

INCEPTION IMPACT ASSESSMENT			
TITLE OF THE INITIATIVE	Legislative initiative to amend Directive 2004/37/EC on the protection of workers from the risks related to carcinogens and mutagens at work		
LEAD DG – RESPONSIBLE UNIT – AP NUMBER	DG Employment, Social Affairs and Inclusion (DG EMPL) – Unit B3	DATE OF ROADMAP	01/04/2016
LIKELY TYPE OF INITIATIVE	Directive		
INDICATIVE PLANNING	<i>Insert hyperlink to forecast report</i>		
ADDITIONAL INFORMATION	<i>Insert link to "Commission decides" or to the specific website for the initiative</i>		
<p>This Inception Impact Assessment is provided for information purposes only and can be subject to change. It does not prejudice the final decision of the Commission on whether this initiative will be pursued or on its final content and structure.</p>			

A. Context, Subsidiarity Check and Objectives

Context
<p>Ensuring a safe and healthy work environment for over 217 million workers in the EU is a strategic goal for the European Commission as reaffirmed in the Communication from the Commission on the EU Strategic Framework on Health and Safety at Work 2014 – 2020.¹ One of the main challenges identified in the EU Occupational Safety and Health (OSH) Strategy is to improve the prevention of work-related diseases by tackling existing, new and emerging risks.</p> <p>The EU legislative framework on the protection of occupational health and safety of workers (OSH Framework) represents a comprehensive, but also complex package of Directives that aims at securing the same minimum level of protection from work related health and safety risks for the workers of all EU Member States.</p> <p>The cornerstone of the OSH Framework is the Framework Directive². It introduces measures that should encourage improvements in the safety and health of workers at work. Following its adoption in 1989, 23 other theme specific Directives were adopted, mostly in the five subsequent years. One of them cover the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD).³ Further substantial improvement is still needed to further reduce occupational exposure to hazardous chemicals in general, and to carcinogenic substances in particular. According to estimates performed in a study commissioned by the European Commission,⁴ at least 20 million workers in the European Union are to a lesser or greater extent exposed to one or several of the 25 chemical agents or work under exposure situations investigated in that study. These 25 substances or exposure situations represent only around 5% of substances or exposure situations identified until August 2015 by the International Agency for Research on Cancer (IARC) of the WHO as known or probable human carcinogens (Groups 1 and 2A respectively) or possibly carcinogenic in humans (Group 2B).⁵ The CMD specifically requires the elimination or reduction to a minimum of the risks arising from occupational exposure to substances and mixtures which are identified as having the potential to cause cancer and/or mutation in humans (carcinogens and mutagens). The identification of those substances and mixtures for the purpose of the Directive is closely linked to the requirements established under Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation).⁶</p> <p>The REACH Regulation⁷ applies without prejudice to the existing EU OSH legislation and EU OSH legislation applies without prejudice to existing or future EU legislation that are more favourable to the protection of the safety and health of workers at work. REACH is complementary to OSH, further improving occupational safety</p>

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332&from=EN>

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332&from=EN>

² 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 of 29.6.1989, p. 1).

³ Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (OJ L 158, 30.4.2004, p.50).

⁴ IOM Research Project P937/100, December 2011 – Health, social-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.

⁵ <http://monographs.iarc.fr/ENG/Classification/index.php>

⁶ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures - <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1396363361882&uri=CELEX:02008R1272-20110419>

<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1396363361882&uri=CELEX:02008R1272-20110419>

⁷ Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1).

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.

Ensuring high social and employment standards are among the key political goals of this Commission. Occupational Health and Safety rules on the protection against carcinogens that are up-to-date, ensuring that workers are adequately protected, is feeding into the Pillar of Social Rights announced in the Commission's Work Programme 2016 and on which a consultation was launched on 8 March 2016 with the aim of enhancing the Member States' employment and social performance and promote convergence. The amendment of the CMD is meant to contribute directly to the achievement those objectives and deliver on the objective of "a social Triple A rating for Europe. Occupational Exposure Limit Values (OELs)⁸ will be proposed for a limited number of recognised human carcinogens. In addition, it is proposed to bring within the scope of the Directive a limited number of so-called process generated substances (PGSs), which are internationally recognised as human carcinogens in other countries (e.g. the USA) or by for example an international organisation like IARC but are not classified under the current EU system (CLP Regulation), as a consequence of which workers exposed to these substances are protected by neither the CMD nor the REACH Regulation. Two amendments of the CMD are envisaged for this initiative to cover four of these PGSs: respirable crystalline silica, diesel engine exhaust emissions, mineral oils and used engine oils, and rubber process dust and fumes. For some of them, also an OEL in Annex III is intended to be proposed (e.g. respirable crystalline silica), for the others, it is currently only envisaged to establish an entry in Annex I, until robust scientific data is available to also allow the establishment of an OEL.

It is envisaged to divide the initiative in 2 steps:

- A 1st amendment of the CMD will aim to extend its scope as regards PGSs and establish OELs for a number of substances. Currently, Annex III to the CMD contains three OELs, out of which two (hardwood dust and vinyl chloride monomer) need to be revised due to new scientific evidence.
- A 2nd amendment of the CMD will aim to extend its scope to include additional PGSs and will establish OELs for additional substances for which only limited data is currently available pending the results of another targeted study.

In view of the high number of work-related cancers every year and the human and economic costs involved, it is considered inappropriate to postpone the amendment of the CMD Annexes until the REFIT overhaul of the Framework Directive has been finalised. This is, all the more so since the preparation of the amendment of the CMD has been ongoing since 2004 and Commission action in this area is long awaited. Possibly, the procedural streamlining could benefit additional future amendments.

With regard to the content of the initiative proposed, it will be taken into account that certain substances under the scope of the CMD either are already or will soon be covered by restrictions or authorisation requirements under the **REACH Regulation**. They both aim at controlling exposure to chemicals which pose particular risks, but REACH regulates *inter alia* the conditions for putting a substance on the market or its use, whereas the CMD regulates the employer's obligations to protect workers against those substances. The impact of the measures under REACH will be taken into account in the Impact Assessment report.

Recently, some industry stakeholders have expressed concern about the interaction between OSH and REACH authorisation. The Commission may make certain exemptions from REACH authorisation under certain conditions, including *inter alia* the existence of specific Union legislation imposing minimum requirements relating to the protection of human health for the use of a substance. The meaning of this provision – and in particular its relationship with the existence of binding OEL values for given chemical agents – has recently been clarified by the General Court.⁹ The implications of this as regards the relationship between REACH authorisation and the application of EU OSH legislation are being assessed by the concerned Commission services.

The use of REACH and OSH risk controls in parallel has potential benefits for worker protection. It should be noted that this OSH/REACH relationship does not have direct bearing on the present initiative to amend existing and establish new entries in the annexes of the CMD.

Issue

Problem I: Exposure of workers to carcinogens is significant

⁸ In a strict sense, when referring to limits set in the CMD, the term BOELV should be used. In parallel, the term OEL is used for example when referring to limits set at the national level. In order to simplify the text, the term OEL is used to refer to any occupational exposure limit (value), whether set in EU or national legislation.

⁹ Case T-360/13 VECCO and Others v COM. This case concerned chromium trioxide (a carcinogen mainly of concern due to worker inhalation risks for which there is no OEL) and the legality of a Commission Regulation which included the substance into REACH authorisation without granting any exemption.

A study published in 2013 estimated that in 2012 cancer caused the death of 1.75 million people in the European Union (EU-27).¹⁰ For occupational cancer, meaning for the fraction of cancers attributable to working conditions, the figures vary between 4¹¹ and 8-12%.¹² Although the exact magnitude of the occupational cancer burden is uncertain, it seems likely that the situation in the majority of EU Member States is comparable to Great Britain, where it is estimated that 14,000 newly occurring cases of cancer annually and over 5% of all cancer deaths (nearly 40 times the number of workplace deaths caused by accidents in the same measurement period) are attributable to occupational exposure.

Problem II: The Carcinogens and Mutagens Directive is outdated - Annex I and III of the CMD need updating

Whether a substance or mixture is under the scope of the CMD is primarily based on its classification as a carcinogen and / or mutagen (category 1A or 1B) according to the criteria established under the CLP Regulation.

There is also a possibility to identify a substance / mixture as falling under the scope of the Directive by including it in Annex I to the Directive. This Annex covers substances, mixtures or processes (or substances / mixtures released by a process referred to in that Annex) which the EU considers should be explicitly in the scope of the Directive but which are not classified according to the CLP Regulation as carcinogens or mutagens - for example some chemical agents which are recognised by other international bodies (like the International Agency for Research on Cancer - IARC) as substances, mixtures or processes of equal concern. These substances are often referred to as process-generated substances or PGSSs.

Currently, Annex I to the CMD, in which PGSSs are listed, contains 5 entries,¹³ while a significant number of workers continue to be exposed to other PGSSs, which are currently not covered by the Directive. This concerns for example diesel engine exhaust emissions, respirable crystalline silica, refractory ceramic fibres, rubber process fume and dust, or used engine oils. According to a study commissioned by the European Commission,¹⁴ currently 3.6 million workers are exposed to diesel engine exhaust emissions, 720,000 are exposed to respirable crystalline silica, 10,000 are exposed to refractory ceramic fibres, 229,000 are exposed to rubber dust or rubber fumes, and 1 million are exposed to mineral oils as used engine oils.

Occupational exposure to these substances or mixtures (or working under conditions during which they are generated), and which are usually out of the scope of the REACH Regulation, can have serious adverse effects on human health. Exposure to diesel engine exhaust emissions is associated with an increased risk of lung cancer,¹⁵ exposure to respirable crystalline silica is associated with the development of silicosis and an increased risk of lung cancer,¹⁶ exposure to refractory ceramic fibres is associated with an increased risk of lung cancer, mesothelioma and other adverse respiratory health effects,¹⁷ exposure to rubber process fume and dust is associated with an increased risk of developing various types of cancer (bladder cancer, leukaemia, lymphopietic cancer, lung cancer, cancer of the larynx)¹⁸, and exposure to mineral oils as used engine oils is associated with skin cancer.¹⁹

In order to reduce the occupational exposure to carcinogens and mutagens, the CMD provides for a hierarchy of preventive and protective measures, amongst which the obligation of the employer to substitute these chemicals by less or non-hazardous substances, mixtures or processes as far as technically possible has the highest priority. If substitution is not technically possible, other measures to prevent exposure like working in a closed system or to reduce the number of workers potentially exposed have to be put in place by the employer. Another obligation of the employers is to ensure that national OELs set taking into account OELs listed in Annex III to the Directive shall not be exceeded.

Reviewing or setting new OELs under CMD follows a specific procedure involving seeking scientific advice and consulting the ACSH. Article 16 of the CMD, which states that scientific/technical data should be included in the basis on which OELs are set, does not determine which scientific body should be the source of such data. In

¹⁰ Ferlay, J. et al., Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012, *European Journal of Cancer*, 49 (2013), pp. 1374–1403.

¹¹ The causes of cancer: quantitative estimates of avoidable risks of cancer in the United States today, R. Doll & R. Peto, *J Natl Cancer Inst.* 1981 Jun;66(6):1191-308. <http://www.ncbi.nlm.nih.gov/pubmed/7017215>

¹² <http://www.etui.org/content/download/7515/71981/file/Occupational+cancer++the+main+challenge+for+the+new+Community+Strategy.pdf>

¹³ 1. Manufacture of auramine. / 2. Work involving exposure to polycyclic aromatic hydrocarbons present in coal soot, coal tar or coal pitch. / 3. Work involving exposure to dusts, fumes and sprays produced during the roasting and electro-refining of cupro-nickel mattes. / 4. Strong acid process in the manufacture of isopropyl alcohol. / 5. Work involving exposure to hardwood dusts.

¹⁴ IOM Research Project P937/99, May 2011 – Health, social-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.

¹⁵ http://www.iarc.fr/en/media-centre/pr/2012/pdfs/pr213_E.pdf, http://www.iarc.fr/en/media-centre/pr/2012/pdfs/pr213_E.pdf, <http://jnci.oxfordjournals.org/content/early/2012/03/05/jnci.djs034.abstract>

¹⁶ <http://monographs.iarc.fr/ENG/Monographs/vol100C/index.php>

¹⁷ <http://www.cdc.gov/niosh/docs/2006-123/pdfs/2006-123Ch1.pdf>

¹⁸ <http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-36.pdf>

¹⁹ <http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-19.pdf>

practice, the Commission and the ACSH principally seek the advice of the Scientific Committee on Occupational Exposure Limits (SCOEL), but can also refer to scientific information sourced elsewhere as long as the data is adequately robust and is in the public domain (e.g. IARC monographs or conclusions of national OEL-setting science committees). SCOEL recommends health-based OELs that describe a threshold below which adverse effects to human health are unlikely to occur. In addition, SCOEL recommendations address the scientific-technical feasibility of monitoring exposure including the availability of suitable measurement techniques.

It is possible to establish health-based OELs for the majority of hazardous substances including a number of carcinogens and mutagens. However, for certain carcinogens and mutagens it is not possible to identify a "safe" exposure level. Any exposure to such substances and mixtures – even at or below OELs established for them – potentially carries a residual risk. OELs are useful practical tools for employers to ensure an effective health and safety protection of workers which can be monitored. They are also useful tools for labour inspectors to check compliance with the legislation.

Currently, Annex III to the CMD, in which OELs are listed, contains three entries. Two of them (hardwood dust and vinyl chloride monomer) need to be revised due to new scientific evidence. For a limited number of additional substances, which are currently not covered by recently or soon to be adopted initiatives under the REACH Regulation, SCOEL recommendations exist, as well as opinions of the relevant advisory committee, representing governments and social partners, for a specific OELs for those substances should therefore be included in Annex III.

Problem III: Lack of OELs has negative consequences for workers and businesses 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 protection.

Where EU OELs are set – as for hardwood dust and vinyl chloride (5 mg/m³ and 7.77 mg/m³ respectively) – some Member States have set lower national limits, e.g. as low as 1 mg/m³ for hardwood dust and 2.5 mg/m³ for vinyl chloride.

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, because businesses located in Member States with less stringent levels (i.e. with absent or higher OELs) have a competitive advantage.

Size of the problem/s and main drivers.

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).

According to a study published in November 2013²⁰, around 8,000-8,500 deaths/year due to occupational cancer are estimated to occur in Italy, corresponding to 170,000 Potential Years of Life Lost and more than 16,000 Potential Years of Working Life Lost, leading to around 360,000,000 euros in indirect economic loss. Health care costs of occupational cancer are estimated at 456,000,000 euros. Similar figures can be expected for other European countries. However, due to the long latency period of up to 60 years between the time when the exposure to a particular carcinogen takes place and the clinical appearance of the disease, it is difficult to predict or estimate the real impact with regard to both, the potential health risks and the potential associated costs.

Who is affected and how (stakeholder mapping)

If no action is taken, workers will continue to be exposed to carcinogenic and mutagenic substances at the workplace as a consequence of which a high number of workers will continue to get cancer and die as a result of the disease.

Via their social security systems, Member States will continue to cover the costs associated with the treatment of occupational cancer, as well as covering the costs associated with early retirements and compensating recognised occupational diseases.

Economic operators will continue to face loss in productivity by losing skilled workers, being forced to invest in training for unskilled workers, and by being faced (at least in some Member States) with higher contributions to social security systems.

Problem at EU level and how it is likely to develop in the future in case no policy action is taken

In the majority of the EU Member States, national limit values for the substances subject to this initiative exist. However, the values sometimes differ, due to for example different methodologies or different data used to derive limit values, and therefore lead to different levels of health and safety protection of workers across the European Union. When OELs are established under the CMD at EU level, EU Member States have a certain

²⁰ Am J Ind Med. Am J Ind Med. 2013 Nov;56(11):1272-9. doi: 10.1002/ajim.22224. Epub 2013 Jun 24.

room for manoeuvre when transposing and implementing these as OELs: they are obliged to establish a corresponding national limit value, from which they can deviate to a lower, more protective, but not to a higher value. By adopting binding OELs under the CMD, particular minimum health and safety standards for workers are established throughout the EU.

In addition, even if OELs do not represent a safe level of exposure, employers and enforcement authorities alike often consider them as values that at least have to be achieved at the workplace and they provide a useful benchmark for employers when selecting appropriate risk management measures to further reduce the occupational exposure.

In the specific case of respirable crystalline silica (RCS) the social partners, representing originally 17, now 18 European industry sectors, signed in 2006 a European multi-sector Social Dialogue Agreement on Workers' Health Protection through the Good handling and Use of Crystalline Silica and its products (NEPSI). According to the reporting exercise of 2012, progress has been made within the signatory sectors of NEPSI for example with regard to the number of employees estimated to be potentially exposed to RCS and covered by risk assessment (8% more than 2010), or by exposure monitoring (8.0% more than 2008). However, this agreement does not apply to all sectors where exposure to RCS occurs, in particular not to the construction sector, which according to a study on the burden of occupational cancer in Great Britain²¹, is the sector which has the largest burden of occupational cancer amongst the industrial sectors. A study commissioned by the European Commission²² estimated the number of cancer registrations and deaths that are expected to occur if no action is taken over the next 60 years. Among the most relevant effects, there would be around 440,000 deaths from exposure to respirable crystalline silica and a similar number of new cancer cases. The related health costs would range between €192 billion and €493 billion. 24,000 new cases and 17,000 deaths are expected over the next 60 years if no action is taken regarding exposure to hexavalent chromium. Exposure to hard wood dust, which potentially concern 3 million workers in Europe, will cause 12,000 cases of cancer and 5,000 deaths over the next 60 years, with estimated health costs between €3 and 16 billion.

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. In addition, 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).

Subsidiarity check

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 and after a two-stage consultation of the social partners (management and labour) in accordance with Article 154 TFEU. Furthermore, action at EU level will set particular common minimum requirements for the protection of the health and safety of workers in all Member States. If the proposed amendments are not set at EU level as particular minimum requirements, there is the risk that disparities in standards for health and safety protection of workers in Member States will continue to exist or even increase. This would undermine the establishment of a level playing field for economic operators in the EU by confronting them with different competitive conditions.

Main 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 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.

B. Option Mapping

Baseline scenario – no EU policy change

²¹ Rushton, L. et al. Occupation and cancer in Britain. [Br J Cancer](#). Br J Cancer. 2010 Apr 27;102(9):1428-37

²² IOM Research Project P937/99, May 2011 – Health, social-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.

No action at EU level to amend Directive 2004/37/EC will mean that the issues identified above remain unresolved.
Improving implementation and enforcement of existing legislation or doing less/simplifying existing legislation
<p>No implementation or enforcement problems have been identified.</p> <p>Any such problem will be discussed and resolved at the level of the EU Senior Labour Inspectors Committee (SLIC), which has the mandate to assist the Commission on all problems related to the enforcement by the Member States of EU law on health and safety at work²³.</p> <p>Not acting is not an option due to the arguments already outlined in previous sections.</p> <p>The absence of a limit value for a particular substance will increase uncertainty for economic operators, in particular for SMEs, with regard to their obligations under the Directive and hinder the work of enforcement authorities compared to a limit value being established.</p> <p>It should also be noted that the standards of legal control established in the Carcinogens CMD Annexes I and Mutagens Directive are strict for all in-scope carcinogens, whether or not entries in Annex I (process generated substances) or Annex III (binding OELs) have been established or amended. Employers must prevent exposure to occupational carcinogens where risks occur, substitute for less-hazardous alternatives where possible, otherwise use 'closed system' containment, and in any case reduce worker exposure to as low a level as is technically possible. The proposed amendments therefore do not directly affect the legal standard of control, which is in any case for minimised exposure.</p> <p>The establishment of additional OELs is intended to facilitate implementation and enforcement.</p>
Amendment of current Directive
<p>The option to be considered is that of amending the Directive as follows:</p> <ul style="list-style-type: none"> - Extending the scope of the CMD to a number of PGSs by including it in Annex I; - Revising existing OELs in Annex III, by taking recent/new scientific evidence and best practices in the Member States into account and establishing new OELs in Annex III for a number of carcinogens currently not included in that Annex. In this context, for each of the chemical agents a value proposed by the ACSH (in most cases on the basis of a SCOEL recommendation) could be considered. Where appropriate and depending on specific characteristics of the agents, flanking options of relatively higher and/or lower OELs could also be taken into consideration.
Alternative policy instruments
<p>Non-regulatory alternatives in the form of 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 Advisory Committee on Safety and Health at work (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.</p> <p>However, it has to be kept in mind that similar tools have already been developed by EU-OSHA and it is questionable if further guidance documents would improve the situation to the extent necessary.</p>
Alternative/differentiated scope
<p>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.</p>
Options that take account of new technological developments
<p>OELs cannot be derived in a digital way. Scientific expert knowledge and analysis is needed. However, all processes leading to the development of OELs at the EU level are transparently performed and reports are published and available via the internet.</p>
Preliminary proportionality check
<p>The initiative is proportionate for the following reasons:</p> <ul style="list-style-type: none"> - It does not go beyond what is necessary to achieve the general and more specific objectives outlined above; - The choice of the instrument (directive) is fully justified due to the fact that the instrument currently in place is also a directive, and noting the legal basis for worker protection policy is TFEU Art 153 which provides for use of minimum standard Directives;

²³ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008D0823&from=EN> / <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008D0823&from=EN>
<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01995D0319-20100101&from=EN>

- The potential administrative costs for national governments, regional or local authorities and economic operators are considered to be minimal and commensurate with the objective to be achieved due to the fact that for most of the substances subject to the proposal, Member States have already implemented national OELs; even if the level of these OELs might differ, the administrative cost to enforce or comply with another OEL should not be different from the administrative costs currently in place.
- The Union initiative does not prevent national initiatives to further protect workers' health and safety.

C. Data Collection and Better Regulation Instruments

Data collection

Further to the social partner consultations described below, in order to gather relevant information, the Commission put to tender two studies:

- The first one (signed in April 2009) mainly dealt with the socioeconomic, health and environmental impacts of amending the CMD by introducing up to three possible OELs for 25 substances in Annex III to the Directive (final report submitted to the Commission in May 2011). This study will be referred to further below as the IOM study.
- The second one (signed in December 2010) evaluated the potential socioeconomic, health and environmental impact of the possible inclusion of substances toxic to reproduction, category 1A and 1B within the scope of the Directive (final report submitted to the Commission in February 2013). This study will be referred to further below as the RPA study.

An in-depth analysis by the Commission services of the IOM study revealed for some agents some data gaps regarding the economic impacts and impacts on the competitiveness of the EU. Two additional studies to provide supplementary data are under way.

The RPA study did not sufficiently clarify the potential costs and benefits of extending the scope of the CMD to substances toxic to reproduction. This potential option will therefore not be included in the amendments of the CMD scheduled for 2016.

Consultation approach

Objectives of the consultation

The objective of the consultation linked to this initiative is to ensure that across a series of consultation activities all relevant stakeholders have been given an opportunity to express their views on all elements relevant for the preparation of the legislative proposal and its Impact Assessment, in particular to make sure that the amendments reflect changes in scientific knowledge and technical progress.

All the various consultation activities described below have already been completed.

Identification and mapping of stakeholders

The legal basis of the Directive is Article 153 TFEU, so the **Social Partner's** must have the opportunity under Article 154 TFEU to be consulted and make a proposal.

ACSH: a tri-partite body: consisting of three full members per Member State, representing national Governments, trade unions and employers organisations. The objective of Council decision 2003/C 218/01 for setting up this committee was to streamline the consultation process

SCOEL: a scientific committee giving recommendations on exposure of limit values. Consisting of 21 scientific experts.

Other stakeholders: Workshops related to topics with Member States, social partners, scientists, the European Agency for Safety and Health at Work (EU OSHA), the Senior Labour Inspectors Committee (SLIC) and the World Health Organisation (WHO).

Identification of appropriate consultation exercises

Social partners' 2-stage consultation as set out in Article 154 TFEU: The Commission started work intended to amend the Directive to reflect changes in scientific knowledge and technical progress by launching the first and second stage of the social partners' consultation according to Article 154 of the TFEU in April 2004 and March 2007 respectively.

The main proposals among others as set out in the second stage of the social partners' consultation were:

- The addition of a limited number of process generated substances to Annex I, thereby bringing these substances within the scope of the Directive;
- The revision of the OELs for the three substances already listed in Annex III;
- New OELs for a limited number of carcinogenic substances to be added to Annex III.

Thereafter, the Commission put to tender the two studies (IOM and RPA) mentioned in the previous chapter C (data collection).

ACSH: Advisory Committee on Safety and Health's Working Party on Chemicals. In June 2011, the Commission started to consult the tri-partite Working Party "Chemicals at the work place" (WPC) of the Advisory Committee on Safety and Health at Work (ACSH) on the possible amendment of the CMD to insert new and revise existing OELs on the basis of the final report of the IOM study. The discussion focussed mainly on the socioeconomic impact and the technical feasibility of the revision of the OELs for the three substances already included in Annex III to the Directive and the inclusion of additional PGSs in Annex I and new OELs for these and other substances in Annex III to the Directive.

Following the discussions in the WPC, the ACSH adopted in December 2012, May 2013 and November 2013 one opinion and two supplementary opinions, in which a common position and – if considered necessary by each interest group – specific comments were provided on

- the inclusion of certain PGSs in Annex I to the Directive; and
- the proposed OELs (revised for existing OELs / new for substances not yet included in Annex III).

SCOEL: The Commission has consulted the Scientific Committee on Occupational Exposure Limits (SCOEL) for the substances subject to the initiative.

Other stakeholders:

A workshop was held in Berlin in 2012 on Carcinogens and Work-related Cancer organised by the EU-OSHA, hosted by the German Ministry of Labour and Social Affairs. The following were represented: European Commission, ACSH, SLIC, SCOEL, the European Chemicals Agency, the IARC (the International Agency for Research on Cancer) and the WHO. They summarised the current understanding regarding exposures to carcinogens and the causes and circumstances of work-related cancer.

Meetings with Industry (notably NEPSi) and workers were organised in 2013 and 2015 on the specific substances subject to the initiative.

Exemption from requirement to undertake a public consultation

The exemption is based on the fact that the full two stage social partner's consultation took place in addition a wide consultation of all other stakeholders as described above.

Will an Implementation plan be established?

Yes 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.

D. Information on the Impact Assessment Process

Considerable work to prepare the amendments of the CMD has been performed over the recent years (see other chapters of this document).

EMPL set up an Inter-Service Steering Group (ISSG) for the IA²⁴ to discuss the results of the study on carcinogens. The (ISSG) was subsequently organised by the Secretariat General, who launched a first meeting to discuss both the REFIT exercise of the Framework Directive and the proposal for an initiative on the CMD in November 2015. The following DGs participating have a specific interest in chemicals, including carcinogens and

²⁴ Meetings in 2011 and 2013.

substances toxic to reproduction: DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROW), DG Environment (DG ENV), DG Health and Food Safety (DG SANTE), DG Research and Innovation (RTD), DG Competition (COMP), DG Budget (BUDG), Financial Stability, Financial Services and Capital Markets Union (FISMA), DG Justice (JUST), DG Communication Networks, Content and Technology (CNECT), DG Migration and Home Affairs (HOME), DG Energy (ENER), the agencies EUROFOUND and EU-OSHA, and the general services Eurostat, the Legal Service (LS), and the Secretariat-General (SG).

E. Preliminary Assessment of Expected Impacts

Likely economic impacts

Due to the fact that 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 those carcinogens or mutagens which are already under the scope of the CMD, the likely economic impact of all options considered above should in principle be limited as regards the substances for which the OELs will be revised. This applies also to SMEs due to the fact that the outlined provisions of the CMD (elimination or reduction to a minimum) exists also already for them. However, due to differences in OELs at national level and the fact, that they are often considered as being the maximum effort to be achieved despite the more further going obligations under the CMD, 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. The exact magnitude of the impact can only be the result of the Impact Assessment.

With regard to the economic impact on the so-called PGs currently not under the scope of the CMD and subject to the proposed action (RCS, RCFs, rubber dust and fumes, mineral oils as used engine oils, diesel engine exhaust emissions), there will be an impact for economic operators in those EU Member States where there are no national OELs or where existing national OELs are higher than those proposed in the initiative. However, any potential negative impacts are expected to be outweighed by the positive impacts, in particular with regard to the establishment of a level playing field between economic operators and also reducing at least in the long term their loss in productivity as outlined above.

Likely social impacts

The correct implementation of effective workplace risk management measures across the Member States in all affected sectors of activity could significantly reduce cancer risks arising from the use of carcinogens and mutagens at the workplace.

Option "Baseline scenario"

There would be no step change in improving the protection of workers' health. However, gradual improvements may be expected as improved practices in risk management become more widely used by employers over time. The baseline health impact indicates that, according to the preparatory study, for the carcinogens under consideration in both batches of substances considered, more than 700,000 cases of occupational cancer will occur during the period 2010-2069. For predicting future burden of occupational exposure to carcinogens, a long forecast period needed to be chosen in order to account for the latency of cancer (10 to 50 years depending on the type of cancer) currently being initiated.

Option "Amending the Directive", the proposed, most effective option

This would introduce a significant change in the protection of workers' health. The amendment of the Directive along the lines of sub-options would bring significant benefits to the health of workers exposed to carcinogens. The introduction in Annex I to the CMD of a certain number of PGs to which a significant number of workers are exposed will protect workers' health and will thus contribute to the reduction of the number of fatalities due to occupational cancer. The revision of existing OELs and the introduction of OELs for additional carcinogens would provide better and more benchmarks that could be used by individual employers when deciding on appropriate and effective risk management measures.

Option "Guidance documents"

In itself this does not resolve the need to update and extend the scope of CMD. However, it could encourage a quicker uptake of the best risk management measures compared to the "Baseline Scenario" option.

Likely environmental impacts

Due to the fact that the substances considered in both batches do not have an environmental adverse effect, the environmental impact of the initiative will be zero.

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. The aim of this initiative is the revision of existing and 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

<p>substances. An impact on simplification is not expected.</p>
<p>Likely impacts on SMEs</p> <p>Due to the fact that SMEs are not (and should not be) exonerated from the obligation to eliminate or reduce to a minimum the risks arising from occupational exposure to those carcinogens or mutagens which are already under the scope of the CMD, the likely economic impact of all options considered above should in not differ much from the general economic impacts described above.</p> <p>Some economic impact for SMEs could stem from the following:</p> <ul style="list-style-type: none"> • some of the OELs have overhead cost, and the smaller the firm, the smaller the revenue base over which these costs can be distributed; • the level of expertise is frequently lower for SMEs; • the SMEs environment is generally more competitive and finance is more difficult to obtain, leading to shorter time horizons and fewer expenditures on what may be perceived as nonessential items.
<p>Likely impacts on competitiveness and innovation</p> <p>It is very likely that the initiative will have an overall positive impact on innovation and competitiveness. This is mainly related to the experience that 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 (use of less amounts or no carcinogenic substances).</p>
<p>Likely impacts on public administrations</p> <p>The impact on public administration will be marginal due to the fact that a transposition deadline of 18 months will be specified. In addition, the potential impact on public administration was not raised by any Member State representative in the ACSH.</p>
<p>Likely impacts on third countries, international trade or investment</p> <p>It is very likely that the initiative will have no impact on third countries, international trade or investment. In most other jurisdictions, OELs for hazardous substances are also in place, often of the same order of magnitude as in the European Union. This applies in particular for our main international competitors like the USA and Japan. If anything a positive impact can be anticipated due to the potential positive effects described in the section on competitiveness and innovation.</p>