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First phase consultation of Social Partners under Article 154 TFEU on revisions of Directive 2004/37/EU to include binding occupational exposure limit values for additional carcinogens and mutagens

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1. INTRODUCTION (WHAT IS THE PROBLEM AND MAIN DRIVERS)

The purpose of this document is to consult the social partners at EU level, in accordance with Article 154(2) of the Treaty on the Functioning of the European Union (TFEU), to obtain their views on the possible direction of European Union action concerning revisions of Directive 2004/37/EC of the European Parliament and of the Council on the protection of workers from the risks related to exposure to carcinogens or mutagens at work ('Carcinogens and Mutagens Directive').[1] The aim of the revisions would be to enhance the relevance and the effectiveness of the Directive by establishing binding occupational exposure limit values for certain additional carcinogens.

The social partners, both at EU and national level, and Member States have called for the establishment of additional binding occupational limit values in Annex III to the Carcinogens and Mutagens Directive. EU level protection of workers concerning carcinogens and mutagens chemicals has been broadly identified by stakeholders and Member States as in need of updating, also in the light of relevant developments such as the list of priority carcinogens established by the European Trade Union Confederation (ETUC)[2].

The European Parliament in its Resolution of 25 November 2015 on the EU Strategic Framework on Health and Safety at Work 2014-2020 reiterated its call on the Commission to present a proposal for a revision of the Carcinogens and Mutagens Directive on the basis of scientific evidence, adding more binding occupational exposure limit values where necessary.

The Council in its conclusions of 5 October 2015 on a new agenda on health and safety at work to foster better working conditions, stressed that increasing the level of protection of workers against carcinogens, mutagens and any other hazardous chemical agents at the workplace is a major and urgent priority. It invited the Commission to consider improvements to the legislation on carcinogens and mutagens, by reviewing the existing binding occupational limit values and adding new ones, as appropriate based on impact assessment and evidence.

[1] 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 (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) (Text with EEA relevance) (OJ L 158, 30.4.2004, p. 50). A first version of the Carcinogens and Mutagens Directive was adopted by the Council in 1990 (Directive 90/394/EEC). The Directive was amended first in 1997 (97/42/EC) and then in 1999 (99/38/EC), when it was extended to mutagens. For the purposes of simplification and clarity, Directive 90/394/EEC and its subsequent amendments were repealed and codified by Directive 2004/37/EC.

[2] https://www.etuc.org/sites/www.etuc.org/files/other/files/suggested_50_boel_candidates_-_april_2015.pdf

Individual Member States and institutes have also issued their views on priorities for EU action such as the list established by the Dutch National Institute for Public Health and Environment.

In its recent Communication "Safer and Healthier Work for All"[3] ('Occupational Safety and Health Communication'), the Commission identified the need to step up the fight against occupational cancer through legislative proposals accompanied by increased guidance and awareness-raising among the top three priorities for action in the area of occupational safety and health.

Occupational cancer, the first cause of work-related deaths in the EU, remains a major challenge[4]. It is primarily caused by exposures to carcinogenic substances. Between 91 500 – 150 500 people with past exposure to carcinogenic substances at work were newly diagnosed with cancer in 2012. Moreover, between 57 700 – 106 500 cancer deaths were attributed to work-related exposure to carcinogenic substances in 2012.

Direct costs of work-related cancer in terms of healthcare and productivity losses amount at least to some 4-7 billion EUR per year. The indirect costs may reach as much as 334 billion EUR each year[5].

2. CURRENT LEGAL FRAMEWORK

Occupational safety and health (OSH) is one of the EU's key priorities in the social field. Article 153 of the TFEU forms the principal basis for policy relating to the health and safety of workers whereby minimum requirements may be adopted to improve worker protection.

The Framework Directive (89/391/EEC)[6] has a wide scope and lays 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, introducing inter alia provisions related to exposure of workers across sectors to dangerous chemicals.

The Carcinogens and Mutagens 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, Authorisation and Restriction of Chemicals ('REACH') are the main pieces of a comprehensive framework for the protection of workers

[3] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy" COM/2017/012 final. http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=2709

[4] SWD/2017/010 final, p. 38. According to estimates for 2012 for the EU and other industrialised countries, occupational cancer had a 57% share in all work-related deaths.

[5] "Work-related cancer in the European Union. Size, impact and options for further prevention. RIVM Letter report 2016-0010 W.P. Jongeneel et al.

[6] 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.

from exposure to carcinogens and mutagens substances and/or any hazardous chemicals. The Pregnant Workers Directive (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 and mutagens substances.

The Carcinogens and Mutagens Directive applies to substances or mixtures which meet the criteria for classification as a category 1A or 1B carcinogens (known or presumed human carcinogens) laid down in the Annex I to the Classification, Labelling and Packaging (CLP) Regulation[7]. The provisions of the Carcinogens and Mutagens Directive 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 five process-generated substances[8] in particular during their manufacturing or specific working activities.

The Carcinogens and Mutagens Directive lays down particular minimum requirements in the area of protection of workers from exposure to carcinogens and mutagens at work including limit values. Employers must identify and assess risks to workers associated with exposure to specific carcinogens and mutagens, and in a hierarchy of preventive measures, firstly, eliminate and substitute to a non or less-hazardous process or chemical agent where this is technically possible, and independently of the results of the risk assessment. Where substitution is not technically possible, carcinogens and mutagens must, as far as it is technically possible, be manufactured and used in a closed system to prevent exposure in accordance with Article 5(2) of the Directive. Where this is not technically possible, worker exposure must be reduced to as low a level as is technically possible under the minimisation obligation under Article 5(3) of the Directive.

In addition to these general minimum requirements, the Carcinogens and Mutagens Directive indicates that the setting of occupational exposure limit values for the inhalation route of exposure for particular carcinogens and mutagens is an integral part of the mechanism for protecting workers[9].

When proposing exposure limit values or definitions of process-generated substances the Commission draws on various sources of scientific advice including the Scientific Committee on Occupational Exposure Limits (SCOEL) and the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) as well as other bodies such as the International Agency for Research on Cancer (IARC) and scientific committees setting national limit values. The scientific assessments serve as the basis for proposals submitted to social dialogue

[7] Regulation (EC) No 1272/2008 of the European Parliament and of the Council, of 16 December 2008, 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. Table 3.6.1 of Annex I of CLP Regulation "Hazard categories for carcinogens" distinguishes between Category 1A, known to have carcinogenic potential for humans, classification is largely based on human evidence, and Category 1B: presumed to have carcinogenic potential for humans, classification is largely based on animal evidence.

[8] 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.

[9] Article 1 (1) and recital 13 of the Directive.

as well as tripartite consultation conducted within the Advisory Committee on Safety and Health at Work. Prior to presenting a proposal for amendment, the Commission also conducts an analysis of social, economic and environmental impacts[10].

Exposure limit values for specific chemical agents are set in Annex III to the Carcinogens and Mutagens Directive, which currently has limit values for three chemicals[11].

With a view to enhancing workers' health protection, the Commission adopted on 13 May 2016 a proposal to amend the Carcinogens and Mutagens Directive to establish, or revise, binding occupational exposure limit values with regard to 13 substances/mixtures. A new proposal improving protection of 4 million workers in the EU by acting on further seven carcinogens was adopted on 10 January 2017[12]. Together it is estimated that both proposals would prevent over 100,000 deaths caused by work-related cancer in the forthcoming 50 years. All proposed limit values followed the advice agreed by the tripartite Advisory Committee on Safety and Health at Work, which takes into account technical and economic feasibility. On 11 July 2017, an agreement has been reached by the representatives of the European Parliament and the Council on the first amendment to the Carcinogens and Mutagens Directive, which, following confirmation by the European Parliament and the Council in accordance with Article 294, paragraphs 3 and 4, of the TFEU, will lead to the adoption by the co-legislator of that amendment to the Directive.

On 26 April 2017, the Commission adopted the European Pillar of Social Rights which sets out 20 key principles and rights to support fair and well-functioning labour markets and welfare systems[13]. These include the right, enshrined in Article 31 of the EU Charter of Fundamental Rights, for workers to a high level of protection of their health and safety at work, and to a working environment which is adapted to their professional needs and which enables them to prolong their participation in the labour market. In this context it is stressed in particular that the Commission – in consultation with the social partners at EU level - will continue to propose further updates of the Carcinogens and Mutagens Directive to introduce

[10] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "Better regulation for better results - An EU agenda" COM/2015/0215 final.

[11] Benzene, Vinyl chloride monomer and Hardwood dusts

[12] In the said proposals:

- binding occupational exposure limit values are proposed for respirable crystalline silica dust; 1,2-Epoxypropane; 1,3-Butadiene; 2-Nitropropane; Acrylamide; Chromium (VI) compounds which are carcinogens within the meaning of Article 2 (a) (i) of the Directive; Ethylene oxide; o-Toluidine; Refractory Ceramic Fibres which are carcinogens within the meaning of Article 2 (a) (i) of the Directive; Bromoethylene; Hydrazine; Trichloroethylene; 4,4'-Methylenedianiline; Epichlorohydrine; Ethylene dibromide. It is proposed to revise existing limit values for hardwood dusts and vinyl chloride monomer. Skin notations independent of limit values are proposed for polycyclic aromatic hydrocarbons mixtures containing benzo[a]pyrene which are carcinogens within the meaning of the Directive and for Oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine.
- it is proposed to include in Annex I to the Directive : work involving exposure to respirable crystalline silica dust generated by a work process and work involving exposure to oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine.

[13] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Establishing a European Pillar of Social Rights COM(2017) 250, and the accompanying Staff Working Document SWD(2017) 201.

binding occupational exposure limit values to combat occupational cancer and protect workers from the exposure to carcinogens and mutagens.

3. ISSUES WITH THE CURRENT EU LEGAL FRAMEWORK

The establishment of binding occupational exposure limit values for additional carcinogens or mutagens and the revision of existing limit values is necessary to reflect new developments in science and technology.

New scientific evidence available plays a crucial role in a better understanding of occupational hazards/exposure and allowing potentially for better prevention and protection. This is particularly relevant in respect of occupational cancer risks. At the same time, rapid technological change and scientific developments put high demands on timeliness and better quality of the scientific assessments. Therefore, there is a need to regularly update the Carcinogens and Mutagens Directive with new or revised occupational exposure limit values.

In terms of effectiveness, the very high level of work-related cancer is one of the main exceptions to declining rates of work-related ill-health in the EU. The latent period for cancer is often particularly long and currently recognised cases are to a large extent the effect of past exposures to chemicals. However, while there is a decrease in exposure to a number of chemical agents, this does not seem to be the case for all substances or mixtures which meet the criteria for classification as carcinogens 1A/1B or mutagens 1A/1B under the CLP Regulation. The absence of occupational exposure limit values for certain carcinogenic and mutagenic substances, mixtures and process-generated substances, as well as the lack of common EU-level definitions for the latter, might lead to continued inefficiencies in the protection of workers from carcinogens at work.

In the majority of the EU Member States, there are national limit values for many carcinogenic and mutagenic substances and mixtures. However, the values often differ by orders of magnitude and therefore lead not only to very different levels of health and safety protection of workers across the EU but also to complex considerations for companies with production across the EU and different level of protection for employees working in each Member State. The setting of EU-wide limit values for chemicals promotes upward levels of protection throughout the EU, contributes to an improvement of the protection of workers and towards a better level playing field for economic operators by reducing divergences in national protection levels and allowing companies to comply with values which take into account economic feasibility. There is also an important element of economies of scale in the complex scientific assessments underlying the establishment of binding occupational limit values for carcinogenic and mutagenic chemicals, which allows Member States to shift more financial resources to protection and prevention measures.

Finally, during the legislative procedure on the first amendment to the Carcinogens and Mutagens Directive, the European Parliament and the Council agreed on a lower value for Chromium (VI) compounds. For the sake of stability of the implementation of the first amendment of the Carcinogens and Mutagens Directive, the Commission will not be proposing a new value in the third amendment of the Directive.

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

In light of the above, the Commission takes the view that an appropriate approach would consist in the periodic revision of Annex III to the Carcinogens and Mutagens Directive to continue to establish binding occupational exposure limit values and directly related provisions (e.g. skin notations) for additional carcinogens and to revise existing limit values in light of evolving scientific and technological developments.

In addition, additional processes and process-generated substances or mixtures could be included in Annex I to the Directive.

The Commission would like to consult the social partners on the establishment and/or revision of further binding occupational limit values in Annex III to the Carcinogens and Mutagens Directive and seek their views, for the purpose of future revisions, on which new process generated substances could be inserted in Annex I to the Directive with a possible corresponding limit value in Annex III to the Directive.

The Commission has identified a list of priority substances, as follows:

i. For a third amendment of the Carcinogens and Mutagens Directive (to be adopted early 2018) to establish and/or revise binding occupational exposure limit values for the following carcinogens:
    - Cadmium and its inorganic compounds that are carcinogens as defined in the Directive
    - Beryllium and its inorganic compounds that are carcinogens as defined in the Directive
    - Arsenic acid and its salts that are carcinogens as defined in the Directive
    - Formaldehyde [CAS No 50-00-0]
    - 4,4'-Methylene-bis(2-chloroaniline) (MOCA) [CAS No 101-14-4]

ii. For subsequent amendments of the Carcinogens and Mutagens Directive, a first proposed list of the following three substances which can be expanded:

    - Nickel compounds that are carcinogens as defined in the Directive

- Acrylonitrile [CAS No 107-13-1]
- Benzene [CAS No 71-43-2]

When selecting the list of priority substances for the third amendment and the first proposed substances for subsequent amendments, the Commission built on the views of bodies and stakeholders referred to above. It heard in particular the Working Party on 'Chemicals at the Workplace' of the Advisory Committee on Safety and Health at Work, where the three interest groups of workers, employers and governments are represented.

In order to prioritise work the Commission has applied the following criteria:

- the degree of evidence for adverse health effects, considering toxicological and epidemiological data,
- the characteristics of the adverse effects (severity, potency, reversibility, and specificity),
- the estimated number of workers exposed,
- the identified exposure patterns that pose difficulties for the control of exposures,
- policy considerations. This could include, for example, problematic disparity with or between relevant threshold values established elsewhere with an impact on workers' health protection, the degree of stakeholders' interest in having a limit value, or other institutional priorities.

The Commission took into account the serious adverse health effects, as follows, of the prioritized substances:

- Cadmium and its inorganic compounds that are carcinogens as defined in the Directive refer to those compounds that meet the criteria for classification as carcinogens category 1A or 1B (known or presumed human carcinogens). At present, several cadmium and inorganic cadmium compounds meet the criteria for classification as carcinogens category 1B. The associated type of cancer is lung cancer.

- Beryllium and its inorganic compounds that are carcinogens as defined in the Directive refer to those compounds that meet the criteria for classification as carcinogens category 1A or 1B (known or presumed human carcinogens). Beryllium and beryllium compounds (with the exception of aluminium beryllium silicates, and with those specified elsewhere in Annex VI of the CLP Regulation) meet the criteria for classification as carcinogens, category 1B. The associated type of cancer is lung cancer. In addition, the substance is also classified as fatal if inhaled, as toxic if swallowed, as causing damage to organs through prolonged or repeated exposure, as causing serious eye irritation, as causing skin irritation, as substances that may cause an allergic skin reaction, and as substances that may cause respiratory irritation.

- Arsenic acid and its salts that are carcinogens as defined in the Directive refer to those compounds that meet the criteria for classification as carcinogens category 1A or 1B (known or presumed human carcinogens). At present, arsenic acid and its salts, with the exception of those specified elsewhere in Annex VI to the CLP Regulation are classified as carcinogens, category 1A. The associated type of cancer is lung cancer. These substances are also classified as toxic if swallowed and as toxic if inhaled.

- Formaldehyde [CAS No 50-00-0] meets the criteria for classification as carcinogen, category 1B and the associated cancer is nasopharyngeal cancer. The substance is also classified as toxic if swallowed, as toxic in contact with skin, as toxic if inhaled, as causing severe skin burns and eye damage, as being suspected of causing genetic defects and as may causing an allergic skin reaction.

- 4,4'-Methylene-bis(2-chloroaniline) (MOCA) [CAS No 101-14-4] meets the criteria for classification as a carcinogen, category 1B. The associated type of cancer is lung cancer. It is also classified as harmful if swallowed, which is the lowest category for acute toxicity.

In addition, the number of workers exposed was considered, for which an overview is presented below based on data collected in the European Union (15 member states at the time) from 1990 to 1993 (CAREX database):

Chemical Agent	Number of workers exposed*
Cadmium and its compounds	207350
Beryllium and its compounds	66069
Arsenic acid and its salts	147569~
Formaldehyde	971402
MOCA	3295
Nickel compounds	547396

Some of these substances have also been prioritized and regulated under the REACH Regulation: arsenic acid and its salts and MOCA are included in Annex XIV (authorisation process) to REACH and cadmium and its compounds[14], arsenic compounds[15], nickel and its compounds[16] and benzene[17] are listed in Annex XVII to REACH with specific restrictions although not completely related to workers.

[14] Cf. conditions of restriction: https://echa.europa.eu/documents/10162/3bfef8a3-8c97-4d85-ae0b-ac6827de49a9.
[15] Cf. conditions of restriction: https://echa.europa.eu/documents/10162/a798c758-371f-41e5-a38d-5f8dc9ba739d.
[16] Cf. conditions of restriction: https://echa.europa.eu/documents/10162/7851171d-53e9-455a-8bb8-7ca22e89ad87.
[17] Cf. Conditions of restriction: https://echa.europa.eu/documents/10162/59f436ca-8afa-4adf-b108-27d7bc8a7751.

Scientific evaluation of the prioritized substances has been either finalised or is ongoing. Sound scientific advice is indeed indispensable to underpin any occupational safety and health action, particularly in relation to dangerous chemicals. The Commission is seeking advice from the SCOEL or from RAC of ECHA.

In line with the Occupational Safety and Health Communication and better regulation guidelines it is particularly important to examine to what extent action under the Carcinogens and Mutagens Directive can usefully complement measures under REACH and vice versa. In this respect, the Commission takes also into account the non-binding conclusions of the Risk Management Option Analysis (RMOA) carried out in the framework of the "Roadmap for Substances of Very High Concern identification and implementation of REACH Risk Management measures from now to 2020"[18] which are publicly available.[19]

5. AIM OF THE CONSULTATION

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 any proposal for action, 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:

- Do you agree with the issues identified above: are the issues accurately and sufficiently covered?
- Do you agree with the approach regarding the third and fourth amendment for the establishment and/or revision of binding occupational limit values in Annex III to Carcinogens and Mutagens Directive?
- What other substances/mixtures in addition to (or instead of) the substances indicated above under point 4 should be considered for inclusion in the next amendments of Annex III to the Carcinogens and Mutagens Directive?

[18] http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205867%202013%20INIT. One of the purposes of the Risk Management Option Analysis is to help identify the most appropriate instrument to address a concern, either in REACH or outside REACH (with another legislation, including the Carcinogens and Mutagens Directive). A case-by-case analysis is carried out by a Member State or ECHA (at the request of the Commission) on a voluntary basis (that is to say it is not part of the processes as defined in the legislation), which is documented and shared with the Member States. Conclusions of the Risk Management Option Analysis only reflect the views of the author authority and are not binding for the Commission.

[19] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact

- What other processes and/or process-generated substances should be considered for inclusion in Annex I to the Carcinogens and Mutagens Directive?
- Would you consider initiating a dialogue under Article 155 TFEU on any of the issues identified in point 3 of this consultation?