Briefing
EU Legislation in Progress
June 2016

European Parliament

Limits on exposure to carcinogens and mutagens at work

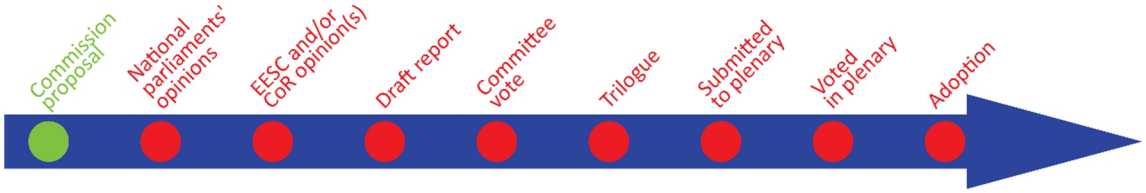
OVERVIEW

The European Commission proposes 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-causing chemical agents in the light of new scientific data. According to the Commission, this would improve workers' health protection, increase the effectiveness of the EU framework and promote clarity for economic operators. The initiative would proceed in two steps, with the current proposal and another to follow later in the year.

Broad discussions with scientists and the social partners fed into the proposal, and it has received a broad welcome from stakeholders. Trade unions nonetheless regret that certain substances are not included, and some on the employers' side oppose the limit value for respirable crystalline silica.

The legislative process is in its initial stages, with the EMPL Committee to consider the proposal in the coming months.

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		
Committee responsible:	Employment and Social Affairs (EMPL)	COM(2016)0248 13.05.2016
Rapporteur:	Marita Ulvskog (S&D, Sweden)	2016/130(COD) Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')
Shadow rapporteurs:	Claude Rolin (EPP, Belgium) Patrick Le Hyaric (GUE/NGL, France)	
Next steps expected:	Discussions in EMPL	



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Introduction

On 13 May 2016, the European Commission presented its proposal to amend Directive 2004/37/EC (the Carcinogens and Mutagens Directive – CMD). The proposal is among the priority actions of the Commission Work Programme for 2016 and is meant to contribute to delivering on the objective of a 'Social Triple A' rating for Europe.[1] According to the Commission, the aims of the proposal are to:

- 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
- achieve more balanced EU-wide protection of workers against carcinogens, while securing greater clarity and a more level playing field for economic operators.

The Commission envisages to proceed in two steps, namely the current proposal and another related proposal by the end of 2016. (For more details, see 'The proposed changes and their potential impact', below).

Context

Cancer is the leading cause (53%) of work-related deaths in the EU. The most common types of occupational cancer include lung cancer, mesothelioma[2] and bladder cancer. The World Health Organization (WHO) estimates that every tenth lung cancer death is closely related to workplace risks. Cancer exposure registers (CAREX) have been established in order to obtain a more comprehensive picture of occupational exposures. Work-related cancers may be prevented by reducing or eliminating exposure to certain carcinogens. 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 carcinogen.

Covenant on raising awareness of risks from exposure to carcinogens

On 25 May 2016, the Austrian Federal Ministry of Labour, Social Affairs and Consumer Protection, BusinessEurope, the Dutch Ministry of Social Affairs and Employment, the European Agency for Safety and Health at Work (EU-OSHA), the European Trade Union Congress (ETUC) and the European Commission signed a covenant, the Roadmap on Carcinogens 2016-2019, in which they committed to raise awareness of the risks arising from exposure to carcinogens in the workplace and to exchange best practice.

Existing situation

The Carcinogens and Mutagens Directive sets general minimum requirements to eliminate or reduce exposure to the chemical agents falling within its scope: 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 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 occupational exposure limit values (OELs) are not exceeded.

The provisions of the Directive 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 Directive, which currently has five entries.[3] These are what are referred to as process-generated substances (PGS) – hazardous chemical agents such as dust, fumes and gases generated during combustion or as by-products during production processes.

The Directive also established occupational exposure limit values for certain carcinogens and mutagens, with a view to protecting workers. It stipulates that such values need to be set for those chemical agents for which they do not yet exist and be revised whenever new scientific evidence becomes available. Currently, the Directive sets three[4] occupational exposure limit values.

Parliament's starting position

It 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.

Preparation of the proposal

The proposal is accompanied by an Impact Assessment (IA), including an Executive Summary, and draft (negative) and final (positive) opinions on the IA by the Regulatory Scrutiny Board. A detailed analysis will be provided in the upcoming EPRS Initial Appraisal of the Commission Impact Assessment.

The IA was preceded 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 Scientific Committee on Occupational Exposure Limits (SCOEL) and the Advisory Committee on Safety and Health at work (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 the proposal.

The Commission's Inception Impact Assessment (IIA) 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 negative consequences of inadequate occupational exposure limit values for workers and businesses across the EU. The IIA envisages proceeding in two stages: first, widening the scope of the Directive and establishing limit values for a number of substances; and second, including more substances and establishing limit values for additional substances, once more data becomes available from the results of another study. (For a detailed analysis, see the EPRS Implementation Appraisal).

The proposed changes and their potential impact

The measures put forward

Firstly, the Commission plans to bring within the scope of the Directive a number of chemical agents that are recognised as human carcinogens in countries outside the EU, such as the USA, or by international organisations, such as the WHO's International Agency for Research on Cancer (IARC), but that are not yet classified under the current EU system.[5] The current proposal would include occupational exposure to respirable crystalline silica dust (RCS)[6] (in Annex I) and establish a corresponding limit value, expressed as maximum concentrations in workplace air (Annex III). RCS would be added as a process-generated substance, meaning dust created by mining, cutting or crushing of materials such as concrete, bricks, or rocks. Crystalline silica in the form of quartz or cristobalite dust is a leading cause of occupational lung cancer and classified by the IARC as carcinogenic to humans (Group 1).

Secondly, the proposal would establish EU-wide occupational exposure limit values for a further 10 carcinogens,[7] so as to reflect the latest scientific evidence. National limit values exist for some of the chemical agents considered in the initiative but, where they exist, they vary considerably. For example, while most Member States have set limits for ethylene oxide and acrylamide, less than half have done so for bromoethylene/vinyl bromide or o-toluidine.[8]

Thirdly, two of the three existing limit values – those for hardwood dusts and vinyl chloride monomer – would be revised in the light of more recent scientific data.

In addition to the current proposal introducing and/or revising limit values for 13 priority chemical agents,[9] the Commission intends to put forward a second proposal covering another 12 agents later in the year, for which additional analysis has still to be carried out.

The impact

According to the Commission's Explanatory Memorandum to the proposal, the measures would prevent **workers** from getting avoidable work-related cancer and would decrease the economic burden in terms of health costs. The cancer deaths avoided would be mainly those relating to respirable crystalline silica, chromium VI and refractory ceramic fibres. (For example, it is estimated that the proposed limit value for respirable crystalline silica dust – 0.1 milligrams per cubic metre (mg/m^3) – would prevent 99 000 cancer deaths by 2069.) The Commission argues that the proposal would benefit workers in the construction sector, in particular, which accounts for almost 70% of all workers exposed to respirable crystalline silica. Other sectors that would benefit from the measures include: chemicals manufacturers; manufacturers of rubber products; the aeronautic, automotive and furniture industries; manufacturers of food products and textiles; the wood working industry; and the healthcare sector and hospitals.[10] According to the Impact Assessment, the measures would result in monetised health benefits (in terms of avoided cancer registrations and deaths) of €12-89 billion.

Moreover, according to the Commission, the introduction of EU-wide occupational exposure limit values 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 chromium (VI) compounds and respirable crystalline silica. For the latter, the total costs to businesses of introducing a limit value of 0.1 mg/m^3 are estimated to be €3. 5 billion until 2069; for the remaining 12 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.)

The European Agency for Safety and Health at Work considers that the proposal will encourage cross-border employment by reducing the differences between Member States in terms of workers' health protection.

Advisory committees

The European Economic and Social Committee and the Committee of the Regions have not yet delivered opinions on the proposal.

National parliaments

The deadline for national parliaments to submit comments on the proposal is 12 July 2016.

Stakeholders' views[11]

The European Cancer Patient Coalition (ECPC) sees the proposal as 'very positive' since it will enable the revision of the Directive 'after 12 years of paralysis'. It considers the Directive 'a very important legislative instrument to fight health inequalities'. The ECPC also underlines the need to ensure early diagnosis of work-related deadly cancers.

The European Trade Union Confederation (ETUC) considers the proposal 'a significant step forward', although it finds some exposure limits inadequate. It deplores the fact that some substances on the list of carcinogens for which it has demanded workplace exposure limits are not included. It also notes that the 13 substances that were selected relate mainly to male exposures, whereas the ETUC list also covers agents to which women are most exposed. The European Trade Union Institute (ETUI), while welcoming the proposal, believes that it does not go far enough. It cites the example of crystalline silica, where the Commission proposes an occupational exposure limit value of 0.1 milligrams per cubic metre, which, in ETUI's view, would not be sufficient to protect the 5 million workers exposed to the substance.

The Industrial Minerals Association – Europe (IMA-Europe) welcomes the proposal, and especially the fact that it acknowledges the NEPSI[12] agreement as a valuable instrument to complement regulatory requirements and to support their effective implementation. According to press reports, the Confederation of European Businesses (BusinessEurope) hopes that the proposal will be based on scientific proof and that it is realistic. It reportedly opposes the limit of exposure to respirable crystalline silica, arguing that the substance is not a direct carcinogen.

Legislative process

The process is in its initial stages. The EMPL Committee will consider the proposal in the coming months. The Employment, Social Policy, Health and Consumer Affairs EU Council took note on 16 June 2016 of the progress report on carcinogens or mutagens at work.

EP supporting analysis

- EPRS Implementation Appraisal: Exposure to carcinogens and mutagens at work, Remáč, M., June 2016

- EPRS Initial Appraisal of the Commission Impact Assessment (upcoming)

Other sources

- Exposure to carcinogens and work-related cancer: a review of assessment methods, European Agency for Safety and Health at Work, 2014

- Proceedings of the conference 'Preventing work-related cancer', organised by the Dutch EU Presidency 2016, 23-25 May 2016

- Protection of workers from exposure to carcinogens or mutagens at work: exposure limit values / European Parliament, Legislative Observatory (OEIL).

Endnotes

1 The Directive is also among the pieces of legislation included in the Evaluation and fitness check (FC) roadmap, to be assessed (by the end of 2017) for overall effectiveness, efficiency, relevance, coherence and EU added value.

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

3 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.

4 For benzene, vinyl chloride monomer and hardwood dusts.

5 According to the Explanatory Memorandum to the proposal, Regulation (EC) No 1907/2006 (REACH) and the Directive are legally complementary: hardwood dust and respirable crystalline silica, which are both substances generated by a work process, are beyond the scope of REACH; while REACH, on the other hand, is not intended to set limit values.

6 In the 2006 'Agreement on workers' health protection through the good handling and use of crystalline silica and products containing it', respirable crystalline silica is defined as 'the mass fraction of inhaled crystalline silica particles penetrating to the unciliated airways'. See also the detailed explanation of RCS and health from a European industry perspective.

7 The ten chemical agents are: 1,2-epoxypropane; 1,3-butadiene; 2-nitropropane; acrylamide; bromoethylene/vinyl bromide; chromium (VI) compounds; ethylene oxide; hydrazine; o-toluidine; refractory ceramic fibres.

8 For a detailed overview of the national limit values for each of the chemical agents considered, see Table 1 in Annex 6 of the Impact Assessment.

9 The Commission states that some of the 13 priority agents identified, such as respirable crystalline silica, hardwood dusts, hydrazine or chromium (VI) compounds, affect very high numbers of workers in the EU (5.3 million, 3.3 million, 2.2 million or 916 000, respectively). Use patterns for some others may be lower, but since the ratio between the number of exposed workers and cancer cases is high, they are nevertheless considered a priority.

10 For an overview table of the sectors, types of cancer caused and estimated exposure levels for the 13 chemical agents under consideration, see the European Commission Fact Sheet.

11 This section aims to give a sense of the debate on the issues surrounding the legislative file and cannot provide an exhaustive account of all the different views expressed. For an institutional perspective on stakeholder participation, see the section on advisory committees. Additional information can also be found in related briefings listed under EP supporting analysis below.

12 The European Network for Silica (NEPSI) is formed by the signatories of the 2006 Agreement on workers' health protection through the good handling and use of crystalline silica and products containing it (see footnote 6).

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