Opinion of the European Economic and Social Committee on 'Proposal for a Directive of the European Parliament and of the Council amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work'

(COM(2018) 171 final — 2018/0081 (COD))

(2018/C 440/24)

Rapporteur: **János WELTNER**

Consultation	European Parliament, 16.4.2018
	Council, 23.4.2018
Legal basis	Article 153 (1 and 2) and Article 304 of the Treaty on the Functioning of the European Union
Decision of the Bureau	17/04/2018
Section responsible	Section for Employment, Social Affairs and Citizenship
Adopted in section	19.7.2018
Adopted at plenary	19.9.2018
Plenary session No	537
Outcome of vote	191/4/11
(for/against/abstentions)	

1. **Conclusions and recommendations**

1.1. The EESC welcomes the proposed amendment to the Carcinogens and Mutagens Directive (CMD) since it present objective data for the sake of safer working conditions.

1.2. As in its previous opinion ([1]), the EESC urges the Commission to carry out an impact assessment of a possible extension of the CMD to include substances that are harmful to reproduction.

1.3. The EESC finds it important, given the reprotoxic effects of many carcinogens and mutagens, that revisions and amendments to the CMD in the near future pay more attention to occupational exposures affecting women and men regarding reproductive aspects, and — in the case of women — especially during the first trimester of pregnancy.

1.4. The EESC welcomes the fact that, in this amendment, the binding occupational exposure limits (BOELs) have been defined on the basis of scientific and statistical evidence. A risk-based approach, as is seen in the background documents, can be easily understood by the stakeholders, and thus provides a good basis for a social compromise.

1.5. The EESC welcomes the evidence-based procedure, under which the Commission sought advice from both the Scientific Committee on Occupational Exposure Limits (SCOEL) ([2]) and the Committee for Risk Assessment (RAC) ([3]) of the European Chemicals Agency (ECHA) ([4]).

([1]) OJ C 288, 31.8.2017, p. 56.
([2]) Health and safety at work — SCOEL, European Commission 30.6.2018.
([3]) Committee for Risk Assessment (RAC), 30.6.2018.
([4]) European Chemicals Agency (ECHA).

1.6. The EESC considers it necessary to set up pilot research programmes and, in a second phase, EU-wide programmes to develop life-long health surveillance in the framework of national social security or public health systems for all those who have been exposed to carcinogens, mutagens and reprotoxic compounds. In accordance with the GDPR ([5]), this surveillance should be conducted in an anonymous manner.

1.7. The EESC stresses that in order to improve workers' protection from carcinogens, mutagens and reprotoxic substances at work, Member States should ensure that labour inspectorates have sufficient financial and human resources to carry out their duties.

1.8. The EESC recommends that all compounds suspected to be carcinogens, mutagens and/or reprotoxic should undergo scientific analysis in this regard, and that they must be included in the CMD if appropriate.

2. **Background**

2.1. This opinion is linked to the EESC's opinion on '*The protection of workers from the risks related to exposure to carcinogens or mutagens at work*' ([6]), which was drawn up in conjunction with the amendment to the CMD in 2017 ([7]). All of the recommendations of the EESC, except those that have been included in the present amendment, are still current ([8]).

2.2. The objectives of the proposal are consistent with Article 2 (Right to life) and Article 31 (Fair and just working conditions) of the EU Charter of Fundamental Rights.

2.3. Ensuring a safe and healthy work environment is a strategic goal for the European Commission as mentioned in the '*EU Strategic Framework on Health and Safety at Work 2014-2020*' ([9]).

2.4. Cancer is the main work-related health problem in the EU-28, causing almost as much damage to workers' life and health as the two following disease groups combined (musculoskeletal disorders and circulatory diseases). Its negative impact is also far greater than that of work-related accidents ([10]). It brings suffering to workers and their family and friends, causes poor quality of life, undermines well-being and, in the worst case, leads to death ([11]).

2.5. The Commission has initiated a continuous process of updating the CMD ([12]) to keep abreast of new scientific and technical developments. This process is in line with the EU Sustainable Development Strategy, which includes the objective of ensuring that, by 2020, chemicals are produced, handled and used in such a way that they do not pose significant threats to human health and the environment. The aim is to eventually replace substances of high concern with suitable alternative substances or technologies ([13]).

3. **Proposal of the Commission**

3.1. In line with this process and based on SWD(2018) 87 and 88, the European Commission has proposed the next amendment to 'Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work' in his document COM (2018) 171 ([14]). Earlier in 2017, the EESC supported the amendment of this Directive; five substances are included in the current amendment ([15]):

([5]) OJ L 119, 4.5.2016, p. 33, Article 4 and see also paragraphs 35, 45, 52, 53 and 155.
([6]) OJ C 288, 31.8.2017, p. 56.
([7]) COM(2017) 11 final.
([8]) OJ C 288, 31.8.2017, p. 56.
([9]) COM(2014) 332 final.
([10]) EU-OSHA (2017).
([11]) SWD (2018) 88, COM(2017) 11 final.
([12]) Directive 2004/37/EC.
([13]) Eurostat 'Sustainable development in the EU', p.189.
([14]) Procedure 2018/0081 (COD).
([15]) OJ C 288, 31.8.2017, p. 56.

3.1.1. *Cadmium and its inorganic compounds under the scope of the CMD*: Occupations in which exposures occur include cadmium production and refining, nickel-cadmium battery manufacture, cadmium pigment manufacture and formulation, cadmium alloy production, mechanical plating, zinc and copper smelting, mining of non-ferrous metal ores, brazing with a silver-cadmium-silver alloy solder, polyvinylchloride compounding and recycling of scrap metal and Ni-Cd batteries. The Commission estimates that about 10 000 workers are at risk.

3.1.2. *Beryllium and inorganic beryllium compounds under the scope of the CMD*: Ten industrial sectors such as foundries, glass and laboratories were identified in which workers are at risk of exposure to beryllium. Copper, aluminium, magnesium and nickel are widely alloyed with beryllium. Approximately 80 % of all beryllium is used in copper alloys. Exposure to beryllium causes lung cancer and incurable chronic beryllium disease. The Commission estimates that 54 000 workers are at risk.

3.1.3. *Arsenic acid and its salts, as well as inorganic arsenic compounds under the scope of the CMD*: Exposure to arsenic compounds occurs, for example, in copper and zinc production, as well as in the glass, electronics and chemical sectors. The Commission estimates that 7 900-15 300 workers are at risk.

3.1.4. *Formaldehyde*: Occurs in formaldehyde manufacturing, and in a wide variety of products (adhesives and sealants, coating products, polymers, biocides and laboratory chemicals); exposure may also happen during activities such as building and construction work, and in the manufacturing of leather and fur, pulp, paper and paper products, textile and wood and wood products. Formaldehyde is also used for tissue preservation and as a disinfectant in pathology departments and autopsy rooms. The number Commission estimates that around 1 million workers are at risk.

3.1.5. *4,4'-Methylene-bis(2-chloroaniline) ('MOCA')*: Exposed workers work in the plastics sector, where MOCA is used for moulding of polyurethane elastomer parts at 89 sites across the EU. The Commission estimates that 350 workers are at risk.

3.2. Member States have different approaches. Some of them have defined BOELs for a large number of carcinogenic, mutagenic and reprotoxic chemicals (CMRs); others for a few only. Five substances are mentioned in this proposal; there is no EU occupational exposure limit (OEL) for any of them. Twelve Member States (BE, BG, CY, CZ, DE, EE, ES, HU, LT, LV, NL, SE) have no OEL for one of the five substances. Three Member States have no OEL for all five (IT, LU, MT). The level of these BOELs can differ from one country to another. The EESC therefore welcomes the proposal amending Directive 2004/37/EC, which sets minimum European BOELs and which, when in force, will ensure equal working conditions for all those workers in any of the Member States who are exposed to these harmful substances.

3.3. Estimates based on a Risk & Policy Analysts Limited (RPA 2018) study ([16]) show that, if adopted, this proposal would improve working conditions in the long term for over 1 million EU workers and prevent over 22 000 cases of work-related ill health. The current disease burden, estimated over the past 40 years, includes 24 770 cases of work related ill-health. If no action is taken, the future disease burden will include 24 689 new cases over the next 60 years.

3.4. According to the Commission Staff Working Document, it is therefore appropriate to consider updating the CMD based on the above information. The principles are the same as in the CMD and in the previous amendment. This amendment expands the previous list found in the Annex of the CMD with the five compounds listed above.

3.5. Scientific advice has been provided by SCOEL for cadmium, beryllium and formaldehyde, and also by RAC for arsenic acid and MOCA. The tripartite Advisory Committee on Safety and Health at Work (ACSH) has adopted opinions on all five.

([16]) Third amendment of the Carcinogens and Mutagens Directive, CMD.

3.6. The OELs for these five carcinogens and mutagens are set based on scientific data and with reference to future health consequences. Different economic consequences are also taken into account.

4. **General comments**

4.1. The main aim and the scope of this amendment is to extend the list in the CMD, which at present is limited to carcinogens and mutagens. A possible extension to encompass substances that are toxic to reproduction or other bodily functions should be considered later on, as mentioned in the EESC opinion ([17]).

4.2. This opinion is backed up by Eurostat's 2017 'Monitoring report on progress towards the SDGs in an EU context' ([18]): 'In 2015, 350 million tonnes of chemicals were consumed in the EU. Of these, 127 million tonnes were classified as hazardous to the environment and 221 million tonnes as substances that might harm human health. Although consumption of toxic chemicals declined in the short term and the long term, the share of most toxic chemicals in total chemical consumption remained nearly unchanged.' (Share of 'carcinogenic, mutagenic and reprotoxic' (CMR) substances in total consumption of chemicals in the EU: 2004: 10,7 %, 2015: 10,3 %).

4.3. The EU strategy against work-related cancers should pay more attention to women.

4.3.1. The pattern of exposure and the pattern of cancer locations may vary between men and women. Breast cancer, for instance, is a very rare disease for men, whereas it is the most common cancer for women. A range of occupational exposures may contribute to breast cancer. To acquire relevant data for decision-making purposes, the incidence of mostly gender-specific cancers should be analysed for women and men separately, and not across the total population of employees.

4.3.2. The Committee urges the Commission to give more systematic consideration to occupational carcinogenic exposures affecting women in further revisions of the Directive. Many types of work in which women are concentrated (health, cleaning, hairdressing, etc.) involve exposure to carcinogenic substances. Binding prevention measures should be set out in this regard (e.g. negative-pressure cabinets for the preparation of cytostatic products for injection by staff in healthcare institutions).

4.4. Regarding the single market, the EESC think it is important for the Commission to define a methodology for the adoption of BOELs in the CMD. This process should involve broad consultation with the social partners, Member States and other stakeholders, including NGOs. In the EESC's view, two elements require particular consideration: first, the consistency of BOELs with regard to the risk level of the different compounds; second, the need to define BOELs on the basis of scientific evidence, including follow-up of changes in the incidence of work-related diseases. They must take into account different factors, such as feasibility and the possibility of measuring exposure levels. In order to help employers prioritise their prevention measures, they should explicitly refer to the level of risk associated with the exposure level.

4.5. For most of the compounds, there is a long latency period between the first exposure and the emergence of cancer. The EESC considers it necessary to protect workers by offering lifelong health surveillance in the framework of social security or national health systems for all workers who are at risk of exposure. This data can be offered by Eurostat to help to refine the Sustainable Development Strategy.

4.6. Public health governance must be based exclusively on evidence-based regulations. Evidence can be obtained from scientific analysis based on good quality and statistically evaluable data. This requirement is supported by the GDPR ([19]) itself in its Article 9 which is about the processing of special categories of personal data ([20]). Further juridical aspects must also be taken into account, according to Directive 2011/24/EU of the European Parliament and of the Council ([21]).

([17]) OJ C 288, 31.8.2017, p. 56.
([18]) Eurostat 2017: 'Sustainable Development in the European Union — Monitoring report on progress towards the SDGs in an EU context', p. 246.
([19]) OJ L 119, 4.5.2016, p. 1.
([20]) OJ L 119, 4.5.2016, Art. 9(h) 'processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee … on the basis of Union or Member State law or …'.
([21]) OJ L 88, 4.4.2011, p. 45. See also OJ L 354, 31.12.2008, p. 70, Article 2.

4.7. The EESC recommends again that more efforts should be focused on scientific and statistical studies. Occupational cancer can be multicausal. More attention and funding should be dedicated to researching the consequences and potential interactions of combined exposure to different factors.

4.8. The EESC stresses that one of the main tasks in the area of protecting workers from carcinogens, mutagens and reprotoxic substances in the workplace is to strengthen control over the implementation and application of the CMD. Member States should ensure that labour inspectorates have sufficient financial and human resources to carry out their duties while helping companies, and in particular SMEs, to comply with these provisions. They should strengthen their cooperation with the European Agency for Safety and Health at Work. The widespread use of the OiRA (Online interactive Risk Assessment) web platform can help with risk assessment in this field.

5. **Specific comments**

5.1. In addition to the essential requirement for prevention and protection of health at work and the need to adapt work to people, provided for by the European legislation, the EESC draws attention to the danger, that ineffective prevention of exposure to carcinogens, mutagens and reprotoxic agents could have negative consequences for businesses, such as higher costs and reduced productivity due to absenteeism, compensation costs to claimants, lost expertise and distorted competition; and for Member States due to increased social security costs and lost tax revenues.

5.2. Member State authorities and employers' and workers' representative bodies within the framework of the tripartite ACSH would very much welcome the legal clarity and increased protection that would result from lower OELs on these substances.

Brussels, 19 September 2018.

The President
of the European Economic and Social Committee
Luca JAHIER