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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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TABLE OF CONTENTS

INTRODUCTION.....	7
1 WHAT IS THE PROBLEM AND WHY IS IT A PROBLEM?.....	8
1.1 Main drivers.....	9
1.1.1 Exposure of workers to carcinogens is significant.....	9
1.1.2 The Carcinogens and Mutagens Directive is outdated.....	10
1.1.3 Inadequate OELs at MS level have negative consequences for workers and businesses across the EU.....	16
1.2 Who is affected by the problem and how?.....	17
1.3 How would the problem evolve?.....	19
2 WHY SHOULD THE EU ACT?.....	21
2.1 Does the EU have the right to act?.....	21
2.2 Why is EU action needed and what is its added value?.....	21
2.3 What are the EU instruments relevant to dealing with carcinogens at the workplace?.....	22
2.4 How does this initiative relate to the envisaged review of the OSH acquis? ..	24
3 WHAT SHOULD BE ACHIEVED?.....	25
3.1 What are the general policy objectives? What are the more specific objectives?.....	25
3.2 Are these objectives consistent with other EU policies and with the Charter for fundamental rights?.....	26
4 WHAT ARE THE VARIOUS OPTIONS TO ACHIEVE THE OBJECTIVES?.....	26
4.1 Complementary measures.....	26
4.2 Discarded options.....	27
4.3 Options retained for consideration.....	30
5 WHAT ARE THE IMPACTS OF THE DIFFERENT POLICY OPTIONS AND HOW DO THEY COMPARE?.....	34
5.1 1,2 Epoxypropane.....	37
5.2 1,3 Butadiene.....	39
5.3 2 Nitropropane.....	42
5.4 Acrylamide.....	44
5.5 Hardwood dust.....	46
5.6 Chromium (VI) compounds.....	49
5.7 Ethylene oxide (EO).....	56
5.8 <i>o</i> -Toluidine.....	58
5.9 Refractory Ceramic Fibres (RCF).....	61
5.10 Respirable Crystalline Silica.....	63
5.11 Vinyl Chloride Monomer (VCM).....	70
5.12 Bromoethylene (vinyl bromide).....	72

5.13	Hydrazine	74
5.14	Summary of the retained options.....	77
6	OVERALL IMPACT OF THE PACKAGE OF RETAINED OPTIONS	78
6.1	Impact on workers	78
6.2	Impact on businesses	80
6.2.1	Impact on SMEs	81
6.2.2	Impact on competition and competitiveness	82
6.3	Impact on Member States/national authorities	83
6.4	Impact on fundamental rights.....	83
6.5	How does the retained option conform to the principles of subsidiarity and proportionality given the size and nature of the identified problem?.....	84
7	HOW WOULD ACTUAL IMPACTS BE MONITORED AND EVALUATED? ..	84
7.1	Monitoring arrangements	84
7.2	Evaluation arrangements	85
	ANNEXES	87
8	ANNEX 1 – PROCEDURAL INFORMATION	87
8.1	Lead DG	87
8.2	Consultation of the Regulatory Scrutiny Board (RSB).....	87
8.3	Evidence used in the impact assessment	89
8.3.1	IARC Monographs	89
8.4	External expertise	90
8.4.1	Use of scientific expertise / Commission expert groups / SCOEL ...	90
8.4.2	Studies performed by external consultants.....	90
8.4.3	Study on chemical agents toxic to reproduction.....	91
9	ANNEX 2 - STAKEHOLDER CONSULTATION.....	92
9.1	Social partner Consultation	92
9.2	Other consultation of stakeholders	94
9.2.1	25 October 2006 - Workshop of setting OELs for Carcinogens	94
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).....	94
9.2.3	Consultation of the tripartite Working Party "Chemicals at the Workplace" (WPCs) of the ACSH	95
9.2.4	September 2012 - Workshop in Berlin.....	96
9.2.5	Consultation of the members of the ACSH on existing national OELs for chemical agents subject to the amendments.....	96
9.2.6	Meetings with Industry and Workers representatives	97
10	ANNEX 3 – WHO IS AFFECTED BY THE INITIATIVE AND HOW?.....	98
11	ANNEX 4 – ANALYTICAL MODEL USED IN PREPARING THE IMPACT ASSESSMENT	100
11.1	Exposure estimation	100

11.2	Health impact – methodology for estimation of the current cancer burden (baseline) as compared with the policy intervention scenarios	101
11.3	Compliance costs.....	109
12	ANNEX 5 – DETAILED INFORMATION ON THE CARCINOGENICITY OF THE CHEMICAL AGENTS.....	110
12.1	Respirable crystalline silica.....	110
12.1.1	Identification.....	110
12.1.2	Synonyms	110
12.1.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity:.....	111
12.1.4	Classification according to IARC.....	111
12.1.5	Recommendation of SCOEL.....	111
12.2	Refractory ceramic fibres (RCFs)	112
12.2.1	Identification.....	112
12.2.2	Synonyms	112
12.2.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity	112
12.2.4	Classification according to IARC.....	113
12.2.5	Recommendation of SCOEL.....	113
12.3	Acrylamide	114
12.3.1	Identification.....	114
12.3.2	Synonyms	114
12.3.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity:.....	114
12.3.4	Classification according to IARC.....	114
12.3.5	Recommendation of SCOEL.....	114
12.4	Vinyl chloride monomer.....	116
12.4.1	Identification.....	116
12.4.2	Synonyms:	116
12.4.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity:.....	116
12.4.4	Classification according to IARC.....	116
12.4.5	Conclusions of SCOEL	116
12.5	Hardwood dust.....	117
12.5.1	Identification.....	117
12.5.2	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity:.....	117
12.5.3	Synonyms	117
12.5.4	Classification according to IARC.....	117
12.5.5	Recommendations of SCOEL	117
12.6	Chromium (VI) compounds	118
12.6.1	Identification.....	118
12.6.2	Synonyms	119

12.6.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity	119
12.6.4	Classification according to IARC.....	119
12.6.5	Conclusion of SCOEL	119
12.7	1-3- butadiene.....	123
12.7.1	Identification.....	123
12.7.2	Synonyms	123
12.7.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity	123
12.7.4	Classification according to IARC.....	123
12.7.5	Recommendation of SCOEL.....	124
12.8	Ethylene oxide	124
12.8.1	Identification.....	124
12.8.2	Synonyms	124
12.8.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity	124
12.8.4	Classification according to IARC.....	125
12.8.5	Conclusion of SCOEL	125
12.9	1,2 Epoxypropane.....	126
12.9.1	Identification.....	126
12.9.2	Synonyms	127
12.9.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity	127
12.9.4	Classification according to IARC.....	127
12.9.5	Conclusion of SCOEL	127
12.10	<i>o</i> -Toluidine	128
12.10.1	Identification.....	128
12.10.2	Synonyms	129
12.10.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity	129
12.10.4	Classification according to IARC.....	129
12.10.5	Conclusion of SCOEL	129
12.11	2 Nitropropane.....	129
12.11.1	Identification.....	129
12.11.2	Synonyms	129
12.11.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity	129
12.11.4	Classification according to IARC.....	129
12.11.5	Conclusion of SCOEL	129
12.12	Bromoethylene	129
12.12.1	Identification.....	129
12.12.2	Synonyms	129
12.12.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity	130

12.12.4	Classification according to IARC.....	130
12.12.5	Conclusion of SCOEL.....	130
12.13	Hydrazine	130
12.13.1	Identification.....	130
12.13.2	Synonyms	130
12.13.3	Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity	131
12.13.4	Classification according to IARC.....	131
12.13.5	Conclusion of SCOEL.....	131
13	ANNEX 6 - EXPOSURE LIMIT VALUES IN EU MEMBER STATES AND SOME NON-EU COUNTRIES	133
14	ANNEX 7 - RELEVANT EU LEGISLATION	139
14.1	Existing EU-OSH framework.....	139
14.1.1	Directive 89/391/EEC	139
14.1.2	Directive 98/24/EC.....	139
14.1.3	Directive 2004/37/EC.....	140
14.1.4	Directive 2009/148/EC.....	140
14.2	Internal Market legislation	140
14.2.1	REACH Regulation.....	140
14.2.2	CLP Regulation	142
14.2.3	Comparison of high level CMD and REACH provisions in relation to occupational carcinogens	143
15	ANNEX 8 – GENERAL INFORMATION ABOUT THE CLASSIFICATION SYSTEMS REFERRED TO IN THE DOCUMENT.....	145
15.1	Carcinogens	145
15.1.1	Classification according to the CLP Regulation	145
15.1.2	Classification according to IARC.....	146
16	ANNEX 9 – ADDITIONAL GRAPHICAL MATERIAL.....	147
16.1	1,2 Epoxypropane.....	147
16.2	1,3 Butadiene.....	147
16.3	2 Nitropropane.....	148
16.4	Acrylamide	149
16.5	Hardwood dust.....	151
16.6	Chromium VI.....	152
16.7	Ethylene oxide	153
16.8	<i>o</i> -Toluidine	155
16.9	Refractory Ceramic Fibres (RCF)	156
16.10	Respirable Crystalline Silica (RCS)	156
16.11	Vinyl Chloride Monomer (VCM)	158
16.12	Bromoethylene (vinyl bromide)	158
16.13	Hydrazine	159
17	ANNEX 10 – ABBREVIATIONS USED	160

INTRODUCTION

Exposure to some chemical agents in the workplace can cause cancer. To ensure that workers are protected against such risks, the EU has adopted the Carcinogens and Mutagens Directive (CMD)¹. The Directive sets out steps to be taken to eliminate or limit exposure to carcinogenic chemical agents. It establishes under Article 16 that the Council shall set out limit values over which exposure is not allowed, on the basis of available scientific and technical data, in respect of all those carcinogens for which this is possible.

The limit values create useful benchmarks for employers and enforcement authorities to decide on which protection measures should be taken. This adds to the general obligation in the CMD for employers to eliminate exposure of workers to carcinogenic substances and makes more explicit the general requirement of the over-arching Occupational Safety Health (OSH) Framework Directive² to eliminate all risks.

In order to fulfil the obligation under Article 16 of the Directive to set limit values in respect of all those carcinogens for which this is possible, the Commission has initiated a scientific and economic assessment of 25 priority chemical agents which have been classified as carcinogens by national and/or international authorities and institutions. In the EU around 20 million workers are exposed to at least one of these chemical agents. Following discussions by scientists, employers, workers, Member States' representatives and labour inspectors in a series of health and safety committees, suggestions for limit values have been developed.

Introducing these limit values in the Directive would provide employers, workers and enforcement bodies with an objective measure to help to ensure that the general principles of the Directive are complied with. This should contribute to a reduction in exposure to these priority carcinogens with a consequential reduction in potential new cases of occupational cancer in the affected workers. It is estimated that under the baseline the considered carcinogens will lead to over 460,000 deaths caused by occupational exposure. Introduction of the proposed limit values could make it possible to avoid some 100,000 of them in the forthcoming 50 years³. These figures are based on estimations made in a study contracted by the Commission⁴.

In certain cases introduction of limit values would impose some costs on enterprises to take the necessary protective measures such as installing ventilation systems and acquiring protective equipment where they do not exist. On the other hand, establishing compliance benchmarks for exposure control through these limit values would mean that businesses have clear minimum standards applied across the internal market.

The calculations underpinning the analysis of costs and benefit for limit values are complicated due to a number of factors, not least that the time between exposure to a carcinogen and the onset of the disease can be up to 50 years. Calculating costs and benefits over such a long period is challenging and based on a number of assumptions regarding gradually reduced exposure in the baseline, production methods, medical knowledge etc.

¹ Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50)

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.

³ Deaths avoided mainly in relation to the following chemical agents: Chromium VI - 1670; Refractory Ceramic Fibres - 50; Respirable Crystalline Silica - 98,670. The analytical model used to arrive at these figures can be found in Annex 4.

⁴ 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 impact assessment looks at the costs and benefits of introducing limit values for 13 of the 25 priority chemical agents. For the remaining chemical agents there is additional analysis of costs and benefits to be done. This analysis will be presented in a further impact assessment.

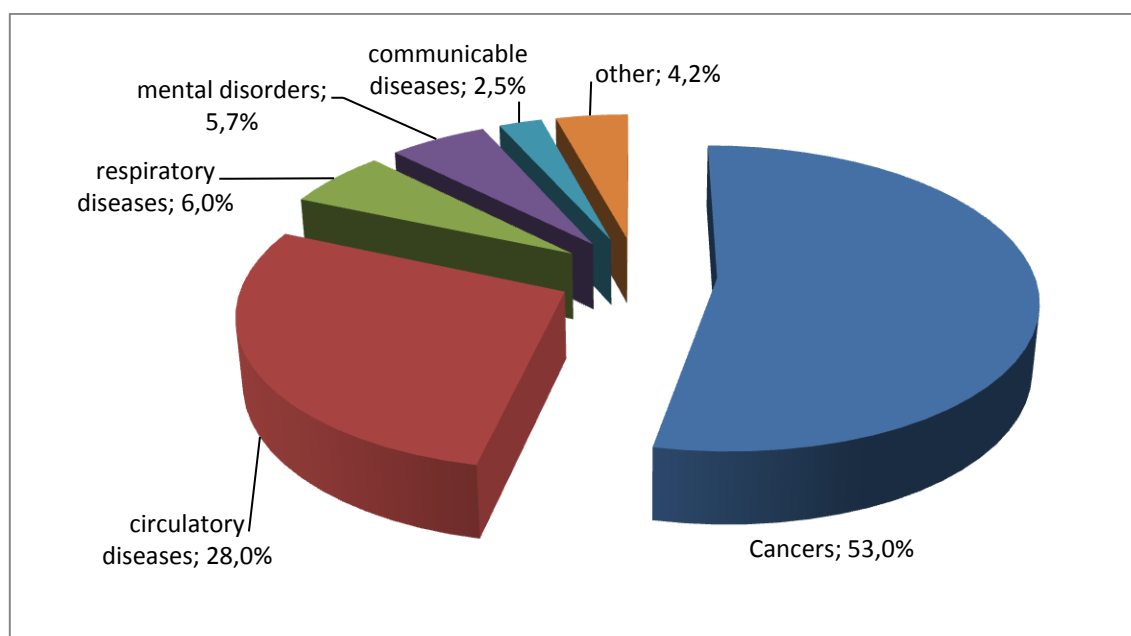
1 WHAT IS THE PROBLEM AND WHY IS IT A PROBLEM?

According to the World Health Organisation (WHO), cancer is the second largest cause of death in most developed countries.⁵ In the European Union in 2013 there were approximately 1.314 mln cancer deaths. In 2012, an estimated 2.7 mln new cases of cancer were diagnosed in EU Member States⁶, and 7.2 mln people were living with cancer (within 5 years of diagnosis)^{7,8}.

Cancer is the first cause of work-related deaths in the EU (see Figure 1 below). 53% of annual occupational deaths are attributed to cancer, compared to 28% for circulatory diseases and 6% for respiratory diseases.

The number of deaths attributed to occupational cancer in the EU is reported to be 102,500 for 2011⁹.

Figure 1. Deaths attributed to work



Source: WSH Institute 2014

⁵ *Are the number of cancer cases increasing or decreasing in the world?*, World Health Organisation, April 2008

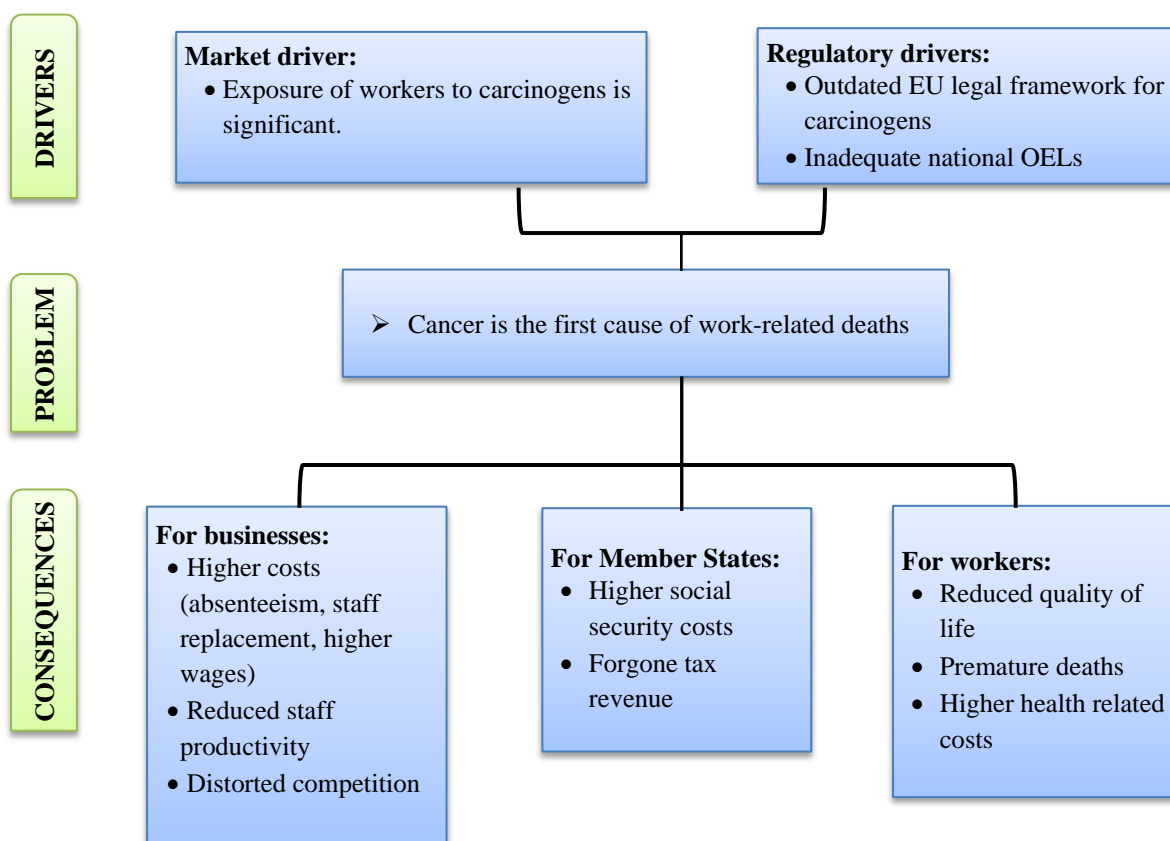
⁶ European Commission, Health at a glance 2014.

⁷ IARC, cancer fact sheets, http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx

⁸ Data for more recent years (2013,2014) are available only for a limited number of Member States, which does not allow compilation of estimates for EU totals (according to Eurostat's guidance an estimate for an EU total can be compiled only if the available figures cover 90% of the EU population).

⁹ *Eliminating occupational cancer in Europe and Globally*, Takala, J, European Trade Union Institute, October 2015.

Figure 2. Problem tree



1.1 Main drivers

1.1.1 Exposure of workers to carcinogens is significant

Different forms of cancer may be initiated or promoted by the exposure to carcinogenic and/or mutagenic chemical agents at work¹⁰. In the EU 32 mln workers (23% of people employed) were exposed to chemical agents classified as carcinogenic or probably carcinogenic to humans by the WHO's International Agency for Research on Cancer (IARC) in 1990-93.¹¹ In France, estimates from 2010 suggest that approximately 2 mln workers were exposed to at least one carcinogen in their most recent week of activity at work, approximately 10% of the working population. Workers in maintenance activities (42.6% exposed) and young workers (below 25 years of age) (15.2% exposed) were found to be particularly exposed, and many of them to several carcinogens, mutagens and reprotoxins at the same time¹².

According to the EU Classification, Labelling and Packaging Regulation (CLP)¹³, 1017 chemical agents (and groups of chemical agents) have received mandatory 'harmonised classification' as 'category 1' carcinogens, attracting the label hazard statement 'may cause cancer'. If the assessment was based primarily on human evidence category 1A is assigned (this

¹⁰ Workplace factors other than chemical agents might contribute to development of cancers (e.g. ultraviolet radiation, infections, etc.). The scope of the Carcinogens and Mutagens Directive is however limited to chemical agents.

¹¹ *Occupational exposure to carcinogens in the European Union*, Kauppinen, T. et al., *Occup Environ Med*, 2000, 57: 10-18.

¹² Les expositions aux cancérogènes, mutagènes et reprotoxiques. Un zoom sur huit produits chimiques. Dares 2015 (see <https://osha.europa.eu/en/oshnews/fr-over-2-mln-people-exposed-least-one-carcinogen-mutagen-or-reprotoxicant-2010>)

¹³ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of chemical substances and mixtures

is the case for 336 agents), with category 1B assigned where animal evidence is primarily used (681 agents are in this category). Chemicals suspected to cause cancer in humans but where data is not sufficiently convincing for category 1 may be classified as 'category 2 carcinogens'.

IARC has identified nearly 500 agents that are carcinogenic for humans (Group 1; 118 agents), probably carcinogenic to humans (Group 2A; 75) or possibly carcinogenic to humans (Group 2B; 288).¹⁴

Table 1 in the section 1.1.2. presents estimates of numbers of workers exposed to the carcinogens covered in this report. The numbers of exposed workers vary significantly across the agents. Some of the carcinogens, like Respirable Crystalline Silica (RCS), chromium (VI) compounds, hardwood dust or hydrazine, affect very high numbers of workers. For some others there are indications that use patterns may be lower. However, the agents are themselves important – for example the ratio between the number of exposed workers and cancer cases may be higher for some of these chemical agents. It is also important to recognise that use patterns change rapidly and for complex reasons. Market forces such as raw material and energy prices, developing technology, as well as regulatory changes can drive increases in use which are not easy to predict. This is the case for example for acrylamide, used for production of polyacrylamide, which is a growing sector.

1.1.2 The Carcinogens and Mutagens Directive is outdated

The current rules

While cancer is a complex disease and some causal factors are difficult to identify, it is clear that cancers caused by work can be prevented by reducing or eliminating the exposures leading to the disease.

The EU principles of worker protection from carcinogens are laid out in the over-arching Occupational Safety Health (OSH) Framework Directive 89/391/EEC and those Directives specifically dealing with chemicals risks – notably the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD). The latter includes a commitment to set Occupational Exposure Limit (OELs) values for all carcinogens or mutagens for which this is possible.¹⁵

Under the OSH framework risks to the safety and health of workers shall be eliminated or reduced to a minimum. In the case of carcinogens, CMD sets a number of concrete provisions.

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.

¹⁴ Monographs on the evaluation of carcinogenic risk to humans, International Agency for Research on Cancer, WHO.

¹⁵ OEL values are stated as quantitative figures representing the airborne concentration of the chemical agent in question as a time weighted average over 8 hours. Concentrations expressed as mg/m³ values indicate milligrams of chemical agent per cubic metre of air at 20 °C and 101,3 kPa (760 mm mercury pressure). To note, in a strict sense when referring to limits set in the CMD, the term 'limit value' should be used – often expressed as a 'binding occupational exposure limit value' or 'BOELV'. In parallel, the term OEL is used for example when referring to limits set at the national level. In order to simplify this text the term OEL is used to refer to any occupational exposure limit (value) whether set in EU or national legislation.

CMD provisions apply to any chemical agent which is classified as a 'Category 1' carcinogen (or mutagen) under the EU CLP Regulation, thus to the 1017 substances above mentioned. They also apply – in full – to any chemical agent which would meet the criteria for such classification if it were placed on the EU market, which means that employers have a responsibility to identify occupational carcinogens to which workers may be exposed but which have not already been classified by their suppliers.

This is the case for example of the so-called 'process-generated substances' (PGS). These are hazardous 'chemical agents' such as dust, fumes, and gases which may, for example, be generated during the combustion of fuel by diesel engines used for mining, or as by-products during production processes, etc.

PGS have the potential to be major sources of occupational exposure to chemical carcinogens – but because they are never 'placed on the market' in the EU they are never subject to the CLP classification system. This can be confusing for employers, workers, and enforcers. It is clear that CMD controls apply to workplace carcinogens – but it may in some cases be unclear whether a 'process generated substance' is hazardous in this way.

CMD therefore also includes a list of identified process generated substances in its Annex I. 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 CLP, is in scope of the CMD controls. Currently, Annex I has 5 entries:

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

CMD also provides that, in any case, exposure of workers must be kept below 'binding occupational exposure limit values' (OELs).

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 non-inhalation hazard such as, for example, a 'skin' notation where the dermal route of exposure is scientifically considered to be relevant.

OELs are set in Annex III of the CMD for some chemical agents which fall under the scope of the Directive - including some of the PGSs identified in Annex I.¹⁶ Annex III currently includes limit values for occupational exposure for three agents: benzene, vinyl chloride monomer (VCM) and hardwood dusts.

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

¹⁶ Setting an OEL is not always possible. For PGSs specifically, this could be related for example to the fact that some of them are a complex mixture of carcinogenic substances, the mixture can be variable as regards the precise composition and relative quantities of each of these substances. Therefore, it would be necessary to set individual OELs for every component substance and to carry out sampling and analysis for each of them for compliance purposes, which in practice would be difficult to do. In other cases, an OEL, which is to protect against risks to health arising from inhalation of the substance, would not be appropriate the critical route of exposure is not by inhalation but instead is by direct absorption through the skin (dermal exposure).

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.

From a more general perspective, OELs promote consistency by defining a 'level playing field' for all users and a common objective for employers, workers and enforcement authorities. This leads to a more efficient system of protection of workers' health.

It should be added that for most carcinogens and mutagens substances it is not possible to identify a safe threshold below which the adverse health effects of exposure can be prevented completely. The genotoxic mode of action of a substance entails that extremely low amounts of a substance reaching the appropriate target (deoxyribonucleic acid or DNA) may initiate a tumoral process¹⁷. Therefore, although for a genotoxic carcinogenic substance the risk cannot be eliminated by setting an OEL, the probability that the effects occur can be lowered by complying with a limit value. In terms of population, it can be said that the percentage of workers affected by a cancer would be lower if the level of exposure is kept lower. This is the reason why the minimisation of the exposure is a basic principle set up in CMD and why OELs for carcinogenic substances are useful to prevent occupational cancer although for most substances (non-threshold substances) there will always be a residual risk that could only be reduced to zero by fully eliminating the presence/use of the substance in the workplace.

The CMD includes a general obligation for the employer to reduce the use of a chemical carcinogen by, where technically possible, substituting to a less- or non-hazardous chemical agent or process and, when requested to do so by the relevant authorities, submit the findings of the associated investigations (CMD Article 4). The adoption of an OEL does not replace this obligation.

The practical implementation of effective chemical substitution policies can deliver significant benefits in terms of protecting the health and safety of workers.

Effective substitution is associated with a number of issues that are not always easy to evaluate in order to facilitate the decision making process. It requires judgment to take account of workers health and safety protection, process performance, the ease and cost of introducing substitutes, environmental considerations and other factors in making a substitution choice. Several approaches to substitution exist ranging from ad-hoc approaches to methods that are defined, structured and documented. Less sophisticated substitution approaches may be more suitable for smaller companies compared to larger better resourced organisations that have a high level of technical expertise. To make substitution happen in practice requires a raised awareness and involvement of all stakeholders.

The European Commission recognises the multi-attribute challenges that substitution presents to individual employers and has published guidance to analyse and evaluate the practical implementation of the principle of substitution of hazardous chemicals at the workplace with a view to further enhance the protection of workers health and safety while taking into account the above-mentioned factors.¹⁸

¹⁷ This constitutes an important difference between carcinogenic effects and non-carcinogenic effects modes of action, and it is one of the reasons, together with the severity of effects, that justify the existence of a specific piece of legislation to protect workers (CMD) in comparison with other chemicals (CAD).

¹⁸ *Minimising chemical risk to workers' health and safety through substitution*, European Commission, July 2012,

Annex I and III of the CMD are not in line with scientific evidence.

Firstly, there is important scientific evidence that the process-generated substance, respirable crystalline silica, is carcinogenic¹⁹.

Secondly, two of the three current OELs defined in Annex III of the CMD, namely on 'work involving exposure to hardwood dust' and vinyl chloride monomer are estimated to be too high to adequately protect workers. Available scientific evidence points also to the need to complete Annex III with OELs for several additional agents²⁰.

As has been established, over 1000 chemical substances have been given 'harmonised' classification as category 1 carcinogens under the CLP Regulation. Many of these chemical agents are, however, almost certainly no longer used in Europe, having been superseded or otherwise phased out of use – and fewer again will be present as occupational carcinogens today. There are, however, many chemical carcinogens which are known to both be in current use in Europe and which pose a risk to workers.

The Commission initiated work to amend or establish OELs for 25 priority chemical agents in 2004.²¹ The selection of these agents took into account the views of stakeholders, principally at MS authority level as communicated to the Commission during exchanges of views including at the meetings of the National Experts Working Group on OELs. In addition for the two of the three existing EU OELs (hardwood dust and VCM) the Scientific Committee on Occupational Exposure Limits (SCOEL²²) had adopted new/revised Recommendations, in 2003 and 2004 respectively that indicated a need to consider the revision of the existing OELs.

Among hundreds of carcinogenic substances, these 25 chemical agents are considered as a priority for protection of workers and the choice is quite consistent with subsequent third party priority lists. For example, of the 25 chemical agents, 11 are listed among the 30 highest priority substances in a report published by the Netherlands National Institute for Public Health and the Environment²³, and 21 were included in a list of 65 candidates for OELs published by European Trade Union Congress in 2015.²⁴ As shown by a study contracted by the Commission to evaluate impacts of introducing OELs for those 25 chemical agents²⁵ (later on referred to as the IOM study), at least 20 million EU workers are considered to be potentially exposed to one or several of them.

¹⁹ The term 'respirable crystalline silica' or 'RCS', as used throughout this report when referring to the chemical agent for which an Annex I entry may be proposed, should be taken to mean 'the respirable fraction of crystalline silica dust generated by a work process'.

²⁰ SCOEL has submitted recommendations for setting new OELs on all the other chemical agents covered by this report except for two (*o*-toluidine and 2-nitropropane). A summary of SCOEL conclusions is provided in Annex 5.

²¹ Because of data challenges which will be explained later in this document, there exists no decisive exposure evidence base for prioritising occupational carcinogens for which OELs should be established.

²² SCOEL aims to establish an exposure threshold for a given chemical agent below which adverse effects to human health are unlikely to occur (health-based limit values). For carcinogens, such health-based limit values can only be derived in very few cases. When no health-based limit value can be set, SCOEL instead estimates the residual risk of developing cancer for workers at different exposure levels. In addition, SCOEL recommendations also address scientific/technical feasibility of monitoring exposure including the availability of suitable measurement techniques.

²³ *Identifying prevalent carcinogens at the workplace in Europe*, RIVM, 2015

²⁴ *List of OEL candidates*, European Trade Union Congress, 2015. To note, this list of 65 chemical agents also includes three for which OELs already exist either in the CMD (benzene), in the Chemical Agents Directive 98/24/EC (inorganic lead and its compounds), or in the separate Directive 2009/148/EC (asbestos).

²⁵ 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 deals with 13 chemical agents from the original 25 for which data is available²⁶.

For the second group of 12 chemical agents, further information gathering and consideration is necessary.²⁷

In the course of the preparatory work, the Commission considered also the possibility to extend the scope of CMD to apply also to chemical agents which are toxic for reproduction. However, as set out in more detail in annexes 1 and 2 (sections 8.4.3, 9.1, and 9.2.2-3) several policy and technical factors, including the already-adequate scope of the CAD, resulted in a conclusion that there is no need for further action at this time.

The first 13 chemical agents and their key characteristics are presented in the Table 1 below.

Table 1. Sectors, types of cancer caused and estimated exposure levels for 13 chemical agents under consideration²⁸

Chemical agents, including CAS numbers where relevant	Classification		Relevant sectors	Types of cancer caused/other illnesses	No. of exposed workers ²⁹
	CLP ³⁰	IARC			
1,2 Epoxypropane 75-56-9	1B	2B	Chemical manufacture; synthetic lubricants, oil field drilling chemicals; polyurethane systems.	Lymphopoietic cancer, haematopoietic cancer, increased leukaemia risk	485-1,500
1,3 Butadiene 106-99-0	1A	1	Manufacture of refined petroleum products, manufacture of rubber products	Lymphohaemato-poietic cancer	27,600
2 Nitropropane 79-46-9	1B	2B	Manufacture of basic chemicals, manufacture of aircraft and spacecraft (downstream use)	Liver tumours ³¹	51,400
Acrylamide 79-06-1	1B	2A	Manufacture of chemicals and chemical products, education, research and development, other business activities, health and social work, public administration and defence.	Pancreatic cancer	54,100
Bromoethylene 593-60-2	1B	2A	Chemicals and allied production; rubber and plastic production; leather and leather production; fabricated metal production for wholesale trade	Liver cancer	n/a

²⁶ See point 4.2 for a description of the identification process.

²⁷ For these chemical agents it is necessary to further consider, for example, the remaining exposure situation for a chemical agent which is already subject to an international convention effectively banning sale and use, and to ascertain whether the definition for certain PGSs is legally robust.

²⁸ 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 13 chemical agents in the report, unless otherwise specified.

²⁹ Estimates, rounded down

³⁰ Harmonised (i.e. mandatory) CLP classifications for carcinogenicity

³¹ According to animal toxicity studies (no epidemiological evidence).

Chromium (VI) compounds	1B	1	Production and use of chromium-containing pigments, paints and metal (conversion) coatings. In terms of downstream use, chromate compounds, including barium chromate, zinc chromate, and calcium chromate, may be used as basic primers and top coats in the aerospace sector.	Lung cancer and sinonasal cancer	916,000 ³²
Ethylene Oxide 75-21-8	1B	1	Extraction of crude petroleum and natural gas; service activities incidental to oil and gas extraction; Manufacture of food products, textiles, chemicals, chemical products, medical, precision and optical instruments, watches, clocks; Hospital and Industrial sterilization; R&D; Public Administration and Defence; Education; Health and Social Work	Leukaemia	15,600
Hardwood dust	n/a	1	Wood working industry, furniture manufacture sectors and construction.	Sinonasal and nasopharyngeal cancers	3, 333,000
Hydrazine 302-01-2	1B	2B	Chemical blowing agents; agricultural pesticides; water treatment	Lung and colorectal cancer	2,124,000
<i>o</i> -Toluidine 95-53-4	1B	1	Manufacture of chemicals, chemical products and man-made fibres; Manufacture of rubber products; Research and development; Public administration and defence; education; health and social work.	Bladder cancer	5,500
Respirable Crystalline Silica (RCS)	n/a	1	Mining, glass manufacturing, construction and electricity, gas, steam and hot water supply industries.	Lung cancer, silicosis	5,300,000 ³³
Refractory Ceramic Fibres (RCF)	1B	2B	Manufacturing (fibre production, finishing, installation, removal, assembly operations, mixing/forming)	Adverse respiratory effects, skin and eye irritation; possibly lung cancers	10,000
Vinyl Chloride Monomer	1A	1	Manufacture of chemicals and chemical products (VCM and	Angiosarcoma, hepatocellular	15,000

³² This figure is an estimate for all chromium VI compounds.

³³ According to the IOM Research Project P937/99 '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' published in May 2011 (p. 21) 'approximately 5,3mln. employees in the EU were potentially exposed to RCS in 2006. Over 4 million of these workers are in the construction sector'.

(VCM)			PVC production)	carcinomas	
75-01-4					

Adoption of the proposal to review Annexes I and III of the CMD with regard to a first batch of carcinogens is envisaged for the first semester of 2016 in the Commission Work Programme. Preparatory work has been going on since 2004, and representatives of Member States authorities, employers' and workers' representative bodies within the framework of the tri-partite Advisory Committee on Safety and Health (ACSH) strongly anticipate a 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'.³⁴

1.1.3 Inadequate OELs at MS level have negative consequences for workers and businesses across the EU

Under the CMD, Member States may adopt a national limit value that is lower (i.e. more stringent) than the EU value. They can also adopt OELs for chemical agents for which it has not been done at EU level. This is consistent with the ultimate objective of the Directive, which is to minimise the level of exposure, as it allows for further advances to take place at Member State's level in light of country-specific and industry-specific developments.

One or more Member States have indeed set limit values for all of the agents covered in this IA. For example, most Member States have set limits for ethylene oxide and acrylamide. Less than half have done so for bromoethylene or *o*-toluidine.

In the absence of EU OELs, national scientific committees and/or other national bodies need to independently evaluate each carcinogen leading to a repetition of identical tasks in several Member States.

While the possibility to set national OELs is in line with the CMD provisions, in practice, where national OELs exist they vary considerably in some cases, leading to significantly different levels of protection. For example for 1,3 butadiene, the values range from 4.5 to 100 mg/m³. For ethylene oxide, values range from 0.84 to 90 mg/m³. A comprehensive overview of the national OELs for each of the chemical agents covered in this report is provided in Annex 9 and a summary overview table can be found in Annex 6.

The lack of national OELs for some chemical agents, and the high levels of others, not only leads to inadequate protection for EU workers but can also have negative consequences for the internal market, because businesses located in Member States with less stringent levels (i.e. with absent or higher OELs) would benefit from an undue competitive advantage. For example, 1,2-epoxypropane producers in FR and RO have to comply with exposure limits 10 times higher (i.e. less constraining) than in other producing countries, such as DE, ES and NL (50 mg/m³ vs 5 mg/m³). Even if the minimisation obligation applies to all employers in Europe, these undue competitive advantages would continue to exist in the absence of an EU-wide OEL, because both employers and surveillance authorities would need to rely on their own judgement on what is "technically possible".

Divergence in national OELs may be partially due to differences in the methodology used for the scientific evaluation of a carcinogen by the respective national limit setting committees. More recently established national OELs may be different (for example more stringent) than those set earlier as a result of improved scientific understanding or availability of data. Further,

³⁴ <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P8-TA-2015-0411+0+DOC+PDF+V0//EN>

specific production process(es) used in one Member State may allow for lower OELs to be set compared to use of alternative production process (for example) in another Member State.

Where Member States have, in the absence of EU OELs, set national OELs that vary from each other this has the potential to create uncertainty on what is expected of employers in terms of risk management. This may be perceived as inefficiency of the system, in particular by employers that operate in more than one Member State.

EU-level OELs do not intend to completely eliminate the variation in national OELs but rather ensure that all Member States introduce a minimum level of protection which is considered appropriate in light of scientific knowledge and the state of technological development. Even if Member States retain the possibility to adopt stricter levels, EU OELs significantly reduce the scope of variation by introducing an upper limit for acceptable exposure levels.

As explained earlier, employers have the obligation to achieve exposure levels as low as technically possible to be compliant with the minimisation principle under the CMD. What is technically possible, however, may be different for the same chemical agent, depending for example on the sector of the industry and the specific type of use of the chemical agents.

Substances such as RCS, for example, can occur in very diverse workplace situations and therefore the possibilities to control exposures will differ. Without an EU-wide OEL, employers who would like to be sure to comply with the legislation ("minimisation to as low a level as technically possible") would need to embark on an extensive research into different practices existing across EU Member States and in different types of industries to arrive at an understanding of what might be the appropriate and feasible exposure limit review for their type of business. In that sense an EU-wide OEL, based on a generally accepted methodology and validated through tripartite discussions as a common denominator should be feasible for all uses of the carcinogen, which simplifies compliance for business.

Similarly, for workers, in the absence of an OEL or where national OELs are too high, it would be challenging to collect evidence that exposure levels in a specific factory are higher than what should be possible. An OEL facilitates therefore discussions between employers and workers on this matter by setting an agreed benchmark for compliance.

1.2 Who is affected by the problem and how?

As mentioned above, the total number of deaths attributed to occupational cancer in the EU is reported to be 102,500 for 2011³⁵.

Epidemiological studies indicate that occupational exposures cause 5.3–8.4 per cent of all cancers³⁶. However, the rates are not the same for all cancers, for some, such as sinonasal cancer linked to wood dust exposure, work-related cancers are estimated in some countries to account for almost half of all cancers in some countries of this type.³⁷

In 2012, cancers of the lung, colorectal, breast and stomach were the most common fatal forms of cancer in Europe. The most common cancer sites were cancers of the female breast, followed

³⁵ *Eliminating occupational cancer in Europe and Globally*, Takala, J, European Trade Union Institute, October 2015.

³⁶ *Eliminating occupational cancer in Europe and Globally*, Takala, J, European Trade Union Institute, October 2015.

³⁷ Imbernon E., « Estimation du nombre de cas de certains cancers attribuables à des facteurs professionnels en France », Institut de veille sanitaire, 2003, Available at http://www.invs.sante.fr/publications/2003/cancers_pro/rapport_cancer_pro.pdf.

by colorectal, prostate and lung, which all together represent half of the overall burden of cancer in Europe.³⁸

According to a UK study based on 2005 data, industries and occupations with high cancer registrations include construction, metal working, personal and household services, mining, land transport, printing/publishing, retail/hotels/restaurants, public administration/ defence, farming and several manufacturing sectors. 56% of occupational cancer registrations in men are attributable to work in the construction industry (mainly mesotheliomas, lung, stomach, bladder and non-melanoma skin cancers).³⁹

The chemical agents subject to this IA have a direct impact on developing the above mentioned types of cancer and are relevant to the sectors with high rates of cancer registrations.⁴⁰

For the workers and their families, cancer results not only in substantial quality of life losses, but also in direct health care costs and indirect loss of present and future earnings (net of taxes) both for the person affected and for the carers, in addition to the administration costs related to the time and expenses incurred claiming for benefits, waiting for treatment etc.

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

As an illustration, according to a study published in November 2013, around 8,000-8,500 deaths per year due to occupational cancer are estimated to occur in Italy alone, corresponding to 170,000 Potential Years of Life Lost and more than 16,000 Potential Years of Working Life Lost, leading to around 360 mln euros in indirect economic loss.⁴¹ To these add the direct health care costs of occupational cancer in Italy, estimated at around 456 mln euros. Another study conducted in Spain estimated direct costs for diagnosis and treatment of occupational bladder and lung cancer to be about 88 mln euros.⁴² This did not cover indirect costs such as costs of absences, production loss, loss of income and impairment.⁴³

For Member States, occupational cancer leads to increased healthcare costs related to treatment and rehabilitation, as well as to higher expenditure on associated inactivity and early retirement and compensation for recognised occupational diseases. It also increases administrative and legal costs related to the handling of requests for benefits and dealing with recognized cases. Foregone earnings and income as a result of ill health also lead to tax revenue losses for social security systems.

For business, occupational cancer also implies costs in terms of productivity, as they lose skilled workers and need to spend more in job search and training of new workers. Given the often long time lag between exposure and illness and the probability of workers changing employers during their work career, the risk of future productivity losses is unlikely to be internalised by

³⁸ *Cancer incidence and mortality patterns in Europe: Estimates for 40 countries in 2012*, Ferlay, J. et al., *European Journal of Cancer*, 49 (2013), pp. 1374–1403.

³⁹ *Occupation and cancer in Britain*. Rushton, L. et al., *British Journal of Cancer*, 2010 Apr 27;102(9):1428-37

⁴⁰ According to animal toxicity studies 2 nitropropane may cause liver tumours in humans (although it should be noted that there is no epidemiological evidence to substantiate this).

⁴¹ *The burden of mortality with costs in productivity loss from occupational cancer in Italy*, *Am J Ind Med*. 2013 Nov;56(11):1272-9. doi: 10.1002/ajim.22224. Epub, June 24 2013.

⁴² García Gómez M, Urbanos Garrido R, Castañeda López R, López Menduina P. Costes sanitarios directos de las neoplasias de pulmón y vejiga de origen laboral en España en 2008. *Rev Esp Salud Pública*. 2012; 86: 127-38. Available at http://scielo.isciii.es/scielo.php?pid=S1135-57272012000200002&script=sci_arttext&tlng=em

⁴³ See Annex 4 for a discussion of terms used here.

companies, and therefore not factored into present businesses decisions. Depending on the relative strength of collective bargaining, some of the affected sectors/companies may also need to pay higher wages to compensate for the higher occupational risk, which would affect their competitiveness vis-à-vis otherwise similar companies which are confronted with less organised labour. Finally, businesses located in Member States with where national OELs are relatively stringent may be at a competitive disadvantage vis-à-vis enterprises in Member States with no or higher OELs.

An indicative estimate of the direct and indirect health costs related to the agents covered in this impact assessment can be found in the following section.

1.3 How would the problem evolve?

Estimations on the numbers of deaths and health costs between 2010 and 2069 have been made in case no action is taken (baseline scenario) regarding the chemical agents subject to this IA.^{44,45} These are summarized in the Table 2 below.

Table 2. Estimated cancer deaths, cancer cases and related health costs in case no action is taken (baseline scenario), 2010-2069

Chemical agent	Expected no. of deaths 2010 – 2069	Expected no. of Cancer cases 2010 – 2069	estimated health costs 2010 – 2069
1,2 Epoxypropane	- ⁴⁶	- ⁴⁷	€2.5 mln - 10.7 mln
1,3 Butadiene	100	160	€41 mln - 167 mln
2 Nitropropane	Not assessed ⁴⁸	Not assessed	n/a
Acrylamide	230	250	€156 mln - 326 mln
Bromoethylene	- ⁴⁹	0	n/a
Chromium (VI) compounds	17,000	24,000	€8.6 - 27 bln
Ethylene oxide	0	0	None
Hardwood dust	5,000	12,000	€3 bln - 16 bln
Hydrazine	710	2,500	€0.5 bln - 3 bln
<i>o</i> -Toluidine	150	490	€86 mln - 696 mln
Refractory ceramic fibres (RCF)	50	60	€33 mln -83 mln

⁴⁴ 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

⁴⁵ 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.

⁴⁶ According to the IOM Research Project, less than one death per year was predicted from past or future exposure - 100 attributable YLLs during 2010-2069 period.

⁴⁷ Less than one per year.

⁴⁸ According to the IOM Research Project, no baseline health impact was made because there was insufficient epidemiological evidence to sustain such an assessment

⁴⁹ According to the IOM Research Project, no deaths were predicted from past or future exposure

Respirable crystalline silica (RCS)	440,000	470,000	€192 bln - 493 bln
Vinyl chloride monomer (VCM)	300	300	€194 mln - 472 mln

It is anticipated that there would be around 440,000 deaths from exposure to respirable crystalline silica (RCS) and a similar number of new cancer cases. The related health costs would range between 192 bln and 493 bln euro. The social partners, representing 18 European industry sectors signed in 2006 a European Multi-Sectoral Social Dialogue Agreement on Workers' Health Protection through the Good handling and Use of Crystalline Silica and its products (NEPSi). The impact of NEPSi on the reduction of cancer cases and deaths in those sectors⁵⁰ implementing the Agreement is under evaluation – results are not available to inform this assessment. Exposure to hard wood dust, which potentially concern 3 mln workers in Europe, is expected to cause 12,000 cases of cancers and 5000 deaths over the next 60 years, with estimated health costs between 3 bln and 16 bln euro. On the other hand, relatively smaller effects are expected from exposure to *o*-Toluidine: 490 new cancer cases and 150 deaths before 2050.

These 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. As this varies across the chemical agents, more information will be provided in Section 5 of the report about the specific situation for each of the carcinogens as well as on the sources of the information. 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 6 presents the current limit values in the EU Member States. The information regarding existing national OELs⁵¹ was gathered through an extensive 2014 survey.⁵² 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.

⁵⁰ Aggregates, cement, ceramics, foundry, glass fibre, special glass, container glass, flat glass, industrial minerals, mineral wool, natural stones, mining, mortar, pre-cast concrete sectors and clay sector.

⁵¹ There is no obligation for Member States to inform the Commission about their intentions update their national lists of OELs, apart from initiatives which would be related to OELs established at EU level.

⁵² Further information on this survey is provided in Annex 2 of this document

2 WHY SHOULD THE EU ACT?

2.1 Does the EU have the right to act?

The Treaty on the Functioning of the EU (TFEU) in Article 153 empowers the EU to support and complement the activities of the Member States as regards the protection of workers' health and safety, and to adopt by means of Directives, minimum requirements for gradual implementation. On this basis the CMD provides a specific basis for action. For more details regarding the full legislative framework see Annex 7.

2.2 Why is EU action needed and what is its added value?

Limit values under the CMD, which according to the Directive are regarded as an important component of the general arrangements for the protection of workers⁵³, should be established for all those carcinogens and mutagens for which the available information, including scientific and technical data, make this possible⁵⁴, and must also be revised whenever this becomes necessary in the light of more recent scientific data.

One of the most important advantages of setting OELs is that they provide robust and objective benchmarks to help demonstrate compliance with the current legal framework. They establish ceiling exposure values above which exposure should not occur (in a weighted average over one working day). This enables the employer, based on the risk minimisation approach, to implement the OSH risk management measures that reflect the needs of their sector. In some cases it may be possible to achieve exposure reductions well below the level at which the OEL is set, for other sectors this may be less achievable. However, in all cases the resultant exposure should not exceed the OEL and over time, with developments in technology, there should be a trend for overall exposures to reduce to a minimum.

The concept and use of OELs is well understood by all the main stakeholder groups. As such they are 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. They can also be used by process plant and machinery designers when planning new, or considering alterations, to existing process plant.

OELs therefore make an effective contribution to the practical implementation of the requirements in the legislation for prevention and reduction of exposure to chemical carcinogens.

The continued support from stakeholders for OELs was restated during a meeting on 18th November 2015 of members of the tri-partite Working Party on Chemicals to discuss those aspects of the overall evaluation of the EU OSH acquis that are relevant to chemicals risk management. During this meeting the Members States', employers' and workers' representatives agreed that 'OELs are an important tool for chemical risk management at the workplace and there is a need to adopt values for more substances based on duly justified reasoning. For example an early focus should be on carcinogenic, mutagenic and reprotoxic substances'.

In addition, during 2015, Commission services asked the Senior Labour Inspectors Committee, via its working group on chemicals (CHEMEX), to assess the utility of OELs from an enforcer's perspective, including the question 'Are OELs considered (by labour inspectors) to be critical/not important when carrying out inspections'?⁵⁵ All respondents considered OELs to be essential and particularly valuable when carrying out inspections and enforcement.

⁵³ recital 13 of Directive 2004/37/EC

⁵⁴ recital 12 of Directive 2004/37/EC

⁵⁵ Summary of the responses to SLIC CHEMEX KSS Questions Set - Implementation of occupational exposure limits at national level – draft response document

It can be concluded that OELs provide an added value as a common, and well understood, objective measure to better facilitate the practical implementation of the general requirements for prevention and exposure reduction. There is a clear support for their continued use from key stakeholders.

For some sectors it may be that a given OEL is the best that can be achieved but in others sectors, or for specific uses, it is possible that much better exposure values can and should be achieved – this is taken into account in the minimum standard nature of OSH in general and OEL setting in particular.

Data presented in this report indicate wide differences in the Member States regarding the setting of OELs for the identified carcinogenic chemical agents⁵⁶. Some Member States have already established legally enforceable OELs which are at the same value or lower than the value recommended by the Advisory Committee on Safety and Health at Work (ACSH). This demonstrates that unilateral national action is possible as regards setting an OEL for these chemical agents. However, as shown in Table 2 in Annex 6 there are also many cases where Member States have no OELs or ones which are less protective of worker health than the value recommended by ACSH.

Under such circumstances a minimum basis of protection against the risks arising from workers' exposure to these carcinogens cannot be ensured for all EU workers in all Member States by an action taken by Member States alone. Table 4 in Annex 6 provides an overview of the proportion of potentially exposed workers who lack such legal protection and this factor is taken into account in the analysis of impacts of introducing an OEL for each of the considered carcinogens. It follows that an action taken at the European Union level to achieve this objective appears to be necessary and in line with Article 5(3) of the Treaty on European Union.

Absent or too high OELs also provide a potential incentive for companies to locate their production facilities in Member States with the lower standards. This distortion of the internal market may be reduced by establishing clear minimum standard OELs at EU level.

Amending the CMD can only be done by action at EU level and after a two-stage consultation of the social partners (management and labour) in accordance with Article 154 TFEU.

2.3 What are the EU instruments relevant to dealing with carcinogens at the workplace?

From the mid-1960s the European Union developed a legal framework addressing control of chemical risks under both social policy and internal market areas of EU policy. This framework places duties on authorities, businesses, and individuals to manage risks associated with the sale and use of chemicals. By the late 1990s a comprehensive and sophisticated system of interdependent Directives and Regulations had been established to protect humans and the environment from hazardous chemicals.

To protect workers from chemical carcinogens both employers and authorities must apply the same three stages necessary for all risk control: i) identify what harm might be caused ('hazard identification'); ii) identify the likelihood and severity of the harm actually being caused ('risk assessment'); and iii) where necessary put in place measures to mitigate harm ('risk management').

Directives setting out an agreed system for chemical hazard identification (i) were developed – augmented where necessary by additional provisions in topic specific Directives. The outcomes of this hazard identification are then applied in Directives and Regulations focussed on the key areas of chemical risk – in the case of worker protection from chemical carcinogens these were laid down in the CMD.

⁵⁶ See Table 1 in Annex 6.

A subsequent process of chemicals risk assessment (ii) by European authorities built on this to identify measures needed to protect the environment or humans as consumers, members of the public, or workers. This risk assessment resulted in recommendations for regulatory risk management (iii) from a suite of available options.

The key EU risk management outcomes for the protection of workers from chemical carcinogens were CMD OELs (under social policy) and/or 'restrictions' on the placing on the market and/or use of certain chemicals (principally under internal market policy).

The REACH Regulation⁵⁷, which was adopted in 2006, 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 therefore protect workers from risks associated with exposure to carcinogens. The two legal acts are complementary. CMD is a more targeted measure intended for protection of those employed by others from occupational carcinogens, while REACH applies more broadly to protect the health of humans and also the environment and also offers mechanisms which can be used to target risk controls to protect workers.

A chemical carcinogen may appear on both CMD Annex III and REACH Annex XIV without systematic conflict⁵⁸. 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.

REACH is designed to integrate with the rest of the EU legal framework with which it co-exists – including CMD. As a key example of this, REACH does not include a mechanism to set EU OELs for carcinogens – these are properly established under social policy Directives where the social partners and co-legislators play a more prominent role.

REACH generates information on chemical agents which are 'placed on the market' (above one tonne per year) and used in the EU. It also includes the 'authorisation' and 'restriction' mechanisms – both of which may, in some cases, be available as risk management options for occupational carcinogens.

Carcinogens are one of several types of hazardous substance which can be added to Annex XIV to REACH, meaning they become subject to 'authorisation'. Once a given 'sunset' date is passed, these substances may only be placed on the EU market and/or used when an authorisation has been applied for and granted by the European Commission, taking into account the advice of the European Chemicals Agency, that either the risks associated with use are adequately controlled or that, if this is not possible, ongoing use of the substance is socioeconomically justified and there are no suitable alternatives.

The Commission may make exemptions from REACH authorisation under certain conditions, including where specific Union legislation already exists which imposes minimum requirements relating to the protection of human health for the use of a substance. So far no exemption has been made for substances used at the workplace.

⁵⁷ 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

⁵⁸ Of the 13 chemical agents considered here for listing in CMD Annexes I (PGSs) or III (OELs) three have been added (in some form) to the Candidate List as 'substance of very high concern' (SVHCs) : Hydrazine, *o*-Toluidine, and RCFs. RCFs have, further, been recommended by ECHA for inclusion in Annex XIV. Certain chromium (VI) compounds have been identified as SVHCs on the Candidate List and also, subsequent to ECHA recommendation, have been added to REACH Annex XIV.

Restrictions set conditions under which placing on the market and/or use of a chemical substance (or mixture or article containing it) may be permitted. These range from a near-total ban through to substance concentration specifications or established risk management measures to be observed by 'downstream users'.

Restrictions are a flexible, targeted chemicals risk management option carried forward from the pre-REACH EU chemicals framework. Restrictions and OELs have long co-existed as different possible outcomes from the EU chemicals risk assessment process – indeed four of the five existing binding OEL values established at EU level under the OSH Directives (asbestos, benzene, lead, and vinyl chloride) are already partnered with REACH restrictions.

As a result of their flexibility it is, conceptually, possible to establish an 'OEL-like' exposure limit via a REACH restriction – in 2013 the Netherlands REACH authorities proposed such a measure. In response, in November 2013, the lead Commission services for the REACH Regulation wrote to the European Chemicals Agency (ECHA), with the common Commission services' view that 'any proposal for adoption of an exposure limit value at the occupational premises should not be implemented under REACH and should only be set under the appropriate workers' protection legislation, which is specifically designed to establish and implement OELs'. In the same month the ACSH adopted an Opinion formally expressing the views of the Member States, employers, and workers' representatives that the OSH acquis is the more appropriate way to establish exposure limits for worker protection to chemicals.⁵⁹

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 REACH status (authorisation and/or restriction) of the 13 chemical agents under consideration in this report is as follows:

- Out of scope of REACH: hardwood dust, process-generated RCS.
- On the Candidate List of 'substances of very high concern' potentially to be made subject to authorisation: acrylamide, hydrazine, RCF, *o*-toluidine.
- Currently subject to authorisation: some chromium VI compounds.

Currently subject to restriction: acrylamide, restricted above a certain concentration for the placing on the market or use in grouting (REACH Annex XVII Entry 60); chromium (VI) compounds, restricted above a certain concentration for the placing on the market or use in cement, with certain exemption (REACH Annex XVII Entry 47); vinyl chloride, restricted (REACH Annex XVII Entry 2) for use as an aerosol propellant. All of the chemical agents in question, where placed on the market, are restricted for supply to the general public (REACH Annex XVII Entries 28 and 29).

A more detailed list of REACH status of the concerned chemical agents can be found in Annex 7 (14.2.1).

2.4 How does this initiative relate to the envisaged review of the OSH acquis?

The CMD is part of an overall OSH acquis, comprising the Framework Directive 89/391/EEC and 23 individual directives. The Commission is currently finalising an ex-post evaluation of the

⁵⁹ The Advisory Committee on Safety and Health at Work, Opinion: Protection of workers' health from risks arising from exposure to chemicals at the workplace: EU Occupational Exposure Limit Values under OSH and limit values under other EU legislation, Doc. 01903/13, adopted on 28 November 2013

acquis, covering the period 2007-2012 and 27 Member States. This evaluation consists of a wide assessment of the legislation, including in terms of benefits, research and new scientific knowledge. It also falls under the remit of the Commission's Regulatory Fitness and Performance Programme (REFIT), which aims to ensure that the EU regulatory framework is relevant, coherent, effective, efficient, provides EU added value and targets ensuring the avoidance of any unnecessary regulatory burden.

The results of the ex-post evaluation may lead to the further assessment of specific issues and potentially impact assessments covering possible initiatives to improve the operation of the regulatory framework. The Commission will be working throughout 2016 on the follow-up of the evaluation as regards collection of any necessary further evidence and justifications for the modernisation of OSH framework with the aim of increasing effectiveness and efficiency, reducing regulatory burden whenever possible without undermining the public interest objectives of the legislation.

Within the framework of the overall ex-post evaluation the CMD was, along with the other individual OSH Directives, subject to a specific assessment through an external evaluation study. The conclusions of this study refer mainly to broader issues such as the interface between the CMD and REACH, or the possibility to merge the CMD with the Chemical Agents Directive (CAD)⁶⁰. The former is discussed at section 2.3 in this report. As for the latter, no clear conclusions can be drawn as views of stakeholders at national and EU level are quite polarised. There is however consensus on maintaining the material provisions of the two acts.

Secondly, concerning specifically OELs, experts discussions conducted in the framework of the evaluation confirmed that these are an important tool for chemical risk management at the workplace. It was indicated that the terminology used to describe different types of OELs (and corresponding procedures) should be aligned and guidance on the practical use of OELs should be developed.

The fact that the evaluation did not question the existence of OELs and pointed to the need to revise them and adopt new ones, together with the further evidence and analysis gathered in the framework of the impact assessment, support the conclusion that the two technical annexes of the Directive should be updated.

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 ensure up-to-date 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 and create a better level playing field for economic operators.

⁶⁰ *Evaluation of the Practical Implementation of the EU Occupational Safety and Health (OSH) Directives in EU Member States – Report by directive: Directive 98/24/EEC on the protection of workers from the risks related to chemical agents at work*, section 7.4 'Coherence; Merging the CAD and CMD', COWI, November 2015, p. 128-129.

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

The objectives of the initiative are consistent with the fundamental rights as set out in the EU Charter of Fundamental Rights, in particular article 2 (Right to life) and article 31 (Right to fair and just working conditions which respect his/her health, safety and dignity).

Ensuring a safe and healthy work environment for over 217 mln workers in the EU is a strategic goal for the European Commission according to the recent Communication from the Commission on the EU Strategic Framework on Health and Safety at Work 2014 – 2020.⁶¹ One of the main challenges identified in the EU OSH Strategy is to improve the prevention of work-related diseases by tackling existing, new and emerging risks.

Improving working conditions and preventing workers from suffering serious accidents and/or occupational diseases and promoting workers' health throughout their working life, is a key principle in line with the ambition for a Triple A Social Europe rating set by the Juncker Commission. It also has a positive impact on productivity and competitiveness and is essential to promote longer working lives in line with the Europe 2020 strategy's objectives for smart, sustainable and inclusive growth.⁶²

The objectives of this initiative are also in line with and complementary to the ILO Convention no. 170, concerning safety in the use of chemicals at work. The Convention, adopted so far by six EU Member States⁶³, establishes minimum universal standards on OSH to be observed worldwide. CMD and CAD reflect these standards and go further, establishing more stringent and protective conditions that EU Member States are in a position to implement. They also provide a stronger motive for MS to enact national measures as they are legally bound to do so. ILO 170 is intended to complement and explicitly envisages, *inter alia*, (Article 13), that 'Employers shall: (a) ensure that workers are not exposed to chemicals to an extent which exceeds exposure limits or other exposure criteria for the evaluation and control of the working environment established by the competent authority, or by a body approved or recognised by the competent authority, in accordance with national or international standards (...)'.⁶⁴

4 WHAT ARE THE VARIOUS OPTIONS TO ACHIEVE THE OBJECTIVES?

4.1 Complementary measures

During discussions in the ACSH⁶⁴ the need for further guidance was called for, in particular on:

- the minimisation obligation under Article 5 of the CMD Directive;
- methodologies for the development of OELs for carcinogens;
- measurement methodologies regarding exposure to hardwood dust, taking account of mixed exposure to both hard- and softwood dust;
- how to take into account in the cost-benefit analysis the EU Charter of Fundamental Rights, in particular Article 1 (Human dignity), Article 2 (Right to life) and Article 3 (Right to integrity of the person).

In the same vein, one of the conclusions of the Social Partners consultation was that there was a need for effective implementation of training and information requirements, which are a key aspect of the prevention policy. Workers called the Commission to set up a strategy to improve coordination and sharing of information at EU level. Employers indicated that there was an

⁶¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0332&from=EN>

⁶² COM(2010) 2020 and COM(2014) 130 final

⁶³ Finland, Germany, Italy, Luxembourg, Poland, and Sweden

⁶⁴ Opinion of the ACSH of 05/12/12

added value in the preparation of guidance documents with recommendations on workers protection against carcinogens and mutagens exposure.

Most of these actions are ongoing or will be undertaken as complementary measures to this initiative. These are not alternative options to updating the CMD but are rather part of the baseline and will further reinforce potential positive effects of the considered options. Non-binding guidance cannot address the issues identified in the problem definition; only clear listing of chemical agents under the CMD and setting OELs will introduce the legal certainty needed for employers, workers and enforcers with regard to managing the exposure to carcinogenic chemical agents in the workplace.

4.2 Discarded options

Several other options which could be considered as alternative mechanisms to control and limit exposures to carcinogens in the workplace have been discarded as they were considered disproportionate or less effective in reaching the objectives of this initiative.

A. *Banning the use of the carcinogenic chemical agents*

As explained above, for most carcinogens even a very low OEL does not completely eliminate the risk of triggering a cancer. In that sense the risk could only be reduced to zero by eliminating the presence/use of the substance in the workplace.

Indeed, substitution is the first option in the hierarchy of risk management measures under the CMD that an employer needs to consider. This means that if it were technically feasible, employers should have already replaced use of the concerned chemical agents with safer alternatives.

Wherever substitution is a suitable alternative for use of the 13 chemical agents in question then the CMD already requires this, regardless of the existence or otherwise of an OEL. As this legal standard already establishes that these carcinogens should not be used in the workplace where alternatives are available, establishing a more strict prohibition in the form of a ban would constitute a disproportionate measure with a strong negative impact on businesses. Moreover, in the case of process-generated substances such as hardwood dust or RCS, banning is not only a counterintuitive option but it would also result in operational challenges which could result in closure of otherwise viable and compliant businesses – potentially across whole industry sectors.

B. *Self-regulation (industry voluntary agreements)*

The NEPSi Agreement, including the practical guidelines to risk management, contributes to the overall protection of workers health in the affected employment sectors.

NEPSi was established in part as a self-regulatory alternative to measures reflected in the current proposal. Stakeholders implementing NEPSi have therefore indicated concern that the current proposal may pose a challenge to industry participation in self-regulation initiatives in the future. However, in addition to any recommendations of the NEPSi evaluation report, which shall be issued by the European Commission in Q2 2016, it should be noted that the effectiveness of this self-regulation initiative is hindered by the following:

- it does not apply to all sectors where exposure to RCS occurs, in particular not to the construction sector, which, has the largest burden of occupational cancer⁶⁵;
- it is not binding and cannot therefore be enforced by national authorities.

⁶⁵ Rushton, L. et al. Occupation and cancer in Britain. *Br J Cancer*. 2010 Apr 27;102(9):1428-37

Consequently, the NEPSi agreement and any similar future initiatives would be an important complementary measure but could not be as effective as OELs in setting and enforcing the same level of minimum protection across the EU and in all sectors of industry.

C. Sector or industry specific OELs

It could be envisaged that, where justified, sector, industry or use specific OELs could be set or derogations could be allowed for specific sectors, industries or uses for a defined time-period or subject to specific conditions.

As a result of such an approach we would have different minimum standards of worker protection across the EU for the same type of work and the same chemical agent, which is not permissible in the context of binding OELs as established under the CMD.

Further the process by which the tripartite ACSH agree their Opinion on appropriate EU OELs under CMD includes extensive consideration of socioeconomic and technical feasibility factors – including sector, industry and use-specific concerns. As a result these concerns are already reflected in the value supported by the ACSH and taken forward in the current proposal.

This option, therefore, had to be discarded as the current legal framework does not provide a legal basis for such provisions.

Where an EU OEL is established, Member States and employers retain the right to implement more protective values than the proposed minimum standards, also taking into account the general CMD duty to substitute, eliminate or otherwise minimise exposures.

D. Providing industry-specific scientific information without setting OELs

Another option could be for the Commission to collect and provide industry-specific scientific information to support employers in complying with the CMD obligations.

Apart from the practical difficulties related to collection of relevant data for the multitude of sectors concerned, it is considered that this option would not be effective in achieving the objectives of the initiative for the following reasons:

- the way the information is used by employers would not be enforceable by surveillance authorities;
- such an option would not fit with the overarching legal framework of the CMD, which provides for general exposure management requirements to be specifically supplemented by EU-wide minimum standard OELs;
- in some cases, extensive industry- and chemical agent- specific information and guidance already exists and should be taken into account by employers during risk assessments – but this has not demonstrably addressed harmful exposures at EU level as identified in the IOM study.

E. Market-based instruments

Market-based instruments such as subsidies, tax breaks or reductions of social insurance contributions, are sometimes used by Member States to incentivise business to comply with health and safety rules. Such instruments can effectively support compliance with exposure limits. However, to be applied effectively in this context, such mechanisms would need to be linked (directly or indirectly) with the actual levels of exposure at firm level. These are generally not observed (as it also emerges from the analysis presented in Section 5 below), and improved data collection would likely result in being extremely costly and cumbersome. It should also be noted that these instruments remain in the hands of Member States and the extent

to which they are used vary significantly⁶⁶. This option alone would therefore not be effective in ensuring the same level of minimum protection across the EU.

F. Regulation under other EU instruments (REACH)

As detailed in section 2.3, other EU regulatory options exist for managing risks to workers associated with exposure to some chemical carcinogens – most notably REACH 'authorisation' or 'restrictions'.

As previously indicated, REACH is a relevant regulatory instrument for protection of workers from hazardous chemicals, including in particular chemical carcinogens. However, in the case of the present proposal CMD is the more appropriate regulatory instrument for the following reasons:

- Hardwood dust and respirable crystalline silica, which are process generated in the workplace, are outside scope of REACH.
- 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.
- REACH sets directly-acting harmonised standards from which Member States cannot deviate except in exceptional (and possibly time limited) circumstances. CMD sets 'minimum standards' which allow Member States to maintain or implement more protective measures – which is appropriate in the interest of worker protection. OELs are an example of this.
- REACH places the onus of risk assessment on the supply chain, and is 'chemical agent specific'. CMD risk assessment is more likely to be workplace- and process-specific and should take into account aggregated exposure of workers to all occupational carcinogens. From the point of view of preventing exposure to carcinogens CMD offers therefore a more holistic approach to workplace risks.
- REACH authorisation is a risk management measure covering all risks arising from given intrinsic properties of a substance, including the risks for workers. In the absence of explicit derogations it applies to all placing on the market for a use and use of subject chemical substances and so is a less targeted measure than a CMD OEL, which applies in the long-established OSH regulatory context and relates specifically to the workplace. REACH authorisation can complement CMD, in particular by strengthening the substitution principle and its full implementation, as well as driving toward additional risk management.
- It should also be noted that, as it is based on social policy provisions of the TFEU⁶⁷, CMD reflects the role foreseen there for the social partners in establishing standards for worker protection.
- OELs are an important part of CMD and of the wider occupational safety and health approach to managing chemical risks. REACH, on the other hand, is not intended to set OELs. The concerned Commission services, Member States, and the social partners have all expressed their view that OSH Directives are the appropriate EU legislative framework to establish limit values for the protection of workers.

A comparison table summarising key characteristics of the CMD and REACH approaches to risk assessment and control of occupational carcinogens can be found in Annex 7 (14.2.3).

⁶⁶ European Agency for Safety and Health at Work. "Economic Impact of Occupational Safety and Health in the Member States of the European Union." Available at <https://osha.europa.eu/en/publications/reports/302>

⁶⁷ Consolidated version of the Treaty on the Functioning of the European Union. *OJ C 326, 26.10.2012*.

From the point of view of enterprises, it is important to note that compliance costs associated with workplace legislation (such as protective measures and equipment) directly contribute to better risk management, and that administrative costs triggered by workplace legislation are relatively small.

In 2015 an ongoing collaboration of 40 European sectoral and cross-sectoral associations, nine national associations, and several corporations, all with interests in manufacturing, importing, and using chemical substances began actively engagement with the Commission services in order to ensure more efficient risk management measures that can combine OSH OELs in addition to REACH risk management options as the more proportionate measure where chemical risks identified during risk assessment relate principally to worker protection.⁶⁸ The Commission services concerned are working with this 'Cross Industry Initiative'⁶⁹ and to discuss the relevance of their proposals in the operation of EU chemicals policies regarding worker protection.

Targeted CMD OELs are appropriate for protecting workers from occupational exposure to the chemical carcinogens subject to the present proposal. The synergies in the relationship between CMD and REACH provide further opportunities for regulatory measures as appropriate.

It should be noted that this impact assessment does not aim to assess whether REACH risk management measures are proportionate and effective. The present proposal does not preclude relevant REACH measures from being proposed where this is justified, and in some cases a combination of CMD OELs and other regulatory (or non-regulatory) risk management measures, including under REACH, may be justified.

4.3 Options retained for consideration

Identification process

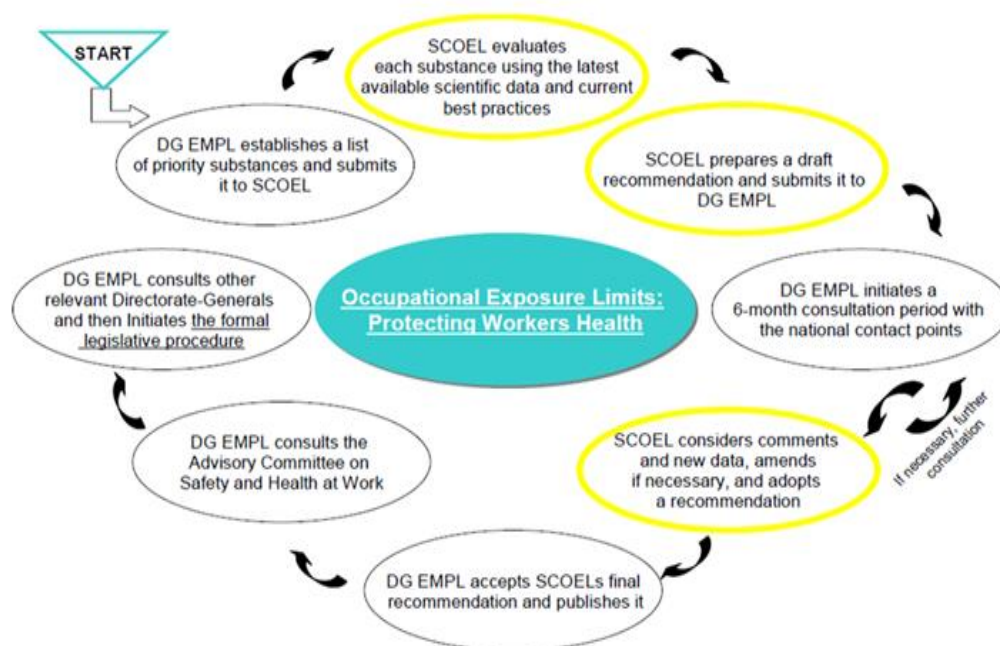
Reviewing or setting new OELs under CMD follows a specific procedure involving seeking scientific advice and consulting the ACSH. Article 16 of the CMD, which states that scientific/technical data should be included in the basis on which OELs are set, does not determine which scientific body should be the source of such data. In 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).⁷⁰

⁶⁸ *Recommendations by an EU-wide cross-industry initiative for better regulation in chemicals management*, position paper, November 2015.

⁶⁹ Position paper available at: http://ec.europa.eu/smart-regulation/refit/refit-platform/docs/submissions/cii_enhancing_the_effectiveness_of_osh_310715_en.pdf

⁷⁰ See "Figure 3. Simple representation of EU OEL setting procedure" (annex 9).

Figure 3. Simple representation of EU OEL setting procedure



The 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.⁷¹

SCOEL carry 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. SCOEL procedures for the adoption of a Recommendation by SCOEL include an external consultation with 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.

The Advisory Committee on safety and health at work (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 Committee's remit is to assist the European Commission in the preparation, implementation and evaluation of activities in the fields of safety and health at work. The Committee 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 – also tripartite but with smaller selected expert membership. The Working Party on Chemicals (WPC) serves the ACSH according to a mandate agreed by the plenary Committee, and in particular undertakes detailed technical and policy negotiation of EU limit values as well as broader chemicals policy support for the ACSH and Commission.

The ACSH discusses adopted SCOEL Recommendations (and/or other appropriate scientific evidence) and adopts a formal Opinion on what, in practice, is considered to be achievable by employers whilst ensuring that workers' health is adequately protected.

⁷¹ As established by Commission Decision 2014/113/EU on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC, OJ L 62, 4.3.2014, p. 18

In the case of the carcinogens considered in this report, SCOEL concluded recommendations on all but two.^{72, 73} Table 1 in Annex 5 sets out the status of relevant adopted SCOEL recommendations.

While the aim of ensuring the protection of the health of workers is maintained, binding OELs set under CMD are usually based on factors beyond the independent scientific advice, because they must also reflect other factors such as 'feasibility' and taking into account the views of the social partners.

Amending the CMD can therefore only be proposed after a two-stage consultation of the social partners (management and labour) in accordance with Article 154 TFEU. This consultation took place in 2004 and 2007 and addressed the following elements: the possibility of extending the scope of the Directive to include reprotoxic substances, the revision of existing OELs and the establishment of new ones for more substances, need to develop a EU-wide methodology for carcinogens and mutagens OELs setting, and the need to improve the training and information requirements for workers.

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.

The consultation process resulted, amongst others, in the support of the following:

- to bring a limited number of so-called process generated substances (PGSs) under the scope of the Directive by including them in Annex I,
- to revise existing OELs in Annex III in the light of most recent scientific data, and
- to add additional OELs for a limited number of substances in Annex III where available information, including scientific and technical data supports this.

The ACSH, in an Opinion adopted in December 2012, and in supplementary Opinions adopted in May 2013 and November 2013, confirmed (with a few dissenting opinions) the OELs initially developed by the SCOEL (where relevant) and approved inclusion of these into CMD.

The three adopted ACSH Opinions include, where necessary, specific comments from the interest groups (the social partners and Member States) which broadly reflect the principal points maintained by each interest group throughout discussions of the Working Party on Chemicals (WPC). In many cases there are no specific comments as there was a consensus view of the three interest groups. As such, the final ACSH Opinions should be taken as representative of the views of stakeholder groups represented.

In addition, the amendment of the CMD is routinely discussed at meetings of the tri-partite WPC. Following adoption of the three ACSH Opinions this discussion has primarily focussed on the state of play and timing of the next steps of the planned amendment of the Directive. They have not expressed additional views on the content of the adopted opinions.

In principle, revision of the Annexes should be conducted on regular basis, as soon as new scientific data is available and the technical feasibility of introducing new or revised OELs has been established. The duration of the current preparatory work reflects that it is a first

⁷² The two exceptions are 2 nitropropane and *o*-toluidine.

⁷³ In December 2015, reflecting scientific developments and updated working procedures, SCOEL was mandated to further consider five of these 13 agents: respirable crystalline silica, chrome (VI) compounds, hydrazine, *o*-toluidine, 2 nitropropane. Ongoing SCOEL work may, in due course, influence the present or future proposals for limit values for the chemical agents concerned.

preparation of a proposal for a relatively large number of new/revised limit values. Appropriate modes of cooperation between all the concerned actors as well as working methods within the advisory bodies had to be developed.

It is expected that the procedures and working methods described above and established in the course of the current exercise will give a good basis to complete preparatory steps leading to eventual future revisions of the CMD in a much shorter time. The fact that a second proposal for the introduction of OELs for additional chemical agents may be presented in the near future should be seen precisely as a step of a continuous, regular process of updating of the CMD, where necessary.

Identified options

The Table 3 below summarises options for different OELs for each of the 13 chemical agents.

A baseline scenario of no further EU action is Option 1 for each chemical agent represented in this initiative.

As explained above, for each of the chemical agents scientific and technical data has been considered and discussions at the ACSH have taken place, resulting in values to be proposed into co-decision as an OEL. Directly adopting the values agreed by the ACSH forms Option 2 for each chemical agent.

Where appropriate and depending on specific characteristics of the agents, flanking options to either propose a OEL which, compared with the ACSH value, is lower (theoretically more protective of worker health) or higher (theoretically less protective of worker health) are also presented as Option 3 and/or 4 respectively for each chemical agent.

These flanking values are drawn from the IOM Study, for which they were established by preference: i) from a SCOEL Recommendation if available; ii) as 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 setting a lower or higher OEL than the ACSH value, these options are discounted. Further detailed information regarding the source of these additional options may be found in the relevant IOM Study reports for each of the chemical agents in question.

In the case of RCS, options 2, 3 and 4 include the possibility of inclusion in the Annex I of CMD along with OEL proposals under Annex III.

In addition, for each chemical agent where SCOEL has identified significant risk of adverse systemic effects resulting from dermal uptake a 'skin notation' ('sk.') is indicated alongside the numerical OEL.

Table 3. Options matrix

Name and CAS no. of the chemical agent where relevant	Option 1 (baseline - existing OEL)	Option 2 (ACSH opinion) (ppm – parts per mln, mg/m³ or f/ml - fibres per ml)	Option 3 (more stringent) (ppm – parts per mln, mg/m³ or f/ml - fibres per ml)	Option 4 (less stringent) (ppm – parts per mln, mg/m³ or f/ml - fibres per ml)
1,2 Epoxypropane (propylene oxide) 75-56-9	none	1 ppm (2.4 mg/m ³)	n/a	5 ppm (12 mg/m ³)
1,3 Butadiene 106-99-0	none	1 ppm (2.2 mg/m ³)	0.5 ppm (1.1 mg/m ³)	5 ppm (11 mg/m ³)
2-Nitropropane 79-46-9	none	5 ppm (18 mg/m ³)	n/a	n/a

Name and CAS no. of the chemical agent where relevant	Option 1 (baseline - existing OEL)	Option 2 (ACSH opinion) (ppm – parts per mln, mg/m ³ or f/ml - fibres per ml)	Option 3 (more stringent) (ppm – parts per mln, mg/m ³ or f/ml - fibres per ml)	Option 4 (less stringent) (ppm – parts per mln, mg/m ³ or f/ml - fibres per ml)
Acrylamide 79-06-1	none	0.1 mg/m ³ Sk.	0.03 mg/m ³ Sk.	n/a
Hardwood dust	5 mg/m ³	3 mg/m ³	1 mg/m ³	n/a
Chromium (VI) compounds	none	0.025 mg/m ³	n/a	0.05 mg/m ³
Ethylene oxide 75-21-8	none	1 ppm (1.8 mg/m ³) Sk.	n/a	n/a
<i>o</i> -Toluidine 95-53-4	none	0.1 ppm (0.5 mg/m ³)	n/a	1 ppm (5 mg/m ³)
Refractory Ceramic Fibres (RCF)	none	0.3 f/ml	0.1 f/ml	1 f/ml
Respirable crystalline silica (RCS)	none	Include in Annex I and establish an OEL of 0.1 mg/m ³ in Annex III	Include in Annex I and establish an OEL of 0.05 mg/m ³ in Annex III	Include in Annex I and establish an OEL of 0.2 mg/m ³ in Annex III
Vinyl chloride monomer 75-01-4	3 ppm (7.8 mg/m ³)	1 ppm (2.6 mg/m ³)	n/a	2 ppm (5.2 mg/m ³)
Bromoethylene (Vinyl bromide) 593-60-2	none	1 ppm (4.4 mg/m ³)	n/a	5 ppm (22 mg/m ³)
Hydrazine 302-01-2	none	0.01 ppm (0.013 mg/m ³) Sk.	n/a	0.1 ppm (0.13 mg/m ³) Sk.

The next section presents an analysis of impacts of the different policy options for each chemical agent. For reasons of space the analysis for each chemical agent is contained in a table which is the basis of the comparison ratings presented⁷⁴.

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

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

Before looking at the comparison between different policy options, it should firstly be noted that the standards of legal control established in the CMD are strict for all in-scope carcinogens, whether or not entries in Annex I (process generated substances) or Annex III (OELs) have been established or amended.

The proposed amendments are thus intended to enhance worker protection by improving clarity for employers and enforcers. The inclusion of chemical agents in Annex I (the list of 'process-

⁷⁴ The comparison table uses 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.

generated substances') confirms that they fall in scope of the Directive control provisions. OELs set out in Annex III establish clear compliance benchmarks for exposure control. These considerations will be inherent in any investment decision, profit projection etc. and should be based on as much legal clarity as possible.

Concretely, comparing the different policy options requires estimating the effects of introducing new or more stringent OELs for the chemical agents under consideration. The methodology followed can be summarised as follows:

- In general, the introduction of an OEL is expected to determine a reduction in the occupational exposure to the carcinogen concerned (as full compliance with the proposed new OEL is assumed). 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 OEL ("Baseline scenario", corresponding to Option 1).
- For a given reduction in exposure levels, it is then necessary to estimate the expected decrease in the incidence of cancer cases 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 health benefits of avoided cancer registrations and deaths can then be expressed in monetary terms by applying standard evaluation methods (value of life years lost, cost of illness, willingness to pay to avoid cancer). 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. This methodology is further explained in Annex 4.

A number of issues need to be taken into consideration in order to better understand the figures and conclusions presented in the following sections, which are mostly derived from the results of the IOM study. As set out above, the CMD requires employers to take measures to protect workers from occupational use of carcinogens. All stakeholders as consulted in the ACSH are in favour of the proposed legislative initiative albeit with some differences regarding appropriate OEL values.

In terms of cost and benefit projection, this renders the updating of the CMD particularly complex; independent of further clarity under the CMD, employers will include more or less stringent protection of workers in their facilities, e.g. costly industrial ventilation combined with personal protective gear. Furthermore, Member States with substantial production involving a certain carcinogenic chemical agent are likely to introduce national OELs irrespective of EU action.

In order to take proper account of the cancer latency period (which the IOM study assumes to be of 10-50 years for solid tumours and of 0-20 years for haematopoietic neoplasms), the future cancer burden is estimated over a 60 years period.

Looking at the methodological challenges in more detail:

- 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 aggregated.⁷⁵ Where exposure data is available, its use as an evidence

⁷⁵ 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

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.⁷⁶ 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 neurotoxicity, severe skin damage, respiratory diseases or renal toxicity).
- 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, based on a constant discount rate of 4%, have been recalculated applying a declining discount rate (4% for the first 20 years, 3% thereafter) in line with the most recent better regulation guidelines. 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).

To allow for a better comparison between net health benefits and net 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

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.

⁷⁶ 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>

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 2013⁷⁷. The outcome of this work is expected to contribute to a better definition of the baseline situation for possible future initiatives on developing OELs for other priority occupational carcinogens.

Analysis of impacted Member States and proportionality

For each of the 13 carcinogens, an analysis of the need for and benefit of action at the EU level is presented by chemical agent in the following sub-sections (and in Annex 9).

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 currently in place at national level is provided in Annex 9, as well as the estimated number of workers potentially exposed by Member State. Similar information is also summarised in Table 4 in Annex 6, which identifies the population of workers occupationally exposed to each chemical agent 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.

This analysis bears the condition that reliable exposure data is scarce. In particular it should be noted that it is not possible to identify the proportion of workers in each Member State who may be employed in tasks where closed system or effective exposure controls are already either eliminating or reducing exposures below the level represented by the OELs recommended by ACSH. The probable over-estimation of exposed populations resulting from this data scarcity is likely to be mitigated by the converse inability to identify specific populations of workers who may experience exceptionally high exposures.

5.1 1,2 Epoxypropane

This chemical agent is associated with lymphopietic cancer, haematopietic cancer and increased leukaemia risk.

The major use of this chemical agent is to make 1,2 epoxypropane polymers that are used in the manufacture of polyurethane foams. Its second most important use is in the production of propylene glycol. About 5% of all 1,2 Epoxypropane production is used in a diverse range of applications such as the manufacture of surfactants and as a stabiliser for dichloromethane.

The productive capacity within the EU is 2.75 mln tonnes per year and it is produced in 14 facilities in eight Member States (BE, FR, DE, NL, PL, SK, ES and RO). There are estimated to be 150-300 user facilities across the EU.

Between 35-70 EU workers are estimated to be exposed to 1,2 epoxypropane during its manufacture and between 450-1,500 EU workers in the chemical industry.

Table 4. 1,2 Epoxypropane – Types of impacts

⁷⁷ 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.

Impact	Option 1 Baseline: No OEL	Option 2 OEL of 1 ppm (2.4 mg/m³)⁷⁸	Option 3 OEL of 5ppm (12 mg/m³)
Economic	-	Costs of compliance not significant (€1-2k). Few if any enterprises would require some additional control measures to meet the OEL. Any enterprises that do not currently comply would need to implement relatively low-cost measures.	No significant impacts v-à-v the baseline are expected as exposure is already largely below this OEL as the vast majority of investment required by industry to comply with this OEL already occurred.
Social (incl. health)	Health costs are estimated between 2.5-10.7 €mln. 100 attributable YLLs and 110 DALYs during 2010-2069 period. ^{79 80}	Small cost saving (e.g. a few €k) from avoided health care and reduced cost of illness due to reduction in YLLs. Expected health benefits mainly in the downstream use sector, which are expected to be a share of total health costs under baseline scenario.	No additional health costs or benefits.
Environmental	There may be some environmental impacts related to humans exposed via the wider environment, rather than costs associated with damage to e.g. ecosystems.	No change compared to baseline (measures relate to training and employee supervision rather than any additional engineering controls).	No change compared to baseline.

Estimates of exposure levels were based on samples obtained during manufacturing and downstream use in 7 facilities. According to these estimates most companies already comply with a level of 1 ppm. For those that do not yet comply, the additional costs are expected to be very low. It is therefore assumed that the introduction of an OEL of 1 ppm would not imply any important costs associated with compliance, neither major social, macro-economic or significant environmental impact.

During the ACSH discussions employers' representatives noted that in routine and manufacturing practices workers' exposures are already well below an OEL of 2 ppm and that a level of 1 ppm during maintenance and loading operations could be ensured through breathing personal protective equipment.

Introduction of an OEL of 1 ppm can be expected to be more effective in reducing exposure to 1,2 epoxypropane compared to the baseline, however the monetised health benefits are minor.

Table 5. 1,2 Epoxypropane – Comparison of options

Criteria	Baseline	Option 2 (1 ppm)	Option 3 (5 ppm)
Effectiveness	0	≈	≈

⁷⁸ The study did not assess directly impacts of introducing an OEL of 1 ppm. However, it concluded that impacts identified for an OEL of 2 ppm would apply equally to an OEL of 1 ppm.

⁷⁹ YYL - Years of Life Lost, DALY - Disability Adjusted Life Years – see Annex 4 for further explanation.

⁸⁰ According to the IOM Research Project, less than one death per year is predicted from past or future exposure - 100 attributable YLLs during 2010-2069 period.

Efficiency	0	≈	≈
Coherence	0	+	≈
Scientific advice (SCOEL)	1 ppm		
ACSH	1 ppm		

The scientific advice and the opinion of the social partners and Member States in the ACSH support option 2, and the CMD further establishes an expectation that OELs be set where it is possible to do so.

Impact on MS and proportionality

In the case of 1,2 epoxypropane, 26 Member States have so far opted either to not to set a limit or to set one which is less protective of worker health than the value recommended by ACSH. Figure 4 in Annex 9 illustrates the ranges of existing national OELs compared to Option 2.

Member States where the production of this chemical agent is concentrated (such as BE, DE, ES, FR, NL, PL, RO and SK)) have no OEL or OELs above the proposed limit value. Introducing an OEL would bring a greater clarity for economic operators across the EU and 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 an OEL of 1 ppm would require changes to the national frameworks of most MS. Due to the generally low number of exposed workers across the EU, no estimates were made about the numbers of exposed workers in those 26 MS. Even if current exposure levels in the EU are estimated to be well below 2 ppm, a minimum basis of protection against the risks arising from workers' exposure to these carcinogens cannot be ensured under the baseline for all EU workers – it follows that an action taken at the European Union level to achieve this objective is proportionate.

5.2 1,3 Butadiene

This chemical agent is associated with an increased risk of lymphohaematopoietic cancer, mainly lymphosarcoma.

Most 1,3 butadiene is polymerized at a relatively small number of sites in Europe to form synthetic rubber. It is also used as a chemical intermediate in the production of neoprene for automotive and industrial rubber goods, in the production of methylmethacrylate-butadiene-styrene polymer, which is used as a PVC reinforcing agent, and in the production of adiponitrile (a nylon precursor). The production capacity in the EU is estimated to be 2.9 mln tonnes.

There were nine plant sites producing emulsion of SBR in July 2010 (IOM report), four producing solution of SBR, seven producing polybutadiene or butadiene rubber and six producing nitrile butadiene rubber. Some of the sites produce two or more of these elastomers at the same location. All companies affected by the proposed OEL value of 1ppm would be SMEs, and the great majority of them (about 90%) would be microenterprises (less than 10 employees).

About 27,600 workers in the EU are estimated to be potentially exposed to this chemical agent.

Table 6. 1,3 Butadiene – Types of impacts

Impact	Option 1 Baseline: No OEL	Option 2 OEL of 1 ppm (2.2 mg/m³)	Option 3 OEL of 0.5 ppm (1.1 mg/m³)	Option 4 OEL of 5 ppm (11 mg/m³)
Economic	<p>A 7% annual decline in exposure levels assumed, so that by 2030 90% of high exposed jobs estimated to be below 0.6 ppm.</p> <p>Costs are expected due to further spending on control measures to reduce exposure (e.g. improving working practice, improved ventilation, improved loading/unloading equipment).</p>	<p>It is estimated that 2% of enterprises (159 enterprises) will require some form of control measure to meet the proposed OEL.</p> <p><u>Investment is expected to occur already under the baseline, only possibly later in time: the costs of anticipating this expenditure by 10-20 years would be in the range of 5.8 - 37.8 mln €.</u></p> <p>No plant closures foreseen.</p>	<p>It is estimated that 4% of enterprises (251 enterprises) will require some form of control measure to meet the proposed OEL.</p> <p><u>Investment is expected to occur already under the baseline, only possibly later in time: the costs of anticipating this expenditure by 10-20 years would be in the range of 9.2-59.9 mln €.</u></p> <p>No plant closures foreseen.</p>	<p>It is estimated that less than 0.3% of enterprises (19 enterprises) will require some form of control measure to meet the proposed OEL.</p> <p><u>Investment is expected to occur already under the baseline, only possibly later in time: the costs of anticipating this expenditure by 10-20 years would be in the range of 0.7-4.4 mln €.</u></p> <p>No plant closures foreseen.</p>
Social (incl. health)	<p>Estimated health costs between 41 €mln (low scenario) and 167 €mln (high scenario) in the period 2010-2069.</p> <p>YLLs: 1,320</p> <p>DALYs: 1,640</p> <p>Some personnel may change their working practices (e.g. wearing respiratory protective equipment) to reduce risks of inhalation exposure.</p>	<p>Estimated health benefits in addition to those under baseline are between 0.2 to 0.6 mln €.</p> <p>No avoided deaths or cancer registrations, nor changes in DALYs, but 10 less YLLs estimated over 2010-2069 period compared to baseline.</p> <p>Behavioural change amongst employees and updating health and safety training will be required.</p>	<p>Estimated health benefits in addition to those under baseline are between 0.2 to 0.6 mln€.</p> <p>No avoided deaths or cancer registrations, but 20 less YLLs and 10 less DALYs estimated over 2010-2069 period compared to baseline.</p> <p>Behavioural change amongst employees and updating health and safety training will be required.</p>	<p>Estimated health benefits in addition to those under baseline are between 0 to 0.1 mln €.</p> <p>No avoided deaths or cancer registrations, but 10 more YLLs and 20 more DALYs estimated over 2010-2069 period compared to baseline.</p> <p>Behavioural change amongst employees and updating health and safety training will be required.</p>

Impact	Option 1 Baseline: No OEL	Option 2 OEL of 1 ppm (2.2 mg/m³)	Option 3 OEL of 0.5 ppm (1.1 mg/m³)	Option 4 OEL of 5 ppm (11 mg/m³)
Environmental	Not estimated.	Possibly more direct emissions (through ventilation) but overall environmental burden should not increase.	As in option 2.	As in option 2.

The exposure levels were estimated across the industries of manufacture of refined petroleum products and manufacture of rubber. The estimates of exposure levels in the manufacture of refined petroleum products (NACE code 23) were based on different studies covering Finland, 13 EU countries, EU and UK. The estimates of exposure levels in the rubber industry (NACE code 251) were based on studies in 27 EU plants, in the Netherlands, Finland and Czech Republic.

Given the estimated decreasing exposure levels to 1,3 Butadiene in the baseline scenario and the fact that it is not possible to identify an exposure level at which there is no risk of lymphohaematopoietic cancer, none of the assessed options would allow a reduction in the numbers of attributable deaths or cancer registrations in the 2010-2069 period. However, introducing an OEL would be effective in ensuring a greater clarity for economic operators across the EU. Option 4 is the least effective as it is estimated to slightly increase the number of years of life lost (YLL) over the 2010-2069 period as compared to the baseline scenario, while YLL are expected to slightly decrease under options 2 and 3. Of those two, option 2 brings about the least additional costs for enterprises.

Employers' representatives at the ACSH accepted the option of an OEL of 1 ppm as feasible while expressing concerns about potential economic impacts of lowering an OEL below that level.

Table 7. 1,3 Butadiene – Comparison of options

Criteria	Baseline	Option 2 1 ppm	Option 3 0.5 ppm	Option 4 5 ppm
Effectiveness	0	≈/+	+	≈
Efficiency	0	-	--	≈
Coherence	0	+	+	≈
Scientific advice (SCOEL)	Additional leukaemia risk with 1ppm exposure for a 40-year working life: from 0 to 10.78 extra leukaemia deaths between ages 25-85 years.			
ACSH	1 ppm (=2.25 mg/m ³) to be reviewed. A revision to be conducted in 3 years.			

The opinion of the social partners and Member States in the ACSH supports option 2, and the CMD further establishes an expectation that OELs be set where it is possible to do so. Introducing an OEL would also be effective in introducing a greater clarity for economic operators across the EU. An OEL of 1 ppm is also set in the US.

Impact on Member States and proportionality

In the case of 1,3 Butadiene 23 Member States have no OEL or one that is less stringent than the ACSH recommended 1 ppm level. Figure 5 in Annex 9 illustrates the ranges of existing national OELs compared to Option 2. The following Figure 6 shows distribution of exposed workers across the Member States.

The Member States where the production or use of this substance is concentrated (such as DE, FR, UK, ES, PL, RO) have no OEL or OELs above the proposed limit value. Introducing an OEL would bring a greater clarity for economic operators across the EU and 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 an OEL of 1 ppm would require changes for a substantial number of Member States. It is estimated that approximately 93% of exposed workers are located in those 23 Member States. Even if current exposure levels in the EU are estimated to be well below 2 ppm, a minimum basis of protection against the risks arising from workers' exposure to these carcinogens cannot be ensured for all EU workers under the baseline scenario – it follows that an action taken at the European Union level to achieve this objective could be justified.

5.3 2 Nitropropane

According to animal toxicity studies 2 nitropropane may cause liver tumours in humans.

Occupational exposures to this chemical agent occur primarily in its production and use as a solvent in inks, adhesives, paints and coatings. It is produced in relatively low volumes. According to the IOM report there was only one plant in Germany which produced 2-nitropropane. In downstream uses exposures were considered only likely to occur in the manufacture of aircraft and spacecraft (NACE code 35.3) and possibly at very low levels in the recycling of non-metal waste and scrap (NACE code 37.2).

No information on EU total production is available.

About 51,400 EU workers are estimated to be exposed to 2 nitropropane.

Table 8. 2 Nitropropane – Types of impacts

Impact	Option 1 Baseline: No OEL	Option 2: OEL of 5ppm (18.25 mg/m³)
Economic	It is assumed that exposures will fall by 7% per year in the future. Therefore, there are expected to be some costs for firms to put into place employee training, PPE and ventilation measures to reduce inhalation and dermal exposure.	No significant additional costs for firms since under the baseline scenario it is estimated that firms are already achieving exposures below 5 ppm. Neither additional health costs nor benefits are expected, as exposure is already estimated to be below an OEL of 5 ppm.
Social (incl. health)	Not possible to estimate health impact as there is no epidemiological evidence of carcinogenicity in humans. However, probably low, considering low and decreasing exposure in the EU.	None, as exposure already estimated to be below the possible OEL.
Environmental	No significant.	No significant.

Estimates of exposure were assumed to decrease by 7% per annum (reference: Creely et al. 2007). The estimates for 2010 exposures were based on worst-case measurements obtained/reported in 1984 from the industries of manufacture of 2-nitropropane and of automotive manufacturing.

Given the estimated low exposure levels (it is likely that no worker in the EU is exposed in excess of the proposed limit value of 5 ppm), option 2 is expected to have no health impact. For the same reason, establishing this OEL at EU level would not impose additional costs on firms, while remaining a measure in terms of promoting a levelled playing field for companies across the EU.

Table 9. 2 Nitropropane – Comparison of options

Criteria	Option 1 Baseline	Option 2 5 ppm
Effectiveness	0	≈
Efficiency	0	≈
Coherence	0	+
Scientific advice (SCOEL)	SCOEL advice is currently being developed. IOM Study considered 5 ppm (18 mg/m ³) for assessment, as 'typical' values for existing national OELs in the EU.	
ACSH	5 ppm (=18.25 mg/m ³)	

The opinion of the social partners and Member States in the ACSH supports option 2, and the CMD further establishes an expectation that OELs be set where it is possible to do so. Introducing an OEL would also be effective in introducing a greater clarity for economic operators across the EU.

Impact on Member States and proportionality

In the case of 2 Nitropropane 14 Member States have so far opted either to not to set a limit or to set one which is less protective of worker health than the value recommended by ACSH. The Figure 7 in Annex 9 illustrates the ranges of existing national OELs compared to Option 2. The following Figure 8 shows distribution of exposed workers across the Member States.

Some of the Member States where production or use of this chemical agent is concentrated and therefore where the numbers of exposed workers are the highest (such as DE, FR, PL or IT) have no OEL or OELs above the proposed limit value. UK and ES have OELs, which are slightly higher than Option 2. Introducing an OEL would bring a greater clarity for economic operators across the EU and 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.⁸¹

Introduction of an OEL of 5 ppm would require changes for a substantial number of MS. It is estimated that approximately 62% of exposed workers are located in those 14 Member States. Even if current exposure levels in the EU are estimated to be below 5 ppm, a minimum basis of protection against the risks arising from workers' exposure to these carcinogens cannot be ensured for all EU workers under the baseline scenario. It follows that an action taken at the European Union level could be justified.

⁸¹ See Figure 7 - 2 Nitropropane – Current national OELs vs. Option 2 ; and Figure 8 - 2 Nitropropane –Number of exposed workers

5.4 Acrylamide

Acrylamide may cause pancreatic cancer, and is also a skin irritant and may be a tumour initiator in the skin, potentially increasing risk for skin cancer.

99% of acrylamide in the EU is used in the production of polyacrylamide⁸². The main uses of polyacrylamide are in wastewater treatment, paper and pulp processing and mineral processing. Three companies are reported as producing acrylamide within the EU (in UK, Germany and the Netherlands). There were also thought to be firms in Spain, Finland and Italy who either supply (from imports) or produce acrylamide. The total plant capacity within the EU is estimated at between 80,000-150,000 tonnes per annum. The IOM report found seven producers of polyacrylamide within the EU (two of which also produced acrylamide), as well as a number of smaller producers throughout the EU.

54,000 EU workers are estimated to be exposed to acrylamide.

It should be noted that the global market for polyacrylamide has been growing and is expected to continue expanding.⁸³

Table 10. Acrylamide – Types of impacts

Impact	Option 1 Baseline: no OEL	Option 2 OEL of 0.1 mg/m³, Sk.	Option 3 OEL of 0.03 mg/m³, Sk.
Economic	Exposures expected to continue falling by 10.5% per year in the manufacture of chemicals and chemical products sector.	No additional economic costs, since industry already expected to comply with an OEL of 0.1 mg/m ³ .	No additional economic costs, since industry already expected to comply with an OEL of 0.03 mg/m ³ .
Social (incl. health)	Total health costs estimated at €156-326mln. Total attributable deaths between 2010-2069: 230 YLLs between 2010-2069: 3,410 DALYs between 2010-2069: 3,480	Total attributable deaths between 2010-2069: 230 YLLs between 2010-2069: 3,410 DALYs between 2010-2069: 3,480 No additional health benefits expected as compared to the baseline scenario, since industry already expected to be complying with this OEL.	Total attributable deaths between 2010-2069: 230 YLLs between 2010-2069: 3,410 DALYs between 2010-2069: 3,480 No additional health benefits expected as compared to the baseline scenario, since industry already expected to be complying with this OEL.
Environmental		No change.	No change.

Estimates of exposure levels are based on a study by Bull et al. (2005), who monitored personal inhalation and dermal exposure at a UK acrylamide and polyacrylamide manufacturing facility, based on measurements between 1992 and 1995. The results of this study were extrapolated to

⁸² It should be noted that a targeted REACH restriction applies to placing on the market or use of acrylamide (above a certain concentration) in grouting applications, which is prohibited. While this restriction is relevant for worker protection, it should not be expected to significantly affect the overall exposure patterns and associated cost benefit assessments made in this report.

⁸³ See Figure 9 – Acrylamide - Global polyacrylamide market, 2012-2019 (in 1,000 tonnes) (Annex 9).

the whole acrylamide and polyacrylamide manufacturing industry in the baseline scenario even if the 10.5% annual decline rate appears optimistic.

On this basis it is assumed that industry is already complying with an OEL of 0.03 mg/m³, and thus no major health impact is to be expected from any of the two options. No economic cost is expected for the implementation of any of both options, although, if any, this would be even lower for an OEL of 0.1 mg/m³ compared to a more stringent OEL of 0.03 mg/m³.

Where there is the possibility of a significant uptake via dermal exposure SCOEL recommend that any OEL be accompanied by a 'skin notation' (in the case of acrylamide ACSH did not comment on this aspect of the SCOEL Recommendation). If adopted and accordingly transposed by Member States, employers are required under the national transposing legislation to take this into account in selecting appropriate risk management measures to protect workers.

Once the need for managing exposure has been established the only risk management measure available in practical terms is to avoid skin contact. Acrylamide has a harmonised classification as a skin irritant (category 2) and skin sensitiser (category 1). These hazards would normally result in employers taking steps to avoid skin contact as a part of routine OSH risk control. Adoption of a 'skin notation' should therefore result in no additional cost for employers.

Table 11. Acrylamide – Comparison of options

Criteria	Baseline	Option 2 0.1 mg/m³, Sk.	Option 3 0.03 mg/m³, Sk.
Effectiveness	0	≈	≈
Efficiency	0	≈	≈
Coherence	0	+	+
Scientific advice (SCOEL)	<p>Genotoxic carcinogen for which the existence of a threshold cannot be sufficiently supported. A reasonable quantitative cancer risk assessment for humans is not feasible.</p> <p>Any regulation that may be established for acrylamide should also be protective against the development of neurotoxicity. While it is difficult to establish a dose-response for neurotoxicity in occupational studies a 'no observed affect level' for neurotoxicity resulting from airborne exposure at about 0.1 mg/m³ or 0.035 ppm (8-hour TWA) can be inferred.</p> <p>Dermal absorption is important in relation to workers under practical working conditions, and a 'skin' notation is therefore warranted.</p>		
ACSH	A range from 0,07 to and including 0,1 mg/m ³ , with a review period of 3 years.		

The opinion of the social partners and Member States in the ACSH supports option 2, and the CMD further establishes an expectation that OELs be set where it is possible to do so. Introducing an OEL would also be effective in introducing a greater clarity for economic operators across the EU.

Impact on Member States and proportionality

In the case of acrylamide 13 Member States have so far opted either to not to set a limit or to set one which is less protective of worker health than the value recommended by ACSH. Figure 10 in Annex 9 illustrates the ranges of existing national OELs compared to Option 2. The following Figure 11 shows distribution of exposed workers across the Member States.

The three Member States where the production and/or use of this chemical agent is concentrated and the numbers of exposed workers are the highest (DE, UK or FR) have no OEL or OELs above the proposed limit value of 0.1 mg/m³. Introducing an OEL would bring a greater clarity for economic operators across the EU and 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.

Introduction of an OEL of 0.1 mg/m³ would require changes for a substantial number of Member States. It is estimated that approximately 64% of exposed workers are located in those 13 Member States. Even if current exposure levels in the EU are estimated to be below 0.03 mg/m³, a minimum basis of protection against the risks arising from workers' exposure to these carcinogens cannot be ensured for all EU workers under the baseline. It follows that an action taken at the European Union level could be justified.

5.5 Hardwood dust

Hardwood dust is listed in the CMD but not classified according to the EU CLP regulation (because it is a PGS); however it is classified as a Group 1 carcinogen ("carcinogenic to humans") by the International Agency for research on cancer. Hardwood dust may cause sinonasal and nasopharyngeal cancers. In addition, hardwood dust may cause non-malignant respiratory health problems, including occupational asthma.

Exposure to hardwood dust occurs mainly in the wood working industry, furniture manufacturing and construction sectors. Over three million EU workers are potentially exposed in over 340 000 companies, mostly SMEs, with a production value of around €230 bln/year.

The estimates of the prevalence and level of exposure to hardwood dust were based on the results of the 2001-2006 WOODEX project and on the timber statistics UNECE. The WOODEX project aimed at estimating occupational exposure to inhalable wood dust by country, industry, level of exposure and type of wood dust in 25 Member States. National labour force statistics, a country questionnaire (in 15 Member States, EU-15), a company survey (in Finland, France, Germany and Spain), exposure measurements (from Denmark, Finland, France, Germany, the Netherlands and the United Kingdom), and expert judgments were used to generate preliminary estimates of exposure to different types of wood dust. These estimates were reviewed and finalised by national experts from 15 Member States.

The study showed that construction employed 33% of exposed workers, mostly construction carpenters. 20% of exposed workers worked in the furniture industry, 9% in the manufacture of builders' carpentry, 5% in sawmilling, 4% in forestry. In addition, 20% were employed in miscellaneous industries employing carpenters, joiners, and other woodworkers. The numbers of exposed workers varied by country ranging from <3,000 in Luxembourg and Malta to 700,000 in Germany. According to the IOM report, the countries with the highest numbers of exposed workers are Germany (19.75% of all EU workers), Spain (12.18%), the UK (19.91%), Italy (9.88%) and Poland (9.29%).

The WOODEX study concluded that the high wood dust concentrations were measured in the furniture industry, in the manufacture of other wooden products, and especially in construction. The mean wood dust concentrations were in fact the highest in construction. Regarding the manufacture of wood products industry, the IOM report estimates that more than 88% of enterprises have between 1 and 9 employees, while only 1.5% have between 50 and 250 employees. The furniture manufacturing sector is similarly mostly composed of very small enterprises (86% with 1 to 9 employees) and few large companies (2.3% with 50 to 250 employees).

Table 12. Hardwood dust – Types of impacts

Impact	Option 1 Baseline: OEL at 5 mg/m³	Option 2: OEL of 3 mg/m³	Option 3: OEL of 1 mg/m³
Economic	Exposures will continue falling by 8% per year. Some costs to put into place ventilation measures expected for firms.	It is considered that EU industry is already compliant with an exposure limit of 3 mg/m ³ . According to the IOM Study no additional significant costs for firms vs. the baseline are expected since the average exposure across sectors is lower than this limit and no change in the manufacturing processes are foreseen because of a lower OEL.	Additional costs for firms are expected compared to the baseline, as the OEL will require changes in manufacturing processes and installation of compliant ventilation systems. Depending on the anticipation of additional investments following the baseline investments (10 or 20 years), those additional compliance costs could be ranging from €13 bln to 52 bln. Such costs risk disproportionately affecting SMEs, possibly forcing some of them out of business or forcing firms to shift to other materials to avoid compliance costs.
Social (incl.health)	The health costs associated with no action up to 2069 are estimated to between €3bln and 16bln, which fall mainly on DE, FR, IT, SP and UK. Total attributable deaths for 2010-2069: 5000.	Total attributable deaths/YLL/DALYs for 2010-2069: data not conclusive ⁸⁴ Net health benefits in addition to those under the baseline are estimated to range between €12mln and 54mln. No significant change to current employment and working conditions is foreseen. There are no foreseen changes in the end products.	Total attributable deaths/YLL/DALYs for 2010-2069: data not conclusive Net health benefits in addition to those under the baseline are estimated to range between €66-325mln. New ventilation system would require training and maintenance efforts, with a small impact as 85% of firms are estimated to already have ventilation in place. New ventilation could positively improve working conditions. There are no foreseen changes in the end products.
Environmental	none	none	none

Assumptions concerning declining exposure trends in the IOM study were based results of two studies – one from UK, another from the US, both showing steady decrease of exposures over approximately 20 years' period. It should be noted however, that other studies do not support the resulting estimate of current compliance with an exposure level of 3 mg/m³. The WOODDEX project provides data on numbers of exposed workers in the EU as well as on levels of

⁸⁴ Analysis of the data on deaths and cancer cases from the IOM study showed some inconsistencies, which led to the decision to limit the impact analysis to monetised health benefits.

exposure⁸⁵. The WOODEX data on levels of exposure for 2000-2003, shows that 25% of all affected workers are exposed to a level of 2-5 mg/m³ (897 000 workers) and as much as 16% are even exposed to levels higher than the legally binding 5 mg/m³ (563 000 workers). In construction, which has the highest number of exposed workers (1,190,000), the proportion of those exposed to levels higher than 5 mg/m³ reaches 21% or 254 000 workers.

Option 3 would be the most effective option in reducing occupational exposure to carcinogens. It also leads to the highest reduction of estimated health costs. However, it does so at the cost of imposing a disproportionate burden on firms and in particular SMEs. It may force SMEs to use other type of material or to close down business. On the other hand, option 2 should lead as well to a substantial reduction in the health costs, while the negative impact on firms remains very low or non-existent. Thus, option 2 is the best scoring option in terms of efficiency.

The impact on mobile machinery might be higher than on stationary machinery as it is considered, based on the results of a report by the French authority quoted in the IOM study, that more companies have already put in place ventilation systems for stationary machinery than they have for mobile machinery. Moreover, concentration exposures vary according to sectors and occupation. It is estimated that the highest concentrations (2-3 mg/m³) are in the construction sectors, while for the other sectors concentrations are estimated to be generally below 1 mg/m³ for those working far from machinery in control rooms or maintenance tasks.

Exposure concentrations for installers and carpenters across all industries were generally estimated to be between 2-3 mg/m³. Therefore it is assumed that there will not be any significant cost to most enterprises to meet Option 2. However, data is missing to assess the impact of the OEL on non-substitutable hand-held machines and whether there are alternative solutions to ensure that exposure levels will be properly implemented. Employers emphasised that some hand-held machinery does not allow going below 5 mg/m³. On the other hand the workers favoured a 2 mg/m³ limit in view of current limit values of 2 mg/m³ or below in the majority of Member States. For some MS, 3 mg/m³ is at the limit of feasibility particularly for SMEs while other MS favour a 1 mg/m³ limit to further reduce occupational cancer cases.

Hardwood exposure is also associated with increased symptoms of the upper respiratory tract and to allergic (asthma) and non-allergic effects in the lower respiratory tract. As explained above, the direct and indirect costs of illnesses other than cancer were not taken into account in the IOM evaluation of the health costs and benefits, leading to a clear under-estimation of the health costs benefits of introducing a lower OEL. A 2014 British study⁸⁶ showed that occupational asthma had a poor prognosis; once a worker develops occupational asthma after a latency period the chances of recovery are small. The average direct costs per annum per case were found to range from £530 to £715 (670 to 900€), whereas the indirect costs range from £1525 to £1685 (1930 to 2140 €).

Table 13. Hardwood dust – Comparison of options

Criteria	Option 1: Baseline OEL at 5 mg/m³	Option 2: OEL at 3 mg/m³	Option 3: OEL at 1 mg/m³
Effectiveness	0	+	++
Efficiency	0	++	--
Coherence	0	+	+

⁸⁵ 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>

⁸⁶ Montano D. Chemical and biological work-related risks across occupations in Europe: a review. Journal of Occupational Medicine and Toxicology (London, England). 2014;9:28. doi:10.1186/1745-6673-9-28.

Scientific advice (SCOEL)	1 mg/m ³ (inhalable dust) is probably below the levels to which the cases of sino-nasal cancers had been exposed.
ACSH	3 mg/m ³ , measured as inhalable dust, with a review period of between 3-5 years is proposed.

The preferred option is 2 (3 mg/m³) because it is the most cost-effective and at the same time is the level which came out of the discussions between employers, employees and MS representatives at ACSH discussions.

Impact on Member States and proportionality

In the case of hardwood dust 18 Member States have so far opted to set a limit which is less protective of worker health than the value recommended by ACSH. Figure 12 in Annex 9 illustrates the ranges of existing national OELs compared to Option 2. The following Figure 13 shows distribution of exposed workers across the Member States.

Among the six Member States with the highest numbers of exposed workers, three have an OEL which is less protective than the value proposed by the ACSH (ES, UK, IT) and thus there is a case of competitive advantage compared to Member States which have adopted more stringent measures. On the other hand, the fact that an OEL at 3 mg/m³ or below is already in place in the other three Member States with high numbers of exposed workers (DE, PL and FR) as well as in six other Member States (AT, BE, CZ, DK EE, NL, SE) indicates that solutions exist to practically implement the OEL. An even lower OEL exists for example in Switzerland (2 mg/m³) as well as in Canada and Australia (1 mg/m³).

It should also be noted that as more than 75% of workers exposed to wood dust are exposed to both hardwood and softwood dusts, the prevention of the risks posed by hardwood dust will also include softwood dust. So in practice, the OEL on hardwood dust would also be beneficial to protection against exposure to softwood dust.

Introduction of an OEL of 3 mg/m³ would require changes for a substantial number of MS. It is estimated that approximately 48% of exposed workers are located in those 18 Member States. Even if it is estimated that EU industry is already compliant with an exposure limit of 3 mg/m³, which appears to be an optimistic assumption when the WOODDEX data is taken into account, an action at EU level could provide a minimum basis of protection against the risks arising from workers' exposure to these carcinogens for a significant proportion of workers at risk.

5.6 Chromium (VI) compounds

Occupational exposure to chromium (VI) compounds – also known as hexavalent chromium compounds - has been associated with an increased risk of lung cancer and sinonasal cancer.

Hexavalent chromium compounds are no longer manufactured in Europe and they are imported less than in the past. The main use of hexavalent chromium is found in wood preservatives, metal coatings, chromium production and catalyst manufacture. In 2006 about 917,000 workers in the EU were exposed. Since 2006, hexavalent chromium has been banned for certain uses (for instance in new vehicles or electronic equipment); the number of workers with high level of exposure is likely to have declined further since then.

The number of workers' exposed to hexavalent chromium was estimated on the basis of the Finnish, Spanish and Italian CAREX estimates. 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 was found for each industry. The average proportion of exposed workers was applied to information on the number of employees in each industry

obtained from Eurostat. To find the number of exposed workers in each industry in each country the average proportion of exposed workers in those three countries was used and multiplied by the number of workers employed in each industry in each country in 2006.

There are no current hexavalent chromium exposure level data available. Exposure levels presented are the result of the analysis done on a sample taken between 1990 and 1999, with geometric mean exposure representative of 1995. The 2010 geometric mean exposures was extrapolated from the 1995 geometric mean exposure based on an estimated decrease in exposure of 7% per year. Due to the limited availability of exposure data it is not possible to present a systematic description of differences in exposure across the EU. The assumption used to determine exposure of different countries consider the extrapolated 2010 exposures level in high exposure industry groups (Table 17) as typical of exposures throughout the EU.

The exposure data available for high exposure NACE industries 27, 28 and 35 were collected from the UK National Exposure Database (NEDB) and data for NACE 24 were compiled for the EU Risk Assessment Report for Chromates using data from industry and the HSE NEDB. No data were found for NACE 28 but exposures are likely to be very similar to NACE 28⁸⁷.

A subset of chromium (VI) compounds (out of over 100), as shown in table 14, are listed in Annex XIV of the REACH Regulation and so are, or will be, subject to 'authorisation' for continued use.

Table 14. Chromium (VI) compounds currently in REACH Annex XIV

Substance	CAS No.	EC No.
Trichloroethylene	1979-1-6	201-167-4
Chromium trioxide	1333-82-0	215-607-8
Chromic acid, oligomers of chromic acid and dichromic acid, dichromic acid	7738-94-5; 13530-68-2	231-801-5; 236-881-5
Sodium dichromate	7789-12-0; 10588-01-9	234-190-3
Potassium dichromate	7778-50-9	231-906-6
Ammonium dichromate	7789-9-5	232-143-1
Potassium chromate	7789-00-6	232-140-5
Sodium chromate	7775-11-3	231-889-5

Available evidence (e.g. from the CAREX database) indicates that sodium, potassium, calcium and ammonium chromates and dichromates have been identified as the most important in terms of workers' exposures, a number of which are already regulated under REACH.

It is not possible based on available data to identify exposed populations or impacts associated only with chromium (VI) compounds which are not listed on REACH Annex XIV, nor to account for the impact REACH authorisation may have on exposures for those important compounds to which it will apply.

The IOM study assessed impacts of introducing an OEL for all chromium (VI) compounds, including those subject to REACH.

While this analysis is based on best available data, it should be noted that this results in likely overestimates of both the costs and benefits associated with setting an OEL under CMD for chromium (VI) compounds.

⁸⁷ Exposures in these NACE groups are similar because arise chiefly from welding and other hot work with stainless steel.

Table 15. Chromium (VI) compounds – Types of impacts

Impact	Option 1 Baseline - no OEL	Option 2 OEL of 0.025 mg/m ³	Option 4 OEL of 0.05 mg/m ³
Economic	<p>It is assumed that exposures will fall by 7% per year in the future. Therefore, there are expected to be some costs to firms where hexavalent chromium exposure requires firms to put into place ventilation measures to reduce inhalation exposure. These would occur regardless of further intervention over the period 2010 – 2069.</p>	<p>It is estimated that 27% of enterprises will require some form of control measure to meet the proposed OEL (estimate for all chromium (VI) compounds). It is assumed that the majority of those will require ventilation systems to reduce exposure levels to meet the OEL.</p> <p><u>Investment is expected to occur already under the baseline, only possibly later in time: the costs of anticipating this expenditure by 10-20 years would be in the range of €13.4bln-€52.3 bln.</u></p> <p>However, there appears to be a significant burden on SMEs.</p> <p>The up-front capital cost of a ventilation system is estimated to be in the region of €42k -252k. This is likely to be a significant cost which may potentially result in those companies stopping their use of chromium or forcing the closure of some companies, if they are dependent upon the use of hexavalent chromium and are unable to make the necessary investment to achieve appropriate levels of to protect workers' health.</p>	<p>It is estimated that 16% of enterprises will require some form of control measure to meet the proposed OEL. It is assumed that the majority of those will require ventilation systems to reduce exposure levels to meet the OEL.</p> <p><u>Investment is expected to occur already under the baseline, only possibly later in time: the costs of anticipating this expenditure by 10-20 years would be in the range of €3.6bln-€13 bln.</u></p> <p>However there appears to be a significant burden on SMEs. The up-front capital cost of a ventilation system is estimated to be in the region of €42k - 252k. This is likely to be a significant cost, which may potentially result in those companies stopping their use of chromium or forcing the closure of some companies, if they are dependent upon the use of hexavalent chromium.</p>

Social (incl. health)	<p>23,640 work-related cancer cases are expected to be registered in the period 2010-2069.</p> <p>No. of deaths from lung and sinonasal cancer in: 17,370.</p> <p>The health costs over the period 2010-69 are estimated to be around €8.6-27bln.</p> <p>As it is assumed that exposures fall by 7% per year in the future, there is expected to be a significant reduction in health costs going forward in the absence of further regulatory intervention.</p>	<p>1810 cancer cases would be avoided compared to the baseline.</p> <p>No. of avoided deaths from lung and sinonasal cancer in 2060: 1670.</p> <p>There are expected to be benefits from avoided health care and reduced cost of illness due to reductions in cancer registrations.</p> <p>The benefits are most apparent from 2040 onwards. Total benefits are estimated at €591mln-1.7 bln.</p>	<p>1320 cancer cases would be avoided compared to the baseline.</p> <p>No. of avoided deaths from lung and sinonasal cancer in 2060: 1240.</p> <p>There are expected to be benefits from avoided health care and reduced cost of illness due to reductions in cancer registrations.</p> <p>The benefits are most apparent from 2040 onwards. Total benefits are estimated at €440mln-1.3bln.</p>
Environmental	<p>It is considered that the controls in place to control environmental emissions are sufficient to control the potential risks to the environment.</p>	<p>No different to the baseline.</p>	<p>Not different to the baseline</p>

The baseline scenario for all industries assumes a 7% annual decline in exposure levels and standards change in employed numbers up to the 2021-30 estimation interval. Due to cancer latency, cancer cases - derived as a consequence of past exposure - will continue to affect workers' population until 2030. This situation urges a timely intervention in regulating exposure levels since the introduction of an EU-wide OEL could have a significant positive long-term impact on workers' health. The number of future cancer cases can be most substantially decreased through full compliance with an OEL of 0.025 mg/m³. In addition to the importance of combating cancer it should be noted that the chemical agents may cause other adverse health effects at comparable threshold levels including nasal irritation, severe skin damage or renal toxicity.

Figure 14 in Annex 9 synthetises the changes in the valence state of chromium at all stages of industrial use from mining production, to downstream industry activity and to end use. Hexavalent chromium and trivalent chromium have been coloured coded to emphasise the different states of chromium at the different stages of use.⁸⁸

In 2005 the main industrial uses of the chromium (VI) compounds are summarised in Table 16. In 2007 the last EU producer of hexavalent chromium compounds, located in the UK, closed down following declines in the market.

⁸⁸ See Figure 14. Overview of Chromium Valence State in Chromium Applications (annex 9).

Table 16. Main industrial uses of the chromium (VI) compounds

Cr (VI) compound	Use
sodium chromate	manufacture of other chromium compounds (in 2010, no longer undertaken)
sodium dichromate	manufacture of other chromium compounds (no longer undertaken in 2010) manufacture of wood preservation products vitamin K manufacture mordant in dyeing wax manufacture metal finishing
chromium trioxide	metal finishing manufacture of wood preservation products catalyst manufacture chromium dioxide manufacture pigment manufacture
potassium dichromate	pigment manufacture manufacture of wood preservation products dye manufacture catalyst manufacture chromium metal manufacture colouring agent in ceramics
ammonium dichromate	magnetic tape manufacture catalyst manufacture mordant in dyeing pigment manufacture

Source: HSE (2007) Human Health Risk Reduction Strategy for Chromates in IOM (2011) Hexavalent Chromium, pp. 5

In the EU certain industries have been classified as high in terms of workers exposure to hexavalent chromium. These industries, grouped by NACE code, were identified from CAREX data and are summarised in the table below.

Table 17. Classification of Industries with High Level Exposure

Industry	NACE	Historical Exposure Classification	Number of People Exposed in 2006
Manufacture of chemicals and chemical products	24	High	42452
Manufacture of basic metals	27	High	29670
Manufacture of fabricated metal products, except machinery and equipment	28	High	288480
Manufacture of machinery and equipment n.e.c.	29	High	134067
Manufacture of other transport equipment	35	High	41643
Manufacture of furniture; manufacturing n.e.c.	36	High	15942

Compliance cost analysis shows that the majority of firms within affected industries would meet the most stringent proposed OEL (0,025 mg/m³) given that the estimated geometric mean (2010) is between 0.002-0.005 mg/m³. However, risks for workers' health are still consistently high as shown in Table 18. There are substantial percentages of workers within each industry (NACE) who are exposed above OELs proposed under options 2 and 4. This situation calls for timely

and effective actions at the EU level to ensure that workers' health and safety at work is safeguarded.

Exposure risks are particularly high in SMEs. Small companies have been found⁸⁹ to be at particular risk of lacking adequate control especially in the manufacture of pigments and dyes, the formulation of metal treatment products electroplating and wood dyeing. An inspection of 29 chrome plating facilities found that those that used hexavalent chromium were considered not to be adequately controlling the risks and most were not complying with the relevant legislation. An EU-wide OEL would then have the positive effect of raising public awareness of these important occupational health hazards and contribute to better monitoring of exposure levels and increased compliance of industries.

Table 18. Estimated percentages of workers with exposures exceeding the proposed OEL (Option 2) in high exposure industries

OEL (mg/m ³)	NACE CODE					
	24	27	28	29	35	36
0.025	13.6%	3.0%	10.8%	10.8%	28.0%	10.8%
0.05	8.1%	0.8%	6.1%	6.1%	19.9%	6.1%

Some firms within affected industries would require further control measures to meet the proposed OEL given that estimated geometric standard deviations range from 3.8-14. For enterprises that would need ventilation systems to comply with an OEL of 0,025 mg/m³ there would be a significant up-front capital cost.⁹⁰

It is possible that some firms might be able to pass through additional costs in the form of higher prices for their final products since the OEL would be applied consistently across the EU. This should create a 'level playing field' for firms across the EU and reduce competitiveness distortions created by differences on OELs across the EU.

On the macroeconomic side, short term spending on risk management measures may also be good for the economy as equipment manufacturers (ventilation systems), installers and others will benefit with money flowing through the economy. With fewer life year lost, there should be also a benefit to the economy through avoided loss of output and consumption in the future (post 2040). However, since compliance with an OEL would not change the current manufacturing process there is unlikely to be any significant change to macro-economic impacts.

It should further be noted that the impact of REACH authorisation on relevant chromium (VI) compounds cannot at this stage be reliably assessed, but should be expected to reduce exposures and result in reduced costs and benefits associated with setting an OEL for these chemical agents. When applying for REACH authorisations, enterprises need to also invest in risk management measures and demonstrate that risks are controlled (either 'adequately' or with 'appropriate and effective risk management measures' according to the case) – potentially driving investment in additional risk management measures.

A targeted REACH restriction (entry 47 of REACH Annex XVII) applies to placing on the market or use of (soluble) chromium (VI) compounds as a component of cement, which is prohibited above a certain concentration. While this restriction is relevant for worker protection, it should not be expected to significantly affect the overall exposure patterns and associated cost benefit assessments made in this report. In any case, this restriction was established prior to REACH (in 2005) and hence its effects have been taken into account in the IOM study.

⁸⁹ Health and Safety Executive (2007) Human Health Risk Reduction Strategy for Chromates

⁹⁰ Based on IOM consultants' discussion with suppliers, a ventilation system is estimated to be in the region of €42k-252k.

Table 19. Chromium (VI) compounds – Comparison of options

Criteria	Option 1 Baseline	Option 2 0.025 mg/m³	Option 4 0.05 mg/m³
Effectiveness	0	++	+
Efficiency	0	-	-
Coherence	0	+	+
Scientific advice	An exposure limit of 0,05 mg/m ³ may well provide adequate protection for workers exposed to poorly soluble hexavalent chromium compounds but consideration could be given to setting exposure limits at 0.025 or 0.01 mg/m ³ for other hexavalent chromium compounds.		
ACSH	OEL of 0.025 mg/m ³ .		

The preferred option is 2 which is more effective reducing exposure and therefore the number of deaths, while slightly more costly than option 4. In addition, it might trigger more investment in research and innovation as well as the adoption of products that do not contain chromium. Option 2 would then be expected to increase the dissemination of improved technologies and production methods. The potential volume of ventilation systems being required across the EU may also stimulate investment in R&D to produce more cost-effective systems. Furthermore, with fewer life years lost and cancer registrations, there should be a benefit to the economy through avoided loss of output and consumption in the future, for example due to greater productivity as well as greater consumption and greater taxes raised.

It should be noted that the workers group in the ACSH argued that even a binding limit of 0.025 mg/m³ would correspond to a high cancer risk. Employers' representatives did not make any specific comments in the ACSH opinion but the metal industry expressed their positive view on the establishment of an EU-wide binding OEL as a way to demonstrate appropriate control of the exposure at the workplace in the course of meetings between Commission services and industry and workers representatives (see point 9.2.6 in Annex 2).

Impact on Member States and proportionality

In the case of chromium (VI) compounds 21 Member States have no OEL for this agent or have one that is less protective of worker health than the 0.025 mg/m³ value recommended by ACSH. This includes 5 Member States where the national OEL is provided as a range, given that different OELs apply for different specific Cr(VI) compounds. Figure 15 in Annex 9 illustrates the ranges of existing national OELs compared to Option 2 the upper limit has been considered for those countries providing a range of values). The following Figure 16 shows distribution of exposed workers across the Member States.

Among the six Member States with the highest numbers of exposed, two have no OEL (DE, IT) Introduction of an EU OEL could ensure that lack of a national OEL or a less stringent OEL does not act as an incentive for business in decisions concerning the plant location. On the other hand, the fact that an OEL equal or close to the value proposed by the ACSH is already in place in one of the Member States with high numbers of exposed workers (FR) as well as in the US indicates that solutions exist to practically implement the OEL such that businesses are able to make appropriate investment to protect workers and demonstrate compliance.

It is estimated that approximately 83% of exposed workers are located in Member States with no OEL for this agent or one that is less protective of worker health. An action at EU level could

provide a minimum basis of protection against the risks arising from workers' exposure to these carcinogens for a significant proportion of workers at risk.

5.7 Ethylene oxide (EO)

EO is classified according to the criteria in the CLP Regulation as a category 1B human carcinogen based on limited human epidemiological evidence and other data that it may cause leukaemia.

It is used in the manufacture of production of consumer goods such as anti-freeze solvents and cosmetics. About 3.8 mln tonnes of EO are produced in Europe each year. The majority is used in the manufacturing of ethylene oxide derivatives such as ethylene glycols, which are used in the production of consumer goods.

It is estimated that approximately 15,600 workers in the EU are potentially exposed and that in the period 2000-2010 in the EU there were about 5 deaths or less per year from leukaemia that were attributable to exposure to ethylene oxide before the early 1980s, which corresponded to about 0.01% of all deaths from leukaemia and a loss of 82 Disability-Adjusted Life Years (DALYs) each year.

Global market for EO is expected to continue expanding.⁹¹

Table 20. Ethylene oxide (EO) – Types of impacts

Impact	Option 1 Baseline - no OEL	Option 2 OEL of 1 ppm, Sk.
Economic	It is assumed that industries affected have already incurred costs of installing control measures to reduce ethylene oxide emissions. Hospitals may replace EO sterilisation units with non-EO alternatives which are associated with fewer health hazards. The development of feasible alternatives may benefit research and development in exposure controls.	Controls on EO in the workplace needed to meet the possible OEL of 1ppm have largely been installed; therefore it is assumed there is not expected to be any significant additional compliance cost in meeting an OEL of 1ppm relative to the baseline scenario. Hospitals may replace EO sterilisation units with non-EO alternatives which are associated with fewer health hazards. The development of feasible alternatives may benefit research development in exposure controls.
Social (incl. health)	There is not expected to be any noticeable social impacts under the baseline scenario. Large-scale implementation of control measures during the 1980s and 1990s means that exposure is already well below 1ppm. Therefore there is not estimated to be a cancer risk from worker exposure ethylene oxide under current conditions.	There are not expected to be any social impacts relative to the baseline scenario from introducing an EU-wide OEL. The impacts of introducing an EU-wide OEL at 1ppm is estimated to have no health benefits as exposure is already estimated to be controlled to below 1ppm .
Environmental	None – controls on EO in the workplace needed have already been implemented.	None – controls on EO in the workplace that would be needed to meet the possible OEL have already been implemented.

⁹¹ See Figure 17 - The Global Ethylene Trade (Annex 9).

No ethylene oxide exposure data were available from industry. The peer-reviewed scientific literature for occupational exposure data for the three main uses of EO (i.e. chemical manufacturing, industrial sterilization, hospital sterilization) shows a baseline scenario that suggest that EO exposures is generally already below 1 ppm. As a consequence there are not health benefit are expected since exposure is already estimated to be controlled to below 1ppm under the baseline scenario.

The economic impact of the baseline scenario highlights that industries affected have already incurred costs of installing control measures to reduce EO. On the other hand, the economic benefits could affect mostly research and development due to the introduction of non-EO alternatives in hospitals.

Other costs and benefits related to 'social', 'macro-economic', and 'environmental' impact of the baseline scenario are negligible.

Administrative costs of setting the limit of 1 ppm for employers (i.e. minimising exposure of workers; redesign work processes; hygiene measures; information of workers; training staff; make information available; consultation with employees; etc.) are estimated to be low since firms have already been required to carry out these measures following national legislation.

Where there is the possibility of a significant uptake via dermal exposure SCOEL recommend that any OEL be accompanied by a 'skin notation' (in the case of ethylene oxide ACSH endorsed this aspect of the SCOEL Recommendation). If adopted and accordingly transposed by Member States, employers are required under the national transposing legislation to take this into account in selecting appropriate risk management measures to protect workers.

Once the need for managing exposure has been established the only risk management measure available in practical terms is to avoid skin contact. Ethylene oxide has a harmonised classification as a skin irritant (category 2). This hazard would normally result in employers taking steps to avoid skin contact as a part of routine OSH risk control. Adoption of a 'skin notation' should therefore result in no additional cost for employers.

Table 21. Ethylene oxide (EO) – Comparison of options

Criteria	Option 1 Baseline	Option 2 1 ppm, Sk.
Effectiveness	0	≈
Efficiency	0	≈
Coherence	0	+
Scientific advice	SCOEL states that at exposures of 1 ppm 'no genotoxic changes could be directly established in exposed humans so far.' ⁹² A skin notation is warranted, as clear signs of systemic toxicity were reported after local application of ethylene oxide.	
ACSH	OEL of 1 ppm (= 1.83 mg/m ³).	

The opinion of the social partners and Member States in the ACSH supports option 2, and the CMD further establishes an expectation that OELs be set where it is possible to do so.

⁹² Recommendation from the Scientific Committee on Occupational Exposure Limits for ethylene oxide, SCOEL/SUM/160, June 2012

Impact on Member States and proportionality

In the case of ethylene oxide nine Member States have no OEL for this agent or have one that is less protective of worker health than the value recommended by ACSH, so introduction of an OEL of 1 ppm would represent a significant change in this sense.

The Figure 18 in Annex 9 illustrates the ranges of existing national OELs compared to Option 2. The following Figure 19 shows distribution of exposed workers across the Member States.

The two Member States where the production and/or use of this chemical agent is concentrated and the numbers of exposed workers are the highest (DE, UK) have no OEL or OELs above the limit proposed by the ACSH. Introducing an OEL would bring a greater clarity for economic operators across the EU and 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. An OEL of 1 ppm is already in place e.g. in Australia, Canada, US, Switzerland, New Zealand and Japan.

It is estimated that approximately 43% of exposed workers are located in the nine Member States with no OEL or an OEL less protective than proposed. Even if current exposure levels in the EU are estimated to be below 1 ppm, 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 achieve this objective could be justified.

5.8 *o*-Toluidine

This chemical agent may cause bladder cancer. Occupational exposure is most likely to occur through inhalation and dermal contact.

o-Toluidine is utilised in the production of dyes and pigments. The industries in Europe that report the highest workers' exposure levels are: i) Manufacture of chemicals, chemical products and man-made fibres; ii) Manufacture of rubber products. In the chemical industry exposure to *o*-toluidine can occur during its production and during its use in the production of herbicides, dyes and pigments, rubber chemicals, epoxy resin hardeners, fungicide intermediates, and pharmaceutical intermediates. *o*-Toluidine appears to have been relatively well controlled in most chemical manufacturing facilities for the past several decades.

The available data indicates that the EU *o*-toluidine production is centred in France, Germany, Italy, the Netherlands and the United Kingdom⁹³. The available information suggests that there is no *o*-toluidine production in the rest of Europe.

In the EU there are approximately 5,500 workers who are potentially exposed to *o*-toluidine. The prevalence of exposure to *o*-toluidine was estimated from the Finnish CAREX estimates. The proportion of exposed workers from the Finnish estimate was applied to information on the number of employees in each industry obtained from the structural business statistics and the Labour Force Survey available on the Eurostat database. The Finnish proportion of exposed workers was multiplied by the number of workers in each industry in each other Member State.

Since Finland does not manufacture *o*-toluidine, the estimate of workers' exposure in manufacturing countries (France, Germany, Italy, the Netherlands and the United Kingdom) might be underestimated.

It was judged that 98% of workers are exposed to less than 0.1 ppm. In recent years exposure levels have been decreasing by about 8.8% per annum.

⁹³ IARC 2010

Table 22. *o*-Toluidine – Types of impacts

Impact	Option 1 Baseline - no OEL	Option 2 OEL of 0.1 ppm	Option 4 OEL of 1 ppm
Economic	There are expected to be costs to <i>o</i> -toluidine related firms to put into place improved training and cleaning measures to reduce inhalation and dermal exposure that would occur regardless of further intervention over the period 2010-2070.	It is estimated that approximately two percent of exposures are above 0.1 ppm. Consequently there are some minimal costs for companies that do not currently comply (€0.5-€2K per company). <u>The total cost for all concerned companies of anticipating investment, which is assumed to take place already under the baseline, is in the range of €0.2-1.3 mln</u>	Minimal – the vast majority of investment required to control exposure associated with the manufacture of <i>o</i> -toluidine has already occurred in the last 20 years.
Social (incl. health)	The health costs of cancer (bladder) over the period 2010 – 2070 are estimated to be €86mln to €696mln It is assumed that exposures will fall by 8.8% per year in the future. Therefore, there is expected to be some reduction in health costs going forward in the absence of further regulatory intervention.	Small cost saving (a few €k) from avoided health care. Benefit €1.3mln to €10.1mln.	No change - There are not expected to be any additional health costs relative to the baseline scenario. There are expected to be negligible additional health benefits relative to the baseline scenario, as exposure is already expected to be largely / wholly below 1 ppm.
Environmental	Minimal - Only 2% of workers exposed to <i>o</i> -toluidine are estimated to be exposed above 0.1 ppm, and therefore most workplaces are unlikely to require further changes to their existing working practice. The risk of more direct or more concentrated emissions of <i>o</i> -toluidine to the environment (through ventilation), is therefore small.	Minimal Cost – it is expected that the imposition of measures would not cause significant additional environmental impacts. At the same time, it is not expected that the measures for human health would lead to any significant additional environmental benefit above the baseline	Similar to the baseline as controls on <i>o</i> -toluidine in the workplace already in place.

On the basis of estimates of the number of workers exposed and the Eurostat data on the distribution of firms by size, broad estimates of the number of enterprises requiring further action to comply with each proposed EU-wide OEL were produced (Table 23-24).

Tables 23-24 show that a total of nine firms are estimated to be affected by an EU-wide OEL at 0.1 ppm while no firms would be affected if an OEL of 1 ppm were to be introduced. It is not expected that there would be any significant and additional potential closure of companies as a result of introducing an EU-wide OEL of 0.01 ppm because compliance costs are likely to be minimal.

Table 23. Numbers of Enterprises affected in NACE group 25.1

NACE 251		0.1ppm	1ppm
No: of employees bands	Average composition of enterprises for all affected NACE sectors	No of enterprises affected	No of enterprises affected
Between 1 and 9	58%	7	0
Between 10 and 19	14%	1	0
Between 20 and 49	12%	0	0
Between 50 and 250	12%	0	0
Greater than 250	5%	0	0
Total affected	-	8	0
Percentage of affected firms relative to total number of firms in the sector		-	-

Table 24. Numbers of Enterprises affected in NACE division 23

NACE 23		0.1ppm	1ppm
No: of employees bands	Average composition of enterprises for all affected NACE sectors	No of enterprises affected	No of enterprises affected
Between 1 and 9	61%	1	0
Between 10 and 19	14%	0	0
Between 20 and 49	11%	0	0
Between 50 and 250	10%	0	0
Greater than 250	4%	0	0
Total	-	1	0
Percentage of affected firms relative to total number of firms in the sector		0.01%	0%

The industrial sector estimated to benefit most from the introduction of an EU-wide OEL is the manufacture of chemicals. The administrative costs for employers are estimated to be low in both baseline scenario and in the intervention scenario of OEL 1 ppm, since most of the investments needed to decrease the exposure have already been made. Low to medium costs would involve firms that do not currently comply with baseline scenario in case an OEL of 0.1 ppm was going to be implemented.

Table 25. *o*-Toluidine – Comparison of options

Criteria	Option 1 Baseline	Option 2 0.1 ppm	Option 4 1 ppm
Effectiveness	0	+	≈
Efficiency	0	≈	+
Coherence	0	+	+
Scientific advice	IOM Study considered potential OELs of 0.1 ppm (0.4 mg/m ³) and 1 ppm (4.4 mg/m ³) as 'typical' values of existing national OELs in the EU.		
ACSH	Proposes an OEL of 0.1 ppm		

Neither option is predicted to give rise to any important reduction in bladder cancer death or registrations over the baseline assumptions, primarily because exposures are already very low. However, the preferred option is 2 as it brings some health benefits while generating only slightly higher costs than option 4. Industry is almost fully compliant with this OEL already and 0.1 ppm has been accepted by all parties in the ACSH discussions. Switzerland and New Zealand have set lower OELs for this chemical agent.

Impact on Member States and proportionality

In the case of *o*-Toluidine 25 Member States have no OEL for this agent or have one that is less protective of worker health than the value recommended by ACSH. The Figure 20 in Annex 9 illustrates the ranges of existing national OELs compared to Option 2. The following Figure 21 shows distribution of exposed workers across the Member States.

Thus, introduction of an OEL of 0.1 ppm would represent a significant change in this sense. It is estimated that approximately 98% of exposed workers are located in those 25 Member States. Even if current exposure levels in the EU are estimated to be largely below 0.1 ppm, a minimum basis of protection against the risks arising from workers' exposure to these carcinogens cannot be ensured for all EU workers under the baseline scenario – it follows that an action taken at the European Union level to achieve this objective could be justified.

5.9 Refractory Ceramic Fibres (RCF)

Occupational exposure to RCFs is associated with adverse respiratory effects as well as skin and eye irritation and may pose a carcinogenic risk based on the results of chronic animal inhalation studies. However, epidemiologic studies have found no association between occupational exposure to airborne RCFs and an excess rate of pulmonary fibrosis or lung cancer. Based on the animal test results, certain RCFs are classified according to the CLP Regulation as Carc. 1B (may cause cancer by inhalation).

RCFs are synthetic vitreous fibres or man-made mineral fibres used in industry for their properties of heat resistance, tensile strength and durability. The total tonnage of RCF used in the EU is about 25,000 tonnes per year, 90% of which is used for industrial insulation. Ceramic fibres are typically used only in industrial settings, implying no consumer exposure.

For the estimations, due to unavailability of epidemiological data, exposure to RCFs has been assumed to be no worse than exposure to chrysotile (white) asbestos in terms of cancer risk.

On the basis on information provided by the European Ceramic Fibre Industry Association, it is estimated that about 10,000 workers are exposed to RCF across the EU. Of these, about 730 are employed in RCF production plants in Germany, France and the UK, and about 9,270 in the downstream user industry (a breakdown by Member State not available. Geometric mean exposures in the industry are less than 0.2 fibres/ml and it is estimated that about 7% of workers in manufacturing facilities and 12% of workers at downstream user facilities have been exposed above 1 fibres/ml. More than half of workers are exposed above 0.1 fibres/ml. A majority of the companies in question (downstream use) are SMEs.

It should be noted that, in December 2011, certain RCFs were identified as 'substances of very high concern' under REACH owing to classification under CLP as a category 1B carcinogen. This constitutes the initial step toward possible inclusion into REACH Annex XIV and hence REACH 'authorisation'. In February 2014 the European Chemicals Agency further recommended to the European Commission that RCF, among other chemical substances, be included into REACH Annex XIV.

Two possible substitutes for RCF are Alkaline-Earth Silicate Glass Wool (AES), which however is an imperfect substitute (having a lower applicable temperature range for thermal insulation), and Polycrystalline Wool (PCW), which however is 20 times more expensive than RCF.

Table 26. Refractory Ceramic Fibres (RCF) – Types of impacts

Impact	Option 1: Baseline: No OEL	Option 2: OEL of 0.3 f/ml	Option 3: OEL of 0.1 f/ml	Option 4: OEL of 1 f/ml
Economic	A 7% annual decline in average exposure is assumed until 2030.	<u>The total cost for of anticipating investment, which is assumed to take place already under the baseline, is in the range of EUR 1-6 mln.</u> Substitution with alternatives would not occur.	To achieve exposure at this level would require a degree of automation and enclosure that is deemed not to be feasible for certain downstream uses. <u>Estimated total additional costs is in the range of EUR 60-139mln.</u> If achieving the OEL is technically or economically infeasible, companies may decide to substitute RCF with alternatives. In such case, the associated total costs could be of the order of EUR 2.5 bln. It is possible that such an OEL could lead to firms relocating production processes outside of the EU.	No additional significant costs for firms vs. the baseline are expected, as average exposure is already below 1 fibres/ml.
Social (incl. health)	Total attributable deaths for 2010-2069: 50. Total YLLs: 830. Total DALYs: 860. The total cancer-related health costs over a 60-year period are estimated to be in the range of EUR 33-83mln.	Total attributable deaths for 2010-2069: 0. Total YLLs: 790 (40 less than the baseline). Total DALYs: 800 (50 less than the baseline). Net cancer-related health benefits are estimated to be in the range of EUR 1.1-3.4mln.	Total attributable deaths for 2010-2069: 0. Total YLLs: 790 (40 less than the baseline). Total DALYs: 800 (50 less than the baseline). Net cancer-related health benefits are estimated to be in the range of EUR 1.2-3.4mln.	Total attributable deaths for 2010-2069: 0. Total YLLs: 790 (40 less than the baseline). Total DALYs: 810 (40 less than the baseline). Net cancer-related health benefits are estimated to be in the range of EUR 1.1-3mln.
Environmental	None.	None.	The use of AES and PCW as substitutes for RCF as a furnace insulation has environmental costs including worsened energy efficiency.	None.

The values of health benefits are relatively low for all the options because of the low level of assumed cancer incidence under the baseline and the existing controls in place.

Option 3 would be the most effective option in reducing occupational exposure to carcinogens and levelling the playing field across the Union. However, it raises significant problems of technical feasibility (the OEL may de facto not be achievable in some instances) and imposes therefore excessive burden on firms even if some of the costs associated with substitution of RCF with more expensive alternatives (such as PCW) would be passed through to consumers via higher prices. Option 2 appears to be more efficient. It leads to a similar reduction of Years of Life Lost and Disability Adjusted Life Years as Option 3, but at a significantly lower cost.

Table 27. Refractory Ceramic Fibres (RCF) – Comparison of options

Criteria	Option 1 Baseline: No OEL	Option 2: 0.3 f/ml	Option 3: 0.1 f/ml	Option 4: 1 f/ml
Effectiveness	0	++	++	+
Efficiency	0	-	--	≈
Coherence	0	+	+	+
Scientific advice (SCOEL)	RCF is considered as a genotoxic carcinogen for which a practical threshold is supported. An OEL of 0.3 f/ml is proposed.			
ACSH	Agrees that an OEL is necessary but could not reach agreement on exact value (between 0.3 f/ml and 0.1 f/ml).			

Option 2 because is the most effective and corresponds to the limit recommended by SCOEL. Some MS have already imposed nationally a similar OEL, and there are no concerns regarding technical feasibility. In addition, this is the minimum common denominator of ACSH discussions. Employers advise to follow the recommendation of SCOEL. They also stress that industries have been working on a 0.5 f/ml exposure limit for many years, and further reductions of exposure are technically difficult. Views of Member States range from 0.3 f/ml to 0.1 f/ml. The workers argue for an OEL 0.1f/ml on the basis of considerations detailed in the scientific explanations given for the exposure risk relationship on aluminosilicate fibres derived in Germany, according to which aluminosilicate fibres exhibit a carcinogenic potency comparable to asbestos.⁹⁴

Impact on Member States and proportionality

In the case of RCF, 24 Member States have no OEL for this agent or have one that is less stringent than 0.3 f/ml. Figure 22 in Annex 9 illustrates the ranges of existing national OELs compared to Option 2. There is insufficient data to provide a breakdown by Member State.

RCF is only manufactured in three MS (FR, UK, DE) but exposure from use and disposal (e.g. from insulation in furnaces) may be located across Europe. Thus, introduction of an OEL of 0.3 f/ml would require changes for a substantial number of MS. The analysis shows that a minimum basis of protection against the risks arising from workers' exposure to these carcinogens cannot be ensured for all EU workers under the baseline scenario – it follows that an action taken at the European Union level to achieve this objective could be justified.

5.10 Respirable Crystalline Silica

RCS is taken here to mean 'the respirable fraction of crystalline silica dust generated by a work process'. RCS, so-defined, is a process generated substance which is not placed on the market

⁹⁴ Begründung zur Exposition-Risiko-Beziehung für Aluminiumsilikat-Fasern, AGS-Geschäftsführung - BAuA

and, as such, is not classified under the CLP Regulation. This is the reason why it is proposed to be included in Annex I of the CMD. In addition, a few options for an OEL value to be included in the Annex III are considered.

IARC has stated its opinion that 'crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans (Group 1)'.⁹⁵

Crystalline silica is abundant in rocks, sands and soils. Exposure to RCS therefore occurs in many industries. Common exposure scenarios include earth moving (eg. mining, quarrying, tunnelling), crushing or grinding of silica-containing material such as concrete, aggregate or mortar, the manufacture of glass and other non-metallic mineral products and the use of sand as moulding media in foundries.

It is estimated that 5,300,000 EU workers are potentially exposed, more than 70% of them in the construction sector. Beside construction, the following industries are estimated to have the highest exposure levels compared to the other industry sectors as well as the highest numbers of exposed workers: manufacture of other non-metallic mineral products, other mining and quarrying, manufacture of basic metals, manufacture of fabricated metal products, electricity, gas, steam and hot water supply.

Table 28. Respirable Crystalline Silica – Types of impacts

Impact	Option 1: Baseline - not under Annex I, no OEL	Option 2: Inclusion in Annex I and OEL at 0,1 mg/m³ in Annex III	Option 3: Inclusion in Annex I and OEL at 0,05 mg/m³ in Annex III	Option 4: Inclusion in Annex I and OEL at 0,2 mg/m³ in Annex III
Economic	<p>It is assumed that exposures fall by 7% per year</p> <p>Therefore firms will already be incurring costs for exposure control measures even without EU intervention.</p> <p>There are not expected to be any noticeable macroeconomic impacts.</p>	<p><u>Investment is expected to occur already under the baseline, only possibly later in time: the costs of anticipating this expenditure by 10-20 years would be around €3.5 bln.</u></p> <p>The greatest costs are predicted to fall on the construction sector given the number of enterprises thought to be affected (around 370,000). An impact on SMEs is</p>	<p><u>Investment is expected to occur already under the baseline, only possibly later in time: the costs of anticipating this expenditure by 10-20 years would be around €15.7 bln.</u></p> <p>The greatest costs are predicted to fall on the construction sector given the number of enterprises thought to be affected (around 485,000). A</p>	<p><u>Investment is expected to occur already under the baseline, only possibly later in time: the costs of anticipating this expenditure by 10-20 years would be around €207 mln.</u></p> <p>The greatest costs are predicted to fall on the construction sector given the number of enterprises thought to be affected (around 250,000). The impact on companies and particularly on SMEs is weaker as costs of compliance would be</p>

⁹⁵ <http://monographs.iarc.fr/ENG/Monographs/vol68/mono68-6.pdf> In making its overall evaluation the IARC Working Group noted that carcinogenicity in humans was not detected in all industrial circumstances studied, and that carcinogenicity may be dependent on inherent characteristics of the crystalline silica, or on external factors affecting its biological activity or distribution of its polymorphs. It should be noted that the common silica 'polymorphs' (i.e. different forms of crystallised silica) quartz, cristobalite and tridymite have all been classified according to the CLP Regulation by suppliers. Some suppliers have classified quartz and cristobalite as carcinogenic category 1. Tridymite has not been so classified. No harmonised (mandatory) classification has been proposed.

Impact	Option 1: Baseline - not under Annex I, no OEL	Option 2: Inclusion in Annex I and OEL at 0,1 mg/m³ in Annex III	Option 3: Inclusion in Annex I and OEL at 0,05 mg/m³ in Annex III	Option 4: Inclusion in Annex I and OEL at 0,2 mg/m³ in Annex III
		<p>foreseen, with a risk of closures or relocations outside the EU. This is due to high costs linked with the installation of exposure control measures.</p> <p>There will be some short terms benefits (for ventilation and respiratory protective equipment manufacturers).</p>	<p>significant impact on SMEs is foreseen, with a high risk of closures or relocations outside the EU. This is due to high costs linked with the installation of exposure control measures.</p> <p>There might be some short terms benefits (ventilation and respiratory protective equipment manufacturers). However compliance costs might be passed on to consumers (higher prices).</p>	<p>lower.</p>
Social	<p>Total attributable deaths for 2010-2069: 440 000 deaths.</p> <p>There is also expected to be some reduction in health costs. The health costs of cancer (lung) over the period 2010- 70 are estimated to be €192-493bln. There is estimated to be a greater number of firms installing and using closed systems and using RPE, PPE and wet cleaning rather than dry cleaning.</p> <p>These should not affect the skills required by</p>	<p>Total attributable deaths for 2010-2069: 341.330, i.e. 98.670 less than under baseline.</p> <p>Net health benefits are estimated to range between €34 and 89 bln.</p> <p>The introduction of the OEL may affect job patterns and would necessitate new health and safety training. The potential closing down or relocation of companies would have a negative impact on employment; however, the reduction of exposure would</p>	<p>Total attributable deaths for 2010-2069: 332.650, i.e. 107.350 less than under baseline.</p> <p>Net health benefits are estimated to range between €36.5 and 97.1 bln.</p> <p>The introduction of the OEL may affect job patterns and would necessitate new health and safety training. The potential closing down or relocation of companies would have a negative impact on employment; however, the reduction of</p>	<p>Total attributable deaths for 2010-2069: 357.620, i.e. 82.380 less than under baseline.</p> <p>Net health benefits are estimated to range between €27.7 and 73.7 bln.</p> <p>As the risks of closure are expected to be smaller – and even minimal if financial assistance schemes are made available for SMEs – there is not significant impact on employment.</p>

Impact	Option 1: Baseline - not under Annex I, no OEL	Option 2: Inclusion in Annex I and OEL at 0,1 mg/m³ in Annex III	Option 3: Inclusion in Annex I and OEL at 0,05 mg/m³ in Annex III	Option 4: Inclusion in Annex I and OEL at 0,2 mg/m³ in Annex III
	<p>workers and training costs are expected to be small.</p> <p>Since the control measures such as closed system reduce risks of human exposure in a way that should not inhibit production, there should also be improvements in working conditions.</p> <p>The use of wet cleaning and RPE should also reduce risks of human exposure, although their use may potentially slow down operations or be perceived to do so.</p>	<p>improve working conditions.</p>	<p>exposure would improve working conditions. The OEL could require workers to be constantly wearing respiratory protective equipment as levels of exposure will be close to the natural background level of RCS in air.</p>	
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Environmental</p>	<p>Very little information is available regarding the ecotoxicity of RCS. No significant environmental effects are expected due to the chemical inertness and slow solubility of the chemical agent. Crystalline silica is resistant to decomposition by weathering, biological activity and further oxidation.</p>	<p>No major environmental impact is foreseen. There might some impact due to increased emission of RCS to the environment, and additional demand for electricity due to ventilation systems.</p>	<p>The same as in Option 2.</p>	<p>The same as in Option 2.</p>

As in the case of all other considered chemical agents, the exposure trends for RCS used to establish the baseline are quoted from the IOM study. The validity of these assumptions is discussed in the introduction to section 5. Specifically for silica the correctness of the assumed

7% decline can be further questioned based on the fact that among the three studies that IOM used to build this assumption, two are only looking at quarries. The only one that analyses all industries comes from the US. Lack of data for the two principal exposure sectors ("construction" and the "electricity, gas, steam and hot water supply") weakens the assumption of exposure decline.

A different exposure trend can be derived for example from a Finnish study (Kauppinen et al., 2013)⁹⁶, which looked at data from FINJEM database, starting in 1950 and projected trends till 2020. This study found that an overall exposure decline was 1% rather than 8%. The data presented in this study shows also that exposures were declining significantly faster between 1950 and 1990, compared to more recent years.⁹⁷

Even with the IOM studies estimates, a high proportion of workers are considered to still be at risk of being exposed above the considered OELs (14% above 0.2 mg/m³, 26% above 0.1 mg/m³, 41% above 0.05 mg/m³), and the estimated mean exposure is 0.07 mg/m³.

The prevalence of exposure to RCS in the IOM report was estimated from a Finnish, a Spanish and an Italian study. The proportion of exposed workers in each industry was taken from each of these three studies and the average proportion exposed across all three countries was found for each industry. The average proportion of exposed workers was applied to information on the number of employees in each industry obtained from the structural business statistics and the Labour Force Survey available on the Eurostat database. The average proportion of exposed workers was multiplied by the number of workers employed in each industry in each country in 2006 to estimate the number of exposed workers in each industry and country.

However there is a limited availability of exposure data, and it is not possible to determine exposure differences across the EU. Moreover, exposure levels and therefore cancer risk vary greatly according to the sectors.

According to the IOM report, the countries with the highest numbers of exposed workers are Spain (26.8% of all EU workers), Germany (11.8%), France (11%) and the UK (9.4%).

In all industries with high prevalence of RCS exposure, the majority (between 58 and 94% depending on the industry) of companies are very small, with 1 to 9 employees. The industrial minerals industry alone consists mainly of SMEs with some large multinational companies. Members of the Industrial Minerals Association operate over 810 sites throughout Europe.

The IOM report recognises that the number of workers and enterprises affected by the proposed reduction in the OEL are likely to be an overestimate since the NACE codes include activities in which workers may not necessarily be exposed to RCS.

In all the considered options, introducing an OEL for RCS will contribute to reducing attributable deaths compared to no action, and the benefits of introducing an OEL may outweigh compliance costs. Moreover, any reduction of exposure will also lower the risk of silicosis. Indeed exposure to respirable crystalline silica in workplace air is associated with the development of silicosis, an irreversible scarring disease of the lung. Silicosis also appears to be a significant risk factor for the development of lung cancer. As the health costs of silicosis were not taken into account in the IOM report, the total health benefits of introducing an OEL are clearly higher than what has been indicated for the purposes of this proposal.

While the compliance costs are relatively high for all three options, they should be compared to the total value of goods and services in the affected sectors, which was €5 trillion in 2006.

⁹⁶ 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>

⁹⁷ See Figure 23 - Occupational inhalation exposure to crystalline silica (quartz dust) in Finland in 1950, 1970, 1990 and 2008 and predicted for 2020, as measured by four different metrics of exposure (Annex 9).

Moreover, the bulk of compliance costs will be already incurred under the baseline scenario (i.e. in the absence of EU action). Imposing an EU OEL would however oblige businesses to anticipate the corresponding investments.

It should also be added that the options have variable impacts on different sectors. For example, for quarrying, costs are significantly lower under option 4 compared to both 2 and 3. For some other sectors, such as foundry, brick manufacture or silica sand production options 2 and 4 result in the same costs. As for the construction sector, which represents a majority of the affected firms, average cost per enterprise is the same under all three options.

Option 3 would be the most effective in reducing occupational exposure to carcinogens but will have a negative impact on some sectors of the industry⁹⁸, and in particular on SMEs. Option 2 has similar characteristics, however its impact should be lower on the industry.⁹⁹ At least 17 countries are reported to have already introduced an OEL of 0,1 mg/m³ or below.¹⁰⁰ A majority of EU countries are therefore already compliant with Option 2, which indicates that the impact of introducing Option 2 would be lower than Option 3. Option 4 would imply the lowest compliance costs and the least negative impact on SMEs, however it would be less effective in reducing cancer. Moreover, the OEL of 0,2 mg/m³ would be higher than the majority of national OELs already in place. No significant environmental impact is foreseen in none of the options.

Some stakeholders argue that the Carcinogens Directive is not the appropriate legal framework to introduce OELs for RCS – instead, they argue for introduction of an EU OEL via the Chemical Agents Directive as the most efficient risk management tool.

A mechanism exists to establish EU OELs via the Chemical Agents Directive – these may be either 'binding' (mandatory maximum) or 'indicative' (indicated maximum) in nature, with Member States committed, as a minimum requirement, to in any case ensure that national OELs are established for the chemical agents in question, taking into account the values set at EU level.

However, RCS is a long- and widely-recognised occupational carcinogen – including long-standing classification by IARC. A clear threshold for silicosis development cannot be identified, and there is sufficient information to conclude that preventing the onset of silicosis will also reduce the cancer risk.¹⁰¹ It is therefore most appropriate to establish an EU OEL under CMD for this chemical agent where it is either generated as a result of a work process or otherwise classified as a category 1 carcinogen according to the CLP criteria.

Stakeholders also put forward existing guidelines and good practices. Most notably, as reported above, NEPSi requires signatories to follow good practices and monitoring protocol, and to provide quantitative data.

⁹⁸ Compared to option 4, option 3 creates higher costs per enterprise in the following sectors: quarry, foundry, ceramics, brick manufacture, silica sand production, scouring powders, stonemasonry.

⁹⁹ Compared to option 4, option 2 creates higher costs per enterprise in only three sectors: quarry, ceramics, stonemasonry.

¹⁰⁰ BE, BG, CZ, DK, EE, ES, FI, FR, HR, IE, LT, MT, NL, RO, SE, SK, UK

¹⁰¹ Further information on the carcinogenicity of silica can be found in Annex 12. The current SCOEL recommendation refers IARC Monograph 68. More recent information on the carcinogenicity of RCS in the IARC monograph volume 100C on arsenic, metals, fibres and dusts, which is likely to be taken into account in a future revised SCOEL recommendation, further confirms the carcinogenicity of RCS based on newer scientific evidence.

Table 29. Respirable Crystalline Silica (RCS) – Comparison of options

Criteria	Option 1: Baseline - not under Annex I, no OEL	Option 2: Inclusion in Annex I and OEL at 0,1 mg/m ³	Option 3: Inclusion in Annex I and OEL at 0,05 mg/m ³	Option 4: Inclusion in Annex I and OEL at 0,2 mg/m ³
Effectiveness	0	+	++	-
Efficiency	0	+	-	++
Coherence	0	++	+	-
Scientific advice (SCOEL)	An OEL should lie below 0.05 mg/m ³ of respirable silica dust			
ACSH	ACSH: A binding OEL at 0.1 mg/m ³ , measured as respirable dust, is justified. The value should be reviewed within 3-5 years.			

Option 2 (0,1 mg/m³) is a feasible option for EU industries, while still guaranteeing a substantial reduction of estimated attributable deaths due to lung cancer. Introducing an OEL of 0.05 mg/m³ would increase the estimated health benefits by around 10%, but would also increase the estimated compliance costs by close to 80%. It is therefore considered that the cost/benefit ratio of introducing an OEL 0,1 mg/m³ is better than introducing an OEL of 0.05 mg/m³.

It is also the level agreed by the ACSH even if there were some questions on the part of employers and some MS whether it would not be more appropriate to legislate under the CAD. Workers stated that further exposure reduction below the proposed binding OEL of 0.1 mg/m³ is paramount to reduce the risks of lung cancer, and silicosis.

According to the IOM report there is a risk that production would be affected as a result of the need to comply with more stringent OELs and with high compliance costs. Indeed, the majority of the companies that would be affected by the imposition of an OEL are SMEs and the costs may be very expensive for a large proportion of the affected sectors. If the costs cannot be passed through to consumer prices and/or some companies will not be able to get access to loans to pay for the necessary investment, there is a possibility of some company closures and, for industries for which it is possible, some relocation of activities in non-EU countries. Such impacts may be differentiated at the sector and sub-sector level, by geographical location, and/or at operator level.

Among the six Member States with the highest numbers of exposed workers (see Figure 25 in Annex 9), two have no OEL (DE, IT) and one has an OEL significantly less protective than 0.1 mg/m³ (PL) thus there is a case of competitive advantage compared to Member States which have adopted more stringent measures. On the other hand, the fact that an OEL equal or below the value proposed by the ACSH is already in place in the other three Member States with high numbers of exposed workers (ES, FR, UK) and in 14 other Member States indicates that solutions exist to practically implement the OEL.

It should also be noted that an OEL at 0,1 mg/m³ is comparable or higher to the levels applied in most non-EU countries (except notably China). For the USA, a new value of 0,05 mg/m³ is being proposed for RCS¹⁰². The proposed revision of the existing value is based on evidence that indicates employees exposed to RCS well below the current value of 0,1 mg/m³ are at increased risk of lung cancer mortality and silicosis mortality and morbidity. At the same time, it is assumed that an OEL of 0.05 mg/m³ would be technologically feasible for most affected

¹⁰² **Federal Register** / Vol. 78, No. 177 / Thursday, September 12, 2013 / Proposed Rules

industries, except two out of 12 construction activities, and would not have any major micro- and macro-economic impact.

Finally, the reluctance on the part of employers to accept that RCS is regulated under the CMD appears to be related to concern regarding the stricter standard for substitution and exposure control (process enclosure) resulting from application of the CMD over CAD. There is also some concern regarding stigmatisation of silica as a carcinogen and associated negative impacts on industry, for instance in case of 'social license'¹⁰³ to operate mines and quarries. It should however be noted that some forms of RCS have been classified as carcinogenic by the IARC since 1987. Potentially, compliance with an OEL provides an opportunity for industry to demonstrate to workers and others that the necessary measures to address the risks of handling this chemical agent are in place.

Impact on Member States and proportionality

In the case of RCS, 11 Member States have no OEL or have one that is less stringent than the ACSH recommended 0.1 mg/m³ level. Figure 24 in the annex 9 illustrates the ranges of existing national OELs compared to Option 2. Figure 25 shows distribution of exposed workers across the Member States.

33% of exposed workers are estimated to work in those 11 MS. Under such circumstances a minimum basis of protection against the risks arising from workers' exposure to these carcinogens cannot be ensured for all EU workers under the baseline scenario – it follows that an action taken at the European Union level to achieve this objective would be justified.

5.11 Vinyl Chloride Monomer (VCM)

Exposure to VCM is associated with increased risks of the usually rare form of liver cancer, angiosarcoma, and possible increased risks of hepatocellular carcinomas. VCM is classified as a Group 1 carcinogen by IARC, and as Cat 1 carcinogen in the EU under the classification and labelling legislation. An OEL of 3 ppm is currently in place at EU level.

95% of VCM¹⁰⁴ produced worldwide is used in the manufacture of Polyvinyl Chloride (PVC) and its associated polymers. The latter is then used to manufacture automotive parts and accessories, furniture, packaging materials, pipes, wall coverings, and wire coatings. VCM production is often located on the same site as the production of PVC. In 2007, 7.2 mln tons of VCM were produced in the EU and Norway in 30-40 plants located in 13 EU Member States¹⁰⁵ and Norway. In total, there are approximately 100 VCM manufacturing or polymerisation sites. There are no substitutes to VCM for VCM production.

In the EU, about 15,000 workers from VCM and PVC plants are estimated to be potentially subject to high exposure levels. No breakdown by Member State is available. Exposure to VCM outside VCM and PVC manufacturing industry is limited, with about 5 000 more workers (in manufacture of rubber and plastic products, water transport, supporting and auxiliary transport activity, R&D) potentially subject to (negligible) background exposure.

The risk estimates used in the IOM study for the assessment of health impacts are based on evidence provided by the existing epidemiologic literature. The estimates on current exposure

¹⁰³ The 'social license' concept describes ongoing approval within a local community or broad social acceptance.

¹⁰⁴ It should be noted that a targeted REACH restriction applies to placing on the market or use vinyl chloride (although not specified in monomer form) for use as an aerosol propellant, which is prohibited. This restriction is not relevant for worker protection, and it should not be expected to affect the exposure patterns and associated cost benefit assessments made in this report.

¹⁰⁵ Belgium, Czech Republic, Germany, Spain, France, Italy, Hungary, the Netherlands, Poland, Romania, Slovakia, Sweden and the UK.

levels used are derived from the existing scientific literature¹⁰⁶, and from exposure data collected in 2008 from 36 VCM and PVC plants (a non-random sample of the around 100 plants present in the EU). No detailed information is available on differences in exposure levels across Member States.

Table 30. Vinyl Chloride Monomer (VCM) – Types of impacts

Impact	Option 1 Baseline: OEL at 3 ppm	Option 2: OEL of 1 ppm	Option 4: OEL of 2 ppm
Economic	All firms are deemed to be compliant with the current EU OEL of 3ppm, with most VCM and PVC plants in the EU currently controlling VCM exposure well below such level. It is estimated that under the baseline scenario firms are already moving towards complying with the 1 ppm OEL.	A large majority of firms already control exposure below 1 ppm. Currently, 25% of the plants are estimated to have 90 th percentile exposure above 1ppm. The costs of upgrading equipment to meet the 1ppm exposure limit could be up to €2.5mln per VCM/PVC production site. The concerned plants would be located mainly in Czech Republic, Romania, Slovakia, Hungary and Poland. Investment is expected to occur already under the baseline, only possibly later in time: <u>the additional costs of anticipating this expenditure by 10 years – 2010 vs 2020 would be in the range of EUR 4-8 mln (€2-3mln if no additional shutdowns).</u>	A very large majority of firms already control exposure below 2 ppm. Currently, only 6% of the plants are estimated to have 90 th percentile exposure above 2ppm. The costs of upgrading equipment to meet the 2ppm exposure limit could be up to €0.25mln per VCM/PVC production site. Investment is expected to occur already under the baseline, only possibly later in time: <u>the additional costs of anticipating this expenditure by 10 years – 2010 vs 2020 would be below € 1 mln.</u>
Social	Total attributable deaths for 2010-2069: 300. Total YLLs: 4,270. Total DALYs: 4,350. The total cancer-related health costs over a 60-year period are estimated to be in the range of EUR 194-472mln.	Total attributable deaths for 2010-2069: 300. Total YLLs: 4,220 (50 less than the baseline). Total DALYs: 4,300 (50 less than the baseline). Net health benefits compared to the baseline are estimated to be between € 1-4 mln.	Total attributable deaths for 2010-2069: 300. Total YLLs: 4,250 (20 less than the baseline). Total DALYs: 4,330 (20 less than the baseline). Net health benefits are estimated to be €1-2mln.
Environmental	None.	None.	None.

Option 2 would be the most effective option in reducing occupational exposure to carcinogens and levelling the playing field across the EU. It also leads to the highest reduction of Years of Life Lost and Disability Adjusted Life Years. Already under the baseline the majority of companies is able to control exposure under the 1ppm exposure level, but option 2 would imply

¹⁰⁶ A summary of results of VCM exposure studies in the EU is reported in the IARC monograph on vinyl chloride, vol. 97, 2008.

that those enterprises who are not currently below that level would no longer be able to delay investment to introduce preventative measures and effectively minimise exposure. There is a ready market for VCM and no plant closures are expected to result from the implementation of a more stringent OEL.

Table 31. Vinyl Chloride Monomer (VCM) – Comparison of options

Criteria	Option 1: Baseline: OEL at 3 ppm	Option 2: OEL at 1 ppm	Option 4: OEL at 2 ppm
Effectiveness	0	++	+
Efficiency	0	≈/-	≈
Coherence	0	+	+
Scientific advice (SCOEL)	A continuous exposure for working life to 1ppm vinyl chloride would be associated with a cancer risk for hepatic angiosarcoma of about 0.3×10^{-3} .		
ACSH	Agreed limit = 1 ppm.		

Option 2 is the most effective and the closest to the limit recommended by SCOEL. In addition, this is the level that has been agreed at ACSH discussions. Some MS have already imposed nationally a similar OEL, and there are no concerns regarding technical feasibility. The same OEL is already in place in the US and Canada.

Impact on Member States and proportionality

In the case of VCM, 25 Member States have so far opted to set a limit which is less protective of worker health than the ACSH recommended 1 ppm. Figure 26 in the annex 9 illustrates the ranges of existing national OELs compared to Option 2.

There is insufficient data to provide a breakdown by Member State. However, given the number of Member States with higher OELs, a minimum basis of protection against the risks arising from workers' exposure to these carcinogens cannot be ensured for all EU workers under the baseline scenario – it follows that an action taken at the European Union level to achieve this objective could be justified.

5.12 Bromoethylene (vinyl bromide)

Bromoethylene may cause liver cancer.

Bromoethylene is used as a flame retardant in the production of acrylic fibres carpet backing materials. Other uses include children's sleepwear and home furnishings.

Number of people exposed in the EU likely to be small, i.e. less than a few hundred, but there is not enough information to assess the actual extent of exposure. Given the uncertainty about the number of exposed workers it is not possible to provide a health impact assessment. Similarly, there are no estimates of health costs of inaction for this chemical agent.

Table 32. Bromoethylene (vinyl bromide) – Types of impacts

Impact	Option 1 Baseline - no OEL	Option 2 OEL of 1 ppm	Option 4 OEL of 5 ppm
Economic	It is assumed that exposures fall by 7% per year in the future. Therefore, there are expected to be some costs to firms where bromoethylene exposure occurs to put into place employee training, Personal protective equipment (PPE) and ventilation measures to reduce inhalation and dermal exposure that would regardless of further interventions over the period 2010 – 2069	(no data) Based on the available measurements and the annual reduction in exposure the consultant judged that occupational exposure levels are currently low, with the highest exposures probably about 3 mg/m ³ (less than 1 ppm).	It is estimated that, under the baseline scenario, firms are already achieving exposures less than 5 ppm. Therefore there are not expected to be any significant additional costs of meeting an OEL of 5 ppm relative to the baseline scenario.
Social (incl. health)	There are not expected to be any noticeable social impacts under the baseline scenario at an EU level. There is insufficient information to calculate the health impacts expected under the baseline.		There are not expected to be any noticeable change to the number of workers required as a result of introducing an EU-wide OEL. No health costs and no health benefits are expected.
Environmental	There are not expected to be any noticeable environmental impacts under the baseline scenario at an EU level.		No workers exposed to bromoethylene are estimated to be exposed above the possible EU-wide OEL of 5 ppm, and therefore most workplaces are unlikely to be affected / require further changes to their existing working practice. Therefore there are not estimated to be any significant changes in environmental impacts.

Based on the available measurements and the annual reduction in exposure the consultant judged that occupational exposure levels to bromoethylene are currently low, with the highest exposures probably about 3 mg/m³ (less than 1 ppm).

There are no predicted health benefits from setting an OEL at 5 ppm, although it can be assumed that the impact would be relatively small because current exposures are estimated to be much lower than 5 ppm. There are no additional costs associated with compliance with an OEL of 5 ppm. There are also no social or macro-economic costs associated with introducing such an OEL. There are no significant environmental impacts foreseen. Lack of data for option 2 does not allow assessing its impacts.

Table 33. Bromoethylene (vinyl bromide) – Comparison of options

Criteria	Option 1	Option 2	Option 4
	Baseline	1 ppm	5 ppm
Effectiveness	0	(++)	≈
Efficiency	0	(+)	≈
Coherence	0	(++)	+
Scientific advice (SCOEL)	SCOEL recommends to use the existing quantitative risk assessment for vinyl chloride (SCOEL/SUM/109) also for vinyl bromide (bromoethylene), considering a three times higher potency of vinyl bromide compared to vinyl chloride.		
ACSH	OEL of 1 ppm is proposed following the SCOEL recommendation for vinyl chloride, the carcinogenic effects of which are similar to vinyl bromide.		

The opinion of the social partners and Member States in the ACSH supports option 2, and the CMD further establishes an expectation that OELs be set where it is possible to do so. Introducing an OEL would also be effective in introducing a greater clarity for economic operators across the EU. At the same time, lack of data does not allow to assess costs/benefits options 2 (ACSH value).

Impact on Member States and proportionality

In the case of bromoethylene 22 Member States have no OEL for this agent or have one that is less stringent than the value recommended by ACSH, so introduction of an OEL of 1 ppm would require changes for a substantial number of MS. Figure 27 in Annex 9 illustrates the ranges of existing national OELs compared to Option 2.

There is no data on numbers of exposed workers per Member State but it is possible that the overall number of exposed workers in the EU is close to zero. An action taken at the European Union level to achieve this objective could be justified as a way to ensure minimum basis of protection against the risks arising from workers' exposure to this carcinogen.

5.13 Hydrazine

Exposure to hydrazine may increase the risk of lung and colorectal cancer. It is classified by IARC as a Group 2B carcinogen (Possibly carcinogenic to humans), and as a Cat 1B carcinogen in the EU under the classification and labelling legislation.

The principal applications of hydrazine solutions include chemical blowing agents, agricultural pesticides and water treatment. Production levels in Europe are estimated to be around 20-25 thousand tonnes per year, and in the EU the largest producers of hydrazine are Germany and France.

The risk estimates used in the IOM study for the assessment of health impacts are based on existing epidemiologic evidence. Estimates of exposure prevalence in the manufacture of basic chemicals for the EU were based on 2009 exposure prevalence data available for Finland (although the Finnish exposure prevalence data may not be applicable to all EU countries). As data on exposure prevalence in agriculture is not available, it is assumed that exposure prevalence is similar to that of fungicide captafol (based on Italian 2005 data).

Data on possible current exposure levels is extremely limited (the most recent data available is from 1998 for Japan). Assuming a declining trend in exposure of 7% per year, the assumed (upper) estimate of current exposure for high, medium and low group industries are of 0.7, 0.1 and 0.06 mg/m³, respectively.

In the EU, about 2,1 mln workers are estimated to be exposed to low levels of hydrazine, about 14,600 to medium levels (in agriculture) and 833 to high levels (in manufacturing of basic chemicals). Overall, it is considered that about 8% of workers are exposed above 0.13 mg/m³, and about 75% above 0.013 mg/m³.

Cost estimates include exposure control measures undertaken by firms in the manufacturing of basic chemicals and in agriculture. As the number of firms potentially affected is not known, an estimate is derived on the basis of the (estimated) number of workers potentially exposed, combined with the available information on firm distribution by size. For agriculture, it is expected that the costs related to use of hydrazine as a herbicide can be controlled through good practice and use of appropriate personal protective equipment (PPE). No significant additional costs are therefore expected, as the latter is already considered to be good practice. In the manufacturing of basic chemicals, the installation of new local exhaust systems (LEVs) may be required by some firms to ensure compliance. Estimates on the number of firms potentially affected are subject to high uncertainty.

Table 34. Hydrazine – Types of impacts

Impact	Option 1 Baseline - no OEL	Option 2: OEL at 0.013 mg/m³, Sk.	Option 4: OEL at 0.13 mg/m³, Sk.
Economic	Under the baseline scenario, there is estimated to be a reduction of exposure at an annual rate of 7% until 2030 towards 0.013mg/m ³ and below. These estimates include costs for PPE in agriculture, as well as some investment in LEVs.	In total there is expected to be around 2,100 firms in agriculture and manufacturing of basic chemicals affected by an OEL at 0.013mg/m ³ . No additional significant costs for firms vs. the baseline are expected. Once the decline in exposure levels under the baseline is factored in, the resulting <u>additional total costs for complying with the OEL would be in the range of €5-32 mln.</u>	In total there is expected to be around 420 firms in agriculture and manufacturing of basic chemicals affected by an OEL at 0.13mg/m ³ . No additional significant costs for firms vs. the baseline are expected. Once the decline in exposure levels under the baseline is factored in, the resulting <u>additional total costs for complying with the OEL would be in the range of €2-12 mln.</u>
Social	Total attributable deaths for 2010-2069: 710. Total YLLs: 10,370. Total DALYs: 12,340. Total cancer-related health costs for the 60-year period are estimated to be between €0.5 to €3 bln.	Total attributable deaths for 2010-2069: 710. Total YLLs: 10,370. Total DALYs: 12,340. Net health benefits are estimated to be between €0.01-0.05 mln.	Total attributable deaths for 2010-2069: 710. Total YLLs: 10,370. Total DALYs: 12,340. Net health benefits are estimated to be between €0-0.02 mln.
Environmental	None.	None.	None.

Option 2 would be the most effective option in reducing occupational exposure to carcinogens and levelling the playing field across the EU (as some MS already have set OELs at 0.013 mg/m³). In terms of compliance costs, in agriculture the costs related to use of hydrazine as an herbicide can be controlled the use of appropriate personal protective equipment, which is considered already as good practice. In manufacturing, no significant additional costs (vis-à-vis option 1) are expected since the costs associated with purchase, maintenance and use of local exhaust systems would have been incurred in any case under the baseline scenario, only possibly more gradually over time.

Where there is the possibility of a significant uptake via dermal exposure SCOEL recommend that any OEL be accompanied by a 'skin notation' (in the case of hydrazine ACSH did not comment on this aspect of the SCOEL Recommendation). If adopted and accordingly transposed by Member States, employers are required under the national transposing legislation to take this into account in selecting appropriate risk management measures to protect workers.

Once the need for managing exposure has been established the only risk management measure available in practical terms is to avoid skin contact. Hydrazine has a harmonised classification as corrosive to the skin (category 1B) and skin sensitiser (category 1). These hazards would normally result in employers taking steps to avoid skin contact as a part of routine OSH risk control. Adoption of a 'skin notation' should therefore result in no additional cost for employers.

Table 35. Hydrazine – Comparison of options

Criteria	Option 1: Baseline: no OEL	Option 2: OEL at 0.013 mg/m³, Sk.	Option 4: OEL at 0.13 mg/m³, Sk.
Effectiveness	0	+	≈
Efficiency	0	≈	≈
Coherence	0	+	+
Scientific advice (SCOEL)	Categorised as a genotoxic carcinogen for which the existence of a threshold cannot be sufficiently supported. The systemic effects seen in animals following dermal contact warrant a 'skin notation'.		
ACSH	0.013 mg/m ³ .		

Some Member States have already imposed nationally an OEL of 0.013 mg/m³, and there are few concerns regarding technical feasibility. Compliance costs are small, not hampering production processes nor business viability.

The opinion of the social partners and Member States in the ACSH supports option 2, and the CMD further establishes an expectation that OELs be set where it is possible to do so. Introducing an OEL would also be effective in introducing a greater clarity for economic operators across the EU. At the same time, option 2 brings only a minor benefit, accompanied by a limited cost for enterprises.

Impact on Member States and proportionality

In the case of hydrazine 24 Member States have no OEL for this agent or have one that is less stringent than the value recommended by ACSH, so introduction of an OEL of 0.013 mg/m³ would require changes for a substantial number of MS. The Figure 28 in the annex 9 illustrates the ranges of existing national OELs compared to Option 2. Figure 29 in Annex 9 shows distribution of exposed workers across the Member States.

It is estimated that approximately 91% of exposed workers are located in those Member States. An action taken at the European Union level could improve legal protection of exposed workers.

5.14 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:

i) Stakeholders' acceptance

For all the considered carcinogens the stakeholders represented in the ACSH support the retained options. 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

Introduction of OELs for all the considered chemical agents will improve legal clarity for employers and workers. For some, however, the effect will be more significant as currently fewer MS have introduced OELs corresponding to the advised level.

- 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 an introduction of an OEL will be useful even if currently few workers are exposed (in the future, due to new uses of the chemical agents this might change), 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

iv) Health benefit

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

- XXX - benefits over 100 mln EUR
- XX - benefits between 10 mln EUR and 100 mln EUR
- X - benefits of less than 10 mln EUR

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 mln EUR
- XX - costs between 10 and 100 mln EUR
- X - costs over 100 mln EUR

Table 36

Name of the chemical agent	Retained option (ppm – parts per mln, mg/m ³ or f/ml - fibres per ml)	Stakeholders acceptance	Legal clarity	Size of the problem	Health benefit	Limited costs for business
1,2 Epoxypropane	1 ppm	XX	XX	X	X	XXX
1,3 Butadiene	1 ppm	XX	XX	X	X	XX
2 Nitropropane	5 ppm	XX	XX	XX	X	XXX
Acrylamide	0.1 mg/m ³	XX	X	XX	X	XXX
Hardwood dust	3 mg/m ³	X ¹⁰⁷	XX	XXX	XX	XXX
Chromium (VI) compounds	0.025 mg/m ³	X ¹⁰⁸	XX	XXX	XXX	X
Ethylene oxide	1 ppm	XX	X	X	X	XXX
<i>o</i> -Toluidine	0.1 ppm	XX	XX	X	X	XXX
Refractory Ceramic Fibres (RCF)	0.3 f/ml	X ¹⁰⁹	XX	X	X	XXX
Respirable Crystalline Silica	0.1 mg/m ³	X ¹¹⁰	X	XXX	XXX	X
Vinyl chloride	1 ppm	XX	XX	X	X	XXX
Bromoethylene (Vinyl bromide)	1 ppm	XX	XX	n/a	X	XXX
Hydrazine	0.013 mg/m ³	XX	XX	XXX	X	XX

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 follows:

¹⁰⁷ ACSH agreed on an OEL of 3 mg/m³. However, during discussions, employers emphasised that some hand-held machinery does not allow going below 5 mg/m³. On the other hand the workers favoured a 2 mg/m³. For some MS, 3 mg/m³ is at the limit of feasibility particularly for SMEs while other MS favour a 1 mg/m³ limit to further reduce occupational cancer cases.

¹⁰⁸ ACSH agreed on an OEL of 0.025 mg/m³. However, during discussions, workers group argued that even a binding limit of 0.025 mg/m³ would correspond to a high cancer risk. Employers' representatives did not make any specific comments in the ACSH opinion.

¹⁰⁹ ACSH agreed that an OEL was necessary but could not reach agreement on exact value (between 0.3 f/ml and 0.1 f/ml). Employers advised to follow the recommendation of SCOEL (0.3 f/ml). They also stress that industries have been working on a 0.5 f/ml exposure limit for many years, and further reductions of exposure are technically difficult. Views of Member States ranged from 0.3 f/ml to 0.1 f/ml. The workers argued for an OEL 0.1f/ml. An OEL of 0.3 f/ml was taken forward in the proposal as the minimum common denominator.

¹¹⁰ ACSH agreed that a binding OEL at 0.1 mg/m³, measured as respirable dust, is justified. The value should be reviewed within 3-5 years. There were some questions on the part of employers and some MS whether it would not be more appropriate to legislate under the CAD. Workers stated that further exposure reduction below the proposed binding OEL of 0.1 mg/m³ is paramount to reduce the risks of lung cancer, and silicosis.

- Respirable Crystalline Silica: an OEL at 0.1 mg/m³ will provide for 99,000 avoided cancer cases by 2069 for a total monetized health benefit quantified between 34 billion and 89 billion EUR;
- Hardwood dust: an OEL of 3 mg/m³ will provide for a total monetized health benefit between 12 million and 54 million EUR;
- Benefits are also expected in relation to introducing a OEL at 0.025 mg/m³ for all chromium (VI) compounds, although it is likely these will have been overestimated as a result of reductions in exposure which may be expected for some important compounds when subject to REACH authorisation.
- Remaining substances: The avoided cancer cases and the monetized health benefits are less significant.

The introduction of retained option would decrease the burden of economic costs derived by workers' exposure to hazardous substances. The main economic costs caused by disability and premature death at work are:

- the worker's lost wages during the period of absence from work;
- the subsequent severe consequences for household's well-being as well as a reduction in tax collection.

By acting as a clear and homogeneous playing field for workers' rights enforcement, the introduction of the retained option will reduce health and safety risks for disadvantaged workers such as precarious and informal workers. The scientific literature (Aronsson, 1999; Quinlan and Mayhew, 2000; Letourneux and Thebaud-Money, 2002) agrees in pointing out that precarious workers have less control over fundamental determinants of their health and safety such as: the ability to change temperature, lighting, ventilation, and work location, and the freedom to choose when to take personal leave; and they are also more likely to be employed in dangerous working environment.

As a consequence, the retained option have the advantage of shielding workers and families from suffering financial and social costs which would otherwise occur in a baseline scenario.

It is important to note that the study underlying the Impact Assessment report was limited to assessing health benefits resulting solely from avoided cancer cases. However, the chemical agents under consideration cause a range of other occupational diseases. These include primarily different forms of respiratory diseases (caused e.g. by hardwood dust, RCS, RCF) and dermatological diseases (e.g. acrylamide, RCF). Enhanced workplace control of exposure to the considered chemical agents will also contribute to decreasing the risk of those occupational diseases.

The available data is not sufficient to estimate the magnitude of related health benefits. However, taking into account general estimates of costs related to these diseases, it could be expected that limiting the risks leading to their onset could be considerable.

Concerning occupational asthma, according to a review of existing research¹¹¹, costs are related to the poor prognosis of the disease and small chances for recovery.¹¹² Estimated 70% of workers diagnosed with occupational asthma show symptoms even several years after complete cessation of exposure¹¹³. According to estimates of the direct and indirect costs of occupational asthma in the United Kingdom¹¹⁴, the average annual direct costs per case are £530-£715. The

¹¹¹ Montano D. Chemical and biological work-related risks across occupations in Europe: a review. *Journal of Occupational Medicine and Toxicology* (London, England). 2014;9:28. doi:10.1186/1745-6673-9-28.

¹¹² Mapp CE, Boschetto P, Maestrelli P, Fabbri LM. *Occupational Asthma*. *Am J Respir Crit Care Med*. 2005;172(3):280–305. [PubMed]

¹¹³ Tarlo SM, Lemiere C. Occupational asthma. *New Engl J Med*. 2014;370(7):640–649. [PubMed]

¹¹⁴ Ayres JG, Boyd R, Cowie H, Hurley JF. Costs of occupational asthma in the UK. *Thorax*. 2011;66(2):128–133.

annual indirect costs range from £1525 to £1685. The total costs of an average case to society is some £120,000-£130,000. The total lifetime costs of new cases to society could lie between £95 and £135 million. Further research showed that some 49% of the present value total costs are borne by the individual, 48% by the state and only 3% by the employer.¹¹⁵

On the subject of occupational skin diseases the same research review quotes a study on costs of occupational hand eczema, conducted in 2013 in Germany.¹¹⁶ The annual direct and indirect costs per worker diagnosed and treated were on average 2646 and 6152 EUR, respectively. An Italian study estimated societal costs of severe chronic hand eczema to be on average 5016 EUR per person-year (min. 411 EUR, max. 27648 EUR).¹¹⁷ The need to conduct occupational retraining, job change, or adverse psychosocial effects result in further costs.¹¹⁸ As for severe occupational skin diseases more than a half of all cases may become persistent and continue even after exposure to a chemical agents discontinued, further direct and indirect costs might occur depending on the degree of disability.^{119, 120} Also research conducted in Australia confirmed that occupational skin diseases had a significant socioeconomic impact, with an estimated annual cost of over \$33 million.¹²¹

6.2 Impact on businesses

From an economic standpoint, the total cost to an economy of occupational morbidity and mortality is the sum of all private economic costs that are also social costs, plus the social costs that are external to all private parties. Thus, the illness of a worker results in lost output for the employer. If the worker is paid during the period of non-production, this mitigates the private cost to the worker but increases the cost to the employer. A loss of production may lead to a loss of profits, which would then be a social as well as private cost, but the firm might have the ability to raise prices, maintain profits, and shift the cost to consumers.

As regards the economic impacts on costs incurred by enterprises for some carcinogens, 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 Chromium (VI) compounds and RCS. As regards RCS, the total costs to industry of introducing an OEL at 0.1 mg/m³ are estimated to be at 3.5 bln EUR until 2069¹²².

For the remaining carcinogens, the impact on operating costs and conduct of business (including small and medium enterprises) will 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.

¹¹⁵ Assessing the cumulative economic impacts of health and safety regulations - Scoping study. Prepared by the Centre for Strategy & Evaluation Services (CSES) for the Health and Safety Executive 2009)

¹¹⁶ 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](#)]

¹¹⁷ Cortesi PA, Scalone L, Belisari A, Bonamonte D, Cannavo SP, Cristaudo A, Pita Od, Gallo R, Giannetti A, Gola M, Pigatto PD, Mantovani LG. Cost and quality of life in patients with severe chronic hand eczema refractory to standard therapy with topical potent corticosteroids. *Contact Dermat.* 2013;70(3):158–168. [[PubMed](#)]

¹¹⁸ Diepgen TL, Kanerva L. Occupational skin diseases. *Eur J Dermatol.* 2006;16(3):324–330. [[PubMed](#)]

¹¹⁹ Rycroft R, Frosch P. In: *Contact Dermatitis*, 4 edition. Frosch P, Menne T, Lepoittevin JP, editor. Berlin: Springer; 2006. Occupational contact dermatitis; pp. 717–734.

¹²⁰ Sajjachareonpong P, Cahill J, Keegel T, Saunders H, Nixon R. Persistent post-occupational dermatitis. *Contact Dermat.* 2004;51(5–6):278–283. [[PubMed](#)]

¹²¹ <http://www.safeworkaustralia.gov.au/sites/swa/media-events/media-releases/pages/mr16032012>

¹²² Estimated costs of anticipating investment needed to reach the exposure level.

It is important, from an economic point of view, to distinguish between costs that do or do not create incentives for improvements in health and safety. The advantages for businesses of introducing EU wide OELs is that the new regulation will help firms addressing costs which would, otherwise, negatively affect their business prospect in the long-term in the case of non-compliance. According to the economic literature these costs are:

- Economic - in this case these costs include unequal firms' costs related to differences in the rate of depreciation of capital equipment or loss of raw material due to the existence of different national OEL; in addition there are 'opportunity costs' – for instance if a firm loses market share due to worker absences from ill-health; finally, company's loss of 'goodwill', which may result from well-publicized cases of industrial accidents or disease, this is an opportunity cost to the firms which can have serious consequences;
- Internal – if retained options are not adopted the enterprise run the risk to be considered accountable for workers' ill-health;
- Variable – the cost derived by workers' ill-health might not simply resolve in a fixed premium compensation but might involve longer-term costs for the firm;
- Routinely visible – cost derived by non-adoption of EU-wide OELs would increase firms' exposure to expensive process of legal and economic information acquisition to deal with the consequences of workers' ill-health.

6.2.1 *Impact on SMEs*

None of the considered options contain lighter regimes for SMEs. SMEs are not exonerated from the obligation to eliminate or reduce to a minimum the risks arising from occupational exposure to carcinogens or mutagens.

For many of the agents covered in this impact assessment, OELs exist already at national level, even if the level as such differs between the EU Member States.

Establishing the OELs foreseen in this initiative should have no impact on those SMEs situated / located in those EU Member States where the national OELs are either equal or lower than the proposed values.

However, due to differences in OELs at national level there will in some cases depending on industry practice be an economic impact in those Member States (and economic operators established therein) which currently have higher OELs established for the chemical agents subject to the initiative.

The major economic impact for SMEs can be summarised in three points. First, some of the OELs have overhead costs, and the smaller the firm, the smaller the revenue base over which these costs can be distributed. Second, the level of expertise is frequently lower for SMEs. Third, the SMEs environment is generally more competitive and finance is more difficult to obtain, leading to shorter time horizons and fewer expenditures on what may be perceived as nonessential items different spending priorities – potentially reducing voluntary investment in equipment or training which may be necessary to implement effective risk management.

The majority of companies that would be affected by the imposition of a RSC limit at 0.1 mg/m³ are small companies. If the costs cannot be passed through to consumer prices and/or some companies will not be able to get access to loans to pay for the necessary investment, there is a possibility of some company closures and, for industries for which it is possible, some relocation of activities in non-EU countries. The extent of this risk is difficult to estimate. 17 EU Member States have already introduced an OEL of 0,1 mg/m³ or below and also from this point of view it appears to be feasible for the industry to adjust to such an exposure limit. Most of the costs incurred in relation to it will be incurred by the construction industry, in which case relocation is not a viable option, so companies are likely to pass the additional costs on to

consumers to some extent. The fact that a majority of MS already have introduced the OEL under consideration and that the same level exists in non-EU countries such as the US, Canada or Australia, indicate that it should be feasible for the sectors concerned to absorb the additional costs.

For chromium VI the IOM study assessed that the costs of compliance will notably affect small firms employing less than 20 people, particularly in the manufacture of fabricated metal products. It is possible that some could either close or cease to use chromium (VI) containing components. However, those estimates are for all Chromium (VI) compounds and, as a result of anticipated exposure reductions resulting from the impact of REACH authorisation on several important compounds, both the costs and benefits can be expected to be overestimated. These figures nevertheless represent the best and most appropriate available data to inform this analysis.

SMEs indicated that OSH legislation in general creates some burdens, particularly in relation to documenting risk management and reporting obligations (even if there is evidence that some burdens might be related to national transposition rather than EU level legislation).¹²³ One of the goals of a future revision of the OSH acquis may be to simplify and/or reduce administrative costs, including for micro and small enterprises CMD limit values do not, however, result in additional reporting or documenting obligations and the clarifications provided in Annexes I and III should in fact decrease the burden on employers by providing clear guidance as for the scope of application and the level of expected compliance.

Moreover, the European Association of Craft, Small and Medium-Sized Enterprises (UEAPME) was among signatory parties of the Cross Industry initiative, which recognised 'EU-wide Occupational Exposure Limits (OELs) as the most effective risk management option for substances where there is a need to address a risk limited to the workplace' and called for the Commission and Member States 'to proceed to set EU-wide OELs for substances, where a risk is identified at the workplace'.¹²⁴

6.2.2 *Impact on competition and competitiveness*

Risk prevention and the promotion of safer and healthier conditions in the workplace are key not just to improve job quality and working conditions, but also to promoting competitiveness. Keeping workers healthy has a direct and measurable positive impact on productivity, and contributes to improving the sustainability of social security systems. There is a correlation between low levels of a country's rating as regards work-related deaths and diseases and its competitiveness rank.¹²⁵

Implementing the retained option would have a positive impact on competition within the internal market. Having EU-wide OEL for those agents will decrease competitive distortion between firms located in Member States with different national OELs. Setting a minimum standard at EU level will not (and should not) prevent Member States from setting even more protective OELs. However, it will provide certainty that there is an enforceable exposure limit for all concerned carcinogens in all Member States. It will also significantly minimise the scope for variation in OELs across the EU. It may be noted that the examples of the current hardwood dust and VCM OELs show that a majority of Member States in practice adopt the EU OEL directly.

On the other hand, the retained option should not have a significant impact on the external competitiveness of EU firms as many of the values proposed are similar to those in other

¹²³ Commission follow-up to the 'Top Ten' Consultation of SMEs on EU Regulation (COM(2013) 446)

¹²⁴ Further information on the initiative and source are provided in section 4.2.D.

¹²⁵ Jukka Takala et al.: Global Estimates of the Burden of Injury and Illness at Work in 2012, available online: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4003859/>

countries (see Table 3 in Annex 6), notably EU largest trading partners, such as US, China or Switzerland. For example, the proposed value for exposure to hardwood dust is 3 mg/m³ while the value in Canada and Australia is 1 mg/m³. The proposed value for vinyl chloride monomer is 1 ppm, the value in the USA and Canada is also 1 ppm. And the value of 0.1 mg/m³ proposed for RCS is also established in the USA, Australia and Canada.

Furthermore, it is to be expected that in some of those third countries, limit values will also continue to be adjusted to new scientific data. The US Occupational Safety & Health Administration (OSHA), for example, recognizes that many of its permissible exposure limits (PELs) are outdated and inadequate for ensuring protection of worker health. Most of OSHA's PELs were issued shortly after adoption of the Occupational Safety and Health (OSH) Act in 1970, and have not been updated since that time.¹²⁶

6.3 Impact on Member States/national authorities

Where no EU OEL exists many Member States conduct their own scientific analysis to determine the acceptable exposure level. Exact costs of this type of exercise are difficult to establish but would be significant given the level of scientific and technical expertise required. 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.

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. From an economic point of view, the coverage and adequacy of EU-wide OELs is the single most important determinant of who bears the cost burden of occupational ill-health.

Administrative and enforcement costs will differ according to present status of each chemical agent in each MS, but should not be significant.

Based on the experience gathered from the work of the Senior Labour Inspectors Committee (SLIC) and having regard to the way the enforcement activities are organised in different MS it is not likely that the introduction of new OELs in the CMD would have any impact on the overall costs of the inspection visits. Those are mostly planned independently of the revised legislation, mainly based on complaints filed during a given year and according to the inspection strategies defined by a given authority. 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.

Additional administrative costs might be incurred by authorities as regards the necessity to provide information and training on the revision to staff, as well as to revise the compliance checklists. However, these costs are minor in comparison to the overall costs of functioning incurred by the enforcement authorities.

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).

¹²⁶ <https://www.osha.gov/dsg/annotated-pels/>

6.5 How does the retained option conform to the principles of subsidiarity and proportionality given the size and nature of the identified problem?

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) and the REACH Regulation. Amending Directive 2004/37/EC can only be done by action at EU level and after a two-stage consultation of the social partners (management and labour) in accordance with Article 154 TFEU.

With regard to the values proposed as retained option it has to be stressed that socio-economic feasibility factors have been taken into account after long and intensive discussions with all stakeholders (representatives from employees' associations, representatives from employers' associations, and representatives from governments).

While monetised benefits of the initiative may be modest, it should be recalled that the initiative would contribute to saving 100,000 human lives in the forthcoming 50 years. These figures are based on the estimations made the IOM study contracted by the Commission¹²⁷. There is a range of additional benefits which have not been quantified (e.g. benefits related to avoided cases of other occupational diseases caused by the chemical agents, positive effects on level playing field, facilitation of legal compliance and enforcement etc.).

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 33% to 98% of exposed workers (see Table 4 in Annex 6).

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.

The planned action therefore complies with the principles of proportionality and subsidiarity.

7 HOW WOULD ACTUAL IMPACTS BE MONITORED AND EVALUATED?

This section presents the monitoring and evaluation arrangements that seem most appropriate at this stage in order to monitor and evaluate the planned legislative initiative. It should however be noted that the overall OSH legislative framework has just undergone a comprehensive evaluation. As a result of this, the Commission might decide to modify the monitoring and evaluation mechanisms currently foreseen in this framework. This would clearly have an impact on the monitoring and evaluation arrangements of the individual Directives within the OSH framework, including the CMD.

7.1 Monitoring arrangements

The operational objectives for the retained option, in relation to the chemical agents covered are:

- The reduction of occupational diseases and occupational related cancer cases in the European Union;
- The reduction of costs related to occupational cancer for economic operators and for social security systems in the European Union.

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

¹²⁷ Deaths avoided mainly in relation to the following chemical agents: Chromium VI - 1670; Refractory Ceramic Fibres - 50; Respirable Crystalline Silica - 98,670.

Table 37

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. ¹²⁸ -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 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).

The monitoring of implementation (transposition and application) is also an indicator of the effectiveness of the initiative to reach its operational objectives. A compliance assessment will be carried out for the transposition of the limit values, by the Commission in two stages: a transposition check and conformity check. The monitoring of application and enforcement will be undertaken by the national authorities in charge of the protection of workers' health and safety and in particular the national labour inspectorates. Information on the practical implementation of the Directive 2004/37/EC at national level is provided every five years by the Member States in accordance with Article 17a of Directive 89/391/EEC. At EU level, the Committee of Senior Labour Inspectors ('SLIC') established by Commission Decision 95/319/EC, informs the Commission on all problems relating to the enforcement of EU OSH Directives, including Directive 2004/37/EC.¹²⁹

7.2 Evaluation arrangements

In accordance with the ex-post evaluation clause in Art. 17a of Directive 89/391/EEC, every five years, Member States are required to submit a single report to the Commission on the practical implementation of the EU OSH Directives. This report includes a chapter dealing with

¹²⁸ Regulation (EC) No 1338/2008 on Community statistics on public health and health and safety at work, OJ L 354/70, 31.12.2008.

¹²⁹ In particular, the SLIC Working Group CHEMEX is mandated to gather, exchange and disseminate information and guidelines for national labour inspectorates on enforcement matters related to chemical exposures in workplaces, and in particular for carcinogenic, mutagenic, reprotoxic or sensitising chemical agents.

the implementation of particular aspects of Directive 2004/37/EC, including specific indicators, where available. On this basis, the Commission will evaluate the implementation of Directive 2004/37/EC in terms of its relevance, of research and of new scientific knowledge, in accordance with Art. 17a (4) of Directive 89/391/EEC.

In accordance with Art. 17a of Directive 89/391/EEC, the Commission is required, within 36 months of the end of the five-year period, 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 in this report it is suggested to make use of the next ex-post evaluation exercise to define the baseline values (benchmark) that will allow assessing the effectiveness of the planned CMD revision. This seems reasonable considering that due to the long latency periods to develop cancer (10 to 50 years), it will not be possible to measure the real impact of the revision before 15-20 years.

Availability of exposure data is presently the subject of a contract study ('HazChem@Work').¹³⁰ It will in due course also contribute to the definition of the benchmark and may enable some further conclusions to be drawn about the effectiveness of the proposed measure. For the foreseeable future, however, the latency of some occupational cancers and other well-explained difficulties in collecting and aggregating exposure data between member states will continue to present significant challenges to their use as indicators.

In that context aggregating exposure data collected from Member State labour inspectorates at EU level could have several important benefits for operation of chemicals policy – but would be a very significant additional burden on both national labour inspectorates and possibly employers. It is also unlikely that such data could in any case be effectively aggregated as reporting structures within companies and between sectors and Member States are unlikely to align.

¹³⁰ 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.

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 in a meeting on 17 February 2016. The RSB required a number of improvements.

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

RSB main recommendations	Changes done to the IA
<p>(1) Context of the initiative and links with the evaluation.</p> <p>further present the heterogeneous landscape in Europe;</p> <p>more thoroughly explain the procedure to update OELs and measures taken to further streamline it;</p> <p>make links with the OSH evaluation findings.</p>	<p>Further information on the situation across the EU (e.g. ranges of existing national OELs, Member States most affected) provided for each of the chemical agents in Section 5 (sections 5.1-5.13) and in Annex 9.</p> <p>The OEL setting process, as well as the steps taken to facilitate swifter future updates, is explained in greater detail in section 4.3.</p> <p>The new section 2.4. focuses on the links with the OSH evaluation.</p>
<p>(2) Need to act and EU added value of the initiative.</p> <p>further substantiate why diverging national OELs are inefficient and why action is required at EU level;</p> <p>further substantiate the added value of providing legal clarity;</p> <p>better explain the interest of different stakeholders (including employers) in setting EU standards;</p> <p>weigh the overall benefits of the initiative (possibly including health gains related to the prevention of diseases other than cancer and results of enhanced clarity for businesses) against its total costs.</p>	<p>Sections 1.1.3, 1.3., 2.2. have been considerably developed in order to better demonstrate the inefficiency of diverging national OELs, the added value of greater legal clarity and the interests of different stakeholders.</p> <p>A summary table has been introduced under section 5.14, weighing the retained option for each of the chemical agents against a number of criteria, including compliance costs and health benefits.</p> <p>Additional data under section 6.1. provides quantitative estimates of the health benefits related to diseases, such as occupational asthma and occupational skin diseases.</p>
<p>(3) Impacts on and views of stakeholders.</p> <p>more systematically present the views of different stakeholders and the expected impacts on particular groups (incl. SMEs), distinguishing when relevant between MS and between specific substances.</p> <p>views on the importance of burden reduction and simplification of the OSH legislation in</p>	<p>Further information, where available, included for each of the chemical agents in Chapter 5 (sections 5.1-5.13).</p> <p>New section 2.4. deals with the issue of simplification. Further discussion on burden reduction is included in the conclusions (sections 6.2.1. and 6.3).</p>

general should be addressed.	
(4) Alternative options. better explain why a broader range of approaches, including non-legislative ones, were not considered or were discarded; reasons for discarding them should be summarised; assess in more details the feasibility and consequences of covering the chemicals included in this initiative through REACH.	A new section (4.2) presents a broader range of alternative approaches (including non-legislative and REACH) and the reasons for discarding them.
Procedure and presentation. further explain the limitations of the data used and their potential effect on the quantification of impacts. Whenever relevant, a sensitivity analysis should be applied.	Further explanations on methodology, assumptions and data limitations is provided in the introductory part of Chapter 5 as well as per chemical agent, where available, in sections 5.1-5.13. A sensitivity analysis regarding the discount rate has been conducted and confirmed that benefits were far more sensitive to discounting than costs. Costs and benefits have been recalculated using a declining discount rate instead of the originally used fix 4% discount rate. The analysis also further clarifies what compliance costs would need to be incurred under the baseline scenario and under each of the options for action.

The RSB issued a positive opinion on 1 April 2016 and several further adjustments were made in the text of the report following RSB's further suggestions, as summarised in the table below.

RSB main recommendations	Changes done to the IA
(1) Costs Costs presented in the report should only be those incurred compared to the baseline, i.e. resulting from the obligation to respect the OEL proposed through a binding measure in the near future compared to reaching it later through the "natural" linear decrease in exposure.	Sections 5.1-5.13 have been revised accordingly.
(2) Value added at EU level Need to extend the range of considered options. In particular, in order to provide legal certainty by industry, there could be the need to set OELs by industry or use of a specific product. As this risks to become very burdensome for the regulators, an alternative option could be to provide scientific information by industry and use, without setting OELs.	Two additional options have been added in section 4.2. Further explanation on EU added value have been added in section 1.1.3
(3) Stakeholders support The report should further expand on the perception of stakeholders regarding the	The IA report includes already opinions of stakeholders relevant for each substance in sections

establishment of OELs at European level for specific substances as opposed to national level. This is especially important as stakeholder support seems to be inversely proportionate to the size of the problem (and potential health benefits – Table 36, p.80).	5.1-5.13 of the report. Further clarification has been provided in the section 5.14.
(4) OSH vs. REACH Introduce a table comparing the OSH framework and REACH as possible instruments to reduce EU workers' exposure to carcinogens.	A table has been added in section 14.2.3.
(5) Presentation Finally, the estimation of 100,000 lives potentially saved through the proposed measures (pp.7, 87) should be more clearly explained and substantiated	The information requested is reflected in changes made in the introduction, and in section 6.5.

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".¹³¹

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.

¹³¹ <http://monographs.iarc.fr/ENG/Preamble/CurrentPreamble.pdf>

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/EC¹³² 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. 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 necessary 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 for in Annex 5 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

Following the two stage consultation of the European social partners (see section 9.1 of this document), DG EMPL/F/4 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 expected 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 run 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.¹³³

¹³² 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)

¹³³ The following links are only provided for those chemical agents subject to the first amendment of the CMD:

- [Executive summary report](#)
- [Summary report](#)
- [1,2-Epoxypropane](#)
- [1,3-Butadiene](#)

8.4.3 Study on chemical agents toxic to reproduction

DG EMPL/F/4 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 are considered as chemical agents of very high concern (SVHC), meaning that they might become subject to the so-called authorisation procedure, which in a nutshell foresees that they cannot be placed on the market of the EU unless the supplier demonstrates in a dossier that the use of the chemical agent is safe.

However, based on the current scientific knowledge, the majority of these chemical agents have a threshold below which a safe use of the chemical agent is possible. Therefore, it can be argued that the protection of workers is already covered under the CAD, and that Indicative OELVs or OELs for these chemical agents should be established under the CAD, and the more stringent protective and preventive measures under the CMD, in particular with regard to the substitution provision, are not proportionate.

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.

However, 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.

-
- 2 Nitropropane
 - Acrylamide - Bromoethylene
 - Chromium VI
 - Ethylene oxide
 - Hydrazine
 - o-Toluidine
 - Refractory Ceramic Fibres
 - Respirable Crystalline Silica
 - Hardwood dust
 - Vinyl chloride monomer

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, ex Article 138 of the EC Treaty).

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 (former Article 138(2) of the EC Treaty), 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 consultation¹³⁴ 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.¹³⁵

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.

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

¹³⁴ 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)

¹³⁵ CISNET EMPL 8676 of 15 June 2006

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 8.4.2). The results of the study as well as SCOEL recommendations, where available, were subsequently discussed by the tripartite ACSH (see point 9.2.3). 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)¹³⁶

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

¹³⁶https://osha.europa.eu/sites/default/files/publications/documents/en/publications/reports/548OELs/survey_OELs_CMV_substances_web_def.pdf

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 States¹³⁷.

With regard to the current initiative it is worth noting that the chemical agents covered by this initiative are in most cases also included in national OEL lists for carcinogens and mutagens. The majority of the MS which reported back have 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) have 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 are 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 appear 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 6.

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 discussed¹³⁸, 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 2011¹³⁹, 2012¹⁴⁰ and 2013¹⁴¹, resulting in one

¹³⁷ 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

¹³⁸ Meeting of the WPC on 15 October 2008; Meeting of the WPC on 26 March 2009; Meeting of the WPC on 20 October 2010;

¹³⁹ Meeting of the WPC on 23 March 2011; Meeting of the WPC on 15 June 2011; Meeting of the WPC on 26 October 2011

¹⁴⁰ Meeting of the WPC on 21 March 2012; Meeting of the WPC on 6 June 2012; Meeting of the WPC on 21 November 2012

¹⁴¹ 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 2012¹⁴² and 2013^{143, 144}.

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 the International Agency for Research on Cancer (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 workshop¹⁴⁵ 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 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 base-line 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.

¹⁴² 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)

¹⁴³ 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)

¹⁴⁴ 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)

¹⁴⁵ The seminar report is available at <https://osha.europa.eu/en/tools-and-publications/seminars/workshop-on-carcinogens-and-work-related-cancer>

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, as well.

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.

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.

In particular with regard to RCS, the Commission discussed intensively possibilities to recognise on the one hand the results of the NEPSi Agreement, and on the other hand to protect also workers currently not covered by the agreement.

The Commission also participated in meetings organised annually by DG GROW with the European Glass and Ceramic Industry, where similar information were presented.

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

For silica, the main concern for industry was the inclusion of the agent in Annex I of the CMD but not the limit value itself, which is attainable in view of the current available technologies and working methods. It was argued that the inclusion of the agent under the scope of the Directive would put a more stringent obligation on substitution and process enclosure, leading to non-affordable costs. It should however be noted that, where no workers were present (e.g. long distance material conveyers), closed processes is not a CMD requirement – and that the substitution principle already applies by means of the Chemical Agents Directive.

On Refractory Ceramic Fibres, the industry expressed their positive view on the establishment of an EU-wide binding OEL as a way to demonstrate appropriate control of the exposure at the workplace – potentially of value in discussions regarding REACH authorisation. The same argument has been presented by the European metals industry as regards Hexavalent Chromium compounds.

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

Who is affected	How
National authorities	<p>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.</p> <p>Member States must transpose the amended Directive into national legislation:</p> <ul style="list-style-type: none"> - assessment of the national scenario and potential impacts - design, if appropriate/needed, of special measures (eg., 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. <p>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.</p>
Employers	<p>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:</p> <ul style="list-style-type: none"> - implementation of the necessary risk management measures (eg., substitution, local exhaust ventilation, closed systems, 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).

	<p>Most of the listed actions are, however, business as usual.</p> <p>The benefits for employers include, inter alia, avoided loss of productivity, simplification in ensuring legal compliance, improved level playing field across the EU.</p>
Workers	<p>As protected subjects, workers would be positively affected by the initiative in terms of a more effective protection of their health.</p> <p>It is to be noted that workers have also the duty to comply with the dispositions provided by the employers as regards the use of preventive and protective measures necessary to comply with OSH legislation (.eg., the newly established OELs).</p>

11 ANNEX 4 – ANALYTICAL MODEL USED IN PREPARING THE IMPACT ASSESSMENT¹⁴⁶

The impacts of the different policy options proposed in this impact assessment were quantified, to the extent possible, based on a methodology as described below¹⁴⁷.

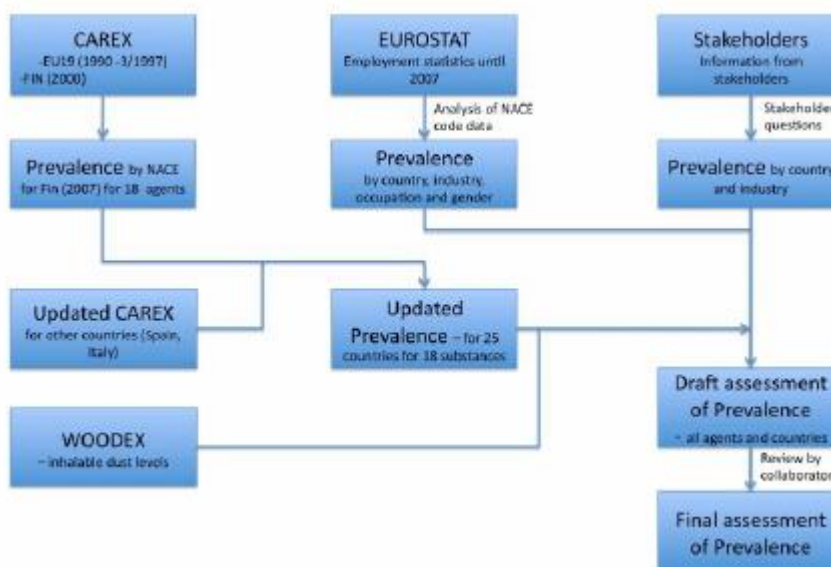
11.1 Exposure estimation

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:

Figure 1



Exposure prevalence data were available from the Carcinogens Exposure database (CAREX), for almost all agents analysed in this impact assessment, except 1,2-Epoxypropane, 2-Nitropropane and Hardwood Dust. For wood dust exposure, information on the prevalence (and level) of exposure was available for 25 countries following an EU project estimating the risk of exposure to wood dust (Kauppinen et al, 2005). For the remaining agents information collected from trade associations and other stakeholders was used.

¹⁴⁶ SHEcan 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 Finnish 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;
- The Woodex database (hardwood dust);
- 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).

11.2 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 et 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):

$$\text{DALY} = \text{YLL} + \text{YLD}$$

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

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

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.

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 disease¹⁴⁹. 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.



Figure 2 DALY component: Years of life lost (VLL)

Monetary estimates of the value of life years lost (VLYL or sometimes known as VOLY¹⁵⁰) 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%, have been recalculated applying a declining discount rate (4% for the first 20 years, 3% thereafter) in line with the most recent EC Better Regulation guidelines¹⁵².

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

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.

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.

Table 2 Components making up a valuation of COI

Components of the COI	Description
Direct costs	<p>These include both the direct medical costs and direct non-medical costs of the disease:</p> <ul style="list-style-type: none">• 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. <p>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:</p> <ul style="list-style-type: none">• 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	<p>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</p> <ul style="list-style-type: none">• 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	<p>The intangible cost components of illness are usually substantial, and in many cases, might dominate the policy agenda. Examples include</p> <ul style="list-style-type: none">• 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]). <p>One approach to estimating the intangible costs is through willingness-to-pay (WTP) studies.</p>

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

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

¹⁵³ <http://www.cdc.gov/owcd/eet/Cost/3.html#costofillness>

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.

Estimating COI

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

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

Where:

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

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

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.

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)

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>

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.

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.

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 4. may differ in existing literature, but the increased segregation allows us to better assign time that may be spent in each cancer stage.

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>

¹⁵⁸ O'Dea (2009) - "The estimated costs - economic and human - of skin cancers in New Zealand" - <http://www.niwa.co.nz/?a=103433>

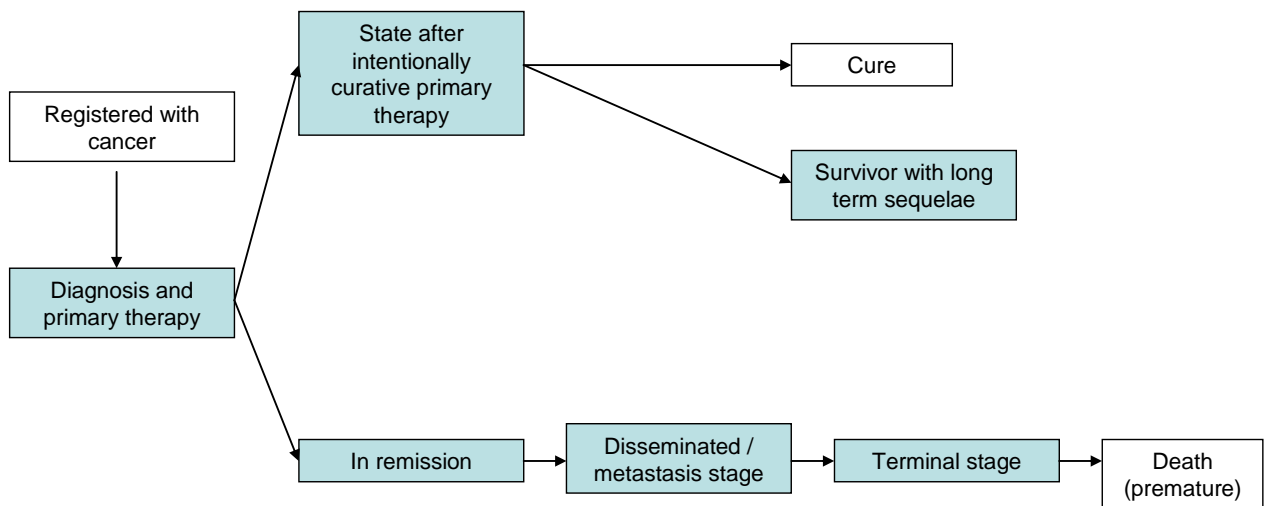


Figure 4. Cancer stages

The SHEcan health impact assessment has estimated the duration of time spent 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 includes¹⁵⁹

- (1) Lost wages¹⁶⁰;
- (2) Medical expenses;
- (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). As shown in Table 3. 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.

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

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. summarises 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).

11.3 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 ANNEX 5 – DETAILED INFORMATION ON THE CARCINOGENICITY OF THE CHEMICAL AGENTS

The table below summarises the current situation as regards the availability of SCOEL Recommendations for the 13 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
Respirable crystalline silica	N/A	1	SCOEL SUM 94	2003	
Refractory ceramic fibres (RCF)	1B	2B	SCOEL SUM 165	2011	
Acrylamide	1B	2A	SCOEL SUM 139	2010	
Vinyl chloride monomer (VCM)	1B	1	SCOEL SUM 109	2004	
Hardwood dust, as inhalable dust	N/A	1	SCOEL SUM 102	2003	
Chrome (VI) compounds	1B	1	SCOEL SUM 86	2004	
1,3 Butadiene	1A	1	SCOEL SUM 75	2007	
Ethylene oxide	1B	1	SCOEL SUM 160	2012	
1,2 Epoxypropane	1B	2B	SCOEL SUM 161	2010	
<i>o</i> -Toluidine	1B	1	No SCOEL Recommendation		IOM Study considered potential OELs of 0.1 ppm (0.4 mg/m ³) and 1 ppm (4.4 mg/m ³) as 'typical' values of existing national OELs in the EU.
2 Nitropropane	1B	2B	No SCOEL Recommendation		IOM Study considered 0.5 ppm (19 mg/m ³) for assessment, as 'typical' values for existing national OELs in the EU.
Bromoethylene	1B	2A	SCOEL SUM 155	2008	
Hydrazine	1B	2B	SCOEL SUM 164	2010	

12.1 Respirable crystalline silica

12.1.1 Identification

Index Number: none
 EC Number: none
 CAS Number: 14808-60-7 (Quartz)
 14464-46-1 (cristobalite)
 15468-32-3 (tridymite)

Silica (silicon dioxide (SiO₂)), occurs in either a crystalline or non-crystalline (amorphous) form. Crystalline silica may be found in more than one form (polymorphism), depending on the orientation and position of the tetrahedra (i.e., the three-dimensional basic unit of all forms of crystalline silica). The natural crystalline forms of silica are α -quartz, α - β ₁-, and β ₂-tridymite, α - and β -cristobalite, coesite, stishovite, and moganite (IARC, 1997). The most common form of naturally occurring crystalline silica are quartz (CAS No. 14808-60-7), Cristobalite (CAS No. 14464-46-1) and tridymite (CAS No. 15468-32-3), but they can also be created during industrial processes, such as the calcination of diatomaceous earth, ceramics manufacturing, foundry processes, silicon carbide manufacturing, and any other process in which quartz is heated to high temperature.

12.1.2 Synonyms

silicon dioxide, crystalline

12.1.3 Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity¹⁶¹:

None.

It should be noted that the polymorphs of silica which comprise RCS are commonly placed on the market and are subject to CLP classification.

The three most common 'polymorphs' of crystalline silica are quartz, cristobalite, and tridymite – all of which have been self-classified by suppliers in the EU. These classifications have been notified to the European Chemicals Agency for inclusion in the Classification and Labelling Inventory (CLI).

Self-classifiers are not bound to adopt any particular classifications and are free to classify their products differently from one another. CLI entries for quartz and cristobalite include some classifications for category 1 carcinogenicity although the majority of the notifications only concerns Specific Target Organ Toxicity (STOT) and according to some notifications the substance is not classified. CLI entries for tridymite do not include classifications for carcinogenicity. The substance has not been classified as hazardous according to CLP.

12.1.4 Classification according to IARC¹⁶²

The International Agency for Research on Cancer (IARC) has stated its opinion that 'crystalline silica inhaled in the form of quartz or cristobalite from occupational sources is carcinogenic to humans (Group 1)' (IARC Monograph 68).

In making its overall evaluation the IARC Working Group noted that carcinogenicity in humans was not detected in all industrial circumstances studied, and that carcinogenicity may be dependent on inherent characteristics of the crystalline silica, or on external factors affecting its biological activity or distribution of its polymorphs.

There is more recent information on the carcinogenicity of RCS in the IARC monograph volume 100C on arsenic, metals, fibres and dusts. This was published in 2012 and represents the views and expert opinions of the IARC Working Group on the Evaluation of Carcinogenic Risks to Humans which met in Lyon, 17 – 24 March 2009. The conclusions of the IARC Monograph 100C confirm, based on more recent scientific evidence, that crystalline silica in the form of quartz or cristobalite dust is carcinogenic to humans (Group 1).

12.1.5 Recommendation of SCOEL¹⁶³

The main effect in human of the inhalation of respirable silica dust is silicosis. There is sufficient information to conclude that the relative lung cancer risk is increased in persons with silicosis (and, apparently, not in employees without silicosis exposed to silica dust in quarries and in the ceramic industry). Therefore, preventing the onset of silicosis will also reduce the cancer risk. Since a clear threshold for silicosis development cannot be identified, any reduction of exposure will reduce the risk of silicosis.

It was observed that the dose-response curve for silicosis appears to be sigmoidal and that maintenance of exposure below 0.05 mg/m³ would avoid being on the steeper part of the dose-

¹⁶¹ The majority of the chemical agents subject to this initiative are not only classified as carcinogens but also for other adverse health effect. Because the other effects are of less importance for the initiative as such, additional classifications for other adverse health effects are not mentioned here

¹⁶² <http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C-14.pdf> and <http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono42.pdf> and <http://monographs.iarc.fr/ENG/Monographs/vol68/mono68-6.pdf>

¹⁶³ Recommendation from the Scientific Committee on Occupational Exposure Limits for Silica, Crystalline (respirable dust); SCOEL/SUM/94, November 2003

response curve, in the region where relatively small increases in exposure entail significant increases in silicosis risk.

The reduction of exposure to 0.05 mg/m³ of crystalline silica is expected to reduce the prevalence of silicosis, ILO category 1/1, to about or less than 5% whereas an average respirable silica concentration of 0.02 mg/m³ reduces prevalence of silicosis to about 0.25 % or less.

It arises that an OEL should lie below 0.05 mg/m³ of respirable silica dust.

No STEL or skin notation are needed.

12.2 Refractory ceramic fibres (RCFs)

12.2.1 Identification

Index Number¹⁶⁴: 650-017-00-8

EC Number¹⁶⁵: -

CAS Number¹⁶⁶: 142844-00-6

12.2.2 Synonyms

The complete name of the chemical agent classified according to the CLP Regulation is "Refractory ceramic fibres with the exception of those species elsewhere in Annex VI to Regulation (EC) 1272/2008 [Man-made vitreous (silicate) fibres with random orientation with alkaline oxide and alkali earth oxide (Na₂O+K₂O+CaO+ MgO+BaO) content less or equal to 18 % by weight]

Vitreous siliceous fibres, alumino-silicate glass wools

12.2.3 Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity

Carc. 1B – Causes Cancer by Inhalation

¹⁶⁴ Entries in Part 3 of Regulation (EC) N° 1272/2008 of the Regulation of the European Parliament and of the Council on the classification, labelling and packaging of chemical agents and mixtures are listed according to the atomic number of the element most characteristic of the properties of the chemical agent. Organic chemical agents, because of their variety, have been placed in classes. The Index number for each chemical agent is in the form of a digit sequence of the type ABC-RST-VW-Y. ABC corresponds to the atomic number of the most characteristic element or the most characteristic organic group in the molecule. RST is the consecutive number of the chemical agent in the series ABC. VW denotes the form in which the chemical agent is produced or placed on the market. Y is the check-digit calculated in accordance with the 10-digit ISBN method. This number is indicated in the column entitled "Index No".

¹⁶⁵ The EC number, i.e. EINECS, ELINCS or NLP, is the official number of the chemical agent within the European Union. The EINECS number can be obtained from the European Inventory of Existing Commercial Chemical Chemical agent (EINECS)[1]. The ELINCS number can be obtained from the European List of Notified Chemical agents (as amended) (EUR 22543 EN, Office for Official Publications of the European Communities, 2006, ISSN 1018-5593). The NLP number can be obtained from the list of 'no-longer polymers' (as amended) (Document, Office for Official Publications of the European Communities, 1997, ISBN 92-827-8995-0). The EC number is a seven-digit system of the type XXX-XXX-X which starts at 200-001-8 (EINECS), at 400-010-9 (ELINCS) and at 500-001-0 (NLP). This number is indicated in the column entitled 'EC No'.

¹⁶⁶ The Chemical Abstracts Service (CAS) provides a system whereby chemical agents are added to the CAS Registry and are assigned a unique CAS Registry Number. Those CAS numbers are used in reference works, databases, and regulatory compliance documents throughout the world to identify chemical agents without the ambiguity of chemical nomenclature

12.2.4 Classification according to IARC¹⁶⁷

Group 2B – The agent is possibly carcinogenic to humans

12.2.5 Recommendation of SCOEL¹⁶⁸

Occupational exposure to RCFs is associated with adverse respiratory effects as well as skin and eye irritation and may pose a carcinogenic risk based on the results of chronic animal inhalation studies. In these studies, exposure to RCFs produced an increased incidence of mesotheliomas in hamsters and lung cancer in rats. Mesotheliomas and sarcomas in rats and hamsters have also been induced after intrapleural and intraperitoneal implantation of RCFs. Intratracheal instillation induced lung tumours in rats.

Epidemiologic studies have found no association between occupational exposure to airborne RCFs and an excess rate of pulmonary fibrosis or lung cancer.

The epidemiological studies in the US and in Europe showed an association between exposure and increased prevalence of respiratory symptoms and conditions such as dyspnoea, wheezing, chronic cough, decreases in pulmonary function, and skin, eye, and upper respiratory tract irritation. These findings, which primarily reflect workers employed before 1980, did not persist with analysis of follow-up production years and accumulated RCF exposure from initial pulmonary function tests. More recent exposures from the late 1980s until 2004 had no deleterious impact on the longitudinal trend of FVC¹⁶⁹ and FEV1¹⁷⁰. During this time the RCF workplace concentrations constantly decreased below 1 f/ml. Since about 1993 the concentrations ranged around 0.2 f/ml in RCF fibre manufacture facilities and decreased from about 0.4 to 0.3 f/ml in customer facilities¹⁷¹. So far none of these studies provide information at what concentration the pulmonary effects are no longer seen. The common presence of other non-fibrous dust further complicates the evaluation of effects and their dose-responses at specific RCF workplace exposures. However, the studies indicate that the exposures since the late 1980s neither had deleterious impact on the lung function, nor diagnosed pleural plaques or mesothelioma. These exposures ranged from approximately 1 fibre/ml to below the limit of detection (Rice et al 1997)¹⁷².

Pulmonary function provides sensitive parameters to evaluate the effects of RCF exposure (see studies in workers in the US: Lockey et al., 1998, 2002; LeMasters et al., 1998; McKay 2010). The first cross-sectional pulmonary function study reported statistically (but not clinically) significant decrements in FVC and FEV1 for workers in the highest exposure category (> 60 fibres-months per cc) compared to those in the lowest exposure category (≤15 f-m/cc), but later studies reported no significant decline in lung function in a longitudinal analysis of male workers providing pulmonary function tests over seven years.

Upon request the authors of the McKay et al. (2010) study provided the following additional information:

¹⁶⁷ <http://monographs.iarc.fr/ENG/Monographs/vol81/mono81.pdf> and <http://monographs.iarc.fr/ENG/Publications/techrep42/TR42-6.pdf>

¹⁶⁸ Recommendation from the Scientific Committee on Occupational Exposure Limits for Refractory Ceramic Fibres SCOEL/SUM/165 September 2011

¹⁶⁹ Force Vital Capacity is the total amount of air exhaled during the FEV test.

¹⁷⁰ Forced expiratory volume measures how much air a person can exhale during a forced breath. The amount of air exhaled may be measured during the first (FEV1), second (FEV2), and/or third seconds (FEV3) of the forced breath.

¹⁷¹ A figure illustrating this trend can be found in the above mentioned SCOEL document on page 14

¹⁷² Rice D, Lockey J, Lemasters G, Levin L, Staley P, Hansen KR (1997) Estimation of historical and current employee exposure to refractory ceramic fibers during manufacturing and related operations. *Appl Occup Environ Hyg* 12, 54-61

- The average cumulative exposure among all workers in the > 60 f-mo/ml group was 147.9 f-mo/ml, and
- When sorted by chronological age, those workers at age 60 in the > 60 f-mo/ml group experienced an average cumulative exposure of 184.8 f-mo/ml.

Assuming a 45 years exposure the average cumulative exposures of 147.9 and 184.8 f-mo/ml, respectively, result in an average fibre concentrations of 0.27 and 0.34 f/ml. Considering these values as no observed adverse effect levels SCOEL proposes an OEL of 0.3 f/ml.

From the available information it is concluded that the genotoxic effects observed in the different studies are secondary so that RCFs are classified as SCOEL Carcinogen group C carcinogens: Genotoxic carcinogens for which a practical threshold is supported.

12.3 Acrylamide

12.3.1 Identification

Index Number: 616-003-00-0
 EC Number: 201-173-7
 CAS Number: 79-06-1

12.3.2 Synonyms

2-propanamide, acryl acid amide, ethylene caroxamide, propenoic acid amide, vinyl amide

12.3.3 Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity:

Carc. 1B – may cause cancer

12.3.4 Classification according to IARC¹⁷³

Group 2 A – The agent is probably carcinogenic to humans

12.3.5 Recommendation of SCOEL¹⁷⁴

As evidenced in animal experiments, acrylamide possesses a number of hazardous properties including neurotoxicity, impairment of male fertility, somatic and germ cell mutagenicity, and carcinogenicity. In relation to neurotoxicity, acrylamide causes impairment of axonal transport, leading to axonal swelling, loss of axons, degenerating myelin and changes to glial cells in the brain, spinal cord and peripheral nervous system. In workers, exposures to acrylamide have led to clinical signs of neurotoxicity such as tremor, in-coordination and reductions in nerve conduction velocity, and symptoms such as tingling and numbness in the hands and feet.

There are reports of skin irritation with an unusual presentation, i.e peeling of the skin on the hands and feet.

Rodent carcinogenicity studies in which acrylamide was administered in the drinking water showed increased tumour incidences in a number of organs/tissues including the testicular mesothelium, adrenals, mammary glands, and thyroid. This tumour profile suggests that the mechanism of carcinogenesis may involve hormonal disturbance but there is no definitive evidence for endocrine disturbance that could account for the diverse range of tumours seen. The fact that acrylamide does not affect fertility in females does not add support to a proposed hormonal mechanism for tumour development. It is also noted that there is evidence suggestive

¹⁷³ <http://monographs.iarc.fr/ENG/Monographs/vol60/mono60-16.pdf>

¹⁷⁴ Recommendation from the Scientific Committee on Occupational Exposure Limits for Acrylamide, SCOEL/SUM/139, September 2011, Annex December 2012

of an increase in glial cell tumours in the brain and spinal cord. In view of the genotoxic properties of acrylamide, a role for genotoxicity cannot be excluded.

In relation to the evidence for carcinogenicity in humans, there are two cohort studies in workers, and a number of studies of dietary exposure in the general population. None of these studies reveal any link between acrylamide and cancer, but there are possible limitations in these studies (low cumulative exposures in the occupational studies and the possibility of exposure misclassification in the dietary studies). Overall, in view of the animal evidence for carcinogenicity, as well as the evidence for somatic and germ cell mutagenicity, there has to be a concern for carcinogenic potential in humans and concern for the possibility of heritable mutations. A clear threshold for such effects cannot be identified. The very clearcut and strong neurotoxicity of acrylamide has led to an avoidance of higher exposures in industrial practice also in the past. Therefore, it is plausible why no direct evidence for acrylamide in exposed humans has been obtained.

The uncertainties surrounding the risk of cancer and genotoxicity (in particular heritable mutations) in workers exposed to acrylamide suggest that a health-based OEL cannot be derived. Although attempts have been published to explain the modes of action of the various tumour types observed in experimental animals (Shipp et al. 2006), the multiplicity of target sites, combined with the directly genotoxic nature of the metabolic intermediate, glycidamide, add significant uncertainties to these explanations (see also the detailed discussion by DFG 2007, 2009). Considering this situation, acrylamide is categorized in the SCOEL carcinogen group B (Bolt and Huici-Montagud 2008), as a genotoxic carcinogen, for which the existence of a threshold cannot be sufficiently supported at present. In consequence, a health-based OEL and BLV cannot be recommended.

A reasonable quantitative cancer risk assessment for humans is not feasible for acrylamide, because of two reasons: (1) Human cancer studies do not provide reliable figures as a basis of a risk quantitation. (2) The cancers observed in rats (testicular mesotheliomas, mammary tumours, glial cell tumours, thyroid tumours, adrenal pheochromocytomas) are significantly influenced by species-specific factors, which make meaningful quantitative extrapolations to humans almost impossible.

However, it is important that any regulation that may be established for acrylamide should also be protective against the development of neurotoxicity, given that there is a wealth of evidence for acrylamide-induced neurotoxicity in workers.

Experimentally, a minimal effect level (LOAEL) for neurotoxicity of 1 mg/kg per day and a NOAEL at the next lower dose of 0.2 mg/kg/day was established in a 90-day drinking water study in rats (Burek et al 1980). Johnson et al. (1984, 1986) repeated this study as part of a chronic study with a dose of 0.5 mg/kg per day and found no effect. Both studies included electron microscopic examinations. Hence, an established NOAEL for neurotoxicity in the rats is 0.5 mg/kg. This would correspond, for the rat (8 h respiratory volume of 0.38 m³/kg) to an inhalation concentration of 1.32 mg.m⁻³, i.e. 0.45 ppm (8-hr TWA).

In occupational studies it is difficult to establish a dose-response for neurotoxicity due to the inability to distinguish the relative contributions of dermal and inhalation exposure. However, a dose-response between neurological symptoms and acrylamide-haemoglobin adducts was reported in a study in tunnel workers (Hagmar et al 2001). The workers in this study were mainly exposed to acrylamide via dermal contact. By using biological monitoring of the haemoglobin adduct of acrylamide (*N*-2-carbamoyl-ethyl-valine), a NOAEL for neurotoxicity of 0.5 nmol adduct/g globin was reported with respect to neurotoxicity in occupationally exposed persons. This is seconded by another notion that no symptoms of peripheral neuropathy were reported in workers with this same adduct level in a biological monitoring study (Jones et al

2006). The adduct level based on these studies of 0.5 nmol/g globin would correspond to an airborne exposure of about 0.1 mg.m⁻³ or 0.035 ppm (8-hour TWA).

Dermal absorption is important in relation to workers under practical working conditions, and a 'skin' notation is therefore warranted. Indeed, in view of the low volatility of acrylamide there is the possibility that the skin is the dominant exposure route.

An Annex on possibilities for biological monitoring of occupational exposures to acrylamide was produced by SCOEL in December 2012.

12.4 Vinyl chloride monomer

12.4.1 Identification

Index Number: 602-023-00-7
EC Number: 200-831-0
CAS Number: 75-01-4

12.4.2 Synonyms:

VCM, chloroethylene

12.4.3 Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity:

Carc. 1A – May cause cancer

12.4.4 Classification according to IARC¹⁷⁵

Group 1 - The agent is carcinogenic to humans

12.4.5 Conclusions of SCOEL¹⁷⁶

Vinyl chloride is an established carcinogen, both in humans and in experimental animals. The primary target of its carcinogenicity is the liver, although there is clear experimental and suggestive human evidence that it also acts at extrahepatic sites. The primary, and most typical, liver tumour is angiosarcoma (hemangioepithelioma), but experimental data also demonstrate formation of hepatocellular carcinomas.

The SCOEL was asked to perform an assessment of human risk of carcinogenicity, related to workplace conditions. As a first step, available data were reviewed, which indicated that a linear high dose–low dose extrapolation of tumour risk was the most appropriate way in this case.

On this basis, the available quantitative risk assessments were reviewed, including those based on human epidemiological data and those based on extrapolation from animal data, by means of PBPK modelling.

The different approaches resulted in final risk estimates which were basically consistent with one another. As a result, it was inferred from epidemiological studies that a continuous exposure for working life (estimated to be 14% of the total lifetime) to *1 ppm vinyl chloride would be associated with a cancer risk for hepatic angiosarcoma of about 0.3×10^{-3} .*

Independent data, derived from animal experiments and using PBPK modelling, point to a similar order of magnitude (between 0.2 and 1.6×10^{-3}), and thus confirm this approach.

¹⁷⁵ <http://monographs.iarc.fr/ENG/Monographs/vol97/mono97-8.pdf> and
<http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-31.pdf>

¹⁷⁶ Recommendation from the Scientific Committee on Occupational exposure Limits, Risk Assessment for Vinyl Chloride, SCOEL/SUM/109 final, November 2004

12.5 Hardwood dust

12.5.1 Identification

Index Number: none
EC Number: none
CAS Number: none

12.5.2 Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity:

none

12.5.3 Synonyms

12.5.4 Classification according to IARC¹⁷⁷

Group 1 - The agent is carcinogenic to humans

12.5.5 Recommendations of SCOEL¹⁷⁸

Exposure to wood dust was shown to be associated with an increase of sino-nasal cancers, though this is a rare cancer. Impairment of respiratory function and increased prevalence of pulmonary symptoms were also observed in humans after exposure to wood dust.

Distinction between softwoods and hardwoods

As regards the risk of **sino-nasal cancer**, it seems that hardwood dusts are particularly dangerous, as they are probably also more dangerous than softwood dusts with respect to adenocarcinomas. However, as has already been stressed, it is impossible at the moment for two essential reasons to clearly identify the particular role of each type of wood in the genesis of cancer: (i) too few studies have addressed this problem and (ii) both types of wood are usually used in most wood-related fields of activity and workers have been exposed to both of them.

As regards the risk of **non-carcinogenic effects on the respiratory tracts**, practically all types of wood can cause various pulmonary symptoms in exposed workers, although only some, red cedar in particular, have been studied in any detail. However, the large number of studies involving red cedar should not be taken to imply that the dust of this species is the only one responsible for asthma and non-allergic affections of pulmonary function. It is very probable that similar results for respiratory effects due to the dusts of other wood species would be found if they had been studied in sufficient detail. This is suggested by the numerous descriptions of asthma cases related to occupational exposure to dust from many types of wood.

Irrespective of their already emphasised inadequacies, the results of experimental studies in animals provide no conclusive argument to justify a distinction between effects specific to softwood dusts and other effects specific to hardwood dusts.

With regard to currently available data and with a view to protecting the health of workers, all in all it does not seem pertinent to distinguish between softwood and hardwood dusts.

Particle size considerations

In the last decade, the rationale for sampling particle sizes relevant to expected health effects has gained recognition with the adoption of health-related aerosol size fraction definitions by the *International Organization for Standardization* (IOS, 1991), the *American Conference of Governmental Industrial Hygienists* (ACGIH, 2000) and the *Comité Européen de Normalisation*

¹⁷⁷ <http://monographs.iarc.fr/ENG/Monographs/vol62/mono62-6.pdf> and
<http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C-15.pdf>

¹⁷⁸ Recommendation from the Scientific Committee on Occupational Exposure Limits: Risk assessment for Wood dust, SCOEL/SUM/102 final, December 2003

(CEN). Three particle size distributions relevant to different capture areas of the human respiratory tract are distinguished: inhalable (any particles which enter the nose and mouth; 50% capture of 100 µm aerodynamic diameter particles); thoracic (particles which pass the larynx; 50% capture of 10 µm particles) and respirable (or alveolar: particles which enter the alveolar region; 50% capture of 4 µm particles). Occupational exposure standards specifically indicating these dust fractions should have two major advantages: reducing the variability due to fluctuations in the size distributions sampled and targeting the appropriate risk factors for wood dust-related disease.

However, most epidemiological studies have not assessed exposure-response relationships using particle size-selective measurements.

Considerable uncertainties exist to establish valid conversion ratios from total dust (as measured by the equipment used for most epidemiological studies), to an inhalable dust level, which is the most appropriate size fraction for the mass effects of exposure to wood dust. However, the available data suggest that a numerical value of an OEL expressed as "inhalable dust" may be set at approximately twice the numerical value for the corresponding limit value for "total dust"¹⁷⁹.

The mechanism underlying carcinogenesis by wood dust has not yet been elucidated. The few positive results in genotoxicity tests were obtained mainly with extracts of woods. The hypothesis of physico-mechanical cancer induction has not been clearly demonstrated by experiments.

The studies available do not provide adequate information for setting a health-based limit value for the protection of workers exposed to wood dust.

Taking into account the uncertainties and limitations of the available studies, it can be stated that exposure above 0.5 mg/m³ induces pulmonary effects and should be avoided. Exposure levels lower than 0.5 mg/m³ were associated with the induction of bronchial asthma only when the exposure was to western red cedar dust. The level of 0.5 mg/m³ (total dust) and 1 mg/m³ (inhalable dust) is probably below the levels to which the cases of sino-nasal cancers had been exposed.

12.6 Chromium (VI) compounds

12.6.1 Identification

Major factors governing the toxicity of chromium compounds are oxidation state and solubility.¹⁸⁰ Chromium (VI) compounds – also known as hexavalent chromium compounds – which are powerful oxidizing agents, appear to be much more toxic systemically than Chromium (III) compounds given similar amounts and solubility¹⁸¹.

Chromates and dichromates exist as a wide variety of compounds with 20 to 30 being of major industrial importance. These include, ammonium chromate and dichromate, barium chromate, calcium chromate and dihydrate, chromic chromate, chromium (IV) chloride, chromium trioxide (chromic acid), chromyl chloride, lead chromates, molybdenum orange

¹⁷⁹ Further information on this topic is provided in an Annex to the above mentioned SCOEL document.

¹⁸⁰ The solubility of chromates varies widely and ranges from virtually insoluble to highly soluble. The various uses of the term solubility have caused much confusion and to harmonise discussions and classification it has been proposed (Cross *et al*, 1997) that the water solubility of hexavalent chromium compounds can be defined as: poorly soluble (<1g/l), sparingly soluble (1-10g/l); highly soluble (>100g/l). Thus, poorly soluble includes lead and barium chromate, sparingly soluble includes strontium, calcium and zinc chromate and highly soluble would include sodium and potassium chromates and dichromate.

¹⁸¹ <http://www.atsdr.cdc.gov/csem/chromium/docs/chromium.pdf>

($\text{PbCrO}_4\text{PbMoO}_4\text{Pb}_2\text{SO}_4\text{Al}_2\text{O}_3$), potassium chromate and dichromate, sodium chromate and dichromate and zinc chromates.

A subset of six chromium (VI) compounds are listed in Annex XIV of the REACH Regulation and so are, or will be, subject to 'authorisation' for continued use. Available evidence (e.g. from the CAREX database) indicates that sodium, potassium, calcium and ammonium chromates and dichromates have been identified as the most important exposures, a number of which are already regulated under REACH.

The assessment of other chemical agents subject to REACH authorisation is deferred from this report. However, as not all chromium (VI) compounds are listed in REACH Annex XIV the same argument does not apply here.

Further, it is not possible based on available data to identify exposed populations or impacts associated only with chromium (VI) compounds which are not listed on REACH Annex XIV, nor to account for the impact REACH authorisation may have on exposures for those important compounds to which it will apply.

The IOM study assessed impacts of introducing an OEL for all Chromium VI compounds, including those subject to REACH.

While this analysis is based on best available data, it should be noted that this results in likely overestimates of both the costs and benefits associated with setting an OEL under CMD for Chrome (VI) compounds.

12.6.2 Synonyms

12.6.3 Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity

Chromium (VI) compounds with the exception of barium chromate and of compounds otherwise specified in Annex VI to the CLP Regulation have a harmonised classification as Carc. 1B – May cause cancer by inhalation. 13 further chromium (VI) compounds have harmonised classification entries as carcinogenic category 1.

12.6.4 Classification according to IARC¹⁸²

Group 1 - The agent is carcinogenic to humans

12.6.5 Conclusion of SCOEL¹⁸³

Non-cancer end-points:

In humans occupationally exposed by inhalation to hexavalent chromium compounds, the main health effects are irritant and corrosive effects on the skin and respiratory tract. Effects on the respiratory tract include inflammation of the nasal septum. Lower respiratory effects include inflammation and obstructive disorders; transient impairment on lung function has been reported. It is uncertain to what extent short-term exposure to high hexavalent chromium levels or direct contamination of the nasal mucosa with chromium may be involved in the development of the nasal lesions and this complicates a clear interpretation of the significance of the reported average exposure levels in relation to these health outcomes. Renal dysfunction has been reported in some studies, indicated by altered urinary protein or enzyme levels. In contrast, some studies have reported no effects on kidney function. Irritant and corrosive effects on the GI tract and effects in the liver have been reported following repeated exposure, but these cannot be

¹⁸² <http://monographs.iarc.fr/ENG/Monographs/vol49/mono49-6.pdf> and <http://monographs.iarc.fr/ENG/Monographs/vol100C/mono100C-9.pdf>

¹⁸³ Recommendation from the Scientific Committee on Occupational Exposure Limits: Risk assessment for Hexavalent Chromium; SCOEL/SUM/86; December 2004

related to exposure data. Hexavalent chromium compounds are potent skin sensitisers in humans and can cause respiratory sensitisation, Sensitised individuals may also react to trivalent chromium compounds. In general, the animal investigations from both single and repeated exposures are supportive of the effects seen in humans although the data do not cover the wide range of hexavalent chromium compounds in common use, most focussed on the highly soluble compounds, and do not allow clear NOAELs to be established for the health endpoints investigated.

Carcinogenicity:

A large number of epidemiological studies are available which have investigated cancer risks. Studies of chromate production workers provide clear evidence of increased lung cancer mortality. Excess risk of lung cancer mortality has also been reported for workers in the chromate pigment industry, producing principally lead and zinc chromates. There is suggestive evidence that zinc chromate, rather than lead chromate, is associated with the increased lung cancer mortality in the pigment producing industry. One study of chrome platers provides clear evidence of increased lung cancer risks and this finding is supported by other less informative studies of chrome platers. Epidemiological investigations of ferrochrome workers, stainless steel production workers and stainless steel welders have generated conflicting results and with the added complication of co-exposure to known carcinogens, allow no conclusions to be reached regarding lung cancer risks in relation to hexavalent chromium exposure in these industries. Overall, only a few of the reported epidemiological studies provide exposure data and no single study includes measurements of occupational exposures for all time periods under investigation. Consequently, any quantification of lung cancer risk is based on limited data.

The carcinogenicity of a number of hexavalent chromium compounds has been investigated in animal studies using various route of exposure; the most informative for the purpose of estimating cancer risks to humans in occupational settings are inhalation, intratracheal instillation and intrabronchial studies. In an inhalation study, in which rats were exposed to sodium chromate (0.025, 0.05 or 0.1mg Cr/m³), increased lung tumours occurred only at the highest dose. In a mouse inhalation study, increased lung tumours were associated with exposure to calcium chromate at the concentration used of (4.3mg Cr/m³). Two mouse inhalation studies showed a nonsignificant increase in lung tumours following exposure to chromium (IV) oxide. These inhalation studies all suffered from some deficiencies in design. Other inhalation studies, some of which investigated less soluble hexavalent chromium compounds, had major deficiencies that prevented any conclusions being drawn. In one intratracheal instillation study, increased lung tumour incidence was reported in rats following exposure to calcium chromate. In the same study, sodium dichromate was associated with increased lung tumour incidence in rats with 1.25mg/kg/week (0.5mg Cr/kg/week) administered as one weekly dose, but not when the same weekly dose was administered in five instillations. Other intratracheal instillation studies had major limitations, which prevented any conclusions being drawn. An intrabronchial implantation study in rats demonstrated elevated lung cancer incidence with calcium chromate, strontium chromate and zinc chromate, but failed to demonstrate evidence for carcinogenicity of poorly soluble compounds (lead chromate or barium chromate) or sodium dichromate, although the method may be inappropriate for highly soluble compounds.

On the basis of the animal carcinogenicity data, it is concluded that there is evidence to suggest a potency difference between hexavalent chromium compounds, probably related to solubility and consequently bioavailability. However, the variation in design of the animal studies and, crucially, the scarcity of reliable data for poorly soluble hexavalent chromium compounds precludes definite distinctions being made, either qualitative or quantitative, between hexavalent chromium compounds on the basis of the available animal studies done alone.

The genotoxicity of hexavalent chromium compounds has been widely investigated in assays for different genetic endpoints and has, with a few possible exceptions, been uniformly positive in *in vitro* assays for mutagenicity and clastogenicity, with evidence of *in vivo* expression of these effects in some compounds. The possible exceptions are lead and barium chromate and these two compounds have required solubilisation to elicit positive results in bacterial cell assays or to enhance their genotoxic activity in mammalian cells. Although there appears to be a difference in genotoxic potential between the various hexavalent chromium compounds tested based on solubility, positive results were obtained with the poorly soluble compounds in some assays. It is therefore not possible to exclude any compounds tested from possessing some mutagenic or clastogenic potential.

Basis for recommending a limit:

The health effects associated with occupational exposure to hexavalent chromium compounds are carcinogenicity, (specifically lung cancer), sensitisation, renal toxicity and irritancy, and corrosivity of the skin, respiratory and gastrointestinal tract. Clearly, the most serious of these outcomes in health terms is lung cancer and, given the magnitude of occupational cancer risks shown in some of the earlier epidemiological studies, and given that hexavalent chromium compounds are comprehensively genotoxic, it follows that lung cancer is the critical effect upon which to base any occupational exposure limit. Ideally, it would be preferable to develop lung cancer risk estimates for individual hexavalent chromium compounds (or a few groups of compounds). Unfortunately, the quantity and quality of the epidemiological data are not sufficient to rank, with any confidence, the carcinogenic potencies of the various hexavalent chromium compounds encountered in industry. The available animal carcinogenicity investigations do not provide this missing information. Notwithstanding the dearth of appropriate human studies, the available human and experimental animal data indicate that poorly soluble hexavalent chromium compounds have a lower carcinogenic potency than soluble compounds. Such an effect might be explained by the relatively lower delivery of bioavailable active chromium ions to the intracellular target in the respiratory epithelium.

Lung cancer risk assessment:

The study of Mancuso (1975) currently dominates the risk assessments of hexavalent chromium; USEPA, 1984; Gibb *et al*, 1986; PCHRG 1993; Crump, 1995. However, this survey, with a total of 41 lung cancer deaths available for analysis, does not constitute a large epidemiological study. In addition, the job histories and exposure histories of study subjects seem to be poorly described.

A risk assessment for hexavalent chromium based on epidemiological data, has been prepared for the US Occupational Safety and Health Administration (OSHA) (Crump, 1995). This assessment identified six sets of epidemiological data that provided some quantitative information on chromium exposures (Mancuso, 1975; Hayes *et al*, 1979; Langård *et al*, 1980; Axelsson *et al*, 1980; Pokrovskaya & Shabynina, 1973; Sjögren *et al*, 1987). The risk estimates prepared for OSHA are that some 6-9 excess lung cancer deaths will be experienced over a lifetime by a cohort of 1000 workers followed-up from the age of 20 years and occupationally exposed to $1\mu\text{g}/\text{m}^3$ of hexavalent chromium until retirement at age 65 years (Crump, 1995). At an occupational exposure level of $50\mu\text{g}/\text{m}^3$, the predicted number of occupational lung cancers was in the range 246 to 342. These assessments were based on data from the Mancuso (1975). When the assessments were based on the cohort of Hayes *et al*, (1979) the corresponding figures were 2 excess lung cancer deaths at an exposure level of $1\mu\text{g}/\text{m}^3$ and 88 excess lung cancer deaths at an exposure level of $50\mu\text{g}/\text{m}^3$. (The 4 other studies were judged to be less suitable for any primary risk assessment.)

The study cohort of chromate production workers described by Hayes *et al* in 1979 was redefined and updated (Gibb *et al*, 2000). The new cohort comprised 2357 workers first

employed between 1950 and 1974; follow-up was to the end of 1992. The new cohort included 990 workers who were employed for less than 90 days. These latter workers were included to increase the size of the low exposure group. Short-term workers are often found to have unusual patterns of mortality and it is unclear whether or not the inclusion of this group has been helpful. The authors put considerable effort into characterising chromium exposures in different jobs and different time periods. Unfortunately, the resulting job-exposure matrix is not reported. What is clear, however, is that many estimated exposures must have been very low because 75% of the cohort have estimated cumulative hexavalent chromium exposures in the range 0 - 0.0769mg/m³/y. A statistically significant non-monotonic positive trend is shown for lung cancer in relation to four levels of cumulative hexavalent chromium exposure and the study provides further evidence of excess lung cancer risks being caused by hexavalent exposure. The incorporation of the study findings into quantitative risk assessment is problematical in that three of the four exposure categories are so low (0 - 0.00149, 0.0015 - 0.0089 and 0.0090 - 0.0769mg CrO₃/m³/y) A further follow-up of 332 workers, first employed at a US chromate plant in the period 1931-37, has been reported by Mancuso (1997); follow-up was to the end of 1993. The study suffers from the absence of standard modern methods of analysis such as Poisson regression. The reader is supplied with much of the raw data in terms of deaths, and person-years-at risk shown by eight age-group categories and seven cumulative chromium exposure categories (total, soluble and insoluble chromium exposure are shown in turn). There then follows a descriptive account of patterns in the data rather than a statistical analysis that seeks to identify the independent effects of different chromium exposures. The data reported does not however, supply sufficient information to carry out the necessary analysis. Interestingly, the overwhelming majority of the Gibb *et al*, 2000 study population (perhaps in order of 90% of the cohort) would be placed in the lowest exposure categories in the Mancuso, 1997 study.

Sorahan *et al* (1998) publishes a worked example of a quantitative risk assessment based on data from a single cohort study of chrome platers. These calculations provided risk estimates that were higher than those shown in the Criteria Document of Cross *et al* (1997). The difference arose, in the main, because different assumptions were made about the exposure conditions pertaining to the study cohort. It is clear that under-or over-estimation of the exposure conditions which gave rise to the observed lung cancer excesses will have dramatic effects on any quantitative risk estimation derived from the epidemiological findings. It seems reasonable to use estimates which are based on more than one study, and the estimates shown in *Table 4* in Appendix 1¹⁸⁴ (column 1 relating to assumption 1) which are based on summary epidemiological findings from ten published cohort studies are considered to involve more reasonable assumptions about exposure conditions than do those predictions shown in other columns of *Table 4*.

The preferred risk assessment (see Appendix 1) is thus based on a summary of ten published studies (Steenland *et al*, 1996) and it has been estimated that about 5-28 excess lung cancers will occur in a cohort of 1000 male workers, followed-up from age 20 to age 85 and occupationally exposed to 50µg/m³ of hexavalent chromium until retirement at age 65. The corresponding number of excess lung cancers has been estimated to be 2-14 for an exposure level of 25µg/m³, 1-6 for an exposure level of 10µg/m³, 0.5-3 for and exposure of 5µg/m³ and 0.1-0.6 for and exposure level of 1µg/m³.

It is important to recognise that there are a number of limitations attached to all the proceeding estimates. They do not include statistical uncertainty and this will be considerable for the OSHA assessments given the small number of deaths available for that analysis. Uncertainty also exists regarding the appropriateness of the dose-response model employed. The model used assumes

¹⁸⁴ see further details in the SCOEL recommendation as such

linear extrapolation of cancer risks through the origin; there is no “threshold” dose, i.e. no dose or dose rate below which there is no carcinogenic effect. This is particularly important in the case of hexavalent chromium, which, because it is comprehensively genotoxic, could be considered an ideal carcinogenic chemical agent to which to apply a “no threshold” linear extrapolation. However, it should also be recognised that the irritant and inflammatory properties of hexavalent compounds may also contribute to the carcinogenic process and that for these effects there will be thresholds. It is not known to what extent irritancy may contribute towards carcinogenicity but it is quite plausible that linear extrapolation to low doses, below those seen in existing studies and where irritancy does not occur may over-estimate the true cancer risk. One should also take into account the lung’s ability to reduce hexavalent chromium to the non-genotoxic and non-carcinogenic trivalent species (De Flora, 2000). Unfortunately, epidemiological data can contribute little to this important issue. Whilst epidemiological data may show no excess lung cancer risk in a low cumulative exposure category, it is most likely that the confidence intervals attached to any such observed estimate of risk will include the (low) projected risk estimate supplied by linear extrapolation of cancer effects observed at higher cumulative exposures. Consequently, this aspect of model definition cannot be tested. In addition, other aspects of the statistical model used in the risk assessment are not based on the source data themselves. For example, any risk modifying effects of sex, age at exposure and period of follow-up have not been estimated. It is also of concern that the risk assessments have a sizable fraction of the total predicted risk occurring at ages beyond the follow-up ages available in the source data.

The proposed risk estimate has, for reasons discussed, not drawn any distinction between highly, sparingly and poorly hexavalent chromium compounds. However the available evidence, albeit incomplete, strongly suggests that poorly soluble hexavalent compounds carry a lesser lung cancer risk although the size of such a reduction cannot be quantified. Thus, in establishing occupational exposure limits a pragmatic approach may be appropriate. As an example, an exposure limit of $50\mu\text{g}/\text{m}^3$ of hexavalent chromium may well provide adequate protection for workers exposed to poorly soluble hexavalent chromium compounds but, on the basis of the risk assessments described in Appendix 1, consideration could be given to setting exposure limits at $25\mu\text{g}/\text{m}^3$ or $10\mu\text{g}/\text{m}^3$ for other hexavalent chromium compounds.

12.7 1-3 Butadiene

12.7.1 Identification

Index Number: 601-01300-X

EC Number: 203-450-8

CAS Number: 106-99-0

12.7.2 Synonyms

buta-1,3-diene, diethylene, divinyl, vinylethylene

12.7.3 Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity

Carc. 1A – may cause cancer

12.7.4 Classification according to IARC¹⁸⁵

Group 1 - The agent is carcinogenic to humans

¹⁸⁵ <http://monographs.iarc.fr/ENG/Monographs/vol97/mono97-6.pdf>

12.7.5 Recommendation of SCOEL¹⁸⁶

1,3 Butadiene was tested adequately for carcinogenicity in mice and rats by inhalation. In independent experiments in mice, tumours were induced in both sexes, at multiple sites, at concentrations ranging from 6.25 to 1,250 ppm. Exposure-related increases were observed for numerous cancer types, including heart angiosarcoma, malignant lymphomas, lung alveolar/bronchiolar adenomas and carcinomas, and forestomach papillomas and carcinomas. In one experiment in rats, multiple-site increased tumour incidence was only seen at 8000 ppm.

The recent updating of the follow-up on a large North-American cohort of styrenebutadiene rubber workers revealed a greater than twofold increase in leukaemia mortality among long-term workers, with a significant dose-response relationship to cumulative exposure to butadiene after adjusting for styrene and dimethyldithiocarbamate exposure; the independent effect of each agent could not be firmly evaluated.

Two smaller cohort studies of butadiene production workers showed slight excesses of lymphohaemopoietic cancers, but these were not considered to be associated with butadiene exposure.

On the basis of the available evidence, the SCOEL agreed that 1,3 Butadiene should be treated as a possible human carcinogen, operating via a genotoxic mechanism. Hence, according to the established approach for such carcinogenic chemical agents, the excess risk entailed in exposure during a working life to various concentrations of butadiene has been calculated using various models; the results are illustrated in the Annexed table.

Based on the model used in the SCOEL recommendation, using the exposure estimates and their associated relative rates reported in the most recent epidemiological study, SCOEL calculated the additional leukaemia risk associated with exposure to 1 ppm (proposed OEL) 1,3 Butadiene for a 40-year working life, as follows:

"In a population of 1.000 adult males experiencing a mortality rate similar to that of the male population of England and Wales, occupational exposure to 1 ppm of 1,3 Butadiene for a working life (40 years between the ages of 25 and 65), will cause from 0.0 to 10.78 extra leukaemia deaths between the ages 25-85 years, in addition to the 5 leukaemia deaths expected to occur in the absence of exposure to 1,3 Butadiene."

No STEL or "skin" notation was considered necessary.

At the levels discussed, no measurement difficulties are anticipated.

12.8 Ethylene oxide

12.8.1 Identification

Index Number: 603-023-00-X
EC Number: 200-849-9
CAS Number: 75-21-8

12.8.2 Synonyms

Oxirane

12.8.3 Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity

Carc. 1B – may cause cancer

¹⁸⁶ Recommendation from the Scientific Opinion on Occupational Exposure Limits: Risk assessment for 1,3 Butadiene

12.8.4 Classification according to IARC¹⁸⁷

Group 1 - The agent is carcinogenic to humans

12.8.5 Conclusion of SCOEL¹⁸⁸

The relevant endpoint for discussion of limiting occupational exposures to ethylene oxide is its carcinogenicity.

Ethylene oxide is a weak alkylating agent that is directly mutagenic and carcinogenic. After external exposure it is distributed within the entire organism, and in quantitative terms DNA alkylation is relatively uniform in the body. This affects in a similar way tumour target and non-target tissues. The carcinogenicity is clearly evident from animal experiments. In rats (Fischer 344), ethylene oxide has induced brain tumours, mononuclear cell leukaemias and peritoneal mesotheliomas, in mice (B6C3F1) lung adenomas and carcinomas. In long-term experiments, significant carcinogenic effects were seen upon repeated daily inhalation of 33 ppm and 100 ppm ethylene oxide. The carcinogenicity of ethylene oxide is reasonably connected with its DNA alkylating and resulting genotoxic properties. IARC (2008) has assessed ethylene oxide to be carcinogenic for humans (“Group 1”), rating the epidemiological evidence itself as being limited, but considering further elements of mechanism/mode of action and “other relevant data”.

Peritoneal mesotheliomas represent a quantitatively major malignancy induced in rats by chemical carcinogens (e.g. acrylamide). In humans, such tumours can be induced by asbestos, but not by such chemicals. There are no epidemiological indications, whatsoever, of such a target site for ethylene oxide-induced carcinogenesis in humans. There are, however, indications of haematopoietic/lymphatic cancer in humans that must be taken seriously, as evaluated by IARC (2008). No consistent evidence in humans could be found for brain, lung and mammary tumours. The available data on human haematopoietic/lymphatic cancer were therefore used as a starting point of published quantitative risk assessments (Kirman et al 2004, Valdez-Flores et al 2010, 2011).

A unique feature for ethylene oxide is that low levels of this chemical are produced endogenously by both the human and animal organism, and ethylene oxide represents therefore a physiological body constituent. In experimental animals, repeated exposures to 10 ppm resulted in statistically elevated DNA adducts, the main adduct being N7-(2-hydroxyethyl)guanine (HOEtG). In earlier publications, the physiological background of HOEtG in rats was estimated to correspond to repeated exogenous exposures at 1 ppm ethylene oxide, but during the last 20 years there have been gradual improvements of the methods of adduct detection and quantitation (see Section 2.7). The most recent experimental study of Marsden et al (2007; see Section 2.7), using LC-MS/MS, arrived at the conclusion that at a single or repeated dose (i.p.) to rats of 0.01 mg/kg of ethylene oxide any DNA adduct increase was negligible, compared to the endogenous damage already present. The extent of DNA damage was linear with the dose applied, and the damage did not accumulate with repeated ethylene oxide administration. The transposition of these data into a human risk assessment is a matter of current research, and more work into the underlying mechanisms will be needed to arrive at valid risk conclusions (Swenberg et al 2011).

One problem is that experimental ethylene oxide exposures of rodents lead to a relatively uniform distribution of HOEtG adducts in the DNA of both target and nontarget organs for carcinogenicity, another problem is that promutagenic adducts other than HOEtG are detected

¹⁸⁷ <http://monographs.iarc.fr/ENG/Monographs/vol97/mono97-7.pdf> and
<http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-28.pdf>

¹⁸⁸ Recommendation from the Scientific Committee on Occupational Exposure Limits for ethylene oxide; SCOEL/SUM/160; June 2012

only after very high experimental exposures. Human field data of Yong *et al* (2007) indicated that human workplace exposures within the studied range of 0.36 ± 0.31 ppm 8-h TWA did not lead to significant elevation of the HOEtG adduct levels in granulocyte DNA over the endogenous background (see Section 2.7). This could suggest that the genotoxic risk of ethylene exposures at lower levels ought to be practically negligible. At higher concentrations, ethylene oxide exposures have led to genotoxic damage in occupationally exposed humans. Cytogenetic signs of genotoxicity were visible at exposure levels of 5 ppm and above. At exposures of 1 ppm, no genotoxic changes could be directly established in exposed humans so far (see Section 2.6.2).

Although a non-linear dose-response (genotoxicity) relationship can reasonably be assumed based on arguments of mode of action (Kirman *et al* 2004), a definite noeffect level based on dose-response data cannot be defined. In this situation, SCOEL provisionally categorises ethylene oxide into “Group B” as a genotoxic carcinogen, for which a threshold is not sufficiently supported (Bolt and Huici-Montagud 2008).

This situation calls for a quantitative cancer risk assessment. Because of the argumentation given above (Section 2.8.3) this should preferably be based on epidemiological data on haematological malignancies. The most recent assessment based on studies in approximately 20 000 workers of the combined NIOSH and UCC/Dow cohorts by Valdez-Flores *et al* (2011) was considered by SCOEL as most reliable at present. The data (for males and females combined) are compiled in Table 1.

There is a solid data base for biological monitoring, based on HOEtVal haemoglobin adduct monitoring. Boogaard (2002) has compiled the argumentations and elements for establishing biological limit values (BLV). A derivation was performed by Boogaard *et al* (1999) for exposure conditions of an 8-h TWA of 0.5 ppm, corresponding to a HOEtVal level of 3.2 nmol per g globin. In consequence, a TWA of 0.1 ppm would correspond to a biological haemoglobin adduct value of 0.64 nmol (640 pmol) HOEtVal/g globin. Other extrapolated figures are included in Table 1. The values given in Table 1 can still be distinguished from the general background value of about 20 pmol HOEtVal/g globin.

A skin notation is warranted, as clear signs of systemic toxicity were reported after local application of ethylene oxide (Section 2.3).

Table 2. Occupational exposure concentrations (TWA; exposure for working lifetime) and haemoglobin adduct values corresponding to specified extra risks of lymphoid cancer mortality for males and females combined, according to the evaluation of Valdez-Flores *et al* (2011).

Extra risk	Corresponding TWA (ppm)	corresponding Hb adducts (nmol HOEtVal/g globin)
4×10^{-3}	21.35	136.6
1×10^{-3}	6.58	42.1
4×10^{-4}	2.77	17.7
1×10^{-4}	0.712	4.56
4×10^{-5}	0.286	1.83
1×10^{-5}	0.072	0.46

12.9 1,2 Epoxypropane

12.9.1 Identification

Index Number: 603-055-00-4
 EC Number: 200-879-2
 CAS Number: 75-56-9

12.9.2 Synonyms

Propylene oxide, methyloxirane

12.9.3 Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity

Carc. 1B – may cause cancer

12.9.4 Classification according to IARC¹⁸⁹

Group 2B - The agent is possibly carcinogenic to humans

12.9.5 Conclusion of SCOEL¹⁹⁰

The primary aspect to be considered in deriving an OEL for propylene oxide is its local carcinogenicity with the nasal epithelium as primary target, which is well established experimentally in rats and mice. So far, there is no evidence of carcinogenicity of propylene oxide from studies in humans.

Propylene oxide is the methyl homologue of ethylene oxide. Like ethylene oxide, it has alkylating properties. This leads to hydroxypropylation of biological macromolecules. Hydroxypropylation of the N-terminal valine in haemoglobin is used as a means of biological monitoring, and hydroxypropylation of DNA bases is viewed in conjunction with genotoxicity. Compared to ethylene oxide, the alkylating power of propylene oxide is about 4 times lower (Pauwels and Veulemans, 1998). The metabolism of both, ethylene oxide and propylene oxide, is qualitatively similar, via glutathione transferase and epoxide hydrolase, but differs quantitatively. At similar conditions of human industrial exposure, the levels of haemoglobin alkylation produced by propylene oxide are about 10 times lower compared to ethylene oxide exposure (Boogaard, 2002).

In contrast to ethylene oxide, the primary target of both toxicity and carcinogenicity of propylene oxide is at the port of entry into the organism. With inhalation exposure, this is the nasal epithelium. The carcinogenic potency at this site of propylene oxide is relatively weak. In long-term experiments mice, nasal tumours were observed at 400 ppm, and no tumours were seen at 200 ppm. In rats, such tumours were detected at 300 ppm, and no tumours were seen at the lower concentration of 100 ppm (chapter 2.8.2).

The EU Risk Assessment Report (ECB 2002) has addressed propylene oxide to be a genotoxic carcinogen, without an identifiable threshold. Yet, recent investigations into the mode of action of rodent nasal carcinogenesis due to propylene oxide inhalation point to decisive contributions of several factors besides genotoxicity. Upon propylene oxide inhalation, glutathione depletion is most marked in nasal respiratory mucosa, where a level of only 43% of control was observed following a single exposure of rats to 50 ppm for 6 h. At inhalation of 5 ppm the glutathione level at this site was maintained at 90% (Lee et al., 2005; see chapter 2.1.1). This is important, because glutathione has an important scavenging function in the detoxification of propylene oxide. For cytotoxic and proliferative changes in the nasal epithelium Eldridge et al. (1995) determined a NOAEL of 50 ppm in a 4-week study in rats (see chapter 2.5.2). Similarly, Kuper et al. (1988) found focal hyperplasia of the nasal turbinates and degenerative changes and proliferative hyperplasia of the nasal epithelium, particularly at the highest concentration tested (300 ppm propylene oxide). At 30 ppm these responses were rated „slight“ and of low incidence (and only identified in the 28-month treatment group), compared to the greater incidence of

¹⁸⁹ <http://monographs.iarc.fr/ENG/Monographs/vol60/mono60-9.pdf>

¹⁹⁰ Recommendation from the Scientific Committee on Occupational Exposure Limits for propylene oxide; SCOEL/SUM/161; August 2010

„moderate“ effects at 100 ppm (Reuzel and Kuper, 1983, Kuper et al., 1988). This study therefore points to a LOAEL of 30 ppm.

Apart from the local toxic and neoplastic effects of propylene oxide at the portal of entry into the organism, a systemic genotoxicity must be considered. Occupational genotoxicity studies performed on propylene oxide are scarce compared to those on ethylene oxide (Preston, 1999; Albertini and Sweeney, 2002). Czene et al. (2002), using the parameter of sister chromatid exchanges (SCE) in human lymphocytes, found that SCE frequencies at low occupational exposures (below 2 ppm propylene oxide) are not distinguished from those of non-exposed controls (see chapter 2.6.2). However, in view of the scattering of the general background of this parameter and of other arguments (Albertini 2003) the practical relevance of this finding is not clear.

Because there is a well-established mode of action for the local carcinogenicity (Albertini and Sweeney, 2002), propylene oxide is assigned to the SCOEL carcinogen group C, which is characterised by a practical threshold (Bolt & Huici-Montagud, 2008).

Considering (i) a LOAEL shown for local changes at the rat nasal epithelium at 30 ppm and (ii) an only minimal local glutathione depletion in the nasal tissue of the rats at 5 ppm, a health-based OEL should be set well below 5 ppm. A species scaling with regard to humans is not required in this case, as it is generally accepted that the nasal epithelium of rodents is more susceptible to irritation and irritation-based carcinogenicity than that of humans. Therefore, it is proposed to set the health-based OEL for propylene oxide at 1 ppm [2.41 mg/m³]. This also takes into account the results of Czene et al. (2002) of a no observed SCE effect in workers below 2 ppm exposure.

According to Boogaard (2002; see chapter 2.1.3) this OEL corresponds to a BLV of 1.3 nmol N-(3-hydroxypropyl)-valine haemoglobin adduct per g globin.

There is no data available to propose a STEL.

This OEL and BLV derivation is also supported by the following:

(i) In chapter 2.6.4 it has been deduced that a mean TWA exposure of 2 ppm propylene oxide would correspond to a mean DNA adduct frequency of N⁷-(2-hydroxypropyl)guanine of 3.3 x 10⁸. Accordingly, the frequency of this major propylene oxide DNA adduct, induced at the proposed OEL, would be 1.65 x 10⁸. This is a factor of 20 below the physiological level of the corresponding ethylene oxide adduct, N⁷-(2-hydroxyethyle)guanine, in human lymphocytes of non-smokers (Zhao & Hemminki 2002; see also SCOEL/SUM/160 for ethylene oxide), and confirms that no substantial genotoxic risk is associated with the proposed OEL and BLV.

(ii) Just recently, Sweeney et al. (2009) have again compiled all arguments, based on mode of action, that propylene oxide represents a carcinogen with a practical threshold. In addition to this, they also performed calculations, based on benchmark dose modelling, of a “human reference concentration” (RfC), according to current guidance of the U.S. Environmental Protection Agency (EPA 2005). Their resulting RfC values were in a range of 0.4 - 0.7 ppm, which is close to the OEL proposed here based on threshold assumption and experimental NOAEL/LOAEL.

There are no data at present on skin absorption of propylene oxide, which could serve as a data base for a skin notation.

12.10o-Toluidine

12.10.1 Identification

Index Number: 612-091-00-X

EC Number: 202-429-0
CAS Number: 95-53-4

12.10.2 *Synonyms*

2-aminotoluene

12.10.3 *Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity*

Carc. 1B – may cause cancer

12.10.4 *Classification according to IARC¹⁹¹*

Group 1 – The agent is carcinogenic to humans

12.10.5 *Conclusion of SCOEL*

Is currently being developed.

12.112 Nitropropane

12.11.1 *Identification*

Index Number: 609-002-00-1
EC Number: 201-209-1
CAS Number: 79-46-9

12.11.2 *Synonyms*

12.11.3 *Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity*

Carc. 1B – may cause cancer

12.11.4 *Classification according to IARC¹⁹²*

Group 2B - The agent is possibly carcinogenic to humans

12.11.5 *Conclusion of SCOEL*

Is currently being developed.

12.12 Bromoethylene

12.12.1 *Identification*

Index Number: 602-024-00-2
EC Number: 209-800-6
CAS Number: 593-60-2

12.12.2 *Synonyms*

- Vinyl bromide

¹⁹¹ <http://monographs.iarc.fr/ENG/Monographs/vol77/mono77-11.pdf>
<http://monographs.iarc.fr/ENG/Monographs/vol99/mono99-15.pdf> and
<http://monographs.iarc.fr/ENG/Monographs/vol100F/mono100F-11.pdf>

¹⁹² <http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono29.pdf> and
<http://monographs.iarc.fr/ENG/Monographs/vol71/mono71-49.pdf>

12.12.3 *Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity*

Carc. 1B – may cause cancer

12.12.4 *Classification according to IARC*¹⁹³

Group 2A - The agent is probably carcinogenic to humans

12.12.5 *Conclusion of SCOEL*¹⁹⁴

Vinyl bromide is clearly carcinogenic in experimental animals. It has been categorized by IARC (2008) as “probably carcinogenic to humans (Group 2A)”. According to the available bioassay data the carcinogenic effects are similar to those of vinyl chloride. The close relation between vinyl bromide and vinyl chloride is supported by comparative data on metabolism, nucleic acid adduct formation and formation of pre-neoplastic hepatic foci. This is consistent with the view of IARC (2008) that vinyl bromide should be considered to act similarly to the established human carcinogen, vinyl chloride. A reasonable quantitative comparison of the experimental carcinogenicity of vinyl bromide and vinyl chloride is possible when toxicokinetic aspects are integrated. This leads to the conclusion that in the occupationally relevant low exposure range vinyl bromide appears to be about 3 times more active than vinyl chloride.

Based on the argumentations on the mode of action for vinyl chloride (SCOEL/SUM/109) and considering the close similarity of both vinyl halides no threshold mechanism can be supported for both vinyl halides. In consequence and according to the SCOEL strategy for carcinogens (Bolt and Huici-Montagud 2008), vinyl bromide is grouped into group A of carcinogens (non-threshold carcinogen; for low-dose assessment of risk the linear non-threshold model appears appropriate).

As the available body of data that can be used for a quantitative assessment of carcinogenic risk is much larger for vinyl chloride than for vinyl bromide, SCOEL recommends to use the existing quantitative risk assessment for vinyl chloride (SCOEL/SUM/109) also for vinyl bromide, considering a three times higher potency of vinyl bromide compared to vinyl chloride.

The hepatic angiosarcoma risk for vinyl chloride, upon inhalation exposure for working lifetime to 1 ppm inferred from epidemiological data, has been assessed by SCOEL to be 3×10^{-4} (SCOEL/SUM/109). Independent data, derived from animals and using PBPK modelling, point to a similar order of magnitude (between 0.2 and 1.6×10^{-3} , and thereby confirm this approach. Accordingly, for a similar exposure to vinyl bromide the hepatic angiosarcoma risk is considered to be 9×10^{-4} .

12.13 Hydrazine

12.13.1 *Identification*

Index Number: 007-008-00-3
EC Number: 206-114-9
CAS Number: 302-01-2

12.13.2 *Synonyms*

Diamide

¹⁹³ <http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono39.pdf>
<http://monographs.iarc.fr/ENG/Monographs/vol71/mono71-40.pdf> and
<http://monographs.iarc.fr/ENG/Monographs/vol97/mono97-9.pdf>

¹⁹⁴ Recommendation from the Scientific Committee on Occupational Exposure Limits for vinyl bromide; SCOEL/SUM/155. September 2008

12.13.3 *Classification according to Regulation (EC) N° 1272/2008 with regard to carcinogenicity*

Carc. 1B – may cause cancer

12.13.4 *Classification according to IARC¹⁹⁵*

Group 2B – The agent is possibly carcinogenic to humans

12.13.5 *Conclusion of SCOEL¹⁹⁶*

The relevant toxicological endpoint for hydrazine is carcinogenicity. IARC (1999) has evaluated the evidence of carcinogenicity in experimental animals as being sufficient and summarised that the compound had been tested by oral administration to mice in several experiments, producing mammary and lung tumours. When tested by oral administration or inhalation exposure in rats, it produced lung, liver and nasal tumours and a few colon tumours in hamsters; it produced liver tumours and thyroid adenomas following oral or inhalation exposure (IARC 1999).

Among this body of data, the most useful information comes from the long-term inhalation studies and is related to the upper respiratory tract. In mice, exposed in a preliminary study for 6 months at 0.2, 1, or 5 ppm, there was an increased incidence of pulmonary tumours in all groups (Haun & Kinkead, 1972; MacEwen, 1974). A subsequent inhalation study in rats, mice, dogs and hamsters (6h/d; 5d/wk at 0.05 ppm [rats, mice], 0.25 and 1.0 ppm [rats, mice, hamsters, dogs] for 1 year with a follow-up for life span or 38 months revealed an increased incidence of benign and malignant nasal tumours at 1 and 5 ppm in rats. At 0.05 ppm, the incidence of nasal tumours in rats was slightly, but not significantly, over the controls. An increased incidence of benign nasal polyps was observed in hamsters at 5 ppm. In addition, hamsters exposed at 0.25 ppm showed pathological degenerative changes, including amyloidosis. An increased incidence of pulmonary adenomas was observed at 1 ppm in mice (MacEwen et al., 1979; Vernot et al., 1985).

The evidence of hydrazine carcinogenicity in humans was evaluated by IARC (1999) as being inadequate. In the meantime, however, the studies of Ritz et al. (1999, 2006) have pointed to the possibility of a carcinogenic effect in exposed areospace workers, in particular to an increased lung cancer mortality (see 2.8.1). This would be compatible with the aforementioned experimental data.

Hydrazine has been characterised as genotoxic. Studies into the mode of action have revealed an indirect mechanism of genotoxicity, involving reaction with endogenous formaldehyde and ultimate formation of a DNA-methylating agent.

In principle, the systemic genotoxicity of hydrazine, based on such an indirect mechanism, may be characterised by a threshold at low exposure levels (when hydrazine-induced DNA methylation becomes insignificant vs. the normal methylation background). However, the critical target upon occupational inhalation exposure is the respiratory tract, and specific studies into the local mode of carcinogenic action, as well as appropriate toxicokinetic modellings, are lacking.

There are considerable species differences regarding hydrazine carcinogenicity at the upper respiratory tract, and caution is warranted in view of the possibility of generation of human lung cancer. In this situation, the derivation of a health-based OEL, or a reasonable quantitative risk assessment based on experimental tumour data, is not possible at the present time.

¹⁹⁵ <http://monographs.iarc.fr/ENG/Monographs/vol1-42/mono4.pdf>
<http://monographs.iarc.fr/ENG/Monographs/suppl7/Suppl7-90.pdf> and
<http://monographs.iarc.fr/ENG/Monographs/vol71/mono71-43.pdf>

¹⁹⁶ Recommendation from the Scientific Committee on Occupational exposure Limits for hydrazine, SCOEL/SUM/164,, August 2010

Therefore, hydrazine is categorised into the SCOEL carcinogen group B, as a genotoxic carcinogen, for which the existence of a threshold cannot be sufficiently supported at present (Bolt & Huici-Montagud, 2007).

The systemic effects seen in animals following dermal contact warrant a 'skin notation'.

As there are no adequate data, a recommendation for biological monitoring cannot be given.

13 ANNEX 6 - EXPOSURE LIMIT VALUES IN EU MEMBER STATES AND SOME NON-EU COUNTRIES

Table 1. OELs in EU MS

	Hardwood dust mg/m ³	Vinyl chloride mg/m ³	Silica (respirable) mg/m ³	RCF ³ f/ml	1,3 Butadiene mg/m ³	Chromium (VI) compounds mg/m ³	Acrylamide mg/m ³	Ethylene oxide mg/m ³	1,2 Epoxy-propane mg/m ³	Bromo-ethylene mg/m ³	2-Nitropropane mg/m ³	<i>o</i> -Toluidine ppm	Hydrazine mg/m ³
AT	2	5	0,15	0,5	11 to 34	0,05-0,1	0,03-0,06	2	6	-	18	0,1	0,13
BE	3	7,77	0,05-0,1	0,5	4,5	0,01 -0,05	0,03	1,8	5	2,2	37	2	0,013
BG	5	2,5	0,07	-	-	0,05	0,03	2	-	-	35	-	0,1
CY	5	7,77	0,3 - 1,0 ¹	2	-	2	-	90	-	-	-	-	-
CZ	2,0	7,5	0,1	0,3	10	0,05	-	1	-	-	-	-	0,05
DE	2	7,77	-	-	-	-	-	-	4,8	-	-	-	-
DK	1	3	0,1	1	22	0,005	0,03	1,8	12	20	18	2	0,013
EE	2	3	0,05-0,1	-	1	0,02	0,03	2	5	-	18	-	0,1
EL	4,92	7,64	0,3 - 1,0 ¹	-	22	0,5	0,3	10	50	-	35	2	0,13
ES	5	7,8	0,05	0,5	4,5	0,01 -0,05	0,03	1,8	4,8	2,2	19	0,2	0,013
FI	5 / 2	7,7	0,05	0,2	2,2	0,05	0,3	1,8	2,4	4,4	18	2	0,13
FR	1	2,59	0,05-0,1	-	-	0,001	0,3	1,8	50	-	-	2	0,1
HR	5	7,77	0,05	-	22	0,05	0,3	9,2	12	20	19	0,2	0,03
HU	5	7,77	0,15	1-2	1	-	0,03	1,8	5	-	-	-	-
IE	5	7,77	0,1	1	36	0,01-0,05	0,03	10	12	2,2	18	0,2	0,01
IT	5	7,77	-	-	-	-	-	-	-	-	-	-	-
LT	5	7,77	0,05 - 0,1	-	1	0,005	0,03	2	5	-	7	-	0,1
LU	5	7,77	-	-	-	-	-	-	-	-	-	-	-
LV	5	7,77	-	-	100	0,01	0,2	1	1	-	-	0,1	0,1
MT	5	7,77	0,025 ²	0,2 ²	4,4	0,01	0,03 ²	1,8	-	5	2,2	2 ²	-

	Hardwood dust mg/m ³	Vinyl chloride mg/m ³	Silica (respirable) mg/m ³	RCF ³ f/ml	1,3 Butadiene mg/m ³	Chromium (VI) compounds mg/m ³	Acrylamide mg/m ³	Ethylene oxide mg/m ³	1,2 Epoxy-propane mg/m ³	Bromo-ethylene mg/m ³	2-Nitropropane mg/m ³	<i>o</i> -Toluidine ppm	Hydrazine mg/m ³
						0,05 ²							
NL	2	7,77	0,075	0,5	46,2	0,025	0,16	0,84	6	0,012	0,036	-	-
PL	2	5	0,3 - 1,0 ¹	0,5-1	4,4	0,1	0,1	1	9	0,4	-	-	0,05
PT	5	7,77	-	-	-	-	-	-	-	-	-	-	-
RO	5	7,77	0,05- 0,1	-	22	0,05	0,03	1,8	50	22	-	-	0,10
SE	2	2,5	0,05- 0,1	0,2	1	0,005	0,003	2	5	-	7	-	-
SI	5	7,77	-	-	11 to 34	2	0,03-0,06	2	6	-	18	0,1	0,13
SK	5	7,77	0,1	0,8	11	0,005 - 0,1	0,03	2	12	-	18	-	0,13
UK	5	7,8	0,1	1	22	0,05	0,3	9,2	12	-	19	0,2	0,03

Note 1: OELs are calculated in a case-by-case basis as a function of the % free silica. In the case of Poland, they provide an indicative range: 0.3-1.0 mg/m³, which is assumed here to be the range for CY and EL as well. Note 2: Values not included in national legislation but referred from national authorities as to be enforceable (technically sound values published by ACGIH).

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

Substance	MS having no or higher OEL	Total number
Hardwood dust	BG,CY, EL, ES, FI _p , HR,HU,IE, IT,LT, LU, LV,MT,PT, RO, SI, SK,UK	18
Vinyl chloride	AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK	25
Silica	AT, CY, DE, EL, HU, IT, LU, LV,PL, PT, SI	11
RCF	AT, BE, BG, CY, DE, DK, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, UK	24
1,3-Butadiene	AT, BE, BG, CY, CZ, DE, DK, EL, ES, FR, HR, IE, IT, LU, LV, MT, NL, PL, PT, RO, SI, SK, UK	23
Chromium (VI) compounds	AT, BE _p , BG, CY, CZ, DE, EL, ES _p , FI, HR, HU, IE _p , IT, LU, MT _p ,PL, PT, RO, SI, SK _p , UK	21
Acrylamide	CY, CZ, DE, EL, FI, FR, HR, IT, LU, LV, NL, PT, UK	13
Ethylene oxide	CY, DE, EL, HR, IE, IT, LU, PT, UK	9
1,2-Epoxypropane	AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SI, SK, UK	26
Bromoethylene	AT, BG, CY, CZ, DE, DK, EE, EL, FR, HR, HU, IT, LT, LU, LV, MT,PT, RO, SE, SI, SK, UK	22
2-Nitropropane	BE, BG, CY, CZ, DE, EL, FR, HU, IT, LU, LV, PL, PT, RO	14
o-Toluidine	BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, MT, NL, PL, PT, RO, SE, SK, UK	25
Hydrazine	AT, BG, CY, CZ, DE, EE, EL, FI, FR, HR, HU,IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, UK	24

p – partially (the OEL is provided as a range that includes the proposed value)

Table 3. OELs in some non-EU countries

Chemical agent	Retained option	<i>Australia</i>	<i>Canada</i>	<i>US</i>	<i>China</i>	<i>Switzerland</i>	<i>New Zealand</i>	<i>Japan</i>
1,2 – Epoxypropane mg/m ³	2,4	48	48 (Québec)	240	5	6	12	n.a.
1,3 Butadiene ppm	1	10	2	1	2,22	5	10	n.a.
2 Nitropropane mg/m ³	18	36	35 (Ontario) 36 (Québec)	90	30	18	19	n/a
Acrylamide (mg/m ³)	0,1	0,03	0,03	0,03	0,3	0.03 inhalable aerosol	0.03	0.1
Bromoethylene (mg/m ³)	4,37	22	22	n/a	n/a	22	22 mg/m ³	n/a
Hexavalent Chromium (mg/m ³)	0,025	0,05	0,05	0,001 NIOSH 0,005 OSHA	n/a	0,05 inhalable aerosol	0,05	0,05
Ethylene oxide (ppm)	1	1	1	1	2	1	1	1
Hardwood dust (mg/m ³)	3	1	1	n/a	n/a	2 inhalable aerosol	1	n/a
<i>o</i> -Toluidine (ppm)	0,1	2	2	5	n/a	0,1	0,2	n/a
Hydrazine (mg/m ³)	0,013	0,013	0,013	1,3	0,06	0,13	0,013	n/a
Refractory Ceramic Fibres (f/ml)	0,3	0,5	0,5	n/a	n/a	0,25	n/a	n/a
Respirable crystalline silica (mg/m ³)	0,1	0,1	0,1	0,05 (NIOSH) 30/(%silica+ 2) total dust and	Inhalable fraction: 1 (10% <= free SiO2 <= 50%) 0,7 (50% < free SiO2 <= 80%)	0,15 respirable aerosol	0,2	n/a

Chemical agent	Retained option	<i>Australia</i>	<i>Canada</i>	<i>US</i>	<i>China</i>	<i>Switzerland</i>	<i>New Zealand</i>	<i>Japan</i>
				10/(%silica+2) respirable dust (OSHA)	0,5 (free SiO ₂ < 80%)			
VCM (ppm)	1	5	1	1	3,85	2	5 ppm	2 ppm

Table 4. Exposures in Member States which have no OEL or an OEL higher than the value proposed by the ACSH (option 2)

	Hardwood dust mg/m ³		Vinyl chloride mg/m ³		Silica mg/m ³		RCF f/ml		1,3-Butadiene mg/m ³		Chromium (VI) compounds mg/m ³		Acrylamide mg/m ³		Ethylene oxide mg/m ³		1,2-Epoxy-propane mg/m ³		Bromoethylene mg/m ³		2-Nitropropane mg/m ³		o-Toluidine ppm		Hydrazine mg/m ³			
	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	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	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 EU workers exposed	3336790		15.000 (NO DATA by MS in the VCM report)		5299616		10.000 (NO breakdown data in IOM report)		27616		916595		54191		15567		485 to 1570 (No data by MS in the IOM report)		NO DATA in IOM report. Estimated to close to 0.		51365		5566		2123858			
AT					95486	1,80%			440	1,59%	16076	1,75%													40333	1,90%		
BE									869	3,15%	15182	1,66%										1038	2,02%	169	3,04%			
BG	NK								415	1,50%	13052	1,42%										56	0,11%	72	1,29%	46526	2,19%	
CY	9400	0,28%			11973	0,23%			28	0,10%	913	0,10%	68	0,13%	13	0,08%						15	0,03%	6	0,11%	1817	0,09%	
CZ									861	3,12%	30503	3,33%	1089	2,01%								782	1,52%	123	2,21%	75754	3,57%	
DE					628021	11,85%			6712	24,30%	173266	18,90%	9665	17,84%	3162	20,31%						10207	19,87%	1153	20,72%	425840	20,05%	
DK									422	1,53%														86	1,55%			
EE																								12	0,22%	8640	0,41%	
EL	68490	2,05%			107236	2,02%			308	1,12%	10147	1,11%	989	1,83%	186	1,19%						493	0,96%	75	1,35%	10643	0,50%	
ES	405960	12,17%							2503	9,06%	123750	13,50%												399	7,17%			
FI	53770	1,61%									7477	0,82%	625	1,15%										59	1,06%	21606	1,02%	
FR									4140	14,99%			6910	12,75%								10502	20,45%	785	14,10%	277524	13,07%	
HR	NK								NK		NK		NK		NK									NK		NK		
HU	83550	2,50%			89436	1,69%					16521	1,80%										136	0,26%	102	1,83%	53925	2,54%	
IE	43500	1,30%							299	1,08%	4011	0,44%			158	1,01%								59	1,06%			
IT	329130	9,86%			245555	4,63%			382	1,38%	142998	15,60%	2693	4,97%	210	1,35%						4936	9,61%	559	10,04%	196294	9,24%	
LT	37120	1,11%																						27	0,49%	21908	1,03%	
LU	2560	0,08%			12173	0,23%			43	0,16%	1042	0,11%	48	0,09%	14	0,09%						1	0,00%	7	0,13%	4228	0,20%	
LV	33470	1,00%			26342	0,50%			79	0,29%			262	0,48%								24	0,05%			13860	0,65%	
MT	3790	0,11%							1	0,00%	46	0,01%												2	0,04%	164	0,01%	
NL									951	3,44%			2262	4,17%										209	3,75%	50003	2,35%	
PL					333727	6,30%			1936	7,01%	58540	6,39%										2787	5,43%	338	6,07%	213605	10,06%	
PT	99330	2,98%			177157	3,34%			386	1,40%	17114	1,87%	945	1,74%	263	1,69%						83	0,16%	84	1,51%	27877	1,31%	
RO	NK								804	2,91%	30650	3,34%												145	2,61%	42667	2,01%	
SE																												
SI	27830	0,83%			26771	0,51%			207	0,75%	5953	0,65%														14171	0,67%	
SK	51260	1,54%							244	0,88%	8220	0,90%												49	0,88%	33963	1,60%	
UK	363540	10,89%							3690	13,36%	85192	9,29%	9201	16,98%	2618	16,82%								760	13,65%	240811	11,34%	
NK: not known		48,33%				33,09%				93,13%	82,99%		64,14%		42,55%											62,41%	97,59%	91,06%
	1612700				1753877				25720		760653		34757		6624							32055		5432		1933955		
COUNT MS	15				11				22		20		12		8							14		24		23		

14 ANNEX 7 - RELEVANT EU LEGISLATION

14.1 Existing EU-OSH framework

14.1.1 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”.

14.1.2 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.¹⁹⁷

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

¹⁹⁷ 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

(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.

14.1.3 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, 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 the International Agency for Research on Cancer - IARC) as chemical agents, mixtures or processes of equal concern.

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

14.1.4 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 cm³ 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.

14.2 Internal Market legislation

14.2.1 REACH Regulation

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

It requires all companies manufacturing and 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.

If a safe use cannot be demonstrated, authorities have the possibilities to restrict its use by either submitting it to the restriction or the authorisation procedure.

'Restriction' is the procedure via which the manufacture, use 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 13 chemical agents under consideration is presented in the table below.

Table 1. REACH status of chemical agents in present proposal

Chemical Agent	REACH STATUS
Acrylamide	1 full registration (joint submission): 100 000 - 1 000 000 tonnes per annum. 2 intermediate registrations (both individual submissions, tonnages undisclosed) Added to Candidate List of 'substances of very high concern' potentially to be made subject to authorisation. Restricted (REACH.XVII.60) for use in grouting (significant but narrow worker protection).
RCF	1 full registration (joint submission): 100 000 - 1 000 000 tonnes per annum Added to Candidate List of 'substances of very high concern' potentially to be made subject to authorisation. ECHA have recommended this agent be added to REACH Annex XIV. REACH authorisation regulatory proposal imminent.
1,3 Butadiene	1 full registration (joint submission): 1 000 000 - 10 000 000 tonnes per annum
Chromium (VI) compounds	Complex REACH status as there are 100+ Chromium (VI) compounds. 50 of these have been pre-registered but not registered or covered by authorisation. Others registered as full

	and/or intermediate registrations. A subset of chromium (VI) compounds are subject to authorisation. ¹⁹⁸ Restricted (REACH.XVII.47) for use (above v low concentration) in cement (ltd. worker protection). Very widespread and important substance.
Ethylene oxide	1 full registration (joint submission): 1 000 000+ tonnes per annum. 4 intermediate registrations (all individual submissions, tonnages undisclosed). Also several registrations for related but distinct substances.
Hydrazine	Added to Candidate List of 'substances of very high concern' potentially to be made subject to authorisation.
2 Nitropropane	1 full registration (joint submission): 1 000 - 10 000 tonnes per annum. Many registrations for related but distinct substances
RCS (crystalline silica, quartz)	Complex registration status. As mineral substances which occur in nature silicone dioxide (i.e. silica) is exempt from the REACH registration obligation. Further, RCS which meets the proposed definition as a process generated substance under CMD would not normally be in scope of REACH registration, which applies to chemical substances placed on the EU market above one tonne per year (and hence not to chemical agents generated <i>in situ</i>). Nevertheless, there are 2 full registrations for silicon dioxide (one joint, one individual) at high tonnages and many related registrations.
<i>o</i> -Toluidine	1 full registration (joint submission): 10 000 - 100 000 tonnes per annum. 1 intermediate registration individual submission, tonnage undisclosed) Added to Candidate List of 'substances of very high concern' potentially to be made subject to authorisation.
Vinyl chloride	3 full registrations: 1 joint submission at 1 000 000 - 10 000 tonnes per annum, 2 intermediate registrations at 10 000 - 100 000 tonnes per annum Restricted (REACH.XVII.2) for use as an aerosol propellant (ltd. worker protection). Existing BOELV to update.
Hardwood dust	Out of scope of REACH
1,2 Epoxypropane	1 full registration (joint submission): 1 000 000+ tonnes per annum. Various intermediate registrations as individual submissions, tonnages undisclosed
Vinyl bromide (bromoethylene)	2 intermediate registrations (individual submissions, tonnages undisclosed)

14.2.2 CLP Regulation

The CLP Regulation (for "Classification, Labelling and Packaging") is the EU Regulation which aligns the previous EU system of classification, labelling and

¹⁹⁸ Trichloroethylene, chromium trioxide, chromic acid, oligomers of chromic acid and dichromic acid, dichromic acid, sodium dichromate, potassium dichromate, ammonium dichromate, potassium chromate, sodium chromate

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 Directive¹⁹⁹) 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).

14.2.3 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 measures.	Sets directly-acting harmonised standards from which Member States cannot deviate except in exceptional (and possibly time limited) 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

¹⁹⁹ 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

	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.

15 ANNEX 8 – GENERAL INFORMATION ABOUT THE CLASSIFICATION SYSTEMS REFERRED TO IN THE DOCUMENT

15.1 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)

15.1.1 Classification according to the CLP Regulation

The harmonised classification²⁰⁰ 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 Regulation²⁰¹. 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.

²⁰⁰ classification of chemical agents listed in Annex VI to the Regulation

²⁰¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20150601&qid=1447160631531&from=EN>

15.1.2 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 website²⁰². 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 based²⁰³, 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"²⁰⁴).

Based on its evaluation, IARC classifies "agents" in 5 groups with regard to their carcinogenicity to humans²⁰⁵:

- 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.²⁰⁶
- 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.

²⁰² <http://monographs.iarc.fr/ENG/Monographs/PDFs/index.php>

²⁰³ 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.

²⁰⁴ <http://monographs.iarc.fr/ENG/Monographs/vol100F/index.php>

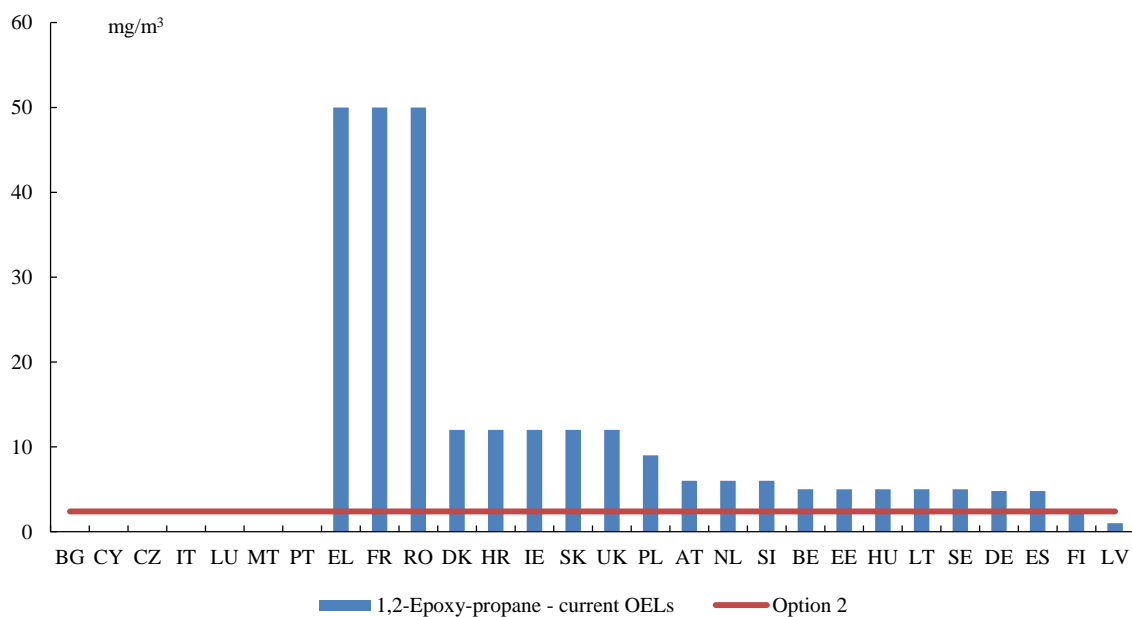
²⁰⁵ The details of the objectives and scope of the IARC Monographs programme, the scientific principles and the procedures used in developing a Monograph, the types of evidence considered and the scientific criteria guiding the evaluations can be found in the preamble of each Monograph and on the following web side: <http://monographs.iarc.fr/ENG/Preamble/index.php>

²⁰⁶ 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*.

16 ANNEX 9 – ADDITIONAL GRAPHICAL MATERIAL

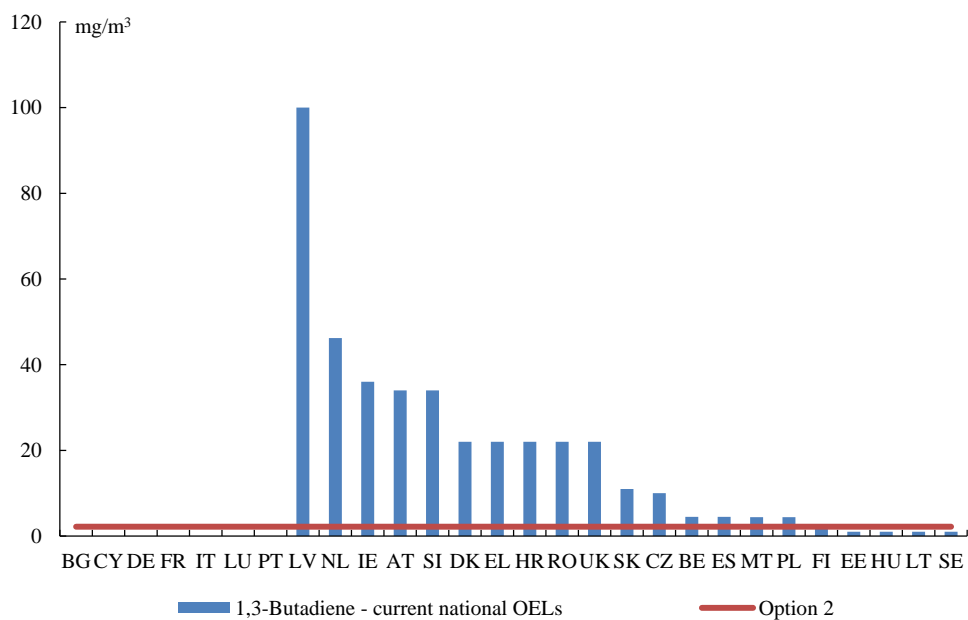
16.1 1,2 Epoxypropane

Figure 4 - 1,2 Epoxypropane – Current national OELs vs. Option 2



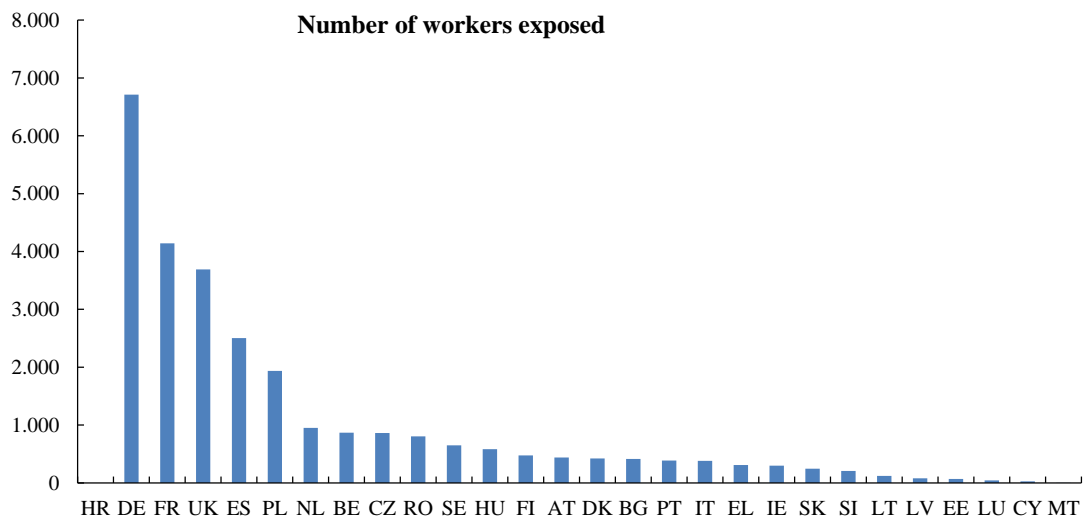
16.2 1,3 Butadiene

Figure 5 - 1,3 Butadiene – Current national OELs vs. Option 2²⁰⁷



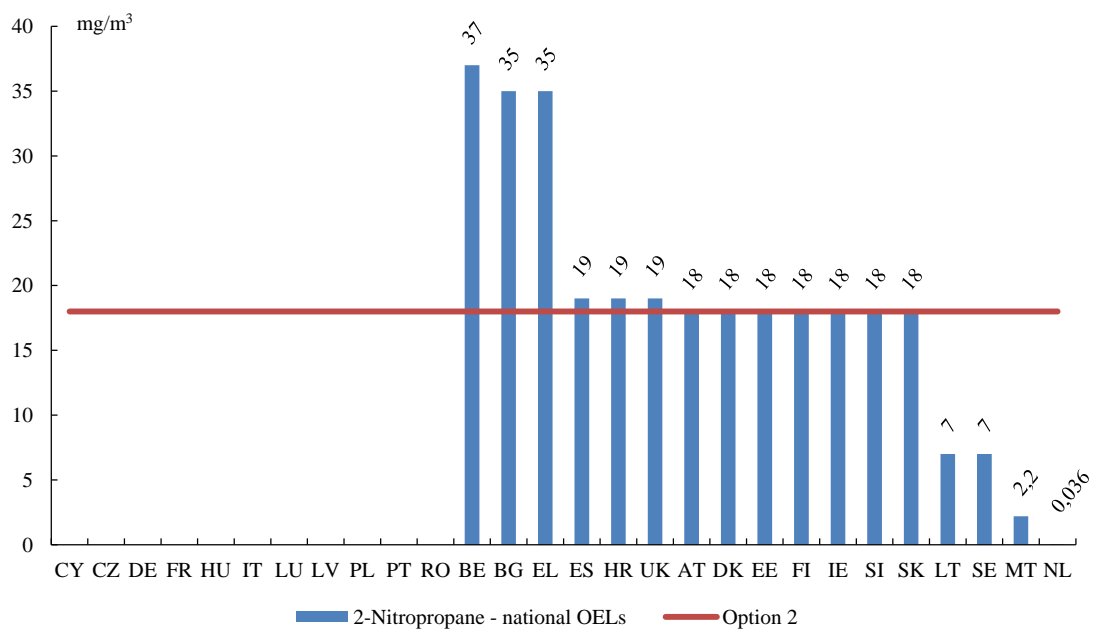
²⁰⁷ Where the OELs have been provided as a range, the upper value has been used in the graph.

Figure 6 - 1,3 Butadiene – Number of exposed workers ²⁰⁸



16.3 2 Nitropropane

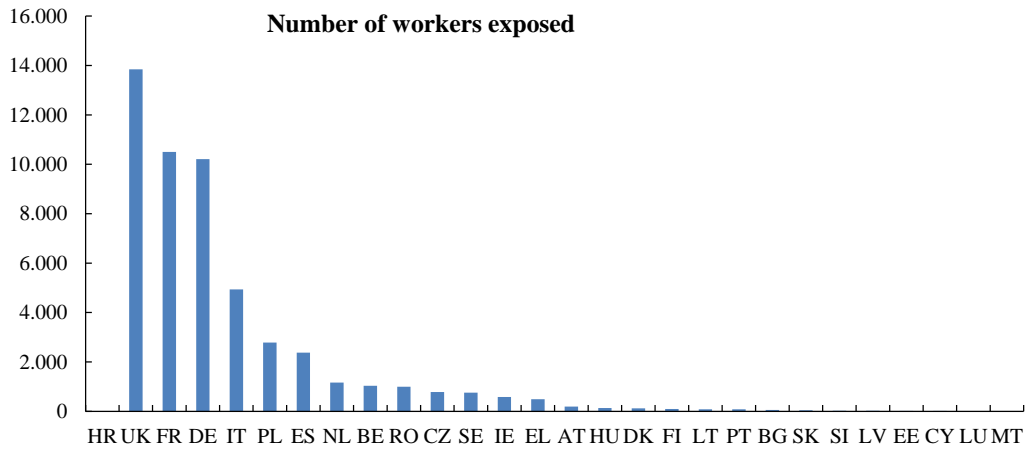
Figure 7 - 2 Nitropropane – Current national OELs vs. Option 2 ²⁰⁹



²⁰⁸ Data for HR are not known.

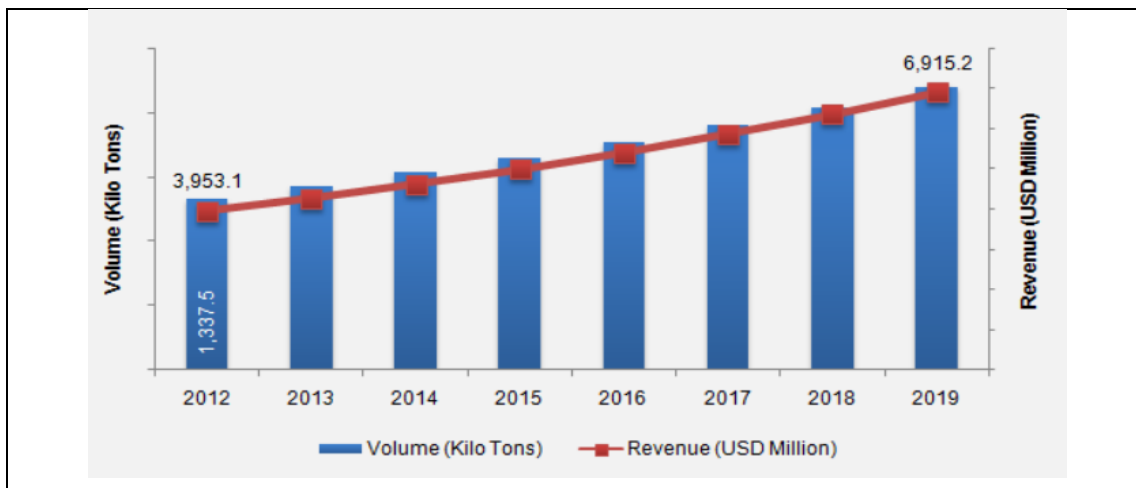
²⁰⁹ ES, HR, UK have an OEL of 19 mg/m³, which is considered approximately equivalent to 18 mg/m³.

Figure 8 - 2 Nitropropane –Number of exposed workers²¹⁰



16.4 Acrylamide

Figure 9 – Acrylamide - Global polyacrylamide market, 2012-2019 (in 1,000 tonnes)²¹¹



²¹⁰Data for HR are not known.

²¹¹Source: <http://www.transparencymarketresearch.com/polyacrylamide-market.html>

Figure 10 – Acrylamide - Current national OELs vs. Option 2²¹²

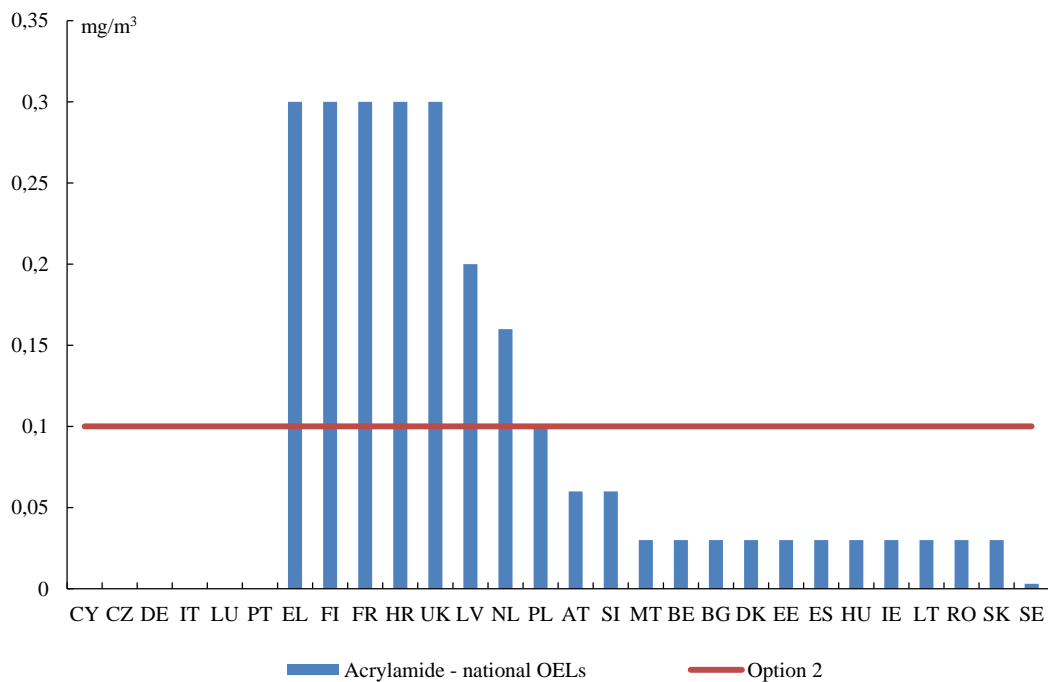
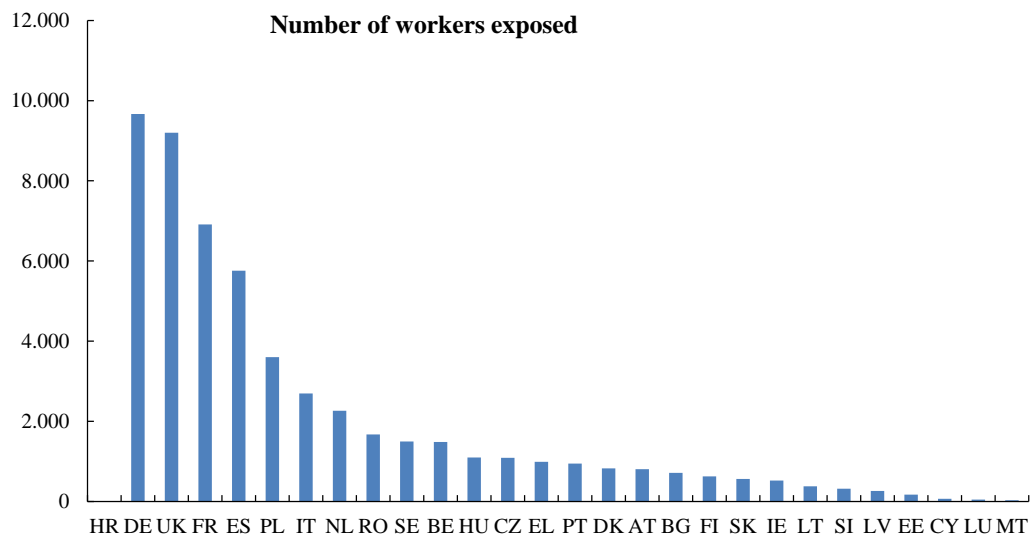


Figure 11 – Acrylamide - Number of exposed workers²¹³



²¹² Where the OELs have been provided as a range, the upper value has been used in the graph.

²¹³ Data for HR not available.

16.5 Hardwood dust

Figure 12 – Hardwood dust - Current national OELs vs. EU OEL and Option 2

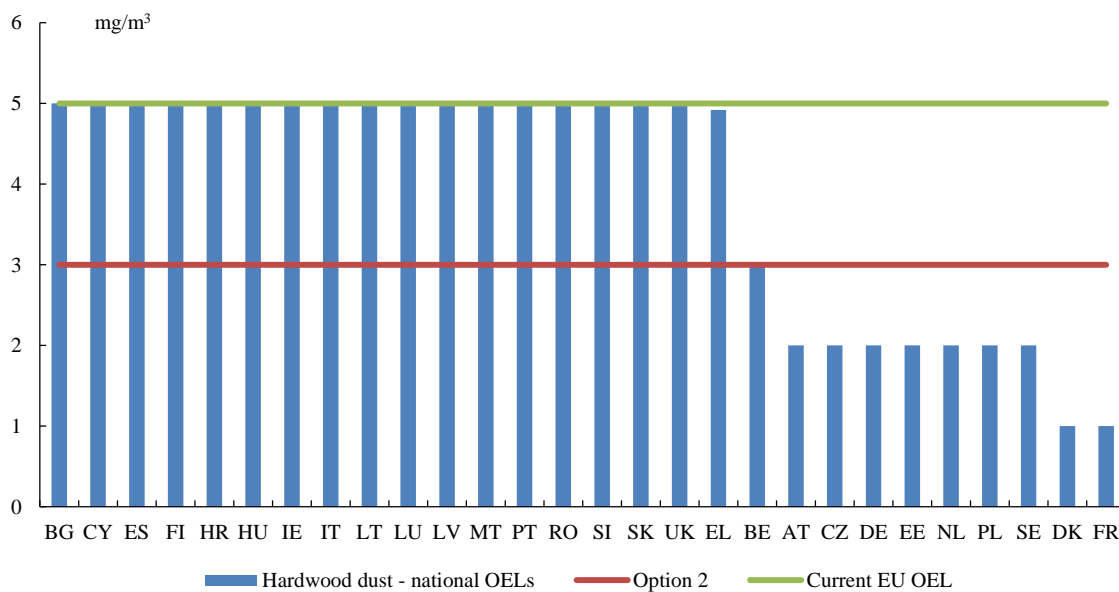
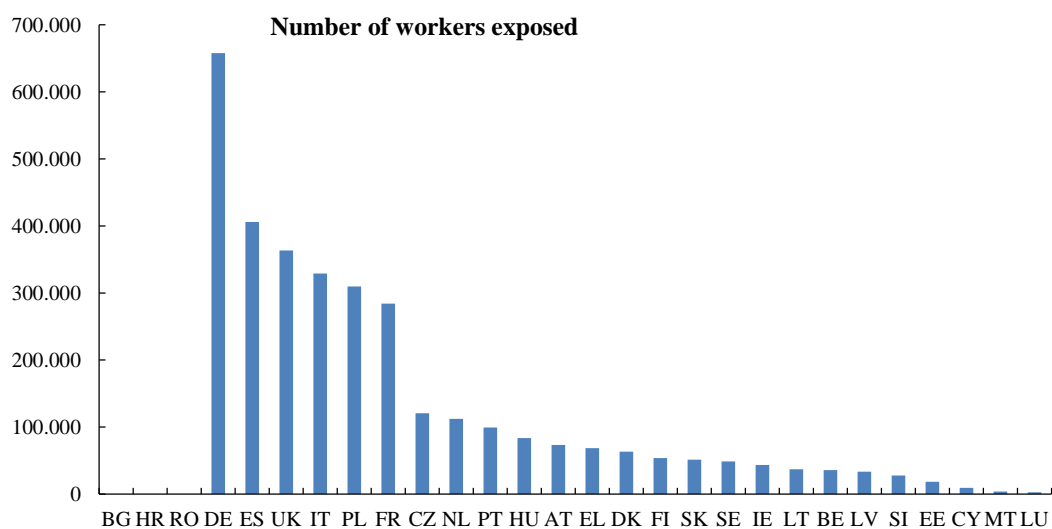


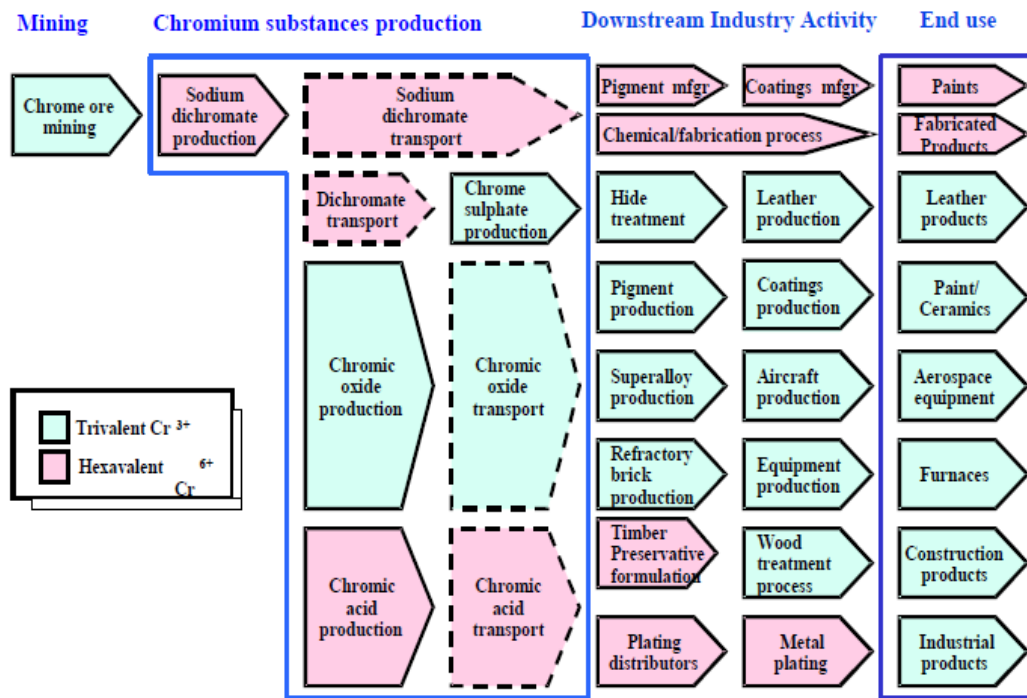
Figure 13 – Hardwood dust - Number of exposed workers²¹⁴



²¹⁴Data for BG, HR and RO not available.

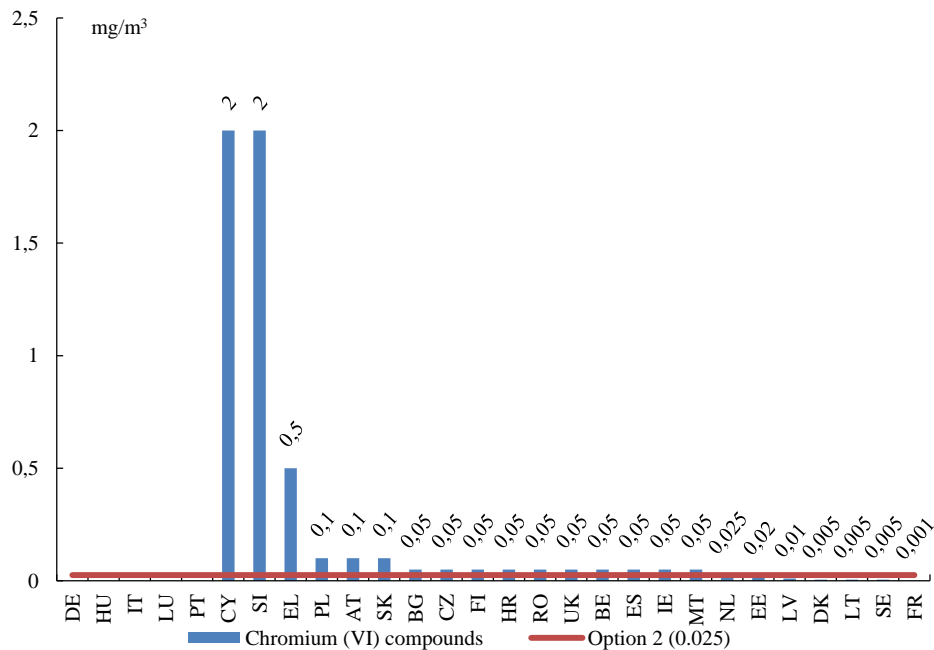
16.6 Chromium VI

Figure 14. Overview of Chromium Valence State in Chromium Applications



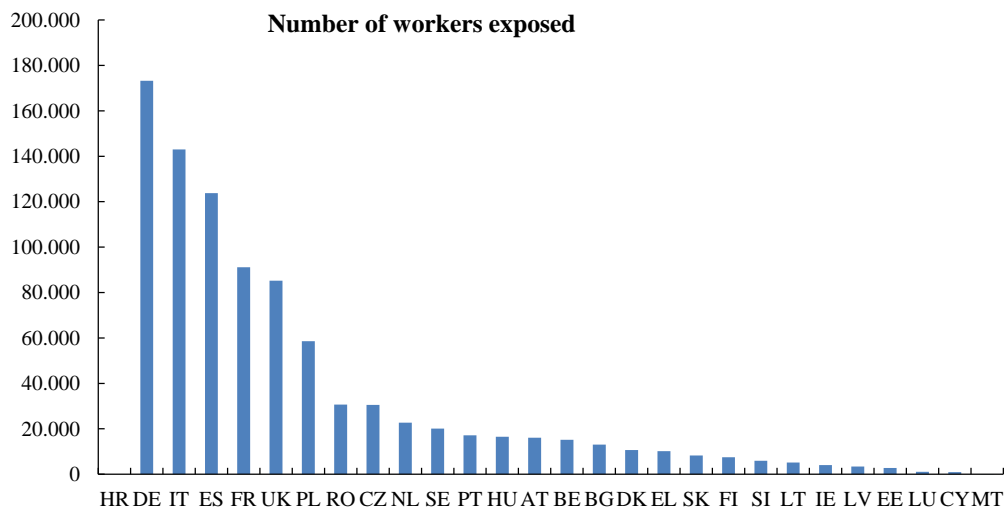
Source: HSE (2007) Human Health Risk Reduction Strategy for Chromates in IOM (2011) Hexavalent Chromium, pp. 4

Figure 15 – Chromium VI - Current national OELs vs. Option 2²¹⁵



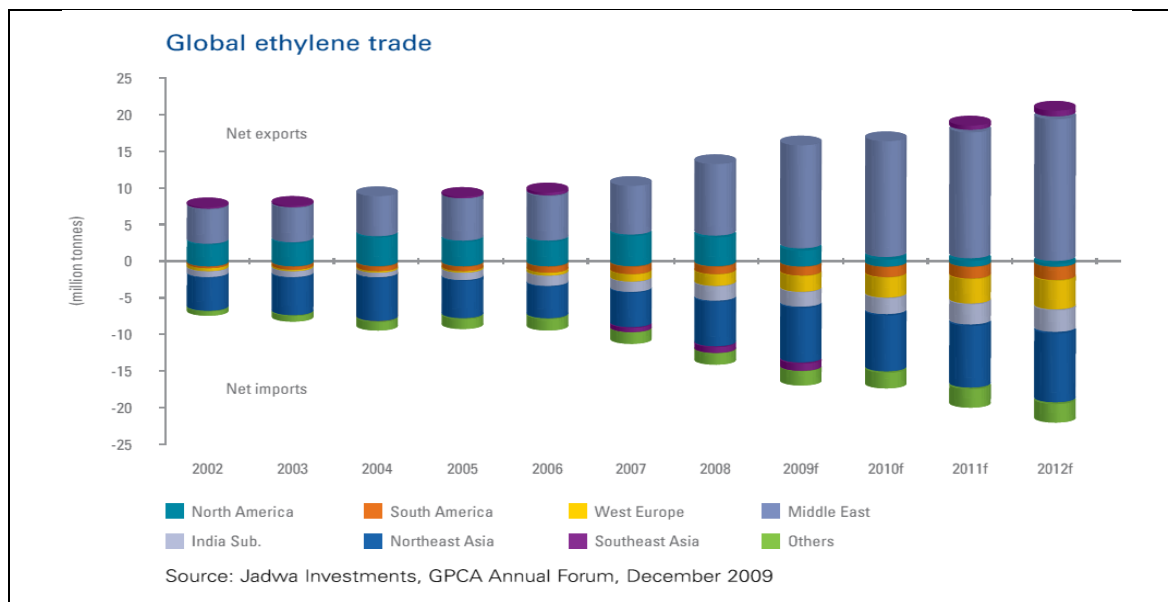
²¹⁵ Where the OELs have been provided as a range, the upper value has been used in the graph.

Figure 16 - Chromium VI - Number of exposed workers²¹⁶



16.7 Ethylene oxide

Figure 17 - The Global Ethylene Trade



²¹⁶Data for HR not available.

Figure 18 – Ethylene oxide - Current national OELs vs. Option 2

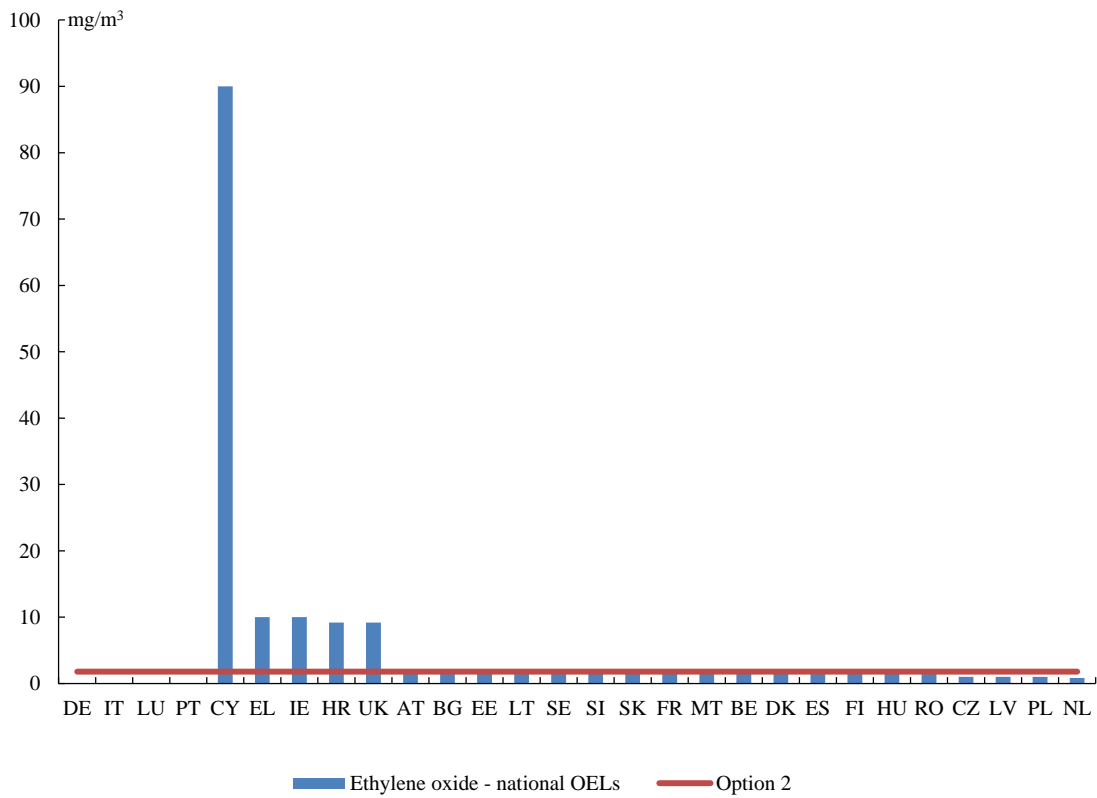
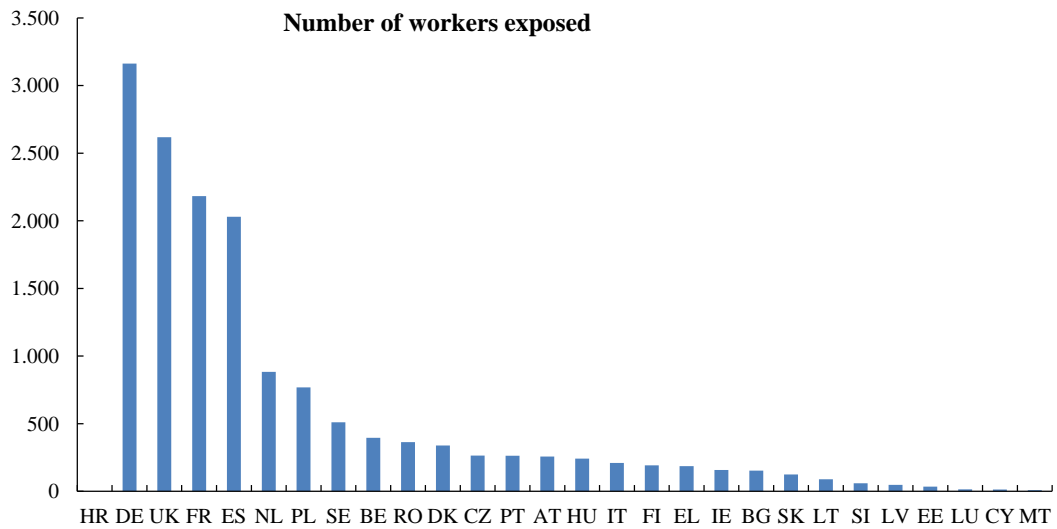


Figure 19 – Ethylene oxide - Number of exposed workers²¹⁷



²¹⁷ Data for HR not available.

16.8 *o*-Toluidine

Figure 20 - *o*-Toluidine - Current national OELs vs. Option 2

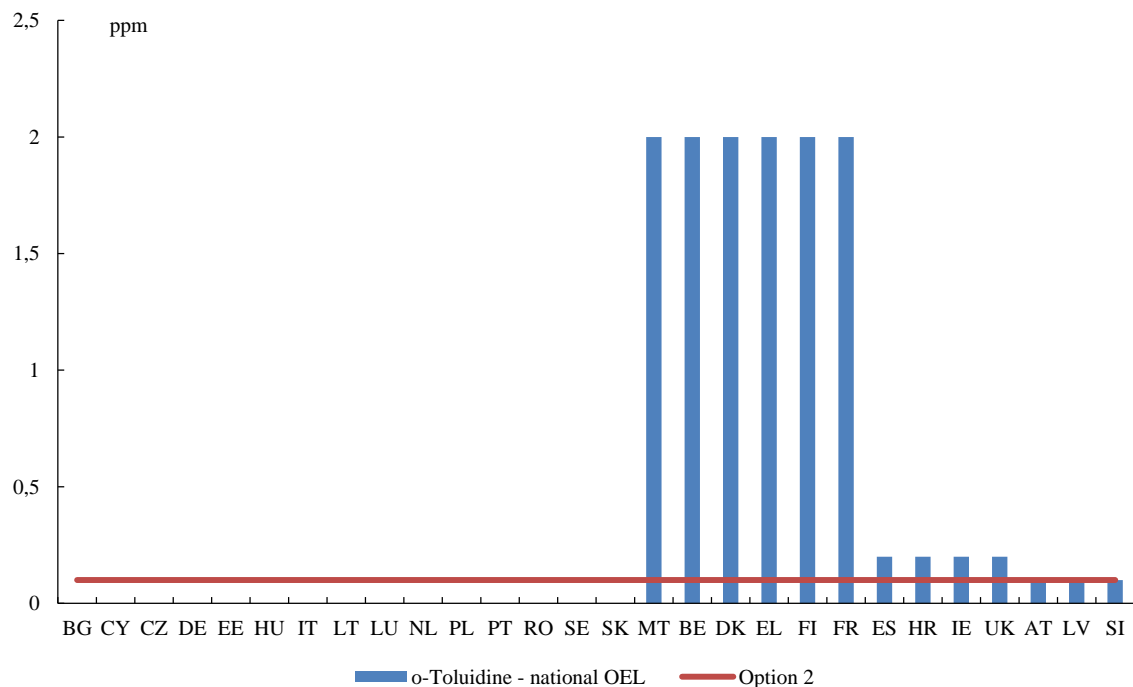
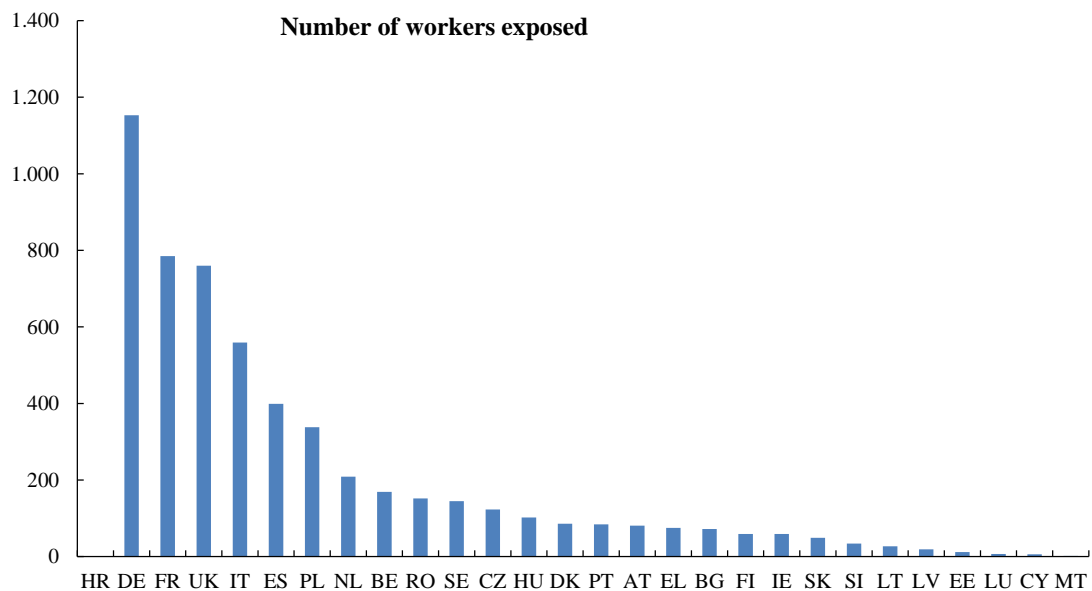


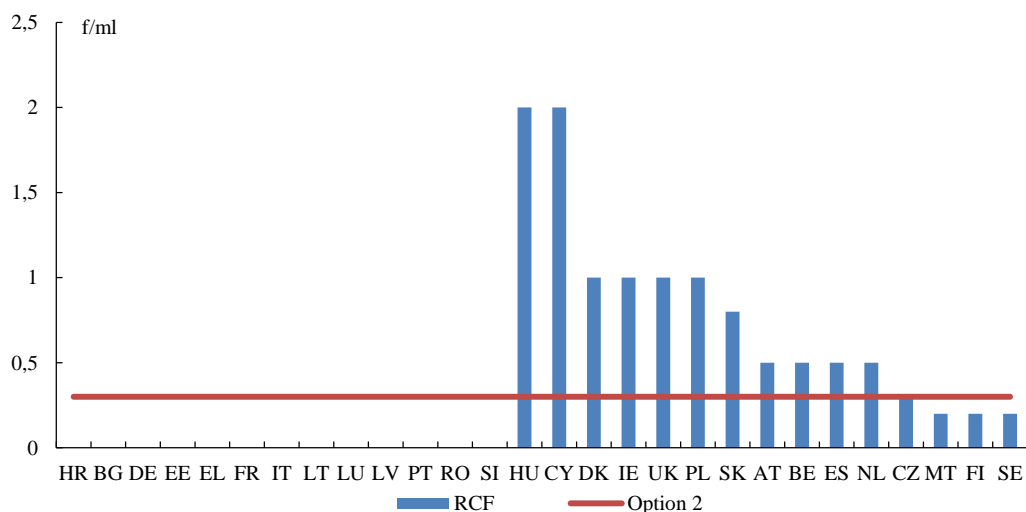
Figure 21 - *o*-Toluidine - Number of exposed workers ²¹⁸



²¹⁸ Data for HR not available.

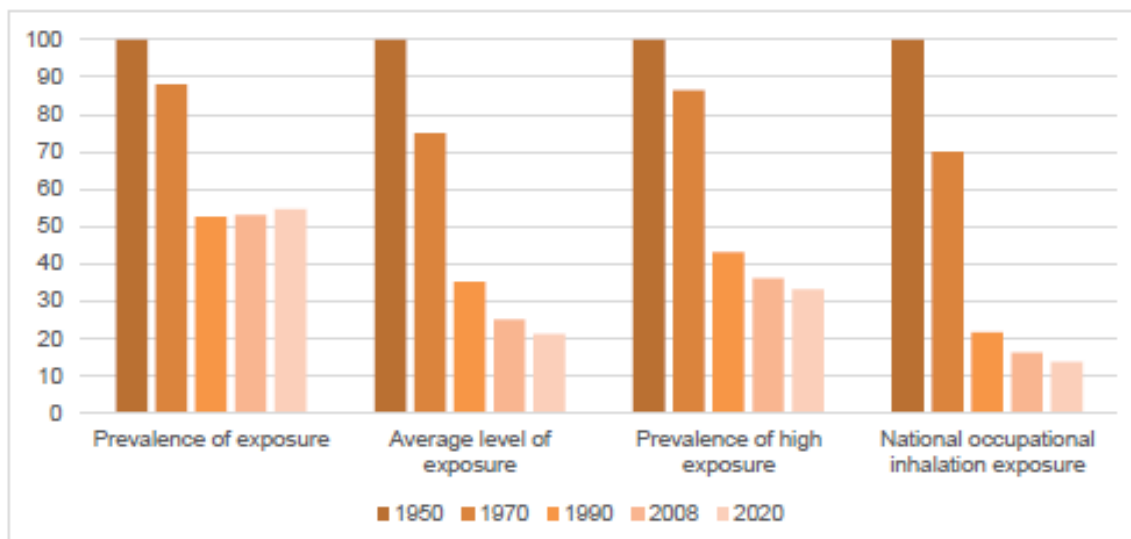
16.9 Refractory Ceramic Fibres (RCF)

Figure 22 – Refractory Ceramic Fibres (RCF) - Current national OELs vs. Option 2²¹⁹



16.10 Respirable Crystalline Silica (RCS)

Figure 23 - Occupational inhalation exposure to crystalline silica (quartz dust) in Finland in 1950, 1970, 1990 and 2008 and predicted for 2020, as measured by four different metrics of exposure²²⁰.



Source: FINJEM database (FIOH, 2013b)

²¹⁹ Where the OELs have been provided as a range, the upper value has been used in the graph. National OELs of CY, HU and SK have been converted from mg/m^3 to f/ml . The original values are: CY – $10 \text{ mg}/\text{m}^3$, HU – $5\text{-}10 \text{ mg}/\text{m}^3$, SK – $4 \text{ mg}/\text{m}^3$

²²⁰ Proportional values as compared with 1950 (baseline = 100).

Figure 24 - Respirable Crystalline Silica (RCS) - Current national OELs vs. Option 2²²¹

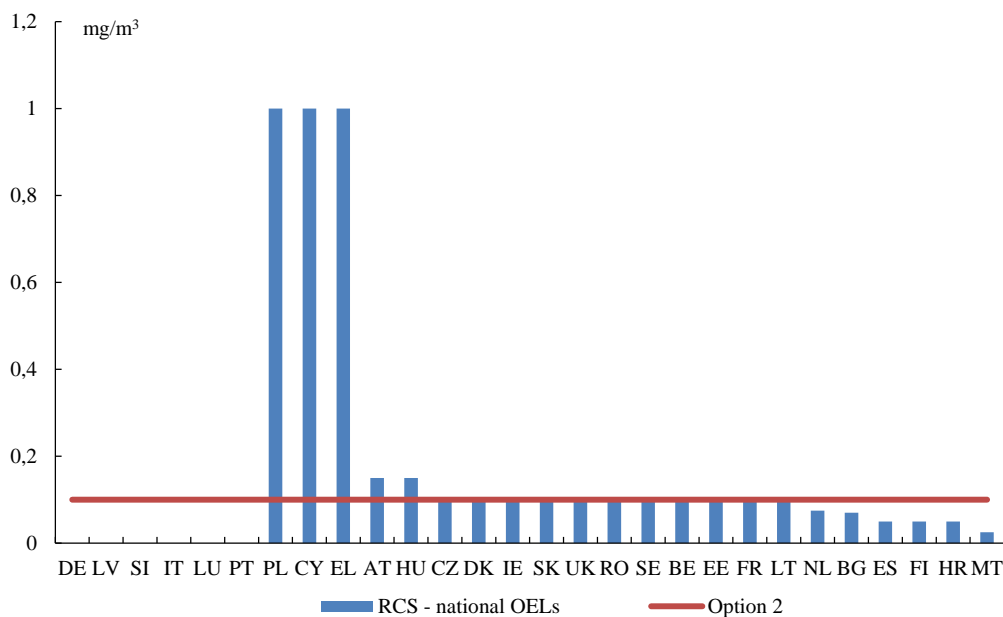
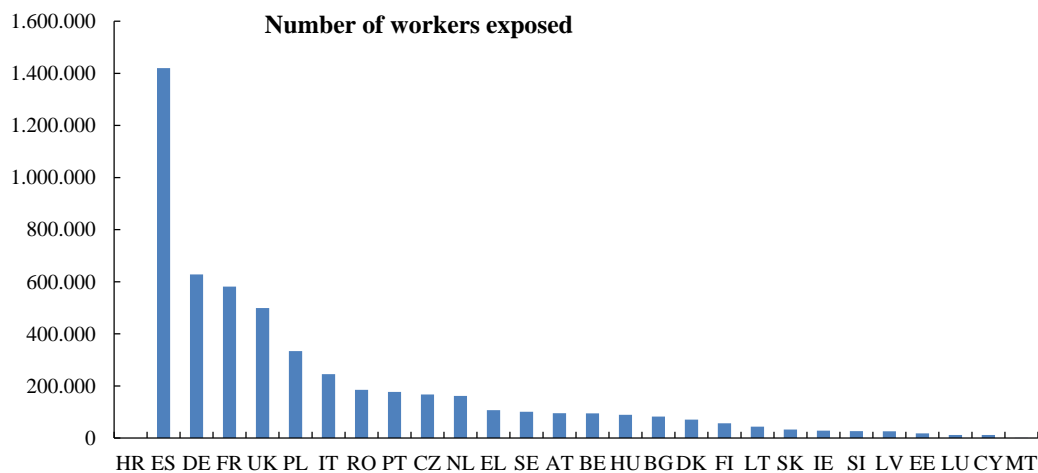


Figure 25 - Respirable Crystalline Silica (RCS) - Number of exposed workers²²²

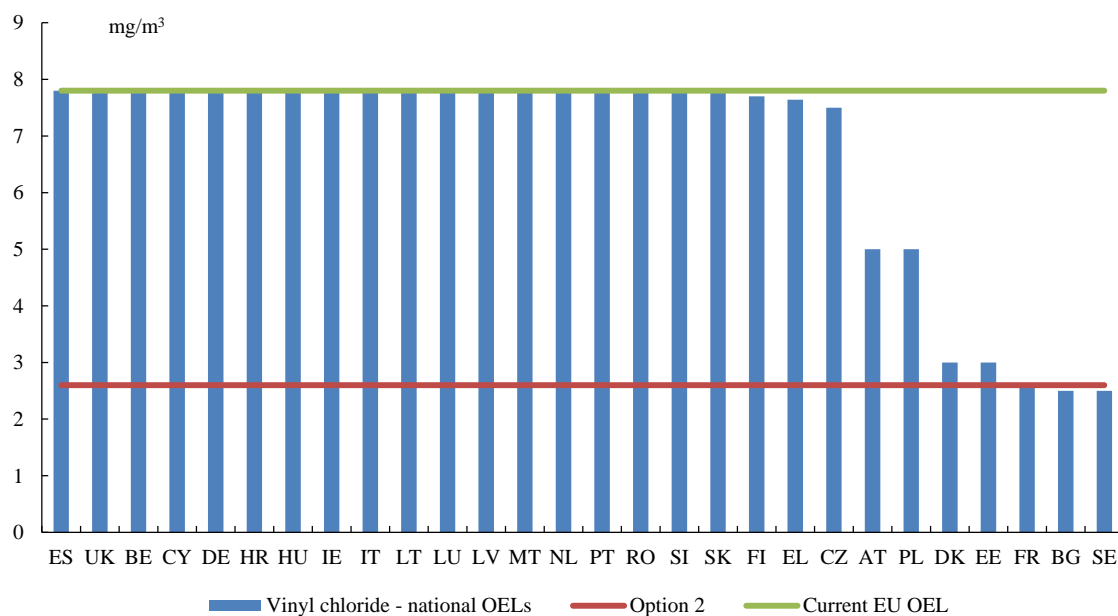


²²¹ In the case of countries with different OELs set for the different types of RCS (quartz, cristobalite, tridymite), the lowest OEL is represented in the graph. For instance, the quartz OELs of Belgium, France, Greece and Estonia are set at 0.1 mg/m³.

²²² Data for HR not available. Where the OELs have been provided as a range, the upper value has been used in the graph.

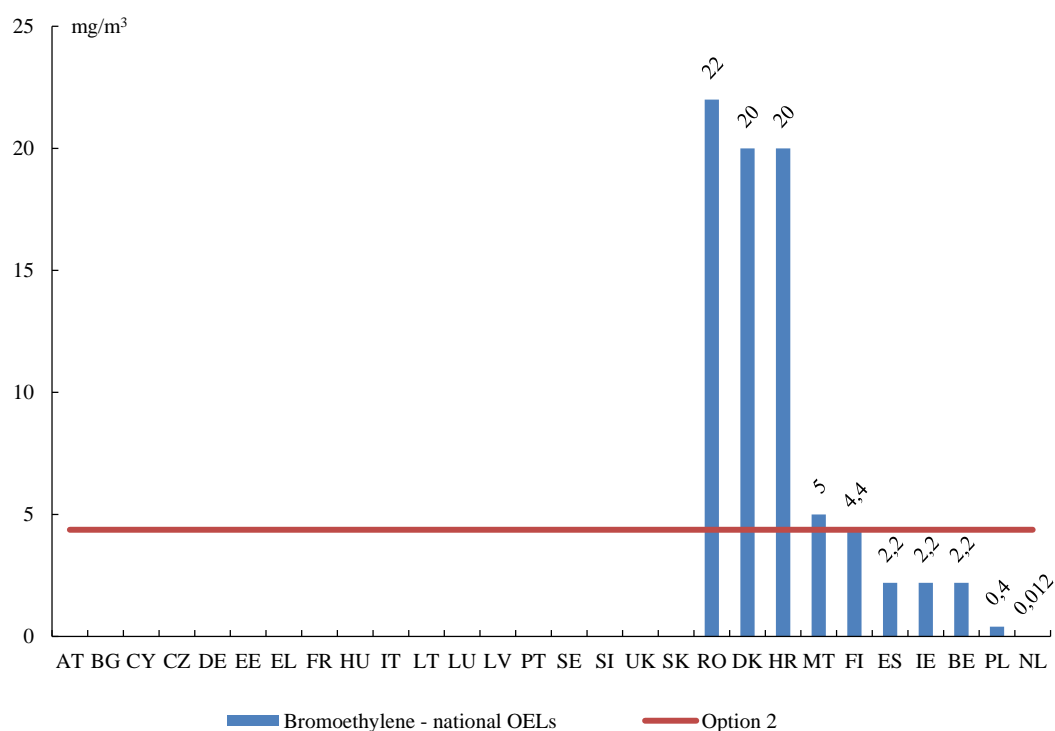
16.11 Vinyl Chloride Monomer (VCM)

Figure 26 - Vinyl Chloride Monomer (VCM) - Current national OELs vs. EU OEL and Option 2



16.12 Bromoethylene (vinyl bromide)

Figure 27 - Bromoethylene (vinyl bromide) – Current national OELs vs. Option 2



16.13 Hydrazine

Figure 28- Hydrazine — Current national OELs vs. Option 2

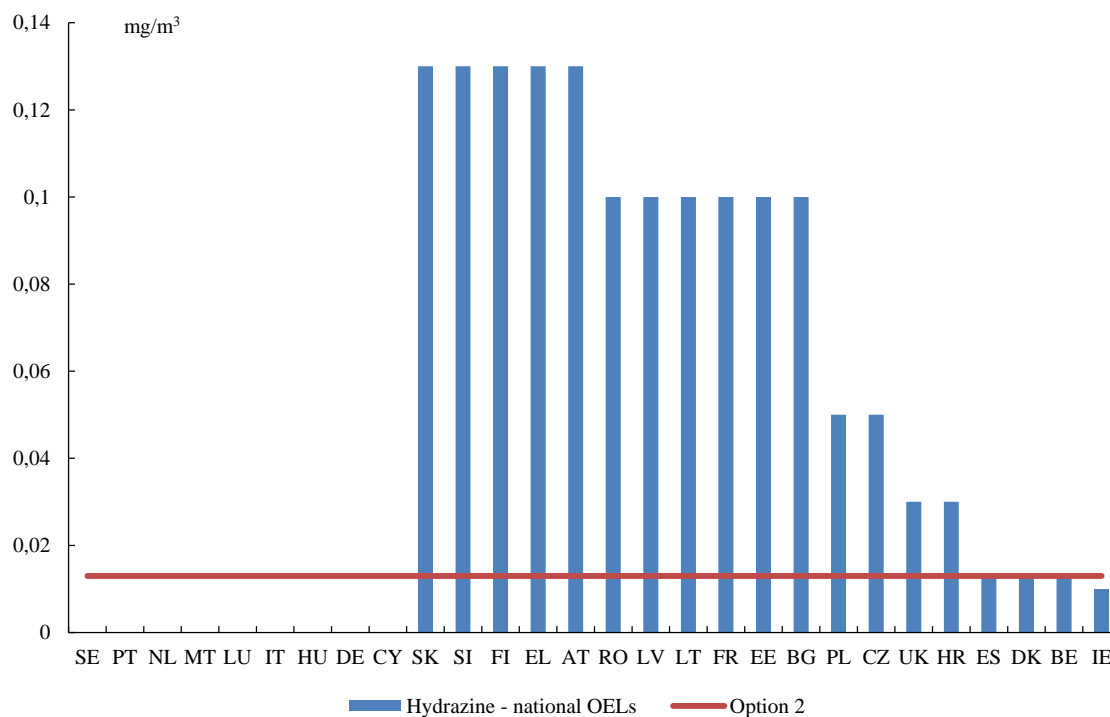
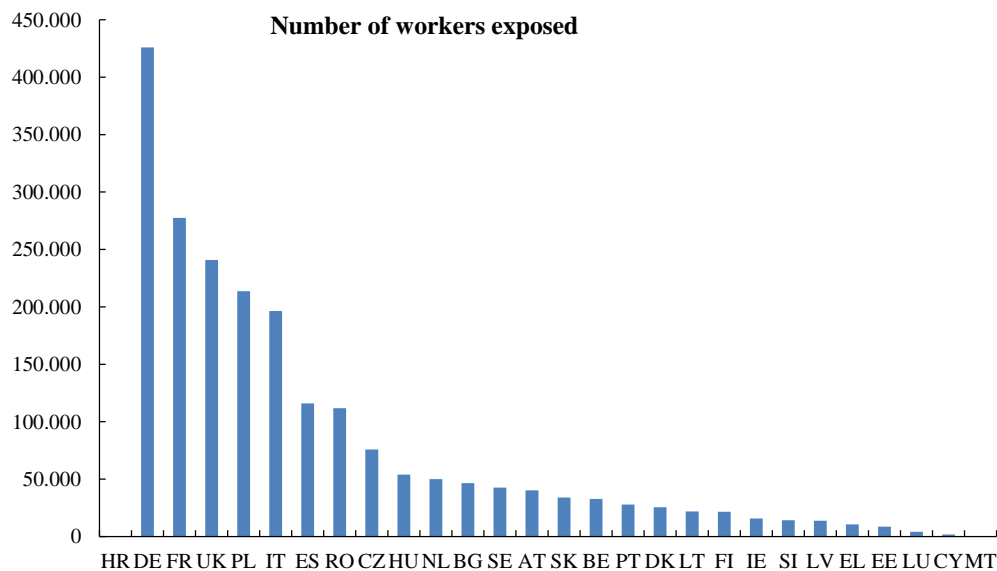


Figure 29- Hydrazine - Number of exposed workers²²³



²²³ Data for HR not available.

17 ANNEX 10 – ABBREVIATIONS USED

ACSH	Advisory Committee on Safety and Health at Work
CAD	Chemical Agents Directive (Directive 98/24/EC)
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
DNEL	Derived No Effect Level
ECHA	European Chemicals Agency
EIG	Employers Interest Group
GIG	Government Interest group
IARC	International Agency for Research on Cancer
mg/m ³	milligram per cubic metre
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
ppb	part per billion
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
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
TWA	Time-weighted average
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'