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Limits on exposure to carcinogens and mutagens at work: Second proposal

The European Commission has proposed to amend Directive 2004/37/EC, by expanding its scope and by including and/or revising occupational exposure limit values for a number of cancer- or mutation-causing chemical agents. The initiative is proceeding in steps. The first proposal, submitted in May 2016, covered 13 priority chemical agents. The current (second) proposal addresses a further seven agents.

Broad discussions with scientists and the social partners fed into both proposals. On the whole, trade unions and employers welcomed the current proposal. Trilogue agreement was reached on 11 October 2018. As proposed by the European Parliament, diesel engine exhaust emissions were included in the scope of the directive. After completion of the legislative procedure, the final act was signed by the presidents of the co-legislators on 16 January 2019. Directive (EU) 2019/130 entered into force on 20 February 2019 and is to be transposed into national laws within two years, by 20 February 2021 at the latest.

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(2017) 11, 10.1.2017, 2017/0004(COD), Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')

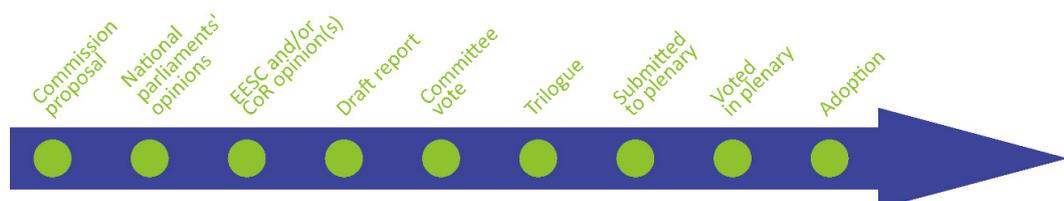
Committee responsible: Employment and Social Affairs (EMPL)

Rapporteur: Claude Rolin (EPP, Belgium)

Shadow rapporteurs: Marita Ulvskog (S&D, Sweden); Anthea McIntyre (ECR, United Kingdom); Enrique Calvet Chambon (ALDE, Spain); Patrick Le Hyaric (GUE/NGL, France); Karima Delli (Greens/EFA, France); Laura Agea (EFDD, Italy); Joëlle Mélin (ENF, France)

Procedure completed. [Directive \(EU\) 2019/130](#)
[OJ L 30, 31.1.2019, p. 112–120](#)

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Introduction

On 10 January 2017, the European Commission published its second proposal to amend [Directive 2004/37/EC](#) (the Carcinogens and Mutagens Directive – CMD). The [second proposal](#) (hereafter referred to as the ‘current proposal’) complements a [first one](#) of 13 May 2016,¹ by addressing another batch of substances for which additional analysis had still to be conducted. (For more details, see ‘The proposed changes and their potential impact’ below.)

According to the Commission, the aims of the current proposal are to:

- > further improve workers’ health protection by reducing occupational exposure to chemical agents that may cause cancer or mutations (‘carcinogens’ and ‘mutagens’);
- > increase the effectiveness of the EU framework for protecting workers by updating it on the basis of scientific expertise and data; and to
- > enhance clarity, facilitate implementation, and contribute to a more level playing field for economic operators by reducing divergences in national protection levels.
- > The current proposal was submitted as part of a new set of measures, presented in a Commission [communication](#), to modernise EU occupational safety and health (OSH) legislation and policy, with a focus on three main actions:²
- > addressing occupational cancer through legislation, including the current proposal and subsequent amendments of the CMD;
- > helping businesses, in particular micro-enterprises and small companies, comply with OSH rules by providing practical tools, such as the [guidance document](#) annexed to the communication;
- > cooperating with Member States and social partners to update or remove outdated rules as well as to refocus efforts on better and broader protection, compliance and enforcement on the ground.

As the Commission points out, the new measures fit within the work around the [European Pillar of Social Rights](#), which aims, among other things, to adapt EU legislation to changing patterns in the world of work and in society.³ Moreover, these measures follow on from an [evaluation](#) of the existing OSH *acquis*, as part of the regulatory fitness and performance (REFIT) programme, intended to make EU legislation more efficient and effective.

1 The first proposal was adopted by the co-legislators as [Directive \(EU\) 2017/2398](#). (For more information, see the EPRS ‘EU Legislation in Progress’ [briefing](#), January 2018, or consult the [EP Legislative Train Schedule](#) on the file.)

2 For a detailed list of the actions scheduled, see [annex 1](#) of the communication.

3 The plan to develop a European Pillar of Social Rights was announced by European Commission President Jean-Claude Juncker in September 2015 (see also an EPRS [briefing](#) and an ‘[At a glance](#)’ note on the topic). The Commission [communication](#) on the Social Pillar was presented in April 2017. The Pillar was [proclaimed](#) on 17 November 2017.

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The Commission is proceeding in steps, and further amendments of the CMD are planned. Meanwhile, a proposal covering a [third batch](#) of substances was adopted on 5 April 2018.

Context

Cancer is the leading cause ([53%](#)) of work-related deaths in the EU. The most common types of occupational cancer include lung cancer, mesothelioma⁴ and bladder cancer. The World Health Organization (WHO) estimated in 2007 that [every 10th](#) lung cancer death is closely related to workplace risks. Work-related cancers may be prevented by reducing or eliminating exposure to certain carcinogens or mutagens. Occupational exposure usually involves a [combination of factors](#), however, and it can be difficult to establish a causal relationship between cancer cases and exposure to a specific chemical agent. The time between exposure and onset of the disease can be up to 50 years. [Cancer exposure registers](#) (CAREX) have been established in order to obtain a more comprehensive picture of occupational exposures.

Existing situation

The CMD sets general minimum requirements to eliminate or reduce exposure to the chemical agents falling within its scope. Furthermore, it establishes occupational exposure limit values (OELs) for certain carcinogens and mutagens with a view to protecting workers. Employers must identify and assess exposure-associated risks for workers; where risk occurs, exposure must be prevented. Where it is technically possible, the process or agent concerned must be substituted with a non-hazardous or less hazardous process or agent. Where substitution is not possible, chemical carcinogens/mutagens must be used in a closed system, or worker exposure must be reduced to as low a level as is technically possible. Employers also have the obligation to ensure that OELs are not exceeded.

The CMD provisions apply to chemical agents that 'may cause cancer' or are 'suspected of causing cancer' according to the criteria set out in [Regulation \(EC\) No 1272/2008](#) on classification, labelling and packaging of substances and mixtures (the CLP Regulation), and also to the substances, mixtures and processes referred to in annex I of the CMD, which currently has five entries.⁵ These are what are referred to as [process-generated substances](#) (PGSs) – hazardous chemical agents such as dust, fumes and gases generated during combustion or as by-products during production processes. The provisions also apply to mutagens as per the CLP Regulation, namely, 'substances known to induce heritable mutations or to be regarded as if they induce heritable mutations in the germ cells of humans'. According to the CMD, OELs need to be established for those chemical agents for which they do not yet exist, and to be revised whenever this becomes necessary in the light of more recent scientific data. Currently, the CMD sets OELs for three⁶ agents.

4 [Mesothelioma](#) is a type of cancer that occurs in the tissue that lines the lungs and other organs (the mesothelium). It is associated with [exposure to asbestos](#).

5 These are: 1. manufacture of auramine; 2. work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch; 3. work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes; 4. strong acid process in the manufacture of isopropyl alcohol; and 5. work involving exposure to hardwood dusts.

6 For [benzene](#), [vinyl chloride monomer](#) and [hardwood dusts](#).



Introduction

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Parliament's starting position

In its [resolution](#) of 14 March 2013 on asbestos-related occupational health threats, Parliament called on the Commission to put forward a proposal to amend Directive 2004/37/EC as a matter of urgency, so that 'the health of workers at risk of being exposed to carcinogens be protected and safeguarded through the promotion and exchange of best practices in prevention and diagnosis'.

In its [resolution](#) of 25 November 2015 on the 'EU strategic framework on health and safety at work 2014-2020', Parliament highlighted the importance of protecting workers against exposure to substances that are carcinogenic, mutagenic or toxic to reproduction (CMRs). It reiterated its calls on the Commission to present a proposal to amend Directive 2004/37/EC on the basis of scientific evidence, add more binding limit values, and develop an assessment system based on clear and explicit criteria. Furthermore, Parliament underlined the need for more stringent protection of workers, taking into account not only exposure periods, but also the mix of chemical and/or toxic substances to which workers are exposed. It also called on the Commission to take action on the exposure of chemical risk factors in the healthcare sector.



Proposal

Preparation of the proposal

The current proposal is accompanied by a Commission [impact assessment](#) (IA) with its [executive summary](#), as well as an [opinion](#) (positive with reservations) by the Regulatory Scrutiny Board. The IA covers the expected costs and benefits from the seven agents included in the proposal. According to the Commission, the IA should be read in conjunction with an [earlier IA](#), where the CMD and its context are considered exhaustively. An analysis of the earlier IA is provided in the [EPRS initial appraisal](#): while acknowledging that the Commission has given sound reasoning with a well-developed methodology, it finds that the proposed range of options limits the scope of the analysis. The initial appraisal concludes that the added value of options 3 and 4 is not evident;⁷ that more information on the consultation with the Scientific Committee on Occupational Exposure Limits ([SCOEL](#)) and the Advisory Committee on Safety and Health at Work ([ACSH](#)) would have been welcomed to better understand how the OELs were set; and that it is not entirely clear why the Commission has launched this proposal before completing the ex-post evaluation of the OSH framework for the 2007-2012 period, undertaken within REFIT.

Both IAs were informed by a two-stage consultation of the social partners in accordance with Article 154 of the Treaty on the Functioning of the European Union (TFEU): one launched in April 2004 and one in April 2007. The process of reviewing and setting limit values involved collecting expertise from the SCOEL and the ACSH. Their input and the results of a 2011 [study](#) by the Institute of Occupational Medicine (IOM) on behalf of the European Commission fed into both proposals.

The Commission's [inception impact assessment](#) (IIA) of the first proposal points to the need for 'substantial improvement' to further reduce work-related exposure to carcinogenic substances in particular. Three issues are identified: significant exposure of workers to carcinogens; an outdated directive that needs updating; and the negative consequences that inadequate OELs for some substances may have for workers and businesses across the EU. The IIA envisages proceeding in two steps: first, widening the scope of the directive as well as establishing limit values and revising existing ones; and second, further broadening its scope and setting limit values for additional substances, for which there is currently only limited data, once the results of another study become available. (See also the [EPRS implementation appraisal](#) of the existing legislation.)

⁷ Option 3 involves adopting OELs that are lower than the ACSH recommendations for each of the 13 agents and thus more protective of workers' health; Option 4 involves adopting OELs that are higher than the ACSH recommendations for each of the 13 agents and thus less protective of workers' health.



The proposed changes and their potential impact

The measures put forward

Following on from its first proposal of May 2016, the Commission's current proposal introduces changes that address occupational exposure to an additional seven priority chemical agents. Firstly, the Commission plans to bring, within the scope of the CMD, work involving oils that have been used in internal combustion engines to lubricate and cool the moving parts within the engine (referred to as '[mineral oils as used engine oils](#)'). On the recommendation of SCOEL and taking into account the [assessment](#) carried out by the WHO's International Agency for Research on Cancer (IARC), the Commission also seeks to assign a skin notation to these oils.⁸ Secondly, the Commission means to introduce EU-wide occupational exposure limits, supplemented by skin notations, for a further five carcinogens.⁹ Moreover, it proposes to establish skin notations (independently of limit values) for two carcinogens, for which the possibility of significant uptake through the skin has been identified: mineral oils as used engine oils, and polycyclic aromatic hydrocarbon (PAH) mixtures containing benzo[*a*]pyrene as an indicator.

The impact

According to the Commission's [explanatory memorandum](#) to the current proposal, the measures intend to lower the risk for **workers** of getting avoidable work-related cancer, and would decrease the economic burden in terms of health costs. The cancer cases and cancer deaths avoided would be mainly those relating to mineral oils as used engine oils and to trichloroethylene. Mineral oils as used engine oils are primarily used in car and motorcycle engines; rail, marine and aircraft engines; and in portable machinery including chain saws and lawn mowers. An estimated 1 million workers are exposed, mostly those working in the maintenance and repair of motor vehicles. [Trichloroethylene](#) is mainly used in intermediate applications¹⁰ in the chemical industry, but also in metal cleaning and in the adhesives industry. An estimated 74 000 workers are exposed. The IA [estimates](#) that the provision regarding mineral oils as used engine oils would prevent 880 deaths and 90 000 cancer cases by 2069, which would result in monetised health benefits (in terms of avoidance of health costs thanks to reduced future exposures leading to less ill health) of €0.3-1.6 billion. The measures related to trichloroethylene are expected to prevent 390 deaths and monetised health benefits of €118-430 million. Other sectors and operations that would benefit from the measures include: manufacture of epoxy resins; pulp and paper production; preparation of dyes and paints; production of plastic and vinyl products; manufacture of polyurethane foams; aluminium, iron and steel production; foundries; waste incineration, mining and oil refining, coke and tar production; coal gasification; bitumen and asphalt production, and road and roof tarring.¹¹ The Commission states that the proposal would result in increased protection of some 4 million workers and bring more clarity for enforcers and economic operators.

8 A skin notation indicates the possibility of significant uptake of a substance through the skin. In many European countries, skin notations [are used](#) to warn against the [potential health effects](#) associated with such uptake, in addition to inhalation exposure.

9 The five chemical agents are: [trichloroethylene](#); [4,4'-methylenedianiline](#); [epichlorohydrin](#); [ethylene dibromide](#); and [1,2-dichloroethane](#) (commonly known as ethylene dichloride).

10 An intermediate substance is defined in Regulation (EC) No 1907/2006 ([REACH](#)) as 'a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance'.

11 For an overview table of the sectors, types of cancer caused and estimated exposure levels for the seven chemical agents under consideration, see the European Commission [fact sheet](#).



Moreover, the introduction of EU-wide OELs would help **employers** avoid costs that could arise in the case of non-compliance and thus negatively affect their businesses in the long term. Since national OELs already exist for several of the chemical agents covered by the proposal, establishing the limit values provided for in the proposal would not impact **companies** in those Member States that have equal or lower limit values. However, businesses in Member States that currently have higher limit values may be faced with operating costs for putting into place additional protective and preventive measures. This would be the case, in particular, for mineral oils as used engine oils and for trichloroethylene. The total cost to businesses of the introduction of the former into the CMD list of process-generated substances are estimated to range between €46 million and 918 million until 2069. For trichloroethylene, the cost estimates of establishing an OEL of 54.7 mg/m³ (10 ppm) range between €154 million and €257 million.¹² For the remaining substances, costs would be minimal.

Furthermore, the proposal would help to mitigate financial losses incurred by the **Member States'** social security systems, which bear the burden and cost of occupational ill health resulting from workers' exposure to hazardous substances (such as healthcare costs for treatment and rehabilitation as well as expenditure on inactivity and early retirement and compensation for recognised occupational diseases).

12 The values [foreseen](#) are 54.7 mg/m³ (10 ppm) as an eight-hour time-weighted average (TWA) and 164.1 mg/m³ (30 ppm) as a short-term exposure limit (STEL). For instance, in the case of trichloroethylene, 17 Member States would have to introduce or update their OEL to bring it down to the 54.7 mg/m³ (10 ppm) value.

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Views

Advisory committees

The European Economic and Social Committee (EESC) adopted its [opinion](#) on 31 May 2017. Among other things, the EESC urged the Commission to carry out an impact assessment of a possible extension of the scope of application of the CMD to substances that are toxic to reproduction. It strongly recommended that the revisions of the directive planned for 2018 pay greater attention to occupational exposures affecting women. Moreover, the EESC considered it necessary to set up programmes for life-long health surveillance, for all persons that have been exposed to workplace carcinogens, in the framework of national social security or public health systems. It also recommended that a binding occupational exposure limit (BOEL) be adopted for formaldehyde.

National parliaments

The [deadline](#) for national parliaments to submit comments on the current proposal was 15 March 2017, and none submitted a reasoned opinion.

Stakeholders' views¹³

The European Trade Union Confederation ([ETUC](#)) welcomes the current proposal, but deplores the lack of ambition of the EU's strategy to eliminate occupational cancers: although the Commission had promised to propose 25 binding occupational exposure limits (BOELs) in 2016 and to reach a total of 50 by 2020, so far only 18 have been added (13 in the earlier proposal of May 2016 and five in the current one). ETUC also regrets that, while the Commission declared that its current proposal was addressing seven carcinogens, only five BOELs have been proposed for inclusion in annex III. The European Trade Union Institute ([ETUI](#)), which equally denounces the lack of ambition of the current proposal, is particularly critical of the fact that diesel-engine exhaust emissions have not been included in the proposal.

The European Association of Craft, Small and Medium-sized Enterprises ([UEAPME](#)), in its reaction to the Commission's OSH set of measures as a whole, welcomes in particular the specific guidance to help micro-enterprises and small companies better implement existing rules.

(For stakeholders' views on the first proposal, see the corresponding EPRS 'EU Legislation in Progress' [briefing](#)).

¹³ This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under 'EP supporting analysis'.

Legislative process

The Council reached a general approach on the proposal during its session of 15 June 2017. The general approach mainly modifies the recitals: the general recitals, including the legal basis, are aligned to those already agreed in the general approach on the first proposal amending the CMD, and the substance-specific recitals are further clarified. Moreover, some additional precisions are introduced in Article 1 and in two entries of the annex (for PAH mixtures and for minerals oils as used engine oils). The limit values as proposed by the Commission are maintained.

Parliament's Committee on Employment and Social Affairs (EMPL) is responsible for the file. Claude Rolin (EPP, Belgium) was appointed rapporteur on 14 March 2017. His [draft report](#) was published on 8 November 2017. Its proposed amendments to the Commission proposal included the following main points:

- > **Diesel engine exhaust emissions:** on the basis of the precautionary principle, work involving exposure to diesel engine exhaust emissions should be included in the scope of the CMD, and an occupational exposure limit of 0.05 mg/m³, calculated on the basis of elemental carbon, should be set.
- > **Polycyclic aromatic hydrocarbons (PAHs):** the skin notation for PAHs containing benzo[*a*]pyrene should be extended to all PAH mixtures (as advocated in the Council's general approach). Moreover, the Commission is asked to propose an exposure limit value for PAHs, calculated on the basis of benzo[*a*]pyrene, as part of the next evaluation of the implementation of the CMD.
- > **Regular and continuous process of revision of the CMD:** the Commission is encouraged to continue with future revisions of the directive. In particular, these should make it possible to review existing limit values, if necessary; set limit values for new substances; and extend the scope of the CMD to substances that are toxic to reproduction (reprotoxic), as supported by Parliament. This is to be done in close cooperation with the Scientific Committee on Occupational Exposure Limits (SCOEL) and the Advisory Committee on Safety and Health at Work (ACSH), whose recommendations provide the Commission with scientific and technical data and formed the basis of the rapporteur's draft report.
- > **Prevention and inspections:** the draft report highlights the importance of (multi)sectoral agreements that enable businesses to take precautions to reduce workers' exposure to carcinogens or mutagens. It also stresses the importance of workplace inspections, whereby the Member States are encouraged to ensure that inspection bodies do not limit their actions to imposing penalties, but also present possible solutions to the companies concerned.

The rapporteur's draft report was considered in the EMPL committee meeting of 28 November 2017; a vote took place in the meeting of 27 March 2018.

Interinstitutional trilogue negotiations started on 17 May 2018 and were concluded at the fourth trilogue meeting, on 11 October 2018. A key element of the agreement is that, as proposed by Parliament, diesel engine exhaust emissions will be included in the scope of the CMD, and a limit value of 0.05 mg/m³ (calculated from elementary carbon) has been set. The final text resulting from interinstitutional negotiations was approved by the Council's Permanent Representatives Committee on 24 October 2018. Parliament's EMPL



committee endorsed it on 15 November. A vote in plenary took place on 11 December, and the final act was adopted by the Council on 20 December 2018. It was signed on 16 January 2019 and published in the Official Journal on 31 January 2019. [Directive \(EU\) 2019/130](#) entered into force on 20 February 2019 and is due to be applicable in national law no later than two years after that date, i.e. by 20 February 2021.



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EP supporting analysis

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