BRIEFING

EU Legislation in Progress

European Parliament

# Limits on exposure to carcinogens and mutagens at work: Fourth proposal

## OVERVIEW

In September 2020, as part of the fight against cancer and to protect the health of workers in a number of industries, the European Commission proposed to amend the Carcinogens and Mutagens Directive (Directive 2004/37/EC), expanding its scope and including and/or revising occupational exposure limit values for a number of cancer- or mutation-causing chemical agents. The initiative is proceeding in steps and has now become a continuous process. Following on from three previous legislative amendments, which covered a total of 26 priority chemical agents, the fourth proposal addresses an additional three.

On 16 December 2021, after interinstitutional negotiations, the Council and the European Parliament reached a provisional agreement on the proposal. The agreed text was endorsed by Coreper, for the Council, on 22 December 2021 and then approved by Parliament's Committee on Employment and Social Affairs on 25 January 2022. Under the agreement, workers will benefit from greater protection, owing to the setting of exposure limits for acrylonitrile and nickel compounds and the lowering of the limits for benzene. The scope of the proposed directive would include reprotoxic substances (which have adverse effects on reproduction and can cause impaired fertility or infertility). Workers who deal with hazardous medicinal products would receive better training on how to handle them safely. A vote in plenary is expected in February 2022.

| **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** | | |
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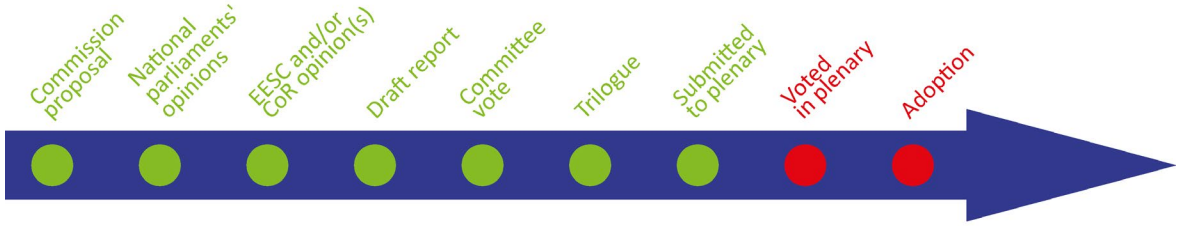
| *Committee responsible:* | Employment and Social Affairs (EMPL) | COM(2020) 571<br>22.9.2020 |
| *Rapporteur:* | Stefania Zambelli (ID, Italy) | 2020/0262(COD) |
| *Shadow rapporteurs:* | Cindy Franssen (EPP, Belgium)<br>Johan Danielsson (S&D, Sweden)<br>Véronique Trillet-Lenoir (Renew, France)<br>Sara Matthieu (Greens/EFA, Belgium)<br>Joanna Kopcińska (ECR, Poland)<br>Nikolaj Villumsen (The Left, Denmark) | Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision') |
| *Next steps expected:* | Final first-reading vote in plenary | |

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# Introduction

On 22 September 2020, the European Commission adopted its fourth proposal to amend Directive 2004/37/EC (the Carcinogens and Mutagens Directive – CMD). The fourth proposal complements the first on the matter from May 2016, a second from January 2017, and a third from April 2018,[1] by addressing a further batch of substances. (For more details, see 'The changes the proposal would bring' below.)

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

- improve workers' health protection by reducing workplace exposure to three substances or groups of substances that may cause cancer ('carcinogens') or mutations ('mutagens');
- provide more clarity for workers, employers and enforcers; and to
- contribute to a level playing field for economic operators.[2]

The proposal was announced as one of the first initiatives in the Commission's work on cancer under Europe's Beating Cancer Plan,[3] designed to help Member States improve cancer prevention, detection, treatment and management in the EU while reducing health inequalities between and within Member States.

According to the Commission, the proposal is informed by the context of the coronavirus pandemic, which also shines a light on the importance of occupational safety and health (OSH) considerations in workplaces. It is in line with the Commission's wider commitment to review the OSH strategy to address the exposure to dangerous substances, as laid out in its January 2020 communication 'A strong social Europe for just transitions', among other things. This, in turn, is part of delivering on the European Pillar of Social Rights and its principle 10, which enshrines workers' right to a healthy, safe and well-adapted work environment.

As the Commission points out, updating and reviewing the CMD in the light of the most recent scientific and technical evidence has now become a continuous process.

# Context

Cancer is the leading cause of work-related deaths in the EU, but occupational cancers could be prevented by reducing or eliminating exposure to certain carcinogens or mutagens. Workplace 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 ('latency period').

There is a widely identified lack of harmonised and comparable EU-level data on occupational exposure to cancer risk factors. In a bid to fill this knowledge gap, the European Agency for Safety and Health at Work (EU-OSHA) is preparing a worker survey on exposure to cancer risk factors.[4] The survey is being developed, tested and carried out in 2021 and 2022, and the initial findings are expected to be published in 2023.

In addition to cancers, workplace exposure to carcinogens or mutagens can lead to other serious health problems, such as respiratory diseases and neurological disorders.

# Existing situation

Workers are currently protected against cancer- or mutation-causing substances under three main EU directives. The overarching Occupational Safety and Health Framework Directive (89/391/EEC) lays out the main principles of workers' safety and health at work, while the Chemical Agents Directive (98/24/EC) and the CMD deal specifically with chemical risks.

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.[5] 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 reduced to as low a level as is technically possible. Employers are also obliged 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 – in its amended version – has eight entries.[6] 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 – as amended – sets OELs for 20 agents.[7]

For one of the carcinogens and mutagens considered in the proposal (benzene), an EU-level OEL already exists, dating from 2004. For the other two substances (acrylonitrile and nickel compounds), no EU-level OELs exist, and the situation as regards national OELs is diverse: several Member States have not yet set national limit values for these two substances; where national OELs exist, they differ in range.[8] As the Commission explains in the explanatory memorandum of the proposal, diverging national OELs lead to different levels of workers' protection across the EU, and possibly entice companies to locate their production in Member States with the lower (that is, less strict) requirements. Differences in labour requirements, in turn, have an impact on competing conditions, due to the different costs they impose on companies. Establishing clear specific minimum requirements for worker protection may reduce this effect.

## Parliament's starting position

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 carcinogens, mutagens and substances that are toxic to reproduction. 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.

With its resolution of 17 June 2020, Parliament set up a special committee on beating cancer (BECA). The BECA committee is specifically tasked with evaluating opportunities for the EU to take concrete action, identifying legislation and other measures that can help prevent and fight cancer, among other things. Its responsibilities include evaluating scientific knowledge on the best possible prevention of cancer and identifying legislative opportunities to act in areas such as exposure to chemicals, air pollution and carcinogens in the workplace, among others.

## Preparation of the proposal

The proposal is accompanied by a Commission impact assessment (IA) and its executive summary, which received a positive opinion from the Regulatory Scrutiny Board. The IA covers the expected costs and benefits of different regulatory options for the three chemical agents included in the

proposal. According to the Commission, the IA should be read in conjunction with the earlier IA for the first proposal, where the CMD and its context are considered exhaustively. EPRS has published an initial appraisal of the Commission's IA.

The Commission points out that, owing to the pandemic and the subsequent delay in the legislative procedure concerning this initiative, no inception impact assessment has been published.

The selection of the specific three agents considered in the IA was based on a consultative approach, which included opinions on each of the chemicals by the tripartite Advisory Committee on Safety and Health at Work (ACSH) and a formal two-stage consultation of the social partners. The first phase of the consultation closed on 30 September 2017, the second phase on 22 December 2017.[9] The scientific advice for the chemical agents covered in the IA was provided by the Committee for Risk Assessment (RAC).[10]

# The changes the proposal would bring

## The measures put forward

Continuing from the three previous legislative amendments to the CMD, which addressed 26 priority chemical agents,[11] the proposal would place new or updated OELs on an additional three (two individual substances and one group of substances). These are:

- acrylonitrile
- nickel compounds
- benzene.[12]

The annex to the proposal sets out the proposed limit values. Transition periods would be established for all three substances.[13]

In addition to the OELs, it is proposed to add a skin notation[14] in the case of acrylonitrile, and a notation for dermal and respiratory sensitisation[15] in the case of nickel compounds. The existing skin notation for benzene would be retained.

## The impact

The substances considered in the proposal are used across a wide range of sectors and activities, including: industrial manufacturing and manufacturing of textiles, leather and fur; production of chemicals; rubber products; plastics products; computer, electronic and optical products; electrical equipment; building and construction work; oil refineries; pigments, glass, metals and alloys; metal surface treatment; batteries; materials recovery; welding; the petroleum industry; maintenance and repair of motor vehicles; foundries and laboratories.

According to the Commission, the measure would contribute to lowering the risk that **workers** contract avoidable work-related cancer (including brain, lung and nasal cancers), as well as suffer other significant health problems[16] caused by exposure to the substances under consideration. In the longer term, the proposed directive would prevent over 1 600 cases of ill health (and 80 miscarriages) and benefit over 1.1 million EU workers in terms of improved prevention and protection, while reducing effects such as the suffering of workers and their families and carers, a reduced quality of life or undermined wellbeing. The greatest benefits would be expected in relation to benzene and nickel compounds, to which an estimated 1 million workers and 88 000 workers respectively are exposed. According to the Commission, the quantified benefits linked to the prevention of ill health among workers exposed to benzene and nickel compounds range between €121-198 million and €72-92 million respectively. The Commission also notes that the proposal would provide more clarity for workers, employers and enforcers regarding the acceptable levels of exposure.

Moreover, the Commission points out that for **employers**, the proposed directive would reduce costs due to work-related ill health and cancer in terms of personnel absence, lost expertise, insurance payments and decreased productivity. It would contribute to a more level playing field

for **companies** in the form of EU-wide minimum standards of protection. While the proposal could result in higher costs for companies that have to put in place additional protective and preventive measures, these investments would represent only a small fraction of companies' turnover. The transitional measures envisaged would give companies more time to make the necessary investments while already improving the protection of workers. There would be no increase in administrative burden for companies.

Furthermore, the Commission explains that the proposal would help **Member States** avoid productivity losses, reduce the costs for social security and healthcare systems, and avoid tax revenue losses due to morbidity and mortality. Although administrative and enforcement costs would differ from one Member State to another (Member States that have equal or lower – that is, stricter – limit values would be less affected than those having higher or no OEL in place), they would not be significant. Given that the process of establishing OELs requires considerable scientific expertise, setting EU-wide occupational exposure limits would eliminate the need for Member States to conduct their own scientific analysis, and so the proposed directive should even help Member States cut administrative costs.

## Advisory committees

The European Economic and Social Committee (EESC) adopted its opinion on 2 December 2020. The opinion notes that, since the EESC unreservedly endorses the proposal's content and has already set out its views on the subject in earlier opinions,[17] it decided to issue an opinion endorsing the proposed text and to refer to the position it had taken in those documents. The European Committee of the Regions (CoR) informed that it had decided not to issue an opinion.

## National parliaments

The deadline for national parliaments to submit comments on the proposal was 18 November 2020. None have submitted reasoned opinions. However, on 18 November 2020, the Italian *Senato della Repubblica* (Senate Committee on European Union Policies) issued a resolution which, in the context of a positive subsidiarity opinion, expressed concerns as regards the respect of the proportionality principle, the compliance with the provisions of the legal basis, and the lack of data in the impact assessment as to the repercussions of the ecological transitions from fossil to green energies. According to the scrutiny information provided on the platform for EU interparliamentary exchange (IPEX) website, the Senate Committee considers it necessary to allow Member States to establish forms of compensation for small businesses to cover the higher investments necessary to align with the limit values proposed. In its reply, the Commission states it is of the opinion that the proposal is in line with the proportionality principle and with Article 153 of the Treaty on the Functioning of the European Union. It confirms that the ecological transition has duly been taken into account in the impact assessment, and notes the Senate's suggestion to enable Member States to adopt forms of compensation, especially for small businesses. Regarding the more technical issues raised in the opinion, the Commission refers to the annex attached to its reply.

## Stakeholder views[18]

The European Commission invited feedback on the initiative from 25 September to 20 November 2020. The feedback received was presented to the European Parliament and Council with the aim of feeding into the legislative debate.

In an October 2020 press release, professional organisations, trade unions and patient groups[19] announced the launch of a 'Stop Cancer at Work' campaign aimed at ensuring that carcinogenic and mutagenic hazardous medicines (such as cytotoxic drugs),[20] as well as substances toxic for reproduction (reprotoxins), are brought within the scope of the proposal. According to the press release, workplace exposure to reprotoxins causes a wide range of reproductive health problems, including reduced fertility or infertility, erectile dysfunction, menstrual cycle and ovulatory

disorders, miscarriage, stillbirth, babies born too soon or too small, birth defects, and child developmental disorders.

In a September 2020 press release, the European Trade Union Confederation (ETUC) welcomed the Commission proposal, but regretted that no action has been taken to limit exposure levels to 20 further cancer-causing substances. The ETUC's objective is to have at least 50 priority carcinogens with binding OELs under the CMD by 2024. Moreover, the ETUC points out that some of the obligations from the previous revisions of the CMD remain to be fulfilled, despite the deadline having expired, and urges the Commission to extend the scope of CMD to both reprotoxins and hazardous medicinal products. In a September 2020 brief, the ETUC stresses the importance of including reprotoxins, such as glycol ethers, certain phthalates, warfarin, lead and its compounds, and some endocrine disruptors (bisphenol A), in the proposal.

In an April 2019 position paper, Petrochemicals Europe, Concawe, FuelsEurope and the European Steel Association (EUROFER)) expressed their view regarding the revision of the benzene OEL. The paper states that at an exposure level below 0.5 ppm, cancer risks are low, and below 0.25 ppm, cancer risks can be ruled out. According to the position paper, 0.25 ppm can be considered a safe exposure level, and lowering exposure below this safe level brings no actual health benefits.

# Legislative process

In the European Parliament, the Committee on Employment and Social Affairs (EMPL) is responsible for the file. The rapporteur, Stefania Zambelli (ID, Italy) was appointed on 10 November 2020. In her draft report of 10 January 2021, the rapporteur proposed 12 amendments to the Commission proposal. They include, in particular, amendments regarding hazardous medicinal products (HMPs), such as bringing HMPs within the scope of the proposal, and calling for the introduction of Commission guidelines and an EU register on HMPs. The draft report also reiterated Parliament's willingness to address the issue of substances that are toxic to reproduction (reprotoxic). The draft report was considered in the EMPL committee meeting on 27 January 2021. Further amendments received (13-112) were considered on 23 February 2021. In addition to HMPs and reprotoxic substances, these amendments concerned, among other things: moving towards a risk-based methodology for setting limit values under the CMD; adapting the different limit values' implementation to take into account exposure to a combination of substances acting by the same mode of action; requesting the Commission to put forward an action plan to achieve limit values for at least 25 additional substances; lowering the proposed OELs for nickel compounds; further reducing the OEL for benzene, and specifying that this OEL be further revised by 2030; and setting OELs for cobalt and cobalt compounds. The draft report was put to a vote in committee on 25 March 2021 and adopted by 46 votes to 0, with 6 abstentions.

In the Council, the Commission presented the proposal to ministers of employment and social policy during a video-conference on 13 October 2020. Work in the Council was conducted in the working party on social questions. In its meeting on 25 November 2020, the Permanent Representatives Committee agreed a mandate for negotiation with Parliament.

Interinstitutional negotiations began on 27 May 2021. And on 16 December 2021, the Council and Parliament reached a provisional agreement on the proposal.

Under the agreement, workers would benefit from greater protection through the setting of occupational exposure limits (OELs) for acrylonitrile and nickel compounds and the lowering of the limits for benzene. These OELs will be introduced in an annex to the directive. The scope of the proposed directive would include reprotoxic substances (which have adverse effects on reproduction and can cause impaired fertility or infertility). Workers who deal with hazardous medicinal products would receive better training on how to handle them safely. In addition, Parliament has insisted that the Commission must present an action plan to set OELs for at least 25 substances or groups of substances before the end of 2022. The Commission is also required to

launch the process to define the upper and lower risk levels of the methodology for establishing OELs and, in 2022, the procedure to reduce the OEL for crystalline silica dust.

The agreed text was endorsed by Coreper, for the Council, on 22 December 2021, and then approved at the EMPL committee meeting of 25 January 2022. The text now needs to be adopted formally by Parliament, and the vote is scheduled for the February 2022 plenary session.

Once adopted, the directive would enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

## EP SUPPORTING ANALYSIS

Scholz N., Limits on exposure to carcinogens and mutagens at work, EPRS, January 2018.

Scholz N., Limits on exposure to carcinogens and mutagens at work: Second proposal, EPRS, March 2019.

Scholz N., Limits on exposure to carcinogens and mutagens at work: Third proposal, EPRS, August 2019.

Vettorazzi S., Initial appraisal of the Commission impact assessment: Protection of workers from exposure to carcinogens or mutagens: Fourth proposal, EPRS, November 2020.

Strengthening Europe in the fight against cancer: Going further, faster, Policy Department for Economic, Scientific and Quality of Life Policies, Directorate-General for Internal Policies, July 2020.

## OTHER SOURCES

Protection of workers from the risks related to exposure to carcinogens or mutagens at work, European Parliament, Legislative Observatory (OEIL).

Fourth proposal amending the Carcinogens and Mutagens Directive (CMD 4), European Parliament Legislative Train Schedule.

## ENDNOTES

1 The first proposal was adopted by the co-legislators as Directive (EU) 2017/2398 (for further information, see an EPRS briefing ('EU Legislation in Progress'), January 2018. The second proposal was adopted as Directive (EU) 2019/130 (see also an EPRS briefing ('EU Legislation in Progress'), March 2019. The third proposal was adopted as Directive (EU) 2019/983 (see also an EPRS briefing ('EU Legislation in Progress'), August 2019.

2 An analysis of the objectives of the initiative is provided in an EPRS initial appraisal of the Commission impact assessment (IA).

3 The plan was presented on 3 February 2021. See also the dedicated Commission website, A cancer plan for Europe, and a March 2021 EPRS briefing.

4 The survey will look at workers exposed to a range of cancer risk factors, including asbestos, benzene, chromium, diesel exhaust, nickel, silica dust, UV radiation and wood dust, and in particular, multiple exposures.

5 The term 'limit value', defined in the CDM, addresses the inhalation route of exposure. It describes 'a maximum airborne concentration level for a given chemical agent above which workers should not be exposed, on average, during a defined time period' (see the explanatory memorandum of the proposal, p.16).

6 In accordance with Annex I of the consolidated version of the CMD, 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; 5. work involving exposure to hardwood dusts; 6. work involving exposure to respirable crystalline silica dust generated by a work process; 7. work involving dermal exposure to mineral oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine; and 8. work involving exposure to diesel engine exhaust emissions.

7 In accordance with Annex III of the consolidated CMD, for hardwood dusts, chromium VI compounds, refractory ceramic fibres, respirable crystalline silica dust, benzene, vinyl chloride monomer, ethylene oxide, 1,2-epoxypropane, trichloroethylene, acrylamide, 2-nitropropane, o-toluidine, 4,4'-methylenedianiline, epichlorohydrine, ethylene dibromide, 1,3-butadiene, ethylene dichloride, hydrazine, bromoethylene and diesel engine exhaust emissions.

8 For an overview of all national OELs for the substances considered, see Table 3 in the IA.

9 See ACSH opinions on acrylonitrile, nickel and its compounds and benzene, adopted on 4 June 2019.

10 See RAC opinion on acrylonitrile, nickel and its compounds and benzene, adopted on 9 March 2018.

[11] Chemical agents considered by the Commission as being a priority for protection of workers. The selection was made on the basis of stakeholders' views (see IA, Annex 8).

[12] None of these substances are subject to authorisation under Regulation (EC) No 1907/2006 (REACH).

[13] Meaning during these periods, transitional measures would apply that provide for higher (that is, less strict) limit values.

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

[15] A notation for dermal sensitisation means that exposure to a substance can cause adverse skin reactions, while a notation for respiratory sensitisation indicates that exposure to a substance by inhalation can cause adverse reactions in the respiratory tract.

[16] For a list of adverse health effects due to the substances under consideration, see IA, p.8.

[17] These are: SOC/545 (Protection from cancer-causing chemicals, adopted on 21 September 2016), SOC/559 (Protection of workers from carcinogens or mutagens at work, adopted on 31 May 2017), SOC/591 (Protection of workers from carcinogens or mutagens at work, adopted on 19 September 2018), and CCMI/130 (Freeing the EU from asbestos, adopted on 18 February 2015).

[18] 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'.

[19] These are: the Standing Committee of European Doctors (CPME); European Association of Pharmacy Technicians (EAPT); European Biosafety Network (EBN); European Cancer Patient Coalition (ECPC); European Federation of Nursing Associations (EFN); European Public Services Union (EPSU); European Specialist Nurses Organisation (ESNO); European Trade Union Confederation (ETUC); European Trade Union Institute (ETUI).

[20] Cytotoxic drugs describe a group of medicines designed to destroy cells that grow in a rapid and uncontrolled manner, preventing their replication or growth. Cytotoxics are increasingly being used in a variety of healthcare settings, primarily in the treatment of cancer.



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