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European Commission

INCEPTION IMPACT ASSESSMENT	
TITLE OF THE INITIATIVE	**Protection of workers from the risks related to carcinogens or mutagens**
LEAD DG – RESPONSIBLE UNIT	DG EMPLOYMENT, SOCIAL AFFAIRS AND INCLUSION (DG EMPL) – UNIT B.3
LIKELY TYPE OF INITIATIVE	Directive
INDICATIVE PLANNING	April 2018
ADDITIONAL INFORMATION	http://ec.europa.eu/social/main.jsp?catId=716&langId=en

This Inception Impact Assessment aims to inform stakeholders about the Commission's work in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options. The Inception Impact Assessment is provided for information purposes only and its content may change. This Inception Impact Assessment does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content.

A. Context, Problem definition and Subsidiarity Check

Context

Ensuring high social and employment standards are among the key political goals of this Commission, as confirmed in the European Pillar of Social Rights[1]. In the specific area of occupational safety and health the Commission identified the need to step up the fight against occupational cancer through legislative proposals accompanied by increased guidance and awareness-raising among the top three priorities for action.[2]

The Carcinogens and Mutagens Directive (CMD)[3], the Chemical Agents Directive[4], and the Asbestos Directive[5] are the main pieces of a comprehensive legal framework for the protection of workers from exposure to carcinogens and mutagens category 1A and 1B and/or any hazardous chemicals based on Article 153 of the TFEU.

In addition, Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals ('REACH')[6] based on Article 114 of the TFEU, is further improving occupational safety and health by providing better information on chemicals, by establishing new channels of communication between employers and suppliers and by identifying and controlling exposure to chemicals which pose particular risks to human health and the environment.

Next to some general minimum requirements, the CMD sets occupational exposure limit values (OELs) for the inhalation route of exposure for particular carcinogens. Selected on criteria like proven carcinogenic and other adverse health effects, existing recommendations by the Scientific Committee on Occupational Exposure Limits (SCOEL) or opinions developed by the Committee for Risk Assessment (RAC) of the European Chemicals Agency, the Commission, in two recent initiatives[7], has proposed to include two additional process-generated

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1 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions establishing a European Pillar of Social Rights (COM/2017/0250 final, 26.04.2017).

2 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

3 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (codified version) (Text with EEA relevance) (OJ L 158, 30.4.2004, p. 50). A first version of the Carcinogens and Mutagens Directive was adopted by the Council in 1990 (Directive 90/394/EEC). The Directive was amended first in 1997 (97/42/EC) and then in 1999 (99/38/EC), when it was extended to mutagens. For the purposes of simplification and clarity, Directive 90/394 and its subsequent amendments were repealed and codified by Directive 2004/37.

4 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11–23)

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

6 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 (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

7 COM(2016)248 and COM(2017)11.

substances (PGS), to revise two existing OELs and to introduce 16 new OELs. However, workers across Europe can potentially be exposed to yet additional substances[8], and for five of them (two individual: formaldehyde and 4,4'-Methylene-bis(2-chloroaniline) (MOCA) and three groups of carcinogenic substances: cadmium and its inorganic compounds, beryllium and its inorganic compounds and arsenic acid and its salts) new scientific evidence is available which allows the Commission to present the next proposal for new OELs for these substances.

Problem the initiative aims to tackle

Problem I: Exposure of workers to carcinogens represents a significant risk to workers' health

Occupational cancer is the first cause of work-related deaths in the EU and remains a major challenge[9]. It is primarily caused by exposures to carcinogenic substances. 53% of annual occupational deaths are attributed to cancer, compared to 28% for circulatory diseases and 6% for respiratory diseases[10]. According to a 2016 report[11], 91 500 – 150 500 people were newly diagnosed with cancer in 2012, caused by past exposure to carcinogenic substances at work. As stated in the same report, 57 700 –106 500 people died in 2012 as a result of a work-related cancer. The most recent estimates reconfirm that cancer is the biggest killer in the occupational strand with 106 307 fatal cases per year in EU28, followed by circulatory illnesses with 49 462 cases.[12]

Problem II: The Carcinogens and Mutagens Directive is not up-to-date considering most recent information

For a number of substances the SCOEL or RAC have derived recently recommendations or opinions, respectively. This concerns the following substances or groups of substances: formaldehyde[13], beryllium and inorganic beryllium compounds[14], cadmium and its inorganic compounds[15], MOCA[16], and arsenic acid and its inorganic salts[17].

According to several sources[18,19,20] the total number of workers exposed to these substances is estimated to be around 1 400 000.

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.

Problem III: Lack of OELs has negative consequences for workers and their families as well as for businesses and social security systems across the EU

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

The lack or high level of national OELs for some substances, not only leads to inadequate protection for EU workers but has also negative consequences for the internal market, as businesses which decide to establish in Member States with less stringent levels (i.e. with absent or higher OELs) have a competitive advantage.

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8 According to a publication of the European Trade Union Institute, at least 50 chemicals are relevant for workers exposure via inhalation at a considerable number of workplaces in Europe https://www.etui.org/content/download/22577/188583/file/Carcinogens%2C+binding+limits+workers%27+exposure+Wriedt+R+136+Web+version+2016.pdf

9 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.

10 European estimates of work-related injury and ill health, Work-related Illnesses Identification, Causal Factors and Prevention Safe Work — Healthy Work — For Life, Takala, J., Workplace Safety and Health Institute, Singapore, presentation to EU Presidency Conference, Athens, June 2014.

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

12 EU-OSHA, The economics of OSH, 2017, https://visualisation.osha.europa.eu/osh-costs#!/

13 https://circabc.europa.eu/sd/a/2882e9bc-d52e-4944-ac08-974b43957ed2/REC-125%20Formaldehyde.pdf

14 https://circabc.europa.eu/sd/a/33c8921a-1dbe-4410-909c-2d4c63d8fb1d/REC-175%20Beryllium%20and%20compounds.pdf

15 https://circabc.europa.eu/sd/a/13cad802-1f3c-40c0-bce4-6838cf5fc4ff/OPIN-336%20Cadmium%20and%20its%20inorganic%20compounds.pdf

16 https://echa.europa.eu/documents/10162/13641/opinion_moca_en.pdf/35756093-0eb9-e468-2ba2-786ca73c5aaa

17 https://echa.europa.eu/documents/10162/13641/opinion_arsenic_en.pdf/dd3eb795-108e-5d3a-6847-dddcc021a9dc

18 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, pp. 10–18.

19 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.

20 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.

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. According to a recent report[21], direct costs of work-related cancer in terms of healthcare and productivity losses amount at least to some 4-7 billion EUR per year; and the indirect costs may reach as much as 334 billion EUR each year. Further recent estimations reconfirm these negative consequences by indicating that the cost of work-related cancers alone amounts to EUR 119.5 billion.[12]

How will the problem evolve without the initiative?

If no action is taken, occupational cancer, as for cancer in general, will likely become a relatively more important cause of morbidity and mortality in European society, because with increasing life expectancy there will be more time for these long-latency diseases to appear. Therefore, the economic and social costs associated with these diseases will increase as a result of this development. National systems will continue to provide different standards for the protection of workers arising from the risks to exposure to carcinogens or mutagens at work. This could also lead to the distortion of the internal market by providing a potential incentive for companies to relocate their production facilities to those EU countries with the lower standard(s).

Apart from the demographic reasons, there is also information available which shows increasing demand for some of the substances subject to this initiative. Following a report published by the Commission in 2014[22], there is a rising demand for beryllium world-wide predicted at an overall rate of 1.8% per year, driven by the growing use of beryllium alloys in a wide range of industrial and electronic applications.

Subsidiarity check (and legal basis)

The Treaty on the Functioning of the EU (TFEU) 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 Directive 2004/37/EC (CMD), and the REACH Regulation. Amending the existing OSH/CMD Directive can only be done by action at EU level.

Such an amendment presents an EU added value in several aspects:

- It will amend the Directive based on the most recent scientific information on protection and prevention;
- It will improve clarity and facilitate enforcement by establishing a common reference point that can be used by employers, workers and enforcers alike to assess compliance with the general requirements of the Directive;
- It will ensure the same minimum level of protection across the EU by establishing minimum requirements for the substances envisaged in the initiative.
- The proposal will in addition reduce the scope for divergences in standards for health and safety protection of workers in Member States and as a consequence reduce the risk of different competitive conditions.

B. Objectives and Policy options

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 specific objectives are:

- To reduce occupational exposure to carcinogens and mutagens in the European Union;
- To increase the effectiveness of the EU framework by updating it on the basis of scientific expertise;
- To achieve a more balanced protection against carcinogens of workers across the EU while ensuring more clarity and level playing field for economic operators.

Baseline scenario – no EU policy change

In the absence of EU action many of the negative consequences identified will continue or even be exacerbated by the demographic and economic trends explained above.

The legislative and non-legislative options to be considered are the following:

As a legislative option, the establishment of new OELs in Annex III for the substances / group of substances subject to this initiative will be considered. For this option, recent/new scientific evidence and best practices in the Member States as well as the values proposed by the Advisory Committee on Health and Safety at Work (ACSH) (on the basis of a recommendation derived by SCOEL or an opinion of RAC) will be taken into account.

Certain substances subject to this initiative are already or will soon be covered by restrictions or authorisation requirements under the REACH Regulation. The impact of the measures under REACH will be taken into account

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

[22] Report on critical raw materials for the EU, https://ec.europa.eu/growth/sectors/raw-materials/specific-interest/critical_en

in the Impact Assessment report.

As non-regulatory alternatives, guidance documents or examples of good practice could be developed and disseminated in co-operation with the European Agency for Safety and Health at Work (EU-OSHA) and/or the ACSH and its relevant working party. This could also include the development of awareness raising campaigns for employers and workers alike on the prevention of risks arising from workers' exposure to categories 1A and 1B carcinogenic and mutagenic substances.

Voluntary industry agreements will be taken into account and evaluated with regard to their applicability across all sectors and Member States concerned.

SMEs and micro-enterprises

Possibilities for lighter regimes and/or adapted solutions for SMEs (especially for microenterprises) will be assessed where relevant. However, these types of enterprises should generally not be exempted from the scope of the initiative as their exclusion would mean that a very significant number of European workers would not be covered by health and safety at work legislation, with a clear distortion and inequality in the application of the EU legislative framework and with a risk of compromising the underlying social policy objectives and fundamental rights.

C. Preliminary Assessment of Expected Impacts

The costs and benefits of each option will be the subject of further analysis in the Impact Assessment. As employers are already obliged under the current provisions of the CMD to eliminate or reduce to a minimum the risks arising from occupational exposure to carcinogens or mutagens, the likely economic impact of the options considered above should be limited to those countries which have not or have a higher limit value than the one to be proposed.

Likely economic impacts

There will be an economic impact in those Member States (and economic operators established therein) which currently have higher OELs established for the substances subject to the initiative. Depending on the measures companies are required to take, their **costs of production** may increase. This applies also to **SMEs** that are equally subject to the CMD. SMEs could find it relatively more costly to comply with the CMD, as (1) compliance with some OELs may lead to additional overhead costs, which can only be distributed over a relatively smaller revenue base; (2) the level of expertise is frequently lower for SMEs; (3) the SMEs environment is generally more competitive and finance is more difficult to obtain, leading to shorter time horizons and fewer expenditures. Nevertheless, the proposal would also help companies addressing costs that would, otherwise, negatively affect their business prospects in the long-term. Companies would, for example, benefit from more productive employees and fewer absences.

The setting of legally-binding limit values for the specified carcinogens would also improve the functioning of the **Internal Market** by reducing further fragmentation from the adoption of possibly different OELs at national level. Although Member States are still free to choose lower OELs, internal coherence will likely be increased. In addition, it is very likely that the initiative will have an overall positive impact on **Innovation** and **Competitiveness**. The establishment of OELs often goes hand in hand with technological progress for example with regard to the development of better ventilation systems, improved measurement techniques or best practices in monitoring approaches. Competitiveness will benefit from reduced loss in productivity, higher motivation of workers that work at a safe workplace, or a better image of the product. By contrast, no significant impact on **third countries, international trade or investment** is expected. In most other jurisdictions and in our main international competitors like USA and Japan, OELs for hazardous substances are also in place, often of the same order of magnitude as in the European Union.

The Impact Assessment will look in detail into this issue and further consideration will be given to how possible negative impacts in particular for SMEs could be reduced.

Likely social impacts

This proposal should prevent workers from getting avoidable work-related cancer and adverse health effects and thus prevent unnecessary suffering, moral pain and illness. In addition, the proposal would prevent unnecessary health costs, such as private direct and indirect medical costs and rehabilitation costs, as well as reduce public healthcare spending and would so improve the sustainability of social security systems.

The quantity and quality of employment could be potentially affected and the impact assessment will explore the likelihood and scale of such potential impacts.

Likely environmental impacts

No direct environmental impacts are expected from any of the options.

Likely impacts on fundamental rights

The objectives of the proposal are consistent with the fundamental rights as set out in the EU Charter of

Fundamental Rights, in particular Article 2 (right to life) and Article 31 (Right to fair and just working conditions which respect his/her health, safety and dignity).

Likely impacts on simplification and/or administrative burden

It is not anticipated that the policy options will have a significant impact on simplification and/or administrative burden. It is not expected to have a negative impact as the aim of this initiative the introduction of new OELs at European level for a limited number of substances for which national OELs already exist in the majority of the Member States. The administrative burden of monitoring national OELs is the same as monitoring EU OELs for the same substances. If any, the impact is expected to be positive as the establishment of limit values at EU level eliminates the need for national authorities to independently evaluate each carcinogen. Moreover, the initiative should improve clarity and facilitate enforcement by establishing a common reference point that can be used by employers, workers and enforcers alike to assess compliance with the general requirements of the Directive.

D. Data Collection and Better Regulation Instruments

Impact assessment

An impact assessment is being prepared to support the preparation of this initiative and to inform the Commission's decision.

Data collection

The following data sources and Better Regulation Tools will be used in preparation of the initiative

- Scientific evidence provided by Commission expert groups
  In preparation of the initiative, Commission services will seek the advice of at least two scientific bodies (Scientific Committee on Occupational Exposure Limits and the Risk Assessment Committee of the European Chemicals Agency) involved in the derivation of limit values.
- Data collection via external studies
  A study has been launched to collect the most recent and updated information to support the initiative, in particular the preparation of the Impact assessment which is requested to accompany the Commission proposal.
- Impact Assessment
  Based amongst others on the information collected via the aforementioned consultations, the Commission services will prepare an Impact Assessment to accompany the final proposal for this initiative. Preparatory work for the impact assessment has already started.

Consultation strategy

The following consultation activities are planned:

- Social Partner Consultation:
  A two-stage Social Partner Consultation is being performed according to Article 154 of the TFEU, to cover substances envisaged for the next amendments of the Directive. These substances were not covered by previous Social Partner Consultations.
  The first stage consultation aimed at obtaining the views of the Social Partners on the possible direction of European Union action concerning a revision of Directive 2004/37/EC to enhance its relevance and effectiveness by establishing limit values.
  The first stage of the Social Partner Consultation was concluded on 30 September 2017. Based on the result of this first-stage consultation, the second stage of the consultation, which is focusing on more concrete aspects to be addressed at EU level, has been launched on 10 November 2017 and will run until 22 December 2017.
- Tripartite consultation (ACSH):
  The tripartite ACSH, composed of three full members per Member State, representing national governments, workers' and employers' organisations, is consulted on regular bases. It gives, taking into account the input of scientific bodies as well as socio-economic and feasibility factors, an opinion which is used to prepare the Commission's proposal.
- Consultation of other stakeholders (e.g. industry associations specifically concerned):
  Representatives of specific industry sectors concerned will be consulted, when necessary, to supplement the information gathered via the consultation of the members of the ACSH.
- Public consultation: Based on the broad consultation of various stakeholders, social partners and Member States' competent authorities, no public consultation on this very technical topic is foreseen.

Will an Implementation plan be established?

No.

Directive 2004/37/EC is already transposed into national legislation in all Member States, and the proposed action only requires additional technical amendment of this national legislation. Also, for PGSs, national limits exist in many Member States. Therefore an implementation plan is considered not to be necessary.