community Oncology (2005), Volume 2, Issue 5, Pages 397-400; Ratner PA, Spinelli JJ, Beking K, et al. Cancer incidence and adverse pregnancy outcome in registered nurses potentially exposed to antineoplastic drugs. BMC Nurs. 2010 9, Connor, Thomas H. et al. Reproductive Health Risks Associated with Occupational Exposures to Antineoplastic Drugs in Health Care Settings: A Review of the Evidence. Journal of occupational and environmental medicine / American College of Occupational and Environmental Medicine 56.9 (2014): 901–910. PMC.*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>7</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 3 d (new)</Article>

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| Text proposed by the Commission | Amendment |
|  | ***(3d)*** ***It is therefore important to protect workers exposed to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of hazardous drugs (including cytotoxic drugs), and work involving exposure to carcinogenic or mutagenic substances in cleaning, transport, laundry and waste disposal of hazardous drugs of materials contaminated by hazardous drugs and in personal care for patients under treatment of hazardous drugs. As a first step, the Commission has issued guidance to reduce occupational health and safety risks in the healthcare sector, including on the risk related to the exposure to cytotoxic drugs, in a dedicated guide to prevention and good practices. As a second step, work involving exposure to hazardous drugs (including cytotoxic drugs) which are carcinogenic should be included in Annex I to Directive 2004/37/EC;*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>8</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 3 e (new)</Article>

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| Text proposed by the Commission | Amendment |
|  | ***(3e)*** ***When including the*** ***work involving exposure to hazardous drugs (including cytotoxic drugs) which are cacinogenic in Annex I to Directive 2004/37/EC , it is also important to acknowledge the specificity of those substances, which are indispensable for treating serious and often life-threatening diseases, and which have been saving the lives of millions patients across the Union. While - in accordance with article 168(1) TFEU-, access to the best available treatments for those patients should not be questionned or jeopardized, occupational safety of workers handling those drugs must be ensured. In particular, it is important to acknowledge that, in the case of hazardous drugs, elimination of the hazard or substitution with a less hazardous chemical is generally not feasible. Conversely, protective measures such as engineering controls (use of biological safety cabinets, isolators, or closed system transfer devices), administrative controls (training and education programs; availability of material safety data sheets; established work practices, policies, and surveillance), use of personal protective equipment (protective gloves, gowns, respiratory protection, eye protection, etc.) are effective measures which allow the safe handling of hazardous drugs.*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>9</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 5</Article>

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| Text proposed by the Commission | Amendment |
| (5) Maximum levels for the exposure of workers to some carcinogens or mutagens are established by values which, pursuant to Directive 2004/37/EC, must not be exceeded. | (5) Maximum levels for the exposure of workers to some carcinogens or mutagens are established by values which, pursuant to Directive 2004/37/EC, must not be exceeded. ***These limit values are expressed, wherever possible, in the form of recognised scientific measurements such as: TLV-TWA (time-weighted average), expressing the limit concentration (weighted average) to which all workers may be exposed, for eight hours per day and a maximum of 40 hours a week for the entire duration of working life, without adverse health effects; TLV-STEL (short-term exposure limit), which is the maximum value allowed for short exposures (no more than 15 minutes), which must be occasional and not exceed four exposures within 24 hours, spaced at least one hour apart; or, if necessary, in terms of TLV-C (ceiling), which is the concentration that must not be exceeded at any time during exposure at work.*** |

Or. <Original>{IT}it</Original>

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<Amend>Amendment <NumAm>10</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 6</Article>

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| Text proposed by the Commission | Amendment |
| (6) 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 evidence-based best practices, techniques and protocols for exposure level measurement at the workplace. That information should, if possible, include data on residual risks to the health of workers, recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL) and 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. Transparency of such information should ***be further encouraged***. | (6) 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 evidence-based best practices, techniques and protocols for exposure level measurement at the workplace. That information should, if possible, include data on residual risks to the health of workers, recommendations of the Scientific Committee on Occupational Exposure Limits (SCOEL) and 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. Transparency of such information should ***always be ensured***. |

Or. <Original>{IT}it</Original>

</Amend>

<Amend>Amendment <NumAm>11</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 13</Article>

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| Text proposed by the Commission | Amendment |
| (13) Beryllium and most inorganic beryllium compounds meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. In addition to carcinogenic properties beryllium is known to provoke chronic beryllium disease (CBD) and beryllium sensitisation (BeS). It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for that group of carcinogens. It is therefore appropriate to establish a limit value for beryllium and inorganic beryllium compounds under the scope of Directive2004/37/EC and to assign a notation for skin and respiratory sensitisation. | (13) Beryllium and most inorganic beryllium compounds meet the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. In addition to carcinogenic properties beryllium is known to provoke chronic beryllium disease (CBD) and beryllium sensitisation (BeS). ***The International Agency for Research on Cancer has designated beryllium and its compounds as carcinogens (category 1A).*** It is possible, on the basis of the available information, including scientific and technical data, to set a limit value for that group of carcinogens. It is therefore appropriate to establish a limit value for beryllium and inorganic beryllium compounds under the scope of Directive2004/37/EC and to assign a notation for skin and respiratory sensitisation. |

Or. <Original>{IT}it</Original>

</Amend>

<Amend>Amendment <NumAm>12</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 14</Article>

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| Text proposed by the Commission | Amendment |
| (14) With regard to beryllium, a limit value of 0,0002 mg/m3 may be difficult to be complied with in some sectors in the short term. A transitional period of ***five*** years should therefore be introduced during which the limit value of 0,0006 mg/m3should apply. | (14) With regard to beryllium, a limit value of 0,0002 mg/m3 may be difficult to be complied with in some sectors in the short term. A transitional period of ***seven*** years should therefore be introduced during which the limit value 0,0006 mg/m3 should apply. ***It will be possible to reduce exposure by means of systems to monitor the area and in particular by means of rotation systems for planned work processes, where possible reducing the production of fumes and performing processes by means of machinery which enables people to work in a less contaminated environment. Member States should also make arrangements for periodic preventive checks to ascertain workers’ predisposition to chronic beryllium disease.*** |

Or. <Original>{IT}it</Original>

</Amend>

<Amend>Amendment <NumAm>13</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 16</Article>

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| Text proposed by the Commission | Amendment |
| (16) With regard to arsenic acid, a limit value of 0,01 mg/m3 may be difficult to be complied with in the copper smelting sector and therefore a transitional period of two years should be introduced. | (16) With regard to arsenic acid, a limit value of 0,01 mg/m3 may be difficult to be complied with in the copper smelting sector and therefore a transitional period of two years should be introduced. ***The reduction of exposure in accordance with the limits laid down in the Directive can be achieved by using, wherever possible, systems to monitor the area and by arranging greater rotation by time slot so as to reduce average exposure within the eight hours of the working day.*** |

Or. <Original>{IT}it</Original>

</Amend>

<Amend>Amendment <NumAm>14</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 17</Article>

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| Text proposed by the Commission | Amendment |
| (17) Formaldehyde meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is a local acting genotoxic carcinogen. It is possible, on the basis of the available information, including scientific and technical data, to set a long and short term limit value for that carcinogen. Formaldehyde is also a contact allergen to the skin (skin sensitiser). It is therefore appropriate to establish a limit value for formaldehyde and to assign a notation for skin sensitisation. In addition, upon request of the Commission, ECHA is also gathering existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses48. | (17) Formaldehyde meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. It is a local acting genotoxic carcinogen. ***There is sufficient evidence that formaldehyde causes nasopharyngeal cancer in human beings, while evidence of nasal and sinus cancer remains limited and there is some evidence of leukaemia.*** It is possible, on the basis of the available information, including scientific and technical data, to set a long and short term limit value for that carcinogen. Formaldehyde is also a contact allergen to the skin (skin sensitiser). It is therefore appropriate to establish a limit value for formaldehyde and to assign a notation for skin sensitisation. In addition, upon request of the Commission, ECHA is also gathering existing information to assess the potential exposure from formaldehyde and formaldehyde releasers at the workplace including industrial and professional uses48. |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| 48 https://echa.europa.eu/documents/10162/13641/formaldehyde\_cion\_reqst\_axvdossier\_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e | 48 https://echa.europa.eu/documents/10162/13641/formaldehyde\_cion\_reqst\_axvdossier\_en.pdf/11d4a99a-7210-839a-921d-1a9a4129e93e |

Or. <Original>{IT}it</Original>

</Amend>

<Amend>Amendment <NumAm>15</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 18</Article>

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| Text proposed by the Commission | Amendment |
| (18) 4,4'-Methylene-bis(2-chloroaniline)(MOCA) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. The possibility of a significant uptake through the skin was identified for MOCA. It is therefore appropriate to establish a limit value for MOCA and to assign to it a skin notation. In addition, it was identified as a substance of very high concern (SVHC) pursuant to Article 57(a) of Regulation EC No 1907/2006 and included in Annex XIV to that Regulation, requiring authorisation before it can be placed on market or used. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for MOCA. | (18) 4,4'-Methylene-bis(2-chloroaniline)(MOCA) meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and is therefore a carcinogen within the meaning of Directive 2004/37/EC. ***Its carcinogenicity, together with its manifest genotoxic characteristics, has made it possible to classify that substance as carcinogenic to humans.*** The possibility of a significant uptake through the skin was identified for MOCA. It is therefore appropriate to establish a limit value for MOCA and to assign to it a skin notation. In addition, it was identified as a substance of very high concern (SVHC) pursuant to Article 57(a) of Regulation EC No 1907/2006 and included in Annex XIV to that Regulation, requiring authorisation before it can be placed on market or used. It is possible, on the basis of available information, including scientific and technical data, to set a limit value for MOCA. |

Or. <Original>{IT}it</Original>

</Amend>

<Amend>Amendment <NumAm>16</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 23</Article>

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| Text proposed by the Commission | Amendment |
| (23) In implementing this Directive Member States should avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings. Member States are therefore invited to assess the impact of their transposition act on SMEs in order to make sure that SMEs are not disproportionately affected, with specific attention for micro-enterprises and for administrative burden, ***and*** to publish the results of such assessments. | (23) In implementing this Directive Member States should avoid imposing administrative, financial and legal constraints in a way which would hold back the creation and development of small and medium-sized undertakings. Member States are therefore invited to assess the impact of their transposition act on SMEs in order to make sure that SMEs are not disproportionately affected, with specific attention for micro-enterprises and for administrative burden, ***where possible making use of tax concessions proportionate to the impact of the investment on the balance sheet, so as to recover the costs and provide an incentive for their conversion. Member States are called upon*** to publish the results of such assessments. |

Or. <Original>{IT}it</Original>

</Amend>

<Amend>Amendment <NumAm>17</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 24</Article>

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| Text proposed by the Commission | Amendment |
| (24) As 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.*** | (24) As this Directive concerns the health of workers at their workplace ***and confines itself to establishing maximum levels of*** ***exposure to carcinogens and mutagens***, it should be transposed within two years***.***  |

Or. <Original>{IT}it</Original>

</Amend>

<Amend>Amendment <NumAm>18</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Article 2 – paragraph 2 a (new)</Article>

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| Text proposed by the Commission | Amendment |
|  | ***2a. Under their domestic legislation, Member States shall grant employers who comply with this Directive incentives proportionate to the impact of the investment on their balance sheet.*** |

Or. <Original>{IT}it</Original>

</Amend>

<Amend>Amendment <NumAm>19</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Article 1 – paragraph 1 – point -1 (new)</Article>

<DocAmend2>Directive 2004/37/EC</DocAmend2>

<Article2>Article 4 – paragraph 1 a (new) </Article2>

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| Text proposed by the Commission | Amendment |
|  | ***(-1) In Article 4 the following paragraph is inserted:*** |
|  | ***“1a. Paragraph 1 shall apply to hazardous drugs (including cytotoxic drugs) referred to in Annex I, only if the reduction of the use of a hazardous drug does not prejudice patients' health or does not decrease the efficiency of the treatment.”*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>20</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Article 1 – paragraph 1 – point -1 a (new)</Article>

<DocAmend2>Directive 2004/37/EC</DocAmend2>

**<Article2>**Article 5 – paragraph 2**</Article2>**

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|  |
| Present text | Amendment |
|  | ***(-1a) Article 5, paragraph 2, is replaced by the following:*** |
| 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. | “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, ***or where the replacement of a hazardous drug (including cytotoxic drugs) referred to in Annex I is not possible without prejudice to patients' health or without the decrease of the efficiency of the treatment,*** the employer shall ensure that the carcinogen or mutagen is, in so far as is technically possible, manufactured and used in a closed system.” |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>21</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Article 1 – paragraph 1 – point -1 b (new)</Article>

<DocAmend2>Directive 2004/37/EC</DocAmend2>

**<Article2>**Annex I – point 5 a (new)**</Article2>**

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(-1b) In Annex I, the following point is inserted:*** |
|  | ***“5a. “Work involving exposure to carcinogenic or mutagenic substances resulting from the preparation, administration or disposal of hazardous drugs (including cytotoxic drugs) which are classified by IARC as carcinogenic (IARC group 1), probably carcinogenic (IARC group 2A) or possibly carcinogenic (IARC group 2B); ”*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>22</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Article 1 – paragraph 1 – point -1 c (new)</Article>

<DocAmend2>Directive 2004/37/EC</DocAmend2>

**<Article2>**Annex I – point 5 b (new) **</Article2>**

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|  |
| Text proposed by the Commission | Amendment |
|  | ***(1c) In Annex I, the following point is inserted:*** |
|  | ***“5b. Work involving exposure to carcinogenic or mutagenic 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 (including cytotoxic drugs) which are classified by IARC as carcinogenic (IARC group 1), probably carcinogenic (IARC group 2A) or possibly carcinogenic (IARC group 2B)”*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>23</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Article 1 – paragraph 1 – point -1 d (new)</Article>

<DocAmend2>Directive 2004/37/EC</DocAmend2>

**<Article2>**Annex II – point 2 a (new) **</Article2>**

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| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(-1d) In Annex II, the following point is inserted:*** |
|  | ***2a. In plants where there is any kind of occupational exposure to cadmium or its carcinogenic compound, it is mandatory that the doctor and/or the authority responsible for the health of workers implements systematic, regular and documented urinary bio-monitoring of cadmium with a BLV of 2µg Cd/g creatinine.*** |

Or. <Original>{EN}en</Original>

</Amend>

<Amend>Amendment <NumAm>24</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Article 1 – paragraph 1 – point 1</Article>

<DocAmend2>Directive 2004/37/EC</DocAmend2>

<Article2>Annex III – Part A – table – row 1</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission |
|  |
| Cadmium and its inorganic compounds | - | - | 0,001 | - | - | - | - | - | Limit value 0,004 mg/m3 until xx yyyy 202z [7 years] |
| Amendment |
| Cadmium and its inorganic compounds | - | - | 0,001***\**** | - | - | - | - | - | Limit value 0,004 mg/m3 until xx yyyy 202z [7 years] |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| ***\* For facilities where the doctor and/or the authority responsible for the health surveillance of workers have implemented bio-monitoring in compliance with Annex II (3), the 8 hours-TWA Limit Value is 0.004 mg/m3 (respirable fraction). In this case no transitional period is needed.***  |

Or. <Original>{IT}it</Original>

<TitreJust>Justification</TitreJust>

*See SCOEL opinion of 8 /02/2017 "An 8h-TWA (...) of 4 μg/m³ (respirable fraction), based on non-cancer respiratory effects, can (...) be considered as being protective for workers (...).and must be seen in close conjunction with a biological monitoring (BLV) of 2 µg Cd/g creatinine)   However, an isolated OEL (8-h TWA) of 4 μg/m3 (not linked with a BLV) would not appear being equally protective against the systemic nephrotoxixity of Cd. (...). In this case an OEL (8h-TWA, not connected with biological monitoring) for Cd and its inorganic compounds should be 1 μg/m3”. See: https://circabc.europa.eu/sd/a/13cad802-1f3c-40c0-bce4-6838cf5fc4ff/OPIN-336%20Cadmium%20and%20its%20inorganic%20compounds.pdf.*

</Amend>

<Amend>Amendment <NumAm>25</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Article 1 – paragraph 1 – point 1</Article>

<DocAmend2>Directive 2004/37/EC</DocAmend2>

<Article2>Annex III – Part A – table – row 2</Article2>

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| --- |
|  |
| Text proposed by the Commission |
|  |
| Beryllium and inorganic beryllium compounds | - | - | 0,0002 | - | - | - | - | dermal and respiratory sensitisation (8)  | Limit value 0,0006 mg/m3 until xx yyyy 202z [***5*** years] |
| Amendment |
| Beryllium and inorganic beryllium compounds | - | - | 0,0002 | - | - | - | - | dermal and respiratory sensitisation (8)  | Limit value 0,0006 mg/m3 until xx yyyy 202z [***7*** years] |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| (8) The substance can cause sensitisation of the skin and of the respiratory tract. |

Or. <Original>{IT}it</Original>

</Amend></RepeatBlock-Amend>

EXPLANATORY STATEMENT

Cancer is the main work-related health problem in the EU-28, causing almost as much damage to workers’ life and health as the next two combined (musculoskeletal disorders and circulatory diseases). However, the adverse impact of high exposure to carcinogens and mutagens at the workplace is a good deal more far-reaching. In addition to cancers, it can also cause a wide range of other health problems, such as respiratory diseases and neurological disorders.

The European Commission has already taken steps to address these issues by adopting two legislative proposals to update Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work in May 2016 and January 2017.

This third legislative proposal examines five additional carcinogenic chemicals: cadmium, beryllium and their inorganic compounds, arsenic acid, formaldehyde and MOCA (4,4’ methylene-bis).

The rapporteur welcomes this third legislative proposal and the limit values that it contains, which, according to estimates, should improve the long-term working conditions of more than a million EU workers, preventing more than 22 000 cases of work-related ill-health (cancers and non-cancers).

The rapporteur has adopted an approach intended to ensure maximum protection for workers without imposing excessive costs on small and medium-sized enterprises. Account can be taken of both these aspects by permitting a transition period for the completion of the necessary changes on the organisational side and more particularly the technical side. Given the weak economic recovery in several European countries, which has persisted for some years, it is considered desirable to grant concessions to businesses which may be divided into two categories:

- active: by paying grants to businesses that comply, including by encouraging planning of EU-subsidised projects, without infringing any European requirements;

- passive: by granting tax relief to businesses that comply.

Finally, the rapporteur wished to tackle in a direct and ambitious manner the problem of workers exposed to carcinogens and mutagens derived from the preparation, administration or disposal of hazardous drugs, including cytotoxic drugs. For that reason she has opted to include in Annex I to the Directive work involving exposure to carcinogenic or mutagenic substances arising from the preparation, administration or disposal of hazardous drugs (including cytotoxic drugs) classified by the IARC as carcinogenic (IARC group 1), probably carcinogenic (IARC group 2A) or possibly carcinogenic (IARC group 2B).