AMENDMENTS
13 - 112

Draft report
Stefania Zambelli
(PE661.965v02-00)

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

Proposal for a directive
**Amendment 13**
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Abir Al-Sahli, Atidzhe Aliева-Veli

**Draft legislative resolution**
**Citation 3 a (new)**

<table>
<thead>
<tr>
<th>Draft legislative resolution</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>- having regard to the Charter of Fundamental Rights of the European Union, and in particular Article 2 (the right to life) and Article 31 (the right to fair and just working conditions),</td>
<td></td>
</tr>
</tbody>
</table>

**Or. en**

**Amendment 14**
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Abir Al-Sahli, Atidzhe Aliева-Veli

**Proposal for a directive**
**Recital -1 (new)**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(-1) A high level of human health protection should be ensured in the definition and implementation of all Union policies and activities.</td>
<td></td>
</tr>
</tbody>
</table>

**Or. en**

**Amendment 15**
Cindy Franssen, Dennis Radtke

**Proposal for a directive**
**Recital 1**

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
</table>

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.


Amendment 16
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Recital 1 a (new)

Text proposed by the Commission

(1a) In the workplace, workers and other persons are often exposed to a cocktail of substances, which can increase health risks, cause adverse effects on their reproductive systems and cause 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 in line with Regulation (EC) No 1907/2006 of the European Parliament and of the Council. This is necessary to better protect workers and their children and to ensure the safe participation of all workers in the workplace, in particular female workers who are pregnant or breastfeeding. In Regulation (EC) No 1907/2006, half of the 211 substances identified as substances of very high concern are reprotoxic substances. As is the case in some Member States, the organisation of workplace prevention should therefore apply the same approach to carcinogens, mutagens and reprotoxic substances, thus ensuring legal coherence and a level playing field across Member States.


Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would
strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 17
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Abir Al-Sahlani

Proposal for a directive
Recital 1 a (new)

Text proposed by the Commission

(1a) This Directive clearly shows the added value of the Union and the need to adopt legislation at the Union level. In addition to setting similar minimum level of protection across the Union, this Directive also improves clarity and enforcement, and contributes to a better level playing field for the economic actors in the sectors using the substances covered.

Or. en

Amendment 18
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Abir Al-Sahlani, Atidzhe Alieva-Veli

Proposal for a directive
Recital 1 b (new)

Text proposed by the Commission

(1b) It is important to protect sexual and reproductive health and to apply a gender perspective to health and safety at work. Workers can be more exposed and more vulnerable to different types of substances depending on their gender. Women are for example over-represented amongst the oncology nurses community potentially exposed to hazardous medicinal products.
Amendment 19  
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive  
Recital 2  

Text proposed by the Commission

(2) Principle 10 of the European Pillar of Social Rights\textsuperscript{46}, 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 \textit{and} mutagens at the workplace.


Amendment

(2) Principle 10 of the European Pillar of Social Rights\textsuperscript{46}, 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 \textit{and reprotoxic substances} at the workplace.


\underline{Justification}

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1\% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 20  
Cindy Franssen, Dennis Radtke
Proposal for a directive
Recital 2

Text proposed by the Commission

(2) Principle 10 of the European Pillar of Social Rights\textsuperscript{46}, 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.

\textsuperscript{46} European Pillar of Social Rights, November 2017, available at:

Amendment

(2) Principle 10 of the European Pillar of Social Rights\textsuperscript{46}, 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, \textit{irrespective of the arrangements for, and duration of employment and exposure}.

\textsuperscript{46} European Pillar of Social Rights, November 2017, available at:

Or. en

Amendment 21
Johan Danielsson, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission

\textsuperscript{(2a)} Following the amendments to Annex III to Directive 2004/37/EC, as set out in this Directive, further limit values for additional substances or group of substances and processes should be introduced by end of 2024. Between 50 and 70 substances or group of substances have been identified by different agencies, stakeholders, and the World Health Organization in priority lists of workplace
carcinogens, mutagens and reprotoxic substances for which binding limit values are needed. The Commission should, no later than the end of 2021, put forward an action plan to achieve occupational exposure limits for at least 25 additional substances or group of substances or process generated substances. The additional substances or group of substances referred to in Annex III to Directive 2004/37/EC should include but not be limited to substances and processes such as welding fumes, asphalt fumes, leather dust, Poly Aromatic Hydrocarbons (PAHs), 1,4-dioxane, isoprene. Reprotoxic substances should include lead and lead compounds, Bisphenol-A, Carbon Monoxide, Mercury and divalent inorganic mercury compounds, N-methyl-2-pyrrolidone, N,N-Dimethylacetamide, Nitrobenzene, N,N-Dimethylformamide, 2-Methoxy ethanol, 2-Methoxyethyl acetate, 2-Ethoxyethanol, 2-Ethoxyethyl acetate, di(2-ethylhexyl)phthalate, benzyl butyl phthalate and dibutyl phthalate.

Justification

Today, there is a broad consensus among stakeholders and governments that additional limit values are needed to protect workers from the risks of exposure to carcinogenic, mutagenic and reprotoxic substances at work. The priority of substances or group of substances for which these limit values are needed have already been identified by national agencies, stakeholders, and the World Health Organisation.

Amendment 22
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Abir Al-Sahlan, Atidzhe Aliëva-Veli

Proposal for a directive
Recital 2 a (new)

Text proposed by the Commission  Amendment

(2a) Europe’s Beating Cancer Plan
Aims to reduce the cancer burden for patients, their families and health systems. Cancer is the first cause of work-related death in the Union: 52% of annual occupational deaths are currently attributed to work-related cancers. Exposure at work accounts for 3.5-4% cases of cancer and is responsible for approximately 120,000 cancers diagnosed and 80,000 deaths every year.

Amendment 23
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Abir Al-Sahlan, Atidzhe Alieva-Veli

Proposal for a directive
Recital 2 b (new)

Text proposed by the Commission

(2b) Tackling exposures to dangerous substances at the workplace is particularly relevant to foster prevention and address health inequalities, as some categories of workers among the most vulnerable can be overexposed. Some workers, such as mobile workers, can additionally face difficulties to access healthcare services.

Amendment 24
Cindy Franssen, Dennis Radtke

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 25
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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, mutagens and reprotoxic substances for which the available information, including scientific and technical data, make this possible.

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.
Amendment 26
Stefania Zambelli, Elena Lizzi

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 for which the available information, including scientific and technical data, make this possible. In that context, the Commission shall also work with the European Chemicals Agency (ECHA) to develop additional binding occupational exposure limit values for other substances where this is warranted, in particular for critical raw materials such as cobalt.

Justification

Cobalt is listed in the EU as a critical raw material and is a key component in lithium-ion batteries. Other strategic uses include alloys in aircraft, electronics, medical devices, and catalyst applications. In the context of a REACH restriction proposal on five cobalt salts, the ECHA Risk Assessment Committee recently concluded that it “considers it necessary, and proposes to the European Commission, to derive a binding occupational exposure limit value (BOELV) for cobalt and its compounds”. The ECHA Socio-Economic Analysis Committee concluded that “it is uncertain whether the restriction [...] is the most appropriate EU-wide measure” and that “uncertainties are related to [...] the discussion of whether a BOEL would be a more appropriate risk management measure to address the risks to workers”. Exposure to cobalt compounds is a workplace issue and should be regulated under worker protection legislation. A BOEL for cobalt compounds should be prioritised for inclusion in the 5th revision of CMD.

Amendment 27
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu
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 substances 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 and 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

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 28
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoş Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Atidzhe Aliева-Veli

Proposal for a directive
Recital 4 a (new)
Commission Recommendation 2003/670/EC recommends that Member States introduce into their national laws, regulations or administrative provisions concerning scientifically recognised occupational diseases liable for compensation and subject to preventive measures. Member States should guarantee, in their national laws, that every worker has the right to compensation in respect of occupational diseases if he or she is suffering from an ailment which can be proved to be occupational in origin and nature.


Amendment 29
Nikolaj Villumsen, Johan Danielsson
Proposal for a directive
Recital 4 a (new)

In sectors in which workers are exposed to carcinogens or mutagens, gender mainstreaming should be an integral part of the development of occupational safety and health policies and prevention strategies. Member States’ authorities should, in consultation with the social partners, take steps to mainstream gender equality and LGBTQI+ considerations in the implementation of Articles 7, 8 and 10 of Directive 2004/37/EC as regards sanitary
facilities, work equipment and personal protective equipment.

Justification

Many professions do not have separate sanitary facilities for workers that identify as a gender different from the male gender nor protective equipment that is suited for workers of female gender.

Amendment 30

Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Abir Al-Sahlani, Atidzhe Alieva-Veli

Proposal for a directive

Recital 4 b (new)

Text proposed by the Commission

(4b) However, the reporting and recognition of occupational cancers as occupational diseases are uneven, due in particular, to a long latency between the exposure to dangerous substances and the diagnosis of the disease, the multifactorial nature of cancer but also to complex procedures to undertake in order to have the illness officially recognised as work-related and to obtain compensation. Data from work-related health problems are often lacking, not reliable or insufficient. Further efforts are therefore needed to improve reporting, prevention, diagnosis, early recognition and compensation of occupational diseases, as well as better medical monitoring throughout life with robust diseases and exposures registries.

Amendment 31

Nikolaj Villumsen, Johan Danielsson
Proposal for a directive
Recital 4 b (new)

Text proposed by the Commission

(4b) Member States’ authorities should ensure that Articles 7, 8 and 10 of Directive 2004/37/EC take due consideration to workers with disabilities especially with regard to sanitary facilities, work equipment and personal protective equipment.

Amendment

Or. en

Amendment 32
Nikolaj Villumsen, Johan Danielsson

Proposal for a directive
Recital 4 c (new)

Text proposed by the Commission

(4c) Sectors such as the steel and chemicals industry as well as the cleaning sector in health services rely on posted workers, third country nationals and migrant workers. Member States’ authorities should especially ensure that the measures in Article 5 on prevention and reduction of exposure measures for workers as well as the information and training requirement in Article 11 of Directive 2004/37/EC are extended to posted workers, third-country nationals and migrant workers.

Amendment

Or. en

Justification

Many sectors such as the steel and chemicals industry as well as the cleaning sector in health services rely on posted workers, third country nationals and migrant workers. Therefore it is important to ensure that the measures on information and training requirements in Article 11 is not restricted due to language barriers etc. for this group of workers.
Amendment 33
Nikolaj Villumsen
Proposal for a directive
Recital 4 d (new)

Text proposed by the Commission

Amendment

(4d) In medical settings and home care, where workers, patients and their family members who are pregnant, breast feeding or trying to conceive, employers should, in addition to Article 5(5) of Directive 2004//37/EC not permit the exposure of such workers to carcinogens, mutagens or reprotoxic substances.

Or. en

Amendment 34
Nikolaj Villumsen
Proposal for a directive
Recital 4 e (new)

Text proposed by the Commission

Amendment

(4e) Swipe testing in cancer care are rare which means that important risks of exposure are not identified. If swipe tests were performed systematically, many risks would be identified and therefore the use of such tests should be added to Article 3 of Directive 2004//37/EC with regard to risk assessment.

Or. en

Amendment 35
Nikolaj Villumsen
Proposal for a directive
Recital 4 f (new)

Text proposed by the Commission

(4f) There is a need for in-depth knowledge on the effect of the substances handled by workers in the healthcare sector. The training requirements in Article 11 of Directive 2004/37/EC should not only be repeated periodically for workers in the healthcare sector but should be repeated systematically for all healthcare workers who are exposed to cytotoxic substances or mutagens.

Or. en

Amendment 36
Cindy Franssen, Dennis Radtke

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

Amendment

(5) This Directive strengthens the protection of workers’ health and safety at their workplace. The Commission should review it on a regular basis and make legislative proposals if appropriate. New binding limit values should be set out in Directive 2004/37/EC. Binding occupational exposure limit values should be evidence-based and measurable, being established on the basis of available information, including updated scientific and technical data, economic feasibility of implementation and compliance and should also be based on a thorough assessment of the 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
from occupational exposure to carcinogens and mutagens. Risk Assessment (RAC) of the European Chemicals Agency (ECHA), as well as opinions of the Advisory Committee on Safety and Health at Work (ACSH) and monographs of the International Agency for Research on Cancer (IARC). 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 37
Joanna Kopcińska on behalf of the ECR Group

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) *The amendments to Directive 2004/37/EC provided for in this Directive aim to strengthen* 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 38
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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 and mutagens.

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. In practice, the current methodology used by the European Commission takes into account a mix of health aspects, technical feasibility and socio-economic factors. Ultimately, the binding OELs proposed for carcinogens are based on cost-benefit analysis.
Amendment 39
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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 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, mutagens and reprotoxic substances.

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.
Amendment 40
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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 and reprotoxic substances to a shorter reference period, in general fifteen minutes time-weighted average (short-term exposure limit values), in order to limit, to the extent possible, the effects arising from short-term exposure.

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 41
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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

Amendment

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

Or. en

**Justification**

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

**Amendment 42**
Johan Danielsson, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Recital 7 a (new)

<table>
<thead>
<tr>
<th>Text proposed by the Commission</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>(7a) In the workplace, workers are often exposed to a cocktail of hazardous substances, which can increase risks and cause adverse health effects. In the case of exposure to a combination of substances acting by the same mode of action or at the same target cell or tissue, it is necessary to adapt the implementation of their possible limit values to take into account the combined effects.</td>
<td></td>
</tr>
</tbody>
</table>

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 to different substances acting by the same mode of action (e.g., different carcinogenic substances present at the workplace).
Amendment 43
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Abir Al-Sahli, Atidzhe Aliева-Veli

Proposal for a directive
Recital 9

Text proposed by the Commission

(9) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council and is therefore carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a long- and short-term limit value for that carcinogen. Acrylonitrile can also be absorbed through the skin. It is therefore appropriate to establish a limit value for acrylonitrile under the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for acrylonitrile. This should be considered when developing guidance on the practical use of biomonitoring.

Amendment

(9) Acrylonitrile meets the criteria for classification as carcinogenic (category 1B) in accordance with Regulation (EC) No 1272/2008 of the European Parliament and the Council and is therefore carcinogen within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set a long- and short-term limit value for that carcinogen. Acrylonitrile can also be absorbed through the skin. Acrylonitrile is acutely toxic and causes neurotoxicity, local irritation of skin, eyes and respiratory tract, and skin sensitisation. It is therefore appropriate to establish a limit value for acrylonitrile under the scope of Directive 2004/37/EC and to assign a skin notation to it. The ACSH, based on the RAC opinion, agreed on the usefulness of the biomonitoring for acrylonitrile. This should be considered when developing guidance on the practical use of biomonitoring.

Justification

This amendment is based on the opinion of the Risk Assessment Committee of ECHA:
https://echa.europa.eu/documents/10162/102477c9-a961-2c96-5c4d-76fcd856ac19

Amendment 44
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Abir Al-Sahlaní, Atidzhe Alieva-Veli

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 four years after entry into force of this Directive should be introduced from which these Occupational Exposure Limit (OEL) values shall apply. Exposure should be reduced as far as technically possible below these limit values.

Or. en

Justification

Where this is not technically possible to replace or substitute the substance, worker exposure must be reduced to as low a level as is technically possible. This is the minimisation obligation under Article 5(2) and Article 5(3) of the Directive 2004/37/EC.

Amendment 45
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Atidzhe Aliева-Veli

Proposal for a directive
Recital 11

Text proposed by the Commission

(11) Nickel compounds meet the criteria for classification as carcinogenic (category

Amendment

(11) Nickel compounds meet the criteria for classification as carcinogenic (category
1A) in accordance with Regulation (EC) No 1272/2008 and are therefore carcinogens within the meaning of Directive 2004/37/EC. It is possible, on the basis of the available information, including scientific and technical data, to set limit values for that group of carcinogens. Exposure to nickel compounds at 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 the nickel compounds under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation.

According to the RAC, the available information on the mechanisms of genotoxicity and cancer support a mode-of-action based threshold for carcinogenic effects. For that reason, the RAC proposed an occupational exposure limit of 0.005 mg/m³ for the respirable fraction and 0.03 mg/m³ for the inhalable fraction under which no significant residual cancer risk is expected for workers. Exposure to nickel 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 the nickel compounds under the scope of Directive 2004/37/EC and to assign a notation for dermal and respiratory sensitisation. Based on the consensus between the social partners within the ACSH, limit values of 0.01 mg/m³ for the respirable fraction and 0.05 mg/m³ for the inhalable fraction are introduced. Exposure should be reduced as far as technically possible below these limit values and, when possible, below the limit values proposed by the RAC.

Justification

This amendment is based on the opinion of the Risk Assessment Committee of ECHA: https://echa.europa.eu/documents/10162/9e050da5-b45c-c8e5-9e5e-a1a2ce908335Where this is not technically possible to replace or substitute the substance, worker exposure must be reduced to as low a level as is technically possible. This is the minimisation obligation under Article 5(2) and Article 5(3) of the Directive.
Amendment 46
Ádám Kósa

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 nickel compounds should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU.

Amendment

(12) With regard to nickel compounds, limit values of 0.01 mg/m³ for the respirable fraction and 0.05 mg/m³ for the inhalable fraction may be difficult to be complied with in a number of sectors or processes, including specifically smelting, refineries and welding. Furthermore, since identical risk management measures can be used both for chromium (VI) and nickel compounds, the transitional measures aiming to reduce the exposure to these two groups of carcinogens should be aligned, and by analogy with the legislation on chromium (VI), an inhalable limit value of 0.05 mg/m³ should be introduced for nickel in the transitional period two years after its entry into force. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU.

Amendment 47
Joanna Kopcińska


Or. hu
on behalf of the ECR Group

Proposal for a directive
Recital 12

(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 those two groups of carcinogens should be aligned. Therefore, a transitional period until 17 January 2025 inclusive should be introduced during which a limit value of 0.1 mg/m³ for the inhalable fraction of the nickel compounds should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU.

(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 those two groups of carcinogens should be aligned. Therefore, a transitional period of six years, up to and including 17 January 2027, should be introduced. From two years up to four years after the entry into force, a transitional limit value of 0.1 mg/m³ for the inhalable fraction of the nickel compounds should apply.

Recital 12

Text proposed by the Commission

(12) With regard to nickel compounds, limit values of $0.01\,\text{mg/m}^3$ for the respirable fraction and $0.05\,\text{mg/m}^3$ 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 $0.1\,\text{mg/m}^3$ for the inhalable fraction of the nickel compounds should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU\(^{48}\).

Amendment

(12) With regard to nickel compounds, limit values of $0.005\,\text{mg/m}^3$ for the respirable fraction and $0.03\,\text{mg/m}^3$ 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 $0.1\,\text{mg/m}^3$ for the inhalable fraction of the nickel compounds should apply. This transitional period would ensure alignment with the date of application of the OEL for Chromium (VI) compounds adopted in Directive 2017/2398/EU\(^{48}\).


Amendment 49

Johan Danielsson, Heléne Fritzon, Lina Gálvez Muñoz, Brando Benifei, Agnes
Jongerius, Rovana Plumb, Manuel Pizarro, Alicia Homs Ginel, Evelyn Regner, Alex Agius Saliba, Elisabetta Gualmini, Gabriele Bischoff, Estrella Durá Ferrandis, Milan Brglez, Vilija Blinkevičiūtė, Marianne Vind, Pierfrancesco Majorino

Proposal for a directive
Recital 12a (new)

\textit{Text proposed by the Commission} \hspace{1cm} \textit{Amendment}

\begin{itemize}
\item \textbf{(12a)} The green economy is expected to expand in the context of the European Green Deal. It is therefore necessary to focus on potential occupational safety and health risks in green jobs. Nickel compounds play a considerable role in the development of green alternatives to fossil fuels. It is therefore likely that the need for nickel compounds will grow and it is essential to protect workers from, and ensure the full and effective implementation of the occupational exposure limit values to that chemical agent.
\end{itemize}

Amendment 50
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Atidzhe Alieva-Veli

Proposal for a directive
Recital 13

\textit{Text proposed by the Commission} \hspace{1cm} \textit{Amendment}

\begin{itemize}
\item \textbf{(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
\item \textbf{(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. \emph{According to the RAC}, a mode-of-action-based threshold for chromosomal damage in workers can be used to establish an occupational exposure limit for carcinogenicity which is considered to have no significant
\end{itemize}
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.

residual cancer risk and to avoid other adverse effects. For this reason, the RAC proposed an Occupational Exposure limit of 0.05 ppm (0.16 mg/m³). 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. Based on a consensus between the social partners in the ACSH, a revised limit value of 0.2 ppm (0.66 mg/m³) is introduced. Exposure should be reduced as far as technically possible below this limit value and, when possible, below the limit value proposed by the RAC.

Or. en

Justification

This amendment is based on the opinion of the Risk assessment committee of ECHA: https://echa.europa.eu/documents/10162/4fec9aac-9ed5-2aae-7b70-5226705358c7 Where this is not technically possible to replace or substitute the substance, worker exposure must be reduced to as low a level as is technically possible. This is the minimisation obligation under Article 5(2) and Article 5(3) of the Directive.

Amendment 51
Stefania Zambelli, Elena Lizzi

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

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.

Amendment 52
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Sara Matthieu

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.
Justification

The ACSH opinion on Benzene agreed on by the three Interests Groups and adopted on 04/06/2019 has not been fully respected by the EU Commission in its legislative proposal. On top of the agreed OELs and transitional periods, a mandatory revision of the limit value by 2030 was part of the deal.

Amendment 53
Joanna Kopcińska
on behalf of the ECR Group

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 0.2 ppm (0.66 mg/m³) may be difficult to be complied with in some sectors in the short term. A transitional period of six years should be introduced, up to and including 17 January 2027, after the entry into force of this Directive. From two years up to four years after entry into force, a transitional limit value of 0.5 ppm (1.65 mg/m³) should apply.

Or. pl

Amendment 54
Nikolaj Villumsen

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

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.

Amendment 55
Johan Danielsson, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Recital 14 a (new)

Text proposed by the Commission

(14a) Cobalt and cobalt 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. 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.

Justification

The ECHA’s Risk Assessment Committee (RAC) has 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). RAC supports the restriction targeted at the five soluble cobalt salts, but additionally recommends to the European Commission to derive a binding occupational exposure limit value (BOEL) for cobalt and its compounds under the CMD.
Amendment 56
Nikolaj Villumsen, Johan Danielsson
Proposal for a directive
Recital 14 a (new)

Text proposed by the Commission

(14a) The limit value for respirable crystalline silica dust (‘respirable fraction’) set out in Annex III to Directive (EU) 2017/2398 should be revised in the light of Article 18a and more recent scientific and technical data.

Amendment 57
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu
Proposal for a directive
Recital 14 b (new)

Text proposed by the Commission

(14b) Hazardous Medicinal Products can cause adverse health effects, such as certain types of cancer and reproductive disorders, in workers who are exposed to them in the course of work involving their preparation, administration, or disposal. Hazardous Medicinal Products affect workers who handle them directly or indirectly. Such workers include healthcare workers using cytostatic or cytotoxic drugs to treat cancer patients in hospitals or at home and workers who carry out activities relating to the cleaning, transport, laundry, or the waste disposal of hazardous drugs or of material contaminated by such drugs. It is therefore important to protect all workers by including relevant pharmacotherapeutic groups of Hazardous Medicinal Products in Annex I to Directive 2004/37/EC. The reduction
and replacement requirements laid down in Article 4 of that Directive do not apply to Hazardous Medicinal Products because they are essential to treat patients. The other provisions of that Directive, in particular Articles 5 to 18a thereof, as amended by this Regulation, apply to workers who are exposed to Hazardous Medicinal Products.

Or. en

Justification

In the healthcare sector alone, 12.7 million workers in Europe (of which 7.3 million nurses), are exposed to Hazardous Medicinal Products at work. Studies show that healthcare workers who handle cytotoxic drugs (all drugs with anti-tumoral activity) are three times more likely to develop cancer (such as breast cancer, haematopoietic cancer) and nurses exposed to cytotoxic drugs are twice as likely to miscarry.

Amendment 58

Proposal for a directive
Recital 14 c (new)

Text proposed by the Commission

(14c) The use at the workplace or while performing job-related duties, of any carcinogens, mutagens or reprotoxins, including those referred to in the annexes to Directive 2004/37/EC, as amended by this Directive, should be reported to the national authorities responsible for supervising workers’ health. When deciding what substances to report, Member States should take into account the implementation reports submitted to the Commission pursuant to Article 17a of Directive 89/391/EEC.

Amendment

Or. en
Amendment 59
Cindy Franssen, Dennis Radtke

Proposal for a directive
Recital 15a (new)

Text proposed by the Commission
(15a) In implementing this Directive Member States should take the everyday existence of small and medium-sized enterprises (SMEs) into account. 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. While maintaining equal protection levels for all the workers, compliance for SMEs and microenterprises should be facilitated; against this background, specific measures such as incentives and digital tools could help them to better comply with the obligations laid down in the Directive 2004/37/EC. In that regard, the social partners should exchange best practices.

Amendment 60
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Dragoș Pîslaru, Sylvie Brunet, Alin Mituța, Stéphane Bijoux, Abir Al-Sahlni

Proposal for a directive
Recital 16

Text proposed by the Commission
(16) The limit values established in this Directive are to be kept under regular scrutiny and review to ensure consistency

Amendment
(16) The limit values established in this Directive are to be kept under permanent scrutiny and regular review to ensure
with Regulation (EC) No 1907/2006\(^\text{49}\).


consistency with Regulation (EC) No 1907/2006\(^\text{49}\).


Or. en

Amendment 61
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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 62  
Véronique Trillet-Lenoir, Marie-Pierre Vedrenne, Sylvie Brunet, Stéphane Bijoux, Abir Al-Sahlani
Proposal for a directive  
Recital 17 a (new)

+ Text proposed by the Commission + Amendment

(17a) It is important to ensure operational feasibility and compliance by SMEs and to take all necessary actions to ensure the safety and health of workers are protected no matter the size of the enterprise. The European Agency for Health and Safety at Work has an important role to play in this regard, in particular to help SMEs assess the risks for their workforce and implement adequate protective measures.

Or. en

Justification

According to the Communication of the Commission "safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy" (COM(2017) 12 final): "microenterprises and SMEs struggle to put in place the necessary occupational safety and health management measures [...] This is related to more limited financial, technical and human resources, lack of awareness and expertise as compared to bigger establishments. All stakeholders, including in the first place SMEs themselves, agree that in this area making exemptions for SMEs is not the right approach, because they fear it may potentially lower the protection level of SME workers [...]. However, compliance should become simpler and less costly and this requires specific support measures for SMEs and microenterprises." EU-OSHA proposes an Online interactive Risk Assessment (OiRA) platform aiming at helping SMEs to assess their risks (https://oiraproject.eu/en/)

Amendment 63  
Cindy Franssen, Dennis Radtke
Proposal for a directive  
Recital 18 b (new)

+ Text proposed by the Commission + Amendment

(18b) Articles 153, 154 and 155 TFEU

AM\1223888EN.docx 39/76  PE680.880v01-00
establish the scope and authority of the social partners to negotiate and enforce agreements relating to occupational health and safety and the Charter of Fundamental Rights of the European Union guarantees, in particular, the fundamental right to life (Article 2) and the right to fair and just working conditions with respect to health, safety and dignity (Article 31(1)).

Amendment 64
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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

Title

<table>
<thead>
<tr>
<th>Present text</th>
<th>Amendment</th>
</tr>
</thead>
</table>

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical
legislation at the EU level.

Amendment 65
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -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) In Article 1(1), the first paragraph is replaced by the following:

“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

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 66
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 b (new)
Directive 2004/37/EC
Article 2 – point b a (new)
Text proposed by the Commission

Amendment

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

"(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;"

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 67
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 c (new)
Directive 2004/37/EC
Article 2 – point c (new)

Present text

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

“(c) ‘limit value’ means, unless otherwise specified, the limit of the time-weighted average of the concentration for a ‘carcinogen 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.

(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.”
According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 68
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 d (new)
Directive 2004/37/EC
Article 2 – point c a (new)

Text proposed by the Commission

Amendment

(-1d) 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, which is to be set in accordance with the procedure laid down in Article 153(2) of the Treaty on the Functioning of the European Union (TFEU)."

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. In practice, the current methodology used by the European Commission takes into account a mix of health aspects, technical feasibility and socio-economic factors. Ultimately, the binding OELs proposed for carcinogens are based on cost-benefit analysis.
Proposal for a directive
Article 1 – point -1 e (new)
Directive 2004/37/EC
Article 3 – paragraph 1

Present text
(-1e) In Article 3, paragraph 1 is replaced by the following:
“1. This Directive shall apply to activities in which workers are or are likely to be exposed to carcinogens or mutagens or reprotoxic substances as a result of their work.”

Justification
According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

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

Present text
(-If) In Article 3(2), the first subparagraph is replaced by the following:
"In the case of any activity likely to involve..."

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. 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. The employer shall supply the authorities responsible at their request with the information used for making the assessment.

Involve a risk of exposure to carcinogens or mutagens or reprotoxic substances; the nature, degree and duration of workers' exposure shall be determined by way of a systematic risk assessment, in order to make it possible to assess any risk to the workers' health or safety and to lay down the measures to be taken. The assessment shall be renewed regularly and in any event when any change occurs in the conditions which may affect workers' exposure to carcinogens, mutagens or reprotoxic substances. The employer shall supply the authorities responsible at their request with the information used for making the assessment."

Or. en

(02004L0037)

Justification

It is important to name the systematic risk assessment as an obligation.

Amendment 71
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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

Present text

Amendment

(-1g) In Article 3(2), the first subparagraph is replaced by the following:

"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
down the measures to be taken. the measures to be taken.”

**Justification**

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

**Amendment 72**

Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

**Proposal for a directive**

**Article 1 – point -1 h (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**

(-1h) *In Article 3(2), the second subparagraph is replaced by the following:* “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.”

**Justification**

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.
Amendment 73  
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive  
Article 1 – point -1 i (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

(-i) In Article 3, paragraph 4 is replaced by the following:

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

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 74  
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive  
Article 1 – point -1 j (new)  
Directive 2004/37/EC  
Article 4 – paragraph 1
In Article 4, paragraph 1 is replaced by the following:

"1. Where a carcinogen, mutagen or reprotoxic substance is present at the workplace, the employer shall reduce its use, 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. This paragraph shall not apply to the use of hazardous medicinal products set out in Annex I."

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Proposal for a directive

Amendment 75
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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 replaced by the following:

"2. Where it is not technically possible to replace the carcinogen, mutagen or reprotoxic substance by a substance, mixture or process which, under its
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.

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

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 76
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -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

(-l) In Article 5, paragraph 4 is replaced by the following:

“4. Exposure shall not exceed the limit value of a carcinogen, mutagen or reprotoxic substance as set out in Annex III.”

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.
Proposal for a directive
Article 1 – point -1 m (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

(-1m) In Article 5, paragraph 4 is replaced by the following:

“4. Exposure shall not exceed the limit value of a substance as set out in Annex III. In the case of exposure to a combination of substances acting by the same mode of action 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

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 to different substances acting by the same mode of action (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 adequately protect workers’ health. It is necessary to adapt the implementation of the different limit values to take into account the combined exposure.

Proposal for a directive
Article 2 – point -1 n (new)
Directive 2004/37/EC
Article 5 – paragraph 5 – introductory part
Present text

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

Amendment

- In Article 5(5), the introductory part is replaced by the following:

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

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 79
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 o (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

(-1o) In Article 5(5), point (a) is replaced by the following:

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

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would
strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 80
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 p (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
(-1p) In Article 5(5), point (c) is replaced by the following:
"(c) design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens, mutagens or reprotoxic substances into the place of work;"

Or. en

Justification
According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 81
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 q (new)
Directive 2004/37/EC
Article 5 – paragraph 5 – point d
Amendment (-1q) In Article 5(5), point (d) is replaced by the following:

“(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;”

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 82
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 r (new)
Directive 2004/37/EC
Article 5 – paragraph 5 – point e

Amendment (-1r) In Article 5(5), point (e) is replaced by the following:

“(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;”
Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 83
Sara Matthieu, Tilly Metz
on behalf of the Greens/EFA Group

Proposal for a directive
Article 1 – point -1 s (new)
Directive 2004/37/EC
Article 5 – paragraph 5 – point i a (new)

Text proposed by the Commission

Amendment

(-1s) In Article 5(5), the following point is inserted:
"(ia) ensure that personal protective equipment is provided;"

Amendment 84
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 t (new)
Directive 2004/37/EC
Article 5 – paragraph 5 – point j

Present text

Amendment

(-1t) In Article 5(5), point (j) is replaced by the following:

(j) demarcation of risk areas and use of adequate warning and safety signs

"(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; including 'no smoking' signs in areas where workers are exposed or likely to be exposed to carcinogens, mutagens or reprotoxic substances;”

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 85
Sara Matthieu, Tilly Metz
on behalf of the Greens/EFA Group

Proposal for a directive
Article 1 – point -1 u (new)
Directive 2004/37/EC
Article 5 – paragraph 5 – point m a (new)

Text proposed by the Commission

Amendment

(-1u) In Article 5(5), the following point is added:

"(ma) in accordance with Directive 92/85/EC, take the necessary measures to ensure that pregnant workers, workers who have recently given birth and workers who are breastfeeding are duly protected and are in no circumstances required to carry out activities which could jeopardise their safety or health.”

Or. en

Justification

Reprotoxic substances can seriously harm pregnant and breastfeeding workers therefore we need special measures targeting this group of workers.
Amendment 86
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 v (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
(-1v) In the first paragraph of Article 6, point (a) is replaced by the following:
“(a) the activities and/or industrial processes carried out, including the reasons for which carcinogens, mutagens or reprotoxic substances are used;”

Justification
According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 87
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 w (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
(-1w) In the first paragraph of Article 6, point (b) is replaced by the following:
“(b) the quantities of substances or mixtures manufactured or used which contain carcinogens, mutagens or...
reprotoxic substances;"

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 88
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 x (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

(-1x) In Article 10 (1), the introductory part is replaced by the following:

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

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.
Amendment 89
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 y (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
(-1y) In Article 10(1), point (a) is replaced by the following:
“(a) workers do not eat, drink or smoke in working areas where there is a risk of contamination by carcinogens, mutagens or reprotoxic substances;”

Justification
According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 90
Cindy Franssen, Dennis Radtke

Proposal for a directive
Article 1 – point -1z (new)
Directive 2004/37/EC
Article 11 – paragraph 1 – subparagraph 2 – indents 1 and 2

Present text
— Adapted to take account of new or

Amendment
(-1 z) In the second subparagraph of Article 11(1), the indents are replaced by the following:
— Adapted to take account of new or
changed risk, and changed risk,
– Repeated periodically if necessary.
– Repeated periodically in healthcare settings for all workers who come in to contact with cytotoxic and mutagens, and
– Repeated periodically in other settings if necessary."

Amendment 91
Sara Matthieu, Tilly Metz
on behalf of the Greens/EFA Group

Proposal for a directive
Article 1 – point -1 aa (new)
Directive 2004/37/EC
Article 11 – paragraph 1 – subparagraph 2 – indents 1 and 2

Present text
Amendment

(-1aa) In the second subparagraph of Article 11(1), the indents are replaced by the following:

– Adapted to take account of new or changed risk, and
– Repeated periodically if necessary.
– Adapted to take account of new or changed risk,
– Repeated periodically if necessary, and
– Repeated periodically in healthcare settings for all workers who are exposed to carcinogens, mutagens or reprotoxic substances, in particular where new drugs occur."

(02004L0037)

Justification

Trainings that are repeated on a regular base are of particular importance in the healthcare sector, which is the most exposed to these substances.
Amendment 92
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 ab (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

(-1ab) In Article 11, paragraph 2 is replaced by the following:

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

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 93
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 ac (new)
Directive 2004/37/EC
Article 14 – paragraph 3 – subparagraph 1
Amendment

(-1ac) In Article 14(3), the first subparagraph is replaced by the following:

“3. If a worker is found to be suffering from an abnormality which is suspected to be the result of exposure to carcinogens 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.”

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 94
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 ad (new)
Directive 2004/37/EC
Article 14 – paragraph 8 – subparagraph 1

Present text

Amendment

(-1ad) In Article 14(8), the first subparagraph is replaced by the following:

“All cases of cancer and reproductive disorder 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.”
notified to the competent authority.”

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 95
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 ae (new)
Directive 2004/37/EC
Article 14 – paragraph 8 – subparagraph 1

Present text

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

Amendment

(-1ae) In Article 14(8), the first subparagraph is replaced by the following:

“8. All cases of cancer and 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. The Member States shall include the information referred to in this paragraph in their implementation reports submitted to the Commission pursuant to Article 17a of Directive 89/391/EEC.”

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to...
at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 96
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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

Text proposed by the Commission

Amendment

(-1af) 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) as part of the implementation reports submitted to the Commission pursuant to Article 17a of Directive 89/391/EEC.”

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 97
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 ag (new)
Directive 2004/37/EC
Article 16 – paragraph 1
Amendment
(-1ag) In Article 16, paragraph 1 is replaced by the following:

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

Or. en

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 98
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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

Amendment
(-1 ah) In Article 16, paragraph 1 is replaced by the following:

1. The European Parliament and the Council shall, in accordance with the procedure laid down in Article 153(2) 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 for which this is possible, and, where necessary, other directly related provisions.

information, including scientific and technical data, in respect of all those carcinogens, mutagens for which this is possible, and, where necessary, other directly related provisions.”

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. In practice, the current methodology used by the European Commission takes into account a mix of health aspects, technical feasibility and socio-economic factors. Ultimately, the binding OELs proposed for carcinogens are based on cost-benefit analysis.

Amendment 99
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

Proposal for a directive
Article 1 – point -1 ai (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 ai) In Article 17, paragraph 1 is replaced by the following:

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

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would
strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 100
Johan Danielsson, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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

Text proposed by the Commission

-Amendment (-1 aj) 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 of relevant stakeholders, prepare Union guidelines on how the implementation of the limit values referred to in Article 5(4) should be adapted in the case of exposure to a combination of substances. Those guidelines shall be published on the website of the EU-OSHA and be disseminated in all Member States.”

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 to different substances acting by the same mode of action (e.g., different carcinogenic substances present at the workplace).

Amendment 101
Stefania Zambelli, Elena Lizzi
Proposal for a directive
Article 1 – point -1 ak (new)
Directive 2004/37/EC
Article 18a – paragraph 4 a (new)

Text proposed by the Commission

Amendment

(-1ak) 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 102
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Sara Matthieu

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

Text proposed by the Commission

Amendment

(-1al) 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.”
The ACSH opinion on Benzene agreed on by the three Interests Groups and adopted on 04/06/2019 has not been fully respected by the EU Commission in its legislative proposal. On top of the agreed OELs and transitional periods, a mandatory revision of the limit value by 2030 was part of the deal.

Amendment 103
Johan Danielsson, Nikolaj Villumsen, Sara Matthieu

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

Text proposed by the Commission

(-1 am) In Article 18a, the following paragraph is added:
“No later than 31 December 2021, the Commission shall, taking into account the existing recommendations from different agencies, stakeholders and the World Health Organization on priority carcinogens, mutagens and reprotoxic substances for which limit values are needed, and after consulting the ACSH, present an action plan to achieve occupational exposure limits values for at least 25 substances, or groups of substances or process generated substances additional to those referred to in this Directive. No later than 31 December 2024, the Commission shall taking into account that action plan to achieve limit values for at least 25 additional substances or group of substances and/or process generated substances, the latest developments in scientific knowledge, and after consulting of the ACSH, present a legislative proposal.”

Or. en
Justification

Today, there is a broad consensus among stakeholders and governments that additional limit values are needed to protect workers from the risks of exposure to carcinogenic, mutagenic and reprotoxic substances at work. The priority of substances or group of substances for which these limit values are needed have already been identified by national agencies, stakeholders, and the World Health Organisation.

Amendment 104
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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

Text proposed by the Commission

Amendment

(-1an) 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 of relevant stakeholders, in particular health practitioners and health professionals, develop a definition of Hazardous Medicinal Products and establish the list of substances covered by the related entry in Annex I. The Commission shall review that list every two years. No later than 1 December 2022, the Commission shall, after the appropriate consultation of relevant stakeholders, prepare Union guidelines and standards of practice for the preparation, administration, and disposal of Hazardous Medicinal Products. Those guidelines and standards shall be published on the website of the European Agency for Safety and Health at Work (EU-OSHA) and shall be disseminated in all Member States. The consultations undertaken to develop the definition, list, guidelines and standards shall be
transparent. The declarations of interests of stakeholders and experts shall be made public in a timely manner.”

Or. en

Justification

Studies show that healthcare workers who handle cytotoxic drugs (all drugs with anti-tumoral activity) are three times more likely to develop cancer (such as breast cancer, haematopoietic cancer) and nurses exposed to cytotoxic drugs are twice as likely to miscarry.

Amendment 105
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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

Text proposed by the Commission

(-1ao) In Article 18 a, the following paragraph is inserted after the second paragraph:

“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 of relevant stakeholders, prepare Union guidelines on the methodology establishing risk-based limit values under this Directive. Those guidelines shall be published on the website of the (EU-OSHA) and be disseminated in all Member States.”

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. In practice, the current methodology used by the European Commission takes into account a mix of health aspects, technical feasibility and socio-economic factors. Ultimately, the binding OELs proposed for carcinogens are based on cost-benefit analysis.

Amendment 106
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu

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

Text proposed by the Commission

Amendment

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

“8a. Work involving exposure to Hazardous Medicinal Products as defined by the process outlined in article 18a 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

Justification

In the healthcare sector alone, 12.7 million workers in Europe (of which 7.3 million nurses), are exposed to Hazardous Medicinal Products at work. Studies show that healthcare workers who handle cytotoxic drugs (all drugs with anti-tumoral activity) are three times more likely to develop cancer (such as breast cancer, haematopoietic cancer) and nurses exposed to cytotoxic drugs are twice as likely to miscarry.

Amendment 107
Johan Danielsson, Cindy Franssen, Véronique Trillet-Lenoir, Nikolaj Villumsen, Sara Matthieu
Proposal for a directive
Article 1 – point -1 aq (new)
Directive 2004/37/EC
Annex II – point 1

Present text

(-1aq) In Annex II, point 1 is replaced by the following:

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

Amendment

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

Justification

According to conservative estimates based on the survey conducted by the French Ministry of Labour - SUMER, 2015, a minimum of 1% of the workforce in each EU country is exposed to at least one substance toxic for reproduction at work. Extending the scope of the Carcinogens and Mutagens Directive (CMD) to allow for the inclusion of reprotoxic substances would strengthen the current OSH system, bring legal coherence, and better alignment of chemical legislation at the EU level.

Amendment 108
Nikolaj Villumsen, Johan Danielsson

Proposal for a directive
Annex – point 1 – introductory part
Directive 2004/37/EC
Annex III – point A – row 4

<table>
<thead>
<tr>
<th>Present text</th>
<th>Amendment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respirable crystalline silica dust</td>
<td>– – 0,1 – – – – – –</td>
</tr>
<tr>
<td>Respirable crystalline silica dust</td>
<td>– – 0,05 – – – – – –</td>
</tr>
</tbody>
</table>

Or. en
Justification

Directive (EU) 2017/2398 obligates the EU Commission to evaluate the need to modify the limit value for Respirable Crystalline Silica (RCS) dust by 2022. Since its inclusion in Annex III of Directive 2004/37/EC in 2017, the limit value remains at 0.1 mg/m³ despite the 341,000 workers expected to die from an exposure at that level between 2010 and 2069. This figure takes solely lung cancer cases into account, even though mortality is expected to be higher due to other diseases caused by exposure. Spain and Finland, and other non-EU countries have a lower limit value nationally (0.05 mg/m³) showing that this is technically and economically feasible.

Amendment 109
Nikolaj Villumsen, Johan Danielsson

Proposal for a directive
Annex – point 1 – introductory part
Directive 2004/37/EC
Annex III – point A

<table>
<thead>
<tr>
<th>Benzene</th>
<th>200-253-7</th>
<th>71-43-2</th>
<th>0.66</th>
<th>0.2</th>
<th>–</th>
<th>–</th>
<th>–</th>
<th>–</th>
<th>Skin (8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The limit value shall apply from four years after entry into force of this Directive. From two years up to four years after entry into force, a limit value of 0.5 ppm (1.65 mg/m³) shall apply.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Amendment

deleted

Or. en

Amendment 110
Nikolaj Villumsen

Proposal for a directive
Annex – point 1
Directive 2004/37/EC
Annex III – point A
### Text proposed by the Commission

| Benzine | 200-753-7 | 71-43-2 | 0.66 | 0.2 | – | – | – | – | Skin (8) | The limit value shall apply from four years after entry into force of this Directive. From two years up to four years after entry into force, a limit value of 0.5 ppm (1.65 mg/m³) shall apply. |

### Amendment

| Benzine | 200-753-7 | 71-43-2 | 0.16 | 0.05 | – | – | – | – | Skin (8) | The limit value shall apply from four years after entry into force of this Directive. From two years up to four years after entry into force, a limit value of 0.5 ppm (1.65 mg/m³) shall apply. |

### Justification

Amendment seeks to lower limit value for benzene from 0.66 and 0.2 to 0.16 and 0.05.

Amendment 111
Marianne Vind, Johan Danielsson, Agnes Jongerius, Alicia Homs, Lina Galvez Munoz, Alex Agius Saliba, Vilija Blinkeviciute, Brando Benifei, Elisabetta Gualmini, Estrella Dura Ferrandis, Evelyn Regner, Heléne Fritzon, Milan Brglez, Pierfrancesco Majorino, Rovana Plumb

Proposal for a directive
Annex – point 2
Directive 2004/37/EC
Annex III – point A – row 2

### Text proposed by the Commission

| Nickel compounds | – | – | 0.01(*) | – | – | – | – | – | Dermal and respiratory sensitisation (11) | The limit value shall apply from 18th January 2025 |
The limit value shall apply from 18th January 2025. Until then a limit value of 0.1 mg/m³ shall apply.

### Amendment

<table>
<thead>
<tr>
<th>Nickel compounds</th>
<th>-</th>
<th>-</th>
<th>0.005&lt;sup&gt;(9)&lt;/sup&gt;</th>
<th>-</th>
<th>-</th>
<th>-</th>
<th>-</th>
<th>Dermal and respiratory sensitisation&lt;sup&gt;(11)&lt;/sup&gt;</th>
</tr>
</thead>
</table>

The limit value shall apply from 18th January 2025.
The limit value shall apply from 18th January 2025. Until then a limit value of 0.1 mg/m³ shall apply.

### Justification

With more than 80,000 exposed workers to nickel compounds (Impact Assessment p130), minimization of exposure is important. The proposed OEL for nickel compounds is high, and less protective than the recommendation of the Risk Assessment Committee (RAC) (0.005 mg/m³ for respirable dust and 0.03 mg/m³ for inhalable dust). Germany has the lowest (strictest) OEL for nickel compounds in the EU (Impact Assessment p10), which corresponds with the level recommended by RAC (0.03 mg/m³ inhalable fraction). The reprotoxic effect including miscarriage due to nickel compounds (Impact Assessment p25 +128) is another good reason to set a more protective OEL for these substances.

### Amendment 112
Johan Danielsson, Sara Matthieu, Nikolaj Villumsen

Proposal for a directive
Annex I – point 2
Directive 2004/37/EC
Annex III – point A – Row 2 a (new)

### Text proposed by the Commission

### Amendment

<table>
<thead>
<tr>
<th>Cobalt and cobalt compounds</th>
<th>-</th>
<th>-</th>
<th>0.0005&lt;sup&gt;(11a)&lt;/sup&gt;</th>
<th>0.001&lt;sup&gt;(11b)&lt;/sup&gt;</th>
<th>-</th>
<th>-</th>
<th>-</th>
<th>-</th>
<th>Dermal and respiratory sensitisation</th>
</tr>
</thead>
</table>

AM\1223888EN.docx 75/76 PE680.880v01-00
Respirable fraction, measured as cobalt
Inhalable fraction, measured as cobalt

**Justification**

The ECHA’s Risk Assessment Committee (RAC) has 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). RAC supports the restriction targeted at the five soluble cobalt salts, but additionally recommends to the European Commission to derive a binding occupational exposure limit value (BOEL) for cobalt and its compounds under the CMD.