|  |  |
| --- | --- |
| European Parliament2014-2019 | EP logo RGB_Mute |

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

<RefProc>2016/0130</RefProc><RefTypeProc>(COD)</RefTypeProc>

<Date>{22/11/2016}22.11.2016</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(2016)0248 – C8‑0181/2016 – 2016/0130(COD))</DocRef>

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

Rapporteur: <Depute>Marita Ulvskog</Depute>

PR\_COD\_1amCom

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

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

CONTENTS

Page

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION 5

EXPLANATORY STATEMENT 19

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(2016)0248 – C8‑0181/2016 – 2016/0130(COD))

(Ordinary legislative procedure: first reading)

*The European Parliament*,

– having regard to the Commission proposal to Parliament and the Council (COM(2016)0248),

– having regard to Article 294(2) and Article 153 (2) of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8‑0181/2016),

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

– after consulting the European Economic and Social Committee,

– after consulting the Committee of the Regions,

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

– having regard to the report of the Committee on Employment and Social Affairs and the opinions of the Committee on the Environment, Public Health and Food Safety and the Committee on Legal Affairs (A8‑0000/2016),

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

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend its proposal substantially or replace it with another text;

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 2</Article>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| (2) ***The limit values should be revised when necessary in the light of*** scientific data. | (2) ***As*** scientific data ***and best practice are developing constantly, Directive 2004/37/EC should be further amended.*** ***Every five years, the Commission should issue a report on the implementation of Directive2004/37/EC, including, where appropriate, proposals for legislative amendments***. |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 2 a (new)</Article>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(2a) It is necessary to highlight the importance of protecting workers against exposure to carcinogens, mutagens and substances that are toxic to reproduction. 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, impaired fertility or infertility, and also have a negative impact on foetal development. 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. Participation of women in the labour market is necessary to achieve the EU2020 headline target that 75 % of the population aged 20 to 64 should be employed by 2020. It is therefore necessary to address reprotoxic substances in the revision of Directive 2004/37/EC to bring it into line with Regulation (EC) No 1907/2006 of the European Parliament and of the Council1a and ensure 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. <Original>{EN}en</Original>

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 2 b (new)</Article>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(2b) Directive 2004/37/EC should be amended to strengthen health surveillance. Due to the lack of consistent data on substance exposure, it is necessary to protect exposed workers or workers who are at risk of exposure by enforcing mandatory health surveillance, rather than surveilling only when it is deemed to be necessary. Due to the gaps in data collection it is not clear when health surveillance is to be deemed to be necessary. It would therefore be prudent to ensure mandatory life-long health surveillance for all exposed workers.*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 2 c (new)</Article>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(2c) Appropriate and consistent data collection by Member States from employers is necessary to improve and ensure safety and proper care for workers. It is also necessary for the correct transposition and implementation of this Directive. The Commission should support best practice exercises on data collection between Member States and propose how data collection can be improved. The Commission should also require Member States to provide it with information for the purposes of its reports on the implementation of Directive 2004/37/EC.*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 2 d (new)</Article>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(2d) In addition to amending the scope and mandatory health surveillance, it is necessary to amend Directive 2004/37/EC in order to address the lack of transparency relating to the risk of cancer arising from carcinogens, mutagens and reprotoxins. The residual level for the occupational exposure limit of each type of substance and the date of the last estimate should therefore be added to the table in Annex III to Directive 2004/37/EC.*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 2 e (new)</Article>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(2e) Following the amendments of Annex III to Directive 2004/37/EC, as set out in this Directive, further limit values for additional substances should be introduced without delay. Between 50 and 70 substances have been identified by different agencies, stakeholders and the World Health Organization as a priority list of workplace carcinogens, mutagens and reprotoxins. The additional substances referred to in Annex III to Directive 2004/37/EC should include but not be limited to substances such as diesel exhaust, formaldehyde, leather dust, cadmium, dichloromethane, gallium arsenide, potassium bromate, titanium dioxidem, phenolphtalein, quinoline, silicone carbide fibres, polychlorinated biphenyls (PCB), vinyl fluoride and vinyl chloride. Reprotoxins should include di(2-ethylhexyl)phthalate, benzyl butyl phthalate, dibutyl phthalate, cadmium, lead, hexachlorobenzene, toluene, nonylphenol, ethylene glycol ethyl ether and benomyl.***  |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 2 f (new)</Article>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(2f) The burden of proof should not be on the victims of the exposure to carcinogens, mutagens and reprotoxins. Instead, wider rights for workers to claim compensation should be established. Member States should, as soon as possible, introduce into their national laws, regulations or administrative, provisions concerning scientifically recognised occupational diseases that give rise to compensation, and the right of a worker to claim compensation in respect of the occupational diseases based on the Commission Recommendation C(2003) 32971a . Insurance and compensation entities should adopt a harmonised approach to the recognition of and compensation for diseases resulting from exposure to carcinogens, mutagens and reprotoxins at work.*** |
|  | ***\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*** |
|  | ***1a Commission Recommendation C(2003) 3297 of 19 September 2003 concerning the European schedule of occupational diseases (OJ L 238, 25.9.2003, p. 28).*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 3</Article>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| (3) For some carcinogens ***and*** mutagens it is necessary to consider other absorption pathways, including the possibility of penetration through the skin, in order to ensure the best possible level of protection. | (3)For some carcinogens, mutagens ***and reprotoxins*** it is necessary to consider other absorption pathways, including the possibility of penetration through the skin, in order to ensure the best possible level of protection. |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 6</Article>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| (6) Guides and good practice developed through initiatives such as the Social Dialogue "Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it" (NEPSi) are valuable and necessary instruments to complement regulatory measures and in particular to support the effective implementation of limit values. | (6) Guides and good practice developed through initiatives such as the Social Dialogue "Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it" (NEPSi) are valuable ***and necessary*** instruments to complement regulatory measures and in particular to support the effective implementation of limit values. |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Recital 7</Article>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| (7) The limit values set out in Annex III to Directive 2004/37/EC for vinyl chloride monomer and ***hardwood*** dusts should be revised in the light of more recent scientific data.  | (7)The limit values set out in Annex III to Directive 2004/37/EC for vinyl chloride monomer and ***wood*** dusts should be revised in the light of more recent scientific data. ***Due to the recommendation from the International Agency for Research on Cancer (IARC), the distinction between hardwood dust and softwood dust should be removed as regards the limit value in Annex III*** ***to Directive 2004/37/EC***. ***According to IARC, excesses of sinonasal cancer were observed among workers primarily exposed to softwood in case–control studies carried out in several countries.*** |

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

</Amend>

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

<DocAmend>Proposal for a directive </DocAmend>

<Article>Recital 8</Article>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| (8) 1,2-Epoxypropane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. On the basis of the available information, including scientific and technical data, it is possible to identify ***a*** ***clear*** exposure level below which exposure to this carcinogen is not expected to lead to adverse effects. It is therefore appropriate to establish such a limit value for 1,2-epoxypropane .  | (8)1,2-Epoxypropane meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 and therefore is a carcinogen within the meaning of Directive 2004/37/EC. On the basis of the available information, including scientific and technical data, it is possible to identify ***an*** exposure level below which exposure to this carcinogen is not expected to lead to adverse effects. It is therefore appropriate to establish such a limit value for 1,2-epoxypropane. |

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

</Amend>

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

<DocAmend>Proposal for a directive </DocAmend>

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

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

<Article2>Title</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(-1) The title is replaced by the following:***  |
|  | ***“Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work”*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

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

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

<Article2>Article 2 – paragraph 1 – point c a (new)</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(-1a) In Article 2, the following point is added:*** |
|  | ***“(c a) ‘reprotoxin’ means a substance which meets the criteria for classification as a category 1A or category 1B substance toxic to reproduction set out in Annex VI to Regulation (EC) No 1272/2008”*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

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

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

<Article2>Article 14</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(-1b) Article 14 is amended as follows:*** |
|  | ***(a) paragraphs 1 and 2 are replaced by the following:*** |
|  | ***“1. The Member States shall establish, in accordance with national laws or practice, arrangements for carrying out relevant mandatory life-long health surveillance of workers for whom the results of the assessment referred to in Article 3(2) reveal a risk to health or safety.*** |
|  | ***2. The arrangements referred to in paragraph 1 shall allow each worker to undergo, if appropriate, relevant life-long health surveillance:*** |
|  | ***- prior to exposure,*** |
|  | ***- at regular intervals during the exposure period,***  |
|  | ***- after the end of the exposure and the end of their employment.”*** |
|  | ***(b) paragraph 5 is deleted.*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

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

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

<Article2>Article 17 a (new)</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***(-1c) The following Article is added:***  |
|  | ***“Article 17a*** |
|  | ***Reprotoxic substances*** |
|  | ***By 1 November 2017, the Commission shall, in consultation with the Member States and the social partners, review the provisions of this Directive and propose any amendments necessary to take into account the inclusion of reprotixic substances in the scope of this Directive.”*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – heading – column 7 a (new)</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***Transitional measures*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – row 1 – column 3</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| ***Hardwood*** dusts | ***Wood*** dusts  |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – row 1 – column 4</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| ***3*** (1) | ***1*** (1) |
| \_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| (1) Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture. | (1) Inhalable fraction: if hardwood dusts are mixed with other wood dusts, the limit value shall apply to all wood dusts present in that mixture. |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – row 1 – column 7 a (new)</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***2 mg/m³ until XXXX (5 years after the date of entry into force of the amending directive)*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – row 2 – column 4</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| ***0,025*** | ***0,001*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – row 3 – column 6</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| ***0,3*** | ***0,1*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – row 3 – column 7 a (new)</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***0,3 f/ml until XXXX (5 years after the date of entry into force of the amending directive)*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – row 4 – column 4</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| ***0,1*** (1) | ***0,05*** (1) |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| (1) Respirable fraction. | (1) Respirable fraction. |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – row 9 – column 4</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| ***0,1*** | ***0,03*** |

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

</Amend>

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

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – row 12 – column 4</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| ***2,2*** | ***1,12*** |

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

</Amend>

<Amend>Amendment <NumAm>26</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – row 12 – column 5</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
| ***1*** | ***0,5*** |

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

</Amend>

<Amend>Amendment <NumAm>27</NumAm>

<DocAmend>Proposal for a directive</DocAmend>

<Article>Annex</Article>

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

<Article2>Annex III – Part A – row 12 – column 7 a (new)</Article2>

|  |
| --- |
|  |
| Text proposed by the Commission | Amendment |
|  | ***1 ppm until XXXX (5 years after the date of entry into force of the amending directive)*** |

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

</Amend>

</RepeatBlock-Amend>

EXPLANATORY STATEMENT

On 13 May 2016 the Commission published its proposal for amending Directive 2004/37/EC to better protect workers from exposure to carcinogens and mutagens in the workplace. The European Parliament had called for a revision of the directive at several occasions both in the current and the previous term.

The Rapporteur welcomes the Commission’s initiative as an important first step towards addressing the overall problem of exposure to carcinogens and mutagens in the workplace. Cancer is the second largest cause of death in Europe and the largest cause of work-related death. All work related cancers are preventable. An update and precise legislative framework in the European Union will contribute to a better prevention of work-related cancers. The annual cost to Member States is estimated at 334 billion EUR[[1]](#footnote-1).

According to the European Agency for Safety and Health at Work (EU-OSHA), Member States report lack of exposure and toxicological data at national level, and that there is a difficulty reaching consensus regarding occupational exposure limits (OELs). The Rapporteur takes the view that the guiding principle for setting binding OELs (BOELs) is to follow best practice in the Member States as well as globally and to act according to the precautionary principle. This principle should be consistently reflected in the directive as recalled by its Recital 14 (‘The precautionary principle should be applied in the protection of workers' health.’).

**I. The inclusions of reprotoxic substances in the scope of the directive**

The rapporteur proposes to broaden the scope of the Directive to allow for the inclusion of reprotoxic substances, which is in line with previous calls from the European Parliament[[2]](#footnote-2) and with legislation in force in some Member States.

According to a recent French study[[3]](#footnote-3) more than 1% of the workers are exposed to reprotoxic substances. Extrapolating those data, there could be between 2 and 3 million workers exposed to reprotoxic substances in the European Union. At present the legislative protection for workers from such substances is very weak because it is basically limited to the general provisions of the Chemical Agents Directive 98/42/EC. Reprotoxic substances are substances of very high concern according to Regulation (EC) No 1907/2006 (REACH). The provisions for workers` protection should be consistent with that finding. The pregnant workers’ directive 92/85/EC does not impose preventative measures before a pregnant worker has informed their employer of their pregnancy. That means that there is no specific protection in early weeks of gestation and no protection for male or female fertility. Carcinogens and mutagens are tied to reprotoxic substances in European legislation for instance through REACH. At Member State level six countries have already extended the scope of the directive (FR, AT, FI, DE, SE and CZ) to include reprotoxic substances in transposition.

In 2004 a survey carried out in France evaluated 50 potential reprotoxic substances scoring them for danger and exposure. The first 10 substances according to this methodology were: di(2-ethylhexyl)phthalate, benzyl butyl phthalate, dibutyl phthalate, cadmium, lead, hexachlorobenzene, toluene, nonylphenol, ethylene glycol ethyl ether, benomyl[[4]](#footnote-4). Examples of effects of reprotoxic substances like phthalates are: testicular toxicity, reduced male and female fertility, foetal toxicity (possibly leading to death or malformations). Alkylphenols and related chemicals have hormone mimicking (imitating) effects and can lead to reduced male fertility, testicular size and sperm quality[[5]](#footnote-5).

**II. Stricter limit values**

The Rapporteur has proposed stricter limit values for six of the substances considered. The rapporteur is of the view that the BOELs set by the European Union should mirror the best practice developed in the Member States. As the Commission has highlighted in the impact assessment, decisions on limit values strike a balance between cancer risk and the estimated cost of preventing it. Where practical difficulties exist due to a lack of alternative substances or technical solutions, additional time for implementing the stricter limit values has been proposed. This ensures time for employers to develop solutions and to offset costs for investment. All of the changes proposed by the rapporteur reflect BOELs that are already in force or exist in some Member States.

*- Crystalline silica*

The Scientific Committee for Occupational Exposure Limits (SCOEL) has advised a limit value of 0.05 mg/m³; the rapporteur shares this view and has proposed the same limit value as the SCOEL. According to the Commission’s impact assessment, such a limit value would result in 107.350 less deaths in the period 2010-2069 as compared to the current scenario.

*- Chromium VI*

The Rapporteur shares the view expressed by several Member States (Belgium, Germany, Denmark, France, The Netherlands, Lithuania and Sweden) during discussions in the Council that the limit value for Chromium IV should be lowered as compared to the Commission’s proposal (0,025 mg/m³). She is concerned that the limit value would be set at a relatively high level despite no up-to-date hexavalent chromium exposure data being available, since the data used to set the proposed limit is from 1995. At present, three Member States have implemented a limit value of 0.001 mg/m³. Again, the precautionary principle should apply.

*- Wood dust*

The rapporteur shares the view of the International Agency for Research on Cancer (IARC) that there is sufficient evidence that no distinction should be made between hard and soft wood dust. As there have been noticeable technical advances in recent years, from a practical perspective it is fully possible to set a stricter limit value for wood dust. As the majority of EU Member States have a limit value set at 2 mg/m3, this should be the common limit value for the European Union until the stricter best practice limit value of 1 mg/m3 (France) can be achieved. An even stricter limit value of 0.5 mg/m3 should be evaluated in the future revision of the Directive based on the health and safety impact, technical feasibility and cost.

*- Refractory ceramic fibres*

Germany, France and Norway have limit values of 0,1 f/ml and this should be the limit value for the European Union as suggested by the rapporteur. The proposed OEL would be more effective in protecting workers compared to the limit value proposed by the Commission (0.3f/ml). The value proposed by the Commission is suggested as a transitional limit value.

*- Acrylamide*

According to the Commission’s impact assessment a limit value of 0,03 mg/m3 is already expected to be complied with in the industry and a corresponding (or lower) BOEL is in place in several Member States (MT, BE, BG, DK, EE, ES, HU, IE, LT, RO, SK, SE). The reason for using this OEL instead of that proposed by the Commission is the concern for the growing use of acrylamide which is also reported in the impact assessment.

*- 1,3-Butadiene*

The substance is tied to lymphosarcoma and the limit value proposed by the rapporteur is in force in one Member State (SE). As it is already possible to meet the Commission limit value, this is the proposed transitional value to allow for time to adapt and meet the new stricter limit value.

**III. Further issues to be addressed**

The Rapporteur has not proposed to introduce BOELs for additional substances in light of the Commission’s explicit intention to further amend the Directive in the very next future. As there are numerous substances that have been identified as carcinogens, mutagens and reprotoxic agents, the Rapporteur welcomes such plans and urges that additional limit values should be introduced without delay to protect many more workers from exposure, to prevent more risks and save more lives.

Improved data collection also needs to be addressed in the revisions of the Directive, through best practice sharing at a European level and with the aid of social partners, especially employers . At present, the lack of clear and comprehensive data collection by the Member States creates barriers to protection, prevention and proper health care, not to mention responsible policy making.

The gaps in data collection also stress the need to introduce mandatory life-long health surveillance of exposed workers. This has been proposed as an amendment to the directive due to the urgent nature of the problem, without sufficient data on workers’ exposure, it is impossible to evaluate when health surveillance is necessary. Until sufficient and comprehensive data is available and can be consistently shared with relevant health professionals, health surveillance must be mandatory for all exposed workers, including after the end of exposure and the end of their working life. This includes all workers, trainees, apprentices and maintenance staff who have been exposed. Early detection of cancer is one of the most important factors which contribute to higher survival rates.

On a general note this revision has to be seen as a first step towards a renewed ambition to protect workers from harmful substances in the workplace. It is important to see which additional policy areas can help support the long term goal of protection, for instance through research and innovation initiatives.

1. Work-related cancer in the European Union: Size, impact and options for further preventionWork-related cancer in the European Union: Size, impact and options for further prevention,, RIVM, 2016 [↑](#footnote-ref-1)
2. European Parliament resolution of 15 December 2011 on the mid-term review of the European strategy 2007-2012 on health and safety at work (2011/2147(INI)) [↑](#footnote-ref-2)
3. Les expositions aux cancérogenes mutagenes et reprotoxiques, INRS, References en sante au travail, No 144, 2015 [↑](#footnote-ref-3)
4. AFSSET – Agence francaise de sécurité sanitaire de l'environnement et du travail, *Identification d’une liste de substances toxiques pour la reproduction et le développement et Proposition d’une méthode de hiérarchisation pour l’analyse des Valeurs Toxicologiques de Référence, Rapport du groupe d’experts ‘VTR reprotoxic’* , 2006, p. 58. [↑](#footnote-ref-4)
5. Evans, T.J.,’ Endocrine disruptors’, Gupta, R.C. (Ed.), Reproductive and Developmental Toxicity, Elsevier Inc., 2011, pp. 874-875. [↑](#footnote-ref-5)