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Subject:	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document 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

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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

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

{COM(2017) 11 final}
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INTRODUCTION

Exposure to some chemical agents in the workplace can cause cancer. To ensure workers' protection against such risks, in 1990 the EU (then EEC) adopted the Carcinogens Directive[1]) as one of the first individual directives under the 1989 occupational safety and health (OSH) 'Framework Directive'.[2] Over the following decade the CMD was updated and extended to become the Carcinogens and Mutagens Directive, which was consolidated in 2004.[3]

CMD obligations require employers to eliminate or otherwise minimise exposure of workers to cancer-causing ('carcinogenic') chemicals and elaborates the general requirement in the Framework Directive to eliminate all risks to workers. CMD establishes certain measures specific to given chemical carcinogens, including identification of 'process-generated' carcinogens (Annex I to the CMD), and limit values over which exposure of workers is not allowed (Annex III).

Scientific knowledge about cancer and carcinogenic chemicals develops. 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 the three Annexes. The Directive requires specifically that occupational limit values must be set out in respect of all those carcinogens or mutagens for which this is possible in the light of the available information, including scientific and technical data.

The Commission has initiated a scientific and economic assessment of 25 priority chemical agents with a view to making appropriate updates to the CMD. Around 20 million EU workers are exposed to at least one of these carcinogens. For 13 of those 25 the evidence base and analysis were adequately advanced by 13 May 2016 for the European Commission to adopt a legislative proposal to amend the CMD[4], accompanied by a full impact assessment.[5]

For a further seven out of those 25 carcinogens policy options are analysed in this Staff Working Document. In the case of the five remaining substances, action through amendment of the CMD requires further consideration before proceeding and has been withheld at this stage.

The aim of the further proposal under consideration remains to reduce exposure to these priority carcinogens with a consequential reduction in potential new cases of occupational cancer in the affected workers in the forthcoming 50 years. The proposal will increase protection and legal certainty for at least four million workers, reducing suffering, and improving the length, quality, and productivity of the working lives of European workers. It is a part of a longer-term process of updating and reviewing the CMD to ensure optimal protection from carcinogenic chemicals at work, with further proposals anticipated in the medium term.

Given the level of scientific and technical knowledge required to identify measures, which at the same time adequately protect workers and are practically feasible for industries, the European

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1 Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)

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 , 29.6.1989, P. 0001 – 0008)

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

4 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

5 Commission Staff Working Document, Impact Assessment, accompanying the proposal for a Directive of the European Parliament and the Council amending Directive 2004/37/EC on the protection of workers from the risks related to carcinogens or mutagens at work (SWD(2016)152/2)

Commission bases proposals in this area on opinions developed by the tripartite Advisory Committee on Safety and Health at Work (ACSH). The opinions of ACSH take into account advice developed by the Scientific Committee on Occupational Exposure Limits (SCOEL) as well as other sources of relevant scientific data. The purpose of this Impact Assessment is to verify, on the basis of available socioeconomic data, the robustness of ACSH opinions and, eventually to consider some complementary measures which could be proposed based on further scientific information.

Representatives of Member States authorities, employers' and workers' representative bodies within the framework of the tri-partite ACSH strongly anticipate a second Commission proposal. In its Resolution of 25 November 2015 on the EU Strategic Framework on Health and Safety at Work 2014-2020, the European Parliament 'firmly reiterates its call on the Commission to present a proposal for a revision of Directive 2004/37/EC on the basis of scientific evidence adding more binding occupational exposure limit values where necessary'.[6]

While this Staff Working Document sets out the case for further action, the supplementary analysis presented here should be read in conjunction with the earlier impact assessment (IA), which provided an exhaustive consideration of the CMD and the policy and legal context of the proposals.

The most essential points are carried over and supplemented by additional information and analysis regarding these seven additional carcinogens. References to the full impact assessment document are given as appropriate.

1 THE PROBLEM AND THE POLICY CONTEXT OF EU INTERVENTION

1.1 Cancer is the first cause of work-related deaths in the EU

53% of annual occupational deaths are attributed to cancer, compared to 28% for circulatory diseases and 6% for respiratory diseases[7]. Different forms of cancer may be initiated or promoted 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)[8] 91,500-150,500 people were newly diagnosed with cancer in 2012, caused by past exposure to carcinogenic substances at work. 57,700 – 106,500 people died in 2012 as a result of a work-related cancer. **That means that every hour in EU28, 7-12 people die of cancer because of past exposure to carcinogenic substances at work.**

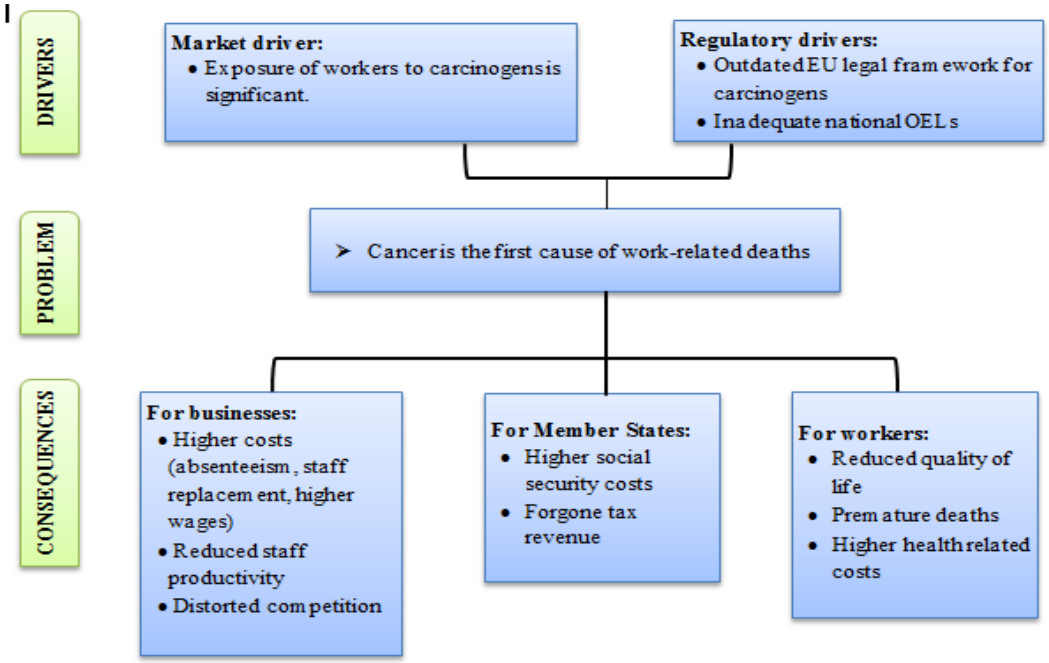
The below problem tree summarises the main drivers behind this problem and the resulting consequences. A detailed description of those is provided in the previous IA.

[6] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2015-0411+0+DOC+PDF+V0//EN

[7] Data concerning the numbers of deaths and diseases attributed to occupational cancer are presented in section 1, page 8 of previous IA (SWD(2016)152/2).

[8] Work-related cancer in the European Union : Size, impact and options for further prevention, 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, p. 11

Figure 1. Problem tree



The carcinogens subject to this assessment have a direct impact on developing different types of cancer and are relevant to the sectors with high rates of cancer registrations. Their key characteristics are presented in a table in Annex 4. In total 12 million EU workers are exposed to at least one of the seven carcinogens (see Table 1 in Annex 4). Complex PAH mixtures with benzo[*a*]pyrene as an indicator, 4,4'-methylenedianiline, or oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine (hereinafter, "mineral oils as used engine oils"), are among the top 10 carcinogenic substances to which the largest numbers of workers are currently exposed.

1.2 Legal context

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 I clarifies the scope of the directive.

Annex I of CMD includes a list of identified 'process generated substances' (PGS). These are hazardous 'chemical agents' such as dust, fumes, and gases which may, for example, be generated as by-products during production processes, etc. The aim of this list is to clarify for workers, employers, and enforcers whether a given chemical agent, if it has not otherwise been

classified according to the Regulation (EC) No 1272/2008[9] (CLP), is in scope of the CMD controls.

Annex III establishes 'binding occupational exposure limit values' (OELs)

For some 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' (OELs) 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.

Under the CMD, OELs should be established for all those carcinogens and mutagens for which the available information make this possible[10] and must also be revised whenever this becomes necessary in the light of more recent scientific data.

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'. CMD OELs do not directly affect in theory 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.

Further information about the Annexes of the CMD and their role is in Annex 8 of this report.

When analysing options for amendments of CMD Annexes, the interface with the REACH Regulation needs to be taken into account as both CMD and the REACH Regulation are relevant for worker protection from carcinogens[11].

Section 3.2.2 provides further information on the interface between REACH and CMD.

1.3 How would the problem evolve

Work-related cancer has a strong impact for workers and their families, for Member States and for the economy at large. The previous IA describes these impacts in more detail[12]. Estimations on the numbers of deaths and health costs between 2010 and 2069 in case no action is taken regarding these carcinogens are, where available, summarised in the Table 1 below[13]. Exposure to, for example, mineral oils as used engine oils, which potentially concern 1 million workers in Europe, is expected to cause 130,000 cases of cancers and 1200 deaths, with estimated health costs between € 445 m – and 2,815 m. These projections are made under the assumption that

[9] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 65/548/EEC and Directive 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1))

[10] Recital 12 of Directive 2004/37/EC.

[11] A detailed analysis of the interface between REACH and CMD can be found in section 2.3, page 29, of SWD(2016)152/2.

[12] See section 1.2 of SWD(2016)152/2.

[13] The reference period of 2010-2069 is established in the IOM study and used throughout the report. No methodologically consistent information is available to modify this reference period to take into account potential development between 2010 and 2015.

employers already comply with the CMD obligation to eliminate or minimise exposures to carcinogenic chemicals and that more detailed or more protective measures have been established by some Member States to complement the minimum requirements set at EU level[14].

The general obligations set by CMD, employers' actions and measures adopted by Member States contribute overall to lowering exposures. As will be shown in section 5, exposure levels have generally been decreasing in the past years and this positive trend could continue in the future. Future forecasts in this area are however far from certain due to scarcity of relevant data and the fact that market forces such as raw material and energy prices, developing technology, as well as regulatory changes can drive decreases or increases in use which are not easy to predict. Even if trends were overall positive, under current circumstances, the existing employers practices as well as protective measures at Member State level, do not always reflect available scientific and technological knowledge.[15] While the Commission does not receive information from Member States as for their intentions for developing their national legislation, national administrations are aware of the preparatory work at EU level and therefore it is likely they will await its results in order not to duplicate efforts.

Table 1. Estimated current exposures and cancer deaths, cancer cases and related health costs in case no action is taken (baseline scenario), 2010-2069

[14] See section 2.3 of this document and Annex 7.

[15] http://www.baua.de/de/Publikationen/Fachbeitraege/F1913-2.pdf?__blob=publicationFile&v=6
http://oiraproject.eu/
http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2015)53&doclanguage=en

Carcinogen including CAS numbers where relevant	**Classification**		**No. of exposed workers**[16]	**Expected no. of deaths 2010 – 2069**[17]	**Expected no. of cancer cases 2010 – 2069**[18]	**Estimated health costs 2010 – 2069**[19]
	CLP	**IARC**[20]				
Epichlorohydrine 106-89-8 (1-Chloro-2,3-epoxypropane)	1B	2A	39,372	2,400	2,600	€ 1,362 m – 2,752 m
Ethylene dibromide (EDB) 106-93-4 (1,2-Dibromoethane)	1B	2A	< 7,691	-	-	-
Ethylene dichloride (EDC) 107-06-2 (1,2-Dichloroethane)	1B	2B	< 3,000	-	-	-
4,4'-Methylenedianiline (MDA) 101-77-9	1B	2B	3,942,581	-	-	-
Trichloroethylene (TCE) 79-01-6	1B	1	74,076	3,300	4,800	€ 1,582 m – 5,657 m
4,4'-Methylene-bis-(2-chloroaniline) (MOCA) 101-14-4	1B	1	2,500	100	280	€ 45 m - 353 m
Complex PAH mixtures with benzo[*a*]pyrene as an indicator 50-32-8 (for benzo[*a*]pyrene)	1B	1	7,505,211	10,000	13,000	€ 6.2 b – 194 b
Mineral Oils as Used Engine Oils (UEO)[21]	n/a	1[22]	1,050,127	1,200	130,000	€ 445 m – 2,815 m
Beryllium and inorganic beryllium compounds 7440-41-7 (for beryllium)	1B[23]	1[24]	64,734[25]	390	390	€ 203 mln - 529 mln
Hexachlorobenzene (HCB) 118-74-1	1B	2B	Insufficient data	Insufficient data	Insufficient data	Insufficient data
Diesel engine exhaust[26]	n/a	1[27]	3,670,792	230,000	270,000	€ 99,084 mln – 258,000 mln
Rubber process dust and fume (RPDF)	n/a	1[28]	366,501	2,990	4,310	€ 721 mln - 859 mln

[16] Estimates.

[17] A "-" in the table indicated that there was inadequate epidemiological evidence to sustain assessment according to the IOM study there.

[18] As above.

[19] As above.

[20] International Agency for Research on Cancer.

[21] SCOEL Opinion 2016/405, adopted on 09 June 2016.

[22] Used Engine Oils, untreated or mildly treated.

[23] Beryllium and beryllium compounds with the exception of aluminium beryllium silicates.

[24] Beryllium & compounds.

[25] In the substance evaluation report according to Article 48 of the REACH Regulation, dated 19 March 2014, performed by the German Competent Authorities, a similar assumption about the number of workers exposed is made. However, the actual number of workers exceeding the DNEL derived by the DE CAs 'could not be identified based on available data'.

[26] Without differentiation between 'old' and 'new' types of engines – see discussion under point 4.2.3.

[27] For engine exhaust, diesel.

[28] For Rubber manufacturing industry.

2 WHY SHOULD THE EU ACT?

2.1 Does the EU have the right to act?

Article 153 of the Treaty on the Functioning of the EU (TFEU) empowers the EU to support and complement the activities of the Member States as regards the protection of workers' health and safety. On this basis the CMD provides a specific basis for action.

2.2 Why is EU action needed and what is its 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 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[29]. In addition, there is scientific information which could serve as a background to including mineral oils as used engine oils in Annex I of the CMD.

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

Including substances in Annex I could contribute to the clarity for employers, workers and enforcement authorities as for what falls under the scope of the Directive, provided that the definitions make it possible to specifically identify the substance.

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, or considering alterations, to existing process plant. Clear support for their continued use has been expressed from key stakeholders[30].

Ensuring the same minimum level of protection across the EU

In case of all carcinogenic chemical agents where OELs are proposed in this initiative at least half of the Member States have not yet established legally enforceable OELs or have less protective ones. For example, 17 Member States have set no limits or less protective ones for trichloroethylene – the same is true for 20 Member States in the case of EDB and 23 in the case of MDA. Also approaches to and definitions of the considered PGS differ significantly.

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.

[29] References to relevant SCOEL conclusions are provided in substance-specific subsections in the Section 5.
[30] See section 2.2, page 27, of SWD(2016)152/2.

Contribution to level-playing field

Additionally, while setting more stringent OELs at national level is in line with the minimum standard nature of the CMD, national OELs vary considerably in some cases – leading to significantly different levels of protection. For trichloroethylene, for example, the values range from 0.6 to 100 ppm (3.3 to 550 mg/m^3).[31]

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 provide a potential incentive for companies to locate their production facilities in Member States with the lower standards. For example, for trichloroethylene producers and professional users in countries such as UK, Cyprus or France, it is sufficient to comply with exposure limits 10 times higher (i.e. less constraining) than in some other countries such as Belgium, Denmark, Spain or Finland among others..[32]

Establishing common definitions in Annex I to the Directive and setting EU OELs in Annex III will not completely eliminate the differences between Member States, as they retain the possibility to adopt more protective measures. However, it will provide certainty that there is a core definition and/or enforceable exposure limit for all concerned carcinogens in all Member States. As illustrated in the graphs in Annex 10 it will also significantly minimise the scope for variation in OELs across the EU. The examples of the currently existing EU OELs (e.g. for hardwood dust, included in the 1st Commission proposal for amendment of the CMD) show that a majority of Member States in practice adopt the EU OEL directly.

Assuming burdens at EU level related to derivation of limit values

The process of establishing limit values is very complex and requires a high level of scientific expertise. An important advantage of setting OELs at EU level is that it eliminates the need for Member States to conduct their own scientific analysis.

Since the establishment of SCOEL the onus for developing OELs for hazardous chemical agents in general, and carcinogens in particular, has shifted to the EU level and the European Commission. Accordingly this important activity to contribute to the protection of workers is now driven principally at EU level, forming important driving context for the present intiative.

The annual budget for the operation of SCOEL in the year 2015-2016 is approximately €400,000, not including significant dedicated resources providing the administrative and scientific secretariat functions.

The cost of undertaking the relevant scientific analysis at Member State level would differ as a result of different organisational requirements, prioritisation and resource allocation and other administrative decisions – making an extrapolation assuming the SCOEL resources are representative is therefore difficult. Assuming that a majority of Member States chose to establish or continue operating scientific committees to undertake equivalent work for all hazardous chemical agents (not just carcinogens and/or mutagens) would imply savings of between €6 000 000 and €12 000 000 at Member State level.

Given the limited resources for OSH at national level, this could release funds currently spent on managing national scientific committees to be redirected into other OSH priorities.

[31] A comprehensive overview of the national OELs for each of the chemical agents covered in this report and a summary overview table can be found in Annex 7.

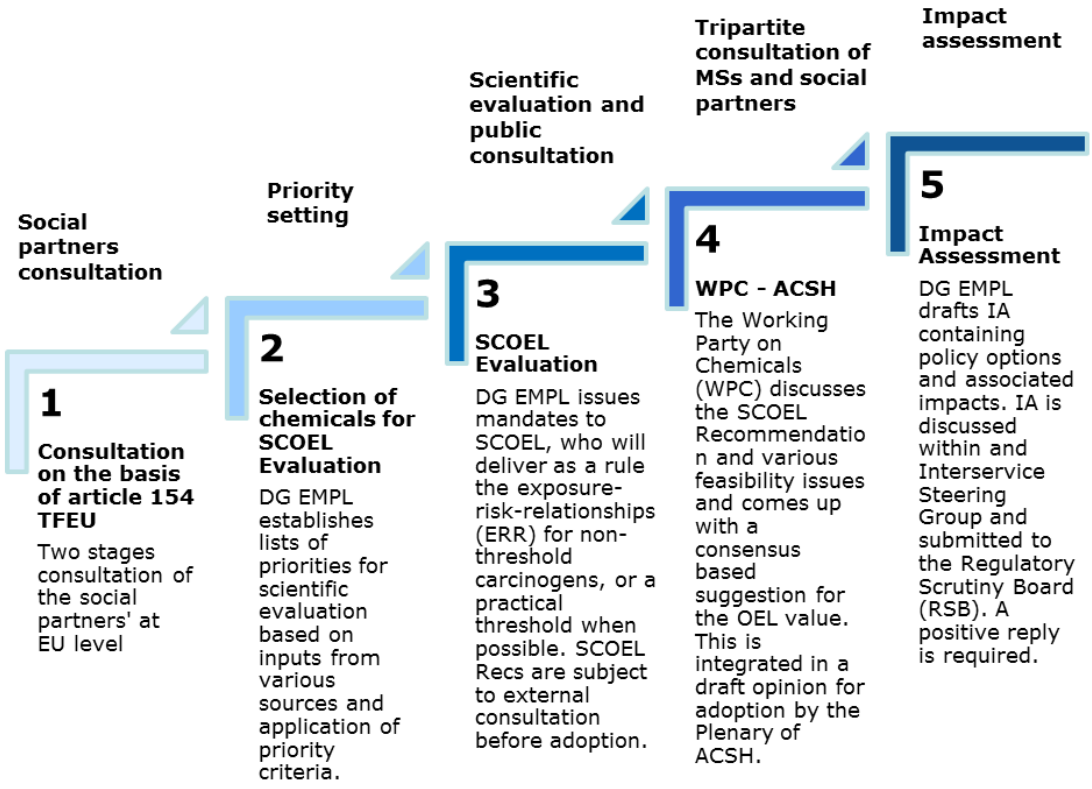
[32] A detailed analysis of the issues related to OELs at MS level is provided in section 1.1.3 of SWD(2016)152/2.

2.3 Process for setting binding OELs and associated provisions under CMD.

A simplified outline of the process for the development of EU Occupational Exposure Limit Values for carcinogens is set out here.

After completion of these steps the Commission prepares and adopts the legislative procedure which then follows the ordinary legislative procedure for adoption and subsequent transposition and implementation at Member States level.

Figure 2. Simple representation of typical EU OEL setting procedure



Step 1: Social partners consultation

TFEU Article 154 requires a formal two-stage consultation of the social partners at EU level (management and labour) prior to submitting proposals in the social policy field. As regards the present initiative this consultation took place in 2004 and 2007. Annex 2 (section 9.1.) provides further information on the outcomes of the consultation.

Due to complex nature of this initiative, a further exchange of views between the Commission services and the social partners took place towards the end of the IA development stage of the overall process, once the policy options had been clarified. This ensured the continued active involvement of the social partners.

Step 2: Priority setting

It is neither realistic nor desirable to set an OEL for every hazardous chemical that may be used at the workplace. Instead it is appropriate to identify and target priority substances.

The selection of the original 25 carcinogens considered in this and previous related Impact Assessment was based on a consultative approach including stakeholder engagement at member states and social partner levels, and taking into account general considerations such as the following:

- the potential to cause adverse health effects resulting from occupational exposure.
- Processes resulting in exposure or combined exposures to chemicals with the potential to cause adverse health effects resulting from a work activity for which markers of exposure are needed.
- Emerging specific issues on a basis of reported evidence and expert judgment.
- Degree of evidence for adverse effects.
- Characteristics of the adverse effects (severity, potency, reversibility, specificity).
- Estimated number of workers exposed.
- Identified exposure patterns that pose difficulties for the control of exposures.
- Policy considerations, such as problematic disparities with or between other relevant threshold values, degree of stakeholders' interest in having an EU OELV, or other institutional priorities.

The Commission is committed to continuing efforts to strengthen application of such criteria in the future.

Step 3: Scientific evaluation and public consultation

Article 16 of the CMD states that scientific/technical data should be included in the basis on which OELs are set. CMD does not determine which scientific body should be the source of such data – in practice the Commission and the ACSH principally seek the advice of 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).[33]

SCOEL is an independent scientific committee, established by a Commission Decision and 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.[34]

SCOEL carries out scientific evaluation at EU level and as a result publish a single evaluation document (previously a 'SCOEL SUM', more recently a Recommendation or Opinion) for hazardous chemicals where there is priority concern for worker protection. The procedures for the adoption of a Recommendation by SCOEL include an external public consultation including directly informing a list of identified contact points in all of the Member States; this ensures scrutiny of the scientific evidence and methodological approach used by SCOEL and ensures transparency of the process.

SCOEL has concluded opinions or recommendations on all the carcinogens analysed in chapter 5 – further details are provided in Annex 6.

Step 4: Tripartite consultation of Member States and social partners

While the aim of ensuring the protection of the health of workers is maintained, binding OELs set under CMD must also reflect other factors such as 'feasibility' and take into account the views of the social partners. For this reason the Opinion of the ACSH is requested.

[33] See "Figure 3. Simple representation of EU OEL setting procedure" (annex 9).

[34] 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

The ACSH is a tripartite body set up in 2003 by a Council Decision (2003/C 218/01) to streamline the consultation process in the field of occupational safety and health and rationalise the bodies created in this area by previous Council Decisions. The ACSH remit is to assist the Commission in the preparation, implementation and evaluation of activities in the fields of safety and health at work. The ACSH is composed of three full members per Member State, representing national governments, trade unions and employers' organisations, also organised in three separate interest groups within the Committee.

The ACSH is supported by working parties of experts on given topics of interest according to mandates agreed by the plenary Committee. These working parties are also tripartite but usually with smaller selected expert membership.

The ACSH Working Party on Chemicals (WPC) undertakes broader chemicals policy support for the ACSH and Commission and in particular detailed technical and policy negotiation of EU limit values. This process is informed by all available evidence regarding appropriate and achievable limit values including adopted SCOEL Recommendations and any national OELs

It is during these, often complex, discussions that the level of ambition which is appropriate for a specific EU OEL for a carcinogen is established, taking into account the views of representatives from the government, workers, and employers interest groups.

The ACSH discusses adopted SCOEL Recommendations (and/or other appropriate scientific evidence) and adopts a formal Opinion.

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. These Opinions are also adopted taking into account that OELs for carcinogens exist within the broader context of the CMD elimination/minimisation obligation, which establishes an appropriate and exceptionally high legal standard for workplace- and process-specific risk control.

Between 2009 and 2011 an external contractor evaluated, on behalf of the Commission, health, socio-economic and environmental aspects of the proposed amendments to CMD in order to inform impact assessment according to the regulatory procedures in place at that time. Between 2010 and 2013 the Working Party on Chemicals of the ACSH undertook detailed discussion on these issues in an increased work schedule, aiming to secure stakeholder engagement and agreement on values to propose for ACSH adoption.

Step 5: Impact assessment

The impact assessment takes all of the above steps into consideration and the IA Report is presented to the Commission services Regulatory Scrutiny Board in accordance with the relevant internal rules for initiatives with foreseeable significant impacts.

The options for action proposed by the ACSH are established through a thorough scientific, technical and socioeconomic discussion and in general the tripartite agreements reached in the Advisory Committee would be put forward in the eventual Commission's proposal. However, in line with the Better Regulation guidelines, an IA is conducted before presenting the proposal. In the IA the Commission verifies the ACSH opinions on the basis of a dedicated study. Other sources of information and data are duly taken into account at this stage. EU-OSHA provides input based on recent scientific research, concerned Commission services are asked for relevant data collected by the European Chemicals Agency (ECHA) and additional input from industries is requested with the help of DG Internal Market, Industry, Entrepreneurship and SMEs. Follow-up meetings with social partners are organised.

As a result of the IA the ACSH-based options could be **withheld, retained or complemented**.

A proposed action is **withheld** if the ACSH opinion has not been sufficiently consensual, and the Commission's assessment leads to concerns about the proposal (e.g. as regards legality or clarity). This does not mean that the Commission discards the option. Rather, important additional elements are needed before further assessing the option.

An option is **retained** if the ACSH opinion has been clear and consensual, there are no concerns about legality and clarity of the option and the socioeconomic assessment confirms the robustness of ACSH opinions in terms of effectiveness, efficiency and coherence.

An option may be further **complemented** if the ACSH opinion did not take into account an important scientific element, such as the need to establish a skin notation.

Agreement of the RSB is a prerequisite before presenting the draft proposal for adoption by the college of Commissioners.

Ensuring the active engagement of stakeholders during the overall process.

The process of setting binding OELs under CMD actively engages the MSs and social partners during the key stages:

- Two stages consultation of the social partners' at EU level in accordance with TFEU.
- External consultation on SCOEL Recommendations before adoption.
- Development of Opinions of the tri-partite ACSH via its Working Party on Chemicals.

A further advantage of an OEL is that it sets an objective to be achieved without being prescriptive in how this should be achieved. Therefore, 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 OEL when, for specific processes, this can be achieved. In this context EU-OSHA plays an important role in facilitating the exchange on good risk management practices within and between industry sectors across the Member States.

3 WHAT SHOULD BE ACHIEVED?

3.1 What are the general policy objectives? What are the more specific objectives?

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

The specific objectives are:

- To further improve protection from occupational exposure to chemical carcinogens in the European Union;
- To increase the effectiveness of the EU framework by updating it on the basis of 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.

3.2 Are these objectives consistent with other EU policies and with the Charter for fundamental rights?

Promoting workers' health is in line with the ambition for a Triple A Social Europe rating set by the Juncker Commission. It has a positive impact on productivity and competitiveness.[35]

3.2.1 Consistency with the Charter for fundamental rights

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. Ensuring a safe and healthy work environment is a strategic goal for the European Commission.[36]

3.2.2 Consistency with the REACH Regulation[37]

The REACH Regulation, adopted in 2006, is of particular relevance for worker protection from risks associated with the presence of hazardous chemicals at the workplace.REACH consolidated and evolved several parts of the EU chemical risk control system – principally those relating to risk assessment and internal market risk management measures. REACH further augmented these changes by establishing a new 'authorisation' risk management option.

Both CMD and the REACH Regulation, are relevant for worker protection from the majority of carcinogens considered in this assessment.[38]

A chemical carcinogen may appear on both CMD Annex III and REACH Annex XIV without systematic conflict. The OSH Framework Directive – under which CMD is made – applies without prejudice to existing or future national and EU provisions which are more favourable to protection of the safety and health of workers at work'. REACH in turn applies without prejudice to worker protection legislation, including the CMD.

Clear synergies between REACH and worker protection legislation can be seen – including in particular that REACH 'registration' should result in more information being available to inform chemicals risks assessment. REACH 'authorisation' also both establishes, for a given chemical agent, a clear and renewed pressure to substitute for safer alternatives, and can drive applicants to improve their worker protection risk assessments and controls. At the same time, adoption of EU OELs can be useful inputs for REACH risk characterisation.

The applicable provisions of REACH authorisation and/or restriction, where relevant of the chemical agents under consideration in this report, are as follows[39]:

- Out of scope of REACH: mineral oils as used engine oils, PAHs (where process generated), rubber process dust and fumes (collectively), DEE;
- Identified as a 'substance of very high concern' (SVHC) and candidate for being made subject to authorisation: benzo[a]pyrene
- Currently subject to authorisation: EDC, MDA, MOCA, TCE;
- Currently subject to restriction: benzo[a]pyrene as a member of the group entry for eight PAHs (Entry 50 of Annex XVII to REACH).

[35] COM(2010) 2020 and COM(2014) 130 final.

[36] Communication from the Commission on the EU Strategic Framework on Health and Safety at Work 2014 – 2020 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332&from=EN.

[37] 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

[38] A detailed analysis of the interface between REACH and CMD can be found in section 2.3, page 29, of SWD(2016)152/2.

[39] A more detailed list of REACH status of the concerned chemical agents can be found in Annex 8.

- Currently not subject to SVHC listing, authorisation, or restriction: Beryllium, EDB, ECH, HCB.

Under REACH 'authorisation' certain chemicals with a specific hazard profile such as carcinogens (and others) may be identified as SVHCs and be subjected to an authorisation requirement. Such substances, which are listed in Annex XIV to REACH, may only be placed on the market and/or used if an authorisation has been granted for a specific use. The conditions for granting an authorisation are set out in Article 60 of REACH. An authorisation may only be granted for specific uses and operators who have demonstrated that the risks (including occupational risks, which is the main exposure scenario today for almost all the substances listed in Annex XIV) 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. In the application for authorisation, and for each of the uses covered in the application, companies must include an assessment of the exposure of workers (and other populations, as well as of man via the environment, if relevant) to the substance(s), and the related risk, at individual workplaces concerned. If the risk management measures set out in the application are not judged (by the ECHA Committee on Risk Assessment) to be appropriate and effective, conditions and/or monitoring arrangements for the control of these risks can be imposed in the authorisation decision to reduce exposure and risks even further.

REACH authorisation provisions are designed to dovetail and complement pre-existing EU regulatory approaches. In particular REACH Article 58(2) states that 'Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled.'

The meaning of the first set of conditions of this exemption ('on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance') is subject to consideration by the General Court in Case T-360/13 VECCO and Others v COM concerning chromium trioxide (a carcinogen mainly of concern for worker inhalation risks for which there is no EU OEL) and the legality of a Commission Regulation which included the substance in Annex XIV to REACH without granting an exemption for certain uses under Article 58(2). The case is currently subject to appeal.

Some uses of substances are in any case exempted from the authorisation requirement. This is the case of 'intermediates'.[40]

Intermediates as defined by REACH are chemical substances which are manufactured for and consumed in or used for chemical processing in order to be transformed into another substance.

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.

INTERMEDIATES: AN EXAMPLE

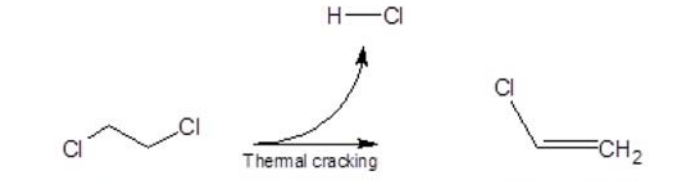
The chemical substance EDC is a carcinogen and as such is subject to CMD. Options relating to setting an inhalation OEL with a skin notation for EDC are considered in this IA. Further details relating to EDC are set out in section 5.3.

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

EDC is also subject to REACH Authorisation. Applications for authorisation have been received for a range of industrial uses of EDC as a process/extraction/emulsifying solvent, reaction/crystallisation medium, or swelling agent.

The main uses of EDC (more than 99% of the total volume) are however as an intermediate and are therefore outside the scope of authorisation.

For example EDC is used as an intermediate in the manufacture of the chemical substance vinyl chloride monomer (VCM, or 'chloroethylene'). The chemical process used consists of continuous feeding of EDC to a dehydrochlorination reactor, where it is transformed into VCM, which is then distilled as an isolate from simultaneously-generated hydrogen chloride (HCl). EDC (1,2 dichloroethane) reacts according to the following reaction scheme



1,2-dichloroethane chloroethylene

Side reactions may take place during the manufacture that result in the formation of ethylene, 1 butene, 2 butene and 1,3 butadiene. These end up in the composition of the manufactured VCM (chloroethylene) as impurities.

This use of EDC would not be subject to REACH authorisation, but workers are protected in EU legislation from potential exposure to EDC during this process and any associated work activity – for example decommissioning of a used dehydrochlorination reactor – by the provisions of the OSH Framework Directive, the CMD and in particular the duty to eliminate or minimise exposures, and would be supported by an EU OEL as considered in this assessment.

REACH registration also contributes to worker protection by ensuring employers receive effective and timely advice regarding risk management from the supply chain.

Unintended process-generated substances would also not be in scope of REACH authorisation.

The co-existence of a CMD OEL alongside REACH authorisation provides several important benefits for the practice of both OSH and REACH 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 non-threshold carcinogens the OEL-setting process provides a relatively 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. This process can support Commission decision-making in implementing the REACH authorisation provisions – in particular whether the exposure of workers demonstrated in authorisation applications can be considered acceptable.

The overall relationship between the REACH Regulation and OSH Directives (including some references specific to the CMD) has been subject of an opinion of the 'REFIT Platform'[41] adopted on 27-28 June 2016.[42]

[41] 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.

In this document the REFIT Platform recognises that the two sets of legislation are mutually reinforcing but points out that the interface between REACH and OSH legislation is complex and that further clarification is needed. The concerned Commission services share that analysis and are working on providing clarifications and on ensuring, in general, better interaction between both areas.

In particular, DG Employment, Social Affairs, Skills and Labour Mobility, DG Environment, and DG Internal Market, Industry, Entrepreneurship and SMEs systematically share participation in technical and policy discussions, hold workshops to further explore how the two regulatory frameworks could interact, formalise cooperation between the REACH and OSH agencies to foster exchanges and avoid scientific conflict, and work in order to promote a better collaboration between the enforcement Authorities at national level.

Some examples of increased cooperation regarding the interaction between OSH and REACH are:

- the ECHA and the SCOEL have been mandated to create a Joint Task Force to further improve their mutual understanding and work towards agreed approaches.
- consideration is given to the OSH legislation during the process of identifying substances as possible candidates for authorisation and restriction under REACH during the so-called risk management option analysis process.
- the ECHA is working actively with stakeholders around safety data sheets in order to facilitate effective communication in the supply chains.
- the Commission plans to hold a workshop on the OSH-REACH interface during 2017.

It is also worth noting that the links between REACH and OSH will be addressed in the ongoing OSH and REACH evaluations, which are expected to be completed in the course of 2017, and that the concerned Commission services are currently working on a Common Understanding Paper considering the interface between REACH and OSH legislation.

4 WHAT ARE THE VARIOUS OPTIONS TO ACHIEVE THE OBJECTIVES?

4.1 Complementary measures

4.1.1 Development of further guidance documents

During discussions in the ACSH[43] and the social partners consultation the need for further guidance was expressed on several issues relating to the CMD[44]. In order to meet this need, actions to develop, for example, additional guidance documents on particular questions raised, are ongoing or will be undertaken as complementary measures to this initiative. These are not alternative options to amending the CMD but are rather part of the baseline and will further reinforce potential positive effects of the considered options.

4.1.2 Biomonitoring

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).

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[42] http://ec.europa.eu/smart-regulation/refit/refit-platform/docs/recommendations/opinion_chemicals.pdf

[43] Opinion of the ACSH of 05/12/12.

[44] See section 4.1, page 32, of SWD(2016)152/2.

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)[45].

Over the years, SCOEL has recommended biological monitoring values for a number of carcinogenic substances, some of them also part of this initiative.

During this impact assessment, the Commission explored possibilities to introduce those SCOEL recommendations as part of an entry for a carcinogen in Annex III to the Directive.

However, in accordance with Article 5 (4) CMD, a biological monitoring value established in Annex III would be 'binding', in the sense that employers would be under the obligation not to exceed that limit value. Such a regulatory approach does not appear legally possible due to the absence in the CMD of specific provisions concerning biological monitoring values. This analysis was confirmed by the Legal Service of the Commission.

The Commission will consult the ACSH on approaches regarding biological monitoring.

4.2 Withheld actions

Commission's analysis led to a conclusion that action in relation to five carcinogens should be at this stage withheld. As described in section 2.3. a course of action proposed by the ACSH can be withheld from further assessment if the opinion has not been sufficiently consensual, and/or if there are concerns about legality or legal clarity of the proposal.

Table 2. Overview of withheld actions

Carcinogen	Outcome of ACSH discussion/Commission's assessment	Next steps
Beryllium and inorganic beryllium compounds	No ACSH opinion adopted to date.	Will be examined once ACSH opinion available.
Hexachlorobenzene (HCB)	ACSH concluded an OEL would not be appropriate given the status of the substance.	Substance banned in the EU. Use will be monitored to ensure that workers safety is not compromised.
Diesel engine exhaust (DEE)	ACSH opinion non conclusive – further research required. Lack of a clear agreed definition of the carcinogen – risk of legal unclarity and unintended effects.	Further research and consultation required including on individual components, aiming for specific OELs.
Rubber process dust and fumes (RPDF)	Mixture complexity makes it difficult to establish a sufficiently clear definition. Lack of agreement on the most appropriate approach between workers and employers representatives in the ACSH.	Further research and consultation required including on individual components, aiming for specific OELs.

[45] Manno, M., Viau, C., in collaboration with Cocker, J., Colosio, C., Lowry, L., Mutti, A., Nordberg, M. & Wang, S., 'Biomonitoring for occupational health risk assessment (BOHRA)', Toxicology Letters, 2010, pp. 3-16

4,4'-Methylene-bis-(2 chloraniline) (MOCA)	ACSH Opinion advised that the establishment of an airborne OEL is not useful to protect workers as this carcinogen has a high potential for dermal absorption.	Further consideration of this substance is necessary before concluding on the best approach which may be a biological limit value together with a 'skin' notation, and possibly to complemented by an airborne OEL in order to improve consistency with REACH.

Further reasoning for withholding action at this stage for each of the five carcinogens is provided below.

4.2.1. Amending CMD in relation to Beryllium and inorganic beryllium compounds

Exposure to beryllium and its compounds at the workplace occurs mainly via inhalation, which can cause lung cancer and may also cause beryllium sensitization and chronic beryllium disease, which is an incurable disease causing scarring of the lung tissue. Dermal exposure may also cause non-carcinogenic ill health effects.

While beryllium is an important chemical for which an amendment of the CMD may be considered in the future, at this stage in the absence of ACSH opinion there is insufficient basis for such a decision.

Consequently action on this carcinogen is withheld at this stage and an amendment of CMD in relation to Beryllium and inorganic beryllium compounds will be considered again once the SCOEL recommendation is finalised, ACSH position agreed and relevant data on impacts collected.

4.2.2. Amending CMD in relation to Hexachlorobenzene (HCB)

HCB is a chlorinated aromatic hydrocarbon. It has been classified by the International Agency for Research on Cancer (IARC) as possibly carcinogenic to humans (Group 2b) and as a Category 1B carcinogen in the EU under CLP.

HCB is listed under the UN Stockholm Convention on Persistent Organic Pollutants (POP) which entered into force on 17 May 2004. The Community ratified the Stockholm Convention on 16 November 2004. The Convention has been implemented at EU level by Regulation (EC) 2004/850.[46] The Regulation bans production, placing on the market and use of the 10 intentionally produced POP substances listed in the Stockholm Convention (HCB is one of them). This Regulation entered into force on 20 May 2004 and is directly applicable in all EU Member States. HCB may still be formed as an unintentional by-product during the manufacture of other chlorine containing compounds or as an impurity formed as a result of various industrial processes. Assumptions that considerable exposure of workers to the substance can still occur in form of a unintentional by-product could however not be substantiated based on available data.

ACSH in its opinion stated that 'No OEL is proposed due to the fact that the substance has already been prohibited globally under the Stockholm Convention and the Protocol on Persistent Organic Pollutants under the UN Convention on Long-Range Transboundary Air Pollution'. Given the legal status of the chemical, it is therefore not considered appropriate to include the substance in this amendment of the CMD. Use of the substance will be monitored to ensure that workers' safety is not compromised.

[46] http://eur-lex.europa.eu/legal-content/AUTO/?uri=CELEX:32004R0850&qid=1475065457841&rid=1

4.2.3. Amending CMD in relation to diesel engine exhaust (DEE)

DEE contains a complex mixture of gases, vapours, liquid aerosols and particulate matter which are the products of combustion and can be hazardous to health.[47] Some of these components are known carcinogens (e.g. PAHs, formaldehyde, 1,3-butadien, or benzene), others are not (e.g. carbon monoxide, carbon dioxide, or oxides of nitrogen). For some of the non-carcinogenic components, like nitrogen dioxide, SCOEL recommended an 8-hour TWA OEL[48]. For DEE as a complex mixture, however, SCOEL in its opinion of June 2016[49] concluded, that 'an occupational exposure level that would be safe for workers could not or not yet be established. Both, toxicological information and human epidemiological data are further evaluated in order to derive such limits.'

ACSH proposed an Annex I entry in the case of DEE but limited it to the emissions from older types of engine. Further investigations for newer engines would however be needed according to the ACSH opinion prior to decision regarding possible inclusion in Annex I. The principle of including an OEL for DEE in Annex III was agreed subject to taking into account, inter alia, feasibility in certain employment sectors, in particular mining and construction and taking environmental background levels into account in certain workplaces. Nevertheless, no potential concrete value has been proposed in the ACSH opinion.

Differentiation between 'older' and 'newer' type of engines is relevant as the technological progress and EU emission standards have led over time to a considerable change in the composition of DEE emissions in general, and to its content of carcinogens in particular. IARC, in its recent monograph on 'Diesel and Gasoline Engine Exhausts and some Nitroarenes'[50] classified diesel engine exhaust as 'carcinogenic to humans' (Group 1) but noted that the 'qualitative and quantitative composition of exhausts depends on the fuel, the type and age of the engine, the state of its tuning and maintenance, the emission control system, and pattern of use', and that 'in the past two decades, progressively tighter emission standards for on-road vehicles, introduced in North America, Europe, and elsewhere, have triggered advances in diesel technology that resulted in lower emission of particulate matter, nitrogen oxides, and hydrocarbons.'

Taking the above mentioned considerations into account it is considered that the ACSH opinion has not been sufficiently consensual, and that there are concerns about legal clarity of the proposal.

More specifically, the option of including DEE in Annex I is withheld at this stage because:

1) the definition of the substance with reference to 'older' or 'traditional' type of engines lacks necessary clarity from a legal point of view and would be very difficult, if not impossible, to implement. Furthermore, in formal terms, a reference to the European emissions standards based on Directive 70/220/EEC combined with a reference to a certain type of engines was not deemed as complying with the requirements for inclusion under Annex I of the CMD;

2) given the lack of clear distinction between 'new' and 'old' type of engines it would be impossible to evaluate the extent of the current use and consequently impacts that inclusion in

[47] The main chemical constituents of diesel engine exhaust emissions are carbon (soot), water , carbon monoxide (CO), carbon dioxide (CO2), nitrogen (N2), oxides of nitrogen (NOx), oxides of sulphur such as sulphur dioxide (SO2), alcohols, aldehydes, ketones, various hydrocarbons, and polycyclic aromatic hydrocarbons (PAHs).

[48] Recommendation from the Scientific Committee on Occupational Exposure Limits for Nitrogen Dioxide, SCOEL/SUM/53 of June 2014.

[49] SCOEL/OPIN/2016-403, Diesel Engine Exhaust, June 2016

[50] http://monographs.iarc.fr/ENG/Monographs/vol105/mono105.pdf

Annex I and the resulting obligation to substitute would have on industry (especially mining and SMEs);

3) on 15th September 2016 a fourth list of indicative occupational exposure limit values was adopted in implementation of the Chemical Agents Directive (CAD, Council Directive 98/24/EC). This list includes indicative OELs for mono-nitrogen oxides (NOx), which are the most notable non-carcinogenic hazardous gases in DEE, and which will require an industry response to control emissions, which will have an additional beneficial effect in reducing exposure of workers to the carcinogenic components in DEE. Analysis of impacts of introducing an Annex I entry under CMD requires further consideration of these factors.

Without an Annex I entry defining the carcinogen, it is impossible to establish an OEL for a PGS such as DEE. Further noting SCOEL's conclusion that establishing a 'health-based' threshold for worker exposure to DEE is currently not possible, that no specific value has been reflected in the ACSH Opinion, and that there are practical difficulties with the measurement techniques suggested by the ACSH .

Amending CMD in relation to DEE is withheld at this stage, pending further investigations into whether a legally clear definition can be proposed. In the meantime the Commission would support any relevant sectoral social dialogue – particularly noting the interest of social partners in the extractive industries – with a view to establish good practices and develop common definitions which could eventually feed into future amendments and complement legislative action. Individual components will be analysed with a view to introducing action in relation to them in further updates.

4.2.4. Amending CMD in relation to rubber process dust and fumes (RPDF)

Working in rubber industry can cause leukaemia and cancers of the larynx and lung. Occupational exposure in the rubber manufacturing industry is classified as group 1 carcinogen by IARC. Because rubber process dust and fume are 'process-generated' and are not 'supplied' as such they are not subject to classification according to CLP. Rubber process fumes and dust are highly complex mixtures, the compositions of which varies considerably, but many studies have shown that they contain carcinogens. The presence and concentration of specific carcinogens depends on the production process and rubber mixture.

The opinions of the social partners represented in the ACSH differ. The employers prefer to use a 'substance by substance' approach and not to include the rubber fumes and rubber process dust in Annex I, arguing that technological progress such as an increased use of closed processes, ventilation and increased automatisation has reduced the exposure levels. Industrial hygiene monitoring of separate substances have also contributed to lower exposure levels. The workers representatives favour inclusion of rubber fumes and dust in Annex I, and making certain processes exempt if it can be shown that those processes are free of carcinogens.

Given the lack of an agreed ACSH position on the most appropriate approach as well as the fact that the complexity of the mixtures makes it difficult to establish a sufficiently clear definition, amending CMD in relation to rubber process dust and fumes is withheld at this time. At the same time, several known carcinogenic components of rubber process dust and fume – namely benzene and PAHs – are already subject to consideration for 'carcinogen specific' measures under CMD.

4.2.5. Amending CMD in relation to 4,4'-Methylene-bis-(2 chloraniline) (MOCA)

MOCA has been classified by IARC as carcinogenic to humans (Group 1) and as a Category 1B carcinogen in the EU under CLP. It is also associated with occupational asthma and chronic obstructive pulmonary disease. In its pure form it is solid at room temperature and has low volatility. It is easily absorbed through the skin and the dermal route of exposure is the most important.

SCOEL and ACSH have, due to the nature of the pattern of exposure, recommended a biological limit value and a skin notation and no airborne OEL.

However, several Member States have established inhalation exposure limit values for MOCA, ranging from 0.005 to 0.22 mg/m^3. Moreover, ECHA's RAC has considered and assessed the inhalation route and derived a dose-response curve for the chemical. This assessment will need to be taken into account in a future proposal for action with regard to the substance in order to ensure the maximum protection of workers and consistency between the approach under CMD and REACH.

Finally, the use of biological limit value, in particular in the framework of the CMD, needs to be discussed and agreed and the Commission will explore the possibilities on how best to address this issue.

4.3 Discarded options

Several other options have been discarded as they were considered disproportionate or less effective in reaching the objectives of this initiative. These options are listed below. The reasons for discarding A, B and C are detailed in the previous IA.

A. Banning the use of the carcinogenic chemical agents

B. Providing industry-specific scientific information without amending CMD

C. Market-based instruments

D. Industry self-regulation

A 'Charter for the safe use of Trichloroethylene in metal cleaning' established by the European Chlorinated Solvents Association 'represents a voluntary agreement open for signature by producers and importers' of TCE as a 'voluntary industry-wide commitment ensure adequate control of risks related to use of trichloroethylene' as identified in an earlier EU risk assessment with a view to 'safeguard the long-term sustainable use of trichloroethylene in closed-systems for metal cleansing'.[51]

The ECSA Charter stipulates that, since the end of 2010, trichloroethylene is only supplied by signatories for metal cleaning or degreasing if the user has an enclosed cleaning system and has confirmed that trichloroethylene will only and exclusively be used in enclosed cleaning equipment. It has been signed by all European Trichloroethylene producers and an importer.

While the ECSA Charter is a welcome initiative, it should be noted that the effectiveness of self-regulation is hindered by the following:

- it does not apply to all uses of TCE;
- TCE importation the EU is not heavily represented; and
- it is not binding and cannot therefore be enforced by national authorities.

Consequently, the ECSA Charter, while an important and valuable industry measure signalling positive intention, is not considered as effective as CMD amendments in setting and enforcing minimum protection for workers across the EU and in all sectors of industry.

E. Regulation under other EU instruments (REACH)

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

[51] http://www.dow.com/scripts/litorder.asp?filepath=safechem/pdfs/noreg/773-12001.pdf

REACH is a relevant regulatory instrument for protection of workers from hazardous chemicals, including in particular chemical carcinogens

REACH and the OSH Directives are complementary, and clear synergies between REACH and worker protection legislation can be seen – these are set out in more detail in section 3.2.2 of this supplementary IA and sections 2.3 and 14.2 of the earlier full IA.

In the case of the present proposal, CMD is the more appropriate regulatory instrument. Among the reasons in support of this approach there is the fact that CMD covers worker exposure to carcinogenic agents released by any work activity, whether produced intentionally or not, and whether available on the market or not, such as process generated substances in the workplace. Furthermore, CMD is intended to set OELs, which are an important part of the wider OSH approach to managing chemical risks[52].

F. Directly adopting the most stringent national OEL

For most of the carcinogens some Member States adopted OELs more stringent than considered in this proposal. It could be argued that workers' protection could be further improved if such OELs were to be made binding across the EU based on an assumption that what is achievable in one Member State should be achievable in all. However, a more stringent OEL may exist in a Member State where, for example, certain industries or industrial processes are less prominent or even not present or where the structure of the industry is different (e.g. relatively less SMEs). Also, there may be significant differences as for access to and affordability of new exposure control technologies. Such an assumption is therefore incomplete.

The EU sets minimum standards in this area and OELs need to be seen in the context of the minimisation principle. This means that Member States are encouraged to establish limit values which are more protective than the EU OELs and that industries have the obligation to minimise exposure below existing OELs if that is technically feasible.

4.4 Options and carcinogens retained for consideration

Table 3 below summarises different policy options for each of the seven chemical agents, which are subject to further impact assessment.

A baseline scenario of no further EU action is Option 1 for each chemical agent represented in this initiative. Directly reflecting the Opinion agreed by the ACSH, forms Option 2 for each chemical agent.

Where appropriate and depending on specific characteristics of the agents, flanking options which, compared with the ACSH Opinion, provide for either lower (more stringent) or higher (less stringent) EU legal requirements, are presented as Option 3 and/or 4 respectively for each chemical agent. These flanking options are drawn from the IOM study, for which they were established by preference: i) from a SCOEL Recommendation if available; ii) as OEL values reflecting available data (for example taking account of existing national OELs); or iii) on the basis of recommendations from the contractor (for example taking into account non-EU OELs). Where available data do not support flanking options, these options are discounted.

In addition, for each chemical agent where SCOEL has identified significant risk of adverse systemic effects from non-inhalation exposures the options are augmented with 'notations' indicating dermal risk in the form of a 'skin notation' ('sk.').

Table 3. Options matrix[53]

[52] See also section 3.2.2 and 15.2.1 of this document. For a detailed analysis of the differences between CMD and REACH see section 4.2, page 34, of SWD(2016)152/2.

[53] OELs at 8hr TWA unless otherwise stated.

Carcinogen	Option 1 (baseline)	Option 2 (ACSH opinion) ($mg/m^3$and ppm – parts per m)[54,55,56]	Option 3 (more stringent) ($mg/m^3$and ppm – parts per m)	Option 4 (less stringent) ($mg/m^3$and ppm – parts per m)
Epichlorohydrine (ECH)	n/a	Annex III entry 1.9 mg/m^3 Sk.	n/a	n/a
Ethylene dibromide (EDB)	n/a	Annex III entry 0.8 mg/m^3 (0.1 ppm) Sk.	n/a	n/a
Ethylene dichloride (EDC)	n/a	Annex III entry 8.2 mg/m^3 (2 ppm) Sk.	Annex III entry 4.1 mg/m^3 (1 ppm) Sk.	Annex III entry 20.5 mg/m^3 (5 ppm) Sk.
4,4'-Methylenedianiline (MDA)	n/a	Annex III entry 0.08 mg/m^3 Sk.	n/a	Annex III entry 0.8 mg/m^3 Sk.
Trichloroethylene (TCE)	n/a	Annex III entry *8TWA* 54.7 mg/m^3 (10 ppm) *STEL* 164.1 mg/m^3 (30 ppm) Sk.	n/a	Annex III entry *8TWA* 273.5 mg/m^3 (50 ppm) *STEL* 164.1 mg/m^3 (30 ppm) Sk.
Complex PAH mixtures with benzo[*a*]pyrene as an indicator	n/a	Annex III entry Sk.	Annex III entry 0.002 mg/m^3 Sk.	n/a
Mineral Oils as Used Engine Oils (UEO)	n/a	Annex I entry Annex III entry Sk.	n/a	n/a

5 WHAT ARE THE IMPACTS OF THE DIFFERENT POLICY OPTIONS AND HOW DO THEY COMPARE?

5.1 Study methodology

Different policy options have been compared based on the following methodology[57]:

- The introduction of a measure is expected to result in a reduction in the occupational exposure to the carcinogen concerned. The extent of such reduction depends on the current levels of exposure, as well as on the projected future levels of exposure in the absence of the proposed measure, i.e. the 'Baseline scenario', corresponding to Option 1. Depending on the specific situation with regard to each chemical (past trends, state of technological

[54] The values are presented as adopted in the ACSH opinions (either only expressed in ppm or mg/m^3 respectively) or converted in one (ppm to mg/m^3) or the other direction (mg/m^3 to ppm)

[55] A conversion from mg/m^3 to ppm only makes sense for substances which, at room temperature and normal atmospheric pressure, exist as a gas or vapour.

[56] The conversion factors used in this table are based on the conversion factors provided in the relevant SCOEL recommendations, and are rounded to one digit after the decimal point. Therefore they can slightly deviate from the values proposed in the ACSH opinions.

[57] Unless indicated otherwise, the main source for the data and analysis presented in the following sections is the IOM study.

developments etc.), the baseline scenario taken from the IOM study foresees static baselines (i.e. where no changes in exposures were expected beyond 2010) or dynamic ones, where current trends (e.g. 4% annual reduction) is expected to continue till at least 2030. This projection of future exposure levels is obtained by extrapolating past declining trends in average exposure levels. It should be noted that any assumed exposure reductions refer to the geometric mean exposure levels (i.e. intensity of exposure) rather than the numbers of workers exposed. Further information on how baselines were defined in the study can be found in annex 5 (especially sections 12.1 and 12.2).

- For a given reduction in exposure levels, the expected decrease in the incidence of cancer cases is estimated over a given timeframe attributable to the carcinogen in question. This requires estimates of the risk of carcinogenicity, which can be derived from the existing toxicological and epidemiological literature, as well as information about the actual level of worker exposure (numbers, level, duration and frequency of exposure). The available epidemiologic evidence is however scarce and not always sufficiently robust, inevitably affecting the reliability of the derived estimates for the number of cancer registrations and deaths.
- The health benefits of avoided cancer registrations and deaths can then be expressed in monetary terms by applying standard evaluation methods. The valuation of health impacts was undertaken based on two approaches. In the low scenario, the estimate per incident is made of its Value of Life Years Lost and the related Cost of Illness (including in that case direct, indirect and intangible costs). In the alternative, high scenario the Willingness To Pay (WTP) approach was applied as the only value per incident case. The WTP approach typically reflects what people are willing to pay to avoid having cancer (both fatal and non-fatal). This under the assumption of the study includes such items as: lost wages, medical expenses, the monetary value of the disutility of illness and the impact of preventive expenditures. The WTP estimate for fatal cancers was used (1,793,776 EUR) in most cases. For the non-melanoma skin cancer a lower WTP was used (38,827 EUR). Those values were derived from the sources and guidance available at the time the study was undertaken[58]. A more recent OECD study[59], summarising a four year-effort to compile and analyse the largest database to date containing all studies based on the States Preference method that have been prepared around the world, proposes a range of 1.8-5.4 million (2005 USD) for the average adult VSL for EU-27, with a base value of 3.6 million USD. In parallel, a study commissioned recently by the European Chemicals Agency (ECHA), found that the WTP values for a premature cancer death ranges between 3,500,000-5,000,000 EUR.[60] This points to a possible underestimation of the benefits as computed under the IOM study.
- These monetised health benefits can in turn be compared to the expected monetary costs that would have to be incurred in order to comply with the proposed OEL. The estimate of the costs was made based on a literature research and data obtained from stakeholder contacts and take into account the following factors: the number of firms needing to apply the relevant Risk Management Measures (RMMs) and the costs of these RMMs over the considered period; the costs of administrative procedures of implementing the OELs (such

[58] This includes in particular the values referred to in Rabl (2004) – 'Valuation of Health End Points for Children and for Adults', Working Paper and the values referred to in the 2009 version of the EC Impact Assessment Guidance.

[59] OECD (2012), Mortality Risk Valuation in Environment, Health and Transport Policies, OECD Publishing.

[60] *Valuing selected health impacts of chemicals*, ECHA (2016). Summary of the results and a critical review of the ECHA study, p. 32. See: https://echa.europa.eu/support/socio-economic-analysis-in-reach/willingness-to-pay-to-avoid-certain-health-impacts

as the costs of monitoring and audit); the potential effect on the market for the substance by the imposition of the OEL.

5.1.1. Analytical challenges

As explained in more detail in the previous IA[61] and in Annex 5 (section 12.4) the cost-benefit analysis poses numerous challenges, related, *inter alia*, to the long latency of cancers, scarcity of reliable data on exposures and effects of existing obligations on employers.

Evolution in exposure

Exposure estimates, derived from the IOM study, are based on the assumption that for many of the concerned chemical agents, past trends of declining exposures will continue. These trends were related to technological progress, changes in work organisation and relative weight of different industrial sectors but also to past legislative developments.

It is difficult to predict whether such trends would indeed continue in the absence of further EU action. The 60-year time frame of the assessment poses also the challenge of anticipating future industrial developments. For each of the carcinogens several industry sectors are relevant, in total a high number of very diverse sectors are concerned (from e.g. car maintenance, through pharmaceutical industry, mining, steel production, asphalt production, textile manufacture, rubber and plastic industries). Analysing technological developments and making more detailed forecasts as for expected evolution for all these diverse sectors would pose a lot of challenges. As many and

These industries are impacted by diverse developments impact these industries, such as technical inventions, oil prices, market structure etc., we cannot predict how all those things will impact the baseline.. The uses of the chemical agents under consideration could either decline or grow and potential new uses could lead to new workplace risks.

In addition, even when declining trends in average exposure levels are observed, it may be misleading to regard these as exogenous. Recent reductions in exposure may have been precisely the result of OELs having been introduced or as an anticipation of those changes.

Moreover, a 2016 report by the Netherlands National Institute for Public Health and the Environment (RIVM)[62] indicates that, despite projected declining exposure levels, 'forecast impacts will probably not be lower than those of 2012' (p. 36).

Period for estimation

The period of estimation was set in order to take into account the long risk exposure period (REP) for specific types of cancer: for solid tumours a latency of 10-50 years was assumed and for haematopoietic neoplasms a latency of 0-20 years was assumed. The future cancer burden is estimated over a 60 years period.

Reliable and timely data

First of all, for most chemical agents under consideration, data on the number of workers exposed is scarce and unreliable (especially for some sectors and/or for some Member States), and data on the current exposure levels across EU Member States is generally not available. Member States record statistics relating to cancer in different ways which cannot be readily

[61] Section 5, p. 34-37 of SWD(2016)152/2

[62] Work-related cancer in the European Union : Size, impact and options for further prevention, 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, p. 11

aggregated.[63] Where exposure data is available, its use as an evidence base for regulatory decision-making is often confounded by the sensitive and sometimes confidential nature of the information, and the potential for source bias. This lack of data is recognized and in order to address this data gap the Commission initiated a study in 2013[64]. The outcome of this work is expected to contribute to a better definition of the baseline situation for possible future initiatives.

Secondly, the available epidemiologic evidence is scarce and not always sufficiently robust, inevitably affecting the reliability of the derived estimates for the number of cancer registrations and deaths. Among the factors contributing to the scarcity of reliable data are the complexity of cancer development and also of workplace exposures. Different carcinogens can, for example, result in the same type of cancer (e.g. lung cancer), and occupational exposure to hazardous agents is characterised by simultaneous exposure to multiple chemical agents. It can therefore be difficult to establish a causal relationship between cancer cases and exposure to a specific carcinogen. Moreover, occupational cancers may develop decades after exposures – including during retirement – complicating the possibility of identifying a causal link. This also has a significantly negative impact on potential to improve evidence base for future proposals.

As explained in more detail in the previous IA[65] and in Annex 5 (section 12.4) these challenges and the fact that effects of diseases other than cancer which may be caused by the chemicals are not taken into account explain why health benefits are likely to be underestimated.

5.1.2. General remarks

Analysis of impacts on Member States, competitiveness, and proportionality

For each of the seven carcinogens, an analysis of possible policy options is presented by chemical agent in the following sub-sections[66].

The IOM study identifies the number of EU workers exposed to each chemical agent and, in most cases, also identifies exposed working populations by Member States. An illustration of the OELs in place at national level is provided in Annex 10, as well as the estimated number of workers potentially exposed by Member State. Furthermore, Table 4 in Annex 7 identifies the population of workers occupationally exposed to each chemical agent in Member States having no OEL or less stringent OELs, and compares this to the overall EU population of exposed workers, resulting in the percentage of workers in the EU for whom legal protection would be improved by adoption at EU level of an OEL under CMD.

In addition to consideration at section 6.2.2 of impacts on competition and competitiveness for the package of retained options, a brief reference to non-EU countries' OELs is given in each sub-section.

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[63] Regulation (EC) No 1338/2008 aims to adopt implementing measures for the relevant domains, including occupational diseases, provided that the intended data is found to be of sufficient quality. The implementing measure would require Member States to supply the Commission with statistics on occupational diseases. CMD Article 14(8) requires that data on cases of cancer resulting from occupational exposure be notified to the competent national authorities. Statistical practices, however, vary between Member States.

[64] Call for tender no. VT/2013/079. Service contract to create a database and develop a model to estimate the occupational exposure for a list of hazardous chemicals in the Member States of the European Union and the EFTA/EEA countries. The contract with the successful bidder, VC/2014/0584, was signed on 23 July 2014.

[65] Section 5, p. 34-37 of SWD(2016)152/2

[66] Unless otherwise specified, all data in the agent-specific analysis comes from the IOM study, with reference periods as specified in that study.

Costs related to skin notations

In order to effectively control total systemic exposure to chemicals at the workplace, it is necessary to take account not only of exposure by the inhalation route, but also of dermal exposure, which may lead to skin penetration and a consequent increase in the total body burden. It is therefore in some cases necessary to assign a 'skin notation' to some carcinogens in order to warn of the possible significant contribution of dermal absorption.

A SCOEL recommendation for a skin notation is not related to CLP dermal hazard classification - it is not intended to give warning of, for example, direct effects on the skin such as corrosivity, irritation, and sensitisation.

Nevertheless, of the seven carcinogens considered for the allocation of 'skin' notations in the retained options below, six are supplied in the EU bearing hazard warnings relating to dermal exposure. As a result of these hazard classifications employers should already be taking steps to manage risks to workers by avoiding dermal exposure – compliance costs for employers (if any) should therefore be minimal.

The main positive effect of establishing a skin notation is that employers should thereby be alerted that a considerable part of the 'body burden' is the result of the uptake via the skin, and that biological monitoring would, if possible, be a valuable additional tool to ensure that adequate risk management measures are in place.

Where the IOM study or this analysis have identified particular additional costs or benefits resulting from assigning a skin notation to a given carcinogen these are addressed in the appropriate sections below.

A more detailed account of general OEL policy considerations, including skin notations, is given in Annex 4 at section 11.2.2.

Comparison key

The comparison tables used in the following sections apply the following ranking symbols: '0' – baseline, '≈' – similar to baseline, '+' more efficient/effective or coherent than baseline; '++' – much more efficient/effective or coherent than baseline; '-' – less efficient/effective or coherent than baseline; '- -' – much less efficient/effective or coherent than baseline.

5.2 Epichlorohydrine (ECH)

Beside its probable carcinogenicity to humans, epichlorohydrine in liquid form has been found to cause skin burns and the vapour can cause irritation of the eyes, nose and throat.

Workers' inhalation and dermal exposures are controlled via the use of closed systems with engineering controls such as vapour return lines during product transfer, the dry disconnect style of fittings for transfer hoses and automated sampling systems. Personal protective equipment is also used to reduce exposure. Significant exposures are therefore likely to occur only during maintenance activities, or during accidental releases.

There are 15 high volume (>1,000 tonnes per annum) producers or importers of epichlorohydrine within the European Union in the following member states: Germany (4), Netherlands (3), United Kingdom (2), Italy (2), Sweden (1), Finland (1), Austria (1) and Belgium (1).[67] Annual production in the EU is estimated at around 360,000 tonnes per annum, while annual global production is estimated at around 900,000 tonnes. The total estimated number of exposed workers in the EU is 43,813.

[67] Source: European Commission Institute for Health and Consumer Protection (2010)

Table 4. Epichlorohydrine – Types of impacts

Impact	Option 1: **Baseline**	Option 2: **Annex III entry** **1.9 mg/m^3 (0.5 ppm)** **Sk.**
Economic	It is assumed that exposure levels remain the same[68] and that firms will not incur costs to reduce exposure under the baseline scenario.	It is estimated that, under the baseline scenario, firms are already achieving exposures less than 1.9 mg/m^3. Therefore no significant additional costs are expected to meet the OEL, nor is negative impact on competitiveness anticipated. As per 'General remarks' skin notations should not result in additional cost as employers should already under the baseline be taking steps to manage risks to workers by avoiding dermal exposure. No impact on employment is expected.
Social (incl. health)	The total number of attributable deaths for 2010-2069 is estimated to 2430, including both lung and central nervous system (CNS) cancers. There is an estimated increase of the number of predicted attributable deaths throughout this period, entirely due to the increase in the longevity of the population. The corresponding health costs are estimated to be between €1362m and €2752m. YLLs are estimated to increase over the period, from 317 to 426 years per annum for lung cancer, and from 324 to 388 years per annum for CNS cancer.	No significant health costs or benefits compared to the baseline are expected with the introduction of the OEL, as exposure is already estimated to be below the value. Skin notations may be expected to improve awareness and enforceability.
Environmental	No significant impact	No significant impact

Prevalence was estimated in the IOM study using the 2006 Labour Force Survey and the 2006 data from the Structural Business Statistics to estimate the proportion of employees in each industry. It was not possible to use CAREX data as epichlorohydrine was not included in the 2007 update. It is likely that all European facilities have already achieved a level of control equal or below 1.9 mg/m^3.

[68] There is very little evidence of change in exposure levels since the 1980s in the data identified by the IOM study. Given the relatively low level of exposure, the IOM study assumes that the exposure levels haven been stable since at least 1980.

Table 5. Epichlorohydrine – Comparison of options

Criteria	**Option 1:** **Baseline**	**Option 2:** **Annex III entry** **1.9 mg/m^3 (0.5 ppm)** **Sk.**
Effectiveness	0	≈ (OEL likely already achieved in practice)
Efficiency	0	≈ (no significant additional costs)
Coherence	0	+
Scientific advice (SCOEL) (Adopted 2011) [69]	Epichlorohydrine is categorised into the SCOEL carcinogen group A as a non-threshold carcinogen. SCOEL strongly recommends avoiding occupational exposure to epichlorohydrine. SCOEL has also proposed a skin notation. SCOEL, in it is Recommendation (SCOEL SUM 169), concluded that it is not possible to derive a health based OEL. SCOEL makes reference to quantitative data on carcinogenicity as assessed by the Dutch Expert Committee on Occupational Standards (DECOS) on the estimated additional lifetime cancer risk	
ACSH	An 8hr TWA of 1.9 mg/m^3 is proposed.	

In the case of epichlorohydrine, in-depth discussions between the representatives of workers, employers and governments in the ACSH resulted in an agreement to propose an OEL as in option 2. No concerns about technical feasibility, overall costs or impact on competitiveness outside the EU have been raised by employers' representatives or government representatives. The fact that SCOEL could not, based on the available data, derive a health-based OEL has been taken into consideration in the discussions in the ACSH during which an agreement was reached on the numerical value of the proposed OEL.

The impact assessment confirms that the option supported by the ACSH opinion (OEL of 1.9 mg/m^3) is appropriate. According to the available data this exposure level is likely to have been achieved in practice. While no immediate health benefits are identified on the basis of current knowledge, introduction of an OEL with a skin notation as recommended by SCOEL would ensure legal protection for workers and enhanced clarity for enforcers and economic operators. **Option 2 is therefore the preferred option.**

Impact on Member States, competitiveness, and proportionality

In the case of epichlorohydrine, 15 Member States will need to introduce (7) or update (8) their OEL to bring it down to 1.9 mg/m^3 (see table 2 of Annex 7 and Annex 10). Around 69% of exposed workers are estimated to work in those 15 Member States and would consequently benefit from improved legal protection as a result of the introduction of this OEL.

Non-EU countries have established a wide range of exposure values. This OEL is equivalent to that in place in countries such as New Zealand and South Korea, although more stringent (China) and less stringent OELs (e.g. US, Australia, Singapore) are applied in some other third countries. As indicated above no significant impact on competitiveness is expected.

[69] SCOEL/SUM/169, September 2011

5.3 Ethylene dibromide (EDB)

Ethylene dibromide (EDB) is classified as a Category 1B carcinogen according to CLP, and has been identified as a Group 2A carcinogen by IARC. EDB is categorised into the SCOEL carcinogen group A as a genotoxic carcinogen without a threshold. EDB is strongly irritant to the eyes, skin and respiratory tract, and acute exposure (200 mg/kg) is lethal to humans.

Figure 3. Sector structure

Number of employees	Average number of workers per class size (rounded)	Composition of enterprises
Between 1 & 9	5	58%
Between 10 & 19	15	14%
Between 20 & 49	25	12%
Between 50 and 250	150	12%
Greater than 250	500	5%
Total	-	**100%**
Percentage of affected firms relative to total number of firms in the sector	-	-

Notes:

EDB is currently used as a chemical intermediate in synthesis and as a non-flammable solvent for resins, gums and waxes. The major chemical made from EDB is vinyl bromide. EDB has also been used as an intermediate in the preparation of dyes and pharmaceuticals. An important use of EDB has been as a lead scavenger in 'antiknock' mixtures added to gasolines, although this use has decreased with banning the use of lead-containing fuels in many countries.

In this context, it is important to notice, that ECHA, in its recent Risk Management Option Analysis (RMOA) for EDB of 16 July 2015 came to the conclusion, that 'The substance is registered for uses within the scope of authorisation (i.e. formulation of anti-knock additive into aviation fuels and potentially some non-intermediate use in fine chemicals/pharmaceutical manufacture). The substance could be proposed to be identified as a Substance of Very High Concern to be included in the Candidate List for potential prioritisation to Annex XIV. However, the European Commission considers that it is more appropriate to address the main non-intermediate use of the substance, i.e. additive in leaded aviation gasoline, at international level and/or under other EU legislation than REACH.'[70]

According to ECHA[71], this substance has three active registrations under REACH, one Joint Submission(s) and no Individual Submission(s). It is manufactured and/or imported in the European Economic Area in 1,000 – 10,000 tonnes per year. Under 8,000 EU workers are estimated to be potentially exposed to 1,2-dibromoethane. Out of them, about 100 workers employed in the chemical manufacturing sector would be confronted with potentially high levels of exposure.

[70] https://www.echa.europa.eu/documents/10162/317e9caf-b149-46f7-847f-189a3d42cdb7
[71] http://echa.europa.eu/brief-profile/-/briefprofile/100.003.132

Table 6. Ethylene dibromide (EDB) – Types of impacts

Impact	Option 1: **Baseline**	**Option 2:** **Annex III entry** **0.8 mg/m^3 (0.1 ppm)** **Sk.**
Economic	A 7% annual decline in average exposure is assumed under the baseline.	It is estimated that less than 1% of enterprises in the chemical manufacturing sector would be affected. The total cost of anticipating investment, which is assumed to take place gradually also under the baseline scenario, is in the range of €30-170k. A majority of companies will incur costs related either to appropriate use of respiratory equipment (€0.5k-2k, per company per year), possibly combined with a better use of ventilation systems (€3k-7k, per company per year). The additional costs for companies are in practice expected to be very low, as the vast majority of companies have appropriate risk management measures already in place. There is no risk of closures or competitiveness losses. Consequently, there are no risks for employment. As per 'General remarks' skin notations should not result in additional cost
Social (incl. health)	No health impact quantification possible.	No health impact quantification possible[72]. Better use of protective equipment and ventilation systems is expected to have a positive (although modest) impact on health. Skin notations may be expected to improve awareness and enforceability.
Environmental	No significant impact	No significant impact

According to the estimations performed in the IOM study about 8% of workers in chemical manufacturing are exposed to average levels above 0.1 ppm. Estimates of current exposure levels were obtained by extrapolating data from existing studies conducted in the 1990s, assuming an average annual reduction in exposure of 7%.

Due to the limited epidemiological information regarding the carcinogenic effects of EDB, it is not possible to identify appropriate relative risks in order to quantify the health impacts of introducing new exposure limits.

Even if majority of companies affected are micro- and small enterprises, compliance costs are expected to be very low and affordable, as the vast majority of companies have appropriate risk management measures already in place. It is therefore assumed that the introduction of an OEL of 0.8 mg/m^3 would not imply any important costs associated with compliance, neither major

[72] No health impact could be quantified due to the unavailability of robust data. Further efforts to obtain that data would have been disproportionate. However, given the intrinsic properties of the carcinogen and the adverse health consequences of occupational exposure it is necessary to ensure a high [or appropriate] level of control at individual workplaces. Since exposures can occur across a broad range of types of workplace a generic marker for exposure control, such as an OEL, is appropriate.

social, macro-economic or significant environmental impact. All interest groups (employers, employees and governmental) of the ACSH agreed that the proposed OEL does not present a difficulty because the predicted costs of compliance are low.

Table 7. EDB – Comparison of options

Criteria	**Option 1:** **Baseline**	**Option 2:** **Annex III entry** **0.8 mg/m^3 (0.1 ppm)** **Sk.**
Effectiveness	0	≈/+ (modest improvement of protection)
Efficiency	0	≈ (very low additional costs)
Coherence	0	+
Scientific advice (SCOEL) (Adopted 2011) [73]	SCOEL, in it is Recommendation (SCOEL SUM 166), concluded that EDB is both a local and systemic experimental carcinogen, its mode of action is clearly genotoxic, and it is categorised as carcinogen group A, meaning a non-threshold carcinogen. SCOEL strongly recommends avoiding occupational exposure to ECH. The quantitative data on carcinogenicity and the present state of toxicokinetic inter-species modelling do not permit a reasonable and reliable quantitative cancer risk assessment for humans to be derived and for this reason SCOEL did not propose a numerical value for an OEL. A 'skin' notation is justified.	
ACSH	0.8 mg/m^3. The opinion of the workers group is that a reduction of the proposed value should be striven for within a review period of not more than three years.	

In the case of EDB, in-depth discussions between the representatives of workers, employers and governments in the ACSH resulted in agreement that the proposed OEL as in option 2 represents a pragmatic risk management measure. No concerns about technical feasibility, overall costs or impact on competitiveness outside the EU have been raised by employers' or governments' representatives. Workers' representatives indicated that the limit value should be further reduced at a future date. The fact that, based on the available data, SCOEL could not derive a reasonable and reliable quantitative cancer risk assessment for humans, has been taken into consideration in the discussions in the ACSH during which an agreement was reached on the numerical value of the proposed OEL.

The impact assessment confirms that the option supported by the ACSH opinion (OEL of 0.8 mg/m^3) is appropriate. Introduction of an OEL with a skin notation as recommended by SCOEL could entail some health benefits (though quantification of those is not possible) and would ensure legal protection for workers and enhanced clarity for enforcers and economic operators. **Option 2 is therefore the preferred option.** This is also in line with the conclusions drawn in the RMOA of ECHA for EDB.

Impact on Member States, competitiveness, and proportionality

In the case of EDB, 20 Member States will need to introduce (11) or update (9) their OEL to bring it down to 0.8 mg/m^3 (see annexes 7 and 10). 81% of exposed workers are estimated to

[73] SCOEL/SUM/166, March 2011

work in those 20 Member States (see table 4 of Annex 7) and would consequently benefit from improved legal protection as a result of the introduction of this OEL.

Few non-EU countries have established exposure values and for those who have, the values are higher than the retained option, except in one case for US-NIOSH (0.045 ppm). No concerns about impact on competitiveness outside the EU have been raised.

5.4 Ethylene dichloride (EDC)

Ethylene dichloride (EDC) is classified as carcinogen (IARC Group 2B and CLP Category 1B) for its carcinogenic effects at multiple sites in rats and mice, both by oral dosing and by inhalation. Next to its carcinogenic properties, EDC is a highly flammable liquid and vapour, is harmful if swallowed, causes serious eye irritation, causes skin irritation and may cause respiratory irritation. Additionally, it is toxic if inhaled.

The substance is subject to REACH Authorisation based on its carcinogenic properties, and included as entry 26 in Annex XIV to the REACH Regulation. The so-called sunset date[74] for the substance is 22 November 2017. The deadline for submitting applications for authorisation was 22 May 2016. 10 applications have been submitted by that deadline. For the purpose of analysis it is assumed that all uses of EDC which are in scope of REACH authorisation are subject to effective worker protection which has been duly considered by the European Chemicals Agency (ECHA) Committees and the European Commission.

However, the main use of EDC (more than 95% of the total volume) is as an intermediate on site in the synthesis of vinyl chloride monomer (VCM). Use as an (transported) intermediate for VCM synthesis represents more than 4% of the total amount of EDC. In addition, small amounts are also used as an intermediate in the production of ethylenediamines, tri- and tetrachloroethylene and other chlorinated solvents and as a solvent in pharmaceutical processing. All these uses of EDC as intermediate (more than 99% of the total volume) are outside the scope of authorisation, and can therefore result in exposure of workers.

According to registration information, the total amount of EDC manufactured in the EU is between 1,000,000 –10,000,000 t/y. Another 10,000 – 50,000 t/y are imported into the EU.

There are at least 18 producers and importers in the EU making more than 10 million tonnes per annum. Less than 3,000 workers are potentially exposed in Europe (2009 data), most in the manufacture of VCM and about 500 exposed when 1,2-dichloroethane is used as a solvent in the pharmaceutical industry. The number of workers exposed outside of VCM manufacturing is small and the amounts of 1,2-dichloroethane used are also small, and it is likely to be well controlled as well.

The IOM Study reports 2,264 workers exposed workers in EDC and vinyl chloride monomer (VCM) manufacturing facilities in the EU. An estimated 11% of EDC and/or vinyl chloride monomer manufacturing workers would be exposed above 4.1 mg/m^3 (1 ppm) 8 TWA and 0.36% above an equivalent 20.5 mg/m^3 (5 ppm.).

[74] The date after which the substance cannot any longer be placed on the market or used by any manufacturer, importer or downstream user, unless an authorisation has been granted.

Table 8. Ethylene dichloride (EDC) – Types of impacts

Impact	Option 1: Baseline	Option 2: Annex III entry 8.2 mg/m^3 (2 ppm) Sk.	Option 3: Annex III entry 4.1 mg/m^3 (1 ppm) Sk.	Option 4: Annex III entry 20.5 mg/m^3 (5 ppm) Sk.
Economic	Calculated decline in exposure of 9% per year. Additionally the substance is now subject to REACH authorisation.	Compliance costs have not been directly calculated for this option but are assumed to lie in between costs for options 3 and 4. As per 'General remarks' skin notations should not result in additional cost - employers should already under the baseline be taking steps to manage risks to workers by avoiding dermal exposure. Impact on employment unlikely.	Compliance cost 2010-2069: 0-€43m (see text below for indication of costs per company) As per 'General remarks' skin notations should not result in additional cost - employers should already under the baseline be taking steps to manage risks to workers by avoiding dermal exposure. Impact on employment unlikely.	Compliance cost 2010-2069: 0-€13m. (see text below for indication of costs per company) As per 'General remarks' skin notations should not result in additional cost - employers should already under the baseline be taking steps to manage risks to workers by avoiding dermal exposure. Impact on employment unlikely.
Social (incl. health)		No health impact quantification possible. Better use of personal protective equipment should have a positive health impact. Skin notations may be expected to improve awareness and enforceability.	No health impact quantification possible. Better use of personal protective equipment should have a positive health impact. Skin notations may be expected to improve awareness and enforceability.	No health impact quantification[75] possible. Better use of personal protective equipment should have a positive health impact. Skin notations may be expected to improve awareness and enforceability.
Environmental	No significant impact	No significant impact	No significant impact	No significant impact

Even if this substance is subject to REACH authorisation as of 22 November 2017, which will eventually phase out all non-essential uses, the impact of the introduction of an OEL on worker protection should not be underestimated. Less than 1% of the total production volume of this substance will be subject to REACH authorisation, and occupational exposure might still occur in the intermediate uses of the substance

[75] See previous remarks on data unavailability.

The IOM Study suggests existing production occurs in closed systems and is highly automated. It is estimated that 5-10 enterprises could be affected by the introduction of an EU-wide OEL of 1ppm and possibly fewer to an OEL of 5ppm, based on the assumption of 12 producers of EDC in the EU and 30-40 enterprises producing VCM. These enterprises are medium to large firms.

Additional costs under all three options may refer to better use of personal protective equipment (PPE): €1-2k annually per company. Some companies might need more significant upgrades of their exposure controls (at 36-183€k annually per company) but given the size of those companies the costs are not considered disproportionally high. The risk of company closures is likely to be small, nor significant impact on competitiveness is expected.

The ACSH recognises that option 2 may be challenging for some activities, especially in the case of multipurpose facilities using the substance in batch processes not operating continuously. The Employers Interest Group (EIG) and subsequent related industry association positions noted difficulty in finding additional technical improvements as a result of optimisation of plant and procedures already undertaken. The ACSH therefore noted that 'additional time may be requested for implementing the OEL at 2 ppm'. It may be further concluded that compliance with option 3, which is more stringent, may not be technically feasible. However, neither the opinion of EIG nor subsequent industry positions provided any quantified data which could indicate costs higher than those identified in the IOM study. Aggregated compliance costs are the highest for option 3. While option 4 (5ppm) comes at the lowest cost, option 2 (2 ppm) represents the most appropriate balance between worker protection and feasibility for industry.

Table 9. Ethylene dichloride (EDC) – Comparison of options

Criteria	**Option 1:** **Baseline**	**Option 2:** **Annex III entry 8.2 mg/m^3 (2 ppm) Sk.**	**Option 3:** **Annex III entry 4.1 mg/m^3** **(1 ppm) Sk.**	**Option 4:** **Annex III entry 20.5 mg/m^3 (5 ppm) Sk.**
Effectiveness	0	≈/+ (increased protection but size unquantifiable)	≈/+ (increased protection but size unquantifiable)	≈/+ (increased protection but size unquantifiable)
Efficiency	0	≈ (modest compliance costs)	- (more significant controls upgrade needed)	≈ (modest compliance costs)
Coherence	0	+	+	+
Scientific advice (SCOEL) (Draft final Recommendation, under public consultation, due for adoption Dec 2016) [76]	EDC is categorised as a genotoxic carcinogen into the SCOEL carcinogen Group A (non-threshold). A 'skin' notation is recommended. With regard to the cancer risk estimates, SCOEL came to the following estimates: • Cancer risk estimate with an excess lifetime cancer risk of 10^{-1} = 38.6 ppm (158660 µg/m³) • Cancer risk estimate with an excess lifetime cancer risk of 10^{-3} = 0.386 ppm (1586.6 µg/m^3)			

[76] Draft Recommendation from the Scientific Committee on Occupational Exposure Limits for 1,2-dichloroethane (ethylene dichloride), SCOEL/SUM/302, 2016.

	• Cancer risk estimate with excess lifetime cancer risk of 10^{-4} = 0.0386 ppm (158.66 μg/m^3) • Cancer risk estimate with excess lifetime cancer risk of 10^{-5} = 0.00386 ppm (15.866 μg/m^3)
ACSH	An 8h TWA of 2 ppm is proposed.

The existing duties in CMD to eliminate or otherwise minimise exposure to carcinogens wherever technically possible, ensure that employers are expected in any case to take whatever measures are technically feasible to protect workers from EDC. Taking this into account, in combination with the analysis set out above, the option indicated in the overall ACSH opinion (OEL of 2 ppm) is appropriate.

Introduction of an OEL with a skin notation as recommended by SCOEL could entail some health benefits (though quantification of those is not possible) and would ensure legal protection for workers and clarity for enforcers and economic operators. **Option 2 is therefore the preferred option.**

Industry remarks regarding feasibility, while unquantified and not substantiated, are taken into account – in particular the ACSH note regarding the possibility of a request for additional transitional measures.

Impact on Member States, competitiveness, and proportionality

In the case of EDC, 23 Member States will need to introduce (5) or update (18) their OEL to bring it down to 2 ppm (see annexes 7 and 10), therefore it is expected that a large proportion of exposed workers could benefit from improved legal protection.

Non-EU countries have established a wide range of exposure values, from 4 to 40 mg/m^3. The retained option is within this range (8.2 mg/m^3) and only China (7 mg/m^3) and Canada-Quebec (4 mg/m^3) have established lower OELs. As indicated above no significant impact on competitiveness is expected.

5.5 4,4'-Methylenedianiline (MDA)

MDA is mostly (99%) used as an intermediate in the production of 4,4'-methylenediphenyldiisocyante (MDI), which is used in the production of polyurethane foams. MDI is also used as an intermediate in processing of 4-4' methylenebis(cyclohexaneamine). Authorisation does not apply for MDA for 'intermediate' use, and therefore the use of MDA for the production of MDI and 4-4' methylenebis(cyclohexaneamine) is outside scope of REACH authorisation.

MDA has been subject to REACH authorisation since 21 August 2014 for the non-intermediate use, for example, as a hardener in epoxy resins and adhesives. However, no applications for authorisation have been received. For the purpose of analysis it can be assumed that all use of MDA which is in scope of REACH authorisation has ceased, and any new use would be subject to effective worker protection which would be duly considered by the Risk Assessment Committee of the European Chemicals Agency (ECHA) and the European Commission. However, this will not have any impact on the estimated number of workers exposed since the production for non-intermediate uses constitutes a negligible share of the total production in chemical industry.

It is estimated that approximately 70-140 people are exposed to airborne MDA in chemical industry[77]. The exposures of workers results either from process-generated or by-product use release.

The number of people affected by dermal exposure during intermediate uses in other industries than the chemical industry that are using MDA is considerably higher. According to the IOM Study the estimates on the number of workers having dermal exposure to MDA were uncertain and were expected to be in the range between 390,000 and 3.9 million workers[78]. Around 60,000-617,000 companies were estimated to employ workers having dermal exposure to MDA.

Figure 4. Sector structure

No: of employees bands	Average number of workers per class size (rounded)	Average composition of enterprises for all affected NACE sectors that use MDA*	Number of workers potentially exposed		Estimated number of enterprises affected by band size	
			Low	High	Low	High
Between 1 & 9	5	74%	287,066	2,870,658	57,413	574,132
Between 10 & 19	15	11%	42,913	429,127	2,861	28,608
Between 20 & 49	25	8%	30,392	303,921	1,216	12,157
Between 50 and 250	150	6%	23,352	233,522	156	1,557
Greater than 250	500	2%	6,277	62,771	13	126
Total	-	-	390,000	3,900,000	61,658**	616,579**

Notes:
* - The average composition of enterprises within each category is based on Eurostat data for NACE code sectors: 24,25,28,29,31,35,45. It is not known whether more exposures occurs in one NACE sector over another and therefore no weightings have been used to determine the average number of workers per enterprise.
** - Numbers exclude the number of enterprises manufacturing MDA who are potentially exposed. This is estimated to between 1 (low) and 6 (high).

Table 10. MDA – Types of impacts

Impact	**Option 1:** **Baseline**	**Option 2:** **Annex III entry** **0.08 mg/m^3** **Sk.**	**Option 4:** **Annex III entry** **0.8 mg/m^3** **Sk.**
Economic	Exposure levels in 2010 expected to decrease by 7% based on historical changes in exposure levels - for inhalation route, not	While the inhalation OEL is not expected to result in any significant costs, skin notation and the related compliance with best practices to reduce	While the inhalation OEL is not expected to result in any significant costs, skin notation and the related compliance with best practices to reduce skin

[77] Mostly in the UK, NL, BE, IT, DE, ES, FI, DK, PT, AT, PL, SL and SK

[78] All Member States have industry sectors where IOM considered dermal exposure to MDA likely. It may be noted that in recent communication the industry association the European Diisocyanate and Polyol Producers Association (ISOPA) have indicated that current EU use sectors are fewer than those identified in the IOM Study – this assessment has been amended to reflect this reduced range of sectors affected, but as updated and substantiated employment figures in affected sectors have not been provided the assessment in the IOM Study has been retained.

Impact	Option 1: **Baseline**	Option 2: **Annex III entry 0.08 mg/m^3 Sk.**	Option 4: **Annex III entry 0.8 mg/m^3 Sk.**
	the dermal uptake.	skin exposure expected to cost €1,000-2,000 per year per enterprise. Impact on employment unlikely.	exposure expected to cost €1,000-2,000 per year per enterprise. Impact on employment unlikely.
Social (. health)	No health impact quantification possible.	No health impact quantification possible. Better practices to reduce skin exposure are expected to have a positive impact on health. Skin notations may be expected to improve awareness and enforceability.	No health impact quantification possible[79]. Better practices to reduce skin exposure are expected to have a positive impact on health. Skin notations may be expected to improve awareness and enforceability.
Environ mental	No significant impact	No significant impact	No significant impact

Regarding airborne MDA, the IOM Study estimated exposure levels in 2010 as at most 0.14 mg/m^3 during manufacture and 0.07mg/m^3 in other industrial sectors. Introduction of an OEL at 0.08 mg/m^3 or 0.8 mg/m^3 is not expected to result in significant costs for companies.

There is little data on the levels of dermal exposure, but IOM considered it likely that exposures in manufacture sector were low, but could be higher in construction. Due to insufficient data no health effects and monetary benefits could be estimated for dermal exposure reduction. However, options 2 and 4 should lead to health benefits (v-à-v the baseline) as a result of more significant reduction of dermal exposure to MDA.

Table 11. MDA – Comparison of options

Criteria	Option 1: **Baseline**	Option 2: **Annex III entry 0.08 mg/m^3 Sk.**	Option 4: **Annex III entry 0.8 mg/m^3 Sk.**
Effectiveness	0	+ (significant dermal exposure reduction)	+ (significant dermal exposure reduction)
Efficiency	0	≈ (modest compliance costs)	≈ (modest compliance costs)
Coherence	0	+	+

[79] Please see earlier remarks on the lack of data.

Scientific advice (SCOEL) (Adopted 2012)[80]	MDA is categorised as a genotoxic carcinogen into the SCOEL carcinogen Group A. A skin notation is recommended A Biological Value of 1 ug/l urine is recommended. SCOEL came to the conclusion that it is not feasible to derive a health-based 8-hrs-TWA limit value because it is a non-threshold carcinogen. SCOEL did not derive an exposure-risk relationship, however, in its recommendation it refers to a 2010 risk assessment performed by the German BAuA for the substance, which came to the conclusion that a value of 0,073 mg/m^3 represents an "acceptable risk" according to the BAuA terminology
ACSH	0.08 mg/m^3 and skin notation

In the case of MDA, in-depth discussions between the representatives of workers, employers and governments in the ACSH resulted in agreement that the proposed OEL as in option 2 represents an appropriate risk management measure. No concerns about technical feasibility, overall costs or impact on competitiveness outside the EU have been raised by employers' representatives or governments' representatives.

The impact assessment confirms that the option supported by the ACSH opinion (OEL of 0.08 mg/m^3) is appropriate. Introduction of an OEL with a skin notation could entail some health benefits (though quantification of those is not possible) and would ensure legal protection for workers and enhanced clarity for enforcers and economic operators. **Option 2 is therefore the preferred option.**

Impact on Member States, competitiveness, and proportionality

In the case of MDA, 23 Member States will have to introduce (12) or update (11) their OEL to bring it down to 0.08 mg/m^3 (see Annex 7 and 10). 82 % of exposed workers are estimated to work in those 23 Member States (Croatia not included) and would consequently benefit from improved legal protection thanks to the introduction of the OEL. Introducing an OEL would also ensure that lack of an OEL or a less stringent OEL does not act as an incentive for business in decisions concerning the plant location.

The introduction of a skin notation in Annex III would facilitate compliance and enforcement of the existing CMD obligation to – so far as technically possible – eliminate or otherwise minimise exposure to these classified carcinogens, and would therefore be justified.

OELs in the non-EU countries considered are equal to or higher (up to 10 times) than the retained option. As indicated above no significant impact on competitiveness is expected.

5.6 Trichloroethylene (TCE)

Trichloroethylene (TCE) has been classified as a group 2A carcinogen by IARC and as a Category 1B carcinogen in the EU under CLP. Exposure to TCE is associated with increased risks of kidney, liver and biliary cancers and non-Hodgkin's Lymphoma (NHL). Exposures to high concentrations may also cause headaches, lung irritation, dizziness, or nerve, kidney and liver damage in the long-term.

[80] SCOEL/SUM/107, March 2012

TCE is mainly used in intermediate applications as well as in the metal cleaning and in the adhesives industry. Consumer use is not permitted. According to REACH registration information available on ECHA's website, trichloroethylene is manufactured and/or imported in the European Economic Area in 10,000 to 100,000 tonnes/year[81]. It is estimated that approximately 74,000 workers in the EU are potentially exposed to TCE.

Figure 5. Sector structure

Size of Enterprise by number of employees:	Distribution (%)
Between 1 & 9	81%
Between 10 & 19	11%
Between 20 & 49	6%
Between 50 and 250	2%
Greater than 250	0.1%
Total	

The use of TCE is regulated by the solvent emissions directive (SED)[82] which requires, where more than 1 tonne of any solvent(s) (including TCE) are used per year) an emission limit equivalent to less than 5 ppm must be complied with. It is therefore assumed that in-scope firms have already taken measures to reduce emissions (of all solvents including TCE) below the SED limits. These measures include putting in place closed systems for metal degreasing, as well as substitution for surface cleaning.

TCE has also been added to Annex XIV to REACH and is therefore subject to REACH authorisation, as a result of which any use outside the terms of a case-by-case authorisation (or a valid pending application) is not permitted from 21 April 2016.

For the purpose of analysis it is therefore assumed that all use of TCE which is in scope of REACH authorisation is subject to effective worker protection which has been duly considered by the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) and the European Commission.

'Intermediate' use and exposures of workers resulting from process-generated substances are not in scope of REACH authorisation. Approximately 75% of the total TCE production, as assessed in the IOM Study, was used in intermediate applications. TCE is also used in the metal degreasing and adhesives industries. TCE use as a solvent has been declining and in 2007 solvent use accounted for approximately 25% of TCE production in the EU. The decreasing use trends are a result of stringent requirements under the Solvents Emissions Directive (SED), REACH and a voluntary industry commitment through the European Chlorinated Solvent Association (ESCA).[83]

This has driven companies to use TCE for surface cleaning only in closed systems, as well as to look for solvent substitution when possible. For metal degreasing, it is estimated that the introduction of automated closed systems and solvent substitution has resulted in the estimated exposure dropping to below 10 ppm.[84]

In 2011 there were two companies in the EU manufacturing TCE, while other companies act as suppliers. Total TCE production in Europe reduced by more than 50% between 1985 and 2007, and is likely to have reduced further due to a manufacturing plant closing in 2009.

[81] Source: European Chemicals Agency https://echa.europa.eu/substance-information/-/substanceinfo/100.001.062, latest update 15/01/2016

[82] Council Directive 1999/13/EC of 11 March 1999 on the limitation of emissions of volatile organic compounds due to the use of organic solvents in certain activities and installations

[83] See: http://www.chlorinated-solvents.eu/index.php/regulatory-compliance/tri-charter

[84] Source: IOM Research Project P937/3, 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 – Trichloroethylene https://echa.europa.eu/documents/10162/13640/svhc_axvrep_france_cmr_trichloroethylene_en.pdf

There are approximately 140,000[85] firms engaged in the 'treatment and coating of metals'. Since TCE is an effective solvent for the cleaning of metals, it may be assumed that all of the enterprises would seek to use it under appropriate economic and safe use conditions.

Italy, Germany, Poland, UK and France gather together more than 60% of all firms. Spain, Czech Republic, Sweden, Portugal and Hungary each have more than 4,000 firms accounting for more than 20% of the total. The structure of the metal degreasing sector is not well known. In the case of the UK, the sector comprises a large number of small companies, with a high proportion having fewer than 20 workers.

Sectors where TCE is subject to non-intermediate use, such as metal degreasing, would not, however, be affected significantly by the introduction of an OEL because TCE has been included into REACH authorisation which – coupled with the SED – should result in effectively controlled exposures.

Note on STEL value

TCE is the only substance for which a STEL is considered in this initiative. A more detailed account of general STEL policy considerations is given in Annex 4 at section 11.2.2.

It is possible to have peak short term exposures which would not bring the 8hr average above an OEL, but which might themselves be harmful. STEL values are therefore necessary where exposure patters are not addressed by 8hr TWA values alone, and short term exposures can result in adverse health effects.

In relation to the calculation of compliance costs, it should be noted that compliance with an 8-hr TWA OEL already requires that necessary equipment, sampling strategy, and other risk management measures be in place at enterprise level, and that STEL values – which are normally significantly higher – should therefore already be complied with where an 8-hr TWA values are established. Therefore, STEL values do not generate any additional costs for companies.

The risk management and monitoring approaches will be the same as both values are for inhalation – the STEL provides an important additional workplace monitoring value to ensure short-term or 'excursion' exposures remain below harmful levels.

Of the 22 Member States which have already a national OEL for TCE in place (regardless whether they are higher, equal to, or lower than the retained option), 16 have also adopted a STEL. (One Member State, IE, has only a STEL and no OEL.) It can therefore be seen that the approach of combining an 8-hr TWA and STEL OELs is supported by the majority of the Member States – indeed 8-hr TWA and STEL values, along with notations, should always be seen as a complementary and mutually dependent package of occupational hygiene inputs.

Table 12. Trichloroethylene – Types of impacts

Impact	**Option 1:** **Baseline**	**Option 2:** **Annex III entry** **54.7 mg/m^3 (10ppm) 8hr TWA** **164.1 mg/m^3 (30 ppm) STEL** **Sk.**	**Option 4:** **Annex III entry** **273.5 mg/m^3 (50 ppm) 8hr TWA** **164.1 mg/m^3 (30 ppm) STEL** **Sk.**
Economic	Exposure levels are estimated to decline by 7% annually up to	Investment is expected to occur already under the baseline, only possibly later in time: the costs of	Investment is expected to occur already under the baseline, only possibly later in time: the costs of

[85] 2006 Eurostat data

Impact	Option 1: **Baseline**	**Option 2:** **Annex III entry** **54.7 mg/m^3 (10ppm) 8hr TWA** **164.1 mg/m^3 (30 ppm) STEL** **Sk.**	**Option 4:** **Annex III entry** **273.5 mg/m^3 (50 ppm) 8hr TWA** **164.1 mg/m^3 (30 ppm) STEL** **Sk.**
	2030, and then to remain constant. Given the requirements of the SED and of the voluntary industry agreement (ECSA), any firm using TCE above 1 tonne per year should already have closed systems in place. Closed systems manufacturers should benefit from increased demand over time.	anticipating this expenditure by 10-20 years would be in the range of €154-257m. The annualised cost of compliance is estimated at 6.000€ per firm affected by the OEL (TWA and STEL values combined). There is insufficient data to estimate the number of firms that would require closed systems in order to meet an OEL of 54.7 mg/m^3 (10ppm). As per 'General remarks' skin notations should not result in additional cost - employers should already under the baseline be taking steps to manage risks to workers by avoiding dermal exposure. No major macroeconomic impacts are expected.	anticipating this expenditure by 10-20 years would be in the range of €22-37m (TWA and STEL values combined). As per 'General remarks' skin notations should not result in additional cost - employers should already under the baseline be taking steps to manage risks to workers by avoiding dermal exposure. No major macroeconomic impacts are expected.
Social (incl. health)	Total attributable deaths for 2010-2069: 3 290 Health costs over the period 2010-69 are estimated to be between €1,582m to €5,657m. YYLs to decrease over the period, from 481 years to 243 years for liver cancer, 189 years to 174 years for kidney cancer, and 196 years to 98 years for NHL.	Total attributable deaths for 2010-2069: 2 900 (390 less) The health cost savings relative to the baseline are estimated to be between €118-430m over this period. YYLs to decrease, from 481 years to 112 years for liver cancer, 189 years to 162 years for kidney cancer, and 196 years to 54 years for NHL. Skin notations may be expected to improve awareness and enforceability.	Total attributable deaths for 2010-2069: 3 430 (this figure suggests more cancers than under the baseline; however this is due to the modelling used by the IOM study, that assumed a 99% compliance to the OEL rather than a 100% compliance). There is not expected to be a reduction in health costs relative to the baseline scenario. YYLs to decrease, from 481 years to 288 years for liver cancer, 189 years to 178 years for kidney cancer, and 196 years to 137 years for NHL. This is a worse prediction than under the baseline. Skin notations may be expected to improve awareness and enforceability.
Environmental	No significant impact	No significant impact	No significant impact

Specifically for TCE, exposure prevalence estimates in the IOM study were based on the 2007 Finnish CAREX, the 2004 Spanish CAREX and the 2000-2003 Italian CAREX. The proportion of exposed workers in each industry was taken from each of these three CAREX estimates and the average proportion exposed across all three countries calculated for each industry. According to the Finnish Job-Exposure Matrix, the average exposure for all occupational groups is estimated to be 5 ppm.

Introduction of an OEL would entail some costs for business (higher in the case of option 2) even though also for companies not covered by the SED it is assumed that the requirements of national OELs, the ECSA Charter and REACH authorisation have led firms to already put in place closed systems, or to substitute TCE. Companies which have not yet made the investments to protect workers either through closed systems or substitution, will need to do so with the introduction of the OEL of 10 ppm. Among those companies, SMEs could be more vulnerable to the capital cost of a closed system. If as a consequence they decide to close down, there could be some limited effects on employment in IT, DE, PL and the UK in particular. It is very unlikely, however, that the costs of compliance would be large enough collectively to cause any significant macroeconomic impacts. It is also possible that some firms will substitute trichloroethylene or use an alternative process for metal degreasing. Therefore, there may only be a small redistribution of goods and services bought rather than any significant change in overall gross output.

There are expected to be more significant health benefits of introducing an OEL at 10ppm (54.7 mg/m^3), which is also the SCOEL recommended level, than at 50 ppm due to the additional reduction in exposure and a decrease in attributable deaths, and the potential for CMD OELs to be used as exposure benchmarks for decision making in other areas.

Table 13. Trichloroethylene– Comparison of options

Criteria	**Option 1:** **Baseline**	**Option 2:** **Annex III entry** **54.7 mg/m^3 (10 ppm) 8hr TWA** **164.1 mg/m^3 (30 ppm) STEL** **Sk.**	**Option 4:** **Annex III entry** **273.5 mg/m^3 (50 ppm) 8hr TWA** **164.1 mg/m^3 (30 ppm) STEL** **Sk.**
Effectiveness	0	+ (significant decrease in number of deaths)	≈ (protection not much improved)
Efficiency	0	- (additional costs proportionate to benefits but potential risk for SMEs)	- (small compliance costs but for no significant additional benefits)
Coherence	0	+	+
Scientific advice (SCOEL) (Adopted 2009)[86]	An 8 hr TWA of 54.7 mg/m^3 (10 ppm), a STEL of 164.1 mg/m^3 (30 ppm), a skin notation, and a biological monitoring value of 20 mg trichloroacetic acid/l. urine is recommended.		
ACSH	An 8hr TWA of 54.7 mg/m^3 (10 ppm) is proposed.		

In the case of TCE, in-depth discussions between the representatives of workers, employers and governments in the ACSH resulted in full consensus that the proposed OEL as in option 2 represents an appropriate risk management measure. No concerns about technical feasibility,

[86] SCOEL/SUM/142, April 2009

overall costs or impact on competitiveness outside the EU have been raised by employers' representatives or governments' representatives.

The impact assessment confirms that the option supported by the ACSH opinion (OEL of 10 ppm) is appropriate. Introduction of this OEL with a STEL, and a skin notation as recommended by SCOEL would result in higher health benefits than the other considered options, would ensure legal protection for workers and enhanced clarity for enforcers and economic operators. **Option 2 is therefore the preferred option.**

Impact on Member States, competitiveness, and proportionality

In the case of trichloroethylene 17 Member States will have to introduce (6) or update (11) their OEL to bring it down to 54.7 mg/m^3 (10 ppm) (annex 7 and 10). Nearly 74% of exposed workers are estimated to work in those 17 MSs (see table 4 of Annex 7) and would consequently benefit from improved legal protection thanks to the introduction of the OEL. Introducing an OEL would also ensure that lack of an OEL or a less stringent OEL does not act as an incentive for business in decisions concerning the plant location.

The retained option is equivalent (Australia, Ontario) or more stringent than the values in non-EU jurisdictions where these have been identified, except in the only case of China where a lower limit value of 30 mg/m^3 is established.

5.7 Complex polycyclic aromatic hydrocarbon (PAH) mixtures with benzo[a]pyrene as an indicator

Polycyclic aromatic hydrocarbons (PAHs) are a large class of organic compounds – more than 100 single PAHs identified, including benzo[*a*]pyrene.

Benzo[*a*]pyrene and complex PAH mixtures are not produced and used as such, but are ubiquitously formed during combustion (burning) and pyrolysis of organic materials – as a result they do not exist in isolation but as components of complex mixtures that contain many different PAH and related compounds.

The largest single source of PAHs is the burning of wood in homes. Automobile and truck emissions are also major sources of PAH. Environmental tobacco smoke, unvented radiant and convective kerosene space heaters, and gas cooking and heating appliances may be significant sources of PAH in indoor air and potentially occupational exposure. Important human (non-occupational) sources of individual exposure to PAH are inhalation of tobacco smoke and contaminated air and ingestion of the compounds in foodstuffs.

Occupational exposure[87]

The most extensively studied individual PAH is benzo[*a*]pyrene (BAP) – which is one of the strongest genotoxic carcinogens, and which significantly contributes to the carcinogenic potency of PAH-rich mixtures. Benzo[*a*]pyrene as a pure chemical is not of occupational relevance. However, it is commonly used as a quantitative indicator compound within complex mixtures of PAHs, which are ubiquitously formed during combustion and pyrolysis processes of organic materials, like the processing and use of coal and coal-derived products[88].

[87] IARC Monograph Volume 92, 2010: Some Non-heterocyclic Polycyclic Aromatic Hydrocarbons and Some Related Exposures

[88] Crude coal tar is usually distilled, and blends of distillation fractions are used for various purposes, such as wood conservation, paints, road tars and roofing materials. PAH concentrations in coal-tar products may range from less than 1% up to 70% or more.

According to the most recent SCOEL recommendation 404[89] and the information provided in the IARC monograph Number 92, the 'production and use of coal tar and coal tar-derived products are major sources of occupational exposure to PAHs.'

This risk to workers is already reflected by entry number 2 of Annex I to the CMD: '2. Work involving exposure to polycyclic hydrocarbons present in coal soot, coal tar or coal pitch.', and are therefore under the scope of the Directive.

Benzo[*a*]pyrene as well as seven other PAHs subject to REACH restrictions[90] are classified as carcinogens, category 1B in the CLP Regulation[91], and are therefore as well under the scope of the Directive[92].

Benzo[*a*]pyrene was examined in the IOM Study, where the impact of introducing an OEL of 0,002 mg/m^3 for benzo[*a*]pyrene was evaluated. IOM concluded that in 2006 234,000 workers were exposed to high (0.001 – 0.01 mg/m^3 or higher), and 7 millions of workers to low, levels (0.000001 – 0.001 mg/m^3) of benzo[*a*]pyrene.

National occupational exposure limit values for benzo[*a*]pyrene (see Annex 7) range from 0,00015 mg/m^3 to 0,01 mg/m^3. However, these are sometimes specific to different types of workplace (e.g. to underground mining)[93], or refer to benzo[*a*]pyrene as a marker of total PAH concentration (DE).

Table 14. Complex PAH mixtures with benzo[*a*]pyrene as an indicator – Types of impacts

Impact	**Option 1:** **Baseline**	**Option 2:** **Annex III entry** **Sk.**	**Option 3:** **Annex III entry** **0.002 mg/m^3** **Sk.**
Economic	A decrease rate of 6% per annum for at least next 20 years is assumed.	Same as baseline. As per 'General remarks' skin notations should not result in additional cost - employers should already under the baseline be taking steps to manage risks to workers by avoiding dermal exposure. No impact on employment.	No macroeconomic effects foreseen as the current exposure concentration is already below the suggested threshold in all MS. The vast majority of investment required by industry to comply with this OEL already occurred. As per 'General remarks' skin notations should not result in additional cost - employers should already under the baseline be taking steps to manage risks to workers by avoiding dermal

[89] SCOEL Recommendation 404 on Polycyclic Aromatic Hydrocarbon mixtures containing benzo[*a*]pyrene, adopted December 2016

[90] entry 50 of Annex XVII of to REACH Regulation contain next to benzo[*a*]pyrene the following PAHs: benzo[e]pyrene (CAS No 192-97-2), benz[*a*]anthracene (CAS No 56-55-3), chrysene (CAS No 218-01-9), benz[*e*]acephenanthrylene, benzo[*b*]fluoranthene (CAS No 205-99-2), benzo[*j*]fluoranthene (CAS No 205-82-3), benzo[*k*]fluoranthene (CAS No 207-08-9), and dibenzo[*a,h*]anthracene (CAS No 53-70-3)

[91] PAHs have been linked to skin, lung, bladder, liver and stomach cancer in well-established animal studies. Exposure to PAHs has also been linked with cardiovascular disease and poor fetal development

[92] This applies as well to any mixture containing benzo[*a*]pyrene or other PAHs classified as a carcinogen, category 1B, in a concentration at or above their generic or specific concentration limit

[93] e.g. in Austria, a value of 0,005 mg/m^3 is applicable to "Cokeries, oven area", and a value of 0,002 mg/m^3 applies to "other workplaces"; in Slovenia and Slovakia a value of 0,005 mg/m^3 is applicable to "Coking", and a value of 0,002 mg/m^3 applies to "others"

Impact	Option 1: **Baseline**	Option 2: **Annex III entry** **Sk.**	Option 3: **Annex III entry** **0.002 mg/m^3** **Sk.**
			exposure. No impact on employment.
Social (incl. health)	Health cost range, in the period 2010-2069, is €6.2bn-194bn (€45-453m for NMSC only) mostly due to previous exposure. Total attributable deaths: 47 bladder, 430 lung, and 2 NMSC in 2010, respectively declining to three, to five, and rising to three. YLL decrease from 544 to 13 per year for bladder and from 6,689 to 61 per year for lung cancer. YLL increase from 24 to 29 for NMSC.[94] DALY decrease from 703 to 17 per year for bladder and from 6,978 to 64 per year for lung cancer. DALY increase from 24 to 29 for NMSC.	Same as baseline. Skin notations may be expected to improve awareness and enforceability. Significant benefit of establishing a skin notation expected as a result of the dermal exposure hazard.	Same as baseline. Skin notations may be expected to improve awareness and enforceability. Significant benefit of establishing a skin notation expected as a result of the dermal exposure hazard.
Environmental	No significant impact	No significant impact	No significant impact

As in the case of all other considered chemical agents, the exposure trends for PAHs used to establish the baseline are quoted from the IOM study. The validity of these assumptions is discussed in the introduction to section 5 of the first wave IA.

Option 2 consists of a skin notation in Annex III, linked to the current Annex I entry. While it is assumed that monetised costs/benefits would closely match the baseline, the added value lies in very useful information for health professionals and employers.

[94] There are no YLDs for NMSC as the majority are dealt with easily and do not incur any lasting disability.

Option 3 links an exposure limit value in Annex III to the current Annex I entry. The IOM Study concluded that exposures in the EU were already well below 0.002 mg/m^3 and no significant health benefits or costs or social or macro-economic costs should result from introducing an OEL at that value. SCOEL is of the opinion that safe health-based exposure limits cannot be derived[95]. ACSH also considered that health benefit of setting an OEL is insufficient to justify action. Introduction of such an OEL could also result in practical difficulties - in recent communication the industry association of the European Plastics Converters (EuPC) have indicated that a limit of 0.002 mg/m^3 'would be difficult to measure… currently no air measurements are available.'

Table 15. Complex PAH mixtures with benzo[*a*]pyrene as an indicator – Comparison of options

Criteria	**Option 1:** **Baseline**	**Option 2:** **Annex III entry** **Sk.**	**Option 3:** **Annex III entry** **0.002 mg/m^3** **Sk.**
Effectiveness	0	≈ (moderately reinforcing existing protection)	≈ (exposure already below OEL)
Efficiency	0	≈ (no significant costs/benefits)	≈ (no significant costs/benefits)
Coherence	0	+	+
Scientific advice (SCOEL) (Draft final Recommendation, under public consultation, due for adoption Dec 2016)[96]	In a recommendation on PAH mixtures containing benzo[*a*]pyrene' currently undergoing public consultation, SCOEL concluded that 'PAH mixtures containing benzo[*a*]pyrene, PAH mixtures and benzo[a]pyrene are *genotoxic carcinogens (SCOEL Group A)* for which safe health-based exposure limits cannot be derived.' As a consequence, no health-based OEL was recommended. SCOEL proposes 0.5 µg 1-hydroxypyrene per g creatinine as a biological monitoring value with sampling advice. A skin notation is warranted.		
ACSH	There is insufficient added health benefit in the proposed OEL of 0.002 mg/m^3 8 hrs TWA [for benzo[*a*]pyrene]. Workers Interest Group: In view of the risk-based values derived in the Netherlands and in Germany of 0.00055 mg/m³ and 0.0007 mg/m³, respectively, any proposed binding limit value should not exceed those values. Given the high number of workers exposed to benzo[*a*]pyrene, such a value should be derived within less than three years		

In the case of this substance, in-depth discussions between the representatives of workers, employers and governments in the ACSH resulted in agreement that at this stage no OEL should be proposed, as in option 2. However, ACSH agreed that an OEL for PAHs is important and work should be carried out to evaluate the scientific aspects with the view to proposing as OEL at some time in the future. Workers' representatives emphasised the need for an OEL in the future.

[95] SCOEL Recommendation 404 on Polycyclic Aromatic Hydrocarbon mixtures containing benzo[*a*]pyrene, adopted December 2016

[96] Draft SCOEL Recommendation 404 on Polycyclic Aromatic Hydrocarbon mixtures containing benzo[*a*]pyrene

The impact assessment supports the course of action proposed by the ACSH opinion (no OEL) and confirms that introduction of a skin notation in Annex III would provide useful information for choosing adequate risk management measures. **Option 2 is therefore the preferred option.**

Even if the current Annex I entry covers major sources of occupational exposure to PAHs (including BAP), it is unclear which other occupational exposure situations exist during which workers are exposed to these substances and their mixtures. The need for a revision of the current Annex I entry should therefore be evaluated in the future.

Impact on Member States, competitiveness, and proportionality

Action taken at the European Union level by introducing a skin notation in Annex III would facilitate compliance and enforcement of the existing CMD obligation to – so far as technically possible – eliminate or otherwise minimise exposure to these classified carcinogens, and would therefore be justified. It would in no way affect industry competitiveness.

5.8 Mineral Oils as Used Engine Oils

Oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine ("mineral oils as used engine oils") consist of blends of hydrocarbons including paraffins, naphthenics, and complex/alkylated polyaromatics and lubricating additives. Engine oils are used in internal combustion engines, which power cars, motorcycles, diesel trains, ships, lawn mowers and other machinery. Occupational exposure is via the dermal route – skin contact during changing of oil or working with engine parts. Recycling of non-metal scrap is another source of exposure, although relatively less important. Inhalation exposure to mineral oils as used engine oils is unlikely.

The composition of engine oils, and hence of mineral oils as used engine oils, has been changing over time to meet the requirements of newer engine designs and performance requirements. The composition of engine oils also varies depending on the needs of different engines and operating conditions, and changes during use with the accumulation of fuel components, water, metals, metal oxides, and combustion products (including PAHs) within the oil.[97]

Exposure to mineral oils as used engine oils may cause skin cancer. Because 'mineral oils as used engine oils' are process-generated – and not 'supplied' as such – they are not subject to classification according to CLP.

Mineral Oils as Used Engine Oils have been thoroughly described and assessed by IARC in 1984. IARC concluded that there was sufficient evidence from studies in humans that used mineral oils, containing various additives and impurities, used in several occupations, were carcinogenic in humans. The final IARC evaluation does not explicitly mention 'used engine oils', but concludes that 'Mineral oils, mildly treated or untreated' are carcinogenic to humans under IARC Group 1.[98] In the Opinion of SCOEL, "mineral oils as used engine oils" defined to mean "oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine" are carcinogenic in SCOEL Group A, for which no health-based exposure threshold can be derived. SCOEL strongly recommends a skin notation.

The number of workers exposed is estimated at 1 million, employed mostly in maintenance and repair of motor vehicles (0.9 million). Other sectors include sales, maintenance and repair of

[97] PAHs are ubiquitously formed during the incomplete combustion and pyrolysis of organic materials. PAHs generally, and their presence in mineral oils as used engine oil, are treated separately in sections xx and xx of this Impact Assessment Report.

[98] It should be noted that these oils occur early in the refining process; they are dermal carcinogens due to the PAHs present, which originate from the crude oil source material. As such, they are not used to make lubricating oils in the EU.

motorcycles (less than 0.1 million) and recycling of non-metal waste and scrap (less than 0.1 million). Around 370,000 companies are working in these sectors and a majority of these companies are SMEs.

Figure 7. Sector structure

No: of employees bands	Average number of workers per class size (rounded)	Average composition of enterprises for all affected NACE sectors that use mineral oils*
Between 1 and 9	5	90%
Between 10 & 19	15	6%
Between 20 & 49	25	3%
Between 50 & 250	150	1%
Greater than 250	500	0%
Total	-	-

Mineral Oils as Used Engine Oils (UEOs) are not 'supplied' *per se* and hence not classified according to the CLP Regulation. It may be noted that polycyclic aromatic hydrocarbon (PAH) substances, including benzo[*a*]pyrene and others, are among the most important carcinogenic components of UEOs. The most harmful types of PAH are classified according to CLP – in the case of benzo[*a*]pyrene this classification includes the potential to cause an allergic skin reaction. Labelling provisions will not, however, apply where they are present in process-generated form. Employers should be aware of the dermal hazard – again, in the case of PAHs present in Mineral Oils as Used Engine Oils (which are process-generated) a skin notation adds value by raising awareness.

Table 16. Mineral Oils as Used Engine Oils – Types of impacts

Impact	**Option 1:** **Baseline**	**Option 2:** **Annex I entry** **Annex III entry** **Sk.**
Economic	No decline in exposure levels assumed, but the number of workers affected will increase due to expected increases in employment and ageing population.	€46m-918m Cost per company and per year are expected to be very low (€100-500).
Social (incl. health)	Total attributable deaths for 2010-2069: 1180 Monetised values: €0.5-2.8 bn Total attributable cases: 128,850 YYL: 10 880	Total attributable deaths 2010-2069: 880 less than under baseline Total attributable cases: 90,000 less than under baseline. Monetised savings: €0.3-1.6 bn related to avoidance of health costs associated with future exposure
Environ-mental	No significant impact	No significant impact

The estimates of the prevalence of exposure to mineral oils as used engine oils in the EU were not available. Instead, the number of affected workers was estimated. It was assumed that the workers exposed are employed in the three sectors mentioned above and belong to the occupational groups most likely to have direct skin contact with mineral oils as used engine oils (technicians, service workers, elementary occupations and others). No European data was

available for cancer numbers, therefore data from Great Britain was used also for other countries in proportion to the age and sex structure of their population.

A range of best practice can be used to limit dermal exposures. These include use of gloves or barrier creams, removal and cleaning of contaminated clothing, avoiding keeping contaminated rags in the pockets, etc. Under the baseline it was assumed that the share of exposed workers in enterprises which do not comply with the best practices lies within the interval of 10% (0.1 m) and 40% (0.4 m).

The estimated deaths increase over the period from 7 in 2010 to 36 per annum in 2060 and afterwards. Likewise, the estimated annual attributable cancer registrations are set to increase from 916 in 2010 to 3,554 in 2060. The forecasted increases are due to forecasted doubling of the people employed in the sectors at risk of exposure. Also, the ageing population plays a role in increasing the prevalence of skin cancer.

Option 2 follows the ACSH Opinion that an Annex I entry in CMD, identifying mineral oils as used engine oils as carcinogenic for the purposes of the CMD and also indicating that concern relates to the dermal route of exposure, is appropriate. It is complemented with a skin notation as strongly recommended by SCOEL.

Option 2 further promotes the aforementioned best practices, establishing a clear legal basis to the requirement of using best practice to reduce dermal exposure, increasing awareness among employers and workers, and improve the ability to enforce the requirement. The costs up to 2030/40 are not expected to differ significantly from the baseline scenario due to past exposure. However, full compliance with good practice could avoid the health costs post-2040. The monetized value of these health benefits is in the range of €0.3-1.6bn.

The maintenance and repair of vehicles is relevant to all Member States with no country having a particularly high exposure. Full compliance with best practices entails costs for businesses, which include costs of familiarisation with requirements, investment in equipment, and time spent on cleaning, training, and administration. It is estimated that 20,000 to 80,000 enterprises will be affected and the compliance costs per enterprise are relatively low, at around €100-500 per year, and these costs are likely to be an overestimate since the current compliance is likely above 60%. This amounts to €2m-39m per year and €46m-918m over the period 2010-2070. The high total costs reflect the high number of businesses and workers affected. The cost of compliance per enterprise in order to reduce skin exposure is between € 100 and € 500 per company per year. Thus, it is not considered to be prohibitive for any enterprise size.

There should not be any negative impact the competitiveness of the concerned firms. The total costs are negligible compared to the value creation in the manufacturing sector (€ 5 trillion in 2006 alone). With fewer life years lost and fewer cancer registrations, there should be a benefit to the economy through avoided loss of output and consumption in the future (post 2040).The high number of small companies indicates a competitive market, thus additional costs should hardly be shifted on the consumer. Most likely, the act of changing their prices would cost the companies more than the additional costs due to protective measures in the short term.

Concerning employment, there are no expectations for any noticeable changes to the numbers of workers required as a result of introducing an EU-wide OEL. However, job patterns may be altered as it is recognised that, in order to meet best practice, behavioural change amongst employees and updating health and safety training is expected to be required.

Table 17. Mineral Oils as Used Engine Oils – Comparison of options

Criteria	**Option 1:** **Baseline**	**Option 2:** **Annex I entry** **Annex III entry** **Sk.**
Effectiveness	0	+ (significant protection increase)
Efficiency	0	≈ (significant extra costs but proportionate v-à-v benefits)
Coherence	0	+
Scientific advice (SCOEL) (Adopted 2016)[99]	Carcinogenic Group A – Non-Threshold. Occupational exposure is via the dermal route – a skin notation is strongly recommended.	
ACSH	An Annex I entry should refer to mineral oils as used engine oils, and specify that the entry covers oils that have been used before in internal combustion engines to lubricate and cool the moving parts within the engine. ACSH did not explicitly recommended a skin notation but noted in its Opinion that the route of exposure of concern is skin. Therefore Option 2 is complemented with a skin notation as strongly recommended by the SCOEL.	

In the case of mineral oils as used engine oils, in-depth discussions between the representatives of workers, employers and governments in the ACSH resulted in full consensus that the proposed Annex I entry as in option 2 represents an appropriate risk management measure. No concerns about technical feasibility, overall costs or impact on competitiveness outside the EU have been raised by employers' representatives or governments' representatives.

The impact assessment confirms that the option supported by the ACSH opinion (Annex I entry) is appropriate, and also identifies additional benefit from amending Annex III. Likewise, a skin notation in Annex III appears appropriate. **Option 2 is therefore the preferred option.**

Impact on Member States, competitiveness, and proportionality

Identification of Mineral Oils as Used Engine Oils as carcinogenic is not possible under the CLP Regulation, and national practices vary considerably as regards identifying mineral oils as used engine oils as carcinogenic and setting relevant OELs. Under these conditions a minimum basis of protection against the risks arising from workers' exposure to these carcinogens cannot be ensured for all EU workers – it follows that an action taken at the European Union level, to clarify that mineral oils as used engine oils are carcinogenic and in scope of the CMD provisions and to introduce a skin notation in Annex III, and hence that exposure to it should be eliminated or otherwise minimised as far as technically possible, would be justified.

5.9 Summary of the retained options

It has been shown in the previous sections that the considered chemical agents vary significantly. The table below summarises the retained options on the basis of several criteria.

[99] SCOEL/OPIN/405, June 2016

Where available evidence presented in this assessment is in a range covering several criteria, the midpoint is used to avoid ambiguity.

i) Stakeholders' acceptance

For all the twelve impact assessed carcinogens, the assessment validates as the retained option for seven carcinogens the position expressed in opinion of the tripartite ACSH, plus additional factors important for worker protection. However, for a few there have been some dissenting opinions in the course of the discussions. The following rating is applied:

- XX - full support in the ACSH;

- X - partial or conditional support in the ACSH.

It should be noted that in case of partial or conditional support by the stakeholders represented in the ACSH, diverging views concerned e.g. ranges of values or feasibility considerations rather than the principle of setting an OEL at EU level.

ii) Legal clarity

The changes considered for the seven carcinogens, will improve legal clarity for employers and workers. In the case of process-generated substances, where identification in Annex I is proposed this is expected to improve legal clarity in every Member State. In the case of OELs, the number of MS needing to introduce or amend national OELs corresponding to the proposed EU value is used to gauge improvements in legal clarity.

- XX - legal clarity will be improved in half or more of the MS

- X - legal clarity will be improved in less than half of the MS

iii) Size of the problem

The numbers of workers potentially exposed to the carcinogens vary substantially. While CMD amendments will be useful even if currently few workers are exposed (for example this might change in the future), an immediate impact will be greater when exposed populations are bigger.

- XXX - over 500,000 exposed workers

- XX - between 50,000 and 499,999 exposed workers

- X - less than 50,000 exposed workers, and/or subject to REACH authorisation

iv) Health benefit

There is also a divergence in the size of monetised health benefits of introducing OELs.

- XXX - benefits over 100 m EUR

- XX - benefits between 10 m EUR and 100 m EUR

- X - benefits of less than 10 m EUR, and/or subject to REACH authorisation

v) Limited costs for business

While all the retained options are expected to be feasible for business, there are different levels of associated costs for business.

- XXX - costs below 10 m EUR, and/or subject to REACH authorisation

- XX - costs between 10 and 100 m EUR

- X - costs over 100 m EUR

Table 18

Name of the chemical agent	Retained option (ppm – parts per m, mg/m^3) [option number]	Stakeholders acceptance	Legal clarity	Size of the problem	Health benefit	Limited costs for business
Epichlorohydrine	Annex III entry 1.9 mg/m^3 Sk. **[2]**	XX	XX	X	X	XXX
Ethylene dibromide (EDB)	Annex III entry 0.8 mg/m^3 (0.1 ppm) Sk. **[2]**	XX	XX	X	X	XX
Ethylene dichloride (EDC)	Annex III entry 8.2 mg/m^3 (2 ppm) Sk. **[2]**	XX	XX	X	X	XX
4,4'-Methylenedianiline (MDA)	Annex III entry 0.08 mg/m^3 Sk. **[2]**	XX	XX	X	X	X
Trichloroethylene (TCE)	Annex III entry *8TWA* 54.7 mg/m^3 (10 ppm) *STEL* 164.1 mg/m^3 (30 ppm) Sk. **[2]**	XX	XX	XX	XXX	X
Complex PAH mixtures with benzo[*a*]pyrene as an indicator	Annex III entry Sk. **[2]**	X	XX	XXX	X	XXX
Used engine oils	Annex I entry Annex III entry Sk. **[2]**	XX	XX	XXX	XXX	X

6 OVERALL IMPACT OF THE PACKAGE OF RETAINED OPTIONS

6.1 Impact on workers

The retained options package (henceforth 'the retained option') should result in benefits in terms of avoided work-related cancer cases and related monetised health benefits. As mentioned in the introduction to section 5 assessing health benefits of action against carcinogenic chemicals is challenging and the quantified benefits are likely underestimated. The greatest assessable benefits are expected in relation to trichloroethylene and mineral oils as used engine oils. In the case of those two substances the retained option would result, until 2069, in:

- Mineral Oils as Used Engine Oils: 880 saved lives, 90,000 less cancer cases and a monetised health benefit of €0.3-1.6 bn related to avoidance of health costs
- Trichloroethylene: 390 saved lives and a monetised health benefit of €118-430m related to avoidance of health costs

Impacts of action for other chemicals under this initiative are relatively smaller or difficult to assess.

Further discussion can be found in the prior Impact Assessment (at p. 79) of expected benefits as regards reduced economic costs caused by disability and premature death, shielding workers and families from suffering financial and social costs which would otherwise occur in a baseline scenario.

The study underlying the present assessment was limited to assessing health benefits resulting solely from avoided cancer cases. Nevertheless, the chemical agents under consideration pose a range of other occupational hazards including, for various carcinogens considered here:

- suspicion of causing genetic defects
- damage to fertility
- damage to an unborn child
- damage to organs through prolonged or repeated exposure
- irritation and/or damage to the eyes, skin, and/or respiratory system
- allergic skin reaction
- causing drowsiness or dizziness

Enhanced workplace control of the considered carcinogens will also contribute to decreasing the risk associated with exposure to these occupational risks. The available data is not sufficient to estimate the magnitude of related health and socio-economic benefits. However, taking into account general estimates of costs related to these diseases, it could be expected that benefits could be considerable. For example, according to a study on costs of occupational hand eczema, conducted in 2013 in Germany[100] the annual direct and indirect costs per worker diagnosed and treated were on average €2,646 and €6,152 respectively. Also research conducted in Australia confirmed that occupational skin diseases had a significant socioeconomic impact, with an estimated annual cost of over $33 m.[101]

6.2 Impact on businesses

Detailed discussion can be found in the prior Impact Assessment (at p. 80) of the range of economic impacts of occupational cancer on business and consumers.

As regards costs incurred by enterprises for risk reduction measures, the retained option will affect operating costs for companies which will have to put in place additional protective and preventive measures. This will be in particular the case for trichloroethylene and mineral oils as used engine oils, where the total costs to industry of the retained option until 2069 are estimated to range between €154-257m for trichloroethylene and €46m-918m for mineral oils as used engine oils.[102]

For the majority of considered carcinogens, impacts cannot be fully quantified based on available data but impacts on operating costs and conduct of business (including small and medium enterprises) are expected to be minimal as only small adjustments will need to be done in specific cases to ensure full compliance. The retained option will not impose any additional information obligations and will not lead to an increase in administrative burdens on enterprises.

[100] Diepgen TL, Scheidt R, Weisshaar E, John SM, Hieke K. Cost of illness from occupational hand eczema in Germany. Contact Dermat. 2013;69(2):99–106. [PubMed]

[101] http://www.safeworkaustralia.gov.au/sites/swa/media-events/media-releases/pages/mr16032012

[102] Including estimated costs of anticipating investment needed to comply with measures reflected in retained option.

6.2.1 Impact on SMEs

The economic impacts for SMEs of changes to CMD – and in particular establishing OELs – are discussed in detail in the prior Impact Assessment (at p. 81).

For a majority of chemical agents covered by this initiative, SMEs represent a large proportion of the relevant industries. Therefore, SMEs specificities, their limitations and particular challenges have been duly taken into account in the overall analysis presented in section 5. The analysis has shown that in most cases costs which will be incurred by SMEs are affordable for the companies. The most significant costs foreseen in the IOM study associated with the considered carcinogens relate to investment in closed systems for use of TCE. Such investment is likely to have already been made by a majority of companies, following the requirements under the SED, national OELs, the ECSA Charter and REACH. Introduction of an OEL will only make a significant impact on companies which have not yet made the investments to protect workers either through closed systems or substitution. Among those companies, SMEs could be more vulnerable to the capital cost of a closed system. If as a consequence they decide to close down, there could be some limited effects on employment. However, it is also possible that some firms will substitute trichloroethylene or use an alternative process for metal degreasing.

6.2.2 Impact on competition and competitiveness

The impacts of changes to CMD – and in particular establishing OELs – on competition and competiveness are discussed in detail in the prior Impact Assessment (at p. 82).

The retained option would have a positive impact on competition within the internal market by decreasing competitive differences between firms operating in Member States with different national OELs and providing certainty re enforceable exposure limit across the EU.

The retained option should not have a significant impact on the external competitiveness of EU firms. On the one hand, the detailed assessment provided above proves that in most cases additional compliance costs per firm are modest. On the other, while non-EU countries have established a wide range of exposure values that vary significantly and inconsistently across jurisdictions (see Table 3 in annex 7), the retained exposure values are not out of line with international practice. In the case of epichlorohydrine, for example, the retained OEL (1.9 mg/m^3) is similar to that in place in countries such as New Zealand and South Korea, although more stringent (China) and less stringent OELs (e.g. US, Switzerland, Singapore) are applied in some other third countries.

It should be noted, however, that OELs established in different jurisdictions cannot necessarily be compared like-for-like. OEL setting methods differ substantially across jurisdictions as a result, for example, of different approaches to whether and how socioeconomic factors may be taken into account, differences in legal enforceability or expectations regarding compliance, use of scientific evidence and analytical method, industrial relations and roles played by industry, worker representatives, and others. As a result, caution should be exercised in making comparisons and drawing conclusions regarding values which may not be directly comparable.

It can however be observed that, in most cases, the retained option fits into the lower range of equivalent measures established in non-EU countries – suggesting that these measures are achievable, reflect available good practice, and are relatively ambitious in aiming to set internationally high standards of worker protection.

Combined with existing duties in CMD to eliminate or minimise exposure to a level as low as is technically possible, the retained option is not expected to significantly impact EU international competitiveness.

6.3 Impact on Member States/national authorities

The cost impacts of changes to CMD – and in particular establishing OELs – on Member States and national authorities are discussed in the prior Impact Assessment (at p. 83). In summary, the retained option should contribute, although not significantly, to mitigate financial loss of Member State social security systems.

Additional administrative costs and enforcement costs might be incurred by enforcing authorities. These costs are not quantifiable as the granularity of Member States' reporting of enforcement activity is not sufficient to distinguish costs related to a particular OEL.

However, it is not expected for the costs to be significant. OEL enforcement will take place according to normal mechanisms for compliance improvement and enforcement, including informal conversations with employers as well as formal correspondence and legal enforcement action. This will normally be brigaded for any given employer with other OSH provisions (for example workplace transport, slips and trips, machinery safety, stress) rather than specific to OELs. Specific reporting would only be the case where Labour Inspectorates undertake targeted occupational chemical carcinogen enforcement activity and OEL campaigns. Costs will therefore be generally affected by Labour Inspectorate resourcing, prioritisation and targeting – no assumption may be made that enforcement, which is a Member State competence, will receive (or demand) greater resourcing and priority as a result of an OEL being set.

At the same time, establishing OELs, and other explicit references to a given carcinogen in the CMD brings clarity regarding legal requirements, and so facilitates the work of inspectors by providing a helpful tool for compliance checks.

Setting OELs at EU level would limit the need for national administrations to conduct duplicating scientific analyses.

6.4 Impact on fundamental rights

The impact on fundamental rights is considered positive - in particular with regard article 2 (Right to life) and article 31 (Right to fair and just working conditions which respect his/her health, safety and dignity).

6.5 Subsidiarity and proportionality

The protection of workers health against risks arising from exposure to carcinogens is already covered by EU legislation, in particular by Directive 2004/37/EC (CMD), which can be amended at EU level after a two-stage consultation of the social partners.

The retained option takes into account long and intensive discussions with all stakeholders (representatives from employees' associations, representatives from employers' associations, and representatives from governments), including consideration of socioeconomic feasibility.

While the quantified benefits of the initiative appear modest, it should be recalled that the initiative would contribute to saving some 1300 human lives in the forthcoming 50 years and that these figures based on the estimations made the IOM study, are likely to be significant underestimates as discussed in chapter 5.There is a range of additional benefits which could not be quantified for the reasons already explained.

Further, it may be noted that, according to a 2016 report by the Netherlands National Institute for Public Health and the Environment (RIVM)[103] three carcinogens addressed by the retained option - benzo[*a*]pyrene (addressed as a PAH indicator), mineral oils (addressed as used engine oil) and MDA are among the top 10 carcinogenic substances to which the largest numbers of workers are currently exposed; another 4 from that list of 10 carcinogens were in the prior proposal – hardwood dust, hydrazine, respirable crystalline silica and chromium VI compounds.

The report also mentions an EU OSHA survey in 2008 in which nine out of 20 Member States mentioned difficulties in the process of deriving OELS for carcinogenic and mutagenic substances, and indicates that, despite projected declining exposure levels, 'forecast impacts will probably not be lower than those of 2012' (p. 36). The RIVM report concludes that 'developing OELs for carcinogens at the EU level will contribute to the overall protection of the workforce in the EU' (p. 17).

The subsidiarity and proportionality check done for each specific agent, indicated that, where relevant data was available, introduction of proposed OELs would improve legal protection for an estimated 69% to 82% of exposed workers (see Table 4 in annex 7).

In addition, the proposal does not set levels to be directly translated into national legislation but maximum limits. Member States can decide to introduce lower levels.

As per the prior Impact Assessment, the planned action therefore complies with the principles of proportionality and subsidiarity.

6.6 Budgetary implications

There are no budgetary implications for the EU budget and no additional costs will arise for the agency EU-OSHA.

7 HOW WOULD ACTUAL IMPACTS BE MONITORED AND EVALUATED?

7.1 Monitoring arrangements

The table below presents the core indicators for each operational objective and the data sources for the monitoring of the core indicators.

Table 19

Operational objective	Indicators	Monitoring arrangements/data sources for monitoring indicators
The reduction of occupational diseases and occupational related cancer cases in the European Union	The number of occupational diseases and occupational related cancer cases in the EU	The data sources for the monitoring of this indicator are: - data that could be collected by Eurostat on occupational diseases if the results of the on-going feasibility study are positive, as well as on and other work-related health problems and illnesses in accordance with Regulation (EC) No 1338/2008.[104] -data notified by employers to the competent national authorities on cases of cancer identified in accordance with national law and/or practice as resulting from occupational

[103] Work-related cancer in the European Union : Size, impact and options for further prevention, 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, p. 11

[104] Regulation (EC) No 1338/2008 on Community statistics on public health and health and safety at work, OJ L 354/70, 31.12.2008.

		exposure to a carcinogen or mutagen in accordance with Art. 14 (8) of Directive 2004/37/EC, and which may be accessed by the Commission in accordance with Article 18 of Directive 2004/37/EC; -data submitted by Member States in the national reports on the implementation of EU OSH acquis, submitted in accordance with Art. 17a of Directive 89/391/EEC
The reduction of costs related to occupational cancer for economic operators and for social security systems in the European Union	The costs related to occupational cancer for economic operators (e.g. loss of productivity) and social security systems in the European Union.	The monitoring of this indicator will require the comparison of the expected figures on the burden of occupational cancer in terms of economic loss and health care costs and the collected figures on these matters after the adoption of the revision. The productivity loss and health care costs can be established on the basis of the data on the number of occupational cancer cases and the number of occupational cancer deaths (the arrangements for the collection of the data on occupational cancer cases are described supra in this table).

A two-stage compliance assessment (transposition and conformity checks) will be carried out by the Commission for the transposition of the limit values. The monitoring of application and enforcement will be undertaken by national authorities, in particular the national labour inspectorates. At EU level, the Committee of Senior Labour Inspectors ('SLIC') informs the Commission regarding problems relating to the enforcement of Directive 2004/37/EC.

While collection of reliable data in this area is complex, the Commission and EU-OSHA are actively working on improving data quality and availability so that the actual impacts of the proposed initiative could be measured in a more accurate way and additional indicators could be developed in the future (e.g. in relation to mortality caused by occupational cancer). Ongoing projects include cooperation with national authorities on the European Occupational Diseases Statistics (EODS) data collection, a Commission-funded project to establish by the end of 2016 a first version of a database on occupational exposure for some hazardous chemicals and EU-OSHA's assessment of the feasibility of a survey on exposure to carcinogens.

7.2 Evaluation arrangements

In accordance with Art. 17a of Directive 89/391/EEC, every five years, Member States are required to submit a report to the Commission on the practical implementation of the EU OSH Directives, including Directive 2004/37/EC.

Using these reports as a basis, the Commission is required to evaluate the implementation of Directive 2004/37/EC and, to inform the European Parliament, the Council, the European Economic and Social Committee and the Advisory Committee on Safety and Health at Work of the results of this evaluation and, if necessary, of any initiatives to improve the operation of the regulatory framework.

Given the data challenges explained earlier, it is suggested to made use of the next ex-post evaluation exercise (2012-2017) to define the baseline values (benchmark) that will allow assessing the effectiveness of the planned CMD revision. Evaluation of the practical implementation of the proposed amendments could possibly be based on the following period (2017-2022).

Annexes

8 ANNEX 1 – PROCEDURAL INFORMATION

Concerning the process to prepare the impact assessment report and the related initiative.

8.1 Lead DG

Lead DG: Directorate-General Employment, Social Affairs and Inclusion, Unit B/3 Health, Safety and Hygiene at Work

8.2 Consultation of the Regulatory Scrutiny Board (RSB)

The Impact Assessment report was reviewed by the RSB and discussed with the author DG in a meeting on 26 October 2016. On 28 October 2016 the RSB issued a positive opinion with reservations.

The revisions introduced in response to the RSB reservations are summarised in the table below:

RSB main reservations	Changes done to the IA
(1) Set out sequence of steps and underpinning evidence. Elaborate on decision to refrain from setting OELs for four substances, including diesel engine exhaust.	More detailed description of the procedure of amending OEL, the roles of SCOEL, social partners and the ACSH as well as of the approach adapted in the IA to verifying options proposed by the ACSH - see the new section 2.3. Description of criteria taken into consideration when not proposing further action on some substances. Clarification that those actions have not been 'discarded' but rather 'withheld'. - see section 2.3. ('Step 5 - Impact Assessment) and the new section 4.2. Amendments in the text referring to the four substances in section 4.2., in particular diesel engine exhaust, to further explain why action is withheld at this stage. Concerning diesel engine exhaust the new text also clarifies that a sectoral social partners action would be considered complimentary rather than as an alternative to a legislative action.
(2) EU added value of OELs. Explain the level of ambition.	Further elements have been added in Section 2.2. to explain EU added value of the initiative. The level of ambition is considered in the description of the procedure in section 2.3. A new discarded option consisting of directly adopting the most stringent national OELs has been explained in section 4.3.
(3) Elaborate on the interface between CMD and REACH.	Section 3.2.2. provides a more thorough description of the interface - and complementarity - of REACH and OSH, including a practical example of where workers would not be protected from exposure to carcinogens covered by REACH. The section refers to the REFIT platform opinion and follow-up actions planned by the Commission services.

(4) Amend or remove references to biomonitoring to ensure consistency with eventual proposal.	Since biological monitoring values cannot, for legal reasons, be part of this initiative, references to options including such values have been removed across the document. A new 4.1.2. introduces biological monitoring values as important complementary measures.
(5) Technical comments	The document has been revised to take into account other comments made by the RSB, most notably: - the problem definition has been amended to cover all 12 substances in sections 1-3. - section 5.1 and a new section 5.1.1. give further explanation of the methodological challenges, including the reasons for a long timeline and difficulties in providing more information on future evolution in exposures. - further explanation re costs of setting a STEL value for an OEL (see 5.1.2. and 5.6). - costs related to skin notations have been more clearly presented in the relevant substance-specific parts of section 5). - substance-specific sections have been amended to add information on impacts on employment, competitiveness, and to clarify further impacts on SMEs. Where available, the breakdown per company size has been added to give a better overview of the relevant industry structure. Revisions have been made in particular concerning TCE, UEO and PAH to address specific comments of the RSB. - a brief description of differences between OEL setting methods across jurisdictions has been in section 6.2.2.). - further information on enforcement costs has been added in section 6.3. - in section 7.1. efforts to improve availability and reliability of data have been described.

8.3 Evidence used in the impact assessment

8.3.1 IARC Monographs

Various IARC Monograph have been used as evidence in preparation of the impact assessment. The exact source of which monograph has been used for each individual chemical agents is provided for in Annex 5 of this document.

Through the Monographs programme, IARC seeks to identify the causes of human cancer. The criteria established in 1971 to evaluate carcinogenic risks to humans were adopted by the Working Groups whose deliberations resulted in the first 16 volumes of the Monographs series. Those criteria were subsequently updated by further Ad-hoc Advisory Groups (IARC 1977, 1978, 1979, 1982, 1983, 1987, 1988, 1991, 1992, 2005, 2006).

As stated in the preamble of the Monographs, 'the objective of the programme is to prepare, with the help of International Working Groups of experts, and to publish in the form of Monographs, critical reviews and evaluations of evidence on the carcinogenicity of a wide range of human exposures. The Monographs represent the first step in carcinogen risk assessment, which involves examination of all relevant information in order to assess the strength of the available evidence that an agent could alter the age-specific incidence of cancer in humans. The Monographs may also indicate where additional research efforts are needed, specifically when data immediately relevant to an evaluation are not available'.[105]

The scope of the programme nowadays now include specific chemicals, groups of related chemicals, complex mixtures, occupational or environmental exposures, cultural or behavioural practices, biological organisms and physical agents.

For further information on for example the selection of agents, the data used for the Monographs, the selection of experts, the working procedures etc. can all be found in detail in the preamble of the monographs (see above reference).

8.4 External expertise

8.4.1 Use of scientific expertise / Commission expert groups / SCOEL

The Scientific Committee on Occupational Exposure Limits for Chemical Agents was set up by Commission Decision 95/320/EC[106] to evaluate the health effects of chemical agents on workers at work. The work of the Committee directly supports Union regulatory activity in the field of occupational safety and health, when available. It develops high quality comparative analytical knowledge and it ensures that Commission proposals, decisions and policy relating to the protection of workers' health and safety are based on sound scientific evidence.

The Committee assists the Commission, in particular, in evaluating the latest available scientific data and in proposing occupational exposure limits for the protection of workers from chemical risks, to be set at Union level pursuant to Council Directive 98/24/EC and Directive 2004/37/EC of the European Parliament and of the Council.

Members of SCOEL are highly qualified, specialized, independent experts selected on the basis of objective criteria. They are appointed in their personal capacity and provide the Commission with Recommendations and Opinions that are helpful for the development of EU policy on workers protection.

For the purpose of this initiative, the Commission services have used the relevant chemical agent-related SCOEL recommendation. The exact reference for the recommendation used for each individual chemical agent is provided in the relevant tables and footnotes in section 6 of this document.

8.4.2 Studies performed by external consultants

Study on 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

[105] http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf

[106] Commission Decision 95/320/EC of 12 July 1995 setting up a Scientific Committee for Occupational Exposure Limits to Chemical Agents (OJ L 188, 9.8.1995, p. 14)

Following the two stage consultation of the European social partners (see section 9.1 of this document), Commission published on 25 July 2008 an open call for tender in order to carry out an assessment of the social, economic and environmental impacts of a number of policy options concerning the protection of workers health from risks arising from possible exposure to carcinogenic chemical agents at the workplace.

The main outputs were a study report containing full reports on 25 carcinogenic chemical agents and two other policy issues relating to the effectiveness of risk management measures and risk based criteria for the setting of occupational exposure limit values.

The contract started on 24 April 2009 and ran until 27 April 2011.

The outcome of this study (summary report and individual chemical agents' reports) provides the main basis for this Staff Working Document and are summarised in the relevant sections of this document. The executive summary report, the summary report as well as the reports for the individual chemical agents are available on the internet[107].

8.4.3 Study on chemical agents toxic to reproduction

Commission published on 22 May 2010 an open call for tender in order analyse at EU-level the socioeconomic and environmental impact in connection with possible amendment to Directive 2004/37/EC to extend the scope to chemical agents toxic to reproduction, category 1A or 1B according to the CLP Regulation.

The underlying consideration was that under the REACH Regulation these chemical agents may be considered as substances of very high concern (SVHC), and they should therefore also be subject to the more stringent protective and preventive measures under the CMD, in particular with regard to the substitution provision.

However, the more stringent preventive and protective measures established for carcinogens and mutagens under the CMD are mainly related to the fact that for those substances health based OELs cannot be derived. However, for the majority of reprotoxic substances, this is, based on the current scientific knowledge, the case. As a consequence, it can be argued that the protection of workers against exposure to these substances is already covered under the CAD, and that Indicative OELVs or OELs for these chemical agents should be established under that Directive.

Nevertheless, and following in particular the request from the workers interest group of the ACSH (see also information provided in annex 2 of this document – Social Partner Consultation), the study was launched in order to complement the available data to enable the Commission to take an informed decision.

The contract started on 30 November 2010 and the final report was submitted to the Commission in February 2013.

The results of the study did not provide sufficient evidence that including these chemical agents under the scope of the CMD would lead to a higher protection of workers. This option was therefore not further considered for this initiative.

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[107] The following links are only provided for those chemical agents subject to the 2nd amendment of the CMD:
- Summary report: http://ec.europa.eu/social/BlobServlet?docId=10149&
- Epichlorohydrine: http://ec.europa.eu/social/BlobServlet?docId=10177&langId=en
- EDB: http://ec.europa.eu/social/BlobServlet?docId=10171&langId=en
- EDC: http://ec.europa.eu/social/BlobServlet?docId=10170&langId=en
- MDA: http://ec.europa.eu/social/BlobServlet?docId=10162&langId=en
- TCE: http://ec.europa.eu/social/BlobServlet?docId=10156&langId=en
- Benzo(a)pyrene: http://ec.europa.eu/social/BlobServlet?docId=10182&langId=en
- Mineral Oils as Used Engine Oils: http://ec.europa.eu/social/BlobServlet?docId=10174&langId=en

9 ANNEX 2 - STAKEHOLDER CONSULTATION

9.1 Social partner Consultation

The TFEU foresees a two stage consultation of the European social partners for legislative initiatives in the field of social policy (article 154).

The Commission launched the first stage of consultation of the social partners on the protection of workers from risks related to exposure to carcinogens, mutagens and chemical agents toxic for reproduction at work on 6 April 2004. In accordance with Article 154(2) of the TFEU, the social partners were asked to give their opinions on the possible direction of EU action in this field.

The first phase of the consultation confirmed that action needs to be taken at Community level to introduce better and standardised methods across the EU, and to tackle situations involving workers' exposure.

All the European social partners who replied by the end of the six-week consultation period to the consultation[108] underlined the importance they attached to protecting workers from the health risks associated with exposure to these chemical agents.

However, while all respondents acknowledged the relevance of the existing legislation, their views differed as to the strategy and direction of future action and which factors should be taken into consideration.[109]

For example, whereas five organisations representing trade union umbrella organisations or the British Occupational Hygiene Society considered to be appropriate to amend or update the CMD, three other organisations representing employers felt that priority should be given to practical guidance documents and enhanced sectorial prevention.

Regarding the extension of the scope of the CMD to cover chemical agents toxic for reproduction and the inclusion of more limit values in the Directive most replies were in favour of an EU initiative. On the other hand, social partners' organisations suggested that national and sectorial approaches were more appropriate to tackle the specific issue of workers exposure to environmental tobacco smoke.

Following the first phase of consultation and due to the classification of respiratory crystalline silica as carcinogenic category 1 (proven carcinogen to humans) by IARC, the social partners of the sectors producing (quarries) and using silica (construction, glass, metal industry, pharmaceutical, etc.) embarked on negotiations in view of a European cross-sectorial agreement for the prevention of exposure to silica respirable dust. Worker's organisations agreed to negotiate on the condition that any future agreement would be without prejudice of any EU initiative setting adequate levels of protection at EU level.

Once the Silica agreement was signed in 2006, the Commission launched on 16 April 2007 the second stage of consultation of the European social partners, in accordance with Article 154(3) of the TFEU on the content of the envisaged proposal.

[108] Union of Industrial and Employers' Confederations of Europe (UNICE), European Centre of Enterprises with Public Participation and of Enterprises of General Economic Interest (CEEP), European Association of Craft, Small and Medium-Sized Enterprises (UEAPME), European Trade Union Confederation (ETUC), European Confederation of Executives and Managerial Staff (CEC), Confederation of National Associations of Tanners and Dressers of the European Community (COTANCE), Hotel, Restaurants and Cafes in Europe (HOTREC), European Federation of Trade Unions in the Food, Agriculture and Tourism Sectors and Allied Branches (EFFAT), Union Network International – Europe Hair & Beauty (UNI-Europa Hair&Beauty)

[109] CISNET EMPL 8676 of 15 June 2006

The specific points for consultation were: 1) Inclusion of chemical agents toxic for reproduction (categories 1A and 1B) in the scope of CMD; 2) Updating OELs for chemical agents in Annex III of CMD; 3) Including OELs for more chemical agents in Annex III of CMD; 4) Introducing criteria for setting OELs for CMR chemical agents; and 5) Focus on training and information requirements.

The Commission received replies from seven European social partner organisations: four from employers' organisations (Business Europe, Eurocommerce, European Association of Craft Small and Medium-sized Enterprises (UEAPME) and European Cement Industry), two from workers organisations (European Trade Union Confederation (ETUC), and European Federation of Building and Woodworkers (EFBWW)) and one from an independent organization (British Occupational Hygiene Society (BOHS)).

In their replies these organizations reaffirmed their approach to the prevention of occupational risks derived from carcinogens and mutagens at work, as outlined in their responses to the 1st stage consultation document. The opinions gathered are summarized below:

Inclusion of chemical agents toxic for reproduction (categories 1A and 1B) in the scope of CMD

There was no agreement on the need to initiate a EU level action, neither in the extension of the scope of the Directive to include reprotoxic chemical agents of categories 1A and 1B according to the CLP Regulation. Employers thought that the effective application of the existing legal framework is enough to attain a suitable level of protection, whilst workers called on the Commission to make legislative changes and to commit to eliminate exposure to occupational carcinogens by 2025. Workers took a positive view in order to extend the scope of the Directive to cover reprotoxic chemical agents. The possibility of launching the negotiation procedure under Article 154 (4) and 155 of the Treaty was not agreed.

Updating OELs for chemical agents in Annex III of CMD and including OELs for more chemical agents in Annex III of CMD

There was **a partial agreement** on the revision of existing binding OELs and on the establishment of new OELs for chemical agents not yet listed in the Directive Annex III of the Directive. While workers indicated a positive attitude based on the fact that it shall ensure equivalent protection of workers at EU level, the employers have expressed their scepticism reasoning that this action could only be justified on the grounds of an evaluation of the Directive 98/24/EC on chemical agents, on the grounds of robust scientific evidence and under the condition that socio-economic and feasibility factors must be taken into account. Furthermore, the revision of binding OELs should be examined in the light of the implementation of the REACH Regulation and of the relationship and interaction between OELs and DNELs (Derived Non Effect Levels) which will be derived under REACH for hazardous chemicals.

Introducing criteria for setting OELs for CMR chemical agents

There were no significant divergences between the replies of both employers and workers on the methodologies to be used and the criteria to be set up for the derivation of OELs. The introduction of criteria for OELs setting was seen as generally positive. However, socio-economic impact assessments and the consideration of feasibility factors should be part of the criteria. Social partners expressed the view that the ACSH should be involved.

Focus on training and information requirements

There was an overall agreement on the need for effective implementation of training and information requirements. This issue is considered to be a key aspect of the prevention policy. Workers call the Commission to set up a strategy to improve coordination and sharing of information at EU level. Employers see an added value on the preparation of guidance documents with recommendations on workers protection against carcinogens and mutagens exposure.

Following the results of the Social Partners consultation, the Commission tendered a study to assess socio-economic aspects of revising OELs and introducing new ones (see point 9.4.2). The results of the study as well as SCOEL recommendations, where available, were subsequently discussed by the tripartite ACSH. The discussions resulted in agreement on limit values, which have been taken forward to this initiative.

9.2 Other consultation of stakeholders

9.2.1 25 October 2006 - Workshop of setting OELs for Carcinogens

In 2006, DG EMPL organised in collaboration with the ACSH a workshop on 'Setting OELs for Carcinogens'. The key questions addressed during the workshop were the following:

- What is the acceptable/unacceptable level of risk?
- What is the maximum level of risk?
- Is it possible to quantify it in terms of incidence rate versus the number of exposed workers?
- In accepting risk levels should a distinction be made for general public and workers?
- What criteria are used in some Member States and what political decisions have been taken in respect to the OEL setting process for carcinogens?
- What criteria should be used to define the border between the acceptable and unacceptable risk?
- Should the approach to address the risk levels be systematic (quantitative/semiquantitative) or stochastic (case by case)?
- Should criteria on the acceptability of risks be regulated at EU level?
- Should the workability of the existing EU legal framework be safeguarded versus subsidiarity, in terms of establishment of OELs for carcinogens?

One of the main conclusions of the workshop was that the existing EU OSH legal framework and its supportive administrative, technical and scientific structure should remain in place and be used for the derivation and adoption of OELs at the EU level. However, it was also acknowledged that the derivation of OELs for Carcinogens, Mutagens and Reprotoxic chemical agents (CMRs) - both genotoxic and non-genotoxic - is a demanding task. The availability of sound and sufficient evidence, and in particular the availability of criteria and methodologies for their derivation, is a critical prerequisite for setting OELs for carcinogens.

More than 80 scientists, technicians and academics contributed to the discussions.

9.2.2 EU-OSHA - Exploratory survey of Occupational Exposure Limits (OELs) for Carcinogens, Mutagens and Reprotoxic chemical agents (CMRs) at EU Member States level (published in September 2009)[110]

Between late 2007 and early 2008, EU-OSHA, at the request of the European Commission, carried out a survey among its network partners aiming at increasing the Commission's knowledge on the existing situation at national levels concerning OELs for CMRs.

Part of the survey was to collect data on existing OELs values for CMRs from the 27 Member States and from selected countries outside of the EU (Australia, Canada, Japan and US). In addition, information was required on the methodology and criteria (scientific, technical and socioeconomic) used when setting an OEL for a carcinogen or a mutagen.

Based on the feedback received, the final survey covered 21 Member States[111].

[110] https://osha.europa.eu/sites/default/files/publications/documents/en/publications/reports/548OELs/survey_OELs_CMR_substances_web_def.pdf

With regard to the current initiative it is worth noting that the chemical agents covered by this initiative are in many cases also included in national OEL lists for carcinogens and mutagens. The majority of the MS which reported back had between 30 to 50 OELs established for carcinogenic and / or mutagenic chemical agents (Belgium, Czech Republic, Denmark, Estonia, Latvia, Lithuania, the Netherlands, Portugal, Slovakia, Slovenia, and UK), and only 4 EU MS (Austria, Finland, Poland and Spain) had listed a higher number than 50.

With regard to the selection and prioritization of carcinogenic and mutagenic chemical agents for OEL setting, it is also important with regard to the current initiative that criteria used in EU Member States were very similar to those used in the EU.

Based on the answers of 11 countries, the most important criteria for the selection of chemical agents for setting of OEL appeared to be (in order of priority): (1) epidemiological evidence, including reported cases of ill-health in the workplace, (2) availability of toxicological data, (3) severity of effects, (4) number of persons exposed, (5) availability of data on exposure, and (6) availability of measurement methods.

Results of the survey have been used to put together the lists of existing OELs in Annex 7.

9.2.3 Consultation of the tripartite Working Party 'Chemicals at the Workplace' (WPCs) of the ACSH

Following the Social Partner Consultation, the Commission informed the members of the WPC at its meeting in April 2008 on its intention to propose a revision of the CMD. Information were provided on a possible launch of a call for tender during 2008 with a view to appointing a contractor to carry out an impact assessment of possible amendments of the Directive, covering amongst other the inclusion of certain PGSs in Annex I to the Directive and the revision of existing and the introduction of new OELs for a number of chemical agents in Annex III to the Directive (the so-called IOM study).

At that point in time, the Commission confirmed that the option of covering chemical agents toxic for reproduction under the scope of the revised Directive was now excluded by the Commission. However, in 2010, the Commission launched another call for tender for a study to explore whether or not these chemical agents should be under the scope of the CMD (the so-called RPA study).

At various meetings of the WPC, the progress on the studies was discussed[112], followed by a first more in-depths discussion on the results of the IOM study based on draft reports for individual chemical agents in March 2011. The discussions on the individual chemical agents took place at various meetings of the WPC in 2011[113], 2012[114] and 2013[115], resulting in one

[111] Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Germany, Greece, Italy, Latvia, Lithuania, Luxembourg, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and the United Kingdom

[112] Meeting of the WPC on 15 October 2008; Meeting of the WPC on 26 March 2009; Meeting of the WPC on 20 October 2010;

[113] Meeting of the WPC on 23 March 2011; Meeting of the WPC on 15 June 2011; Meeting of the WPC on 26 October 2011

[114] Meeting of the WPC on 21 March 2012; Meeting of the WPC on 6 June 2012; Meeting of the WPC on 21 November 2012

[115] Meeting of the WPC on 6 March 2013; Meeting of the WPC on 19 June 2013; Meeting of the WPC on 2 October 2013

opinion and two supplementary opinions adopted by the plenary of the ACSH in 2012[116] and 2013[117, 118].

The OEL values agreed upon by the ACSH were taken forward to this initiative.

9.2.4 September 2012 - Workshop in Berlin

A workshop 'Carcinogens and Work-Related Cancer' was organised by the European Agency for Safety and Health at Work (EU-OSHA) and hosted by the German Ministry of Labour and Social Affairs at their offices in Berlin on 3 and 4 September 2012. About 60 representatives from various European countries, the European Commission, the Advisory Committee on Safety and Health's Working Party on Chemicals, the Chemex group of the Senior Labour Inspectors Committee (SLIC), the Scientific Committee on Occupational Exposure Limits (SCOEL), the European Chemicals Agency and IARC of the World Health Organisation (WHO) attended.

The aim of the workshop was to summarize the current understanding regarding exposures to carcinogens and the causes and circumstances of work-related cancer, and to discuss how this knowledge can be used across the European Union (EU) to reduce the future burden of these cancers.

The workshop[119] highlighted the need to enhance research efforts to estimate the burden of occupational disease and build on links between occupations and exposures to set priorities for prevention, disease recognition and compensation. In this regard the on-going study HazChem@Work will collect the available occupational exposure data on chemicals across the EU countries. Interim results of this study have shown difficulty in finding data on occupational exposure as it is not routinely collected and centralised at the national level. It is been also identified that the measurements can be performed under different conditions and for different purposes – this can hamper the comparability among different data sets. The final results are expected by the second semester of 2016.

It was generally agreed that the current legislative framework in Europe and its implementation and enforcement is essential for the effective prevention of cancer in the workplace. The need to provide the same minimum level of protection to all workers was also stressed.

9.2.5 Consultation of the members of the ACSH on existing national OELs for chemical agents subject to the amendments

In order to establish a baseline scenario for the establishment of OELs subject to the initiative, the Commission services requested from the members of the ACSH at its plenary meeting on 28 November 2013 to submit updated information on the national OELs for the chemical agents covered by the IOM study.

9.2.6 Meetings with Industry and Workers representatives

Between the beginning of 2013 and end of 2015, a number of meetings between Commission services and industry and workers representatives concerned about specific chemical agents subject to the initiative took place.

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[116] Opinion on the approach and content of an envisaged proposal by the Commission on the amendment of Directive 2004/37/EC on Carcinogens and Mutagens at the workplace. Adopted on 05/12/2012 (Doc. 2011/12)

[117] Supplementary opinion on the approach and content of an envisaged proposal by the Commission on the amendment of Directive 2004/37/EC on Carcinogens and Mutagens at the workplace. Adopted on 30/05/2013 (Doc. 727/13)

[118] Supplementary opinion No. 2 on the approach and content of an envisaged proposal by the Commission on the amendment of Directive 2004/37/EC on Carcinogens and Mutagens at the workplace. Adopted on 28/11/2013 (Doc. 2016/13)

[119] The seminar report is available at https://osha.europa.eu/en/tools-and-publications/seminars/workshop-on-carcinogens-and-work-related-cancer

The following organisations, among others, discussed bilaterally with the Commission services on specific chemical agents subject to the initiative:

- NEPSi (European Network for Silica formed by the Employee and Employer European sectoral associations),
- Euromines and IMA (Industrial Minerals Association) for Silica;
- ECFIA (European Ceramic Fibre Industry Association) and Unifrax for Refractory Ceramic Fibers (RCF);
- CEEMET (Council of European Employers of the Metal, Engineering and Technology-Based Industries) and Eurometaux for metals as Chromium and Beryllium
- BeST (Beryllium Science & Technology Association) for Beryllium.
- Rubber industry

The main purpose of the meetings asked for by industry was to achieve information on the process for amending the legislation in general, and on the intention of the Commission with regard to the proposed value for a particular chemical agent.

Some conclusions can be drawn from these meetings regarding the position of the industry representative organisations on specific substances.

10 ANNEX 3 – WHO IS AFFECTED BY THE INITIATIVE AND HOW?

Who is affected	How
National authorities	Given the substantial economic costs imposed on workers due to their exposure to hazardous substances, the retained option also contributes to mitigate financial loss of the Member State's social security system. Member States must transpose the amended Directive into national legislation: - assessment of the national scenario and potential impacts - design, if appropriate/needed, of special measures (e.g., transitional periods, exemptions, additional provisions for specific sectors,…) - tripartite consultation of the proposal (workers, employers, authorities) - facilitate implementation of the national legislation by providing, among other measures, technical guidance to employers. These costs are minor in comparison to the overall costs of functioning incurred by the enforcement authorities. - enforce the national legislation. Introduction of new OELs in the CMD would not have any significant impact on the overall costs of the inspection visits. Those are mostly planned independently of the revised legislation. On the other hand, the existence of an OEL, by bringing clarity regarding the acceptable levels of exposure, facilitates the work of inspectors by providing a helpful tool for compliance checks. The establishment of OELs at EU level eliminates the need for national public authorities to independently evaluate each carcinogen thereby removing an inefficiency of repetition of identical tasks.
Employers	As duty holders, employers must comply with the whole set of OSH national legislation provisions. Given the nature of the proposed amendment, this would mainly be: - implementation of the necessary risk management measures (eg., substitution, closed systems, local exhaust ventilation, limitation of number of workers exposed, personal protection equipment) in order to comply with the new or revised OELs - implementation of a sampling strategy and airborne concentrations measurement programme for the chemical agents with a new or revised OEL, as part of the risk assessment process and effectiveness check of the existing measures - ensure that the chemical agents included in Annex I will be managed in line with the provisions of the carcinogens and mutagens national legislation - ensure compliance with other provision in the legislation (specific information and training to workers as regards the new working methods if such is the need in order to comply with the new OELs, health surveillance, if appropriate, for chemical agents now under the scope of the legislation, collection of records, information to competent authorities, etc.). Most of the listed actions are, however, business as usual. The benefits for employers include, inter alia, avoided loss of productivity, legal clarity as well as simplification in ensuring legal compliance.
Workers	As protected subjects, workers would be positively affected by the initiative in terms of a more effective protection of their health.

	It is to be noted that workers have the duty to apply preventive and protective measures set by the employers necessary to comply with OSH legislation (e.g., the newly established OELs).

11 ANNEX 4 – OVERVIEW OF THE SEVEN CARCINOGENS

11.1 Sectors, types of cancer caused and estimated number of workers exposed

Annex 4 Table 1. Sectors, types of cancer caused and estimated number of workers exposed for seven chemical agents under consideration[120]

Carcinogen, including CAS numbers where relevant	**Classification**		**Key sectors/uses**	**Types of cancer caused / other adverse health effects**	**No. of exposed workers** [121]
	CLP [122]	**IARC**			
Epichlorohydrine 106-89-8 (1-Chloro-2,3-epoxypropane)	1B	2A[123]	Production of epoxy and phenoxy resins, manufacture of glycerine, curing of propylene-based rubbers, solvent for cellulose esters and ethers, and in resins with high wet-strength for the paper industry.[124]	Lung cancer. CLP harmonised classification, also: • toxic if inhaled • toxic in contact with skin • toxic if swallowed • causes severe skin burns • causes eye damage • may cause an allergic skin reaction.	40,000
Ethylene dibromide (EDB) 106-93-4 (Dibromoethane)	1B	2A[125]	Current use as a chemical intermediate in synthesis and as a non-flammable solvent for resins, gums and waxes and has been used as an intermediate in the preparation of dyes and pharmaceuticals. Historically used as a 'lead scavenger' in antiknock mixtures added to gasolines (which decreased with banning of lead-containing fuels in many countries) and as a pesticide and ingredient in soil and grain fumigant formulations.[126]	Caused tumours in rats and mice at several different tissue sites and by several different routes of exposure.[127] CLP harmonised classification, also: • toxic if swallowed • toxic in contact with skin • toxic if inhaled • causes serious eye irritation • causes skin irritation • may cause respiratory irritation.	8,000

[120] Source: 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. This report is the source of all figures concerning the 12 chemical agents in the report , unless otherwise specified.
[121] Estimates, rounded
[122] Harmonised (i.e. mandatory) CLP classifications for carcinogenicity.
[123] IARC Monograph 11, Sup 7, 71, 1999
[124] SCOEL recommendation 169, 2011
[125] IARC Monograph 15, Sup 7, 71, 1999
[126] SCOEL SUM 166.
[127] https://ntp.niehs.nih.gov/ntp/roc/content/profiles/dibromoethane.pdf

Carcinogen, including CAS numbers where relevant	**Classification**		**Key sectors/uses**	**Types of cancer caused / other adverse health effects**	**No. of exposed workers** [121]
	CLP [122]	**IARC**			
Ethylene dichloride (EDC) 107-06-2 (1,2--Dichloroethane)	1B	2B[128]	Production of vinyl chloride to make a variety of plastic and vinyl products including polyvinyl chloride (PVC) pipes, furniture and automobile upholstery, wall coverings, housewares, and automobile parts. Also used to as a solvent and is added to leaded gasoline to remove lead.[129]	Caused tumours in mice and rats at several different tissue sites.[130] CLP harmonised classification, also: • harmful if swallowed • causes serious eye irritation • causes skin irritation • may cause respiratory irritation.	3,000
4,4'-Methylenedianiline (MDA) 101-77-9	1B	2B[131]	Intermediate in the closed-system production of 4,4'-diaminodiphenylmethane diisocyanate (MDI) and polyisocyanates. Also used as a cross-linking agent for epoxy resins, in the determination of tungsten and sulphates, as an analytical agent, as a corrosion inhibitor, as an antioxidant and curative agent in rubber and to prepare azo dyes. Potential exposure occurs during production, packaging and reprocessing of the chemical and during its use in epoxy resins.[132]	Liver and thyroid cancer in rats and mice[133] CLP harmonised classification, also: • suspected of causing genetic defects • causes damages to organs (Specific Target organ toxicity after single exposure) • may cause damage to organs through prolonged or repeated exposure • may cause an allergic skin reaction	3,900,000
Trichloroethylene (TCE) 79-01-6	1B	1[134]	Mainly used for vapour degreasing and cleaning of metal parts, in adhesives, as a solvent and for synthesis in the	Liver cancer, kidney cancer CLP harmonised classification, also:	74,000

[128] IARC Monograph 20, Sup 7, 71, 1999
[129] http://www.atsdr.cdc.gov/toxfaqs/tf.asp?id=591&tid=110
[130] https://ntp.niehs.nih.gov/ntp/roc/content/profiles/dichloroethane.pdf
[131] IARC Monograph 39, Sup 7
[132] SCOEL recommendation 107, 2012
[133] http://www.baua.de/en/Topics-from-A-to-Z/Hazardous-Substances/TRGS/pdf/910/910-4-4-methylenedianiline.pdf?__blob=publicationFile&v=1
[134] IARC Monograph Sup 7, 63, 106, 2014

Carcinogen, including CAS numbers where relevant	**Classification**		**Key sectors/uses**	**Types of cancer caused / other adverse health effects**	**No. of exposed workers** [121]
	CLP [122]	**IARC**			
			chemical industry, e.g. in the production of HFC 134a and HCFC 133a.[135]	• suspected of causing genetic defects • causes serious eye irritation • causes skin irritation • May cause drowsiness or dizziness	
Complex PAH mixtures with benzo[*a*]pyrene as an indicator 50-32-8 (for benzo[*a*]pyrene)	1B	1[136]	Polycyclic aromatic hydrocarbons (PAHs), including the most hazardous example benzo[*a*]pyrene, are widespread environmental contaminants formed during incomplete combustion or pyrolysis of organic material. Industries where occupational exposure to benzo[*a*]pyrene has been measured and reported include: coal liquefaction, coal gasification, coke production and coke ovens, coal-tar distillation, roofing and paving (involving coal-tar pitch), wood impregnation and preservation with creosote, aluminium production (including anode manufacture), carbon-electrode manufacture, chimney sweeping, and power plants. Especially high exposures to PAHs are observed in aluminium production (Soderberg process) with values up to 0.1 mg/m^3. Mid-range levels are observed in roofing and paving (e.g. 0.01−0.020 mg/m^3) and the lowest concentrations (i.e. at or	Multiple animal studies in many species demonstrating BAP to be carcinogenic following administration by numerous routes[138] CLP harmonised classification, also: • may cause an allergic skin reaction may cause genetic defects • may damage fertility • may damage the unborn child.	7,000,000

[135] SCOEL recommandation 142, 2009
[136] IARC Monograph Sup 7, 92, 100F, 2012
[138] http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-14.pdf

Carcinogen, including CAS numbers where relevant	**Classification**		**Key sectors/uses**	**Types of cancer caused / other adverse health effects**	**No. of exposed workers** [121]
	CLP [122]	**IARC**			
			below 0.001 mg/m^3) are observed in coal liquefaction, coal-tar distillation, wood impregnation, chimney sweeping and power plants.[137]		
Mineral Oils as Used Engine Oils (UEOs)[139]	n/a	1[140]	Oils that have been used before in internal combustion engines to lubricate and cool moving parts. Used in automobile and motorcycle engines, diesel rail engines, marine engines, aeroengines, and in portable machinery including chain saws and lawn mowers. The composition of engine oils (and hence of used engine oils), changes continually to meet the requirements of newer engine designs and performance requirements, and to comply with EU legislation. The composition of mineral oils as used engine oils further varies with duration of use, engine temperatures and conditions, and other factors.	Skin cancer	1,000,000

[137] https://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-14.pdf
[139] SCOEL Opinion 2016/405, adopted on 09 June 2016
[140] IARC Monograph 33, Sup 7, 100F, 2012 for Mineral oils, untreated or mildly treated,

11.2 Legal and policy considerations specific for the proposal - Risk management measures under CMD

11.2.1 Annex I to the CMD – Process-Generated Substances (PGS)

Many industrial processes generate contaminants which can be hazardous to health. Combustion, mechanical abrasion (sanding, grinding, sawing) or other processes physically or chemically degrade the starting material.

The CMD provisions apply to any substance or mixture which meets the criteria for classification as a category 1A or 1B carcinogen and/or germ cell mutagen set out in Annex I to Regulation (EC) No 1272/2008[141] (CLP Regulation), which applies in principle to all substances and mixtures supplied (placed on the market) in the Union. As PGSs are not 'placed on the market', the CMD provided for the possibility to include those substances and processes in Annex I to the Directive in order to facilitate the obligation of employers to perform the risk assessment and to establish the necessary protective and preventive measures. A list of identified PGS is contained in CMD Annex I[142]. The previous proposal included definition of one PGS (respirable crystalline silica, RCS) and this report considers inclusion into Annex I of a further PGS, mineral oils as used engine oils.

11.2.2 Annex III to the CMD – OEL[143]

Occupational exposure limit values (OELs) are set to prevent occupational diseases or other adverse effects in workers exposed to hazardous chemicals in the workplace. Within the CMD, there is an obligation for employers to ensure that limit values set out in Annex III to the Directive are not exceeded. OELs set out in Annex III to the CMD are risk-based[144].

OELs may be *'health based'* - an OEL of this type may be established where a review of the total available scientific database leads to the conclusion that it is possible to identify a clear threshold dose/exposure level below which exposure to the substance in question is not expected to lead to adverse effects.

OELs for carcinogens often cannot be 'health-based' because for many carcinogens no such threshold dose/exposure level can be established. In such cases exposure at any level, theoretically, results in risk to worker health – therefore an OEL set for a non-threshold carcinogen is not fully protective of worker health and there is a remaining 'residual risk'.

In any case, in addition to a heath-based threshold dose or to considerations of residual risk, CMD OELs are always set taking into account technical and socio-economic feasibility factors.

OELs set out in Annex III to the CMD are, therefore, usually not 'health-based'.

Within the CMD, there is an obligation for employers to ensure that limit values set out in Annex III to the Directive are not exceeded.

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[141] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 65/548/EEC and Directive 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1)

[142] See section 1.1.2, page 11 of SWD(2016)152/2.

[143] Scientific Committee on Occupational Exposure Limits, *Methodology for the Derivation of Occupational Exposure Limits: Key Documentation (version 7)*, 2013

[144] For some adverse effects (in particular genotoxicity, carcinogenicity and respiratory sensitisation) it may not be possible on present knowledge to define a threshold of activity. In such cases it must be assumed that any level of exposure, however small, might carry some finite risk and OELs for substances possessing these properties must be established following a risk-based approach.

This report assesses the option of setting OELs for the majority, but not all, of the considered chemicals. Exposures occur mainly via airborne or dermal route and depending on the characteristics of the chemical OELs under this initiative may be expressed as:

- Inhalation, 8 TWA
- Inhalation, STEL
- Other (notations), Skin

Inhalation, 8 TWA

It is normal to establish OELs for exposure via the airborne route in relation to a reference period of 8 hours (a typical working day). They are also normally set on the basis of a nominal 40-hour working week and for a working lifetime. They will be expressed in units of mg/m^3 or ppm.[145]

Inhalation, STEL

An 8-hour TWA OEL is the usual limit recommended by SCOEL for the purposes of preventing adverse health effects arising from exposure to a specific substance. There will, however, be substances for which an 8-hour TWA OEL alone provides insufficient protection. In such cases SCOEL may decide also to recommend the establishment of a short-term exposure limit (STEL), usually involving a 15-minute reference period.

STELs are needed where adverse health effects (immediate or delayed) are not adequately controlled by compliance with an 8-hour TWA. This is likely to arise for substances for which a critical effect is observed following a brief exposure (e.g. nuisance, irritation, CNS depression, cardiac sensitisation) and where the 8-hour TWA OEL is established at a level not very much lower than exposures at which there might be a risk of short-term effects occurring. Such a situation will be apparent from an initial review of the data base.

Even when there is compliance with an 8-hour TWA, there will be variability in exposure around the mean value when measurements are made over shorter periods. SCOEL will derive STELs in situations where these variations are likely to produce exposures at levels sufficiently high to trigger adverse effects.

Other (notations), Skin

In order effectively to control total systemic exposure to chemicals at the workplace, it is necessary to take account not only of exposure by the inhalation route, but also of dermal exposure, which may lead to skin penetration and a consequent increase in the total body burden. Dermal absorption will have a greater relative impact on total body burden (and thus present a greater health risk) when exposure by the inhalation route is controlled to relatively low levels, i.e. for substances which have low OELs. In some situations (e.g. field application of pesticides) the contribution from dermal absorption may greatly exceed the contribution from respiratory intake. It is thus necessary to assign a 'skin notation' to some OELs in order to warn of the possible significant contribution of dermal absorption to the total body burden.

It should be noted that a skin notation relates specifically to dermal absorption of the material (whether as solid, liquid or gas), i.e. it is determined by the toxicokinetic properties of the material in relation to the level at which the OEL is established. It does *not* relate to and is not

[145] OELs are usually expressed as milligram per cubic meter (mg/m^3) of air, which can be converted to parts per million (ppm) for gases and vapours, corresponding to cm^3 of gases or vapours per m^3 of air. At 1 atm and 25 °C, the conversion is 1 ppm = (the molecular weight of the compound) /24.45 mg/m^3

intended to give warning of direct effects on the skin such as corrosivity, irritation and sensitisation, criteria for which are described in in the CLP Regulation.

12 ANNEX 5 – ANALYTICAL MODEL USED IN PREPARING THE IMPACT ASSESSMENT[146]

The impacts of the different policy options proposed in this impact assessment were quantified, to the extent possible, based on a methodology as described below[147].

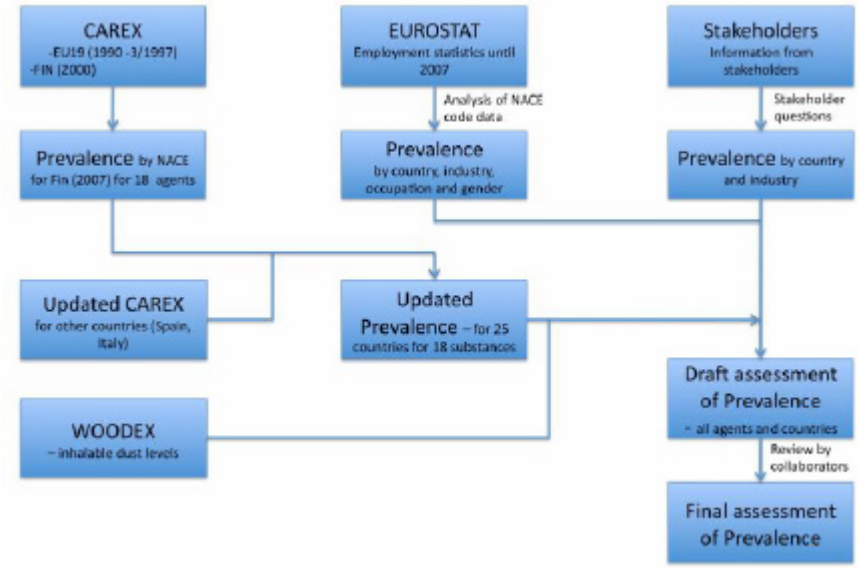
12.1 Exposure estimation

The following occupational exposure information was required for each substance for estimating the health impact of any changes in exposure:

- Prevalence of exposure by industry (current);
- Classification of industries into high, medium, low and background exposure, or a subset of these categories;
- Distribution of exposure (the geometric mean (GM) and geometric standard deviation (GSD), ideally by country, across industries, and
- Temporal change in exposure (% change per year) arising from general improvements in European workplaces and work processes, not taking into account the impact of changes to the Carcinogens Directive.

The graphic below provides an overview of the general procedure used for estimating the prevalence of exposure:

Annex 5, Figure 1



Exposure prevalence data were available from the Carcinogens Exposure database (CAREX), for almost all agents analysed in this impact assessment Information collected from trade associations and other stakeholders was used.

[146] IOM Study Report *Valuing health benefits*

[147] The methodology was developed under the coordination of the Institute of Occupational Medicine in collaboration with team members representing the following entities: the Imperial College of London; AMEC Environment & Infrastructure UK Ltd; the Finish Institute of Occupational Health; IRAS, University of Utrecht; IEH, Cranfield University.

The information from CAREX and other sources, were combined with data from Eurostat (number of workers exposed by relevant sector of activity) to obtain estimates of exposure prevalence.

The level of intensity was assessed using:

- Published scientific literature;
- Information from European Risk Assessment Reports compiled in relation to the Existing Substances Regulations;
- Information provided by industry stakeholders.

The overall weighted geometric mean (GM) and geometric standard deviation (GSD) exposure level for each agent was estimated across all 'medium' and 'high' exposure industries across the EU using @Risk (Palisade Corporation, New York).

Where possible, exposures were simulated using GM and GSD for each country. The number of values each industry contributed was weighted according to the number of workers exposed in that industry.

Temporal changes in exposure were determined from information from the literature, which was ideally specific to the substance being considered but in situations where this was not available, the study relied on the results of a systematic review of the literature (Creely et al, 2007).

12.2 Health impact – methodology for estimation of the current cancer burden (baseline) as compared with the policy intervention scenarios

In order to assess the current burden of occupational cancer related to the exposure to substances subject to this impact assessment, the analysis made was built on work to quantify the burden of cancer due to occupation in Great Britain (Rushton at al, 2010).

The primary measure of the burden of cancer used in this project was the attributable fraction (AF) i.e. the proportion of cases that would not occur in the absence of exposure; this was then used to estimate the attributable numbers.

The estimates were made considering the risk exposure period (REP) for specific types of cancer: for solid tumours a latency of 10-50 years was assumed and for haematopoietic neoplasms 0-20 latency was assumed. The proportion of the population ever exposed to each carcinogenic agent or occupation in the REP was obtained from the ratio of the numbers ever exposed to the carcinogens of interest in each relevant industry/occupation over the total number of people ever employed. Estimates of employment turnover for grouped main industry sectors and of life expectancy were used to estimate the exposed population, and adjustment factors were applied to the exposure prevalence data to take account of the change in numbers in the industry sector groups.

The attributable fraction (AF) for each cancer/occupational carcinogen was estimated using Levin's method (Levin, 1953).

The relative risk (RR) for cancer(s) in question for the relevant agent or work environments, were derived from a review of the published epidemiological literature. Risk estimates were obtained from key studies, meta-analyses or pooled studies, taking into account quality, relevance to the EU, sample-size, effective control for confounders, adequate exposure assessment, and clear case definition.

For predicting the future burden, the risk exposure windows were projected forward in time, and estimation was carried out for a series of forecast target years (FTYs) that stretch far enough into the future to account for the latency of cancers initiated at the time when the study was performed (i.e. the decade starting 2060). Estimates were made for alternative scenarios of

changes in exposure levels and proportions exposed, for example assuming the introduction of new or reduced exposure limits, which were assumed introduced in 2010. The projections were made each time under the assumption of full compliance with the legislation (i.e. 99% of exposures less than the limit value).

To predict future cancer numbers based on the pattern of past and current exposure either a 'static' baseline, where no change in exposed numbers or exposure levels is expected beyond 2010, or a 'dynamic' baseline was used, where current trends are forecast to continue until 2030.

The socioeconomic health impacts of the different policy options were then assessed in terms of the cost of the disability and death based on the estimated cancer burden under each policy option.

In this respect, several approaches exist to assessing potential health impacts ranging from non-monetary approaches such as Quality Adjusted Life Years (QALY), Disability Adjusted Life Years (DALY) and Health Life Years (HLY) to monetary methods such as the Cost of Illness (COI), Value of Statistical Life (VSL) and Value of Life Year Lost (VLYL).

As part of this study, Imperial College have developed a model to estimate DALYs based on exposure data from Institute of Occupational Medicine (IOM) and the Finish Institute for Occupational Health. The DALYs uses time as a common metric taking into consideration both premature death and 'healthy' years lost due to problems associated with living with the disease or health condition (i.e. cancer for this study). DALYs are calculated as the sum of the years of life lost due to premature mortality (YLL) and the years lost due to disability (YLD):

$$DALY = YLL + YLD$$

Each DALY represents one lost year of 'healthy' state. The DALYs can be used as one approach to compare different options (e.g. cost effectiveness analysis) especially when different Occupational Exposure Limit (OEL) values have been proposed. Entec have also used the underlying data developed by Imperial College to attempt to monetise health impacts associated with introducing EU-wide OELs. This will allow for a more formal cost benefit analysis to be used to compare different policy options. This paper sets out this approach to monetising human health impacts.

The approach used to estimate a monetary value on changes in health impacts is dependent on the data available such as the population at risk (i.e. data on the exposed population) and any evidence of dose-response relationships. Since it is not possible to develop dose-response functions for each chemical agent, the approach to valuing changes in human health is based on estimating the monetary loss (damages or costs) that might occur if no changes were made (Business-As-Usual scenario) in comparison to the avoided health related costs under the introduction of an EU-wide OEL level(s). The difference in health impacts between the BAU scenario and the scenario(s) with an OEL is the main health benefits valued in this project.

The valuation of health impacts are divided into two main aspects:

Life years lost – This is calculated by using the year's life lost (YLL) estimated by Imperial College and multiplying this with a valuation of the Value of Life Year Lost (VLYL). This values the time (years) lost due to premature death.

Cost of Illness (COI) – This is often the main market-based approach in relation to health impact (ECHA 2008)[148]. Depending on the valuations available, it can include the direct, indirect and intangible costs of cancer. This is a monetary cost of the time spent with cancer. In this study, a unit COI estimate is multiplied by the number of cancer registrations.

[148] (ECHA 2008) – Applying SEA as part of restriction proposals under REACH

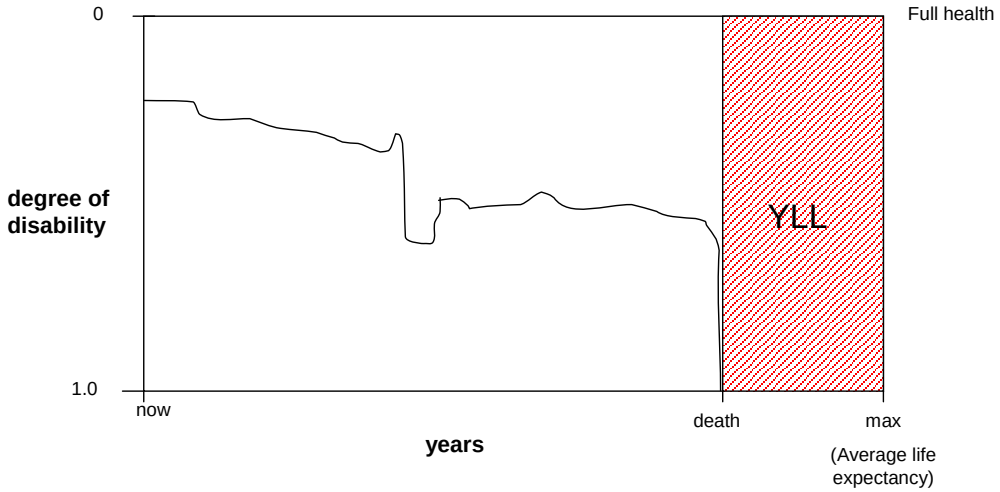
Each of these two impacts is explained in more detail below as well as using willingness-to-pay (WTP) estimates as an alternative approach.

Value of life years lost (VLYL)

The years of life lost (YLL) are estimated by multiplying the number of disease specific deaths times average life expectancy after average age at death from the specific disease[149]. EU and Member State specific average life expectancies were used for this project. Essentially years of life lost are the difference between death and average life expectancy ('premature death'). This is illustrated in Figure 2.

[149] Data on disease specific deaths by age were not available so age weighting factors were not used.

Annex 5, figure 2 DALY component: Years of life lost (VLL)



Monetary estimates of the value of life years lost (YLYL or sometimes known as VOLY[150]) allows us to put a value on VLL. The latest EC Impact Assessment guidance applicable at the time of the study (EC 2009)[151] suggested using estimates of €50,000-100,000 in Europe for the purpose of an Impact Assessment, if no more specific estimates are available. Markandya (2003) uses an estimate of €50,000 and is also used more widely in other assessing health policies such as CAFE. Therefore for the purposes of this study the €50,000 is used as a lower estimate and €100,000 as an upper estimate. This should therefore help encompass the uncertainties associated with the VLYL.

These valuations are increased by 2% each year in the future in part to present costs in real terms (i.e. adjusting for inflation in prices) and to reflect societies increasing value attached to their health (as economic growth typically increases over a long period of time).

The values originally reported in the IOM study, based on a constant discount rate of 4%. Given the very long time frame considered, and in line with the guidance in the Better Regulation Toolbox, they have been recalculated applying a declining discount rate (4% for the first 20 years, 3% thereafter)[152].

Cost of illness (COI)

Introduction

The cost of illness (COI) is one of the most common market based approaches to valuing health impacts. It involves multiplying the number of cancer registrations occurring under each scenario (i.e. with and without proposed changes) with the valuation for COI.

The COI might include health sector costs (direct costs), the value of lost productivity by the patient (indirect cost), and the cost of pain and suffering (intangible costs)[153]. This will however depend on data availability as in most cases intangible costs are unlikely to be included in valuations of COI. These three components are described in Table 2.

[150] Value of Life Years (VOLY)
[151] EC (2015) Better Regulation Guidelines (19.5.2015). http://ec.europa.eu/smart-regulation/guidelines/docs/swd_br_guidelines_en.pdf
[152] This is consistent with some other European Commission studies and is standard practice for air quality under the Clean Air for Europe (CAFE) programme.
[153] http://www.cdc.gov/owcd/eet/Cost/3.html#costofillness

Annex 5 Table 2 Components making up a valuation of COI

Components of the COI	Description
Direct costs	These include both the direct medical costs and direct non-medical costs of the disease: • Direct medical costs can include costs associated with the direct treatment of pain, including analgesic medication, medical procedures and technology, hospitalisations, use of emergency department services, and physician office visits for pain (Fortner et al. 2003)[154]. • Direct non-medical costs might include: transportation related expenses, childcare expenses, household expenses, medicine expenses, household assistance, educational materials and counselling or psychotherapy. From a social perspective, it is also possible to divide the costs into costs borne by the health service and those borne on the household: • Costs to the health Service – hospitalisation, medication, emergency (ambulance) transportation and care, outpatient and primary clinic • Costs to the household - Out-of-pocket payments (user fees) for hospitals and drugs, medication, transportation of the patient and family, costs for taking care of dependents and modifications in home as a result of illness
Indirect costs	Indirect costs or productivity losses are the labour earnings that are forgone as a result of an adverse health outcome. The decreased productivity can be a result of illness, death, side effects, or time spent receiving treatment. Indirect costs include lost earnings and productivity of both patients and the family members who take care of them. For some diseases with premature death, the indirect cost is the loss in potential wages and benefits. Indirect costs associated with premature death might be very high. Examples of indirect illness costs include • the value of time spent when unable to work as productively because of an illness or side effect, • earnings lost while travelling to health-care facilities, and • productivity losses associated with caregiver time.
Intangible costs	The intangible cost components of illness are usually substantial, and in many cases, might dominate the policy agenda. Examples include • disfigurement (e.g., breast cancer with surgery), • functional limitations (e.g., paralysis from polio), • pain (e.g., rheumatoid arthritis or bone metastasis), or • fear (e.g., HIV, rabies, or bovine spongiform encephalopathy [BSE]). One approach to estimating the intangible costs is through willingness-to-pay (WTP) studies.

Source: Centers for Disease Control and Prevention – U.S. Department of Human Health & Services:

http://www.cdc.gov/owcd/eet/Cost/3.html#costofillness

Estimating COI

Outlined below is an approach to valuing COI for cancer (excluding intangible costs):

$$\textbf{Cost of Illness (COI)} = \text{Number of cancer registrations} \times \left(\frac{\text{Direct cost per}}{\text{registration}} + \frac{\text{Indirect cost per}}{\text{registration}} \right)$$

Where:

$$\frac{\text{Direct cost per}}{\text{registration}} = \text{Direct outpatient costs} + \text{Direct inpatient costs} + \text{Direct homecare costs}$$

$$\frac{\text{Indirect cost per}}{\text{registration}} = \text{Value of production} \times \left(\text{Production lost because of illness} + \text{Production lost because of care-} \right)$$

[154] (Fortner et al. 2003) – "Description and Predictors of Direct and Indirect Costs of Pain Reported by Cancer Patients" – Journal of Pain and Symptom Management – Volume 25. No 1 January 2003.

giving

It is extremely difficult to gather information required to estimate direct and indirect costs for each type of cancer and estimate values of production and production lost for each sector affected. In most cases, this information is not publicly available. Therefore, COI estimates have been taken from existing studies related to cancer.

Rabl (2004)[155] provides values of unit costs (i.e. per patient) that are used in France for different morbidity risks. It includes estimates for COI and willingness-to-pay (WTP) related to avoiding the suffering and inconvenience of disease. The COI includes direct and indirect costs of cancer but not the intangible costs of cancer. Intangible costs are however included in the WTP estimates. These estimates are set out in Table 3.

Annex 5 Table 3. Estimated unit costs of cancer (€ 2009 prices) – except for NMSC

Health endpoint	Cost of Illness (COI)	WTP to avoid suffering
Cancer, fatal (per incident)	€ 48,601	€ 1,768,256
Cancer, non-fatal (per incident)	€ 48,601	€ 486,271

Note: Prices have been updated from USD to EUR using historical exchange rates for 2004 and updated to 2009 prices using the EU harmonised index of consumer prices (HICP).

It was not possible to find an estimate for COI for each type of cancer and therefore the estimate (€ 48,601) is used for all cancers, with the exception for nonmelanoma skin cancer (NMSC) where there is a greater survival rate and costs of treatment may be less expensive.

Costs for NMSC are presented in Table 4. Costs for NMSC are based on a simple meta-analysis of various studies examining the economic costs of NMSC. Of particular relevance was a study by Miljoministeriet (2004)[156] in which the direct costs of NMSC and willingness to pay (WTP) studies to avoid the permanent scars were reviewed. The study (along with other studies) suggests that NMSC can typically be treated within a year and is assumed, in general, to not result in death.

The WTP to avoid scarring (249,424 DKK in 2002 prices) is taken from the Miljoministeriet (2004) study and converted to Euros (€38,827 in 2009 prices) and is used as a high estimate. The study also provides a possible low COI estimate of €2,926 (18,795 DKK in 2002 prices). A comparable estimate is also derived from Morris et.al (2005)[157] which estimates COI at €2,601 in 2009 prices (based on an estimate of £1,413 in 2002 GBP prices). The latter is used as the low estimate in the current analysis.

[155] Rabl (2004) – "Valuation of Health End Points for Children and for Adults", Working Paper.

[156] Miljoministeriet (2004) - "Valuation of Chemical Related Health Impacts - Estimation of direct and indirect costs for asthma bronchiale, headache, contact allergy, lung cancer and skin cancer" - Report prepared by COWI A/S for the Danish Environmental Protection Agency http://www2.mst.dk/udgiv/publications/2004/87-7614-295-7/pdf/87-7614-296-5.pdf

[157] Morris et.al (2005) - "cost of skin cancer in England" - Report by S. Morris, B. Cox and N. Bosanquet for Tanker Business School, Imperial College London - http://www3.imperial.ac.uk/pls/portallive/docs/1/43013.PDF

Another study by O'Dea (2009)[158] estimated the overall costs of NMSC to New Zealand. If divided by the number of incidents, this gives a broad estimate of €538 per incident (867 NZD in 2007/08 prices). However this was excluded as the per-registration costs was not explicitly estimated and also may not necessarily be representative of costs for the EU.

Annex 5 Table 4 Summary of cost variables used for NMSC only (€ 2009 prices)

Cost/benefit elements	Low scenario	High scenario
VLYL - Each year lost	€ 50,393	€ 50,393
COI or WTP - Unit cost (per cancer registration)	€ 2,601	€ 38,827 (WTP)

Note: As the WTP to estimate relates to not having permanent scars and does not include the costs associated with life years lost, the high scenario also incorporates the impacts of any life years lost. This differs from the approach used for other types of cancer whereby the WTP already includes life years lost (and is therefore excluded to avoid double counting benefits).

There are relatively few alternative monetised estimates of COI for cancer in existing literature and therefore it is very different to understand how representative these costs are for the rest of Europe. Fortner et al. (2003) estimates the mean monthly direct medical and non-medical pain related costs per patient (in the US) at around $891 (~$10k p.a.), with a maximum cost of $20k per month. Rabl's actual unit estimate of $54,970 (2004 USD price) would seem an appropriate estimate for cancer treatment in the EU for this project, when taking into consideration the typical times spent in cancer stages related to treatment.

As part of the calculations to estimate the years lived with disability (YLD), Imperial College needed to estimate the mean duration spent in each cancer stage for each disease. The names and number of stages presented in blue in Figure 3. may differ in existing literature, but the increased segregation allows us to better assign time that may be spent in each cancer stage.

The health impact assessment has estimated the duration of time a patient may spend in each cancer stage and what proportion survive and die prematurely from cancer. The time spent in diagnosis and primary therapy is particularly relevant for assessing the costs of treatment. The time spent varies significantly with each type of cancer, ranging from 2 weeks for Non-Melanoma Skin Cancer (NMSC) to up to 18 months for leukaemia.

Taking into consideration that Fortner *et al*'s mean estimate (~$10k p.a.), does not include indirect costs due to a loss of productivity, it is reasonable to assume that the updated Rabl estimate (€ 48,601) is suitable for the purposes of this study in the absence of further COI estimates for cancer. As with the estimate of VLYL, the COI unit cost is increased by 2% each year to account for inflation and discounted using a 4% discount rate and using a declining discount rate (for impacts occurring after 30 years). For sensitivity analysis, the discount rate is changed; using a declining discount rate and no discounting is also considered.

Willingness to pay (WTP)

An alternative to COI is Willingness-to-pay (WTP). WTP typically includes[159]

(1) Lost wages[160];
(2) Medical expenses;

[158] O'Dea (2009) - "The estimated costs - economic and human - of skin cancers in New Zealand" - http://www.niwa.co.nz/?a=103433
[159] See: http://www.ers.usda.gov/publications/aer784/aer784f.pdf
[160] In some instances with premature death, this term drops out the calculations of WTP unless a bequeath motive is specified

(3) The monetary value of the disutility of illness; and
(4) The impact of preventive expenditures.

The WTP estimates reflect what people are willing to pay to avoid the having cancer (both fatal and non-fatal). These estimates also include intangible costs which are very difficult to value within COI estimates (i.e. 3 and 4). WTP costs are significantly higher than the COI estimates which only estimate those impacts which can be calculated using market prices. It has been suggested that the COI can be used as a lower bound to WTP estimates. For the purposes of this study, the low benefits scenario is estimated using COI + YLYL and the high scenario using WTP only. The reader can make their own judgement on either COI should be viewed as a lower bound to the WTP results.

In order to use the estimate for the WTP to avoid suffering under each scenario, it is necessary to be able to split cancer registrations to those that result in fatalities (premature death) and those which result in non-fatal cancers. It is however very difficult to make this split without making critical assumptions, since most studies are based on cancer survival times in intervals of 1, 5 and 10 years rather than fatal and non-fatal cancers. It is not possible for this study, to determine (with sufficient confidence) what proportion of cancer registrations will be fatal and non-fatal. Since WTP is used as a high cost scenario, the WTP estimate for fatal cancers is used (€1.8m). Since NMSC is not considered to necessarily be fatal a lower WTP is used (€38,827).

It is recognised in reality, that the average proportion of cancer registrations being fatal or non-fatal may vary depending on several factors such as; the type, size and spread of the cancer (e.g. can vary depending on if the cancer has been identified at an early or late stage) and the patient itself; age, gender, general health, marital status and income level. However the range of costs in the low and high scenarios might provide a useful comparison to the reader.

Summary – values used in this study

The tables below summarise the cost variables used in the study. Table 5. summaries the costs variables used in this study for all types of cancer, with the exception for nonmelanoma skin cancer (NMSC) where there is a greater survival rate and costs of treatment may be less expensive. The costs specifically for NMSC are summarised in Table 6.

Table 5. Summary of cost variables used in this study for all cancers except NMSC (€ 2009 prices)

Cost/benefit elements	Low scenario	High scenario
VLYL - Each year lost	€ 50,393	€ 0 (note 1)
COI or WTP - Unit cost (per cancer registration)	€ 49,302 (COI)	€ 1,793,776 (WTP)

(Note 1) – By using WTP (€1.8m) in the high scenario instead of COI, the WTP can include the costs of premature death and therefore there was a risk of double counting benefits if VLYL costs were included.

Table 6. Summary of cost variables used for NMSC only (€ 2009 prices)

Cost/benefit elements	Low scenario	High scenario
VLYL - Each year lost	€ 50,393	€ 50,393
COI or WTP - Unit cost (per cancer registration)	€ 2,601	€ 38,827 (WTP)

Note: As the WTP to estimate relates to not having permanent scars and does not include the costs associated with life years lost, the high scenario also incorporates the impacts of any life years lost. This differs from the approach used for other types of cancer whereby the WTP already includes life years lost (and is therefore excluded to avoid double counting benefits).

12.3 Compliance costs

In order to assess the compliance costs of meeting the proposed amendments to the Directive, particularly the introduction of a limit value, the main uses leading to exposures that are a risk to human health were identified. Minor uses were considered but not assessed.

Consideration was given to possible risk management measures (RMM) that may be applied in order to meet the investigated OEL and whether these RMMs may have already been applied - in some countries or all EU countries. Background information on all agents in the project was obtained from published literature and stakeholder contacts to identify:

- the uses and activities that lead to workplace exposure risks to human health;
- the structure of the sectors in which exposure occurs;
- exposure control measures currently in place, available and required to meet the proposed OEL and
- the possible costs of exposure control measures.

In order to understand the economic impacts on sectors in which specific uses cause a risk to the health of workers, the contractor has used Eurostat data about the number of enterprises operating in different sectors, the number of enterprises in the EU, and financial measures such as turnover, personnel costs and research and development expenditure.

Estimates were made of:

- the number of firms needing to apply RMMs and the cost of the RMMs over the same time period as health benefits (2010-2069);
- the cost of the administrative procedures of implementing the OEL (e.g. the cost of monitoring and audit);
- the potential effect on the market for the substance by the imposition of the OEL – i.e. the change in the market for the substance as a result of increased cost of control – leading to adoption of substitutes and possible change in price of the substance itself.

The final analysis comprises a comparison of the costs and benefits of the 'baseline (do nothing)' option with the scenario in which the possible OEL is added to the CMD Directive over the analysis time frame i.e. 2010-2069.

12.4 Analytical assumptions and challenges

IOM exposure and cancer incidence estimates

Exposure estimates, derived from the IOM study, are based on the assumption that for many of the concerned chemical agents, past trends of declining exposures will continue. These trends were related to technological progress, changes in work organisation and relative weight of different industrial sectors but also to past legislative developments. It is difficult to predict whether such trends would indeed continue in the absence of further EU action. The 60-year time frame of the assessment poses also the challenge of anticipating future industrial developments whereby uses of the chemical agents under consideration could either decline or grow and where potential new uses could lead to new workplace risks.

Another important assumption in the study is that for some of the chemical agents the industry has already achieved relatively low exposure levels, sometimes lower than the proposed OELs. Generally speaking, however, even where it is estimated that current exposure levels are already very low, lack of EU OELs or too high EU OELs mean that it will still not be clear for employers and workers and enforcing authorities whether the achieved exposure level is satisfactory from the point of view of compliance with the minimisation principle of the CMD.

Table 1 in Annex 7 presents the current limit values in the EU Member States. The information regarding existing national OELs was gathered through an extensive 2014 survey. 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 both worker protection and the internal market.

Methodological challenges (section 5)

- For most chemical agents under consideration, data on the number of workers exposed is scarce and unreliable and data on the current exposure levels across EU Member States is generally not available. Member States record statistics relating to cancer in different ways which cannot be readily aggregated. Where exposure data is available, its use as an evidence base for regulatory decision-making is often confounded by the sensitive and sometimes confidential nature of the information, and the potential for source bias.
- For many of the carcinogens, the baseline scenario taken from the IOM study foresees a constant reduction in average exposure levels (e.g. of 7% annually). This projection of future exposure levels is obtained by extrapolating past declining trends in average exposure levels. However, for some substances this (large) declining trend assumption is contested by other studies.[161] In addition, even when declining trends in average exposure levels are observed, it may be misleading to regard these as exogenous. Recent reductions in exposure may have been precisely the result of OELs having been introduced or as an anticipation of those changes. With respect to the cost and benefit analysis, therefore, the projected decline in average exposure levels under the baseline scenario may bias the estimated health impacts downward.
- The available epidemiologic evidence is scarce and not always sufficiently robust, inevitably affecting the reliability of the derived estimates for the number of cancer registrations and deaths. Among the factors contributing to the scarcity of reliable data are the complexity of cancer development and also of workplace exposures. Different carcinogens can, for example, result in the same type of cancer (e.g. lung cancer), and occupational exposure to hazardous agents is characterised by simultaneous exposure to multiple chemical agents. It can therefore be difficult to establish a causal relationship between cancer cases and exposure to a specific carcinogen.
- The cost-benefit analysis underestimates benefits as only the cancer-related health impact is considered. Exposure to the chemical agents under consideration is also associated with additional non-cancer health effects which can induce further health costs (such as for example severe skin damage, respiratory diseases, skin or eye irritation).
- When a declining trend exposure is considered under the baseline scenario, it would be incorrect to factor in among the costs of compliance with OELs based on the proposed OEL the full value of the investment required to reduce exposure: such investment would have occurred in any case also under the baseline scenario (in order to justify the decline in exposure), but possibly only later or more gradually over time. As a result the cost estimates of introducing an OEL reported in the IOM study would be overestimated.

Finally, to allow for a comparison between the monetised health benefits and compliance costs, the net present values of the streams of costs and benefits over the 60-year period under consideration are computed. The values originally reported in the IOM study were based on a constant discount rate of 4%. Given the very long timeframe considered, and in line with the

[161] Exposure to carcinogens and work-related cancer: a review of assessment methods, EU-OSHA 2014, Available at https://osha.europa.eu/en/tools-and-publications/publications/reports/report-soar-work-related-cancer/view

Better Regulation Toolbox, they have been recalculated applying a declining discount rate (4% for the first 20 years, 3% thereafter).[162] Still, benefits estimates are disadvantaged as discounting reduces much more the present value of impacts taking place in the longer term (typically health benefits) than those happening at the beginning of the period (typically compliance costs).

As it was not possible to obtain new estimates of health benefits assuming a constant level of exposure under the baseline scenario for all chemical agents, the costs presented in the IA report are indicative estimates of the actual *additional* costs of compliance assuming some delay (e.g. of 10-20 years) in the realisation of the investment needed to achieve a certain level of compliance.

The lack of reliable exposure data on both the numbers of workers exposed and on the levels of exposure is recognized. To address this data gap the Commission initiated a study in 2013[163] which is expected to contribute to a better definition of the baseline situation for possible future initiatives on developing OELs for other priority occupational carcinogens.

13 ANNEX 6 – CARCINOGENICITY OF THE CHEMICAL AGENTS

The table below summarises the current situation as regards the availability of SCOEL Recommendations for the seven chemical agents in question.

Table 1. Current situation regarding SCOEL Recommendations for chemical agents in the present proposal.

Chemical Agent	**CLP Harmonised Class.**	**IARC Class.**	**SCOEL Recommendation**	**Year**	**Comments**
1,2-Dibromoethane	1B	2A	SCOEL SUM 166	2011	The substance is a genotoxic carcinogen without a threshold, SCOEL Group A
1,2-Dichloroethane	1B	2B	SCOEL/REC/302	2016 under public consultation until 30 November 2016	The substance is a genotoxic carcinogen without a threshold, SCOEL Group A The chemical agent is worked on by SCOEL. Project stage is 40.20.
Benzo[*a*]pyrene	1B	1	SCOEL/REC/404 [164]	2016	The substance is a genotoxic carcinogen without a threshold, SCOEL Group A The chemical agent is worked on by SCOEL.
Epichlorohydrine (1-Chloro-2,3-epoxypropane)	1B	2A	SCOEL/SUM/169	2011	The substance is a genotoxic carcinogen without a threshold, SCOEL Group A
MDA (4,4'-Methylenedianiline)	1B	2B	SCOEL/SUM/107	2012	The substance is a genotoxic carcinogen without a threshold, SCOEL Group A

[162] This is consistent with some other European Commission studies and is standard practice for air quality under the Clean Air for Europe (CAFE) programme.

[163] Call for tender no. VT/2013/079. Service contract to create a database and develop a model to estimate the occupational exposure for a list of hazardous chemicals in the Member States of the European Union and the EFTA/EEA countries. The contract with the successful bidder, VC/2014/0584, was signed on 23 July 2014.

[164] The SCOEL recommendation deals with 'Polycyclic Aromatic Hydrocarbon mixtures containing benzo[*a*]pyrene'

Mineral oils as Used Engine Oils	n/a	1	SCOEL/OPIN/2016-405	June 2016	The substance is a genotoxic carcinogen without a threshold, SCOEL Group A
Trichloroethylene	1B	1	SCOEL/SUM/142	2009	The substance is a genotoxic carcinogen, SCOEL Group C

14 ANNEX 7 - EXPOSURE LIMIT VALUES IN EU MEMBER STATES AND SOME NON-EU COUNTRIES

14.1 Annex 7 Table 1. OELs[165] in EU MS

Carcinogen →	ECH	EDB	EDC	MDA	TCE[166]		BAP (re PAHs)	Mineral Oils (re used engine oils)
CAS	106-89-8	106-93-4	107-06-2	101-77-9	79-01-6		50-32-8	
proposed OEL (mg/m^3)	1.9	0.8	8.2	0.08	8TWA 55 (10 ppm)	STEL 165 (30 ppm)		
notation				skin				skin
AT	12(167)	0.8(168)	20	0.1(169)	3.3	13.2	0.005(170) 0.002(171)	
BE	2		41	0.82	55	137		5(172)
BG			4		135		0.00015	5
CY		145	412		535			5
CZ	1	1(173)	10(174)	0. 1	250	750	0.005	5
DE	8			0.7	60		0.0007	
DK	1.9	1	4	0.8	55	20		
EE								
EL	10	4	40	0.8	538	1080	0.005	5
ES	1.9	3.9	20	0.82	55			5
FI	1.9	0.78	4	0.08	50		0.01	5(175)
FR	(176)		40		405	1080		
HR	1.9	3.9	21	0.8	550	820	0.005	
HU	1.9	0.8	10	0.81			0.002	
IE	2	4	20	0.08		137.5		0.2(177)
IT	2		412		54	140		5(178)

[165] Values relate to exposure by the inhalation route, 8 hr TWA, unless otherwise stated. Short Term Exposure Limit (STEL) values set at MS level are referenced in relation to TCE.
[166] In converting the units for Trichloroethylene values from ppm into mg/m^3, the latter has been round up to the nearest whole number.
[167] Also notation for 'skin' and an equivalent for 'sensitisation'.
[168] Also skin notation.
[169] Also notations for 'skin' and 'skin sensitisation'.
[170] For 'strong pitch preparation and loading, outside the range of coke ovens'. Also notation 'skin sensitisation'.
[171] For 'for the rest'. Also notation 'skin sensitisation'.
[172] BE value covers only a sub-group ("Paraffin oils") of what has been evaluated by SCOEL ("Mineral Oils as Used Engine Oils").
[173] Also skin notation.
[174] *Ibid.*
[175] For 'oil mist'.
[176] FR only adopted STEL value of 10 mg/m^3.
[177] Used in metal working (Inhalable).
[178] For 'mineral oil mist'.

Carcinogen →	ECH	EDB	EDC	MDA	TCE[166]		BAP (re PAHs)	Mineral Oils (re used engine oils)
CAS	106-89-8	106-93-4	107-06-2	101-77-9	79-01-6		50-32-8	
LT	1.9		412		50	134	0.002	1
LU								
LV	1	10	10		10		0.00015	5
MT					55	137.5		-
NL	0.19	0.002	7	0.009			0.00055	5
PL	1	0.01	50	0.08	50	100	0.002	5(179)
PT								
RO	1	0.8	30	0.8	100	150		
SE	1.9		4		50	140	0.002	
SI	12	0.8	20		270	1080	0.005(180) 0.002(181)	
SK	12	0.8	20	0.1	275		0.005(182) 0.002(183)	1
UK	1.9	3.9	21	0.08	550	820		

[179] For 'mineral oils highly refined excluding lubricants'. Inhalable fraction.
[180] For 'coking'.
[181] For 'others'.
[182] For 'coke'.
[183] For 'others'.

14.2 Annex 7 Table 2. OELs in EU MS – compared to levels recommended by the ACSH (option 2)

Carcinogen [proposed EU OEL][184]	MS having no or higher OEL (8-hr TWA)	Total number
Epichlorohydrine [1.9 mg/m^3, sk.]	AT, BE, BG, CY, DE, EE, EL, FR[185], IE, IT, LU, MT, PT, SI, SK	15
Ethylene dibromide (EDB) [0.8 mg/m^3, sk.]	BE, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, IE, IT, LT, LU, LV, MT, PT, (SE[186]), UK	(20)19
Ethylene dichloride (EDC) [8.2 mg/m^3, sk.]	AT, BE, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, LV, MT, PL, PT, RO, SI, SK, UK	23
4,4'-Methylenedianiline (MDA) [0.08 mg/m^3, sk.]	AT, BE[187], BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, HU, IT, LT, LU, LV, MT, PT, RO, SE, SI, SK The UK has also adopted a Biological Monitoring Guidance Value of 50 µmol MDA /mol in urine.[188]	23[189]
Trichloroethylene (TCE) [8TWA 10 ppm, 54.7 mg/m^3 STEL 30 ppm, 164.1 mg/m^3, Sk.]	BG, CY, CZ, DE, EE, EL, FR, HR, HU, IT, LU, NL, PT, RO, SI, SK, UK	17
Complex PAH mixtures with benzo[*a*]pyrene as an indicator [N/A]	15 EU MSs (AT, BG, CZ, DE, EL, FI, HR, HU, LT, LV, NL, PL, SE, SI, SK) have OELs established at national level, varying between 0.022 mg/m^3 (DE) to 0.00015 mg/m^3 (BG and LV) UK has also adopted a Biological Monitoring Guidance Value of 4 µmol 1-hydroxypyrene/mol creatinine in urine.[190]	
Mineral Oils as Used Engine Oils (UEOs) [Skin notation only]	13 MSs (BE, BG, CY, CZ, EL, FI, IE, IT, LT, LV, NL, PL, SK) have adopted national OELs, all but one (LT) for 5 mg/m^3. However, the definition of what is covered by the entry differs considerably between MS	

[184] 8 hr TWA unless otherwise stated

[185] FR has not adopted an 8 hrs TWA value but STEL values, which are in the same range of STEL values of other MSs which have adopted a value two times higher than the proposed ACSH OEL

[186] According to the EMPL B3 questionnaire circulated in December 2013 to the MSs in order to get information about their OELs for the substances concerned, Sweden replied that "Handling of this substance requires authorization from the Swedish Work Environment Authority. So Sweden should not really be counted in this list.

[187] BE supports a lower EU OEL than in its own national legislation

[188] http://www.hsl.gov.uk/media/66141/4.4%20methylenedianiline_layout%201.pdf

[189] 3 out of these 23 MSs (AT, CZ, SK) have national OELs very close to the one proposed (0.1 mg/m3 instead of 0.08 mg/m3), which might be just the result of different ways of presenting and rounding values

[190] http://www.hsl.gov.uk/media/1644/pah.pdf

14.3 Annex 7 Table 3. OELs in some non-EU countries[191]

Carcinogen [proposed EU OEL][192]	Australia	Canada	US	China	Switzerland	New Zealand	Japan	Singapore	South Korea
Epichlorohydrine [1.9 mg/m^3, sk.]	7.6 mg/m^3 2 ppm	Ca-O: 0.5 ppm Ca-Q: 2 ppm	NIOSH: No value OSHA: 19 mg/m^3; 5ppm	1 mg/m^3	8 mg/m^3 2 ppm	1.9 mg/m^3 0.5 ppm	No value	7.6 mg/m^3 2 ppm	1.9 mg/m^3 0.5 ppm
Ethylene dibromide (EDB) [0.8 mg/m^3, sk. – 0.1 ppm]	no value	Ca-O: no value Ca-Q: no value	OSHA: 20 ppm NIOSH: 0.045 ppm	No value	0.8 mg/m^3 0.1 ppm	3.9 mg/m^3 0.5 ppm	No value	No value	No value
Ethylene dichloride (EDC) [8.2 mg/m^3, sk. – 2 ppm]	40 mg/m^3 10 ppm	Ca-O: 10 ppm Ca-Q: 4 mg/m^3, 1 ppm	NIOSH: 4 mg/m^3;1ppm OSHA: 50 ppm	7 mg/m^3	20 mg/m^3 5 ppm	21 mg/m^3 5 ppm	10 ppm	40 mg/m^3 10 ppm	40 mg/m^3 10 ppm
4,4'-Methylenedianiline (MDA) [0.08 mg/m^3, sk.]	0.81 mg/m^3 0.1 ppm	Ca-O: 0.04 mg/m3 Ca-Q: 0.1 ppm, 0.81 mg/m3	NIOSH: no value OSHA: 0.01 ppm	No value	0.1 mg/m3	0.08 mg/m^3 0.01 ppm	0.4 mg/m^3	0.81 mg/m^3 0.1 ppm	0.8 mg/m^3 0.1 ppm
Trichloroethylene (TCE) [8TWA 10 ppm, 54.7 mg/m^3 STEL 30 ppm, 164.1 mg/m^3 Sk.]	54 mg/m^3 10 ppm	Ca-O: 10 ppm Ca-Q: 269 mg/m^3, 50 ppm	NIOSH: 25 ppm OSHA: 100 ppm	30 mg/m^3	110 mg/^{3} 20 ppm	269 mg/m^3 50 ppm	135 mg/m^3 25 ppm	269 mg/m^3 50 ppm	270 mg/m^3 50 ppm

191 Values or cells marked in red indicate OELs lower than the option retained.

192 8 hr TWA unless otherwise stated

14.4 Annex 7 Table 4. Exposures in Member States which have no OEL or an OEL higher that the retained option

(where relevant and data is available)

	Epichlorohydrine		Ethylene dibromide (EDB)*		Ethylene dichloride (EDC)**		4,4 Methylenediani line (MDA)*		Trichloroethylene (TCE)	
No EU workers exposed	39.372		7.691		3.000		3.942.581		74.076	
MS with no or higher limits	No. of workers exposed	% of exposed all EU workers	No. of workers exposed	% of exposed all EU workers	No. of workers exposed	% of exposed all EU workers	No. of workers exposed	% of exposed all EU workers	No. of workers exposed	% of exposed all EU workers
Austria	392	1,00%					63547	1,61%		
Belgium	2248	5,71%	183	2,38%			48486	1,23%		
Bulgaria	573	1,46%	115	1,50%			63100	1,60%	994	1,34%
Croatia	NA		NA				NA		NA	
Cyprus	35	0,09%	32	0,42%			1717	0,04%	65	0,09%
Czech R.			151	1,96%			239430	6,07%	2902	3,92%
Denmark			101	1,31%			56461	1,43%		
Estonia	74	0,19%	25	0,33%			13574	0,34%	268	0,36%
Finland										
France	5841	14,84%	1258	16,36%			460036	11,67%	7884	10,64%
Germany	9674	24,57%	1418	18,44%			774628	19,65%	16463	22,22%
Greece	836	2,12%	216	2,81%			27200	0,69%	455	0,61%
Hungary							111240	2,82%	1454	1,96%
Ireland	1038	2,64%	44	0,57%						
Italy	5431	13,79%	175	2,28%			541429	13,73%	9200	12,42%
Latvia			44	0,57%			9829	0,25%		
Lithuania			50	0,65%			12521	0,32%		
Luxemb.	3	0,01%	25	0,33%			6553	0,17%	41	0,06%
Malta			5	0,07%			197	0,00%		
NL									1695	2,29%
Poland										
Portugal	646	1,64%	176	2,29%			62550	1,59%	1306	1,76%
Romania							206946	5,25%	2919	3,94%
Slovakia	272	0,69%					60111	1,52%	789	1,07%
Slovenia	206	0,52%					43215	1,10%	506	0,68%
Spain			701	9,11%			320563	8,13%		
Sweden			192	2,50%			119575	3,03%		
UK			1299	16,89%					7695	10,39%
TOTALS	27269	**69,26%**	6210	**80,74%**			3242908	**82,25%**	54636	**73,76%**

* No. of EU workers exposed is maximum estimate

** No data available

15 Annex 8 - Relevant EU legislation

15.1 Existing EU-OSH framework

15.1.1 Directive 89/391/EEC

The aim of the Framework Directive is to introduce measures to encourage improvements in the safety and health of workers at work. To this end it contains general principles concerning the prevention of occupational risks, the protection of safety and health, the elimination of risk and accident factors, the informing, consultation, balanced participation in accordance with national laws and/or practices and training of workers and their representatives, as well as general guidelines for the implementation of the said principles.

The Framework Directive applies to all sectors of activity, both public and private. It establishes in particular the duty of the employer to ensure the safety and health of workers in every aspect related to the work. It requires the employer to take the measures necessary for the safety and health protection of workers, including prevention of occupational risks and to implement these measures on the basis of general principles of prevention, among which 'avoiding risks', 'evaluating the risks which cannot be avoided', 'combating the risks at source' and 'replacing the dangerous by the non-dangerous or the less dangerous'.

15.1.2 Directive 98/24/EC

The Directive lays down minimum requirements for the protection of workers from the risks to their safety and health arising, or likely to arise, from the effects of chemical agents that are present at the workplace or as a result of any work activity involving chemical agents.

The Directive provides for the drawing up of indicative occupational exposure limit values (IOELs) and binding occupational exposure limit values (OELs) as well as binding biological limit values (BBLVs) at EU level.[193]

For any chemical agent for which an IOEL is established at EU level, Member States must establish a national occupational exposure limit value (OEL), taking into account the EU limit value. Along the same lines, OELs and BBLVs may be drawn up at EU level taking into account feasibility factors. For any chemical agent for which a OEL or a BBLV is established at EU level, Member States must establish a corresponding national binding OEL or a binding BLV that does not exceed the EU limit value.

The employer must determine whether any hazardous chemical agents are present at the workplace and assess any risk to the safety and health arising from their presence.

The employer must take the necessary preventive measures set out in Article 6 of Directive 89/391/EEC and risks must be eliminated or reduced to a minimum following the hierarchy of prevention measures, among which substitution (replacing a hazardous chemical agent with a chemical agent or process which is not hazardous or less hazardous) must by preference be undertaken, whereas wearing personal protective equipment is the least preferred option.

In addition to the above mentioned requirements, which are most relevant for this topic, the employer must also take other preventive and protective measures on a regular basis (e.g. health surveillance of workers, training of workers). The competent authorities of the Member States have the obligation to ensure compliance with these requirements.

The Directive has been implemented into national law in all Member States.

15.1.3 Directive 2004/37/EC

Directive 2004/37/EC requires eliminating or reducing to a minimum the risks arising from the occupational exposure to carcinogenic or mutagenic chemical agents and mixtures. In order to further reduce the occupational exposure to these particular hazardous chemical agents / mixtures, the Directive lays down specific requirements,

[193] The distinction between IOELs, on the one hand, and BOELs and BBLVs, on the other hand, lies in the methods used for their derivation: while IOELs are purely health based, BOELs and BBLVs are drawn up also taking into account feasibility or workability factors. IOELs constitute thresholds of adverse health effects and therefore exposure below these limit values should not, in theory, result in a risk for the workers' health

which go beyond the preventive and protective measures foreseen in the Framework Directive 89/391/EEC and the Chemical Agents Directive 98/24/EC.

Whether a chemical agent or a mixture is under the scope of the Directive is primarily based on their classification as a carcinogen or a mutagen (category 1A or 1B) according to the criteria established under the CLP Regulation).

However, there is also a possibility to bring a chemical agent / mixture under the scope of the Directive, by including it in Annex I to the Directive. This Annex covers chemical agents, mixtures or processes (or chemical agents / mixtures released by a process referred to in that Annex) – so-called process-generated chemical agents or PGSs - which are not classified according to the CLP Regulation as carcinogens or mutagens, but are recognised by other international bodies (like IARC) as chemical agents, mixtures or processes of equal concern.

The Directive has been implemented into national law in all Member States.

15.1.4 Directive 2009/148/EC

Directive 2009/148/EC applies to activities in which workers are or may be exposed in the course of their work to dust arising from asbestos or materials containing asbestos.

It requires in particular that a risk assessment be carried out by employers 'in the case of any activity likely to involve a risk of exposure to dust arising from asbestos or materials containing asbestos' and in such a way as to determine the nature and degree of exposure. Depending on the initial risk assessment, the asbestos fibres in the air are to be measured regularly. Employers must ensure that exposure is reduced to a minimum via the adoption of several risk management measures and in any case below the limit value of 0,1 fibres per cm 3 as an 8-hour time-weighted average. The Directive also establishes specific obligations regarding the information, training and health surveillance of workers and contains specific requirements as regards demolition, asbestos removal work, repairing and maintenance.

The provisions of Directive 2004/37/EC apply as regards asbestos whenever they are more favourable to health and safety at work. All Member States have transposed this Directive.

15.2 Internal Market legislation

15.2.1 REACH Regulation

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals.

It requires all companies manufacturing and/or importing chemicals into the EU in quantities of one tonne or more per year to register this chemical with the European Chemical Agency (ECHA) in Helsinki, to evaluate the risks resulting from the use of those chemicals and to take the necessary steps to manage any identified risk to human health and the environment. Industry has the burden of proving that chemicals manufactured and placed on the EU market are safe.

'Restriction' is the procedure via which the manufacture, use and/or placing on the market of the chemical is subject to a restriction. A Member State, or ECHA on request of the European Commission, can propose restrictions if they find that an unacceptable risk needs to be addressed on EU wide basis.

'Authorisation' aims to ensure that the risk from a 'Substance of Very High Concern' (SVHC) is properly controlled and that these chemicals are progressively replaced by less hazardous suitable alternatives. SVHC are amongst others chemical agents which meet the criteria for classification as carcinogenic, mutagenic or toxic to reproduction,

Category 1A or 1B according to the CLP Regulation. Chemicals subject to authorisation cannot any longer be placed on the market or used after certain date, unless an authorisation is granted for their specific use, or the use is exempted from authorisation. In order to receive an authorisation, manufacturers, importers or downstream users have to apply for authorisation if they want to use the chemical agent after the aforementioned date.

REACH status of the chemical agents under consideration in the present proposal is presented in the table below.

Table 1. REACH status of the chemical agents in the present proposal.

Chemical Agent	**REACH status**
Ethylene dichloride (EDC)	subject to authorisation
MDA	subject to authorisation
Trichloroethylene (TCE)	subject to authorisation
Benzo[*a*]pyrene	subject to restriction (as part of the group entry 50 of Annex XVII for eight PAHs). Identified as a SVHC.

15.2.2 CLP Regulation

The CLP Regulation (for 'Classification, Labelling and Packaging') is the EU Regulations which aligns the previous EU system of classification, labelling and packaging of chemical agents and mixtures to the UN Globally Harmonized System. It complements the REACH Regulation and replaces the current system.

The regulation requires companies to appropriately classify, label and package their chemical agents and mixtures before placing them on the market. It aims to protect workers, consumers and the environment by means of labelling which reflects possible hazardous effects of a particular chemical.

Five OSH Directives (CAD, CMD, Pregnant Workers Directive, Young Workers Directive, Safety Signs at Work Directive[194]) are directly related to the CLP Regulation by providing a link to the hazard classification of chemical agents and mixtures according to the CLP Regulation, and the resulting obligations for employers under the OSH Directives (e.g. chemical agents and mixtures classified as carcinogens or mutagens, category 1A or 1B are under the scope of the CMD).

15.2.3 Comparison of high level CMD and REACH provisions in relation to occupational carcinogens

CMD	**REACH**
Scope includes process-generated chemical agents	Scope does not include process-generated chemical agents
Sets 'minimum standards'. Member States may maintain or implement more protective	Sets directly-acting harmonised standards from which Member States cannot deviate except in exceptional (and possibly time limited)

[194] Council Directive 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 245, 26.8.1992, p. 23

measures.	circumstances.
Risk assessment is, in all cases, specific to the workplace where exposures occur taking into account any specific processes, operating conditions, workforce characteristics, etc.	Risk assessment for majority of chemical substances is undertaken by actors in the supply chain (primarily manufacturers and/or importers). May be specific to specific workplace/s or more generic applying to a larger number of workplaces.
Risk assessment takes into account aggregated exposure of workers to all carcinogens at workplace level.	Risks assessed and identified risk management measures are specific to the chemical substance or mixture being manufactured, used and placed on the market. REACH should result in improved information being provided down the supply chain to employers to inform their OSH risk assessment.
EU OEL applies only in workplaces, and so is targeted solely at occupational exposures.	REACH covers all risks arising from given intrinsic properties of a substance which are not made subject to specific derogations. These may include risks for workers, the public, consumers, and the environment.
Occupational carcinogens must be substituted by a safer alternative where technically possible, then exposure must be eliminated where technically possible or otherwise minimised. An EU OEL for a given carcinogen does not alter this expectation, but provides a compliance and enforcement benchmark for employers, workers and enforcers.	REACH can complement a CMD OEL, in particular by strengthening the substitution principle and its full implementation.
As social policy, under TFEU the social partners play a key role in establishing standards for worker protection by adopting agreed positions on which chemical agents should be made subject to EU level OELs, at what level, and with additional commentary where appropriate.	As an internal market Regulation social partners have no formal role according to the TFEU in policy or development of legal standards. However, all stakeholders are invited to provide comments during the established public consultations.
OELs are established under and are an important part of CMD.	REACH is not intended to set OELs.

16 ANNEX 9 – GENERAL INFORMATION ABOUT THE CLASSIFICATION SYSTEMS REFERRED TO IN THE DOCUMENT

16.1 Carcinogens

In this report, reference is mainly made to 2 systems to classify 'agents' as carcinogens or carcinogenic:

- The EU classification, packaging and labelling system based on the CLP Regulation (EC) No 1272/2008;
- The classification system of the International Agency for Research on Cancer (IARC)

16.1.1 Classification according to the CLP Regulation

The harmonised classification[195] of a chemical agent listed in Annex I to the CLP Regulation and the resulting / associated labelling and packaging provisions is legally binding for suppliers placing a chemical agent on the European market. An entry in Annex I is established by the Commission via an amendment of the CLP Regulation, following a scientific evaluation of the available information by the Risk Assessment Committee of the European Chemicals Agency (ECHA). If a chemical agent is not listed in Annex VI of the Regulation, suppliers must self-classify its chemical agent according to the criteria established under the CLP Regulation before placing it on the market. Following Article 2 ('Definitions') of the CLP Regulation, a 'chemical agent' is means 'a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the chemical agent or changing its composition'.

Mixtures (composed of two or more chemical agents) are classified, labelled and packaged based on the content of their classified components ('chemical agents') or based on test results for the mixture as a whole following again the classification criteria established under the CLP Regulation.

The exact criteria to classify chemical agents and mixtures according to the CLP Regulation can be found in section 3.6 of that Regulation[196]. For the purpose of this report it is important to notice, that the CMD applies 'only' to chemical agents and mixtures meeting the criteria for classification as category 1A or 1B carcinogens set out in Annex I to the CLP Regulation.

- Category 1A carcinogens are chemical agents known to have carcinogenic potential for humans; their classification is largely based on human evidence (so-called epidemiological evidence)
- Category 1B carcinogens are chemical agents presumed to have carcinogenic potential for humans; their classification is largely based on animal evidence.

Suspected human carcinogens (Category 2 carcinogens according to the CLP Regulation) are not under the scope of the CMD.

[195] classification of chemical agents listed in Annex VI to the Regulation

[196] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20150601&qid=1447160631531&from=EN

16.1.2 Classification according to IARC

The evaluations of carcinogenic risk are made by international working groups of independent scientists and are qualitative in nature, and is published in the form of so-called Monographs available on the IARC website[197]. Contrary to the EU system, IARC evaluates also the carcinogenicity of occupational or environmental exposures, cultural or behavioural practices, biological organisms and physical agents.

Even if the IARC approach is - like the EU approach - also hazard and not risk based[198], it goes beyond the chemical agent based approach of the EU by evaluating not only chemical agents but also certain occupational exposure situations (for example 'Occupational Exposures in the Rubber Manufacturing Industry' or 'Occupational Exposure as a Painter'[199]).

Based on its evaluation, IARC classifies 'agents' in 5 groups with regard to their carcinogenicity to humans[200]:

- Group 1 – The agent is carcinogenic to humans / This category is used when there is *sufficient evidence of carcinogenicity* in humans.
- Group 2A – The agent is probably carcinogenic to humans / This category is used when there is *limited evidence of carcinogenicity* in humans and *sufficient evidence of carcinogenicity* in experimental animals.
- Group 2B – The agent is possibly carcinogenic to humans / This category is used for agents for which there is *limited evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals.[201]
- Group 3 – The agent is not classifiable as to its carcinogenicity to humans / This category is used most commonly for agents for which the evidence of carcinogenicity is *inadequate* in humans and *inadequate* or *limited* in experimental animals.
- Group 4 – The agent is probably not carcinogenic to humans / This category is used for agents for which there is *evidence suggesting lack of carcinogenicity* in humans and in experimental animals.

[197] http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php

[198] A hazard is any source of potential damage, harm or adverse health effects on something or someone under certain conditions at work; the isk is the chance or probability that a person will be harmed or experience an adverse health effect if exposed to a hazard.

[199] http://monographs.iarc.fr/ENG/Monographs/vol100F/index.php

[200] The details of the objectives and scope of the IARC Monographs programme, the scientific principles and the procedures used in developing a Monograph, the types of evidence considered and the scientific criteria guiding the evaluations can be found in the preamble of each Monograph and on the following web side: http://monographs.iarc.fr/ENG/Preamble/index.php

[201] The terms probably carcinogenic and possibly carcinogenic have no quantitative significance and are used simply as descriptors of different levels of evidence of human carcinogenicity, with probably carcinogenic signifying a higher level of evidence than *possibly carcinogenic*.

17 ANNEX 10 – ADDITIONAL GRAPHICAL MATERIAL

Graphs are provided only where data is available in IOM Study

17.1 Epichlorohydrine

Figure 3 – Epichlorohydrine - Current national OELs vs. Option 2

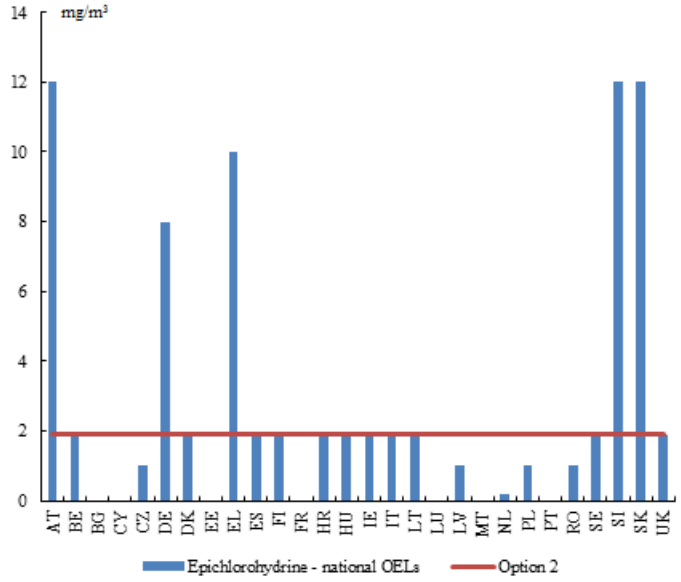
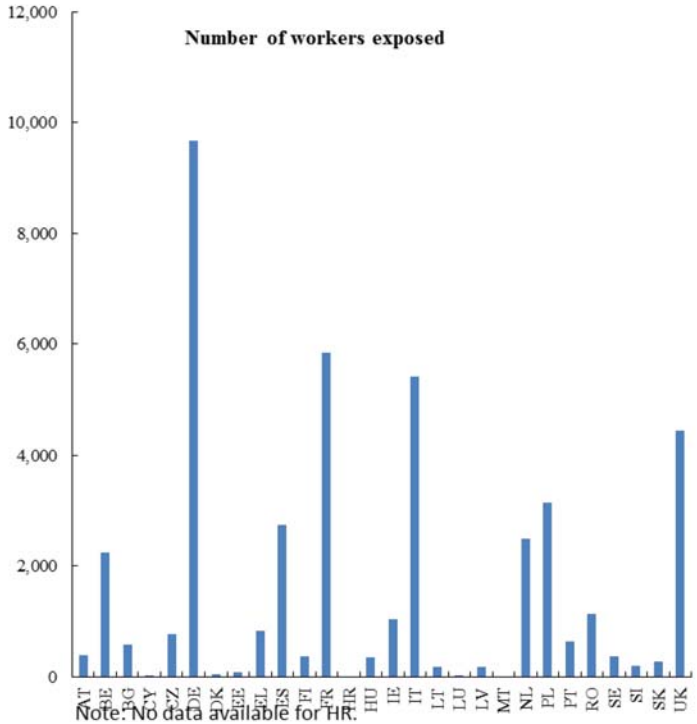
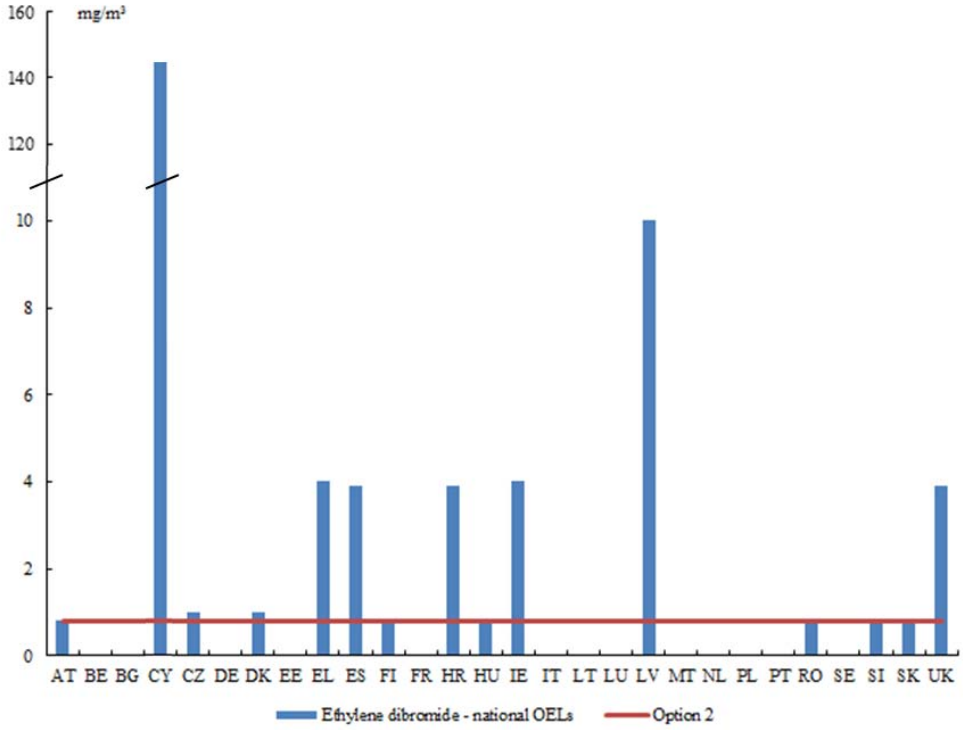


Figure 4 - Epichlorohydrine – Number of exposed workers



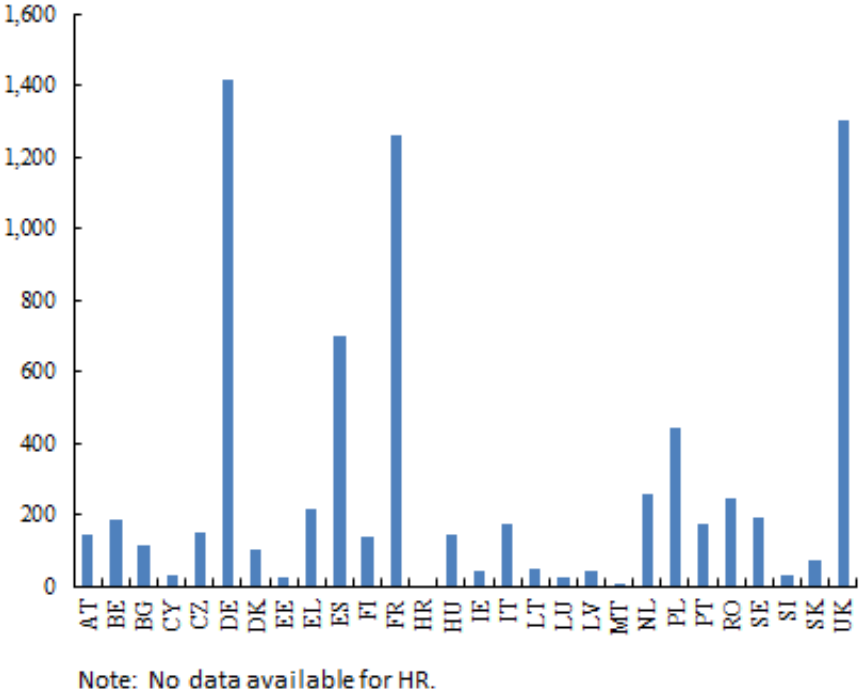
17.2 Ethylene dibromide

Figure 5 – Ethylene dibromide – Current national OELs vs. Option 2



N.B. note interrupted and varied scale on *y*-axis

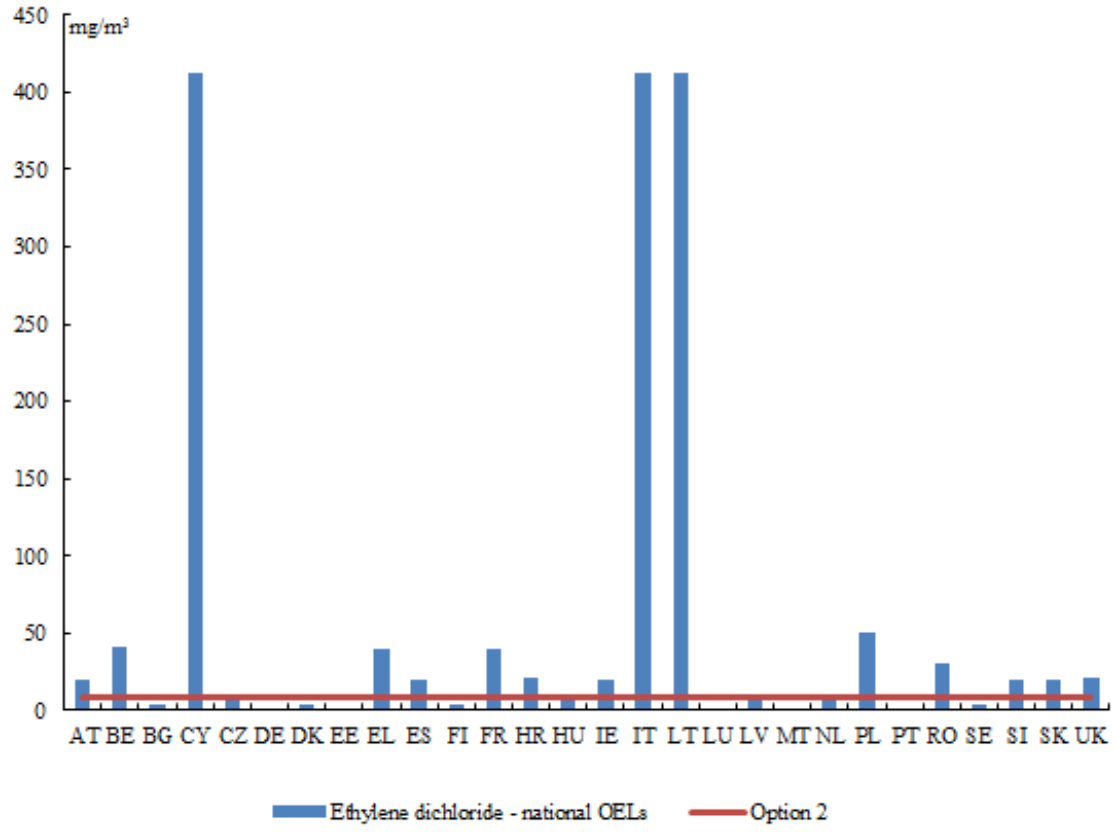
Figure 6 – Ethylene dibromide - Number of exposed workers



Note: No data available for HR.

17.3 Ethylene dichloride

Figure 7 – Ethylene dichloride - Current national OELs vs. Option 2



17.4 4,4,'Methylenedianiline

Figure 8 – 4,4,'Methylenedianiline - Current national OELs vs. Option 2

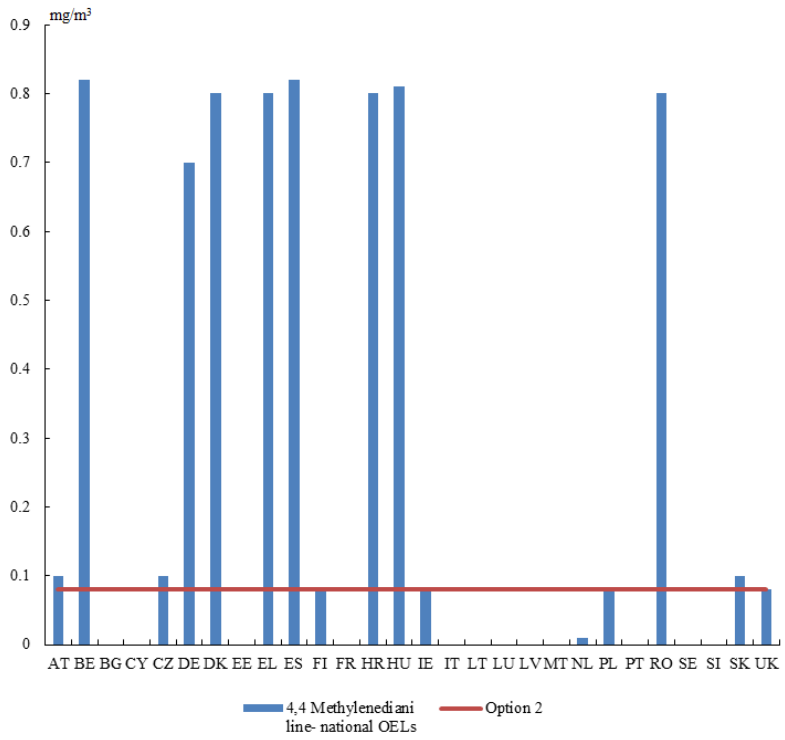
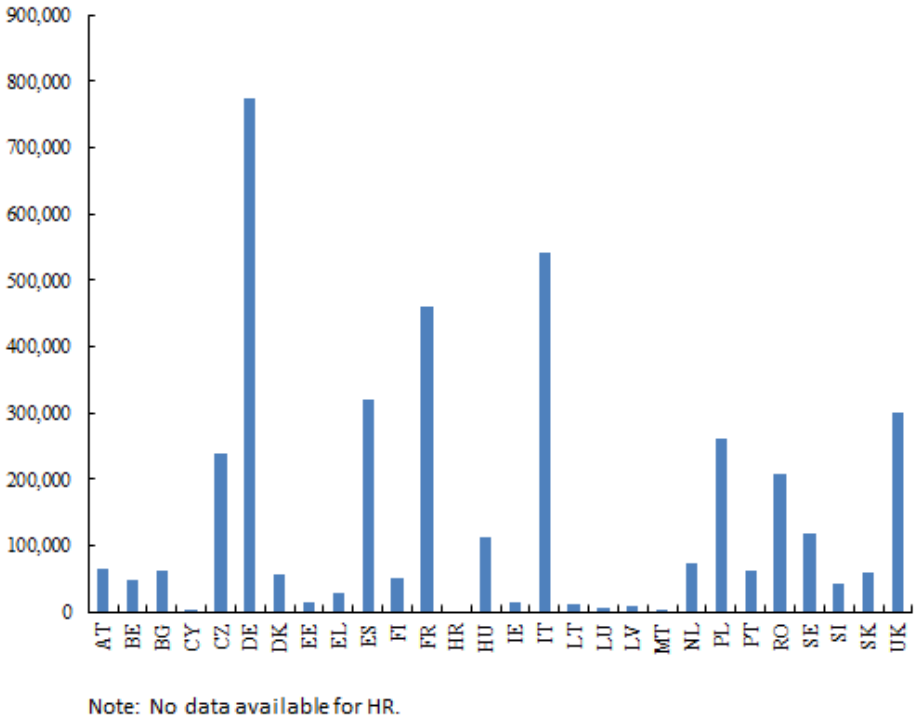


Figure 9 – 4,4,'Methylenedianiline - Number of exposed workers



17.5 Trichlorothylene

Figure 10 – Trichlorothylene - Current national 8 hr TWA OELs vs. Option 2

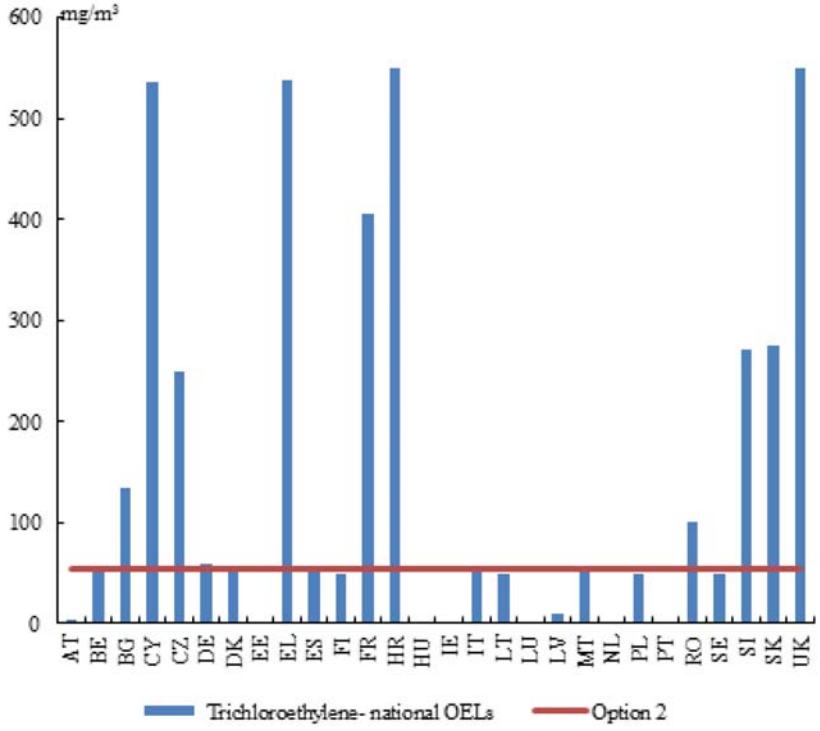


Figure 11 – Trichlorothylene - Current national 15 min STEL-OELs vs. EU OEL and Option 2

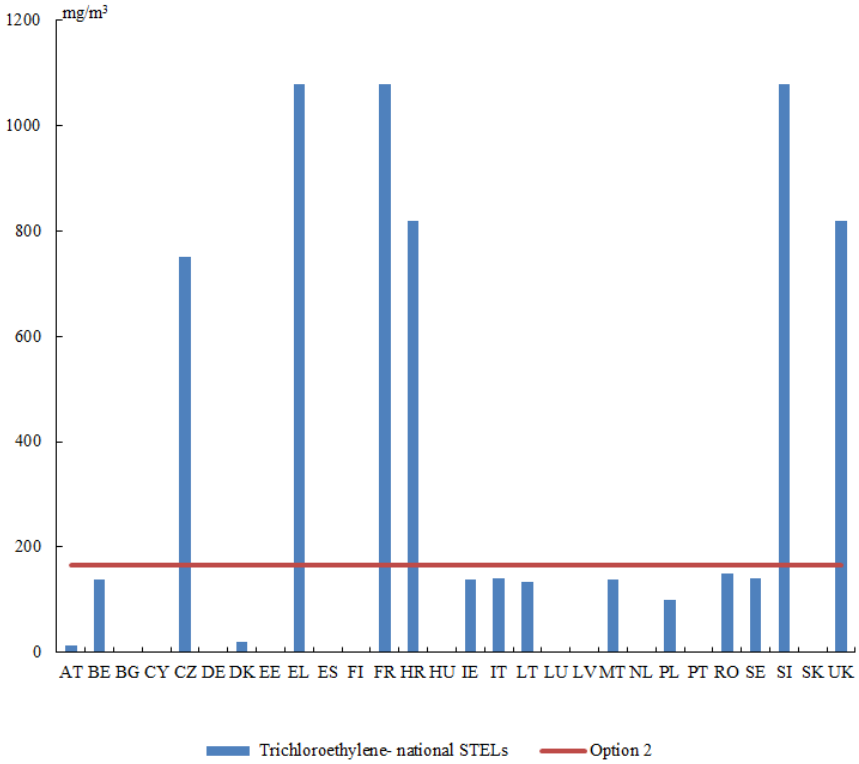
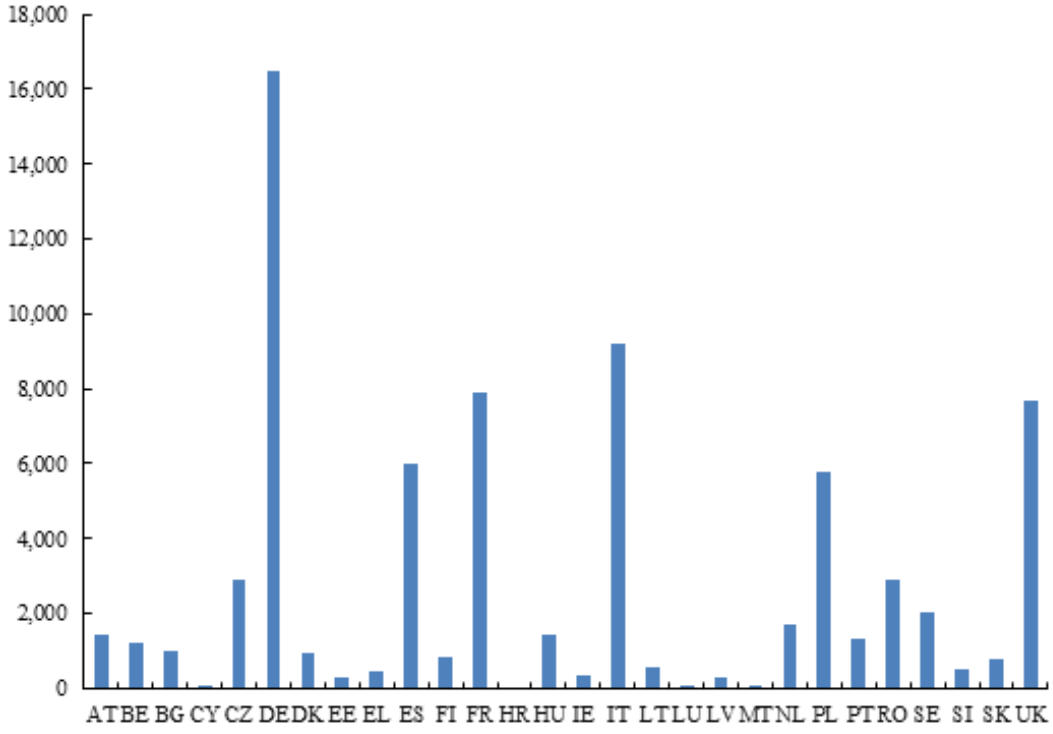


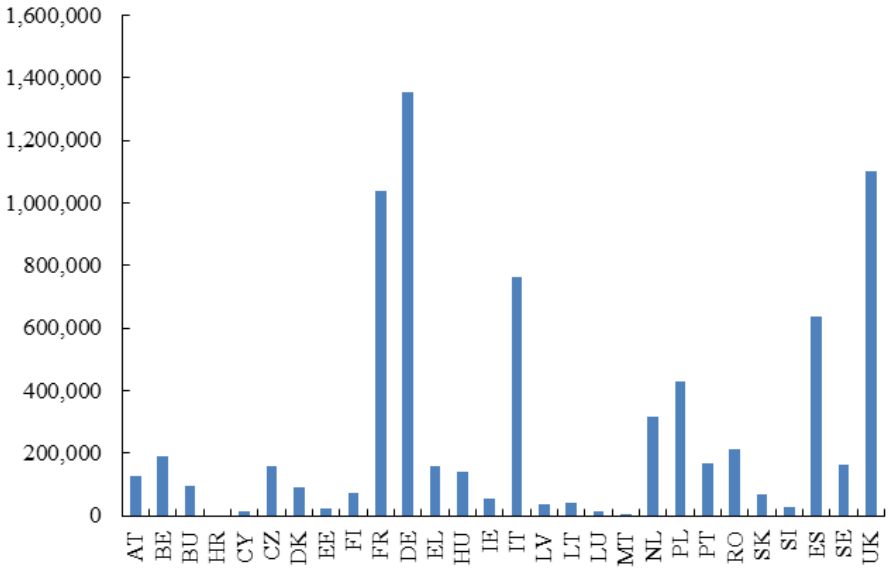
Figure **12– Trichlorothylene - Number of exposed workers**



Note: No data available for HR.

17.6 Complex PAH mixtures with benzo[*a*]pyrene as an indicator

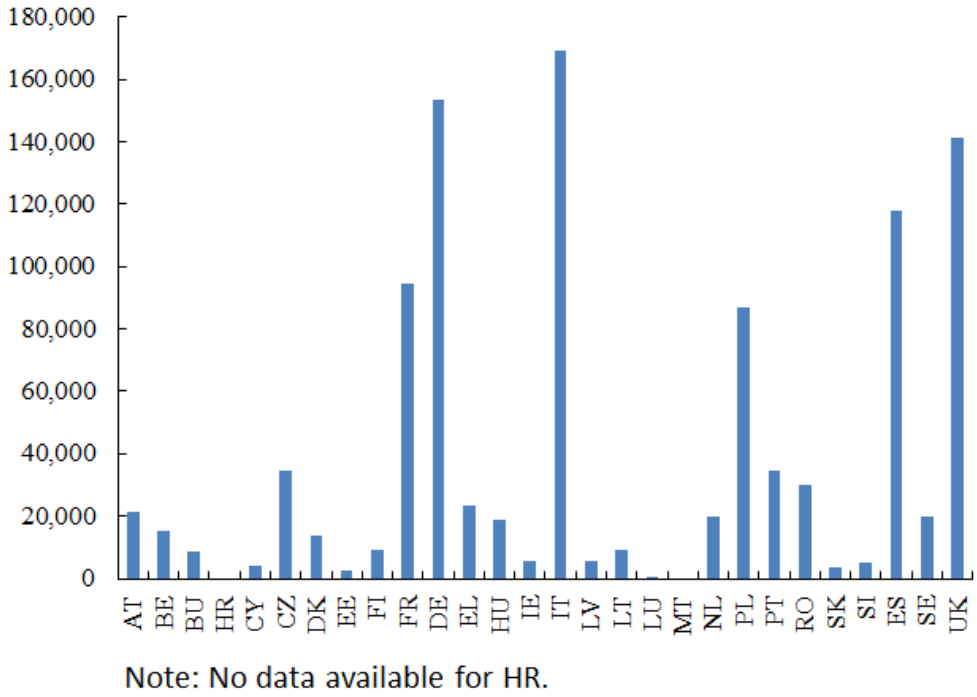
Figure 13 – Complex PAH mixtures with benzo[*a*]pyrene as an indicator - Number of exposed workers



Note: No data available for HR.

17.7 Mineral Oils as Used Engine Oils

Figure 14 – Mineral Oils as Used Engine Oils - Number of exposed workers



Note: No data available for HR.

18 ANNEX 11 – ABBREVIATIONS USED

ACSH	Advisory Committee on Safety and Health at Work
BAP	Benzo[*a*]pyrene
Be	Beryllium
BGV	Biological Guidance Value
BLV	Biological Limit Value
BIOLOGICAL MONITORING VALUE	Biological Monitoring Value
CAD	Chemical Agents Directive (Directive 98/24/EC)
CBD	Chronic Beryllium Disease
CLP	Classification, Labelling and Packaging Regulation (Regulation (EC) No 1272/2008)
CMD	Carcinogens and Mutagens Directive (Directive 2004/37/EC)
CMR	carcinogenic, mutagenic, and chemical agents toxic to reproduction
DEE	Diesel engine exhaust
DNEL	Derived No Effect Level
ECHA	European Chemicals Agency
EDB	Ethylene dibromide
EDC	Ethylene dichloride
EIG	Employers Interest Group
ECH	Epichlorohydrine

GIG	Government Interest group
HCB	Hexachlorobenzene
IARC	International Agency for Research on Cancer
MOCA	4,4'-Methylene-bis-(2-chloroaniline)
MDA	4,4'-Methylenedianiline
mg/m^3	milligram per cubic metre
MOs	Mineral oils
NEPSi	Agreement on Workers' Health Protection Through the Good Handling and Use of Crystalline Silicas and Products Containing it
OEL	Occupational Exposure Limit (Value)
OSH	Occupational Safety and Health
PGSs	Process Generated Substances
ppm	parts per million
RAC	Risk assessment Committee of ECHA
RCF	Refractory Ceramic Fibres
RCS	Respirable Crystalline Silica
REACH	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (Regulation (EC) No 1907/2006)
REFIT	Regulatory Fitness and Performance Programme
RPDF	Rubber Process Dust and Fumes
SCOEL	Scientific Committee on Occupational Exposure Limits
SMEs	Small and Medium Sized Enterprises
STEL	Short Term Exposure Limit
SWD	Staff Working Document
SVHC	Substance of Very High Concern
TFEU	Treaty on the Functioning of the EU
TCE	Trichloroethylene
TWA	Time-weighted average
UEOs	Mineral Oils as Used Engine Oils
UN	United Nations
VCM	Vinyl Chloride Monomer
YYL	Years of Life Lost
WIG	Workers Interest Group
WHO	World Health Organisation
WPC	Working Party 'Chemicals at the Workplace'