EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR EMPLOYMENT, SOCIAL AFFAIRS AND INCLUSION

The Director-General

Brussels
EMPL.C.2/WT

BACKGROUND DOCUMENT

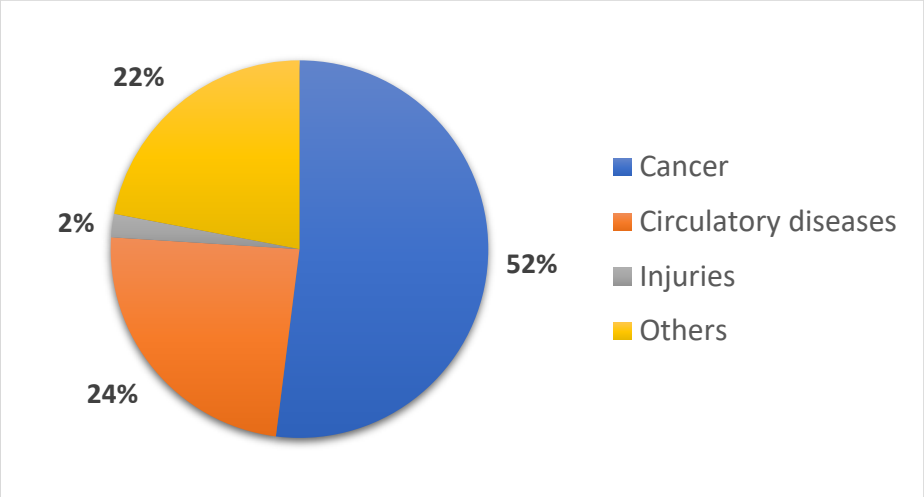
Subject: First phase consultation of the social partners under Article 154 of the Treaty on the Functioning of the European Union, on the protection of workers from risks related to exposure to carcinogenic, mutagenic or reprotoxic substances at work

1. INTRODUCTION

Cancer is the first cause of work-related death in the EU (figure 1). Each year, about 120 000 work-related cancer cases occur because of exposure to carcinogens at work in the EU, leading to approximatively 80,000 fatalities[1]. It has an impact not only on individual health, family life, but also on the national health and social systems, the governmental budgets and the productivity and growth of the economy.

Improving prevention of workplace accidents and illnesses, including occupational cancer, is a key objective of the European Commission as outlined in the new EU strategic framework on health and safety at work 2021-2027[2] .

Figure 1: Causes of work-related fatalities (%) in the EU[3]



Data source: "An international comparison of the cost of work-related accidents and illnesses", EU-OSHA 2017

In February 2021, the Commission presented its Europe's Beating Cancer Plan[4], with the aim of tackling the entire disease pathway, from prevention to quality of life of cancer patients and survivors. Actions to fight cancer at the workplace, through the continuous revision of the Carcinogens, Mutagens and

1 National Institute for Public Health and the Environment (2016), *Work-related cancer in the European Union*.
2 EUR-Lex - 52021DC0323 - EN - EUR-Lex (europa.eu)
3 EU figures date from before 2021, thus including the UK
4 EUR-Lex - 52021DC0044 - EN - EUR-Lex (europa.eu)

Reprotoxic substances Directive 2004/37/EC[5] (CMRD) and the Asbestos at Work Directive 2009/148/EC[6], are key components of the Plan.

Over the last few years, the EU legislative initiatives in the area of occupational safety and health (OSH) have contributed to considerably improving working conditions, by strengthening the protection of workers from 41 hazardous substances through four revisions of the CMRD. A proposal for a fifth revision of the CMRD addressing lead and its compounds and setting limit values for diisocyanates under Directive 98/24/EC on chemical agents (CAD), was adopted by the Commission on 13 February 2023.

In the EU strategic framework on health and safety at work 2021-2027, the Commission committed to addressing the following substances, groups of substances or process-generated substances ('substances') through a sixth revision of the CMRD: welding fumes, polycyclic aromatic hydrocarbons, isoprene, 1,4-dioxane and cobalt and inorganic cobalt compounds. These five substances were also identified as priority substances by the tripartite Advisory Committee on Safety and Health at Work[7] (ACSH), and in the Commission Staff Working Document setting out the list of substances to be scientifically assessed for the purposes of CMRD[8].

This sixth revision of the CMRD will be a contribution to Principle 10 of the European Pillar of Social Rights[9], which states that every worker has the right to a healthy, safe and well-adapted work environment.

2. CURRENT LEGAL FRAMEWORK

Article 153 TFEU forms the principal basis for policy relating to the health and safety of workers, whereby minimum requirements may be adopted to improve workers' protection. The Framework Directive (89/391/EEC)[10] has a broad scope, laying down principles for the introduction of measures to encourage improvements in the safety and health of workers. These principles are further developed in individual Directives that introduce provisions such as those related to exposure to dangerous chemicals of workers across sectors.

The Carcinogens, Mutagens or Reprotoxic Substances Directive (2004/37/EC), the Chemical Agents Directive (98/24/EC), the Asbestos Directive (2009/148/EC) and Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals ('REACH') are the main pieces of a comprehensive framework for the protection of workers from exposure to carcinogens, mutagens or reprotoxic substances or any hazardous chemicals. The Pregnant Workers Directive

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5 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, (OJ L 158, 30.4.2004, p. 50– 76)

6 Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work, (OJ L 330, 16.12.2009, p. 28-36)

7 ACSH opinion (2021) on 'priority chemicals for new or revised occupational exposure limit values under EU OSH legislation', Doc. 006-21

8 Commission Staff Working Document 'List of substances to be scientifically assessed for the purposes of Article 18a, third paragraph, of Directive 2004/37/EC on presenting an action plan to achieve new or revised occupational exposure limit values for at least 25 substances, groups of substances or process-generated substances, SWD(2022) 438 final.

9 Interinstitutional Proclamation on the European Pillar of Social Rights, (OJ C 428, 13.12.2017, p. 10–15)

10 Council Directive 89/391/EEC on the introduction of measures to encourage improvements in the safety and health of workers at work, OJ L183, 29.6.1989, p. 1

(92/85/EEC), the Young Workers Directive (94/33/EC) and the Safety Signs at Work Directive (92/58/EEC) also contain important provisions referring to carcinogens, mutagens or reprotoxic substances.

2.1 Carcinogens, Mutagens and Reprotoxic substances Directive

The CMRD applies to substances or mixtures which meet the criteria for classification as category 1A or 1B carcinogens (known or presumed human carcinogens), category 1A or 1B germ cell mutagens (known or presumed human mutagens) and category 1A or 1B reproductive toxicants (known or presumed human reprotoxics) laid down in the Annex I to the Classification, Labelling and Packaging (CLP) Regulation[11].

The provisions of the CMRD also apply to any substance, mixture or process referred to in its Annex I as well as to a substance or mixture released by a process referred to in that Annex. Currently, Annex I has a list of eight process-generated substances[12] in particular during their manufacturing or specific working activities.

To reduce the occupational exposure to substances or mixtures within its scope, the CMRD provides for a hierarchy of preventive and protective measures. The employer has the obligation to substitute these chemicals by less or non-hazardous substances, mixtures, or processes as far as technically possible. If substitution is not technically possible, other measures to prevent exposure like working in a closed system or to reduce the number of workers potentially exposed, must be put in place by the employer.

Another obligation of the employers is to ensure that occupational exposure limits (OEL) and binding biological limit values (BLV) set out in Annex III and Annex IIIb to the CMRD respectively must not be exceeded. With the entry into force of the fourth amendment to the CMRD in April 2022, Annex III lists 41 substances and Annex IIIb addresses 1 substance (lead and its ionic compounds). For EU OELs and binding BLVs adopted under the CMRD, Member States must establish a corresponding national limit value at least at the EU level or lower value (more protective).

2.2 Involvement of relevant stakeholders

During the process of developing a legislative initiative setting new or revised OELs for chemicals or adding new entries in annex I of the CMRD, the Commission seeks the advice of the ACSH. Its opinions are a key element in the process, as they take account of the scientific evaluation provided by the European Chemicals Agency's (ECHA) Risk Assessment Committee (RAC), ECHA's reports, as well as feasibility and socio-economic factors. This tripartite consultation between Member States and social partners plays a key role in making the EU OSH legislative framework future-proof and in ensuring proper compliance and enforcement.

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[11] Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

[12] 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) 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.

In accordance with Article 154(2) TFEU, through this consultation the Commission seeks the views of social partners on the possible direction of EU action aiming to further improve the protection of workers from risks related to exposure to hazardous chemicals at work by amending the CMRD. The recently adopted Commission Communication on social dialogue[13] foresees that in agreement with the European social partners, two-stage social partners consultations can be carried out through two ad-hoc meetings with the participation of all concerned recognised social partners. Having received the agreement of social partners and considering the extensive discussions already held in the Tripartite ACSH, the Commission has decided to conduct this consultation through meetings. More information is provided in the cover note accompanying this background document.

The Risk Assessment Committee (RAC) of the European Chemicals Agency adopted scientific opinions for polycyclic aromatic hydrocarbons[14], 1,4-dioxane[15], isoprene[16] and cobalt and inorganic cobalt compounds[17], in which it evaluates exposure to these substances to assess the option of an airborne OEL, other limit values (e.g. BLVs) and notations. In addition, ECHA finalised on 30 November 2022 a scoping study[18], in which it assesses and defines the scope of "welding fumes and fumes from other processes such as plasma cutting and air carbon arc gouging that generate fume in a way that is similar to welding" to allow for a description of the relevant processes, or sub-processes, to be included in annex I to the CMRD to ensure legal certainty of inclusion within the scope of the Directive.

3. ISSUES WITH THE CURRENT LEGAL FRAMEWORK

The establishment of binding limit values for additional carcinogens, mutagens or reprotoxic substances is necessary to reflect new developments in science and technology. New available scientific evidence plays a crucial role in a better understanding of occupational hazards or exposure and allowing potentially for better prevention and protection. This is particularly relevant in respect of occupational cancer or reproductive ill-health risks.

The need for regulatory action to address adverse ill-health effects of the 5 substances through the revision of the CMRD is justified as follows:

3.1 Welding fumes

[13] COM (2023) 40 final

[14] Committee for Risk Assessment's Opinion on scientific evaluation of occupational exposure limits for polycyclic aromatic hydrocarbons, ECHA/RAC/OEL-O-0000007198-66-01/F

[15] Committee for Risk Assessment's Opinion on scientific evaluation of occupational exposure limits for 1,4-dioxane, ECHA/RAC/OEL-O-0000007101-89-01/F

[16] Committee for Risk Assessment's Opinion on scientific evaluation of occupational exposure limits for isoprene, ECHA/RAC/OEL-O-0000007102-87-01/F

[17] Committee for Risk Assessment's Opinion on scientific evaluation of occupational exposure limits for cobalt and inorganic cobalt compounds, ECHA/RAC/OEL-O-0000007197-68-01/F

[18] ECHA Scoping Study Report for evaluation of limit values for welding fumes and fumes from other processes that generate fume in a similar way at the workplace

According to the European Welders Association, about 2 million welders work in the EU[19]. However, it is likely that the number of workers exposed to welding fumes is higher and includes other metal workers involved in construction and maintenance of infrastructure and machinery.

In 2018, the World Health Organization's International Agency for Research on Cancer (IARC) classified welding fumes and UV radiation from welding as "carcinogenic to humans" (Group 1)[20]. Exposure to welding fumes may lead to lung damage and various types of cancer, including of the lung, larynx and urinary tract.

Only some of the substances contained in welding fumes meet the criteria of the CLP Regulation as 1A and 1B carcinogens, mutagens or reprotoxics and are already within the scope of the CMRD. Welding fumes, overall as a process generated mixture, are not classified as carcinogenic at the EU level and therefore do no fall within the scope of CMRD until they are included in its Annex I.

Consequently, there is a need for assessing the appropriateness of inclusion of welding fumes in Annex I to CMRD.

3.2 Polycyclic aromatic hydrocarbons (PAHs)

PAHs occur naturally in coal, crude oil, and gasoline. They are also produced in different kinds of combustion processes. Workers in industries or trades producing coal or coal products are at highest risk for PAHs exposure. It can lead to cancer such as lung, skin, leukaemia or cancer of the bladder.

In Annex 1 to the RAC opinion, ECHA indicates that the economic activities with the most common exposure to PAHs are construction (146 506 workers in the EU), personal and household services (110 039) and iron and steel basic industries (75 120).

PAHs present in coal soot, coal tar or coal pitch are already included in the Annex I to the CMRD. Certain PAHs mixtures meet the criteria for classification as carcinogenic (category 1A or 1B) and therefore fall within the scope of the CMRD. 14 Member States[21] in the EU set an occupational limit value for PAHs in their own national legislation, varying from 0.00007 mg/m3 to 0.2 mg/m3. In the second revision of the CMRD[22], the co-legislators agreed on the necessity to further investigate the need to set an OEL for PAHs in Annex III. In its opinion, RAC indicated that benzo(a)pyrene is considered as a marker substance for carcinogenic PAHs.

3.3 Cobalt and inorganic cobalt compounds

Cobalt and inorganic cobalt compounds are hazardous substances frequently used in renewable technologies and battery production, whose use is expected to grow in the future due to the green transition.

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[19] Addressing health risks from Welding Fume: guidance for National Labour Inspectors - Roadmap on Carcinogens

[20] International Agency for Research on Cancer (2018), Monographs on the Evaluation of Carcinogenic Risks To Humans for Welding, Molybdenum Trioxide, and Indium Tin Oxide, volume 118.

[21] Austria, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Hungary, Latvia, Lithuania, The Netherlands, Poland, Romania and Sweden.

[22] Directive (EU) 2019/130 of the European Parliament and of the Council of 16 January 2019 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, (OJ L 30, 31.1.2019, p. 112-130)

According to the Cobalt Institute, about 80 000 workers in the EU are exposed[23]. Cobalt and cobalt compounds are used in a wide range of sectors, including manufacture of batteries, alloys and hard metal tools. A more in-depth analysis will be carried out to identify relevant sectors and uses where workers are exposed to cobalt and inorganic cobalt compounds.

Cobalt and inorganic cobalt compounds in the scope of the CMRD are a list of substances that range from 1A to 1B carcinogenicity class. Workers exposed to these substances can suffer from lung cancer and non-cancer respiratory effects. Other toxic effects of cobalt and its compounds include respiratory and skin sensitising properties and reproductive toxicity.

Today, 21 Member States[24] have already set an OEL for cobalt, from which 7 have also set a short-term exposure limit[25] (STEL). However, the level of these limit values are highly diverging (ranging from 0.0025 to 0.1 mg/m^3) and do not take into account particle size considerations.

In 2020, RAC adopted an opinion on a possible REACH restriction on 5 cobalt compounds, in which it inter alia recommended that the Commission set a binding OEL under the CMRD for cobalt and all its compounds. Following this opinion, the Commission adopted a Decision[26] in April 2022 to terminate the REACH procedure with regard to those 5 cobalt compounds and initiated instead proceedings to address all cobalt and all its inorganic compounds in accordance with the CMRD. Furthermore, the co-legislators agreed in the fourth revision of the CMRD[27] that the Commission puts forward an OEL for cobalt and inorganic cobalt compounds by no later than 2024.

3.4 Isoprene

Isoprene is primarily used as a chemical intermediate in the polymerisation in the chemical and rubber producing industry. According to ECHA in Annex 1 to the RAC opinion, the polymerisation to form elastomeric polymers accounts for over 95% of all isoprene use within the EU. Isoprene can be produced industrially as a by-product of ethylene production. Further research is ongoing to get more information on the number of workers at risk of exposure to isoprene in the EU.

Isoprene (2-methyl-(1,3) butadiene) is a carcinogen, classified as 1B. Consequently, it is under the scope of CMRD but no OEL has yet been defined. In addition to cancer, exposure to isoprene can lead to other severe health effects such as spleen and bone marrow toxicity and potential reprotoxic effects.

Very few Member States (Germany, Latvia and Poland) have set OELs for isoprene.

3.5 1,4-dioxane

[23] Protecting People at Work - Cobalt Institute

[24] Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Lithuania, The Netherlands, Poland, Romania, Slovakia, Spain, and Sweden.

[25] Limit value above which exposure should not occur and which is related to a 15-minute period

[26] DocsRoom - European Commission (europa.eu)

[27] Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work, (OJ L 88, 16.3.2022, p. 1-14)

The main uses of 1,4-dioxane are as solvent, in laboratories (both industrial and professional settings) and at industrial sites in polymerisation processes. Preliminary calculations[28] indicate that 35 000 workers would be exposed to 1,4-dioxane in the EU. Additional research is currently ongoing to refine this information. According to RAC, occupational exposure to 1,4-dioxane occurs during the production, processing and use of 1,4-dioxane, via inhalation or dermal uptake.

1,4-dioxane was recently reclassified by the European Union as a 1B carcinogen and consequently is now in the scope of CRMD. Exposure to this substance may lead to nasal cavity and liver cancer, respiratory tract irritation, nephrotoxicity and hepatotoxicity.

In 2009, the EU set an indicative OEL for 1,4-dioxane under the Chemical Agents Directive. The ACSH agreed on prioritising this substance in view of reviewing its OEL in line with the latest scientific and technical data. Since 1,4-dioxane is now within the scope of the CMRD, its OEL has to be set in this Directive.

Today, 15 Member States[29] have already set an OEL for 1,4-dioxane, which are all above the OEL recommended by RAC for a safe workers' exposure. Furthermore, 6 Member States have currently set a short-term limit value for 1,4-dioxane in their own legislation. Such a short-term exposure can lead to nose, throat and eyes irritation and RAC recommends to also set a STEL.

4. POSSIBLE APPROACH TOWARDS THE IMPROVEMENT OF THE PROTECTION OF WORKERS' HEALTH FROM RISKS ARISING FROM EXPOSURE TO CARCINOGENS, MUTAGENS OR REPROTOXIC SUBSTANCES AT WORK (POSSIBLE DIRECTION OF EU ACTION)

Further improving the protection of workers' health can be obtained by extending Annex I or establishing new limit values in Annex III for the following priority substances or groups of substances: welding fumes, polycyclic aromatic hydrocarbons (using benzo(a)pyrene as a marker), isoprene, 1,4-dioxane and cobalt and inorganic cobalt compounds.

The Commission's preliminary assessment confirms the need for a sixth revision of the Directive's Annexes I and III. This revision presents an EU added value in several aspects:

- It will update the Directive based on the most recent scientific information on protection and prevention;
- It will improve clarity and enforcement by establishing a common reference point that can be used by employers, workers and enforcers alike to assess compliance with the general requirements of the Directive;
- It will ensure a similar minimum and coherent level of protection across the EU by establishing minimum requirements for the substances envisaged in the initiative.

5. AIM OF THE CONSULTATION

[28] Preliminary calculation were carried out by the external contractor in charge of the study supporting the impact assessment for the sixth revision of the CMRD

[29] Austria, Belgium, Denmark, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, The Netherlands, Poland, Romania, Spain and Sweden

Under Article 154(2) of the Treaty on the Functioning of the European Union, before submitting proposals in the social policy field, the Commission must consult management and labour on the possible direction of Union action. The Commission will examine the views expressed by the social partners. If, having considered those views, the Commission concludes that there is a need for action at EU level, it will launch a second-phase consultation of the social partners on the content of the envisaged proposal, in accordance with Article 154(3) TFEU. The questions on which the Commission would be grateful for the views of the social partners at this first stage are as follows:

(1) Do you agree that the issues identified above are accurately and sufficiently covered?
(2) Do you consider that the EU should address these issues through a binding instrument?
(3) Would you consider initiating a dialogue under Article 155 TFEU on any of the issues identified in this consultation?