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CONSULTATION DOCUMENT

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

{C(2017) 7466 final}

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INTRODUCTION

Occupational cancer is the first cause of work-related deaths in the European Union[1]. 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 EUR 4-7 billion per year. The indirect costs may reach as much as EUR 334 billion each year.[2]

This is why fight against occupational cancer is one of top European Commission's priorities in the area of occupational safety and health, as stated in the recent Communication on "Safer and Healthier Work for All".[3]

The main legislative tool to ensure workers' protection against risks related to carcinogenic chemicals is the Carcinogens and Mutagens Directive (CMD)[4], an individual directive under the 1989 occupational safety and health (OSH) 'Framework Directive'.[5]

EU action was also supported by sectoral Social Partner agreements which have been implemented by Social Partners in an autonomous manner. [6]

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1 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.

2 RIVM (2016): Work-related cancer in the European Union: Size, impact and options for further prevention, Jongeneel WP, Eysink PED, Theodori D, Hamberg-van Reenen HH, Verhoeven JK. Report 2016-0010. Available at: http://rivm.nl/en/Documents_and_publications/Scientific/Reports/2016/mei/Work_related_cancer_in_the_European_Union_Size_impact_and_options_for_further_prevention

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. Available at: http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=2709

4 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 Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

5 Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, P. 0001 – 0008).

6 An example such an agreement was reached in the past, when the European Network for Silica formed by the Employee and Employer European sectoral associations signed the Social Dialogue "Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silica and Products Containing it" in 2006. Similarly, the beryllium industry, which is not a Social Partner organisation, namely the Beryllium Science and Technology Association (BeST) created the 'Be Responsible Beryllium Voluntary Product Stewardship Program' to help educate and guide industries using beryllium, beryllium workers, trade unions and governmental authorities. The program includes easy access web-based information and printable guides to improve worker safety during the production and processing of beryllium-containing materials.

Scientific knowledge about cancer and carcinogenic chemicals is developing. At the same time technological progress brings new methods of measuring and controlling exposures. In order to ensure optimal protection of workers through the risk management measures established in the CMD, the Directive needs to keep abreast with the scientific and technological developments by updating its Annexes. The Directive requires specifically that occupational exposure limit values (OELs) must be set out for all those carcinogens or mutagens for which this is possible in the light of the available information, including scientific and technical data.

Updating existing or establishing new OELs in the light of new information is not only a legal requirement under the Directive, but is also called for by Social Partners and the co-legislators.

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 CMD on the basis of scientific evidence, adding more binding occupational exposure limit values where necessary.

Also 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. The Council 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 assessments and evidence.

In response to those calls, the European Commission already adopted two legislative proposals, in May 2016 [7] and in January 2017 [8] respectively, updating the Directive and addressing together 20 carcinogens. The co-legislators reached an agreement in July 2017 on the first of those proposals, and a publication in the Official Journal is expected before the end of 2017. Regarding the second proposal, the Council adopted a general approach on 15 June 2017. Consultation with the European Parliament will start once it has adopted its report, currently foreseen for February 2018.

The aim of legislative proposals in this area is to further reduce workers exposure to priority carcinogens with a consequential reduction in potential new cases of occupational cancer in the forthcoming 50 years. The Commission aims to increase protection and legal certainty for workers, reduce suffering, and improve the length,

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[7] COM(2016) 248 final of 13 May 2016, 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.

[8] COM(2017) 11 final of 10 January 2017, 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.

quality, and productivity of the working lives of European workers, while contributing to an improved level playing field for business across the EU. This last aspect is mainly achieved by reducing divergences in national protection levels, thereby for example enhancing predictability for economic operators regarding the legal provisions in all EU Member States in this area, as well as improving clarity regarding the appropriate risk management measures to be taken.

The legislative proposal will also facilitate surveillance and thereby implementation in EU Member States by supporting for example national enforcement authorities by providing them with a helpful tool for compliance. It also reduces costs for Member States which have no national system in place to derive OELs.

Updating and reviewing the CMD is a continuous process. Therefore, between 26 July and 30 September 2017 the Commission conducted a first phase consultation of the European Social Partners[9], in accordance with Article 154 of the Treaty on the Functioning of the EU (TFEU), on the possible direction of European Union action concerning further revisions of the CMD. The aim of the revisions would be to enhance the relevance and effectiveness of the Directive by establishing binding occupational exposure limit values for certain additional carcinogens.

This document provides an overview of the results of the first phase consultation and an analytical background to a second phase consultation of the European Social Partners on possible legislative action. It identifies the problems to be addressed through the initiative, presents the objectives of an EU intervention, and explores the added value of EU action. The analysis provides an overview of the current situation across Member States for the substances or groups of substances which are considered for possible future amendments of the CMD. The document also gives first indications to the expected impacts of the possible avenues of EU action set out in the second phase consultation document.

1 RESULTS OF THE FIRST PHASE SOCIAL PARTNERS CONSULTATION

The first phase of Social Partner consultation closed on 30 September 2017.

The Commission consulted the Social Partners on the establishment and/or revision of further binding occupational limit values in Annex III to the Carcinogens and Mutagens Directive as well as sought their views on which carcinogens and mutagens could be added in future reviews of the Directive for regulation under Annex I and/or Annex III to the Directive.

[9] Consultation Document of 26.0.2017, First phase consultation of Social Partners under Article 154 TFEU on revisions of Directive 2004/37/EC to include binding occupational exposure limit values for additional carcinogens and mutagens, C(2017) 5191 final.

Following a process described in more detail further down in this chapter, the Commission identified a list of priority substances in the first phase consultation document[10], as follows:

(1) for a third amendment of the Directive (to be adopted early 2018) to establish and/or revise binding occupational exposure limit values for the following carcinogens:

   (a) Cadmium and its inorganic compounds under the scope of the CMD
   (b) Beryllium and inorganic beryllium compounds under the scope of the CMD
   (c) Arsenic acid and its salts under the scope of the CMD
   (d) Formaldehyde [CAS No 50-00-0]
   (e) 4,4'-Methylene-bis(2-chloroaniline) (MOCA) [CAS No 101-14-4]

(2) For a subsequent amendments of the Directive 2004/37/EC, a first proposed list of the following three substances which can be expanded includes:

   (a) Nickel compounds under the scope of the CMD
   (b) Acrylonitrile [107-13-1]
   (c) Benzene [CAS No 71-43-2]

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 in the Member States or outside the EU with an impact in workers' health protection, or the degree of stakeholders' interest in having a limit value.

In addition, the Commission consulted institutions and stakeholders, in particular the Working Party on Chemicals (WPC) of the Advisory Committee on Safety and Health at Work (ACSH), where the three interest groups of workers, employers and governments are represented.

[10] Consultation Document of 26.7.2017, 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; C(2017) 5191 final.

1.1 Workers' organisations

Three trade unions replied to the first phase consultation: the European Trade Union Confederation (ETUC), European Confederation of Independent Trade Unions (CESI), European Federation of Building and Woodworkers (EFBWW).
They all acknowledged the importance of the existing legislation; however, their views sometimes differ as to which strategy should be used and which factors should be taken into consideration.

Possible improvements to the EU legal framework

The workers' organisations agreed, broadly, with the issues described in the consultation document and confirmed the importance they attach to protecting workers from the health risks associated with exposure to carcinogens and mutagens. However, ETUC and EFBWW consider it necessary to extend the scope of the CMD to include reprotoxic substances, and to streamline this field with other policy areas such as public health and environment.
Concerning the approach regarding the third and fourth amendments, ETUC and EFBWW agree with the list of 8 priority substances identified by the Commission. However, both organisations consider that the fourth amendment should be expanded in order to reach the target of 50 binding OELs in 2020. ETUC has proposed a priority list of such substances (see Annex 1 of the Social Partners second phase consultation paper that this document accompanies). CESI considers that the latest available data need to be used when revising the CMD.
As regards the other substances to be added to Annex III, while CESI suggests that they should be identified on the basis of sound and independent scientific research, ETUC and EFBWW insist, as mentioned above, that '50 substances in Annex III' has to be achieved by 2020. After 2020, the process of setting OELs should continue on a dynamic way in order to include most of the substances at the workplace. ETUC considers that publishing a multi-annual plan containing the complete list of substances to be addressed and the deadlines by which OELs are to be defined would greatly heighten the predictability of future legislative developments.
With regard to Annex I to the CMD, ETUC considers it important to include all processes for which International Agency for Research on Cancer (IARC) monographs are available. More specifically, concerning diesel engine exhaust emissions ETUC considers that it should be addressed as soon as possible, while not delaying the Commission's adoption of the third and fourth batches of proposals for revising the CMD. In the enclosed annex of its priority substances list ETUC has indicated it as a candidate for the fourth amendment. ETUC also suggests that the OEL for crystalline silica is set at 50 $\mu g/m^3$. EFBWW expressed similar views concerning diesel engine exhaust emissions and crystalline silica. CESI suggested carrying out in-depth study to identify other processes and / or process generated substances for inclusion in Annex I of the CMD.
Among other issues, ETUC and EFBWW stressed the need for more consistent and transparent criteria for setting OELs and for better cooperation between the expert groups

working on OELs at the EU level as well as in Member States, and that purely health-based OELs should prevail whenever possible. They also proposed that the Senior Labour Inspectors Committee should support the implementation of the CMD, and that European research and development programmes should support research on possible substitution of carcinogens and mutagens. Further, ETUC suggested the need to take into account multiple exposures and improve the quality of data. Concerning data availability, they consider that the development of databases, involving all Member States, and the improvement and transparency of information sources would facilitate the identification of occupations and activities with higher risk of cancer. CESI and EFBWW considered that legislative initiatives should be complemented by other measures, for example, fostering preventative health-oriented behaviour and information on best available technology.

Apart from the revision of the CMD, ETUC and EFBWW suggested to adapt other EU legislation to establish a coherent strategy for fighting occupational cancers, e.g. concerning asbestos, solar radiation, occupational exposure to nanomaterials, occupational exposure to endocrine disruptors and occupational exposure to pesticides. ETUC further mentioned biological agents, electromagnetic fields, ionizing radiation, radon and radon progeny, night work and posted work and environmental tobacco smoke.

Willingness to enter into negotiations

The workers' organisations do not want to launch a negotiation procedure pursuant to Article 155 TFEU concerning the third and fourth amendment of the CMD and urge the Commission to make progress on this.
ETUC indicates, however, that it might wish to discuss complementary issues with employers and seek convergent positions on certain questions.

1.2 Employers' organisations

Four employers' organisations replied to the first phase consultation: BusinessEurope, the European Association of Craft Small and Medium-sized Enterprises (UEAPME), the European Chemical Employers Group (ECEG) and the Council of European Employers of the Metal, Engineering and Technology-based industries (CEEMET).
The employers' organisations supported the objective to effectively protect workers from occupational cancer, including by setting OELs at EU level. They consider this is in the interest of workers and businesses and contributes to a level playing field. However, they also raised some concerns about the approach taken when setting such values.

Possible improvements to the EU legal framework

Concerning the issues identified in the consultation paper, the employers' organisations supported the general direction of the Commission to pursue revisions and update of Annexes I and III of the CMD, subject to certain conditions. In their opinion, binding

OELs should be set for priority substances only. The process of limit values setting should be based on sound scientific evidence, technical and economic feasibility, socio-economic impact assessment and opinion of the tripartite ACSH, as it is done currently by the Commission. While the employers' organisations considered that the Commission's criteria for prioritising substances are relevant, they suggested that the criteria of technical and economic feasibility should also be included. Such a comprehensive framework would allow identifying and prioritising substances to be addressed in a short- and long-term perspective. BusinessEurope and CEEMET further emphasized that proposing a series of substances on the basis of unofficial lists should be avoided, as should setting an arbitrary numerical target of additional binding OELs without clear criteria of prioritisation. In addition, CEEMET expressed the need for EU validated protocols for measuring exposure to hazardous substances in order to ensure better consistency. UEAPME and CEEMET further stressed the need to assess impact on small and medium-sized enterprises (SMEs), in particular on micro-enterprises, in terms of proportionality and feasibility of action, as well as to take account of sectoral differences. The employers' organisations also suggested that consideration should be given to expedite the process for setting binding OELs at EU level and make it more efficient. There is also a need to ensure coherence with other EU chemicals legislation. They further considered that guides, examples of good practice and other tools can assist in implementing this Directive.

Concerning the third amendment, BusinessEurope overall, supported the Commission's approach. Regarding the fourth and subsequent amendments, they stressed that inclusion of specific substances should depend on whether they meet the conditions / criteria mentioned above and whether the preparatory work has been completed. Further they stressed the benefit of recommending Biological Limit Values, where scientifically justified and relevant. ECEG and CEEMET supported the overall process for developing and adopting binding OELs as long as the above criteria and processes are correctly applied. UEAPME, on the other hand, considered that without having seen concrete proposals for limit values it is not possible to take a complete position with regard to this question. They further suggested that the latest available data need to be used when revising the CMD (supported by CEEMET) and that too restrictive limit values could be very burdensome for employers leading to a risk of non-compliance. For example, beryllium, cadmium and formaldehyde play important role in recycling and too low limit values would have negative impact on this sector.

The employers' organisations agreed with the Commission's current approach for periodic revision of Annex III of the CMD, with BusinessEurope and ECEG further reiterating that binding OELs should be established only for those substances which meet the above conditions and which have gone through the necessary preparatory procedures.

UEAPME agreed with the Commission's current approach for periodic revision of Annex I. On the other hand, BusinessEurope considered that further extending Annex I would provide only limited benefit as it is often not clear to which specific substance exposure should be reduced or avoided and to which extent/level. In this respect, BusinessEurope suggested to consider possibility to move substances already included in Annex I, where relevant, to Annex III, if the chemicals which are responsible for the

hazard have been identified. ECEG also was not convinced about the benefit of extending Annex I.

Willingness to enter into negotiations

The employers' organisations consider that the existing preparatory procedures already involve Social Partners, including the ACSH consultations. Therefore, they do not want to launch a negotiation procedure pursuant Article 155 TFEU.
That being said, BusinessEurope would welcome discussing in an informal way with the trade unions how the existing preparatory procedures could be made more efficient and smoother. ECEG similarly would welcome such discussions. CEEMET would welcome a further role for sectoral Social Partners in the setting of binding OELs at EU level.

1.3 Consultations of scientists and stakeholders

The process of setting binding OELs under CMD actively engages the Member States and Social Partners during the key stages:

- Two stages consultation of the Social Partners at EU level in accordance with TFEU.
- External consultation on the Scientific Committee on Occupational Exposure Limits (SCOEL) recommendations or seeking other scientific advice e.g. from the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) before adoption.
- Development of opinions of the tri-partite ACSH via its WPC.

1.3.1 Scientific evaluation

Article 16 of the CMD states that scientific/technical data should be included in the basis on which OELs are set. In the past, the Commission sought advice of SCOEL which was set up in 1995 by the Commission to evaluate the potential adverse health effects of occupational exposure to chemicals. SCOEL is an independent scientific committee composed of 21 experts appointed in their personal capacity as leading experts in fields relevant for protection of workers from risks associated with workplace exposure to hazardous chemicals.[11]

In cases where SCOEL has not yet finalised its evaluation, the Commission can also refer to scientific information sourced elsewhere as long as the data is adequately robust and is

[11] As established by Commission Decision 2014/113/EU on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC, OJ L 62, 4.3.2014, p. 18.

in the public domain (e.g. IARC monographs or conclusions of national OEL-setting science committees, as well as for example the opinions derived by RAC.[12]

Regarding the substances identified as priority substances for a third amendment of the CMD, the Commission sought advice from SCOEL[13] and RAC[14]. The scientific assessments from these sources will serve as the basis for proposals subject to impact assessment and social dialogue as well as tripartite consultation.

For the three proposed priority substances, to be considered in the 4th amendment of the CMD the Commission has requested RAC to provide scientific assessments for three substances[15], to be delivered to the Commission by 26 March 2018.

1.3.2 Consultation of Member States and Social Partners via the Advisory Committee on Health and Safety at Work

The ACSH is a tripartite body set up in 2003 by a Council Decision (2003/C 218/01) which is composed of three full members per Member State, representing national governments, trade unions and employers' organisations. The ACSH is supported by tripartite working parties of experts on given topics of interest.

The ACSH discusses adopted SCOEL recommendations (and/or other appropriate scientific evidence) and adopts a formal opinion, which in the case of binding OELs as adopted under the CMD also reflect other factors such as 'feasibility' and socio-economic considerations.

In practice an OEL emerging from this process reflects a deep technical, socioeconomic, and political consideration of what is achievable by employers across the EU and also ensures that workers' health is adequately protected.

Regarding the priority substances foreseen for the third amendment of the CMD, the ACSH has adopted opinions for all of them[16].

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12 For further information on SCOEL please contact the following website: http://ec.europa.eu/social/main.jsp?catId=148&intPageId=684&langId=en

13 Formaldehyde, beryllium and inorganic beryllium compounds, cadmium and its inorganic compounds, and MOCA.

14 MOCA and arsenic acid and its inorganic salts.

15 Nickel compounds, acrylonitrile and benzene.

16 The text of the adopted opinions can be found on CIRCA-BC under the following links:
Formaldehyde: https://circabc.europa.eu/sd/a/25162551-6341-46d1-9e90-4360cd6a1d0d/Doc.1280_EN-WPC%20June%20Opinion%20Formaldehyde.pdf

Beryllium: https://circabc.europa.eu/sd/a/7e95cab5-6c71-4cbc-8147-f1f6d460ba2f/Doc.662-17-EN_WPC_Opinion%20on%20Be_Adopted%2031.05.2017.pdf

Cadmium: https://circabc.europa.eu/sd/a/bf0521f0-b54a-4712-b256-a30d7adcfdf6/Doc.663-17-EN_WPC%20Opinion%20Cadmium_Adopted%2031.05.2017%20.pdf

MOCA: https://circabc.europa.eu/sd/a/2214b88e-5a69-4c2e-a98a-331aa13dc264/Doc.1336_EN-WPC_Opinion%20MOCA_Adopted%2019102017.pdf

Arsenic acid and its salts: https://circabc.europa.eu/sd/a/9813acc5-604a-49f9-9d4b-afaeceb12705/Doc.1334_01_EN_WPC_Opinion%20Arsenic_Adopted%2019102017.pdf

2 PROBLEM DEFINITION

2.1 What is the problem and why is it a problem?

Cancer is the first cause of work-related deaths in the EU and other industrialised countries. 57% of annual occupational deaths are attributed to cancer, compared to 23% for circulatory diseases and 6% for respiratory diseases[17]. Different forms of cancer may be initiated or worsened by the exposure to carcinogenic and/or mutagenic chemical agents at work. According to a 2016 report by the Netherlands National Institute for Public Health and the Environment (RIVM)[18] 91 500 – 150 500 people were newly diagnosed with cancer in 2012 in the EU, caused by past exposure to carcinogenic substances at work. 57 700 – 106 500 people died in 2012 in the EU as a result of a work-related cancer. The European Agency for Safety and Health at Work (EU-OSHA)[19] confirms this analysis in 2017 by estimating that cancer is the main cause of work-related death with 106 307 fatal cases per year in the EU-28.

That means that every hour in EU-28, 7-12 people die of cancer because of past exposure to carcinogenic substances at work.

Apart from the significant social and financial burden to those affected by the disease including their families, cancer is also associated with significant costs to society from dealing with cancer (e.g. loss of productivity, cost for social security systems). Recent estimations indicate that the cost of work-related cancers alone amounts to EUR 119.5 billion [20].

The below problem tree summarises the main drivers behind this problem and the resulting consequences for workers, business and Member States.

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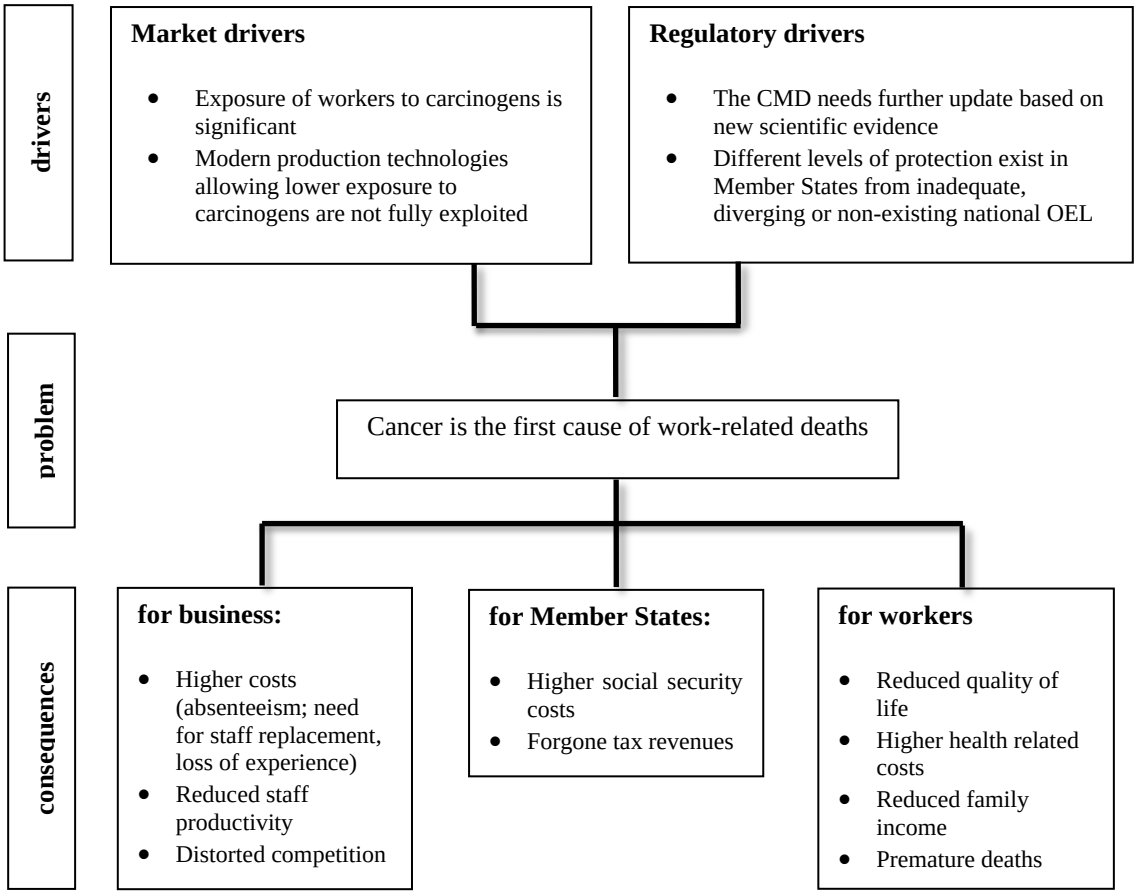
17 Jukka Takala, Päivi Hämäläinen, Kaija Leena Saarela, Loke Yoke Yun, Kathiresan Manickam, Tan Wee Jin, Peggy Heng, Caleb Tjong, Lim Guan Kheng, Samuel Lim, Gan Siok Lin (2014): Global Estimates of the Burden of Injury and Illness at Work in 2012, Journal of Occupational and Environmental Hygiene, 11:5, p. 326-337, DOI: 10.1080/15459624.2013.863131.

18 RIVM (2016): Work-related cancer in the European Union: Size, impact and options for further prevention, Jongeneel WP, Eysink PED, Theodori D, Hamberg-van Reenen HH, Verhoeven JK. Report 2016-0010. Available at: http://rivm.nl/en/Documents_and_publications/Scientific/Reports/2016/mei/Work_related_cancer_in_the_European_Union_Size_impact_and_options_for_further_prevention

19 EU-OSHA (2017): What are the main work-related illnesses and injuries resulting in death and in DALY? Available at: https://visualisation.osha.europa.eu/osh-costs

20 EU-OSHA (2017): The economics of OSH. Available at: https://visualisation.osha.europa.eu/osh-costs



2.2 Market drivers

2.2.1 Exposure of workers to carcinogens is significant.

This section presents estimations[21,22,23] of numbers of workers exposed to substances for which new scientific recommendations by SCOEL or scientific opinions by RAC are available and which could be subject to the third wave revision of the Directive. In addition to estimates of occupational exposure, also the main adverse health effects are presented.

[21] Kauppinen, T., Toikkanen, J., Pedersen, D., Young, R., Ahrens, W., Boffetta, P., Hansen, J., Kromhout, H., Maqueda Blasco, J., Mirabelli, D., de la Orden-Rivera, V., Pannett, B., Plato, N., Savela, A., Vincent, R. & Kogevinas, M. (2000): Occupational exposure to carcinogens in the European Union. Occ Environ Med 57, p. 10–18.

[22] IOM, Institute of Occupational Medicine (2011): Health, socio-economic and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work. IOM Research Project: P937/99, May 2011, IOM, Institute of Occupational Medicine, Edinburgh, UK.

[23] RPA (2017): Second study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

2.2.1.1 Cadmium and its inorganic compounds under the scope of the CMD

2.2.1.1.1 Occupational exposure

Occupations in which the highest potential exposures occur include cadmium production and refining, nickel-cadmium (Ni-Cd) battery manufacture, cadmium pigment manufacture and formulation, cadmium alloy production, mechanical plating, zinc smelting, brazing with a silver-cadmium-silver alloy solder, and polyvinylchloride compounding.[24] Recycling of scrap metal and Ni-Cd batteries may also involve some exposure. [25]

The major routes of occupational exposure are inhalation of dust and fumes and incidental ingestion of dust from contaminated hands, cigarettes or food. Occupational uptake of cadmium occurs via inhalation of cadmium-containing dusts and fumes[26].

According to the most recent available publication (IARC monograph 100C-8[27]), the most recent estimates of the number of workers potentially exposed to cadmium and its compounds have been developed by CAREX in Europe, based on the occupational exposure known and suspected carcinogens collected during 1990-93 in the 15 EU Member States at that time. CAREX estimates that 207 350 workers were exposed to cadmium and cadmium compounds.

In industrial settings, airborne exposure levels typically have been reported to range from 0.005 to 0.05 mg/m³; with extreme values up to 0.4 mg/m³ [28].

2.2.1.1.2 Adverse health effects

Cadmium is an established human and animal carcinogen. Most evidence is available for elevated risk for lung cancer after occupational exposure;

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[24] IARC (2016) Monograph: Cadmium and Cadmium Compounds. Available at: https://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C-8.pdf

[25] SCOEL (2017): Recommendation from the Scientific Committee on Occupational Exposure Limits for Cadmium and its inorganic compounds. SCOEL/OPIN/336. Available at: https://circabc.europa.eu/sd/a/13cad802-1f3c-40c0-bce4-6838cf5fc4ff/OPIN-336%20Cadmium%20and%20its%20inorganic%20compounds.pdf

[26] SCOEL (2017): Recommendation from the Scientific Committee on Occupational Exposure Limits for Cadmium and its inorganic compounds. SCOEL/OPIN/336. Available at: https://circabc.europa.eu/sd/a/13cad802-1f3c-40c0-bce4-6838cf5fc4ff/OPIN-336%20Cadmium%20and%20its%20inorganic%20compounds.pdf

[27] IARC (2016) Monograph: Cadmium and Cadmium Compounds. Available at: https://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C-8.pdf

[28] JRC (2007) European Union Risk Assessment Report - Volume 74 cadmium metal, Part II: Human Health (publication EUR 22767 EN). Available at: https://echa.europa.eu/documents/10162/4ea8883d-bd43-45fb-86a3-14fa6fa9e6f3

however, associations between cadmium exposure and tumours at other locations including kidney, breast, and prostate may be relevant as well.[29]

Cadmium can be considered as a genotoxic carcinogen for which a practical threshold can be identified.

2.2.1.2 Beryllium and inorganic beryllium compounds under the scope of the CMD

2.2.1.2.1 Occupational exposure

Different sources provide varying data on the number of workers exposed to beryllium. RPA[30] estimates that between 1 500 and 65 000 workers are potentially exposed to beryllium. Institute of Occupational Medicine (IOM) estimates that about 65 000 workers might be exposed to beryllium in the EU, with 3 000 people in Europe employed in foundry or other similar processes likely to generate the highest exposure levels, mostly in Italy, France, Germany, UK, Switzerland and Hungary. Average exposure levels amongst foundry workers (NACE[31] code 27) are probably about 0.0005 mg/m^3, with less than 10% of exposure in all sectors exceeding 0.002 mg/m^3.

2.2.1.2.2 Adverse health effects

Exposure to beryllium and its compounds at the workplace occurs mainly via inhalation; dermal exposure can also occur at certain workplaces.

Exposure to beryllium can cause lung cancer, as well as beryllium sensitization and chronic beryllium disease (CBD). CBD is an incurable disease causing scarring of the lung tissue.

Dermal exposure may also cause non-carcinogenic ill health effects.

2.2.1.3 Arsenic acid and its salts under the scope of the CMD

2.2.1.3.1 Occupational exposure

According to the very recent RAC opinion on 'arsenic acid and its inorganic salts'[32] exposure is primarily through inhalation of arsenic-containing

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29 SCOEL (2017): Recommendation from the Scientific Committee on Occupational Exposure Limits for Cadmium and its inorganic compounds. SCOEL/OPIN/336. Available at: https://circabc.europa.eu/sd/a/13cad802-1f3c-40c0-bce4-6838cf5fc4ff/OPIN-336%20Cadmium%20and%20its%20inorganic%20compounds.pdf

30 RPA (2017): Second study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

31 Statistical classification of economic activities in the European Community (***N****omenclature statistique des* ***a****ctivités économiques dans la* ***C****ommunauté* ***e****uropéenne).*

32 RAC (2017): Opinion on Arsenic acid and its inorganic salts of 29 May 2017. Committee for Risk Assessment, European Chemicals Agency. Available at: https://echa.europa.eu/documents/10162/13641/opinion_arsenic_en.pdf/dd3eb795-108e-5d3a-6847-dddcc021a9dc

particulates, but ingestion (skin-to-mouth) exposure may be significant in particular situations (e.g. chromium copper arsenate (CCA)-treated timber); dermal absorption is considered to be limited. It is extremely rare for workers to be exposed to arsenic alone; the exposure is usually to arsenic in combination with other elements[33].

RAC refers to the Dutch Expert Committee on Occupational Safety (DECOS)[34] as providing the most recent review of the carcinogenicity of 'arsenic and inorganic arsenic compounds', with regards to exposure in the working population. A more recent update to reflect the situation in the EU following the implementation of OHS legislation, the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (the REACH Regulation) and the Biocidal Products Regulation is not available, so RAC added relevant, recent references to update the situation in their opinion.

CCA-treated timber, copper smelting (of lower grade ores) and metal extraction and handling of mining waste have become the most prevalent sources of occupational exposure to arsenic. Occupational exposure to arsenic from CCA wood preservatives mainly occurs today from dismantling of wooden structures and recycling of wood, as treatment of wood and imports of CCA-treated timber in the EU is banned since 2013.

Occupational exposure to arsenic may also be significant in other industries, such as arsenic production, electronics (gallium arsenide semiconductors), glass manufacturing and in the pharmaceutical industry. Estimates of the number of workers potentially exposed to arsenic and arsenic compounds has been developed by CAREX in Europe, based on data collected during 1990-93 in 15 EU Member States. CAREX estimates that 150 000 workers were exposed to arsenic and arsenic compounds.[35]

2.2.1.3.2 Adverse health effects

Inorganic arsenic compounds produce lung tumours in both, animals and humans, following inhalation, oral or parenteral exposures.[36] Exposure to high levels of inorganic arsenic compounds in drinking water has been associated

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33 WHO IPCS (2001): Environmental Health Criteria: 224 – arsenic and arsenic compounds. 2nd edition. World Health Organisation, Inter-Organization Programme for the Sound Management of Chemicals, Geneva, p. 66.

34 Health Council of the Netherlands (2012): Arsenic and inorganic arsenic compounds. Health-based calculated occupational cancer risk values. The Hague: Health Council of the Netherlands, publication no. 2012/32.

35 Kauppinen, T., Toikkanen, J., Pedersen, D., Young, R., Ahrens, W., Boffetta, P., Hansen, J., Kromhout, H., Maqueda Blasco, J., Mirabelli, D., de la Orden-Rivera, V., Pannett, B., Plato, N., Savela, A., Vincent, R. & Kogevinas, M. (2000): Occupational exposure to carcinogens in the European Union. Occ Environ Med 57, p. 10–18.

36 RAC (2017): Opinion on Arsenic acid and its inorganic salts of 29 May 2017. Committee for Risk Assessment, European Chemicals Agency. Available at: https://echa.europa.eu/documents/10162/13641/opinion_arsenic_en.pdf/dd3eb795-108e-5d3a-6847-dddcc021a9dc

with skin, and urinary tract or bladder cancer or both in humans. Tumours at other sites including the adrenal glands, bladder and liver have also been reported in some animal studies.

Arsenic acid and its salts are classified as Carcinogen 1A under the Classification, Labelling and Packaging Regulation (EC) 1272/2008 (CLP Regulation), and the broader group arsenic, and inorganic arsenic compounds are considered to be human carcinogens (Group 1) by IARC.

2.2.1.4 Formaldehyde

2.2.1.4.1 Occupational exposure

According to IARC, occupational exposure to formaldehyde occurs in a wide variety of occupations and industries. In a table published by IARC[37] (see Annex 3), the total estimated number of workers exposed above background levels in the European Union amounts to 971 000 workers. This estimate is based on the CAREX data collection in 15 EU Member States during 1990-93. Based on the same data collection, Kauppinen et al. estimated that the number of exposed workers in the European Union in 1990–93 amounts to 990 000 workers.[38].

Formaldehyde can be inhaled, ingested and absorbed through the skin. Inhalation is considered to be the main route of exposure of exogenous formaldehyde. As critical effects associated with formaldehyde exposure are directly linked to the contact surface, the oral pathway may not be negligible.[39]

In IARC Monograph Volume 88 from 2006[40] data were reviewed on occupational exposure to formaldehyde by type of industry. The highest continuous exposures (2–5 ppm; 2.5–6.1 mg/m^3) were measured in the past during varnishing of furniture and wooden floors, in the finishing of textiles, in the garment industry, in the treatment of fur, and in certain jobs within manufactured board mills and foundries. Short-term exposures to high levels (3 ppm and higher; $\geq$ 3.7 mg/m^3) have been reported for embalmers, pathologists, and paper workers. Lower concentrations have usually been encountered during the manufacture of man-made vitreous fibres, abrasives and rubber, and in formaldehyde-production industries. A very wide range of

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37 IARC (2012) Monograph: Formaldehyde.
Available at: http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-29.pdf

38 Kauppinen, T., Toikkanen, J., Pedersen, D., Young, R., Ahrens, W., Boffetta, P., Hansen, J., Kromhout, H., Maqueda Blasco, J., Mirabelli, D., de la Orden-Rivera, V., Pannett, B., Plato, N., Savela, A., Vincent, R. & Kogevinas, M. (2000): Occupational exposure to carcinogens in the European Union. Occ Environ Med 57, p. 10–18.

39 SCOEL (2016): Recommendation from the Scientific Committee on Occupational Exposure Limits for Formaldehyde. SCOEL/REC/125. Available at: https://circabc.europa.eu/sd/a/2882e9bc-d52e-4944-ac08-974b43957ed2/REC-125%20Formaldehyde.pdf

40 IARC (2006) Monograph: Formaldehyde.
Available at: http://monographs.iarc.fr/ENG/Monographs/vol88/mono88-6.pdf

exposure levels has been observed in the production of resins and plastic products.

2.2.1.4.2 Adverse health effects

Formaldehyde is classified, based on the CLP Regulation, as a Cat.1B carcinogen (may cause cancer). According to RAC formaldehyde is a local acting genotoxic carcinogen. RAC states that there is limited evidence of carcinogenicity in humans mainly from the positive association of nasopharyngeal tumours in one industrial cohort, but that there is sufficient evidence of carcinogenicity from animal studies[41].

SCOEL based its opinion for the proposed OEL on their assessment that formaldehyde is a genotoxic carcinogen, for which a mode-of-action based limit value can be derived.

2.2.1.5 4,4'-Methylene-bis(2-chloroaniline) (MOCA) [CAS No 101-14-4]

2.2.1.5.1 Occupational exposure

The most important occupational exposure route for MOCA during use of the chemical agent in the polyurethane industry (manufacture of polyurethane and plastic products) is via dermal exposure after contact with contaminated surfaces. Inhalation and ingestion represent minor routes of occupational exposure to MOCA.

ECHA received one full, joint registration for MOCA, indicating use in the EU of 1 000-10 000 tonnes per year. MOCA is subject to authorisation under the REACH Regulation, and ECHA received one application for authorisation for MOCA covering its industrial use as a curing agent/chain extender in cast polyurethane elastomer production used at ca. 89 potential sites in the EU. Manufacturing of MOCA is reportedly outside the EU. The applicant estimated the total number of potentially exposed workers is ca. 200.

However, IOM[42] have estimated there are approximately 2 500 exposed workers in the EU with 1 400 workers potentially exposed in the manufacture of rubber and plastic products.

2.2.1.5.2 Adverse health effects

MOCA is classified, based on the CLP Regulation, as a Cat. 1B carcinogen (may cause cancer) and has been classified by IARC as a Group 1 carcinogen,

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41 RAC (2012): Opinion proposing harmonised classification and labelling at EU level of Formaldehyde. Committee for Risk Assessment, European Chemicals Agency. Available at: https://echa.europa.eu/documents/10162/254a73cf-ff8d-4bf4-95d1-109f13ef0f5a

42 IOM, Institute of Occupational Medicine (2011): Health, socio-economic and environmental aspects of possible amendments to the EU Directive on the protection of workers from the risks related to exposure to carcinogens and mutagens at work. IOM Research Project: P937/99, May 2011, IOM, Institute of Occupational Medicine, Edinburgh, UK.

taking also into account mechanistic and other relevant data[43]. As an aromatic amine the reasonable human target of carcinogenicity is the urothelium. This is supported by limited data in humans and by the induction by MOCA of urothelial carcinomas in the dog, which is known from experiments with other aromatic amines, which are clear human carcinogens (benzidine, 2-naphthylamine), to respond in this respect similar to humans.

The substance is easily absorbed via the skin. Therefore a "skin" notation[44] is warranted. This underlines the relevance of biological monitoring[45]. For biological monitoring, the measurement of total (mostly conjugated) MOCA in post-shift urine appears as a means of choice[46].

2.2.2 *Modern production technologies allowing lower exposure to carcinogens are not fully exploited.*

A wide-spread transition to state-of-the-art industrial production processes would allow for the further reduction of occupational exposure to carcinogenic, mutagenic and other hazardous substances in the workplace.

For example, exposure to cadmium and MOCA could be further reduced by a higher degree of automation, e.g. in plating and coating processes and in the production of nickel-cadmium batteries[47], and regarding exposure to MOCA, also in the manufacture of rubber products[48].

Risk management measures, such as improved local exhaust ventilation systems, would reduce exposure of workers to formaldehyde e.g. in wood panel

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43 IARC (2008) Monograph: Some aromatic Amines, Organic Dyes, and Related Exposures. Available at: https://monographs.iarc.fr/ENG/Monographs/vol99/mono99.pdf

44 A skin notation is assigned to substances for which the dermal route of exposure is scientifically considered to be relevant.

45 Biomonitoring or biological monitoring is a way of assessing exposure to a certain hazardous chemicals by measuring the chemical or its breakdown products in a biological sample (usually urine, blood or breath). Biomonitoring provides very useful information for employers, workers, health practitioners, and enforcers to help them undertake effective and appropriate health surveillance in particular in cases where biomonitoring is considered to be an additional or sometimes the single most appropriate tool to evaluate the exposure of workers to a particular carcinogen (e.g. where chemicals can be significantly absorbed through the skin.

46 RAC (2017): Opinion on 4,4'-methylene-bis-[2-chloroaniline] (MOCA) of 29 May 2017. Committee for Risk Assessment, European Chemicals Agency. Available at: https://circabc.europa.eu/sd/a/ccd6160e-bf6b-45b0-8210-fa9b928572c9/05.%20Final_opinion%20of%20RAC_MOCA-29-5-2018.pdf

47 SCOEL (2017): Recommendation from the Scientific Committee on Occupational Exposure Limits for Cadmium and its inorganic compounds. SCOEL/OPIN/336. Available at: https://circabc.europa.eu/sd/a/13cad802-1f3c-40c0-bce4-6838cf5fc4ff/OPIN-336%20Cadmium%20and%20its%20inorganic%20compounds.pdf

48 RAC (2017): Opinion on 4,4'-methylene-bis-[2-chloroaniline] (MOCA) of 29 May 2017. Committee for Risk Assessment, European Chemicals Agency. Available at: https://circabc.europa.eu/sd/a/ccd6160e-bf6b-45b0-8210-fa9b928572c9/05.%20Final_opinion%20of%20RAC_MOCA-29-5-2018.pdf

production[49], to arsenic acid and its salts in manufacturing of copper foils[50] and in recycling facilities, and to beryllium in manufacturing of alloys and ceramics[51], to levels which would be in compliance with the OELs based on the values recommended by the tripartite ACSH.

2.3 Regulatory drivers

Under CMD, employers must identify and assess risks to workers associated with exposure to specific carcinogens (and mutagens), and must prevent exposure where risks occur. Substitution to a non- or less-hazardous process or chemical agent is required where this is technically possible. Where carcinogens cannot be substituted they must, so far as is technically possible, be manufactured and used in a closed system to prevent exposure. Where this is not technically possible either, worker exposure must otherwise be reduced to as low a level as is technically possible. This is the so-called minimisation obligation under Article 5 of the CMD. This is a more strict standard than for other hazardous chemicals, where the duty to control risks is always qualified by an assessment of risk by the employer.

Those general provisions of the directive remain relevant. However, in the light of available scientific data concerning the covered carcinogenic chemicals, there are grounds for considering the update of Annexes of the CMD, which provide further clarification of employers' obligations with regard to protecting workers from carcinogenic chemicals:

Annex III establishes 'binding occupational exposure limit values'

For some chemical agents which fall under the scope of the Directive, CMD provides that, in any case, exposure of workers must be kept below 'binding occupational exposure limit values' as established in Annex III of the Directive. An OEL addresses the inhalation route of exposure, describing a maximum airborne concentration level for a given chemical agent above which workers should not be exposed, on average, during a defined time period. OELs can further be annotated with appropriate indications of additional body burden resulting from non-inhalation routes such as, for example, a 'skin' notation where the dermal route of exposure is scientifically considered to be relevant.

As explained above, employers must prevent or minimise exposure to occupational carcinogens where risks occur. The principle of minimisation of the exposure is stated in article 5.3 of the CMD: 'the employer shall ensure that the level of exposure of workers is reduced to as low a level as is technically possible'. In theory, CMD OELs do not directly

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[49] ECHA (2017): Investigation Report: Formaldehyde and Formaldehyde releasers, reply by FORMACARE to Call for evidence, p. 67.

[50] RAC (2017): Opinion on Arsenic acid and its inorganic salts. Committee for Risk Assessment, European Chemicals Agency. Available at: https://echa.europa.eu/documents/10162/13641/opinion_arsenic_en.pdf/dd3eb795-108e-5d3a-6847-dddcc021a9dc

[51] SCOEL (2017): Recommendation from the Scientific Committee on Occupational Exposure Limits for Beryllium and inorganic beryllium compounds. SCOEL/REC/175. Available at: https://circabc.europa.eu/sd/a/33c8921a-1dbe-4410-909c-2d4c63d8fb1d/REC-175%20Beryllium%20and%20compounds.pdf

affect the legal standard of control, which is in any case for minimised exposure. In practice, however, the existence of an OEL provides a clear benchmark that enables professionals to 'operationalise' the concept of minimised exposure, thereby allowing them to easily determine the level to which the exposure should at least be reduced.

With regard to this legal framework the following reasons explain the need to propose further updates of the CMD.

a) New scientific and technical evidence is available that could lead to updating of existing or establishment of new OELs.

According to Article 16(1) of the CMD, the Council shall, in accordance with the procedure laid down in Article 137(2) of the Treaty, set out limit values in Directives on the basis of the available information, including scientific and technical data, in respect of all those carcinogens or mutagens for which this is possible, and, where necessary, other directly related provisions.

For a number of substances the SCOEL or RAC have recently derived recommendations or opinions, respectively. This concerns the following substances or groups of substances:

- Formaldehyde,
- Beryllium and its inorganic compounds, under the scope of the CMD,
- Cadmium and its inorganic compounds under the scope of the CMD,
- 4,4'-Methylene-bis-[2-chloroaniline] (MOCA), and
- Arsenic acid and its salts under the scope of the CMD.

For formaldehyde; beryllium and its inorganic compounds, MOCA, arsenic acid and its salts as well as for cadmium and its inorganic compounds, currently no EU OEL exists.

SCOEL has derived recommendations for health-based OELs for three of the substances:

- Formaldehyde[52]

  SCOEL recommends a health-based 8-hour TWA[53] value of 0.3 ppm (0.369 mg/m^3); in addition, a STEL value[54] of 0.6 ppm (0.738 mg/m^3) is recommended.

[52] SCOEL (2016): Recommendation from the Scientific Committee on Occupational Exposure Limits for Formaldehyde. SCOEL/REC/125. Available at: https://circabc.europa.eu/sd/a/2882e9bc-d52e-4944-ac08-974b43957ed2/REC-125%20Formaldehyde.pdf

[53] Time-weighted average - average exposure to a contaminant to which workers may be exposed without adverse health effect over a period of 8-hour per day usually expressed in units of ppm (volume/volume) or mg/m^3.

[54] Short Term Exposure Value - a STEL is a limit value above which exposure to a chemical substance should not occur and usually relates to a 15 minute reference period. The aim of a STEL is to prevent adverse health effects and other unwanted effects due to peak exposure that may not be controlled by the application of an 8 hour TWA limit.

Formaldehyde is known for causing upper respiratory tract cancer.

- Beryllium and its inorganic compounds[55] under the scope of the CMD

  SCOEL recommends a health-based 8-hour TWA value of 0.00002 mg/m^3 (inhalable fraction), as well as a STEL value of 0.0002 mg/m^3 (inhalable fraction). In addition, a Biological Guidance Value of 0.00004 mg/l urine is recommended.

  Beryllium and its inorganic compounds are known to cause lung cancer.

- Cadmium and its inorganic compounds[56] under the scope of the CMD

  SCOEL recommends a health-based 8-hour TWA value of 0.001 mg/m^3 for cadmium and its inorganic compounds. No STEL value is recommended. However, SCOEL also recommends a Biological Limit Value of 0.002 mg cadmium / g creatinine in urine.

  Cadmium and its inorganic compounds are known to cause lung cancer.

Neither RAC nor SCOEL derived a health-based OEL for MOCA[57] or arsenic acid and its inorganic salts[58] under the scope of the CMD. The ACSH has adopted opinions for all priority substances foreseen for the third amendment of the CMD[59], proposing a binding OEL for all of them and in addition a skin notation for MOCA as possible approaches for these chemicals.

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55 SCOEL (2017): Recommendation from the Scientific Committee on Occupational Exposure Limits for Beryllium and inorganic beryllium compounds. SCOEL/REC/175. Available at: https://circabc.europa.eu/sd/a/33c8921a-1dbe-4410-909c-2d4c63d8fb1d/REC-175%20Beryllium%20and%20compounds.pdf

56 SCOEL (2017): Recommendation from the Scientific Committee on Occupational Exposure Limits for Cadmium and its inorganic compounds. SCOEL/OPIN/336. Available at: https://circabc.europa.eu/sd/a/13cad802-1f3c-40c0-bce4-6838cf5fc4ff/OPIN-336%20Cadmium%20and%20its%20inorganic%20compounds.pdf

57 RAC (2017): Opinion on 4,4'-methylene-bis-[2-chloroaniline] (MOCA) of 29 May 2017. Committee for Risk Assessment, European Chemicals Agency. Available at: https://circabc.europa.eu/sd/a/ccd6160e-bf6b-45b0-8210-fa9b928572c9/05.%20Final_opinion%20of%20RAC_MOCA-29-5-2018.pdf

58 RAC (2017): Opinion on Arsenic acid and its inorganic salts. Committee for Risk Assessment, European Chemicals Agency. Available at: https://echa.europa.eu/documents/10162/13641/opinion_arsenic_en.pdf/dd3eb795-108e-5d3a-6847-dddcc021a9dc

59 The exact text of the opinions can be found on CIRCA-BC under the following links:
Formaldehyde: https://circabc.europa.eu/sd/a/25162551-6341-46d1-9e90-4360cd6a1d0d/Doc.1280_EN-WPC%20June%20Opinion%20Formaldehyde.pdf
Beryllium: https://circabc.europa.eu/sd/a/7e95cab5-6c71-4cbc-8147-f1f6d460ba2f/Doc.662-17-EN_WPC_Opinion%20on%20Be_Adopted%2031.05.2017.pdf
Cadmium: https://circabc.europa.eu/sd/a/bf0521f0-b54a-4712-b256-a30d7adcfdf6/Doc.663-17-EN_WPC%20Opinion%20Cadmium_Adopted%2031.05.2017%20.pdf
MOCA: https://circabc.europa.eu/sd/a/2214b88e-5a69-4c2e-a98a-331aa13dc264/Doc.1336_EN-WPC_Opinion%20MOCA_Adopted%2019102017.pdf
Arsenic acid and its salts: https://circabc.europa.eu/sd/a/9813acc5-604a-49f9-9d4b-afaeceb12705/Doc.1334_01_EN_WPC_Opinion%20Arsenic_Adopted%2019102017.pdf

It is therefore necessary to consider updating the CMD based on the above mentioned information.

Regarding the substances currently foreseen for a fourth amendment of the CMD (Benzene, nickel, and acrylonitrile), RAC has been requested to deliver an opinion by the end of March 2018.

b) In the EU Member States workers are subject to different levels of protection due to inadequate, diverging or non-existing OELs for some substances or groups of substances.

While no EU OELs have been established for the five carcinogens considered for a third update of the CMD, there is a diverse situation as for legal protection in national legislations.

The national OELs for formaldehyde vary for example from 0.15 mg/m^3 in the Netherlands to 2.5 mg/m^3 in Ireland and the United Kingdom. In 9 Member States (Greece, Italy, Luxembourg, Malta, Poland, Romania, Slovakia, Slovenia and Spain) there exist no national OELs.

For MOCA, 13 Member States have no OELs established (Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, and Sweden[60]). In the remaining Member States, the value ranges from 0.005 mg/m^3 (in Ireland and in the UK) to 0.22 mg/m^3 (in France and in Romania).

For cadmium and its inorganic compounds, current national OELs for 8 hours TWA range from 0.002 mg/m^3 for respirable particles in Belgium and Spain, 0.005 mg/m^3 for all types in Denmark and the Netherlands, to a maximum OEL of 0.05 mg/m^3 in Bulgaria, Estonia (total dust) and Lithuania (inhalable fraction).

Regarding beryllium and its inorganic compounds, OELs in Member States vary between 0.002 mg/m^3 for total particulate fraction, 0.001 mg/m^3 in the Czech Republic and Denmark, to 0.005 mg/m^3 in Greece.

The national OELs for arsenic acids and it salts range from 0.01 mg/m^3 in Denmark, Latvia, Poland, Ireland and Finland, to 0.2 mg/m^3 in France.

ANNEX 1 shows a summary of national OELs in EU Member States for the substances considered for the 3rd wave.

2.4 Consequences of the problem

2.4.1 Consequences for workers

As discussed above, Member States have introduced national OELs for some, but not for all of the agents considered in this consultation. Where national OELs exist they vary considerably, leading to different levels of protection of workers across the EU.

[60] In Sweden working with this substance requires permission from the Swedish environmental authority before it can be used.

A high exposure to carcinogens has negative consequences for workers and their families across the EU. As mentioned above, high numbers of people with past exposure to carcinogenic substances at work are newly diagnosed with cancer every year. For the workers and their families cancer results in substantial losses of the quality and duration of their lives, causing unnecessary suffering and moral pain. Moreover, affected workers not only face considerable direct and indirect health care and rehabilitation costs, but also indirect loss of present and future earnings both for the person affected and for the carers. In addition, administration costs related to the time and expenses claiming for benefits, waiting for treatment etc. incur.

2.4.2 Consequences for businesses

For businesses, occupational cancer implies costs in terms of reduced productivity, as they lose skilled workers and need to spend more in recruitment and training of new workers. Given the often long time lag between exposure and illness and the probability of workers changing employers during their work career, the risk of future productivity losses is unlikely to be internalised by companies, and therefore not factored into present businesses' decisions. A study commissioned by the Commission (2011)[61] considers the socio-economic costs of accidents and ill-health relating to work and the benefits to employers of implementing effective health and safety management policies. The report estimates that the cost to employers for a single case of a high-severity accident or disease is EUR 11 660. This figure is based on data pertaining to cost categories such as:

- reduced productivity of the injured employee after re-employment;
- costs of a replacement (difference in salary, reduced productivity);
- overtime of colleagues to compensate;
- rehabilitation costs (those paid by employer);
- medical costs (those paid by employer);
- administrative follow-up;
- reorganising the work; and
- training the replacement (time of the trainer).

As result of negotiations between employers and trade unions some of the affected sectors/companies may also need to pay higher wages to compensate for the higher occupational risk, which could affect their competitiveness vis-à-vis otherwise similar companies.

Finally, businesses located in Member States where national OELs are relatively stringent may be at a competitive disadvantage vis-à-vis enterprises in Member States with no or higher OELs. Thus, varying OELs negatively impact the functioning of the Internal Market by causing fragmentation from the adoption of possibly different rules at national level. Also the competitiveness may be negatively affected, not only by a loss of productivity, but also by less encouragement for technological progress and innovation.

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[61] De Greef, M. Van den Broek, K. Van Der Heyden, S., Kuhl, K., Schmitz-Felten, E. (2011): Socio-economic costs of accidents at work and work-related ill health. Available at: http://ec.europa.eu/social/BlobServlet?docId=7416&langId=en

Regarding OELs in countries outside the EU, it is impossible to provide an overview on OELs for cadmium and its inorganic compounds, beryllium and its inorganic compounds and arsenic acid and its salts, because these names, as indicated already, refer to group of substances and not individual substances. Nevertheless, an overview of OELs for MOCA and formaldehyde in Australia, Canada, China, South Korea, Switzerland and the USA are provided in ANNEX 2 of this document.

The ranges for these substances are similar with those mentioned for the EU above.

2.4.3 Consequences for Member States

Apart from the significant social and financial burden to those affected by cancer, including their families, the disease is also associated with significant costs to society from coping with cancer. If national OEL exist, they vary considerably at present, and thus the consequences for Member States differ in their impact.

For Member States, occupational cancer leads to increased healthcare costs related to treatment and rehabilitation, as well as to higher expenditure on associated inactivity and early retirement and compensation for recognised occupational diseases. According to a recent report, direct costs of work-related cancer in terms of healthcare and productivity losses amount to at least to some EUR 4 – 7 billion per year; and the indirect costs may reach as much as EUR 334 billion each year.[62] Occupational cancer also increases administrative and legal costs related to the handling of requests for benefits and dealing with recognized cases. Foregone earnings and income as a result of ill health also lead to tax revenue losses for social security systems.

Occupational cancer also impacts the economy at large, reducing labour supply (either temporarily or permanently) not only by the person affected but also by his/her carers, decreasing labour productivity, and increasing the burden on public finances through avoidable public expenditure on health care, disability benefits, pensions for early retirement, and other benefits.

[62] RIVM (2016): Work-related cancer in the European Union: Size, impact and options for further prevention, Jongeneel WP, Eysink PED, Theodori D, Hamberg-van Reenen HH, Verhoeven JK. Report 2016-0010. Available at: http://rivm.nl/en/Documents_and_publications/Scientific/Reports/2016/mei/Work_related_cancer_in_the_European_Union_Size_impact_and_options_for_further_prevention

3 EU COMPETENCE AND EU ADDED VALUE

3.1 Necessity and EU added value

Amending the CMD can only be done by action at EU level, and it presents an EU added value in several respects.

Updated scientific basis of prevention and protection

Scientific knowledge about carcinogenic chemicals is constantly developing and technological progress enables improvements in protection of workers. In order to ensure that the mechanisms for protecting workers from carcinogenic chemicals established in the CMD are as effective as possible, the Directive needs to be kept more up to date with those developments.

Available scientific evidence points to the need to establish new OELs in Annex III to CMD for a number of substances for inhalation exposures including for information on other routes of exposure (e.g. dermal) which could contribute significantly to the overall body burden of the workers.

Updating CMD to take account of newer scientific evidence is an effective way to ensure that preventive measures would be adjusted accordingly in all Member States.

Improved clarity and enforcement

Establishing new OELs in Annex III could provide a common reference point that can be used as a practical tool by employers, workers and enforcers to assess compliance with the general CMD requirements. OELs can also be used by process plant- and machinery designers when planning new production lines or considering alterations to existing process plants.

Ensuring the same minimum level of protection across the EU

In case of all carcinogenic chemical agents where OELs are considered in this consultation for the third wave at least half of the Member States have not yet established legally enforceable OEL for one , several or all substances

Lack of EU action will most likely mean that there will remain Member States where no limit values exist for certain carcinogens or where those values are too high to ensure adequate worker protection. A minimum standard across the EU will not be ensured, to the detriment of worker protection.

Contribution to level-playing field

National OELs vary considerably in some cases – leading to significantly different levels of protection. For MOCA, for example, the values differ by a factor of more than 40 in those Member States which have introduced an OEL.

This can also have negative consequences for the internal market because businesses operating in Member States with less stringent levels or no exposure limit value at all would benefit from an undue competitive advantage. It may also provide a potential incentive for companies to locate their production facilities in Member States with the lower standards.

Introducing EU OELs in Annex III would not completely eliminate the national differences, as it sets only minimum standards and therefore Member States retain the possibility to adopt more protective measures. However, it could provide certainty that there is a core definition and/or enforceable exposure limit for all concerned carcinogens in all Member States. It could also significantly minimise the scope for variation in OELs across the EU. The examples of the currently existing EU OELs show that a majority of Member States in practice adopt the EU OELs directly.

3.2 Foundations of the right to act

- *Legal basis*

The Treaty on the Functioning of the EU in Article 153 empowers the EU to support and complement the activities of the Member States as regards improvements, in particular of the working environment to protect workers' health and safety and to adopt, by means of directives, minimum requirements for gradual implementation, having regard to the conditions and technical rules obtaining in each of the Member States.

The protection of workers' health against risks arising from exposure to carcinogenic and mutagenic substances is already covered by EU OSH legislation, in particular by the CMD, as well as under the REACH Regulation.

Amending the CMD can only be done by action at EU level.

- *Political basis*

Promoting workers' health is in line with the ambition for a 'Triple A Social Europe rating' set by the Juncker Commission. Up-to-date occupational health and safety rules which ensure an adequate protection of workers against exposure to carcinogens are also feeding into the Pillar of Social Rights adopted on 26 April 2017. It serves, amongst others, as a reference framework to screen the Member States' employment and social performance and as a compass for the renewed process of convergence towards better working and living conditions in Europe.

In his Letter of Intent as part of the State of the Union Address of 14 September 2016[63], President Jean-Claude Juncker explicitly mentioned the "*modernisation of existing occupational health and safety legislation to better protect the safety and health of workers, through better implementation, an updated legislative framework and enhanced protection from the risks related to carcinogens and mutagens"* as part of the 10 priorities for the forthcoming year.

3.3 Coherence with other relevant EU instruments

3.3.1 Coherence with the Charter of Fundamental Rights of the EU

The objectives of the initiative are consistent with Article 2 (Right to life) and Article 31 (Right to fair and just working conditions) of the EU Charter of Fundamental Rights.

[63] Juncker, J.-C. (2016): State of the Union 2016. Available at: https://publications.europa.eu/en/publication-detail/-/publication/c9ff4ff6-9a81-11e6-9bca-01aa75ed71a1/language-en/format-PDF/source-30945725

Ensuring a safe and healthy work environment is a strategic goal for the European Commission.[64]

3.3.2 Consistency and synergies with the REACH Regulation [65]

The REACH Regulation, adopted in 2006, consolidated and evolved several parts of the EU chemicals legislation – principally those relating to risk assessment and internal market risk management measures. The REACH Regulation established the 'registration' of all chemicals above 1 tonne on the EU market and 'authorisation' and 'restriction' as risk management measures to control the exposures of chemicals, including substances of very high concern (SVHC), at the workplace or for industrial uses.

Both the CMD and the REACH Regulation are relevant for worker protection for the majority of carcinogens considered in this consultation.

A carcinogenic chemical may appear complementary on both, CMD Annex III and the REACH Regulation Annex XIV (the list of SVHCs which can only be placed on the market or used if an authorisation has been granted for a specific use by the European Commission), as well as on the REACH Regulation Annex XVII (restricted substances).

The OSH Framework Directive – under which CMD is operational – applies without prejudice to existing or future national and EU provisions which are more favourable to the safety and protection of the health of workers at work. The REACH Regulation in turn applies without prejudice to worker protection legislation, including the CMD.

Clear synergies between the REACH Regulation and worker protection legislation exist – in particular the REACH Regulation 'registration' should result in more information being available to inform chemicals risks assessment.

The REACH Regulation 'authorisation' and 'restrictions' also establishes, for a given chemical agent, a clear and renewed pressure to substitute it with safer alternatives, and can drive applicants to improve their risk management measures and operational conditions to improve worker protection. At the same time existing OELs and/or the underlying information used for setting the OEL can be used to derive DNELs under the REACH Regulation.[66]

An authorisation under the REACH Regulation may only be granted for specific uses and operators who have demonstrated that the risks are either adequately controlled (the 'adequate control route') or are lower than the socio-economic benefits derived from the use (the 'socio-economic route') and there are no suitable alternatives.

Workers exposure is the main exposure scenario today for almost all substances listed in Annex XIV as most of these chemicals are used in industrial settings.

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64 Communication from the Commission on the EU Strategic Framework on Health and Safety at Work 2014 – 2020. COM(2017) 12 final.

65 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

66 ECHA 2012 (updated 2016): Guidance on Information Requirements and Chemical Safety Assessment, Chapter R.8. Available at: https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Applicants for authorisation must include, amongst other elements, for each of the uses covered in their application, an assessment of the exposure of workers to the substance(s) and the related risk, at the individual workplaces concerned or over a representative sample of workplaces. If the risk management measures set out in the application are not judged to be appropriate and effective by ECHA's Risk Assessment Committee, conditions and/or monitoring arrangements can be imposed in the authorisation decision to reduce exposure and risks further, including biomonitoring and regular occupational exposure measurements.

However, some uses of substances are not covered by the authorisation requirement, namely intermediates[67] and unintended process generated substances. The former is for example very relevant for formaldehyde, which is predominantly used as a chemical intermediate.

Intermediates as defined by the REACH Regulation are chemical substances which are manufactured for and consumed in or used for chemical processing in order to be transformed into another substance[68]. Occupational exposure to intermediates may nevertheless occur for example during cleaning, maintenance, etc. where residues may be present and/or where process-streams are interrupted and containment may be compromised.

The co-existence of a CMD OELs alongside the REACH Regulation authorisation will provide several important benefits for the practice of both OSH and the REACH Regulation worker protection provisions:

- CMD applies to all potential worker exposures – including those associated with intermediates, and process-generated substances, or resulting from unintended or misuse-related release.
- For so-called non-threshold carcinogens the OEL-setting process provides a thorough and robust process for establishing minimum standard exposure levels – ultimately passing through the co-legislator for adoption – based on a science and stakeholder consultation based process. The overall relationship between the REACH Regulation and the OSH Directives (including some references specific to the CMD) has been subject of an opinion of the 'REFIT Platform'[69] adopted on 27-28 June 2016.[70]

  In their document the REFIT Platform recognises that the two sets of legislation are mutually reinforcing but points out that the interface between the REACH Regulation and OSH legislation is complex and that further clarification is needed. Furthermore, the ongoing review of the REACH Regulation revealed areas where improvements in the interaction of both areas can be made.

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67 Apart from 'non-isolated intermediates' which, during synthesis, are not intentionally removed (except for sampling) from the equipment in which the synthesis takes place.

68 Article 3(15) of REACH.

69 The European Commission established the 'REFIT Platform' of Member State government and EU stakeholder representatives to support the simplification of EU law and the reduction of regulatory burden without detracting from the policy objectives of EU law.

70 European Commission (2016): REFIT Platform Opinion. Available at: https://ec.europa.eu/info/files/refit-platform-recommendations-chemicals-ii2a-reach-osh_en

The concerned Commission services are working on providing clarifications and are together developing a common understanding approach on the interface between the REACH Regulation and OSH legislation as regards hazardous chemicals at the workplace.

Status of the substances under the REACH Regulation

The applicable provisions of the REACH Regulation authorisation and/or restriction, where relevant, for the chemical agents under consideration in this report, are as follows:

The placing on the market and use of **cadmium and its inorganic compounds** in various mixtures and articles has been restricted since 1991, with several amendments:

Name of agent in Annex XVII	Entry No.	Conditions of the restriction
Cadmium and its compounds	23	https://echa.europa.eu/documents/10162/3bfef8a3-8c97-4d85-ae0b-ac6827de49a9

Cadmium compounds are also SVHCs on the candidate list for possible inclusion in Annex XIV to the REACH Regulation:

Name of agents in candidate list	CAS No.	EC No.	Identified as SVHC
Cadmium	7440-43-9	231-152-8	20/06/2013
Cadmium chloride	10108-64-2	233-296-7	16/06/2014
Cadmium fluoride	7790-79-6	232-222-0	17/12/2014
Cadmium oxide	1306-19-0	215-146-2	20/06/2013
Cadmium sulphate	10124-36-4, 31119-53-6	233-331-6	17/12/2014
Cadmium sulphide	1306-23-6	215-147-8	16/12/2013

Arsenic acid and its salts are subject to authorisation (Annex XIV) :

Name of agents in Annex XIV	CAS No.	EC No.	Sunset date[71]
Arsenic acid	7778-39-4	231-901-9	22/08/2017
Diarsenic pentaoxide	1303-28-2	215-116-9	21/05/2015
Diarsenic trioxide	1327-53-3	215-481-4	21/05/2015

Arsenic compounds are also restricted in placing on the market and use for the treatment of wood:

Name of agent in Annex XVII	Entry No.	Conditions of the restriction
Arsenic compounds	19	https://echa.europa.eu/documents/10162/a798c758-371f-41e5-a38d-5f8dc9ba739d

[71] Date from which the placing on the market and the use of that substance shall be prohibited unless an authorisation is granted.

4,4'-Methylene-bis(2-chloroaniline) (MOCA) is subject to authorisation:

Name of agent in Annex XIV	CAS No.	EC No.	Sunset date
2,2'-dichloro-4,4'-methylenedianiline	101-14-4	202-918-9	22/11/2017

Beryllium and its inorganic compounds and **formaldehyde** [CAS No 50-00-0] are currently not identified as SVHC or subject to restrictions under the REACH Regulation.

The REACH Regulation status of the first proposed substances for a 4th wave amendment is as follows:

Nickel and its compounds are restricted under the REACH Regulation and shall not be used in articles intended to come into direct and prolonged contact with the skin:

Name of agent in Annex XVII	Entry No.	Conditions of the restriction
Nickel and its compounds	17	https://echa.europa.eu/documents/10162/7851171d-53e9-455a-8bb8-7ca22e89ad87

Benzene [CAS No 71-43-2] is restricted under the REACH Regulation and shall not be placed on the market as a substance or constituent of substances or mixtures, and shall not be used in toys and part thereof:

Name of agent in Annex XVII	Entry No.	Conditions of the restriction
Benzene	5	https://echa.europa.eu/documents/10162/59f436ca-8afa-4adf-b108-27d7bc8a7751

Acrylonitrile [CAS No 107-13-1] is currently not subject to SVHC listing, authorisation, or restriction under the REACH Regulation.

4 POLICY OBJECTIVES, AVENUES FOR EU ACTION AND THEIR POTENTIAL IMPACT

4.1 Policy objectives

The main general policy objective of this initiative is to ensure and maintain a high level of protection of workers' health and safety in the European Union.

The objectives of the Commission's work are more specifically:

- To further improve protection from occupational exposure to chemical carcinogens in the European Union;
- To increase the effectiveness of the EU framework by considering current scientific expertise;
- To ensure more clarity, facilitate implementation, and contribute towards a better level playing field for economic operators by reducing divergences in national protection levels.

4.2 Possible avenues for EU action

Given the challenges related to a wide use of these chemicals in European industries, the Commission is considering a range of possible measures:

(1) No EU action / baseline scenario

(2) Guidance documents

(3) Legislative action / introducing OELs and/or 'skin' notations in Annex III of the Directive

These possibilities are not mutually exclusive, as guidance documents can be combined with legislative action.

The first possibility is that of doing nothing at EU level. This is the baseline scenario against which the other avenues for action will be assessed. The baseline takes into account how the problem would evolve, considering all relevant societal, economic and technical developments that would probably occur in the following decades.

The second possible avenue for EU action, guidance documents, is to develop brochures containing recommendations how to protect employees from exposure to the substances specified. The Commission could entrust the EU-OSHA to develop, for the use by national authorities and employers, guidance to good practice addressing these substances.

The third possible measure for consideration, legislative action, would set binding OELs in all Member States of the European Union. Proposing binding OELs would be based in the first place on the scientific evaluation provided by either SCOEL or RAC on the individual substances as well as on the opinions delivered by the A CSH taking also socio-economic feasibility factors into account. However, it has to be kept in mind that the different interest groups might not always come to the same conclusions in the opinions. In addition, it is also an obligation of the Commission to also take competitive aspects with countries outside the EU into account. Based on the Impact Assessment, which evaluates all these aspects, the Commission might deviate in the final proposal from the values proposed by the ACSH.

Likewise, all companies, from micro-enterprises to multinational corporations, across all industries would be required by law to adhere to the same OELs specified in the CMD. The level of the OELs would be set to decrease the occupational cancer burden, taking into account the related costs that would accrue due to additional expenses for businesses.

4.3 Impacts of possible avenues for EU action

The main benefits from lowering exposure levels accrue from a reduction of occupational cancer among European workers. EU-OSHA estimates that cancer is the main cause of work-related death with 106 307 fatal cases per year in the EU-28. Moreover, 815 DALYs (Years of life lost and lived with disability) per 100 000 workers are caused

yearly by work-related cancer in the EU-28. Following on from this, EU-OSHA estimates that the cost of work-related cancers amounts to EUR 119.5 billion in the European Union.

The positive as well as the negative impacts from a reduction in occupational exposure to carcinogens depend on the specific exposure levels achieved, but also on determinants such as the number or workers exposed, the toxicity of the chemical and the market structure of the industries using the carcinogen.

The three possible avenues for EU action are likely to differ in their effectiveness and impacts. Specifically, benefits would accrue for workers and their families, businesses and Member States, but also costs for businesses and workers could occur.

Table 1 gives and overview over potential impacts for the different avenues for EU action.

Table 1: Possible avenues for consideration and their impacts

Possible measures for consideration	Impacts			
	Social (including health)	**Economic**	**Legislative**	**Environmental**
1. No EU action / baseline scenario	Gaps in worker protection will persist. Significant costs in terms of avoidable deaths, suffering and healthcare.	The costs for businesses will continue to vary significantly between MS. No increased costs for businesses, but disadvantages in terms of productivity and competitiveness.	No legislative action required.	No significant impact expected.
2. Guidance documents	Gaps in worker protection will persist. A possible reduction of some avoidable deaths and suffering, and healthcare costs.	Small voluntary costs for businesses. Disadvantages in terms of productivity and competitiveness will persist.	No legislative action required.	No significant impact expected.
3. Legislative action / introducing OEL and/or skin notations in Annex III of the CMD	Significant reduction in avoidable deaths, suffering and healthcare costs expected.	Costs for businesses regarding protective measures. Benefits from a healthier workforce.	Amendment of the CMD via ordinary legislative procedure.	No significant impact expected.

Under the first possibility, the baseline scenario, the EU would not act. It is expected that a considerable amount of occupational cancer would continue to be caused by the carcinogens covered in this document, and that significant differences in national OELs would persist. Thus, it is not expected that there would be any benefits for workers or business, or any additional costs for businesses under this scenario. Worker protection would have to rely on future developments under the REACH Regulation risk management measures (authorisation and restriction). A scientific study commissioned by the European Commission will look further into the costs and benefits that would occur under the baseline scenario.

Concerning the second possible avenue, guidance documents, it is voluntary for businesses to follow such advice. A general positive impact is expected from such an initiative, as some cancer cases could be avoided by following best practice. However,

there might be several reasons for this option not being effective, such as cost pressure on companies not to invest in OSH, the lack of knowledge about these guidance documents, or general ignorance about OSH best practice. Subsequently, it is likely that gaps in workers protection would persist, with a significant amount of occupational cancer caused. Also, no effects on the internal market or overall competitiveness are expected and diverging national OELs would be maintained.

The third possible avenue, the setting of legally-binding limit values for the specified carcinogens, would require all companies to adhere to specified OELs, and thus very likely reduce the occupational cancer burden. Moreover, legally-binding limit values for the specified carcinogens would improve the functioning of the internal market by reducing further fragmentation from the adoption of possibly different rules at national level. Although Member States are still free to choose more protective OELs, internal coherence will likely be increased. As an OEL sets an objective to be achieved without being prescriptive in how this should be achieved, it can accommodate technical developments in the world of work such as new or enhanced processes and is consistent with the policy objective of employers further lowering the level of exposure below the level of the OELs when, for specific processes, this can be achieved. On the other hand, businesses will face increasing costs to comply with the OELs, including likely expenses for ventilation systems and personal protective equipment. The magnitude of the costs and benefits of possible OELs will depend on the specific limit value proposed.

For all possible avenues, no environmental impacts are expected. As the setting of OELs only applies to exposure levels within the workplace, which is usually inside a building, the emission of these substances into the environment is not significantly affected by measures to protect workers. Local exhaust ventilation systems must follow the provisions of air pollution legislation, such as the Industrial Emissions Directive[72] and its national implementing legislation.

Table 2 specifies the possible benefits and costs for the three main stakeholder groups regarding a potential reduction in occupational exposure to carcinogens. These benefits accrue under all policy avenues if a reduction of occupational exposure is achieved, for example by following guidance documents, or by following legal provisions.

The commissioned study will, to the extent possible, further explore costs and benefits as well distributive effects, regarding the market structure and business composition, the characteristics of workers affected and the geographical scope of the industries affected for the substances included in the third wave.

[72] Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control).

Table 2: Expected impacts from a reduction in occupational exposure to carcinogens

	Workers and their families	Businesses	Government/ Administration
Benefits	Longer and healthier lives: Avoided cancer cases, avoided other adverse health effects (such as e.g. respiratory conditions, dermal conditions) and avoided deaths	Higher labour productivity (reductions in absenteeism, production losses, production disturbances and higher employee motivation, better company image)	Lower healthcare cost for treatment and rehabilitation
	Avoided moral pain and suffering	Reduced administrative and legal costs connected to ill or disabled workers	Lower expenditure for early retirement, disability benefits and compensation for recognised occupational diseases
	Avoided loss of present and future income, for workers and informal carers	Reduction in sick leave payments, rehabilitation costs insurance contributions (and/or disability compensation)	Reduced administrative and legal costs related to dealing with recognized cases and benefit payments
	Avoided private direct and indirect medical costs and rehabilitation costs	Reduced costs of replacement, overtime of colleagues to compensate, reorganising the work	Tax revenue loss of foregone earnings
	Avoided cost of time claiming benefits, waiting for treatment	Increased clarity and guidance as regards the application of the relevant provisions and avoided administrative and other burdens	Increase in labour supply by workers and caring relatives
	Reduction in insurance contributions in the long term	Incentives for innovation, leading to increased competitiveness	
Costs	Fewer employment opportunities, if businesses, potentially SMEs, are forced to close	Expenses for company and personal protective equipment	Costs for the establishment of mechanisms to surveillance the measures
		Changes in the production processes, cost of substitution by less hazardous substances	

4.4 Chemical agents under consideration

4.4.1 Cadmium and its inorganic compounds

Cadmium and its inorganic compounds have a wide variety of uses, including in nickel-cadmium (Ni-Cd) batteries, in pigments, coatings, plating, stabilisers, alloys, photovoltaic cells and other semiconductors.[73] Cadmium is used for a wide variety of applications because it has a high thermal and electrical conductivity, favourable corrosion resistance properties, high ductility and a low melting point. In terms of the production of cadmium and its applications, 79% is used for electrode materials in batteries; 11% as pigments in ceramics, plastics and glasses; 2% as stabilisers in PVC and related salts mostly as organic salts; 7% for coating in steel and non-ferrous metals and 1% in alloys and other uses.[74] ECHA notes that cadmium is manufactured and/or imported in the European Economic Area in 1 000 - 10 000 tonnes per year.[75] One application for authorisation for the use of 516 tonnes has been received by ECHA[76].

4.4.2 Beryllium and its inorganic compounds

Beryllium compounds are used for manufacturing a wide range of products, such as telecommunications equipment and computers. In smartphones, copper beryllium alloys are used to make battery contacts and electronic connectors. Beryllium is also used in medical applications (medical imaging, HIV tests, etc.), transportation (beryllium alloys are used in automobile components and airplane equipment), energy (oil and gas extraction, solar energy, etc.) and defence and security (weapon systems).[77] The various inorganic beryllium compounds are primarily used as intermediates in the preparation of beryllium metal or its alloys. The most significant uses of beryllium are in three forms: as the free metal, as alloys and as an oxide. ECHA notes that beryllium is manufactured and/or imported in the European Economic Area in 10 - 100 tonnes per year.[78]

Moreover, beryllium occurs naturally in air, soil, and water. As a result, some workers are exposed not only to beryllium that is introduced to the supply chain by suppliers of beryllium metal and alloys but also to naturally occurring beryllium. This means that occupational exposure to beryllium also occurs in sectors that are not a part of the beryllium supply chain in the sense that beryllium originates from beryllium metal or

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73 CAREX Canada (2016): Cadmium. Available at: http://www.carexcanada.ca/en/cadmium/

74 SCOEL (2010): Recommendation from the Scientific Committee on Occupational Exposure Limits for Cadmium and its inorganic compounds. Report SCOEL/SUM/136.

75 ECHA (2017): Substance information Cadmium. Available at https://echa.europa.eu/substance-information/-/substanceinfo/100.028.320

76 ECHA (2017) Adopted opinions and previous consultations on applications for authorisation. MOCA. Available at: https://echa.europa.eu/applications-for-authorisation-previous-consultations/-/substance-rev/15329/term

77 BEST, Beryllium Science & Technology Association (2017): Uses of Beryllium. Available at: https://berylliumsafety.eu/wp-content/uploads/2017/02/Attachment-1-Uses-of-Beryllium.pdf

78 ECHA (2017): Substance information Beryllium. Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.028.318

alloy suppliers. Information by the Beryllium Science & Technology Association (BeST) suggests that such sectors may include, for example, cement, concrete product, construction material, and fertiliser manufacturing, construction, farming, oil & gas, electric utilities, and steel and aluminium production.[79]

4.4.3 Arsenic acid and its salts

Arsenic acid has been identified as being used in the treatment of copper foil for the manufacture of printed circuit boards. According to the REACH Regulation registration dossiers, two of its salts, calcium arsenate and tri lead diarsenate are used as intermediates in the manufacture of basic metals, including alloys. Authorised under the REACH Regulation are uses of diarsenic trioxide and diarsenic pentoxide in zinc production, gold plating and in production of ammonia. According to ECHA, arsenic acid is manufactured and/or imported in the European Economic Area in 100 - 1 000 tonnes per year.[80]

4.4.4 Formaldehyde

Formaldehyde, a chemical building block, is used primarily as an intermediate in the production of other industrial chemicals such as 1,4-butanediol, 4,4′-methylenediphenyl diisocyanate, penta-erythritol, and hexamethylenetetramine and other chemicals which are used in coatings and plastics, for example polyurethane.[81] Formaldehyde is used in the production of various types of formaldehyde-based resins: phenolic, urea, and melamine resins have wide uses as adhesives and binders in the wood-production, pulp-and-paper, and the synthetic vitreous fibre industries, in the production of plastics and coatings, and in textile finishing. Polyacetal resins are widely used in the production of plastics.

These resins have uses in construction and furniture applications and also for aerospace applications.

Formaldehyde is also used for tissue preservation, in embalming fluids and is used in pathology departments and autopsy rooms. Formaldehyde is also used as a disinfectant.[82]

The European Union is the second largest producer of formaldehyde after Asia, producing over 3.6 million tonnes of formaldehyde each year which accounts for about 30% of global production (EU capacity in 2009). Annual sales of formaldehyde-based chemicals in the EU are roughly EUR 9.5 billion a year, and 22 of the 27 EU Member

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79 RPA (2017): Second study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

80 ECHA (2017): Substance information Arsenic acid. Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.029.001

81 Formacare (2014): Applications. Available at: http://www.formacare.org/applications/

82 IARC (2012) Monograph: Formaldehyde. Available at: http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-29.pdf

States manufacture formaldehyde.[83] Latest available figures from Eurostat show that in 2016 the total EU-28 production stood at 2 861 765 tonnes. Germany was the largest producer of formaldehyde with 785 973 tonnes, followed by Italy (372 799 tonnes), Poland (273 295 tonnes) and the Netherlands (271 326 tonnes).[84]

4.4.5 MOCA

The main use of MOCA is in the production of polyurethane pre-polymers/polymers to give specific properties to these materials, such as high abrasion resistance, heat, fuel and solvent resistance, high load-bearing and good mechanical and dynamic properties, to polyurethane products. The function of MOCA within the polymer may be as a curing agent, cross linker or chain extender. In some cases, it may also be used as a chemical intermediate in the production of pre-polymers. The polyurethane pre-polymers/polymers produced with MOCA are subsequently used in the production of polyurethane articles/products, e.g. castable urethane rubber products (hot cat elastomers) such as shock-absorption pads and conveyor belts.[85] According to ECHA, MOCA is manufactured and/or imported in the European Economic Area in 1 000 - 10 000 tonnes per year.[86]

4.4.6 Nickel and its inorganic compounds

Nickel is a hard, silvery-white metal. It is very widely distributed in mining, in the heavy industries (milling, foundries, refining) and in the manufacturing industries (production of stainless steel and steel alloys, production of nickel alloys, hot cutting and welding, nickel plating, chemical production and mixing, manufacture of catalysts, manufacture of nickel-cadmium batteries, manufacture of coins, jewellery, pigments, and powders). Nickel species relevant for occupational exposure include metallic nickel, poorly soluble nickel species such as oxides and sulphides as well as water soluble nickel salts.[87] According to ECHA, Nickel is manufactured and/or imported in the European Economic Area in more than 100 000 tonnes per year.[88]

4.4.7 Acrylonitrile

Acrylonitrile is a colourless liquid, which is produced in a catalytic reaction in closed systems. It is used as an intermediate, mainly in the production of fibres and

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83 SCOEL (2016): Recommendation from the Scientific Committee on Occupational Exposure Limits for Formaldehyde. SCOEL/REC/125. Available at: https://circabc.europa.eu/sd/a/2882e9bc-d52e-4944-ac08-974b43957ed2/REC-125%20Formaldehyde.pdf

84 Eurostat (2017): Production statistics, manufactured goods. Available at: http://ec.europa.eu/eurostat/web/prodcom/data/database

85 RPA (2017): Second study to collect updated information for a limited number of chemical agents with a view to analyse the health, socio-economic and environmental impacts in connection with possible amendments of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

86 ECHA (2017): Substance information 4,4'-methylenebis[2-chloroaniline]. Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.002.654

87 SCOEL (2011): Recommendation from the Scientific Committee on Occupational Exposure Limits for Nickel and inorganic nickel compounds. SCOEL/SUM/85.

88 ECHA (2017): Substance information Nickel. Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.028.283

thermoplastic polymers, such as acrylonitrile-butadiene-styrene resins and styrene-acrylonitrile co-polymers for the manufacture of plastics. It is also an intermediate in the production of other organic compounds such as acrylamide and adiponitrile.[89]

According to registration data from ECHA, 1 000 000 – 10 000 000 tonnes of acrylonitrile are manufactured or imported in the European Economic Areas per year.[90]

Latest available figures for acrylonitrile from Eurostat show that in 2016 the EU-28 total production stood at 734 270 tonnes.[91]

4.4.8 Benzene

Benzene occurs in very low concentrations in the natural environment. However, it is a natural component of crude oil (up to 0.49%) and can be formed during heating and incomplete combustion of organic material. It occurs widely as a constituent of refined and unrefined petroleum, of unrefined natural gas and of light oil recovered from coal carbonisation gases. Benzene is produced in high volumes in the EU with a production volume of about 5 million tonnes. The main part of the produced benzene, about 90%, is derived from crude oil using processes such as catalytic reforming (20%), toluene hydro-dealkylation (20%) and pyrolysis of naphtha and gas oil (50%). The main source in former times, coal carbonisation, now provides less than 10% of the benzene production. The main uses of benzene are as constituent of petrol (up to 5% v/v) and as a raw material in the chemical industry for the production of ethylbenzene, styrene, cumene, cyclohexane, nitrobenzenes, alkylbenzenes, maleic anhydride and chlorobenzenes.[92]

According to ECHA, benzene is manufactured and/or imported in the European Economic Area in 1 000 000 - 10 000 000 tonnes per year.[93]

Latest available figures for benzene from Eurostat show that in 2016 the EU-28 total production stood at 6 065 015 tonnes.[94]

4.4.9 Diesel engine exhaust emissions

As regards diesel engine exhaust emission, the European Trade Union Confederation requested in its reply to the 1st phase of the Social partner Consultation, to include this "substance" in the directive in both, Annex I (as process generated substance) and Annex

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89 SCOEL (2003): Recommendation from the Scientific Committee on Occupational Exposure Limits for Acrylonitrile. SCOEL/SUM/104.

90 ECHA (2017): Substance information Acrylonitrile. Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.003.152

91 Eurostat (2017): Production statistics, manufactured goods. Available at http://ec.europa.eu/eurostat/web/prodcom/data/database

92 SCOEL (1991): Recommendation from the Scientific Committee on Occupational Exposure Limits for Benzene. SCOEL/SUM/140.

93 ECHA (2017): Substance information Benzene. Available at: https://echa.europa.eu/substance-information/-/substanceinfo/100.000.685

94 Eurostat (2017): Production statistics, manufactured goods. Available at http://ec.europa.eu/eurostat/web/prodcom/data/database

III with a value of 50 µg/m³ calculated on the basis of the concentration of elemental carbon. This proposal is based on a value recently adopted in Germany.

However, it has to be said that diesel engine exhaust emissions is a complex issue for example in terms of defining exposure and identifying adequate measurement methods. This is the reason why the Commission is continuing its efforts to find the most appropriate action.

According to SCOEL[95], diesel engine exhaust emissions are mixtures of hundreds of chemical compounds, which are emitted partly in the gaseous phase, partly in the particulate phase. Known to be of toxicological relevance with regard to their carcinogenicity are for example aldehydes like formaldehyde, acetaldehyde, or acrolein, benzene, 1,3-butadiene, toluene, and polycyclic aromatic hydrocarbons (PAH) and nitro-PAH and particles of different sizes.

Diesel engine exhaust emissions vary in their chemical composition and particle size distribution depending on engine types, engine operating conditions, fuel formulations, lubricating oil, additives, and emission control systems. In order to take this fact into account, at least two approaches are being explored – to address this mixture as a process generated substance or to take a component-specific approach. Progress was however insufficient to include diesel engine exhaust emissions in this analysis.

In addition, the qualitative and quantitative composition of the diesel engine exhaust emissions has changed during the last years, beginning from the early 1990s, due to the introduction of stringent emission regulations in the EU. This triggered the development and application of new technology for diesel engines with changes in (the composition of) diesel particulate matter and gaseous constituents in the exhaust. [96]

Technological progress is also reflected at EU level in Regulation (EU) 2016/1628[97] on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery.

A proposal for an OEL for Diesel Exhaust Emissions should take all the above mentioned aspects into account.

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95 SCOEL (2016) Opinion 403 on Diesel Engine Exhaust, adopted in December 2016.

96 SCOEL (2016) Opinion 403 on Diesel Engine Exhaust, adopted in December 2016. Available at: https://circabc.europa.eu/sd/a/c5a2cbe0-dbca-477f-988c-65416e07ae25/OPIN-403%20Diesel%20Engine%20Exhaust.pdf

97 Regulation (EU) 2016/1628 of the European Parliament and of the Council of 14 September 2016 on requirements relating to gaseous and particulate pollutant emission limits and type-approval for internal combustion engines for non-road mobile machinery, amending Regulations (EU) No 1024/2012 and (EU) No 167/2013, and amending and repealing Directive 97/68/EC.

5 CONCLUSIONS

The analysis demonstrates that the availability of OELs is varying in Member States for the substances considered in this report. A number of Member States have established national limit values for specific carcinogens, others have not set any limit values for the substances analysed in this document.

If national OELs have been set, the values often differ by orders of magnitude, leading not only to unequal workers protection, but also to complex socio-economic considerations for companies operating across the EU.

The setting of EU-wide OELs reflecting the latest available scientific evidence is an effective way to ensure a minimum level of workers protection in all Member States and would, at the same time contribute to level playing field.

Establishing new limit values would provide a common reference point for employers, workers and labour inspectors enforcing the implementation of the CMD.

In the first phase consultation the Social Partners presented diverse views with regard to the optimal way of setting EU OELs and respective values. However, they agree that binding OELs at EU level are beneficial for workers, businesses and the society in general and urge the Commission to proceed with the process aiming at amending the CMD.

The Commission considers setting of EU wide limit values for the exposure to the carcinogens analysed in this document is a significant element in the fight against occupational cancer as set out in the Strategic Framework on Health and Safety at Work 2014-2020[98].

The continued establishment of new limit values, as well as the revision of existing ones, implements the Commission Communication of 10 January 2017: "Safer and Healthier Work for All - Modernisation of the EU Occupational Safety and Health Legislation and Policy" [99], highlighted by President Juncker in his 2016 'Letter of intent' as a key priority for the Commission[100] towards 'A deeper and fairer internal market with a strengthened industrial base'.

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98 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on an "EU Strategic Framework on Health and Safety at Work 2014-2020"
Available at: http://ec.europa.eu/social/BlobServlet?docId=11828&langId=en

99 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. Available at: http://ec.europa.eu/social/main.jsp?langId=en&catId=89&newsId=2709

100 Juncker, J.-C. (2016): State of the Union 2016.
Available at: https://publications.europa.eu/en/publication-detail/-/publication/c9ff4ff6-9a81-11e6-9bca-01aa75ed71a1/language-en/format-PDF/source-30945725

6 ANNEX 1

OELs in EU Member States

Current Binding OELs in EU Member States					
Member State	**Cadmium and inorganic compounds**	**Beryllium and inorganic beryllium compounds**	**Arsenic acid and its salts**	**Formaldehyde**	**MOCA**
Austria	0.03 mg/m^3 (manufacture of batteries, thermic extraction of zinc, lead and copper, welding of Cd containing alloys) 0.015 mg/m^3 (other uses)	5 µg/m^3 (inhalable) grinding of Be-metal and its alloys 2 µg/m^3 (inhalable) fraction for the rest	0.1 mg/m^3 (arsenic acid and its salts and arsenic and compounds, except arsine, as arsenic, inhalable aerosol)	0.6 mg/m^3 (=0.5ppm)	0.02 mg/m^3
Belgium	0.01 mg/m^3 (total dust) 0.002 mg/m^3 (respirable particles)	2 µg/m^3 (inhalable)	0.1 mg/m^3 (for arsenic and its inorganic compounds), 0.01 mg/m^3 (for arsenic and compounds, except arsine, as arsenic, total dust)	-	0.11 mg/m^3 (0.01ppm)
Bulgaria	0.05 mg/m^3	2 µg/m^3	0.05 mg/m^3	1 mg/m^3	-
Croatia	-	2 µg/m^3	-	-	-
Cyprus	-	2 µg/m^3	-	-	-
Czech Republic	0.05 mg/m^3	1 µg/m^3	0.1 mg/m^3	0.5 mg/m^3	-
Denmark	0.005 mg/m^3 (cadmium and cadmium compounds as total dust except CdO fume and CdS pigments)	1 µg/m^3	0.01 mg/m^3 (arsenic and compounds, except arsine, as arsenic, total dust) 1 mg/m^3 (calcium arsenate)	0.4 mg/m^3 (=0.3ppm)	0.11 mg/m^3 (=0.01ppm)
Estonia	0.05 mg/m^3 (total dust) 0.01 mg/m^3 (respirable dust)	2 µg/m^3	0.03 mg/m^3 (for arsenic and its inorganic compounds)	0.6 mg/m^3 (=0.5ppm)	-
Finland	0.02 mg/m^3 (inhalable) (and cadmium oxide fume = 0.01 mg/m^3)	0.1 µg/m^3 (inhalable)	0.01 mg/m^3 (arsenic acid and its salts, as As, total dust)	0.37 mg/m^3 (=0.3ppm)	0.11 mg/m^3 (=0.01 ppm)
France	0.05 mg/m^3 (cadmium and cadmium compounds as total dust except CdO fume and CdS pigments)	2 µg/m^3 (inhalable)	0.2 mg/m^3	0.5ppm	0.22 mg/m^3 (=0.2ppm)
Germany	0.001 mg/m^3	0.06 µg/m^3	8.3 µg/m^3 + (arsenic and	0.37 mg/m^3 (=0.3ppm)	-

Current Binding OELs in EU Member States					
Member State	**Cadmium and inorganic compounds**	**Beryllium and inorganic beryllium compounds**	**Arsenic acid and its salts**	**Formaldehyde**	**MOCA**
	(inhalable) +	(respirable) 0.14 µg/m^3 (inhalable)	compounds, except arsine, as arsenic, inhalable fraction)		
Greece	-	5 µg/m^3	-	-	-
Hungary	0.015 mg/m^3 (cadmium and cadmium compounds as total dust except CdO fume and CdS pigments)	2 µg/m^3	-	0.6 mg/m^3	-
Ireland	0.01 mg/m^3 (cadmium and cadmium compounds as total dust except CdO fume and CdS pigments) 0.002 mg/m^3 (same as above, respirable) 0.025 mg/m^3 (cadmium oxide, respirable dust) 0.03 mg/m^3 (cadmium sulphide and cadmium sulphide pigments, respirable fraction)	0.2 µg/m^3 (total particulate)	0.01 mg/m^3 (arsenic and compounds, except arsine, total dust)	2.5 mg/m^3 (=2ppm)	0.005 mg/m^3
Italy	-	-	-	-	-
Latvia	0.01 mg/m^3 (total dust)	1 µg/m^3	0.01 mg/m^3	0.5 mg/m^3	-
Lithuania	0.05 mg/m^3 (inhalable fraction) and 0.01 mg/m^3 (respirable fraction)	2 µg/m^3	0.03 mg/m^3 (arsenic and its inorganic compounds)	0.6 mg/m^3 (=0.5ppm)	-
Luxembourg	-	-	-	-	-
Malta	-	2 µg/m^3	-	-	-
Netherlands	0.005 mg/m^3 (CdO, fume or respirable dust, CdCl2, calculated as Cd)	-	0.05 mg/m^3 (water insoluble) 0.025 mg/m^3 (water soluble)	0.15 mg/m^3	0.02 mg/m^3
Poland	0.01 mg/m^3 (cadmium & cadmium compounds as total	0.2 µg/m^3 (total particulate)	0.01 mg/m^3 (arsenic and compounds, except arsine, total dust)	0.5 mg/m^3	0.02 mg/m^3

Current Binding OELs in EU Member States					
Member State	**Cadmium and inorganic compounds**	**Beryllium and inorganic beryllium compounds**	**Arsenic acid and its salts**	**Formaldehyde**	**MOCA**
	dust except CdO fume & CdS pigments) 0.002 mg/m^3 (respirable)				
Portugal	-	2 µg/m^3	-	-	0.01ppm
Romania	-	2 µg/m^3	-	-	0.22 mg/m^3
Slovakia	0.03 mg/m^3 (battery production, heat extraction of zinc, lead and mercury, cadmium alloys welding) 0.015 mg/m^3 (other)	Metal and alloys: 5 µg/m^3 Other: 2 µg/m^3 (both inhalable)	0.1 mg/m^3	-	0.02 mg/m^3
Slovenia	-	Grinding: 5 µg/m^3 Other: 2 µg/m^3 (both inhalable)	0.1 mg/m^3	-	0.02 mg/m^3
Spain	0.01 mg/m^3 (inhalable fraction) 0.002 mg/m^3 (respirable fraction)	0.2 µg/m^3 (inhalable)	0.1 mg/m^3 (arsenic acid and its salts) 0.01 mg/m^3 (arsenic and compounds, except arsine, total dust)	-	0.1 mg/m^3 (=0.01ppm)
Sweden	0.02 mg/m^3 (cadmium & cadmium compounds as total dust except CdO fume & CdS pigments) 0.005 mg/m^3 (respirable dust)	2 µg/m^3 (total particulate)	0.01 mg/m^3 (arsenic and compounds, except arsine, total dust)	0.37 mg/m^3 (0.3ppm)	*
United Kingdom	0.025 mg/m^3 (cadmium and cadmium compounds as total dust except CdO fume and CdS pigments) 0.03 mg/m^3 (cadmium sulphide and cadmium sulphide pigments)	2 µg/m^3 (inhalable)	0.1 mg/m^3 (arsenic and compounds, except arsine and lead arsenate, total dust)	2.5 mg/m^3 (=2ppm)	0.005 mg/m^3
+ In Germany, this concentration is not regarded as a fixed OEL (AGS; TRGS 910; https://www.baua.de/DE/Angebote/Rechtstexte-und-Technische-Regeln/Regelwerk/TRGS/pdf/TRGS-910.pdf?__blob=publicationFile&v=4), but as an upper limit, i.e. "tolerable risk level": usually 4:1000 excess risk. However, exposures below the "tolerable risk level" but above the "acceptable risk level" need to be minimised in order to avoid cancer risk.					

Current Binding OELs in EU Member States					
Member State	Cadmium and inorganic compounds	Beryllium and inorganic beryllium compounds	Arsenic acid and its salts	Formaldehyde	MOCA
*Handling of MOCA requires authorisation from the Swedish Work Environment Authority.					

7 ANNEX 2

Exposure limit values (mg/m^3) in other jurisdictions outside the European Union

	Australia	**Canada**	**China**	**Japan**	**South Korea**	**Switzer-land**	**USA**
MOCA	0.22	0.22 (Quebec) 0.005 (Ontario)	n.a	0.005	0.11	0.02	0.003 (NIOSH)
Formaldehyde	1.2	n.a	n.a	0.12	0.75	0.37	n.a

8 ANNEX 3

Estimated numbers of workers exposed to formaldehyde above background levels in the European Union

Industry, occupational activity[101]

Manufacture of furniture and fixtures, except primarily of metal	179 000
Medical, dental, and other health and veterinary services	174 000
Manufacture of wearing apparel, except footwear	94 000
Manufacture of wood and wood and cork products, except furniture	70 000
Personal and household services	62 000
Construction	60 000
Manufacture of textiles	37 000
Iron and steel basic industries	29 000
Manufacture of fabricated metal products, except machinery	29 000
Manufacture of other non-metallic mineral products	23 000
Manufacture of machinery, except electrical	20 000
Manufacture of industrial chemicals	17 000
Manufacture of other chemical products	17 000
Manufacture of plastic products not classified elsewhere	16 000
Agriculture and hunting	16 000
Manufacture of paper and paper products	13 000
Printing, publishing and allied industries	13 000
Wholesale and retail trade and restaurants and hotels	13 000
Manufacture of transport equipment	11 000
Manufacture of electrical machinery, apparatus and appliances	10 000
Manufacture of footwear	9 000
Manufacture of glass and glass products	8 000

[101] IARC (2012) Monograph: Formaldehyde. Available at: http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-29.pdf

Research and scientific institutes	7 000
Non-ferrous metal basic industries	6 000
Manufacture of leather and products of leather or of its substitutes	6 000
Beverage industries	4 000
Manufacture of instruments, photographic and optical	4 000
Other manufacturing industries	3 000
Food manufacturing	3 000
Crude petroleum and natural gas production	2 000
Manufacture of rubber products	4 000
Financing, insurance, real estate and business services	3 000
Education services	2 000
Sanitary and similar services	2 000
Services allied to transport 2000	
Manufacture of miscellaneous products of petroleum and coal	1 000
Other industries	2 000
Total (all industries)	971 000

9 ANNEX 4 – LIST OF ACRONYMS

ACSH	Advisory Committee on Safety and Health at Work
CBD	Chronic Beryllium Disease
CCA	Chromium Copper Arsenate
CEEMET	Council of European Employers of the Metal, Engineering and Technology-based industries
CESI	European Confederation of Independent Trade Unions
CLP	Classification, Labelling and Packaging Regulation (EC) 1272/2008
CMD	Carcinogens and Mutagens Directive
DECOS	Dutch Expert Committee on Occupational Safety
ECEG	European Chemical Employers Group
ECHA	European Chemicals Agency
EFBWW	European Federation of Building and Woodworkers
ETUC	European Trade Union Confederation
EU	European Union
EU-OSHA	European Agency for Safety and Health at Work
IARC	International Agency for Research on Cancer
IOM	Institute of Occupational Medicine
IPCS	International Program on Chemical Safety
MOCA	4,4'-Methylene-bis(2-chloroaniline)
NACE	**N**omenclature statistique des **a**ctivités économiques dans la **C**ommunauté

	européenne (Statistical classification of economic activities in the European Community)
Ni-Cd	Nickel-Cadmium
OELs	Occupational Exposure Limit values
OSH	Occupational Safety and Health
RAC	Risk Assessment Committee
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) 1907/2006
RIVM	National Institute for Public Health and the Environment
SCOEL	Scientific Committee on Occupational Exposure Limits
SMEs	Small and Medium-sized Enterprises
STEL	Short Term Exposure Limit
TFEU	Treaty on the Functioning of the EU
TWa	Time-weighted average
UEAPME	European Association of Craft Small and Medium-sized Enterprises
WHO	World Health Organisation
WPC	Working Party on Chemicals